

FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume One

GENERAL DESCRIPTION AND SURVEILLANCE PROCEDURES

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual

Volume One

GENERAL DESCRIPTION

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VOLUME I
GENERAL DESCRIPTION

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CHAPTER ONE

GENERAL DESCRIPTION AND STUDY MANAGEMENT

1.1 BACKGROUND

1.1.1 General

A review of existing data by the Subcommittee on Cardiovascular and Cerebrovascular Disease of the Secretary of Health and Human Service's Task Force on Black and Minority Health concluded that information on CVD in American Indians is inadequate and strongly recommended epidemiologic studies of this problem. The Strong Heart Study is designed to respond to this recommendation.

1.1.2 Scientific Background

A. Rationale for studying heart disease in American Indians

Cardiovascular disease has become the leading cause of death in American Indians. Cardiovascular morbidity and mortality rates may be increasing in some tribes, and the rates appear to differ greatly among various tribes. Cerebrovascular disease is the fourth leading cause of death for American Indians.

Several problems have made it difficult to determine the prevalence and severity of cardiovascular disease among American Indians. Small community size, relatively young age, cultural and anthropologic diversity, and the geographic dispersion of the American Indian population have made it difficult to include large numbers of Indians in research examinations and surveys of vital statistics. High rates of CVD in younger Indians suggest that the overall CVD rates will increase as the population ages and that CVD may be a more serious health problem among Indians in the future. Definitions of the term "Indian" are variable in published reports, and the denominators from which disease rates were calculated often were based on uncertain estimates of the population at risk. Definitions of disease and methods of its ascertainment have also varied among studies. In addition, health care services available to Indians differ considerably in different geographic areas and possibly contribute to differences in reported rates of cardiovascular disease morbidity and mortality.

B. Description of Strong Heart Study, Phases I, II, and III

The Strong Heart Study (SHS) is a study of cardiovascular disease among American Indian men and women supported by the National Heart Lung and Blood Institute since October 1, 1988 and is the largest study of American Indians ever undertaken. The SHS, which uses standardized methodology, is designed to estimate cardiovascular disease mortality and morbidity and the prevalence of known and suspected cardiovascular disease risk factors in

American Indians and to assess the significance of these risk factors in a longitudinal analysis. The study population consists of 13 tribes in three geographical areas: an area near Phoenix, Arizona, the Southwestern area of Oklahoma, and western and central North and South Dakota.

The SHS has included three strategies. The first is a survey to determine cardiovascular disease mortality rates from 1984 to 1994 among tribal members aged 35 - 74 years of age residing in the 3 study areas (the community mortality study).

The second is the clinical examination and morbidity and mortality surveillance of resident tribal members (the cohort). During the baseline (Phase I) examination, conducted between 1989 and 1991, 4549 tribal members, ages 45-74 years of age (62% of the total population ages 45-74 yrs.), were seen. The second examination (Phase II), between 1993 and 1995, re-examined 89% of all surviving members of the original cohort. The final examination (Phase III) between 1997 and 1999 re-examined 90% of all surviving participants. In the Phase I examination, medical history, family history of related illnesses, diet, alcohol and tobacco consumption, physical activity, degree of acculturation, and socioeconomic status were assessed in personal interviews. The physical examination included measurements of body fat, body circumferences, and blood pressure, an examination of the heart and lungs, an evaluation of peripheral vascular disease, and a 12-lead resting electrocardiogram. Laboratory measurements in the baseline exam included fasting and post-load glucose and fasting insulin, fasting lipids, apoproteins B and AI, apo E phenotype, fibrinogen, Lp(a), LDL size, Gm allotype, and glycated hemoglobin. Measures were also made of urinary creatinine and urinary albumin, and DNA from lymphocytes was isolated and stored. During the second examination, medical history was updated and a 24-hour dietary recall was performed on all individuals. Alcohol and tobacco consumption were reassessed. The physical examination included measures of body fat, body circumferences and blood pressure, an evaluation of peripheral vascular disease, and a 12-lead resting electrocardiogram. Measures of pulmonary function, an echocardiogram, and a gallbladder sonogram were added. Laboratory measurements included fasting and post-load glucose, and fasting insulin, fasting lipids, fibrinogen, PAI1, glycated hemoglobin, and urinary albumin and creatinine; red blood cell allotypes were also assessed. DNA from lymphocytes was again stored at -70°C.

The third examination included personal habits and medical history update, twenty-four hour dietary recall, and assessment of alcohol and tobacco consumption. The physical exam included measures of body fat, body circumferences and blood pressure, an evaluation of peripheral vascular disease, and a 12-lead resting electrocardiogram. Ultrasound assessment of carotid arteries and measurement of peripheral sensation were added; skin testing, and monitoring of pulmonary function were done in those with history of asthma. Laboratory measures included fasting and post-load glucose, and fasting insulin, fasting lipids, fibrinogen, PAI1, glycated hemoglobin, and urinary albumin and creatinine, hematocrit and Chemistry Profile (SMAC 12, including electrolytes, BUN, creatinine, total protein, SGPT, and SGOT).

The third strategy, added with Phase III, was an assessment of heritability of CVD and risk factors in families that included three or more siblings from the original cohort. 945 men

and women over 18 years of age in 32 families underwent a physical exam which included all aspects of the baseline exam from the cohort study plus carotid ultrasound and measures of peripheral sensation.

CVD incidence data from the SHS clearly show that CHD rates in American Indians now exceed rates in other US populations and that CHD may more often be fatal in American Indians than in other groups. Compared to reported CHD incidence rates in 45 to 64 year old African American and white women and men in the Atherosclerosis Risk in Communities (ARIC) Study, American Indian women have nearly two-fold higher rates and men have rates that are approximately 1.5 times higher. Surveillance data are substantiated by data from carotid ultrasound measures comparing overall prevalence of atherosclerosis in American Indians in the SHS compared to age-matched individuals in the ARIC Study. The prevalence of carotid atherosclerosis is higher in American Indians in the SHS than in whites and blacks in the ARIC Study.

A mortality review of the 13 communities in the three geographic areas from which the SHS cohort was derived shows CVD death rates approximately 30% higher than those of the general populations of these areas, i.e., Arizona, Oklahoma and North/South Dakota. Thus, there appears to be a rising tide of CVD among American Indian communities that is reaching epidemic proportions. This phenomenon may be a preview of what will happen to CVD rates in other US populations with increasing prevalence of diabetes.

C. Rationale for Phase IV of the Strong Heart Study

The Strong Heart Study is the largest multicenter study of CVD in American Indians and is one of the best resources for standardized data on many other diseases related to CVD in this population. Analyses of the community mortality data from 1984-1988 indicated differences between centers in types of CVD and in several other causes of death compared to non-Indians in the three geographic areas.

The continued surveillance of the cohort becomes more valuable as they age. Participants now range in age from 57-86 years. The availability of data from the baseline and two follow-up examinations will allow the evaluation of the effects of a large number of risk factors on the incidence of CVD and the progression of prevalent disease in this population. Since all the SHS communities have high rates of diabetes and glucose intolerance, continued surveillance will provide a unique resource to evaluate risk factors for and mechanisms of CVD in diabetic individuals. Since there are now many elderly individuals in this population, the risk factors for cerebrovascular disease can also be more fully examined. Finally, lifestyles are changing rapidly in all three areas and, in addition, there have been marked recent improvements in the economic situation in some of the communities because of the initiation of gaming and monies gained from land settlements. This provides the opportunity to examine effects of those changes on incidence of disease and mortality.

Since it is well established that many risk factors for CVD and the tendency toward atherosclerosis and atherosclerotic events are familial, the Strong Heart Study now provides a very valuable resource for evaluating genetic determinants of CVD. DNA is available from individuals from the cohort from Phases I, II, and III. Since family sizes are large (median live births = 5; range 0-18), and since there were siblings from many families examined in all three centers, we have the opportunity to map genes that influence cardiovascular risk factors in this population. It is most valuable, however, to collect data on risk factors and target organ damage and DNA on large kindreds. This population provides a particularly promising opportunity for such a study, since the average family size is large and the communities are very stable. Thus, many people remain on the reservation or within the Indian communities all of their lives. Even if they move, many of their relatives remain who know the location of these individuals. The close ties that Strong Heart Study investigators have with community members allow us to communicate the importance of the information that can be gathered from large families.

Family Studies -

Studies over the past 50 years have identified numerous risk factors for CVD, including increased serum lipid levels, male gender, cigarette smoking, sedentary lifestyle, a diet high in fat and cholesterol, various diseases such as hypertension, diabetes, and obesity, and a positive family history of CVD. The Strong Heart Study is the only large-scale study of CVD risk factors in American Indians. Until now, however, analyses of the contribution of genetic factors to CVD risk have not been included in the Strong Heart Study.

There is ample evidence that the development of CVD is genetically mediated, although the genes identified so far have been for the most part relatively rare mutations with extreme effects (the APO E polymorphism is a notable exception). A long-term goal of the Strong Heart Family Study is to detect and map new polymorphic genes that influence variation in risk factors for CVD and other related disorders in American Indians. The family study will take the first steps toward achieving that goal.

We will establish a resource of extended families beginning with sibships who already are Strong Heart Study participants. Using new statistical and molecular genetic methods for human gene mapping, we will conduct a genome-wide search for genes that influence CVD risk. Among the measures to be analyzed are risk factors such as plasma concentrations of lipoproteins, and apolipoproteins, insulin and glucose, measures of obesity, measures associated with hemostasis, and target organ features such as carotid artery wall thickness and stiffness. Such quantitative variables have the advantage that they provide more information for genetic analysis and are less subject to error than are dichotomous traits defined by imposing a (sometimes arbitrary) threshold on a continuous distribution. Genes that influence these disease risk factors have the potential to account for a high proportion of the variation in disease risk among individuals and thus to be of substantial public health importance.

We expect our results to lead to estimates of the magnitude of the genetic effects on CVD risk factors in American Indians, and to generate testable hypotheses that will form the focus of

further genetic studies of CVD risk in American Indians. The detection and mapping of genes that influence CVD risk as well as selected measures of preclinical CVD will set the stage for the larger task of isolating these genes. Future research will determine how they exert their effects on disease susceptibility in American Indians, and how gene action is influenced by environmental factors. This research will enable identification of individuals who, on the basis of their genotypes, will most benefit from specific therapies or lifestyle changes.

SHS demonstrated in Phase III that it was able to recruit and retain large kindreds from which physiologic measurements were made and blood samples taken for direct genotyping. This effort will continue in Phase IV to recruit and examine 90 more families and perform linkage analysis on a total sample of 3600 individuals.

Phase IV of the Strong Heart Study will perform the following:

1. Continued mortality and morbidity surveillance of the Phase I examination cohort.
2. A continuation of the effort to examine family participants (first degree relatives and grandchildren) of members of the Strong Heart Study. Thirty families with at least 30 members will be identified at random from each of the three centers from among Strong Heart Study participants where two or more siblings were examined at baseline. The examination on these individuals will include all components of the Phase III family examination and DNA samples isolated for genotyping. Heritabilities of selected risk factors will be estimated, and risk factors will be screened for linkage to genetic markers distributed throughout the genome.
3. The 945 members of the original 32 families examined during Phase III will be reexamined, repeating components expected to change (as in the Phase II exam) and including both carotid and **cardiac** ultrasound.

Rationales for Major Components of Phase IV of the Strong Heart Study

1. Carotid Ultrasound and Pressure Waveform Analysis

Recent progress makes available non-invasive methods to evaluate arterial structure and function. Ultrasound measurement of carotid wall thickness (combined intimal and medial thickness) has been validated using gross and histopathologic reference standards and has been found to be highly reproducible. Ultrasonography permits the detection of discrete atheromata within the extracranial carotid arteries. The presence of carotid atherosclerosis is strongly correlated with coronary atherosclerosis and constituted an independent risk factor for the development of subsequent myocardial infarction in the Kuopio Heart Disease Risk Factor Study. For each 0.1mm increase in common carotid artery intimal-medial thickness, the risk of myocardial infarction increased by 11%. Thus the inclusion of this measure will give precise measures of structure and detect atheromatous plaque and early atherosclerosis. Additional recording of the arterial pressure waveforms will allow assessment of arterial compliance and

permit assessment of the relation of diabetes and other CVD risk factors, prevalent CVD, and symptomatic atherosclerosis to arterial dysfunction. The combination of these data with the previously collected echocardiographic data and the ongoing surveillance of mortality and CVD morbidity will allow a comprehensive assessment of cardiovascular structure and function in the Strong Heart Study participants and afford an opportunity to evaluate its relationship between these measures and several CVD risk factors and the presence of diabetes and its complications.

2. Measures of LV Structure and Function by Echocardiography

Echocardiographic structural and functional abnormalities are very prevalent in diabetic American Indians and appear to be strong predictors of CVD events. A particular dramatic finding in the SHS is that LV mass on SHS Exam II echocardiograms obtained between August 1993 and December 1995 predicted higher CVD mortality through the end of 1997 (2.6 vs. 0.8%, odds ratio =3.4[1.8-6.3], $p<.001$). In regression analysis that considered other predictors of mortality, cardiovascular death was most strongly predicted by higher LV mass/height^{2.7} ($p=0.0001$), older age ($p=0.0009$), higher urine albumin/creatinine ratio ($p=0.05$) and lower BMI ($p=0.003$). When analyses were restricted to participants with DM at the second SHS examination, all-cause mortality, cardiovascular death, and non-fatal cardiovascular events were all more common in those with LV hypertrophy.

Measures of LV function derived by echocardiography also strongly predict adverse outcomes in patients with DM. When stress-corrected LV midwall shortening was considered as a predictor of cardiovascular death, SHS participants with low LV myocardial function had a substantially increased rate of CVD death (5.2 vs. 1.0%, $p<0.001$, OR =5.3 [2.6-10.9]). In logistic regression a strong predictor of shortening was a strong predictor of CVD death ($p=0.0002$) along with older age ($p=0.0001$) and higher albumin/creatinine ($p=0.006$). These analyses confirm that echocardiographic measures of LV mass and myocardial function strongly predict CVD death in diabetic American Indians despite a relatively short follow-up period, demonstrating the robustness of these variables as predictors of CVD events. In one of the first analyses of prognostic implications of abnormal LV diastolic filling in a population-based sample, we showed that an elevated ratio of early diastolic/atrial phase LV filling (E/A ratio)(>1.5) was a stronger predictor ($p=0.0003$) of cardiovascular death than age ($p=0.0072$), DM ($p=0.001$), or systolic BP, ($p=0.04$) and that reduced E/A (<0.6) also predicted CVD death. The high prevalence of LV hypertrophy (32%), myocardial dysfunction (15%), and abnormal LV filling (24%) detected by echocardiography in SHS participants may contribute to the high CVD death rate in diabetic American Indians.

3. Laboratory Tests

In Phase IV, based on the death rate observed so far, there should be more than 1000 deaths in the cohort, approximately one-third of which are expected to be from cardiovascular disease. Therefore, in the interest of economy, certain measurements are planned using a case-

cohort design. Analyses will be done on stored samples from the baseline (Phase I) examination. These will include measures of:

A. Thyroid Stimulating Hormone (TSH)

Over the years, several studies have identified hypothyroidism as a stimulus to dyslipidemia and, potentially through that mechanism, coronary atherosclerosis. Since these studies have depended on use of coronary arteriography, an invasive technique with a measurable complication rate, little is known of the relation of thyroid metabolism to atherosclerosis in population-based samples. In addition, it is well known that skeletal muscle relaxation is slowed in the setting of hypothyroidism, but whether this phenomenon occurs in arterial and cardiac muscle is unknown. Preliminary data from SHS reveals that 553/4475 subjects in Phase I were receiving thyroid replacement therapy. This yields a prevalence of treated hypothyroidism of 3.4% vs. a pooled prevalence of 0.5-2% in nationally published studies.

B. Endothelin and VCAM-1

The coronary arteries have an active role in the pathogenesis of atherosclerosis and coronary heart disease; they are not simply the passive repositories of injury caused by oxidative stress, dyslipidemia, thrombosis and shear injury. Both genetic and environmental factors affect the vessel's susceptibility to injury and its response in terms of tone and vascular wall proliferation.

Since SHS began, a great deal has been learned about the molecular processes leading to vascular wall injury and its responses to damage. These responses are regulated by the production and release of a variety of substances including prostacyclins, nitric oxide, cellular adhesion molecules, vasoactive growth factors and G-protein-coupled receptor agonists including endothelin. There is accumulating in vitro evidence that these factors are essential elements in the acute and long term responses to injury and development of atherosclerotic cardiovascular disease (ASCVD). In addition, vascular responses mediated by nitric oxide are abnormal in established pathological states such as essential hypertension, stroke, atherosclerotic coronary heart disease and heart failure. There is no agreement on a clear relationship or cascade between these factors and the vessel wall. However, it is hypothesized that risk factors for atherosclerosis such as dyslipidemia, hypertension, diabetes and oxidative stress impair nitric oxide bioactivities. Reduced nitric oxide activity may, in turn, adversely affect coronary vasodilation and antithrombotic activities. Reduced synthesis (or intravascular residence time) of nitric oxide also appears to increase inflammation by stimulating the expression of vascular adhesion molecules (e.g., vascular cell adhesion molecule-1 or VACM-1) for monocytes, and the growth of vascular smooth muscle through the production of local growth factors. Vascular wall injury also causes production and release of endothelin, a G-protein-coupled-receptor agonist. Endothelin elicits cell growth through production of both autocrine and paracrine factors.

In Phase IV of SHS, we will measure endothelin and VCAM-1 in stored Phase I plasma samples. While these factors appear to be elevated in established vascular injury, it is not clear what role they play in pre-clinical or pre-morbid states of ASCVD. Specifically, we will test the hypothesis that VCAM and endothelin are elevated in the blood of individuals who were initially free of clinically apparent ASCVD, but subsequently developed “definite” or “probable” CHD. Our data may allow us to infer that those elevated blood levels of VCAM and endothelin are pre-clinical risk factors for CHD. The practical importance of this may relate to earlier, focused interventions designed to reduce vascular wall injury. These interventions may include ACE inhibitors, estrogen, lipid lowering agents, physical activity, improved diabetic and blood pressure control, and the development and use of new agents such as endothelin or VCAM selective antagonists.

For the case-cohort studies, the control group will be a large random sample of the Phase I examination cohort. Selecting controls in this way will allow them to serve as controls for each of the case groups studied.

1.2 RESEARCH OBJECTIVES

The Strong Heart Study-IV (SHS, Cardiovascular Disease in American Indians Phase IV) is to continue the mortality and morbidity surveillance on the original cohort, to continue the study of the inheritance of risk factors in families, and to re-examine the members of the original families initiated in Phase III.

The study will address the following specific aims:

Specific Aim #1. Expand the available data and power for genetic analyses of CVD and its risk factors by extending the pilot family study.

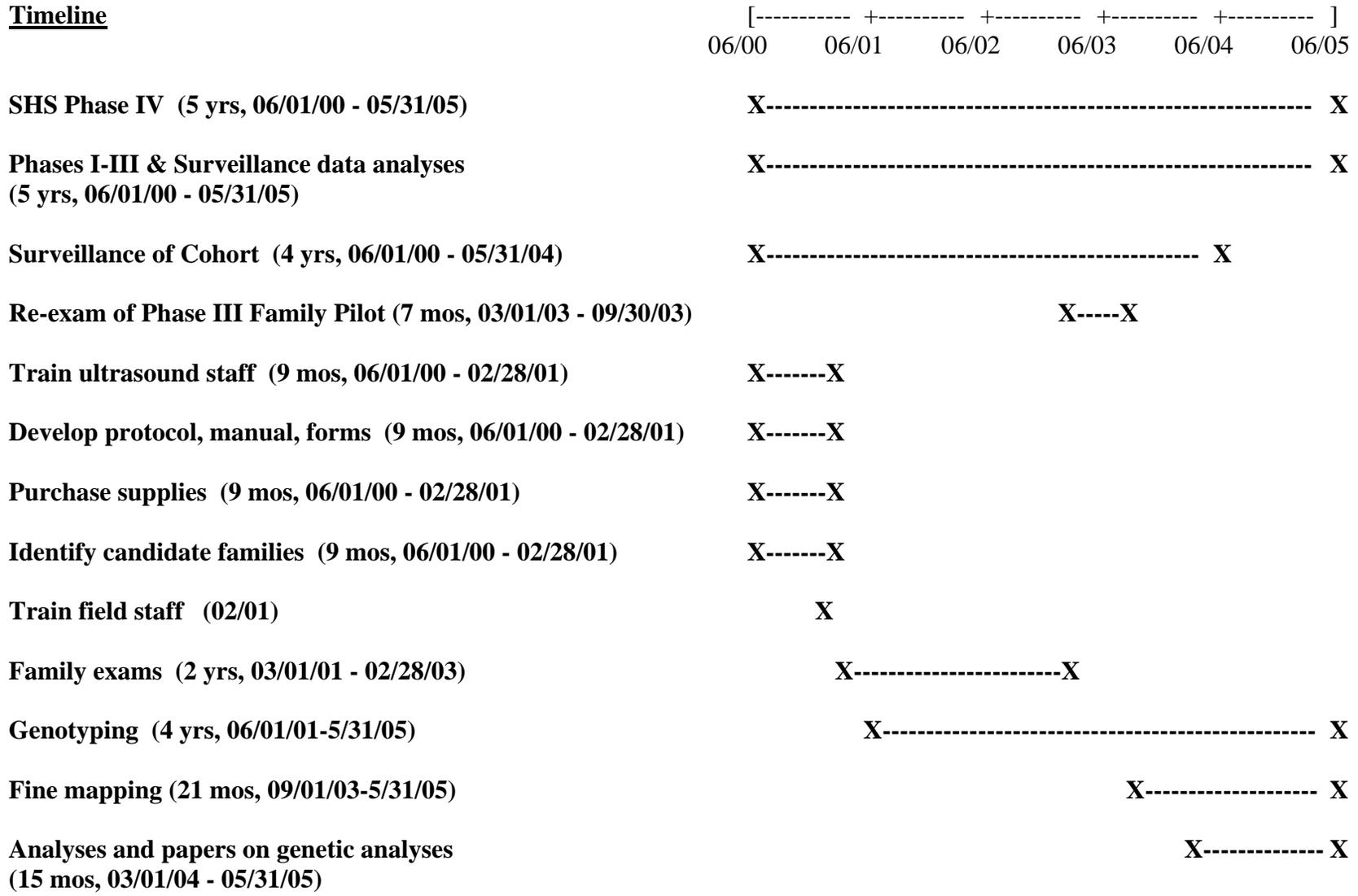
- a. Identify and recruit 30 families with approximately 30 members each, ages 15 years and older in each of 3 geographic areas (Arizona, Oklahoma, South/North Dakota).
- b. Estimate heritabilities, covariate and household effects, and genetic and environmental correlates for a large set of CVD risk factor phenotypes as well as echocardiographic and carotid atherosclerosis measures by quantitative genetic analysis.
- c. Generate a 10 centimorgan map that includes genotyping or 386 short tandem repeats in each of the 2700 newly recruited individuals.
- d. Screen the phenotypes for linkage using a variance component approach in full pedigrees and do finer scale mapping in regions of interest.
- e. Assess changes in risk factors and carotid atherosclerosis by reexamining the original 900 family members.

Specific Aims #2. Continue Morbidity & Mortality surveillance of the original cohort (45-74 years at baseline) in order to explore the role of the many biomarkers and measures of cardiovascular function made in the baseline and two follow up exams.

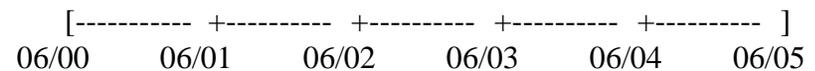
- a. Determine CVD mortality and morbidity rates and all cause death rates.
- b. Compare rates and risk factors for differing manifestations of CVD – coronary, cerebral, and peripheral.
- c. Relate quantitative measures of systemic atherosclerosis, cardiac hypertrophy, and cardiovascular dysfunction (ECHO, carotid and tonometry) to CVD incidence.
- d. Determine the relations of some additional biomarkers (TSH, endothelin, and VCAM-1) with CVD using stored baseline blood samples in a nested case control design.

1.3 STUDY DESIGN -

Timeline



Timeline



1.3.1 Surveillance

In Phase IV of the SHS, surveillance will include annual ascertainment of deaths and non-fatal CVD events in the Phase I cohort.

For the mortality surveillance, death certificates will be reviewed and independently classified for all deaths, regardless of the cause. Annual contacts with participants and annual reviews of IHS listings of relevant ICD-9 codes will be used to identify non-fatal events that have occurred since the date of last contact with the participant. Included in the morbidity surveillance will be annual ascertainment of the occurrence of hospitalized non-fatal myocardial infarction and stroke.

Individuals will be designated at each center to be specifically responsible for mortality and morbidity surveillance activities. Surveillance contacts will be accomplished using a variety of approaches specific to the SHS populations. These approaches include home visits, monitoring of IHS facility records, telephone calls and mail contacts. All reports of primary endpoints and selected secondary events of interest obtained through surveillance procedures will be validated from medical records. (See Volume Two – Morbidity and Mortality Surveillance)

1.3.2 Clinical Examination

Components of the Clinical Examination. These are described on page III-2 of this manual. The clinical examination will include a personal interview and a physical examination of family members from the 90 newly recruited families, as well as family members seen in Phase III. For the latter, only information that is likely to have changed since the last exam will be collected. All of the procedures will be the same as in Phases I - III. Procedures are described in brief below, with details presented in the manual Volume III.

i. Personal Interview

The following questionnaires will be administered:

- 1) Demographic information: income, residence, marital status, number of household members and employment will be determined. Tribal enrollment, degree of Indian blood, marital status, education/income, use of native language, smoking and alcohol use, medical conditions, and reproductive history will be ascertained.
- 2) Health habits: Smoking and alcohol intake will be assessed.
- 3) Medical history, including Rose questionnaire for angina pectoris and intermittent claudication will be assessed.
- 4) Dietary survey: The Block Food Frequency Questionnaire (FFQ) will be used.
- 5) Quality of life and psychosocial parameters: The Quality of Life instrument (Rand MOS SF-12) will be used in Phase IV rather than the longer SF-36 that was used

in Phases II and III. Other psychosocial instruments will include a cultural assessment, CES-D to assess depression, Locus of Control, Social Support, and Anger & Hostility (Anger & Hostility will be optional).

ii. Physical Examination

The physical examination includes the following procedures that were used previously:

- 1) Anthropometric measurements will be made with participants in loose clothing with shoes and heavy objects removed from pockets:
 - i) Weight -- The scale will be balanced on a level and firm surface prior to weighing a participant. The participant will stand in the middle of the scale platform, head erect and looking straight ahead. Results will be rounded to the nearest kg.
 - ii) Height -- The participant will stand erect on the floor with his back against the vertical mounted ruler, heels together and looking straight ahead. The right angle will be brought down snugly but not tightly on the top of the head so that height can be accurately measured.
 - iii) Waist and hip circumferences -- For the waist, anthropometric tape will be applied at the level of the navel with the patient supine and breathing quietly. Results will be rounded to the nearest cm. For the hip, the participant will stand erect but relaxed with weight distributed equally over both feet. The measure will be made at the level of maximum protrusion of the hips with the tape kept horizontal.
 - iv) Body fat measurement -- Using an RJL bioelectric impedance meter, resistance and reactance are recorded. Percent body fat will be estimated by the RJL formula based on total body water.
 - v) Arm circumference -- The participant will sit on a table so his right arm hangs freely with the right hand resting on the right knee. The tape measure will be placed horizontally at the midpoint between the acromium and olecranon. Results will be rounded to the nearest cm. The measure will be used to select the proper size blood pressure cuff.
- 2) Examination of the following:
 - i) Pedal pulses -- The presence of posterior tibial (palpating inferior to the medial malleolus of each foot) and dorsalis pedal (palpating superior) pulses will be determined.
 - ii) Ankle edema -- With foot coverings removed, participant will be examined in the supine position. Gentle but firm pressure will be applied along the mid-tibia, anteriorly down to the ankle in each leg. The degree of edema (0-4) will be recorded.

- 3) Blood pressure measurements:
 - i) With the participant sitting with right arm on table, the cuff will be connected to a standard manometer and the pulse obliteration pressure will be established and recorded. After five minutes, the cuff will be reconnected and inflated to +30 mm above the obliteration pressure and held constant for 5 seconds. The cuff will be slowly deflated (2 mm/sec) while reading pressures for 1st and 5th phases. Before measurements 2 and 3 are taken, the participant will raise the arm for five seconds. After another 25 seconds with arm on the table, the measurement will be repeated a second and third time. The average of the last two measurements will be used for analysis.
 - ii) Using a Doppler, with the participant supine, right brachial and both ankle systolic pressures will be measured two times.
- 4) Twelve-lead resting ECG measurement -- Using a Marquette Mac-PC or Mac1200-based system, a 12-lead EKG will be obtained in a standard manner. EKGs will be electronically transmitted to Cornell University and confirmed interpretations will be transmitted back to field location to be filed in the participant's medical record. Tracings will be Minnesota coded.
- 5) Fasting blood samples will be obtained for measurements of total triglyceride (TG) and cholesterol, LDL and HDL cholesterol, plasma fibrinogen, PAI-1, DNA isolation, glucose, creatinine, insulin, and CBC. The complete blood count (CBC) will be measured at the local IHS laboratory.
- 6) Urine will be collected at the beginning of the physical examination for measurements of albumin and creatinine.
- 7) The following cardiovascular procedures will be performed:
 - i) Ultrasound examination of the carotid artery (see Manual Volume V, Special Studies for details).
 - ii) Echocardiography (see Manual Volume V, Special Studies for details)
 - iii) Radial Artery Tonometry (see Manual Volume V, Special Studies for details)

The clinical examination will last approximately three hours. The participant will arrive at the clinic fasting in the morning. After registration, a study staff member will explain the study and procedures to the participant, answer questions, if any, and administer the consent form. The participant will then be instructed to go to the laboratory for blood drawing and to obtain the urine specimen. The participant is then offered a light snack. The nurse clinician and other staff will then conduct the personal interview, obtain anthropometric measurements, blood pressure, impedance measurement for body fat composition, and ECG measurements. Project staff who have been trained and certified will perform echocardiography, ultrasound exams of the carotid

artery, and radial artery tonometry. After all the procedures are completed, the participant will receive payment or sign a payment form, will be provided appropriate health educational material to reduce his/her cardiovascular risk, and will be thanked for his/her participation.

If possible, all of the components will be completed in one visit. If an individual leaves before the examination is completed, every effort will be made to complete all components of the examination before the study is completed. The personal interview and consent may be completed up to two weeks prior to the physical examination, if such arrangements are more convenient.

Each center will pilot the exam in at least 10 persons and appropriate revisions in the procedure will be made and standardized for use in all three centers for 900 family members age 15 or over at each center. If no major revisions are made in the procedure, data from the pilot participants will be included in the analysis. For pregnant women, the examination will be conducted no earlier than six weeks after delivery. Lactating women will be included in the study if six weeks or more postpartum.

1.4 STUDY QUESTIONS

The wealth of data from this and the previous three phases of SHS will provide answers to many **important questions concerning CVD** which will impact the health care of American Indians. Since the SHS now contains the largest number of diabetic individuals in a longitudinal study of CVD in the US, the results will also benefit many other populations throughout the US and the world who have high rates of diabetes.

The genotyping of the extended families coupled with the availability of risk factors provides a unique database of CVD risk factors in a population with insulin resistance and high rates of obesity and diabetes to ask:

- a. Are there genes that have large effects in explaining the low plasma cholesterol in American Indians, and can their chromosomal locations be determined?
- b. Are there detectable genes that influence diabetes susceptibility in American Indians? Can these genes be mapped to specific chromosomal regions?
- c. Are the amount and distribution of body fat in American Indians influenced by genes with large effects, and are their chromosomal locations near those of genes for diabetes?
- d. Are there genes that have significant effects on renal disease as assessed by albuminuria that can be mapped to specific regions?
- e. Are LDL size and other measures of the dyslipidemia associated with the insulin resistance syndrome influenced by a gene or genes with large effects and can these genes be mapped to specific chromosomal regions?

The availability of comprehensive ECHO and carotid measures provides a unique opportunity to ask:

- a. Are intima-media wall thickness (IMT) and atherosclerotic plaque influenced by one or a few genes whose chromosomal locations can be determined?
- b. Are measures of ventricular mass, function, and other echocardiographic parameters influenced by one or a few genes whose chromosomal locations can be determined?

The continued surveillance of the cohort with very high completion rates and systematic assessment of endpoints will allow us to ask:

- a. How do incidence rates for various manifestations of CVD change with age and diabetes in this population?
- b. What are the major risk factors for stroke in this population and do they differ by gender and diabetic status?
- c. Is the strong predictive value of renal disease attributable to its relations to general vascular impairment?
- d. Are high TSH, endothelin, or VCAM-1 levels independent predictors of CVD?

The unique availability of ECHO, carotid and tonometry data on individuals allows us to ask:

- a. Which echocardiographic measures of cardiac function are significant predictors of CVD and how do these predictors interact with other established risk factors?
- b. Is arterial stiffness as measured by tonometry a predictor of CVD events?
- c. What aspects of carotid wall thickness and morphology are predictive of CVD in this population, and how do they relate to established CVD risk factors?

1.5 STUDY MANAGEMENT

1.5.1 Introduction

The Strong Heart Study Phase IV is funded by the National Heart, Lung, and Blood Institute, and directed by the Clinical and Genetic Epidemiology Branch, Epidemiology and Biometry Program, Division of Epidemiology and Clinical Applications. The Principal and Co-investigators are listed in Appendix 1 below. An organizational chart of the Strong Heart Study Phase IV is given in Appendix 2. The operations of the study are directed by the Strong Heart Study Phase IV Steering Committee, which includes members from each center and the NHLBI Project Manager (see Appendix 3 for the members of Steering Committee). In addition to being a field center, the Oklahoma Center assumes the responsibility of the Coordinating Center and the Arizona Center acts as the Core Laboratory. The Cornell University Reading Center under the direction of Dr. Richard Devereux serves as both the ECG Reading Center and the Carotid ultrasound reading center. Analysis of the family study genetic component is directed by Dr. Jean MacCluer at the Southwest Foundation for Biomedical Research. SHS-IV Sub-Committee members are listed in Appendix 4. Other key personnel at each center and consultants of the Study are listed in Appendix 5 and 6, respectively

1.5.2 Confidentiality of Data

All personnel with access to data collected for the study at each center are required to sign a confidentiality pledge which states that they understand the sensitive and confidential nature of the data and that divulgence of any information will result in disciplinary action. The pledge will be co-signed by the principal investigator. A sample of the confidentiality pledge is given in Appendix 7.

Completed data forms will be placed in locked file cabinets in offices assigned to the study at each study center. Only authorized staff members have the key to the office and access to the data forms.

Data on computers at the Coordinating Center will be safeguarded by a password, which is known only to authorized personnel.

1.5.3 Communications

1. Newsletter:

The Coordinating Center periodically prepares and distributes a newsletter to facilitate communication among Study staff and with the SHS participants. In general, each edition includes: (1) reports from the Program Office, the Steering Committee, the Coordinating Center, the Core Laboratory, the Cornell Reading Center (ECG, Carotid Ultrasound, and Echocardiogram), and the Southwest Foundation for Biomedical Research (Genetic Study Center), (2) a description of the facilities and staff of a field center or central agency, (3) general

information on data management, (4) information about new ancillary studies, and (5) upcoming events. The newsletter also provides reports on issues such as recruitment and participant follow-up rates, the development and use of new equipment, and preliminary study results and abstracts.

2. Electronic Mail:

E-mail through Internet and FAX continue to be the major electronic mail facilities used by all field centers, the Coordinating Center, Core Laboratory, Cornell Reading Center, Genetic Study Center, and the Program Office. This electronic mail network allows rapid and efficient communication among centers for messages such as announcements, meeting agendas, abstracts for clearance, and acknowledgments of receipt of data.

3. Web Site <http://strongheart.ouhsc.edu/>

A list of scientific publication from the Strong Heart Study is available and linked to abstracts. This Phase IV Manual and the study Newsletters will also be available on the web site in Phase IV.

4. Field Center Visits:

The Program Office and staff from the Coordinating Center, Cornell Reading Center, Core Laboratory, and Genetic Study Center conduct periodic monitoring visits to field centers as needed to: (1) maintain channels of communication with field center investigators and staff, (2) monitor participant recruitment and surveillance procedures, (3) monitor adherence to the protocol, and (4) provide technical support for activities such as data management and quality control.

1.6 DATA MANAGEMENT AND STATISTICAL ANALYSIS

1.6.1 Development and Production of Study Manual and Data Collection Forms

The Coordinating Center worked closely with the Steering Committee in the development and production of the study manual and data collection forms. A Forms Committee reviewed all forms and made recommendations for revisions, deletions, and additions of forms. The Psychosocial Committee held frequent conference calls and devised a set of psychosocial forms comprised of forms used previously in SHS and elsewhere. The Manual was revised by Steering Committee members and the Field Coordinators. Revisions were circulated by email attachments, and further input and improvements were provided during the training sessions held in Oklahoma City (January 29 – February 2, 2001). After pilot testing the data forms in February 2000, the entire manual was reviewed page by page and modifications were incorporated.

a. Sources of data

Data forms for the SHS are generated from a variety of sources.

- i. From the three field centers: Clinical examination forms (personal interview, medical history, physical examination, quality of life and other psychosocial forms, machine reading of ECG, and local clinic lab assays of blood chemistry and CBC), Death Certificate Form, and Morbidity Survey Medical Chart Review Form.
- ii. From the Core laboratory at Medstar Research Institute: Lipids, fasting glucose, insulin, plasma creatinine, glycated hemoglobin, urinary albumin and creatinine.
- iii. From Cornell University, cardiologist's ECG reports, computerized Minnesota ECG codes, blood pressure tonometry waveform data, echocardiography, and carotid ultrasound data.
- iv. From Mr. Karl Wise (study nosologist): ICD-9 coded cause of death.
- v. From Dr. Maurice Sievers: Mortality study final decision package (Mortality Study Chart Review Form, Final Decision Form, and Informant Interview Form).
- vi. From Mortality and Morbidity Review Committees (Mortality or Morbidity Study Chart Review Form, Mortality or Morbidity Final Decision Form, and Mortality Informant Interview Form).
- vii. From Dr. Jean MacCluer: DNA data.
- viii. From Block Dietary Data Systems: Analyses of the Food Frequency Questionnaire.

b. Database development

In SHS-IV, the Coordinating Center continues to use a distributed data entry system. In Phase IV the Coordinating Center is using Microsoft (MS) ACCESS to develop the data entry programs (as before) and MS Windows 2000 Terminal Services to support real-time data entry (as opposed to batch transmission as used in Phase III) via

high-speed Internet connections with state of the art field center computers. Separate files have been created for each data form; these files and the data files are stored solely on the server(s) at the Coordinating Center. Maintenance of the data programs and files occurs on the server(s) at the Coordinating Center; the field centers transmit the exam data to the Coordinating Center for data cleanup and permanent storage.

The laboratory data and data from special studies are transmitted to the Coordinating Center electronically over the Internet or by sending data-containing media such as diskettes. The Coordinating Center stores the raw data sent from the specific study centers and converts them into SAS data files for analysis.

c. Procedures for data entry and verification of completeness

Each field center reviews every data form for completeness and accuracy before entering it into the field computer. Details of the data entry process and data management can be found in Volume 7 of this SHS IV Operations Manual. The completeness of data entry for each form is checked again by the Coordinating Center. Any incomplete items (missing, questionable, unclear) are recorded, and the corresponding field center is contacted to find out the reason. When these items are completed by the individual center and received by the Coordinating Center, the information is updated in the Coordinating Center's database. To ensure the data quality, the field centers are required to double enter all of the forms in the first 2 months. If the disagreement rate is less than 0.5% in these two months, the double entry ratio drops to 10% of the data or at least one double entry per transmission. The Coordinating Center checks the disagreement rate for double entry on a monthly basis. If the disagreement is greater than 0.5% in that transmission, that center is asked to re-enter (as second entry) the data of all the forms in that transmission.

The data received from the Core Laboratory via the Internet as ASCII files are directly converted into SAS datasets. Before these data are merged into the permanent data files, various quality and consistency checks are performed.

Uniform data entry forms for all information to be collected have been designed by the Coordinating Center for use by each Study Center. Each study subject will have a unique identification number (ID number). Please see the Strong Heart Study Phase I Manual page 12a for the detailed procedure to assign the study ID number. For those original cohort members who participate in Phase IV, the original ID number assigned in the Strong Heart Study Phase One will still be used. The ID number will be stamped on every page of all forms at each center. For laboratory specimens, printed labels supplied by the Core Lab will be used.

<u>Center</u>	<u>Family ID</u>	<u>SHS ID</u>
Arizona	AZxxyyy	360001 - 36zzzz
Oklahoma	Okxxyyy	260001 - 26zzzz
South and North Dakota	Dkxxyyy	160001 - 16zzzz

Where xx : family number.

yyy : 001 - 999 for each family member.

zzzz : a unique number for each family member who participates in the examination and interview.

Standard IHS community codes will be used to identify the community where the participant resides. A list of community codes for the three centers is given in Appendix A-1 of Volume 2. Hospitals where a Phase I cohort member died or was treated for CVD are also coded. Standard IHS facility codes will be used to identify IHS hospitals and clinics. Codes for other non-IHS hospitals will be assigned by each center. The hospital/clinic codes are given in Appendix A-2 and A-3 of Volume 2, respectively. In addition, every member of the Study is assigned a Personnel Code which will be used to identify the person who filled out a specific data form. The Personnel Codes for the three centers are listed in Appendix A-4 of Volume 2. Additional Codes will be added sequentially as new employees begin to work on the project.

All data forms must be filled out legibly and completely. Each and every form must be reviewed and checked for completeness and legibility before it is entered into the computer.

1. All forms should be filled out in black pen. Print all information in block capital letters, with one letter only in each box, so that data entry errors can be minimized. For example, one should differentiate: 7 from 1, U from V, 4 from 6, P from D, M from N, C from O, and T from J.
2. For names and addresses, start from the leftmost box and leave the unused boxes blank. Include periods for initials.
3. For numerical values, fill in the boxes in a right justified manner and leave the unused boxes blank.
4. For dates, two digits are allowed for the month and day, and four digits for the year. If the number has only one digit, use zero in front of the number.
5. When recording dates, use the following rule for missing dates:

If date is unknown/missing :	01/01/1001
If only year is known:	06/30/year (assign mid-year as the date)
If only year and month are known:	month/15/year (assign mid-month as the date)
6. To correct an error, draw a single line through the mistake and write the correct value above.

7. Fractions should be rounded up to the nearest whole number if the fraction is 0.5 or more, otherwise, drop the fraction, e.g. $2.25 = 2$; $2.75 = 3$; $3.5 = 4$.
8. If an interval is given, record the midpoint of the interval if it is a whole number. If the midpoint includes the fraction 0.5, use the rounding rules previously given.
9. Unless otherwise instructed, no item on any of the forms should ever be left blank. Codes to be used in the event of missing or incomplete data are given under the heading of each specific item. If there is not a code for the "unknown" category, draw two parallel lines horizontally through the box or boxes to indicate that the interviewer or abstractor did not ignore the question. For example, if the time of death is unknown, draw two lines across the boxes.

1.6.2 Procedures for data entry and verification of completeness -- See *SHS-IV Operations Manual Volume VII - Data Entry*

1.6.3 Data Transmission

The lab data, ECG data, and ultrasound data will be electronically transmitted to the Coordinating Center, and will be converted to SAS datasets. However, before these data are merged into the permanent data files, they are checked against the values given by the laboratory on paper to ensure the conversion is correctly done.

1.6.4 Data Backup

Several backup procedures are suggested to ensure the safety of the SHS data files in both field centers and the Coordinating Center.

- a. Daily backup: Two sets of cartridges are rotated to backup the data every day from Monday through Thursday (one for Monday and Wednesday and the other for Tuesday and Thursday).
- b. Weekly Backup: Similar to daily backup, two sets of cartridges are rotated, each for every other week. Backup of the week's data set is done every Friday.
- c. Optical disk backup: Additional permanent files are stored in the optical disk for long term storage.
- d. Storage of backup data: Cartridges and optical disks are stored in locked file cabinets in different offices and one set of them will be stored in a different building.

1.6.5. Quality Assurance (QC) Program

The quality control (QC) program was improved in Phase II with close monitoring of the quality of all measurements and interview data. At the beginning of SHS-III, a Quality Control Subcommittee was formed to oversee the QC program of the Study. The members of this Subcommittee include the NHLBI Project Manager, a representative from the Coordinating Center, one principal investigator, and the three Field Center Coordinators. The Quality Control Committee meets periodically via conference calls during the examination period to assess the results of quality control activities. The QC Committee reviews the QC data and summary statistics provided by the Coordinating Center and reports to the Steering Committee with recommendations. Recommendations are made to the appropriate centers when problems are identified. Follow-up procedures are established and monitored for all the QC activities. After each site visit, reports are reviewed. If indicated, field staff are retrained, re-certified, and re-monitored by the QC personnel. For lab data, aberrant pairs are investigated and corrective actions are taken both in the core lab and in the field sites. The quality control program includes: a) data collection, b) site visits, c) routine maintenance and monitoring of instrument performance, d) duplicate measures for physical examinations, laboratory tests, observations of personal interviews, QC for cardiology tests, and QC for surveillance (each of these components is described below). Each clinical center has a quality control officer who is responsible for all aspects of quality control at that center. The Coordinating Center closely monitors the recruitment and progress of the Study. According to the target numbers to be recruited by each center during the whole study examination period, the CC develops a timetable to indicate the projected goal for each month. The field centers report the number of participants actually examined to the CC, and the CC then compiles these numbers on a monthly basis. Cumulative achievement for each field center is then calculated by comparing the actual number examined to the projected number for the corresponding month. In addition to recruitment, the CC also monitors whether each field center had completed their quotas for double entry of data, QC physical examinations, and QC blinded blood samples. The CC submits progress reports to the SHS Steering Committee as a tool to monitor the progress of the study. If the percentage of projected recruitment in a certain field center falls below 80%, the PI and the field coordinator are informed, so that the efforts can be focused on recruitment in the following months. Field center coordinators are responsible for reviewing all QC data as they become available and following up on any problems that are detected. The QC committee monitors the efficacy of retraining and problem solving.

1. Data Collection

Every data form will be checked for completeness at the field center. Ambiguous or erroneous items will be clarified and corrected. The data entry programs, which will be generated by the Coordinating Center, will provide an additional quality control check by building in range and logic checks. The program will refuse to accept such data until the errors are corrected. During the first two months of examination, all forms will be double entered. After this initial period, 10% of the examinations will be randomly selected for double entry.

The Coordinating Center will track the data entry error rates. If the data entry error rate of any field center is greater than 0.5%, that center will have to double enter all the examination data of that month. Computer printouts of inconsistent data items will be sent back to each field center for clarification or correction. Summary statistics such as mean, median, range, maximum and minimum for continuous variables and frequency distributions for categorical variables will be calculated monthly for each center, and data not meeting consistency checks will be flagged. Summary statistics will be generated quarterly to identify any peculiar or unreasonable values. Further verifications will be made and errors corrected.

2. Quality Control Site Visits

Two quality control site visits will be made to each of the three centers in the first year and one in each year thereafter. The site visit teams will include representatives from the program office at NHLBI and investigators and staff members from each of the centers. Procedures used in the clinical examination will be carefully observed for adherence to protocol. Equipment will be inspected and problems noted. The site visitors then will meet with all the clinic staff to inform them of any observed discrepancies. In addition, a written evaluation including corrections or improvements needed will be sent to each center.

3. Quality Control -- Equipment

Other quality control measures will include maintenance of the scale, sphygmomanometer, Doppler, and ECG machine. The scale will be zeroed daily and calibrated with a known weight (50 lbs) every month or whenever the scale is moved. The standard sphygmomanometer will be inspected once a month. These inspections will include checking of the zero level, mercury leakage, manometer column for dirt or mercury oxide deposit, and the condition of all tubing and fittings. Other quality control measures for the blood pressure measurements will include simultaneous Y-tube observation of each technician and frequent staff meetings to provide feedback.

4. Quality Control -- Examination

1) Anthropometry and blood pressure

Duplicate measures of brachial artery blood pressure (systolic and diastolic) simultaneously using a double head stethoscope with two observers will be taken. Duplicate measures of anthropometry (height, weight, waist, hip, and electrical impedance measurements) will be performed by a second observer on a 5% random sample of participants. These data will be sent to the Coordinating Center for monthly analysis. Results of the analysis will be provided to the field centers and the Steering Committee on a quarterly basis. Differences between duplicate measures exceeding the following values will be considered unacceptable:

- i.) Systolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.

- ii.) Diastolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.
- iii.) Height: 1 cm
- iv.) Weight: 1 Kg
- v.) Resistance: 15 ohms
- vi.) Waist circumference: 2 cm
- vii.) Hip circumference: 2 cm

Duplicate data for blood pressure, height, weight, impedance, hip, and waist circumferences will be compiled by the Coordinating Center and reported to the clinics and Steering Committee quarterly; in addition, distributions of measurements and digit preference for each staff member will be compiled and repeated quarterly.

Anthropometric measurements and blood pressure by standard sphygmomanometer will be observed and evaluated quarterly by the clinic supervisor. This person will also assure that each of the other operators of the impedance meter is re-certified quarterly by having him/her perform an impedance measure on the same participant as the supervisor. In addition, a simultaneous Y tube observation of each observer by the blood pressure supervisor will be made. All results will be analyzed by the Coordinating Center on a quarterly basis.

2) Laboratory tests

Duplicate blood and urine specimens will be collected on approximately 10% of the participants in the first 3 months of Phase IV and then on approximately 5% of the participants thereafter. These duplicates will be sent to the Core Laboratory in a blind fashion. Results obtained for each test will be analyzed monthly by the Coordinating Center for accuracy and consistency. The percent of pairs with differences within 5% and 10% will be computed. Correlation coefficients and technical error rates will be calculated. Poor correlation or unreasonably high technical error will be reported to the Laboratory and the Steering Committee.

3) Personal interview

Personal interviews by new staff will be observed monthly by the study coordinator until the staff member meets the standards of the study. Then new staff will be observed on a quarterly basis along with experienced interviewers. Problems and errors are identified using a checklist and corrected immediately.

4) Food Frequency Questionnaire (FFQ)

Block FFQ is self-administered; participants will receive guidance in how to fill out the questionnaire. The developer, Block Dietary Data Systems, has provided a specification manual that describes each question. Ellie Zephier, SHS Nutrition Investigator, will use this manual to train the field staffs in how to instruct participants. Those participants who have difficulty will be assisted by trained staff.

5) Quality control for surveillance data

Surveillance activities at each center are monitored on a monthly basis by the Coordinating Center. Contact rates, numbers of potential events, rate of medical record abstraction and forwarding of packets for review are evaluated each month according to pre-set, expected completion rates. Final decisions on possible CVD deaths and morbid events are made by members of the Mortality Review and Morbidity Review Committees. These surveillance Committees also evaluate the quality of chart reviews and advise clinic staff when changes are needed. The Mortality Review Committee is composed of a primary physician reviewer who reviews all deaths (Dr. Maurice Sievers) and a group of six physicians who serve as secondary reviewers for all potential CVD deaths. Each physician independently determines the classification of the cause of death, and the Coordinating Center then compares the results from both physicians. Two neurologists from the Mayo Clinic are secondary reviewers and adjudicators for all cases of potential stroke. The entire Mortality Committee adjudicates potential CVD cases when there is a disagreement between the primary and secondary reviewers. A detailed description of the steps in the process of identifying deaths and confirming the underlying cause is given in Volume 2. Monthly reports are reviewed by the Steering Committee in order to monitor the progress of surveillance and event reviews. An example of a monthly surveillance report is included in Volume 2.

6) Certification of technicians

Each center will recruit the most qualified personnel. Clinical staff will be centrally trained and certified before the examination begins and newly hired personnel will be trained at each clinic. The study coordinators will monitor the technicians quarterly to ensure accurate and consistent performance.

7) Confidentiality and security of data

All personnel with access to the collected data are required to sign a confidentiality pledge (see Appendix 7 below). Completed data forms are placed in locked file cabinets at every center and are accessible by authorized staff members only. At the Coordinating Center, the data are stored on computers that are used exclusively by the Strong Heart Study and are safeguarded by passwords that are known only to authorized personnel. The data are stored on hard disk and four copies of floppy/optical diskettes. Two of the Zip disks/optical diskettes are stored in two different locations other than the Coordinating Center office.

8) Monitoring of study progress

The Coordinating Center will work closely with the field centers to monitor recruitment and progress of the examinations. At the beginning of the study, a projected monthly number of participants to be recruited will be generated, and the Coordinating Center will monitor the progress of each field center according to these projected numbers and provide monthly progress

reports to the Steering Committee. If the percentage of projected recruitment in a certain field center falls below 80%, the PI and the field coordinator will be informed, so that the efforts can be focused on recruitment. This program proved to be an efficient tool for monitoring the progress of SHS-III and will be continued, and refined if necessary, in Phase IV of SHS. The Coordinating Center will also monitor the number of double entries, QC physical exams, and QC blinded blood samples and report to the Steering Committee monthly.

1.6.6. Statistical Analysis

a. Major statistical analyses of the SHS Phase IV data will include:

1) Epidemiological analyses:

- i. determination of mortality and morbidity rates for CVD and all causes of death in the SHS cohort.
- ii. estimation of the incidence of CVD and other diseases of interest in the SHS cohort.
- iii. identification of risk factors that are related to cohort mortality and incidence of CVD and other diseases of interest.
- iv. determination and comparison of the associations of identified risk factors for CVD, diabetes, coronary heart disease (CHD), peripheral vascular disease (PVD), and other diseases of interest and associations among the risk factors.
- v. identification of markers from comprehensive echocardiography and carotid data and their association to the incidence of CVD, carotid atherosclerosis, stroke, left ventricular mass, and cardiac wall motion abnormalities, and to other risk factors.
- vi. determination of changes, pattern of changes, and age effects of risk factors for CVD, diabetes, CHD, PVD, and other diseases of interest.

2) Familial aggregation analyses:

- i. familial aggregation analysis of CVD, diabetes, CHD, PVD, carotid atherosclerosis, stroke and other diseases of interest to compare and estimate the correlation of the disease outcomes within different family relationships, such as parents and siblings, and to compare the odds of disease for individuals with a diseased relative with the odds of disease for individuals without a diseased relative.

- ii. estimation of the effects of age, household, and environment as well as their interactions with genetic factors on identified risk factors of CVD, diabetes, and other diseases of interest, and comparison of the results with other ethnic populations.
- iii. in collaboration with investigators of the SW Foundation, study the genetic and environmental etiologies of quantitative phenotypes, such as cholesterol level, body fat and blood pressure, and complex traits such as CVD and diabetes, locating and characterizing the underlying putative genes and comparing the results with other ethnic populations.

b. Methods for epidemiological analyses:

1) Mortality rates:

From the cohort mortality surveillance data, we will be able to estimate mortality rates for CVD and other causes of death. We will calculate age-, sex-, center-, and cause-specific mortality rates by using person-years which will be computed from the time of Phase I examination to the date of death or last-follow-up, whichever comes first. The total number of person-years will be the denominator and the number of deaths the numerator. The mortality rates will be expressed per 100 or 1000 person-years. These rates will then be compared to those obtained in the US and in other ethnic populations, and to those obtained in the community mortality survey of the same population. Life-table analysis techniques (1) will be used to estimate median remaining lifetime.

2) Incidence rates:

Data on disease status obtained from the cohort morbidity surveillance will be used to estimate incidence rates of CVD, diabetes, PVD, renal disease, etc. If the date of diagnosis is unknown, we can estimate an 11-year (baseline is Phase I) cumulative incidence or a 7-year (for Phase II baselines) cumulative incidence. The number of disease-free participants at baseline will be the denominator, and the number of new cases identified during the follow-up period will be the numerator. If the exact date of first event is available, we will compute the incidence rate (or incidence density) by using person-years. Incidence rates so obtained will be compared to those from other studies.

3) Association study and modeling related observations:

Statistical analyses related to mortality and to morbidity include comparisons of cumulative incidence, incidence density, mortality rates, disease-free time, and survival time distributions between “exposure” subgroups. The survival time will be calculated from the Phase I examination to the time of death or last-follow-up, and the disease-free time will be from the Phase I examination to the date of diagnosis or last-follow-up. The

distributions of survival time and disease-free time will be estimated by the Kaplan-Meier method (1). The cumulative incidence between “exposure” subgroups will be compared using the chi-square test, and the incidence rates (density) and mortality rates between “exposure” subgroups will be compared by using methods by Rothman (2). The distributions of survival time and disease-free time in different “exposure” subgroups can be compared by using the logrank or K-sample tests (1) or Cox proportional hazards model (1) or some parametric (1) (e.g. Weibull, lognormal, gamma and log-logistic) models with covariates. In order to handle longitudinal observations from Phase I to IV, the distributions of survival time and disease-free time will be modeled further as non-proportional hazards models such as the Cox model with time-dependent covariates (1), stratified model (1), multiplicative hazards model (3) and piecewise exponential model.

The association of risk factors to disease can be analyzed by using conditional or unconditional logistic regression models or the classical Cochran-Mantel-Haenszel test (4) to adjust for possible confounding factors. The data used in analyses will be accumulated from successive risk factors data observed in the SHS Phase I-III exams and disease status data observed in Phase II-IV. To adjust the effects that may be caused by related observations in the study, namely, the repeated measurements from different SHS phases for each participant, the association of disease outcome with risk factors or the association of a risk factor with the other risk factors will be assessed and modeled by utilizing the marginal models (5), generalized linear or nonlinear mixed models (6,7,8) (which include the usual models like linear or nonlinear mixed, logistic regression with or without random effects, random coefficients, repeated measurements models, etc. as special cases) under different assumptions of covariance structure of related observations. The effects of related observations on estimating and testing the parameters in these models have been adjusted by their covariance. By using these models, we will be able to assess and model the association while taking care of the problem of the related observations and the changes in disease risk factors over time and age effects. For instance, we may use a generalized linear mixed model for CVD status on covariates (such as age, sex, center, blood pressure, lipoproteins, etc.) and assume that measures (e.g., lipoproteins) for a person observed from different examinations are correlated.

c. Methods for family data analyses:

Familial aggregation analyses. By applying the marginal model, generalized linear model, or nonlinear mixed model to the family data, we will be able to assess the effects of age and different family relationships on different risk factors and then on CVD and other diseases of interest, to compare with the respective results from the SHS Phase I-III, and to compare among different age groups. For example, we may use a generalized linear mixed model to estimate and compare CVD prevalence rates among different age groups or between siblings whose parents have CVD and siblings whose parents do not have CVD in the Family Study, assuming CVD risks among members in a family are correlated. It is possible that only a few observations will be available in certain

subgroups in the family data, and therefore analyses based on the few observations may be unreliable. Thus, in addition to using the marginal models and generalized linear and nonlinear mixed models for analysis of the family data, the multivariate composite estimation method (9), various Bayes models, and empirical Bayes procedures will be used. These methods will be used in estimating and modeling risk factors and associations of risk factor to diseases in order to reduce the variance of the estimators by using additional information from other related groups.

The marginal models, generalized linear or nonlinear mixed models, and variance components models (10,11,12) will be adopted to estimate the effects of heritability, covariates, and environment, as well as their interactions, on quantitative risk factors or qualitative diseases status under different family relationships. For instance, we may use a logistic regression model for a disease status on covariates (such as age, sex, center, tribe, household, degree of Indian heritage, education, income, smoking status, alcohol consumption, physical activity, dietary covariates, family history of this disease or other related diseases) and different family relationships (e.g., husband-wife, parents-offspring, sib pairs, etc.), or a linear mixed model for a quantitative risk factor on the covariates and different family relationships. Some preliminary results from the SHS Phase III family studies have shown applications of the variance components models in heritability assessments of CVD-related phenotypes (e.g., total cholesterol, LDL, and HDL) and diabetes-related phenotypes (e.g., fasting insulin, hemoglobin, please see SW Foundation's application).

d. Literature Cited for Statistical Analysis

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1.7 PUBLICATION POLICY

The SHS Steering Committee appointed the following members to form a Publications and Presentations Committee (P&P Committee):

Dr. Elisa Lee (Chair)
Dr. Lyle Best
Mr. Richard Fabsitz
Dr. Barbara Howard
Dr. Jean MacCluer
Dr. Mary Roman

The P&P Committee shall review and approve/disapprove all paper and thesis proposals. When the P&P Committee does not reach a consensus on a proposal, or when issues concerning a proposal (or other publication matters) are particularly problematic, the matter will be referred to the SHS Steering Committee (SC). The P&P Committee will present the issues and any of its recommendations to the SC, which shall have final authority for approval or disapproval of the paper or thesis proposal (or other publication matters).

The P&P Committee shall meet or discuss by telephone, monthly, or as needed, proposals submitted for a paper or a thesis (and any other publication matters).

1.7.1 Submission of a Paper Proposal

I. Proposal

A formal paper proposal (see Appendix 8 below - this form can be downloaded – see SHS website: <http://strongheart.ouhsc.edu>) must be submitted to the Chair of the P&P Committee (Elisa T. Lee, PhD at elisa-lee@ouhsc.edu) at least one week prior to the P&P meeting. Upon review for completeness (including preliminary review of the analysis plan by a statistician), the proposal will be added to the agenda of the next P&P Committee meeting for action. The Chair is responsible for distributing copies of the proposal to the members of the Committee.

A formal paper proposal must include the following as a minimum:

1. Title (To maintain a cohesive body of literature, each publication using SHS data should include the phrase "Strong Heart Study" in its title and listed as a keyword whenever possible. Titles not meeting this guideline must be justified at the time of manuscript proposal submission.)

2. Primary author's name, contact information including fax and e-mail, and affiliation. Via distribution of P&P Committee minutes, the P&P Committee will periodically report its decisions to the SHS Steering Committee (SC), and SC may nominate additional co-authors for any papers that have been approved by the P&P Committee.
3. Suggested co-authors
4. Suggested key words
5. A detailed outline which includes:
 - a) Introduction (rationale)
 - b) Methods
 - c) General analysis plan
6. Analysis responsibility (authors or Coordinating Center, CC)
7. References (the timeliness and originality of a proposal should be supported by the supplied references).
8. When submitting a proposal, authors are encouraged to send a copy of any journal articles that would support their choices for methods of statistical analysis. This will simplify the review process on the part of the statistician performing the preliminary review of the proposal.
9. Prior to submission, all proposals must be approved by an SHS P.I.

II. Review of Paper Proposal by the P&P Committee

The P&P Committee shall review all formal proposals and make the following decisions:

1. Approval (or approval with recommendation), deferral, or disapproval (with reasons).
2. Upon approval, the paper is given an SHS Paper Approval Number.
3. In the event a proposal does not receive full approval (approved with recommendations or disapproved), the P&P Committee will supply the author with a complete explanation and recommendations for re-submission, when applicable.
4. The decision of the P&P Committee will be forwarded to the submitting author.
5. Along with an approval memo from the Chair, the author of each approved manuscript proposal will receive an Author Agreement Form (an SHS author/investigator agreement must be signed by the author obtaining SHS data for a paper), Data Request Form, Data

Analysis Monitoring Form, and Data Analysis Request Form (Data Request/Analysis Forms are to be used by the author as needed). For maintaining better tracking, each form will be marked with the assigned SHS Paper Approval Number (see forms in Appendix 8 below). The author needs to complete, sign, and return the forms to the P&P Committee. CC (or the appropriate SHS PI) then provides required data to the authors. All primary authors must sign an agreement form before CC or the appropriate PI will provide the data.

6. The P&P Committee recommends that authors requesting data from the CC understand that a clear and concise rationale for data extraction is imperative. Representatives of the CC are well capable of streamlining the extraction of the database and analysis processes when supplied with this rationale.
7. If data analysis from the Coordinating Center (CC) is requested, the CC will assign a statistician to work with the primary author after the proposal is approved and all the required forms are returned to P&P Committee by the author. The paper may then be given a priority score if analyses are to be done by the CC. For those authors who choose to analyze their own data, CC representatives will be available for consultation. All statistical analyses in the penultimate draft that were performed outside of CC must be verified by CC before finalizing the paper.
8. Whenever an approved SHS paper proposal has no SHS PI as a co-author, the first draft of the paper must be sent to the P&P Committee Chair. The Chair will send the paper to 2 or more reviewers, and the comments of the reviewers will be communicated to the submitting author.
9. Prior to submission to a journal, the paper must be submitted by the author to NHLBI for review and to the IHS Area IRBs and the tribes for review and approval (see details in section IV below). **Please note that as an integral part of the manuscript approval process, the IHS IRBs in the three centers require that all SHS manuscripts must contain the following disclaimer (verbatim): “The opinions expressed in this paper are those of the author(s) and do not necessarily reflect the views of the Indian Health Service.”** A cover letter must be attached, requesting review and approval. The paper may not be submitted to a journal until the authors have received the NIH review (normally within one month of submission to NIH). The primary author is responsible for making sure that all Tribal/IHS approvals have been obtained prior to publication by contacting the responsible individual at each of the three field centers (see section IV below).
10. Minutes from the P&P Committee are circulated to the Steering Committee.

III. Analysis

If CC is responsible for the analysis, CC will assign a statistician to work with the author upon receiving the completed and signed "Request for Data Analysis Form" from the author.

The statistician is the CC representative to the writing group. Whenever the workload for CC is heavy, CC will work with the investigators in analyzing the data according to the priority scores assigned by the P&P Committee.

Guidelines for authors to use in dealing with CC are:

1. Communicate with the CC representative on the writing group and discuss the objectives of the paper, appropriate statistical methods to be used, format of presentation (tables and figures), etc.
2. Determine a timetable with the CC representative. Be sure that analysis requests are made clearly and in writing (using the "Request for Data Analysis" form) and in a way that will allow sufficient time to complete the analyses.
3. If CC falls behind, the investigator should inform the P&P Committee; if there is a problem, deadlines can be changed.
4. When the relevant statistical analyses have been performed outside of CC, the penultimate draft (next to final) must be submitted to CC so that all analyses utilized in the paper may be verified by CC prior to finalization of the manuscript.

IV. Summary of Paper Publication Process

1. An author submits a paper proposal in standard format (see form in Appendix 8 below) to the P&P Committee Chair. (Note: the phrase "Strong Heart Study" should be included in the title and listed as a keyword whenever possible).
2. The P&P Chair notifies the author of the committee decision.
3. Whenever an approved SHS paper proposal has no SHS PI as a co-author, the first draft of the paper must be sent to the P&P Committee Chair. The Chair will send the paper to 2 or more reviewers, and the comments of the reviewers will be communicated to the submitting author.
4. All statistical analyses in the penultimate draft that were performed outside of CC must be verified by CC before finalizing the paper.
5. Prior to submission to a journal, the paper must be submitted by the author to NHLBI for review (to be returned to the author within 1 month of submission) and to the IHS Area IRBs and the tribes with a lay summary and an attached cover letter requesting review and approval. These approvals are obtained through the following procedures:

- a. The primary author will first send the paper to the co-authors for their input. **When the primary author feels the paper is ready for NIH review and IHS Institutional Review Board (IRB) and Tribal approval, he/she will send a copy of the manuscript (including a Tribal/lay summary) simultaneously to the following with the clear designation that the paper is being sent for such approval:**

1) Dakota Center: LaVonne Looking Elk
Strong Heart Study - Dakota Center
P.O. Box 9010
Rapid City, SD 57709
Phone: (605) 355-2377
Fax: (605) 355-2502
email: llooking@rapidcity.aberdeen.ihs.gov

2) Oklahoma Center: Lee Keese
Univ of Oklahoma Health Sciences Center
CHB 112
P.O. Box 26901
Oklahoma City, OK 73190
Phone: (405) 271-3090
Fax: (405) 271-4390
email: Lee-Keese@ouhsc.edu

3) Arizona Center: Nanette Oram
Aztec Building - Ste 250
1616 E Indian School
Phoenix, AZ 85016
Phone: (602) 277-0488
Fax: (602) 277-5979
email: noram@medstarresearch.com

with cc to: Marie Russell, MD
Director, MedStar Phoenix Field Center
email: mrussell@medstarresearch.com

- 4) NHLBI: NHLBI has instituted an electronic means for submission of manuscripts for NHLBI Review, and authors are instructed to use this system for NHLBI REVIEW. Comments will be returned to the email address provided by the author in the submission process. All manuscripts need to be submitted to the following email address for NHLBI Review: ebpdocs@nhlbi.nih.gov

NOTE: Please cc Dr. Richard Fabsitz, Project Officer-Strong Heart Study, (FabsitzR@nhlbi.nih.gov) when emailing your manuscript to the above NHLBI email address.

The three individuals listed in 1-3 above are then responsible for sending the manuscript for approval by Indian Health Service IRBs and the Tribes.

- b. **The author must include a Tribal/lay summary** for all manuscripts, since such summaries are essential for obtaining Tribal and IHS IRB approval. The Tribal/lay summary should be no longer than one page of easily understandable text. One or two graphics illustrating major points could be included. Such summaries are critical to ensure tribal understanding of research results, and, hopefully, maintain tribal support for SHS research. **The intended journal should be mentioned for all papers in the cover letter/memo.**
- c. The paper may not be submitted to a journal until the authors have received NIH review (see #4 above). Authors must check with Oklahoma, Arizona, and Dakota Centers (see contact info in #1-3 above) to ensure that IHS IRB and Tribal approvals have been obtained. This should be done at the time when the author receives reviewers' comments from the journal and is in the process of making final revisions. The primary author is responsible for making sure that all approvals have been obtained prior to publication.
- d. The manuscript must include the following disclaimer (verbatim) (usually in the Acknowledgments or in a footer on the first page): **“The opinions expressed in this paper are those of the author(s) and do not necessarily reflect the views of the Indian Health Service.”**

The intention of this procedure is to ensure that all principal investigators are aware of the status of publications and also to ensure that appropriate review by NIH and approval by IHS and the Tribes occur prior to publication.

6. After the article is published, the primary author must send at least one reprint of the published article to the NHLBI Project Officer

Richard Fabsitz, PhD
Project Officer-Strong Heart Study
Two Rockledge Center-Rm 8178
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Phone: (301) 435-0458
Fax: (301) 480-1667 or 480-1455
email: FabsitzR@nhlbi.nih.gov

and to each of the three persons designated in the field centers (as listed above in #1-3), who will then distribute the published articles to Tribes and Service Units in their center. The primary author should also send reprints of the published article to all co-authors.

7. **NOTE:** Papers that are likely to result in press coverage or substantial press/media interest require notice in advance to the NHLBI (contact Dr. Fabsitz) so that the staff and public information office can be prepared.
8. The P&P Chair will maintain a list of published SHS papers and papers in various stages of preparation (posted on the SHS website: <http://strongheart.ouhsc.edu>). In order to help update the status of their papers in the SHS publication list, authors are required to notify the P&P committee by sending the cover letter each time when submitting their papers to the NIH/IRBs and to a journal. Also they are required to notify the P&P when the papers are accepted by a journal for publication and when published. If using electronic transmission to submit papers, they need to copy Dr. Momotaz Begum (momotaz-begum@ouhsc.edu).
9. To track the progress of approved paper proposals, the P&P Committee distributes a status survey of the approved papers by emailing a Paper Tracking Status Form every six months. The authors must fill out the respective space regarding the progress/current status of their paper(s) and return the form to the committee.
10. If the P&P Committee determines that progress on a manuscript is taking an unduly long time, the Chair will communicate with the author, asking for a plan of action for completing the paper or for the author(s) to release the topic for authorship by someone else.
11. In rare cases, the P&P Committee may need to make a recommendation to the Steering Committee regarding reassignment of a paper topic.

NOTE: It must be recognized that any step of this approval process may entail requested revisions and re-submissions by the authors.

V. Approval of Abstracts (Please note that a Lay Summary is now required by the IHS IRB of the Dakota Center)

1. It is assumed that all SHS abstracts will have at least one SHS PI as a co-author. The PI co-author is responsible for ensuring that the abstract abides by SHS standards and guidelines. If none of the PIs is a co-author, the abstract must be approved by the PI who works most closely with the authors. The title of the abstract should include the phrase "Strong Heart Study" whenever possible.
2. Abstracts must be submitted for NHLBI review. NHLBI has instituted an electronic means for submission of abstracts for NHLBI Review, and authors are instructed to use this system for NHLBI REVIEW. Comments will be returned to the email address provided by the author in the submission process. All abstracts need to be submitted to the following email address for NHLBI Review:

ebpdocs@nhlbi.nih.gov

3. Abstracts must also be sent to the Dakota Center for approval by their IRB. (The Oklahoma and Arizona Centers do not have this requirement.) Please include a brief LAY SUMMARY of the work to be presented. Please specify that the abstract is being forwarded for Dakota Center IRB approval, include information about the meeting or other venue intended for the presentation, and send the abstract to:

LaVonne Looking Elk
Strong Heart Study - Dakota Center
P.O. Box 9010
Rapid City, SD 57709
Phone: (605) 355-2377
Fax: (605) 355-2502
email: llooking@rapidcity.aberdeen.ihs.gov

4. Prior to presenting the paper, the presenting author should verify (if notice has not been received) that the NHLBI review and Dakota Center IRB approval have been received.

VI. Summary of Thesis Approval Process

1. A college student who wishes to use SHS data for a thesis must submit a thesis proposal to the P&P Committee Chair. (See thesis proposal form below in Appendix 8 - also, the form can be downloaded – see SHS website: <http://strongheart.ouhsc.edu>)
2. The Thesis Proposal must include the Prospectus for the Doctoral Thesis/Dissertation or an Outline for a Masters/Bachelor Thesis. If a prospectus is not required by the doctoral degree program, the student needs to submit a detailed outline.
3. A thesis proposal (see Appendix 8 below) must include: Title of Thesis, Name of Degree Candidate, Type of Degree, Candidate Affiliation including the contact information (full address, telephone, fax and email) and name of the Primary Mentor, including the same type of contact information.
4. Upon approval, the thesis is given an SHS Thesis Number, and the P&P Chair notifies the student of the committee decision. The student is provided with the Agreement Form, Data Request Form, and Data Analysis Monitoring Form to complete, sign, and return to the P&P Committee (see forms in Appendix 8 below). CC (or the appropriate SHS PI) then provides required data to the student.
5. As part of the agreement, the student agrees to write at least one paper based on the approved thesis proposal. At the time the student is ready to develop a paper for publication, the student must submit a separate paper proposal to the P&P Chair and follow all of the P&P paper approval procedures described above.

VII. Forms for Paper and Thesis Proposals

Appendix 8 below contains the desired formats for paper and thesis proposals submitted to the P&P Committee. Also, the forms can be downloaded from the Internet – see SHS website: <http://strongheart.ouhsc.edu> . Additionally, upon receiving requests from the SHS authors, these forms will be transmitted electronically by email. For the electronic forms, email or word processing software may be easily implemented for form completion and submission. "Cut and Paste" or other electronic means may be used to download the proper form, to fill it in (electronically expanding the space as much as needed for each section), and to submit the form to the P&P Chair by email, or more traditional means if desired. An electronic file containing the SHS Publication Policy will also be included with the proposal form to make the prospective authors aware of the rules and procedures of the SHS P&P Committee.

The SHS P&P paper and thesis proposal forms (see Appendix 8 of this Volume) are:

1. Strong Heart Study Paper Proposal
2. Strong Heart Study Thesis Proposal Form
3. Agreement for Data Distribution/Paper/Thesis Proposals
4. Strong Heart Study Data Analysis Monitoring System
5. Strong Heart Study Request For Data
6. Strong Heart Study Request For Data Analysis
7. Sample of paper proposal approval Memo
8. Sample of thesis proposal approval Memo
9. Agreement for Ancillary Studies
10. Collaborative Agreement for Sharing SHS Data

1.8. ANCILLARY STUDIES POLICY

1.8.1 General Policy

To enhance the value of the Strong Heart Study and to ensure the continued interest of the investigators, the Steering Committee welcomes proposals from individual investigators to carry out ancillary studies. Nevertheless, to protect the integrity of the Study, such ancillary studies must be reviewed and approved by the Steering Committee before their inception. In general, ancillary studies require outside (non-Strong Heart Study) funding.

1.8.2 Definition of an Ancillary Study

An ancillary study is one based on information from the Study participants in an investigation, which is not described in the Strong Heart Study protocol and involves data which are not collected as part of the routine Strong Heart Study data set. The core Strong Heart Study includes the use of blood and DNA stored for case-control studies selected by the Steering Committee; these are not considered ancillary studies.

1.8.3 Requirements for Approval of an Ancillary Study

Before an ancillary study can be approved, it must be shown that the ancillary study will have scientific merit but will not do any of the following:

- (1) Interfere with the completion of the main objectives of the Strong Heart Study.
- (2) Adversely affect participant cooperation or compliance in the Strong Heart Study.
- (3) Create a serious diversion of study resources (personnel, equipment, or study samples), either locally or centrally.
- (4) Jeopardize the public image of the Strong Heart Study.

1.8.4 Preparation of Request for Approval of an Ancillary Study

A written request for approval of an ancillary study should be submitted to the Steering Committee and should contain the following information:

- (1) Description of objectives.
- (2) Scientific merit of study.
- (3) Methodology for data collection.
- (4) Proposed statistical analyses.
- (5) Names of definite or possible collaborators.
- (6) Proposed funding sources.
- (7) Discussion of impact on main Strong Heart Study.

1.8.5 Review of Ancillary Study Proposals

The Steering Committee, often in consultation with the Sample Committee, will review and will approve, reject or request modification of ancillary study proposals in a timely manner. At least one Strong Heart Study investigator must be included as a co-investigator in each proposal. Strong Heart Study investigators other than those submitting the proposal may request to become collaborators on a proposal, if they have a specific interest in the topic. The key criteria for approval of proposals are scientific merit and impact on the main Study. Formal IRB approval will be required, if such studies require interviews or additional procedures of the participants. The principal investigator of the ancillary study, working with the three field centers, is responsible for obtaining approval from the Indian communities, the grantee institution IRBs, and the three area IHS IRBs.

If the proposal will utilize laboratory specimens and data previously collected or routinely collected as part of SHS to answer research questions related to cardiovascular and pulmonary diseases, the IRBs will be informed of the changes in protocol with the annual IRB report. If the Steering Committee feels that the ancillary study will result in a major change in the protocol, the principal investigator will be required to seek IRB approval prior to conducting the study. Any ancillary study that is not related to cardiovascular or pulmonary diseases will require IRB approval.

1.8.6 Analysis and Publication of Results of Ancillary Studies

The principal investigator of the ancillary study, and if necessary the Steering Committee, will consult with the Coordinating Center during data analysis to ensure that all study data used in analysis of ancillary study results are consistent with data in the main study database. Ancillary study investigation personnel will be required to sign an Agreement for Ancillary Studies Form (see form in Appendix 8 below). This agreement stipulates that the ancillary study investigators agree to submit paper proposals for approval by the SHS P&P Committee and to submit draft manuscripts for approval by the NHLBI, the IHS IRBs, and the tribes (see section 1.7.1 IV above). Additionally, abstracts for presentations at meetings require approval by the NHLBI and the Dakota Center IHS IRB (see section 1.7.1 V above). The investigator who assumes lead responsibility for the ancillary study shall be listed as senior author. The phrase "The Strong Heart Study" should be included in the manuscript title and listed as a key word whenever possible. Manuscripts will also contain an acknowledgment section listing individuals deemed appropriate. Upon publication, reprints must be distributed as specified above in section 1.7.1 IV.

1.8.7 Feedback of Results of Ancillary Studies to Participants

Results of ancillary studies shall be reported to participating tribes and to participants and/or their physicians, if medically useful. Such reporting should follow standard Strong Heart protocol for notification of participants.

RELATED READING

1. Report of the Secretary's Task Force on Black and Minority Health. Vol IV: Cardiovascular and Cerebrovascular Diseases Part 2. U.S. Department of Health and Human Services (Washington, D.C., U.S. Government Printing Office, January, 1988).
2. Rhoades ER, Hammond J, Welty TK, Handler AD, Amler RW. The Indian - Burden of Illness and Future Health Interventions. Public Health Reports 1987; 102: 261-368.
3. U.S. Congress. Office of Technology Assessment. Indian Health Care. OTA-H-290 (Washington, D.C., U.S. Government Printing Office, April, 1986.)
4. Coulehan JL. Cardiovascular Disease. In: Indian Health Conditions, An IHS Report. May 1990.
5. Lee, ET. Statistical Methods for Survival Data Analysis, Second Edition, Wiley, New York, 1992.
6. Mantel N and Haenszel W. Statistical aspects of the analysis of data from retrospective studies of disease. J. Nat'l Cancer Inst. 1959; 22: 719-748.
7. Sievers ML. Myocardial infarction among Southwestern American Indians. Ann Int Med 1967;67:800-807.
8. McKee PA, Castelli WP, McNamara PM and Kannel WB. The natural history of congestive heart failure: The Framingham Study. The New England J. of Med., 1971; 285: 1441-1445.
11. The National Heart, Lung and Blood Institute, ARIC (Atherosclerosis Risk in Communities Study) Manual, 1987.

APPENDIX

APPENDIX 1

THE STRONG HEART – FAMILY STUDY CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

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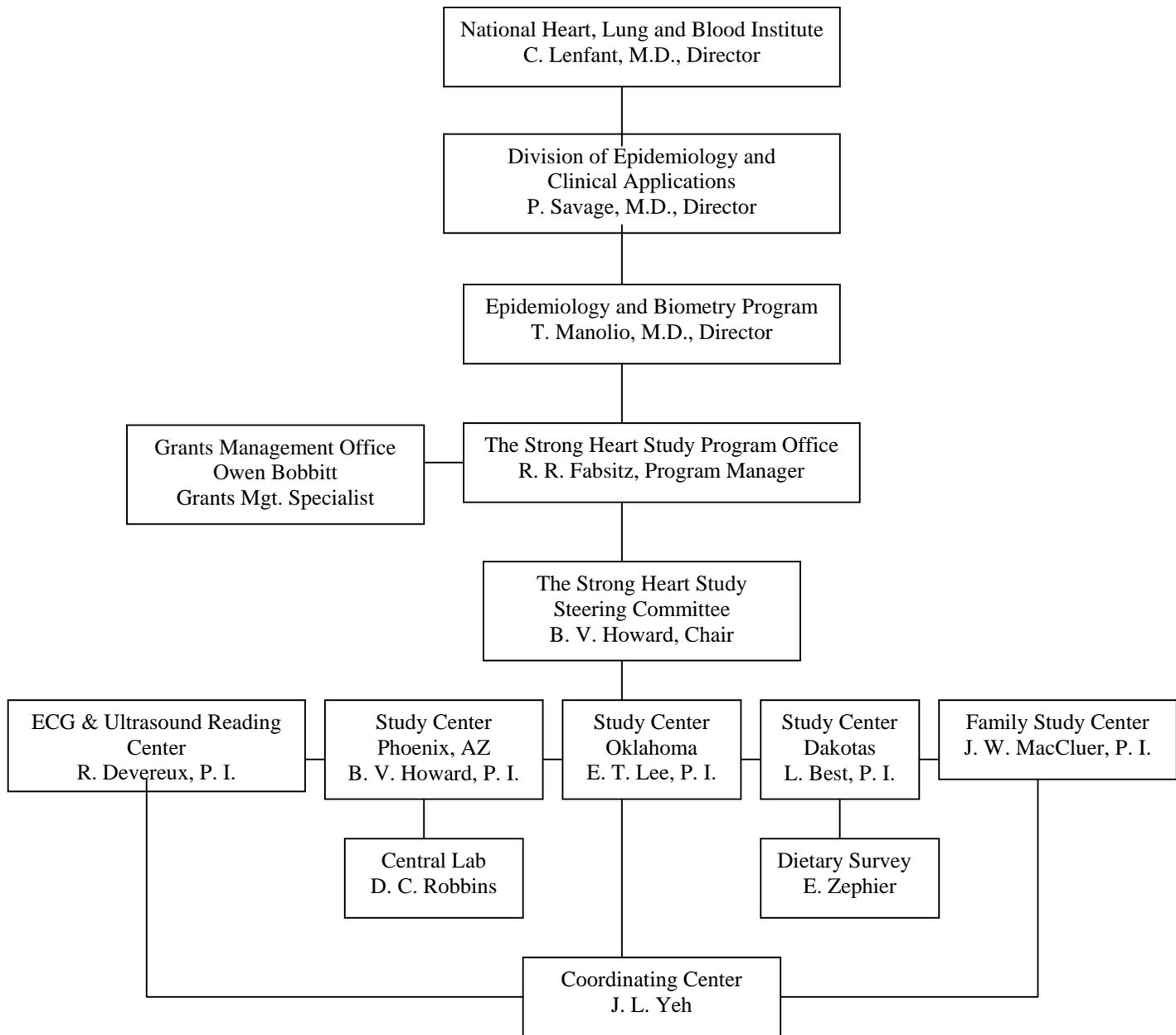
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APPENDIX 2

**THE STRONG HEART – FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV**

Organizational Chart



APPENDIX 3

THE STRONG HEART – FAMILY STUDY CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

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APPENDIX 7

THE STRONG HEART STUDY IV

Cardiovascular Disease in American Indians

Confidentiality Pledge

I, _____ understand that data obtained for subjects of research projects are confidential.

I will not reveal to unauthorized persons any patient's name or any identifying information or any other information obtained from subjects of the project entitled, "Cardiovascular Disease in American Indians (The Strong Heart Study)".

I will not allow any persons who are not authorized members of the Strong Heart Study staff to have access to any information collected from or about the subjects.

I will properly store the data forms, computer printouts and other documents in locked file cabinets or drawers to protect confidentiality.

I understand that breach of this confidentiality pledge is grounds for dismissal from employment on the Strong Heart Study.

I will return all data to the Principal Investigator when my employment terminates.

Staff Member

Principal Investigator

Date

APPENDIX 8

P&P FORMS

STRONG HEART STUDY

PAPER PROPOSAL

Title of Paper: (include the phrase “Strong Heart Study” whenever possible)

Name of Primary Author:

Author Affiliation:

Suggested Co-Authors:

Suggested Key words:

Outline of Paper:

- a) **Introduction (Rationale)**
- b) **Methods**
- c) **General analysis plan**

Analysis Responsibility: (authors or Coordinating Center)

Note: 1) If the authors perform the statistical analyses, they must agree to submit the penultimate (next to final) draft to the Coordinating Center for verification of all analyses utilized in the manuscript.

2) Authors must comply and respond regularly to the status survey on their approved paper proposals conducted by the SHS P&P Committee twice a year.

3) Papers lacking a PI as a co-author. Drafts of these papers will need to be sent to the P&P committee for review by at least two (2) reviewers (selected by the Chairperson). This review is the first step that must be completed prior to review of the penultimate draft by NHLBI/Tribes/IHS.

4) **PLEASE NOTE:** A Lay Summary is required **when submitting the completed draft** for NHLBI review and IHS IRB and tribal approvals. **Also, the IHS IRBs require that all SHS manuscripts must contain the following disclaimer (verbatim):** “The opinions expressed in this paper are those of the author(s) and do not necessarily reflect the views of the Indian Health Service.”

Submitted by: (Corresponding author, address, telephone, fax and e-mail for correspondence)

Date:

STRONG HEART STUDY
THESIS PROPOSAL FORM

Title of Thesis:

Name of Degree Candidate:

Type of Degree:

Candidate Affiliation:

Primary Mentor: (With e-mail, telephone and fax numbers, and address for correspondence)

Descriptions of Thesis Plan:

1. **Prospectus - for Doctoral Thesis/Dissertation (if prospectus is not required by your degree program submit a detailed outline).**
2. **Outline - for Masters/Bachelor Thesis**

Submitted by: (Corresponding candidate, with telephone and fax numbers and address for correspondence)

Date:

Agreement for Data Distribution/Paper/Thesis Proposal*

To: Strong Heart Study Coordinating Center

From: _____ (Principal Investigator / First Author)

Institution/Address: _____

Name of the associated SHS PI / Mentor: _____

Title of Study, Paper, or Thesis: _____

Paper/Thesis Number (if known): _____

I agree to read and follow the SHS protocol with regard to distribution and analysis of Strong Heart Study data that I request or that I generate in my research/paper/thesis. I have attached a research protocol or a paper/thesis proposal describing how I will use these data to better understand cardiovascular disease and its related diseases in American Indians.

I agree to protect the confidentiality and privacy of the SHS participants and the security of the data. I am not to transfer or disclose any individually identifiable information about the SHS participants at any time. Violation of the confidentiality agreement is considered a breach of confidentiality and may leave requesting investigator liable to legal action on the part of Study participants and their families. I also agree that the SHS data provided to me by the SHS Coordinating Center or SHS investigators are to be used **only** for the research protocol or the paper/thesis approved by the SHS P&P Committee or the Steering Committee. **I further agree not to distribute SHS data to anyone else.**

For each paper I wish to write using any SHS data, I agree to comply with the SHS Publication Policy and to submit a paper proposal for review and approval of the SHS P&P Committee. Further approvals from the NHLBI, IHS, and the participating tribes will be needed prior to submission to any journal for publication. **If approval from the SHS P&P Committee, the NHLBI, IHS, or the participating tribes is not granted, I agree not to publish these results.**

I understand that the SHS P&P Committee or Steering Committee will assist me in revising my paper in such a way that will make it acceptable for publication. I agree to include at least one of the SHS investigators as a co-investigator and a co-author. I will send a reprint of my published article to the NHLBI Program office, and all other as detailed in the **SHS P&P Publication Policy**.

Signed: _____ Date: _____

* Each requesting investigator must complete this agreement separately.

Strong Heart Study Data Analysis Monitoring System

When authors/researchers request Strong Heart Study (SHS) data for any purpose, the Strong Heart Study Coordinating Center (SHS-CC) would like to know how you manage and analyze the data. By answering the following questions, the SHS-CC is better able to track SHS data utilization patterns and to provide needed information for quality control. Thank you for your cooperation.

1. Do you use any of the following statistical package(s) for data analyses?
Check all applicable.

a. SAS

b. SPSS

c. BMDP

d. S+

e. Statistic

f. StatXact

g. Other, specify: _____

2. Other than the routine SHS derived variables, do you plan to derive any variables for your analysis purposes?

Yes.

No.

3. If you plan to derive your own variable(s), will you consult with the SHS-CC?

Yes.

No.

If you derive certain variables for your analysis purpose, please attach a copy of the algorithm that you will use to define your variable(s) and the program to generate the variable(s)

4. Do you usually use any of the following procedures in your statistical analyses?
Check all applicable.

- a. Multiple regression
- b. Logistic regression
- c. Time-related variables analysis
- d. Modeling
- e. Simulation
- f. Other, specify: _____

5. What training does your statistician(s) have?
Check all applicable.

- a. Doctoral degree in statistics/biostatistics/math statistics.
- b. Doctoral degree in other field but with quantitative training.
- c. Master degree in statistics/biostatistics/math statistics.
- d. Master degree in other field but with quantitative training.
- e. Bachelor degree in statistics/biostatistics/math statistics.
- f. Bachelor degree in other field but with quantitative training.
- g. Other, specify: _____

Feedback:

Please return to Strong Heart Study-Coordinating Center either by email or fax as soon as possible.

STRONG HEART STUDY

REQUEST FOR DATA

Title of project:

Investigator(s):

Purpose: Paper
Abstract for professional conference
Invited talk
Pilot data for grant or contract submission
Quality control or local monitoring
Other

Date Needed: / / *(please allow 1-2 weeks from data request received)*
 mm dd yy

Data for Study Period: Phase-I Phase-II Both

Center:
 Arizona Oklahoma South/North Dakota All 3 centers

Variables Needed:(List all the variables)

COORDINATING CENTER USE ONLY:

Date Received:

Date Data Delivered:

STRONG HEART STUDY
REQUEST FOR DATA ANALYSIS

Title of project:

Major hypotheses: 1)
2)
3)
4)
5)

Purpose: Paper
Abstract for professional conference
Invited talk
Pilot data for grant or contract submission
Quality control or local monitoring
Other

Investigator(s):

Expected date of completion: _____
mm / dd / yy

Variables to used: (List all the variables)

Statistical methods to be used (check all that apply):

- Summary statistics and frequencies
- Simple correlation and partial correlation
- Regression analyses
- t-test, ANOVA, and multiple comparison
- Logistic regression
- Other

(Specify)

Comments:

COORDINATING CENTER USE ONLY:

STRONG HEART STUDY PAPER NUMBER:

ANALYSIS NUMBER:

DATA ANALYST:

DATE REQUEST RECEIVED:

DATE RESULTS SENT OUT:

**THE UNIVERSITY OF OKLAHOMA
HEALTH SCIENCES CENTER
CENTER FOR AMERICAN INDIAN HEALTH RESEARCH**

FAX TRANSMITTAL

TO:

FAX NO.:

FROM: Elisa T. Lee, PhD
SHS P&P Committee

FAX NO.: (405) 271-4390

DATE:

SUBJECT: Paper proposal entitled:

SHS P&P Committee decision:

_____ Approval with recommendations as listed below:

_____ Disapproval

Recommendations:

Assigned paper no.:

(Please fill out and return all the forms attached with this memo. Refer to the above number for all correspondence about this paper. When the penultimate draft is ready to circulate, a copy must be provided to the statistician(s) performing the analyses at the CC. Please inform us when this paper is approved by the NIH or accepted by a journal and if there is a change of the title. It is very important that you respond promptly during our 'Paper Progress Survey' done twice a year.

College of Public Health, P.O. Box 26901, Oklahoma City, OK 73190, Phone: (405) 271-3090

**THE UNIVERSITY OF OKLAHOMA
HEALTH SCIENCES CENTER
CENTER FOR AMERICAN INDIAN HEALTH RESEARCH**

FAX TRANSMITTAL

TO: _____ FAX NO.: _____

FROM: Elisa T. Lee, PhD FAX NO.: (405) 271-4390
SHS P&P Committee

DATE: _____

SUBJECT: Dissertation/Thesis proposal entitled:

SHS P&P Committee decision:

_____ Approval with recommendations as listed below:

_____ Disapproval

Recommendation:

Assigned thesis approval no.: **T**

Please fill out and return all forms attached with this memo to SHS P&P Committee. Please include the above thesis approval number in all correspondence with us about this thesis. Also, be advised that, you need to write a paper for publication based on the SHS data used for this thesis, and you must submit a paper proposal to the SHS P&P Committee prior to writing that paper.

NUMBER OF PAGES _____ (INCLUDING COVER SHEET)

College of Public Health, P.O. Box 26901, Oklahoma City, OK 73190, Phone: (405) 271-3090

Agreement for Ancillary Studies

To: Strong Heart Study Coordinating Center

From: _____

Name of the Ancillary Study: _____

I agree to read and follow the SHS protocol with regard to analysis of Strong Heart Study data that I request or that I generate in my ancillary study. I will comply with the SHS policies regarding maintaining data security and confidentiality. I have attached a research protocol describing how I will use these data to better understand cardiovascular disease and its related diseases in American Indians and how to benefit the health of American Indians.

I agree that the SHS data obtained by me in my ancillary study or provided to me by the SHS Coordinating Center or SHS investigators is to be used only for studies approved by the SHS Steering Committee. I further agree not to distribute SHS data to anyone else.

I agree to comply with the SHS Publication Policy and to submit any papers resulting from the ancillary study for review and approval of the SHS P&P Committee, NHLBI, IHS, and the participating tribes. If approval for publication is not granted, I agree not to publish these results.

I understand that the SHS Steering Committee will assist me in revising my report in such a way that will make it acceptable for publication (after achieving proper approvals). I agree to include at least one of the SHS investigators as a co-investigator and a co-author. I will send a reprint of my published article to the NHLBI Program office and all others as detailed in the **Publication Policy**.

Signed: _____ Date: _____

Collaborative Agreement for Sharing SHS Data*

To: Strong Heart Study Coordinating Center

From: _____(Principal Investigator)

Institution/Address: _____

Name of the associated SHS PI: _____

Title of Collaborative Project: _____

I agree to read and follow the SHS protocol with regard to distribution and analysis of Strong Heart Study data that I request or that I generate in my collaborative project. I have attached a collaborative project protocol describing how I will use these data to better understand cardiovascular disease and its related diseases in American Indians.

I agree that the above-named SHS PI or his/her designee will be included as a member of the collaborative group in order to represent SHS and to participate actively and fully in development of all analysis plans for the collaborative project.

I agree to protect the confidentiality and privacy of the SHS participants and the security of the data. Violation of the confidentiality agreement is considered a breach of confidentiality and may leave the requesting investigator liable to legal action on the part of the SHS participants and their families. I will not transfer or disclose any individually identifiable information about the SHS participants at any time. I will not make any portion of the SHS database available to the public. I also agree that the SHS data provided to me by the SHS Coordinating Center or SHS investigators are to be used **only** for the above-named collaborative project, as approved by the SHS P&P Committee or the SHS Steering Committee. **I further agree not to distribute SHS data to anyone else.**

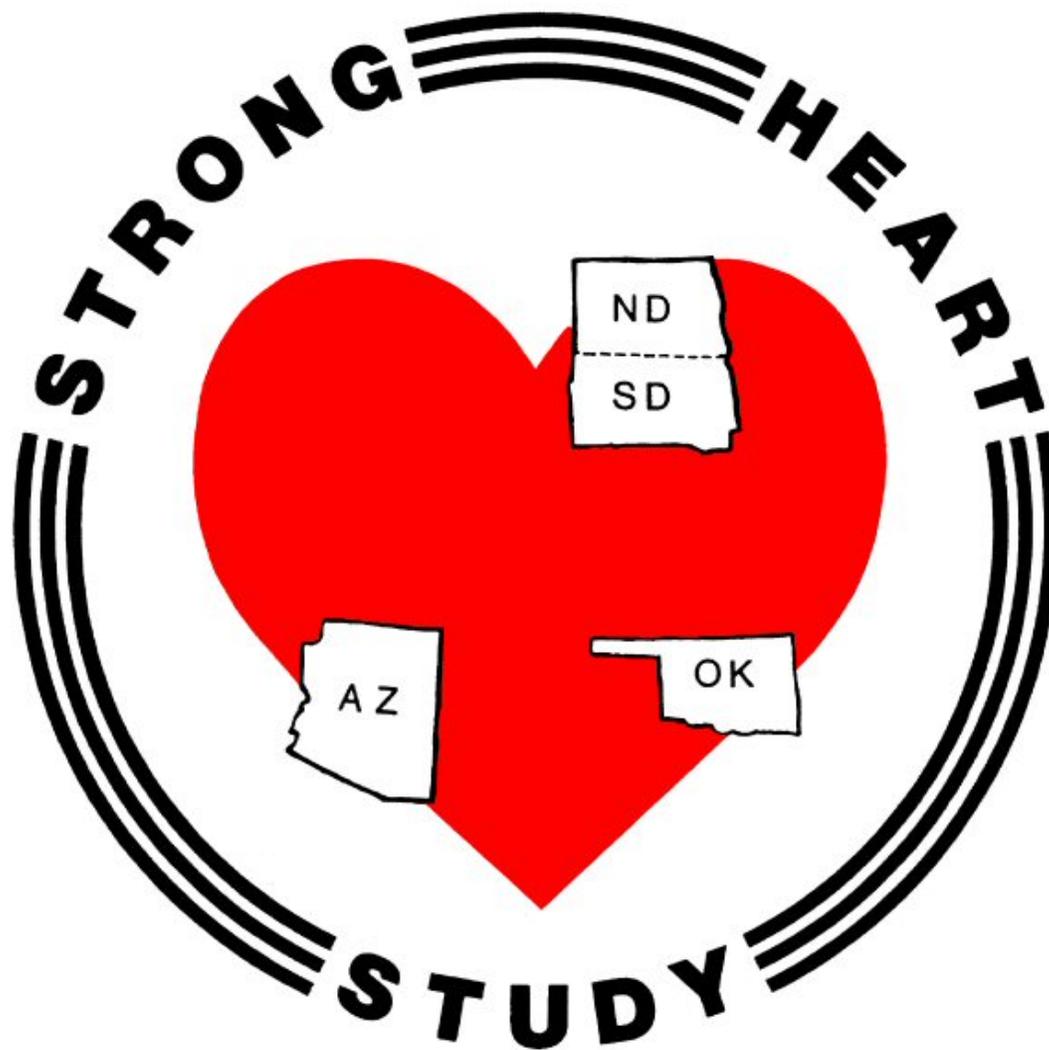
The SHS data provided for this collaborative project and any data derived through this collaboration will be accessed solely by me or individuals working on this project under my supervision. I agree to maintain confidentiality of the data through storage of data in locked file cabinets and secure computers. Upon completion of all analyses for this collaborative project, I agree to delete all copies of the SHS data and derived data from all computers and media in which the data have been stored. I further agree to destroy or return to the SHS Coordinating Center any non-eraseable media, such as CD-ROMs and hardcopies containing the SHS data and derived data.

For **each** paper I wish to write using any SHS data, I agree to comply with the SHS Publication Policy (see SHS Phase IV manual, vol. 1, sect. 1.7, available at <http://strongheart.ouhsc.edu/>) and to submit a paper proposal for review and approval of the SHS P&P Committee. Further approvals from the NHLBI, IHS, and the participating tribes will be needed prior to submission to any journal for publication. **If approval from the SHS P&P Committee, the NHLBI, IHS, or the participating tribes is not granted, I agree not to publish these results.** If my paper is published, I will send a reprint of the published article to the NHLBI Program office and all others as detailed in the **SHS P&P Publication Policy, sect. 1.7.1, IV** (see vol. 1 of SHS Phase IV manual at <http://strongheart.ouhsc.edu/>).

I agree to acknowledge the contributions of the SHS Investigators in any and all oral and written presentations and publications resulting from analysis of data. I will include the following disclaimer in my manuscript(s): “The opinions expressed in this paper are those of the author(s) and do not necessarily reflect the views of the Indian Health Service.”

Signed: _____ Date: _____

*The **principal investigator** of the collaborative project must sign this agreement.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Two

MORBIDITY & MORTALITY SURVEILLANCE PROCEDURES

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Two

MORBIDITY & MORTALITY SURVEILLANCE PROCEDURES

June 01, 2001

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
College of Public Health

P.O. Box 26901
Oklahoma City, OK 73190

VOLUME II
MORBIDITY AND MORTALITY SURVEILLANCE PROCEDURES

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CHAPTER ONE

OVERVIEW OF STRONG HEART STUDY PHASE IV MORTALITY AND MORBIDITY SURVEILLANCE

1.1 OBJECTIVES

All surviving participants from the SHS Phase I examination are eligible for morbidity and mortality follow-up in Phase IV. The primary objectives of surveillance of the exam cohort are to capture events that can be related to possible risk factors for CVD and to provide annual mortality and morbidity rates in these populations. Table 1.1 summarizes the non-fatal endpoints ascertained in the SHS by various mechanisms. All deaths in cohort members will be identified and the cause of death determined by review of medical records information. Selected non-fatal events and procedures will also be ascertained annually, thus providing on-going and up-to-date information about the cohort, independent of the Phase IV examination. Surveillance activities in Phase IV will continue until May 31, 2004.

It is important in designing and implementing the surveillance protocol that the intensity of ascertainment is the same at all three centers; otherwise, there is likely to be bias in both the frequency and nature of events ascertained, and what may appear to be center differences would, in fact, be artifactual.

1.2 OVERVIEW OF SURVEILLANCE PROCEDURE

1.2.1 General Surveillance Methodology

The general approach to surveillance at each center is to divide the total number of participants into twelfths from a listing of surviving Phase I participants, ordered by calendar time from least to most recent exam date. This would result in an approximately equal distribution of participants across the calendar year, and the Phase IV follow-up would begin with those seen earliest in Phase III.

Using this monthly division, the persons listed for that month would be followed up (methods described below) to determine their vital status and if living, whether any of the study events of interest had occurred since last contact. The monthly listing provided by the Coordinating Center includes all known identifying information for the individual, their Phase I, II and III exam dates, and the dates of any morbid events already ascertained (providing an event history that is useful when doing the follow-up). A sample of the tracking form is given in Figure 1.1. When a new event (either fatal or non-fatal) is identified, procedures for obtaining the necessary information for physician review are implemented. Using this approach, each member of the cohort is contacted (either directly or indirectly) once a year, and the physicians' review of events are done on an on-going basis.

Table 1.1 Endpoints for Phases I, II, and III

<u>Endpoints/Events</u>	<u>Type of Rate</u>	<u>Source of Data</u>
<i>Primary Clinical Endpoints</i>		
Myocardial Infarction	I	S, E III
Stroke	I	S, E III
Congestive Heart Failure	I	S, E III
ECG evidence of new MI	I	E III
Coronary bypass surgery/angioplasty	I	S, E* III
<i>Secondary Events of Interest/Pre-clinical Disease</i>		
Valvular Heart Disease	P	E III
Angina	I	E III
Peripheral Vascular Disease	I	E III
Cardiac catheterization, positive	I	S, E* III
Positive treadmill test	I	S, E* III
Left ventricular hypertrophy (LVH)	P	E III
Global evaluation of LV function	P	E III
Cardiac wall motion abnormalities	P	E III
Obstructive lung disease (Ratio FEV1/FVC or FEV1/SVC)	P	E III
End-stage renal disease (ESRD)	I	E*III

I = Incidence P = Prevalence S = Surveillance contact
E = Examination, Phase II or Phase III E* = By interview, with medical record confirmation

Endpoints for Phases I, II, and III are listed in Table 1.1. For each event, there is a designation as to whether it is an incident or prevalent event and the source(s) through which it was initially ascertained. Because baseline data for the primary endpoints are available from Phase I, new events ascertained in Phase II and Phase III were incident events, and all of the primary endpoints, with the exception of ECG evidence of new myocardial infarction, were identified through surveillance contacts. The majority of secondary events of interest shown in the table were not specifically ascertained in Phase I, and thus, persons identified with these conditions in Phase II were prevalent cases. Subsequent new onset events would be incident.

Endpoints for Phase IV of the original cohort are shown in Table 1.2. All participants will be contacted within the last year of morbidity and mortality surveillance that ends 05/31/2004. The primary advantages of this surveillance approach are: 1) each individual is contacted annually and vital status is automatically ascertained when determining morbidity status, 2) annual (or biannual) data on the frequency of events can be provided to NIH for monitoring purposes, 3) the flow of work is more evenly distributed, and 4) the intensity of surveillance is the same at each center.

Table 1.2 Endpoints in Phase IV

<u>Endpoints/Events</u>	<u>Type of Rate</u>	<u>Source of Data</u>
<i>Primary Clinical Endpoints</i>		
Myocardial Infarction	I	S
Stroke	I	S
Congestive Heart Failure	I	S
Coronary bypass surgery/angioplasty	I	S
ESRD	I	S+
Valvular heart disease	I	S+
Procedures for the treatment of Peripheral vascular disease	I	S+

S+ = added to surveillance as of January 1, 2003

Secondary Events of Interest/Pre-clinical Disease

Cardiac catheterization, positive	I	S
Positive treadmill test	I	S

I = Incidence P = Prevalence S = Surveillance contact

1.2.2 Specific Surveillance Approaches

Table 1.3 presents the percentage of each SHS center's population who have a telephone and who have a P.O. address.

Table 1.3 Frequency of Home Telephones and P.O. Mailing Addresses by SHS Center (SHS Phase II, 8/96)

Type of Contact		AZ	OK	SD/ND
Home Telephone	N	640	964	767
	%	55%	77%	65%
Mailing Address is PO Box	N	654	427	863
	%	56%	34%	74%

It is clear that the ability to contact individuals by typical follow-up measures varies by center. The percent of participants who get their care exclusively through IHS and thus, for whom monitoring of IHS user listings would be nearly complete, also varies by center. IHS

computerized user listings are a useful source for each center, however, they will be augmented with other methods, especially in Oklahoma. Thus, the following approaches, to be carried out in the order listed, are used for monthly surveillance contacts.

For each name on the monthly list, check:

1. IHS computerized user listings (both inpatient and outpatient) for the occurrence of SHS events of interest
2. For participants who do not regularly receive care at IHS facilities:
 - a. check with physicians who have previously provided information to the SHS for that participant
 - b. if feasible at your center, send a follow-up questionnaire by mail to the participant, with a telephone call to non-respondents within 4 weeks of mailing (telephone could be used first).
 - c. make a home visit to obtain surveillance information if there is no telephone and contact questionnaire is not returned.
3. After 3 months of repeated attempts to contact an individual have passed without success, contact efforts should be terminated for that contact year.
4. The National Death Index will be queried near the end of the study to determine whether SHS participants who are lost to follow up have died. If they have died, then copies of their death certificates will be obtained so that they can be included in the mortality review process.

Other methods specific for each center may be developed in collaboration with the M&M coordinators, but these methods must be reviewed and approved by the Steering Committee prior to implementation to ensure equal ascertainment across all three centers.

1.3 SURVEILLANCE STAFF

FIELD CENTERS: Each field center has an individual specifically responsible for mortality and morbidity follow-up of the cohort (the Mortality and Morbidity (M&M) Coordinator). The M&M Coordinator is responsible for the monthly surveillance contacts of cohort members, obtaining and forwarding the requisite medical records information for review for fatal and non-fatal events, and completing the monthly surveillance report and forwarding it to the Coordinating Center.

COORDINATING CENTER: The Coordinating Center has a specific individual designated as responsible for all aspects of M&M surveillance, including the distribution of packets for QC review, monitoring of progress at each center, and processing of data received.

1.4 SURVEILLANCE REPORTING

Monthly surveillance is done to account for all of the surviving SHS participants at least once each year. The purpose of the surveillance is to determine the vital status of each cohort member, and if still living, whether they have had any of the CVD events of interest to the study. An example of the monthly reporting form is given in Figure 1.2.

Monthly reports should be provided as a cumulative total since the start of surveillance for that contact year. The contact rate ($\# \text{ contacted} \div \text{target number}$) and the abstraction rate ($\# \text{ abstracted} \div (\# \text{ events identified})$) will be used to track the field staff's surveillance completion rate. The following are explanations of each of the entries in the report.

TARGET NUMBER: The number of persons for whom M&M information should be determined. This number is equivalent to approximately 1/12th of the total surviving cohort at each center.

NUMBER CONTACTED: This is the number of target persons who have been accounted for. To account for someone means to determine whether or not they are alive or dead, and if alive, whether or not they MAY HAVE had an event of interest since the date of last contact. If you have NO information on someone, then they have NOT been accounted for yet and are pending contact.

CONTACT METHODS CAN INCLUDE:

- 1) IHS computerized user listings. (For the first year of surveillance, visits within the past 3 years are sought. If none are found and the person is KNOWN to have no other sources of care, and you are sure that the listings are complete, then you may stop and consider this person as having had no events of interest. If these criteria cannot be met, you need to pursue other methods of follow-up.)
- 2) Telephone call with short questionnaire.
- 3) Letter, with short questionnaire.
- 4) Home visit to complete short questionnaire.
- 5) Chart review

PARTICIPANTS WITH POTENTIAL EVENTS: This is the number of people for whom contact has been made and who MAY have a morbidity event of interest or who are reported to be deceased. Mortality and morbidity are reported separately. Included here can be persons who are known to have been hospitalized but for whom the reason for hospitalization is unknown.

EVENTS IDENTIFIED: This is the total number of CVD EVENTS (there may be multiple events per participant) and total number of reported deaths (this number will match the number of participant deaths) that need to be abstracted. Included here can be events of hospitalization for which the reason is unknown prior to checking the record.

ABSTRACTED: This is the total number of potential events for which abstracts have been completed.

FORWARDED PACKETS: These are the total numbers of mortality and morbidity packets which have been forwarded for panel review. This number will be used to track the review panels' work-loads and completion rates.

Figure 1.2 Monthly Surveillance Progress Report

Site	Month	Target#	Contacted	Participants With Potential Events		Total # of Potential Events		Events Abstracted		Ineligible Events		Packets Forwarded For Review		Rates		
				Mort	Morb	Mort	Morb	Mort	Morb	Mort	Morb	Mort	Morb	Mort	Morb	Contrate
OK	Dec00	1246	1191	179	159	179	224	154	200	0	20	154	126	0.956	0.860	0.980
OK	Jan01	101	101	179	15	179	15	155	12	0	2	155	12	1.000	0.866	0.923
OK	Feb01	202	202	182	24	182	35	159	31	0	3	159	19	1.000	0.874	0.969
OK	Mar01	304	304	184	35	184	52	160	43	0	6	160	26	1.000	0.870	0.935
OK	Apr01	406	406	188	45	188	65	165	53	0	9	165	32	1.000	0.878	0.946
AZ	Dec00	1093	1093	242	148	242	392	234	392	0	0	234	148	1.000	0.967	1.000
AZ	Jan01	87	87	246	10	246	22	237	22	1	0	237	10	1.000	0.967	1.000
AZ	Feb01	169	169	249	20	249	48	240	48	0	0	240	20	1.000	0.964	1.000
AZ	Mar01	258	258	250	33	250	69	243	69	0	0	243	33	1.000	0.972	1.000
AZ	Apr01	347	347	256	40	256	90	244	90	0	0	244	40	1.000	0.953	1.000
SD	Dec00	1140	1106	208	213	208	591	196	591	0	0	196	213	0.970	0.942	1.000
SD	Jan01	95	20	211	16	211	16	196	6	0	0	196	6	0.211	0.929	0.375
SD	Feb01	190	155	218	30	218	30	196	6	0	0	196	6	0.816	0.899	0.200
SD	Mar01	190	155	218	30	218	30	196	6	0	0	196	6	0.816	0.899	0.200
SD	Apr01	285	255	233	38	233	38	206	31	0	0	206	22	0.895	0.884	0.816
SHS	Dec00	3479	3390	629	520	629	1207	584	1183	0	20	584	487	0.974	0.928	0.997
SHS	Jan01	283	208	636	41	636	53	588	40	1	2	588	28	0.735	0.926	0.784
SHS	Feb01	561	526	649	74	649	113	595	85	0	3	595	45	0.938	0.917	0.773
SHS	Mar01	752	717	652	98	652	151	599	118	0	6	599	65	0.953	0.919	0.814
SHS	Apr01	1038	1008	677	123	677	193	615	174	0	9	615	94	0.971	0.908	0.946

05/03/2001

1.5 GENERAL GUIDELINES FOR PROCESSING MORTALITY AND MORBIDITY PACKETS

Mortality and morbidity packets are assembled by the M&M Coordinators in each field center according to the checklists provided in Appendix C in the Manual of this Volume. All mortality packets are forwarded to Dr. Maurice Sievers at the Arizona center. After review by Dr. Sievers, the original non-stroke mortality packet, *excluding* Dr. Sievers' decision form, is forwarded to the next member of the Mortality Review Panel listed on the assignment sheet provided by the Coordinating Center. Thus, all deaths are reviewed by two members of the Mortality Review Committee, one of whom is always Dr. Sievers. Discrepancies between the 1st and 2nd reviewer are identified by the Coordinating Center. In instances when both reviewers determine the death to be non-CVD, but the assigned causes differ, Dr. Sievers' decision will be taken as the cause of death. For those cases in which one of the two reviewers assigns a CVD cause or when there is a discrepancy in type of CVD, the chart will be forwarded for mortality adjudication. Dr. James Howard and the adjudicators will have the results of the other two reviews available to them so that the process in Phase IV is consistent with that used in Phases I, II and III. All fatal events judged to be strokes by Dr. Sievers will be directly forwarded to Dr. David O. Wiebers at the Mayo clinic but not to the next member of the Mortality Review Panel.

Lists of reviewers for morbidity packets are provided to each center by the Coordinating Center for forwarding morbidity packets for review to members of the Morbidity Review Committee on a prescribed, alternating schedule. All non-stroke morbidity packets will be forwarded to Morbidity Review Committee members. Suspected non-fatal stroke events (without any other event of interest to the SHS) abstracted by the M&M coordinator in each field center are forwarded to Dr. David O. Wiebers at the Mayo Clinic for review by him or his staff but not to the members of Morbidity Review Committee. Participants with suspected non-fatal stroke events plus other events of interest will have their charts abstracted, the stroke portion forwarded to Dr. David O. Wiebers, and the non-stroke events forwarded to the next on the list of the Morbidity Review Panel.

A complete listing of the members of each of the physician review panels is given in Volume 1, Appendix 4, M&M Review Committee, of this manual.

When either a set of mortality or morbidity packets are forwarded by the field to the reviewers, the M&M Coordinator should do the following:

- a. include inside the box a copy of the shipping list of the contents of the box.
- b. FAX or e-mail a copy of the shipping list to the recipient (so they know what is coming) and a copy to the M&M contact person at the CC (so they know what has been sent).

When preparing morbidity and mortality packets for forwarding to the physician reviewers, please observe the following guidelines:

- a. Materials are organized IN ORDER according to the photocopy check list for that event. Multiple events should be organized IN CHRONOLOGICAL ORDER from least to most recent.
- b. A copy of the monthly tracking sheet (provided by the CC) for the individual for whom you are doing a packet are included in the packet. This is because the tracking sheets include listings of all events previously reviewed and entered in the CC database and having this history is useful to the reviewers. This sheet is also intended to be useful to the field centers by providing a listing of what work has already been done for that participant.
- c. All relevant information FOR A GIVEN EVENT is collected before sending the packets off for review.
- d. The CC provides the reviewers with blank decision forms.
- e. Reviewers contact the M&M Coordinator at the field site from which the packet was sent, if they need additional material or require clarification of something in the packet.

Specific instructions for reviewing and assigning causes of death and for documenting non-fatal CVD events are given in the next two sections of this manual.

** When packets are ready to be sent to the Coordinating Center, send the box(es) by FED EX economy service using forms provided by the Coordinating Center that include the CC account number for payment. Packets should be sent to:

Center for American Indian Health Research
University of Oklahoma Health Sciences Center
801 NE 13th Street, CHB-100
Oklahoma City, OK 73104

Attn: M&M Surveillance Coordinator
Phone No.: (405) 271-3090

CHAPTER TWO

MORTALITY SURVEILLANCE

2.1 MORTALITY SURVEILLANCE

The examination cohort will be monitored in an on-going fashion to identify deaths. The following sources will be monitored on a regular basis to identify additional deaths in the cohort as they occur: local newspapers and community notices, community and tribal members, and IHS, tribal and BIA records. Near the end of 2004, the final year of data acquisition in Phase IV, the State Health Departments will be contacted to identify death certificates in the study communities for those deaths that may have been missed using other sources. A combined list from all three centers of “missing” participants will also be sent to the National Death Index.

2.1.1. Detailed Procedures for Mortality Surveillance

a. Cohort Mortality (date of Phase III exam through May 31, 2004)

Of the original 4,549 members of the Phase I cohort, 500 deaths had occurred through the end of Phase II exam, and an additional 650 deaths had occurred before starting the Phase IV family study examination. Thus, it is estimated that 3,400 surviving individuals will be eligible for mortality surveillance for Phase IV. All members of the Phase I examination cohort, regardless of whether they participated in the Phases II and III exams, are eligible for ongoing cohort mortality surveillance. Each member of the cohort will be contacted annually during Phase IV to determine his/her vital status. Based on the death rates experienced thus far in the cohort, it is anticipated that collection of mortality data will be required for approximately 30-35 deaths from each center each year.

When a death is identified in a SHS cohort member, the death certificate will be coded by the Study nosologist, Mr. Karl Wise. All deaths will be investigated, regardless of the cause indicated on the death certificate. In order to conduct an independent, standardized review of cohort deaths, the following types of information will be collected (processing forms are given in Appendix C of this volume).

- 1) discharge summary of the terminal hospital admission and all other admissions within one year of death
- 2) emergency room report and related information
- 3) ambulance report and any clinical notes regarding those dead on arrival
- 4) autopsy report (if done)
- 5) pathology report (if done)
- 6) laboratory reports from the terminal visit (or those obtained closest to the date of death) for tests relevant to the possible causes of death, including X-ray, ECG, enzymes, liver function tests, cultures, etc. For non-CVD deaths, cause-specific tests will be used.
- 7) consultation reports regarding diagnoses pertinent to possible causes of death

- 8) medical examiner, coroner reports / police reports for unattended, out-of-hospital deaths, and special tests, such as toxicology studies.
- 9) informant interview (see Appendices B and C of this volume) for possible CVD deaths when medical records data are not sufficient or for deaths listed as “unknown”.
- 10) if not hospitalized in the year prior to death, copies of notes and test results from the last IHS outpatient visit (IHS records only).

The following information should be collected for specific types of non-CVD causes listed:

- 1) CANCER:
 - a) pathology report on which the original diagnosis was based, or if not available
 - b) any diagnostic reports that may help to determine the *primary* site of the tumor (i.e., X-ray, CT, MRI, ultrasound) or a later report with information on cell type and origin of the tumor.
- 2) INFECTIONS:
 - a) culture results or, if not available or culture negative
 - b) diagnostic serology
 - c) TB or other skin test results, if relevant
 - d) CBC and differential
 - e) temperature record from nurses notes.
- 3) LIVER FAILURE OR OTHER GI CONDITION
 - a) liver function tests (SGOT, Alkaline phosphatase, GGT, Bilirubin (direct and indirect), LDH, CPK, Ammonia levels)
 - b) biopsy results
 - c) reports of other diagnostic tests (e.g., CT, MRI, endoscopy).
- 4) MULTI-SYSTEM PROBLEMS -- obtain all consultant reports when the cause is not clear-cut (e.g., cancer, septic shock, gunshot wound).
- 5) INTENTIONAL OR UNINTENTIONAL INJURY -- Police and EMS reports, if available. Alcohol use information, including blood alcohol.

Potential CVD deaths in the examination cohort are documented and reviewed by the SHS Mortality Review Committee. In addition, the SHS Mortality Review Committee will review the material obtained for each non-CVD death among SHS Phase I participants according to the procedure described by Sievers, et al. Underlying and contributing causes of death will be coded. All causes of death will be coded from this review, but analyses will generally be restricted to a slightly modified list of the 15 leading causes of death (and their inclusive ICD-9 codes) used by Sievers, et al. These causes are: diseases of the heart, malignant neoplasms, cerebrovascular disease, unintentional injuries, and adverse effects, chronic obstructive

pulmonary disease and allied conditions, pneumonia and influenza, diabetes mellitus, chronic liver diseases and cirrhosis, atherosclerosis, suicide, homicide and legal intervention, nephritis, nephrotic syndrome and nephrosis, septicemia, and HIV/AIDS. Each death will be coded by two members of the review committee, and discrepancies in CVD diagnosis will be adjudicated by Dr. James Howard and the Mortality Committee.

Eligible deaths outside of the study area, but within the State, are included in the review and confirmation procedure. For eligible out-of-state deaths, attempts will be made to obtain an abstract or summary from the hospital where they died, and an interview will be done with an informant concerning the circumstances of death. Local medical records for the decedent will also be reviewed.

b. Procedure

The identification and confirmation of CVD deaths will involve the following steps: (1) identification of all deaths occurring in the SHS-I examination cohort, (2) obtaining all death certificates, (3) coding of all death certificates by the central nosologist, (4) obtaining Coroner's/Medical Examiner's report, (5) review autopsy reports, (6) chart review, and (7) independent confirmation of cause of death by the Mortality Review Committee.

STEP 1: Identification of all deaths

All deaths in members of the Phase I cohort will be identified by each center from tribal records, IHS hospitals, BIA, State Department of Health and/or the National Death Index. The name, date of birth, date of death and place of death will be obtained for each eligible death. Persons who died out-of-state when visiting other states will be included.

STEP 2: Obtaining death certificates and reviewing charts

With the names of the decedents, dates of birth, dates of death, and places of death, copies of death certificates of all deaths will be obtained from the State Department of Health. The Death Certificate Form (see Appendix B-1 for form instructions and Appendix C for the form) will be completed by the local data abstractor and transmitted to the Coordinating Center.

STEP 3: Coding of death certificates by central nosologist

The local center will record the ID on the back of the death certificate and send only the death certificate to the central nosologist:

Mr. Karl E. Wise
36 Fox Grape Lane
Southern Shores
Kitty Hawk, NC 27949

Mr. Wise will code the death certificate of the cause of death. The corresponding Death Certificate Forms will simultaneously be sent to the Coordinating Center. Mr. Wise will, in a standardized approach using ICD 9th Revision, record the codes on the back of the death certificate and return it to the Coordinating Center. The nosologist's codes will be entered into the computer. A copy of the codes will be sent to the Study Center by the Coordinating Center.

STEP 4: Obtaining Coroner's/Medical Examiner's / Police Report

If it is indicated on the death certificate that an autopsy was performed, the autopsy report and Coroner's/Medical Examiner's Report will be obtained by each study center. Police report should also be obtained for injury deaths, if available. Photocopy the autopsy report, complete the Photocopy Checklist, attach both to the death certificate, and send the entire package to Dr. Sievers for confirmation. Dr. Sievers will fill out the autopsy report form (Appendix C) based on the cause(s) listed on the report.

STEP 5:

Review medical chart to see if the decedent was hospitalized within one year prior to death and fill out Photocopy Checklist (Appendix C). All hospital admissions between exam and death must be reviewed.

STEP 6: Confirmation of Cause of Death

- a. If the decedent was hospitalized within one year prior to death, the Photocopy Checklist will be completed. The Photocopy Checklist, Mortality Survey Packet Checklist, the death certificate, the autopsy report, the Coroner's/Medical Examiner's report, and police report, if available, and relevant medical records information are sent to Dr. Sievers for confirmation. (Mortality Survey Final Decision Form, Appendix C).
- b. If the decedent died prior to arrival at the hospital, upon arrival, or in any other non-hospital location (e.g., home, nursing home), and if available information is not sufficient to determine whether the death was due to a cardiovascular problem, the attending physician or nursing home staff, and an informant will be identified from the death certificate or other sources and contacted for an interview. The Informant Interview Form, and the Photocopy Checklist will be completed (Appendix C). These two forms as well as the death certificate, autopsy report, and coroner's/medical examiner's report (if available) will be forwarded to Dr. Sievers. The Informant Interview is done for: 1) deaths that were not medically attended (traumatic or violent are excluded), and 2) those that are requested by a member of the Mortality Review Committee. Unattended deaths in persons with end-stage renal disease who have voluntarily

discontinued dialysis and those occurring in persons with cancer who are in hospice care and for whom there is no suspicion of CVD do NOT require an Informant Interview. Deaths for which an autopsy was done also do NOT require an Informant Interview. If there is any question as to whether or not an interview is needed in a particular circumstance, field staff should consult with their local Mortality Review Committee physician.

- c. Dr. Sievers will return the completed Final Decision Form to the Coordinating Center for data entry. All of the mortality packets will be forwarded to the next reviewer for independent classification of cause of death. Once their review is completed, their Final Decision Form and the mortality packet are forwarded to the Coordinating Center.

2.1.2 Review of Medical Charts of the Decedents

Unless the Coroner's / autopsy report is conclusive, medical records of the decedent will be reviewed and pertinent data photocopied using the Photocopy Checklist. For deaths that occurred in hospitals other than IHS hospitals, additional efforts will be made to secure medical information. If the patient was hospitalized in more than one facility without intervening discharge, all available medical records will be reviewed. Discharge summaries, ECGs, X-ray reports, etc. will be photocopied and attached to the Checklist. If the patient died in a hospital as an in-patient, data accumulated in the period of hospitalization will be reviewed. If the patient died out-of-hospital or died upon arrival at the hospital, available information in the medical records for relevant hospitalizations and outpatient visits within one year prior to death will be reviewed.

2.1.3 Informant Interview

Informant interviews are very helpful in deaths that occur outside the hospital, especially if no autopsy, coroner, or medical examiner reports are available. It is important to note that the most useful portion of the interview is that which describes what happened to the person during the last few hours (day) of his or her life. Often these descriptions of the person's symptoms or behaviors are the best indicators of likely cause of death. Thus, this portion of the interview should be a major focus, as well as questions regarding timing of any symptoms in relation to death. Using name and address information from the death certificate, an attempt will first be made to contact and interview the spouse or a first-degree relative (i.e., parent, son, daughter, or sibling) of the decedent, or someone else who witnessed the death including nursing home staff, if applicable. The following procedure will be followed:

- (1) Find the informant's telephone number and/or address.
- (2) If the telephone number is available, call him/her to request permission to interview and to set up an interview appointment. The interview may be

conducted over the telephone, or if necessary, in person using the Informant Interview Form.

- (3) If phone contact is not possible, the local community health representative or public health nurse will be asked to assist in arranging the interview.
- (4) If the informant cannot be contacted by phone or in person, a form letter, a reply letter and a self-addressed and stamped envelope will be sent asking the informant for permission for an interview and convenient time for the interview. If the form letter is sent and no reply is received in three weeks, another such letter is sent by certified mail. If no reply is received within one month, no further effort to contact the individual is made.

When the death is witnessed by someone other than a member of the decedent's family, both a family member and the witness are interviewed. In such a case, the information from both interviews is recorded on separate Informant Interview Forms. Up to three (the three best) Informant Interview Forms may be completed for a given event.

The SHS field coordinators oversee the informant interview to ensure that the staff members who conduct such interviews are appropriately trained and not overly stressed by the conduct of the interview. Informant interviewers will be trained in bereavement counseling when possible, and the SHS center coordinator will debrief the interviewer after each interview is complete. In this way, SHS staff will assist the family with bereavement, and necessary support will be provided to the interviewers, who conduct these difficult interviews.

2.1.4 Death Occurring Outside of the Study Community

Eligible deaths outside of the study area, but within the State, will be included in the above review and confirmation procedure. For eligible out-of-state deaths, attempts will be made to obtain an abstract or summary from the hospitals where they died and, if these cannot be obtained, to interview an informant. Their local medical charts will also be reviewed.

2.2 DEFINITIONS OF CVD DEATHS

The following will be the primary events of interest:

- (1) Definite fatal myocardial infarction (MI)
- (2) Definite sudden death due to coronary heart disease (CHD)
- (3) Definite fatal CHD
- (4) Possible fatal CHD
- (5) Definite fatal Stroke
- (6) Possible fatal stroke
- (7) Definite fatal congestive heart failure (CHF)
- (8) Possible fatal CHF
- (9) Other fatal CVD

Criteria used for ascertaining the primary CVD deaths are the International Diagnostic criteria for acute myocardial infarction and acute stroke and criteria for fatal CHF of the Framingham study:

2.2.1 Definite fatal myocardial infarction (MI)

(1a) Definite MI within 4 weeks of death by criteria:

1. Evolving diagnostic ECG

AND/OR

2. Diagnostic ECG and abnormal enzymes

AND/OR

3. Prolonged cardiac pain and abnormal enzymes.

OR

(1b) Acute MI diagnosed by autopsy

AND

- (2) No known non-atherosclerotic or non-cardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

2.2.2 Definite sudden death due to coronary heart disease (CHD)

- (1) Death witnessed as occurring within 1 hour after the onset of severe cardiac symptoms (cardiac pain - see below, shortness of breath, fainting) or within 1 hour after the subject was last seen without symptoms

AND

- (2) No documentation of definite acute MI within, 4 weeks prior to death by criteria (see (1)a. in Section 2.2.1 for criteria for definite MI)

AND

- (3) No known non-atherosclerotic or non-cardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician report.

2.2.3 Definite fatal CHD

- (1) Death certificate with consistent underlying or immediate cause(s) (ICD-9 codes 410-414)

AND

- (2) No documentation by criteria of definite acute MI within 4 weeks prior to death

AND

- (3) Criteria for sudden death not met

AND

- (4) No known non-atherosclerotic or non-cardiac-atherosclerotic process or event that was probably lethal according to death certificate, autopsy report, hospital records, or physician records

AND

- (5a) Previous history of MI according to relative, physician, or hospital records, or definite MI (see criteria above) or possible MI by criteria below:

(One or more of the following categories: *)

- 1) Equivocal enzymes and equivocal ECG (with or without pain)
- 2) Equivocal enzymes and diagnostic ECG (no pain)
- 3) Abnormal enzymes and other ECG (no pain)

- 4) Abnormal enzymes and equivocal ECG (no pain)
- 5) Abnormal enzymes alone (no pain, ECG absent or uncodeable)
- 6) Prolonged cardiac pain and equivocal enzymes (ECG absent or uncodeable)
- 7) Prolonged cardiac pain and equivocal ECG (enzymes incomplete)
- 8) Prolonged cardiac pain and diagnostic ECG (equivocal or incomplete enzymes)
- 9) Prolonged cardiac pain alone (ECG and enzymes incomplete)
- 10) Prolonged cardiac pain, "other" ECG, equivocal enzymes
- 11) Prolonged cardiac pain, "other" ECG, incomplete enzymes

OR

- (5b) Autopsy reporting severe atherosclerotic-coronary artery disease or old MI without acute MI (50% proximal narrowing of two major vessels or 75% proximal narrowing of one more vessel if anatomic details given)

OR

- (5c) Rapid death:

Death occurring greater than 1 and less than or equal to 24 hours after the onset of severe cardiac symptoms or after subject was last seen without symptoms.

* Definitions are given in Section 2.3.

2.2.4 Possible fatal CHD

- (1) No documentation by criteria of definite acute MI within 4 weeks prior to death

AND

- (2) No documentation by criteria of definite sudden death

AND

- (3) No documentation by criteria of definite fatal CHD

AND

- (4) Death certificate with consistent underlying or immediate cause (ICD-9 codes 410-414)

AND

- (5) No known non-atherosclerotic or non-cardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

2.2.5 Definite Fatal Stroke (for definitions of stroke sub-types, see pp. II-25-II-26)

- (1a) Cerebral infarction or hemorrhage diagnosed at autopsy

AND

- (1b) No other disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit with or without coma - according to death certificate, autopsy, hospital records, or physician records

OR

- (2a) History of rapid onset (approximately minutes to hours from onset to time of maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness

AND

- (2b) Documentation of focal neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of death with >24 hours duration of objective physician findings

AND

- (2c) See list under (1b) above.

2.2.6 Possible “Undocumented” Fatal Stroke (for definitions of stroke sub-types, see pp. II-25-II-26)

- (1) Death certificate with consistent underlying or immediate cause (ICD-9 codes 431-437) but neither autopsy evidence nor adequate pre-terminal documentation of the event

AND

- (2) No evidence at autopsy examination of the brain, if performed, of any disease process other than cerebral infarction or hemorrhage that could cause focal neurologic signs (see (1b) above).

2.2.7 Definite Fatal CHF

Two major or one major and 2 minor criteria must be present concurrently.

Major criteria

- Paroxysmal nocturnal dyspnea or orthopnea
- Neck vein distention
- Rales
- Cardiomegaly
- Acute pulmonary edema
- S₃ gallop
- Increased venous pressure > 16 cm water
- Circulation time \geq 25 seconds
- Hepatojugular reflux

Minor criteria

- Ankle edema
- Night cough
- Dyspnea on exertion
- Hepatomegaly
- Pleural effusion
- Vital capacity reduced by one-third from predicted
- Tachycardia (rate of heart \geq 120/min)

Major or Minor criterion

Weight loss \geq 4.5 kg in 5 days in response to treatment. No known non-cardiac process, such as renal failure, leading to massive fluid overload.

2.2.8 Possible Fatal CHF

Death certificate with consistent underlying or immediate cause, but neither autopsy evidence nor adequate pre-terminal documentation of the event.

2.2.9 Other Fatal CVD

1. Definite other fatal CVD

(1a) Autopsy evidence consistent with other CVD as cause of death

OR

(1b) Death certificate with consistent underlying or immediate cause

AND

- (2) Adequate documentation in medical records

2. Possible other fatal CVD

Death certificate with consistent underlying or immediate cause, but does not satisfy any of the above criteria.

2.3 DEFINITION OF ABNORMAL ECG, ABNORMAL ENZYMES, PROLONGED CHEST PAIN, AND STROKE TYPES

2.3.1 Abnormal ECG

1. Evolving Diagnostic ECG

An evolving pattern on serial ECGs of a diagnostic ECG. (An evolving pattern of changes [appearance or disappearance within lead groups: anterior (V_1 - V_5); lateral (I, aV_L , V_6); or inferior (II, III, aV_F)] establishes the infarct as acute. Two or more ECG recordings during the hospitalization are needed for this classification.)

To qualify as a Q wave, deflection should be at least 0.1 mV (1 mm.) in amplitude.

Possibilities:

- a. No Q wave in one ECG record followed by a record with a diagnostic Q wave.

OR

- b. An equivocal Q wave and no major ST segment depression in one ECG followed by a record with a diagnostic Q wave PLUS a major ST segment depression.

OR

- c. An equivocal Q wave and no ST segment elevation in one ECG record followed by a record with a diagnostic Q wave PLUS ST segment elevation > 1 mm.

OR

- d. An equivocal Q wave and no major T wave inversion in one ECG record followed by a record with a diagnostic Q wave PLUS a major T wave inversion.

OR

- e. No Q wave and no ST Junction depression ≥ 0.5 mm. and flat or down-sloping ST segment depression followed by a record with an equivocal Q wave PLUS ST Junction and flat or down-sloping ST depression of 0.5 mm.

OR

- f. No Q wave and no ST elevation > 1 mm. followed by a record with an equivocal Q wave PLUS ST elevation > 1 mm.

OR

- g. No Q wave and no T wave findings diagnostic of infarction followed by a record with an equivocal Q wave PLUS T wave findings diagnostic of infarction.

2. DIAGNOSTIC ECG WITH Q WAVE

- a. Diagnostic Q and QS patterns.

3. DIAGNOSTIC ECG WITHOUT Q WAVE

- a. ST segment elevation PLUS T wave depression indicative of infarction.
(T wave depression cannot be used in the presence of ventricular conduction defects.)

4. EQUIVOCAL ECG WITH Q WAVE

- a. ECG with Q and QS pattern possibly representing infarction.

5. EQUIVOCAL ECG WITHOUT Q WAVE

- a. ST junction (J) and segment depression or T wave inversions or ST segment elevations possibly representing infarction.

6. OTHER

- a. All other findings, including normal.

7. UNCODEABLE ECG

- a. Missing Leads
- b. Baseline drift (1 in 20) if it obscures ST-T segment.
- c. Muscle tremor giving 2 mm. peak-to-peak oscillation.
- d. Other technical errors making Q wave measurements impossible.
- e. Major abnormal QRS conduction patterns(BBB, pacemaker, etc.)

2.3.2 Abnormal Enzymes

To be able to be used to evaluate an MI, enzymes must have been measured within 1-4 days of admission or onset of acute event, whichever is later.

1. Abnormal Cardiac Enzymes

Enzymes are classed as "abnormal" if any appropriately-timed enzyme values meet any of the following criteria:

- 1) Troponin is ≥ 2 times the upper limit of the normal range used by the lab at which the test was done or it is reported as "abnormal".

OR

- 2a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or the CK-MB (heart fraction) is at least twice the upper limits of normal (if hospital uses quantitative criteria) or 10% of the total CK value, and total CK is at least twice the upper limit of normal.

AND

- 2b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.

OR

- 3a) The ratio $LDH_1 : LDH_2 > 1$

AND

- 3b) There is no evidence of hemolytic disease.

OR

- 4a) Total CK and LDH are both at least twice the upper limits of normal. (These increases do not have to occur on the same day.)

AND

- 4b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

2. Equivocal Cardiac Enzyme

Enzymes are classed as "equivocal" if the criteria for abnormal are not met and if:

- 1) Either total CK or total LDH are at least twice the upper limits of normal.

OR

- 2) Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)

OR

- 3) CK-MB= 5-9% of total CK or is "weakly present".

A summary of the enzyme diagnostic criteria, as related to total CK and LDH is given in the following algorithm:

	Twice Upper Limit of Normal	<i>Equivocal</i>	<i>Equivocal</i>	Abnormal
TOTAL LDH	Upper Limit of Normal	Normal	<i>Equivocal</i>	<i>Equivocal</i>
	Normal	Normal	Normal	<i>Equivocal</i>
		Normal	Upper Limit of Normal	Twice Upper Limit of Normal
				TOTAL CK

2.3.3 Prolonged Cardiac Pain

Pain having the following characteristics: Occurring anywhere in the anterior chest, left arm or jaw, which may also involve the back, shoulder, right arm, or abdomen on one or both sides and lasting for more than 20 minutes.

2.3.4 Stroke Types (See Petty GW et al. *Stroke* 2000;31:1062-1068 and Broderick JP et al. *Stroke* 1992;23:1250-1256.)

2.3.4.1 Cerebral Infarction

2.3.4.1.1 Cardioembolic Stroke

Defined by the presence of one or more major cardiac sources of embolism, or of a condition consistent with a cardioembolic etiology: (1) congestive heart failure at stroke onset; (2) myocardial infarction within 2 months prior to stroke onset; (3) hemodynamically significant mitral valve disease; (4) prosthetic mitral or aortic valve; (5) atrial fibrillation or flutter; (6) cardiomyopathy; (7) congenital heart disease; (8) recent systemic arterial emboli; (9) stroke within 48 hours after coronary artery bypass surgery; (10) stroke within 48 hours after left ventricular aneurysm surgery; (11) stroke related to cardiac catheterization or pacemaker implantation; (12) left ventricular aneurysm; (13) intracardiac thrombus; (14) valvular vegetations; (15) sick sinus syndrome; (16) autopsy evidence of recent myocardial infarction that could be dated at the time of or before the stroke; (17) autopsy evidence of rheumatic heart disease; (18) autopsy or imaging (arteriography, magnetic resonance angiography, computed tomography angiography) evidence of recent systemic arterial emboli that could be dated at the time of or before the stroke; and (19) autopsy or imaging (arteriography, magnetic resonance angiography, computed tomography) evidence of embolic occlusion of an intracerebral vessel with little or no evidence of cervical or intracranial atherosclerotic disease.

2.3.4.1.2 Atherothrombotic Stroke

Characterized by the presence of occlusion or a $\geq 50\%$ stenosis of a cervicocephalic artery (carotid, vertebral, basilar, middle cerebral, anterior cerebral, or posterior cerebral) supplying the vascular territory of the stroke, as documented by ultrasound, transcranial Doppler, oculopneumoplethysmography, cerebral angiography, magnetic resonance angiography, computed tomography angiography or autopsy.

2.3.4.1.3 Lacunar Stroke

Classified based on the presence of a clinical syndrome consisting of pure motor stroke, pure sensorimotor stroke, pure sensory stroke, ataxic hemiparesis, or clumsy hand-dysarthria. Brain CT or MRI demonstrates either no lesion to explain the syndrome or a deep ischemic stroke, ≤ 15 mm in size, in a location consistent with the clinical syndrome.

2.3.4.1.4 Other, Unknown Infarction

Cerebral infarction defying classification into any of the above categories. This includes cryptogenic infarction, i.e., infarction of uncertain cause despite a thorough evaluation or because the evaluation is incomplete; infarction in the setting of competing potential etiologies (e.g., a 70% ipsilateral carotid stenosis in the presence of left ventricular thrombus); and infarction attributable to uncommon etiologies, such as vasculitis, fibromuscular dysplasia, etc.

2.3.4.2 Intracerebral (Intraparenchymal) Hemorrhage

The acute onset of focal neurological deficit possibly associated with headache, vomiting, altered level of consciousness, signs of meningeal irritation, or blood stained CSF. If performed, CT, MRI, or autopsy will demonstrate a parenchymal hemorrhage. Rupture of a lesion resulting in parenchymal hemorrhage, which is not associated with hemorrhage into the subarachnoid space, is classified as an intracerebral hemorrhage. Intraparenchymal hemorrhage extending into the subarachnoid space is also classified as an intracerebral hemorrhage.

2.3.4.3 Subarachnoid Hemorrhage

The abrupt onset of headache, with or without altered consciousness, and with associated signs of meningeal irritation. A focal neurologic deficit may develop acutely or with a delay of hours or days after the other criteria have been present. CT, MRI, CSF examination, or autopsy will show blood in the subarachnoid space. A subarachnoid hemorrhage is one that is confined to the subarachnoid space. Imaging studies or autopsy may show an intraparenchymal hemorrhage that occurred either at or after the onset of primary subarachnoid hemorrhage. Intraparenchymal hemorrhage extending into the subarachnoid space is classified as an intracerebral hemorrhage.

2.3.4.4 Transient Ischemic Attack

A transient ischemic attack (TIA) is an episode of focal neurological symptoms with abrupt onset and rapid resolution lasting less than 24 hours and due to altered circulation to a limited region of the brain. Transient visual disturbances associated with retinal ischemia will be excluded. Transient symptoms such as syncope, unexplained unconsciousness, dizziness, or wooziness will be excluded unless associated with other symptoms of brainstem ischemia. Symptoms such as vertigo, dysarthria, or diplopia which occur in isolation without other symptoms of brainstem ischemia are excluded. The diagnosis of TIA is a clinical one; results of neuroimaging studies are recorded but do not affect the diagnosis of TIA.

2.4 MORTALITY SURVEY FORMS (see Appendix C)

1. **Mortality Survey Death Certificate Form:** This form codes relevant information directly from the death certificate.
2. **Final Decision Form I - Autopsy Report Form:** This form is designed to capture the underlying cause of death as designated by the pathologist, medical examiner or coroner when an autopsy has been performed. The form is completed by Dr. Sievers when an autopsy report accompanies the mortality packet. The form is completed by transcribing the relevant information from the autopsy report, and does not involve decision-making.
3. **Photocopy Checklist for Medical Records Review - Mortality Surveillance - CVD and Non-CVD:** This check list is intended to assist the field staff in collecting the appropriate medical records information for review of the cause of death in SHS participants. It also serves as a computerized record of the materials collected to support the mortality review for each event. The form is completed by the field staff collecting information on a SHS death.
4. **Mortality Survey - Final Decision Form:** This form records the judgment of the SHS Mortality Review Committee member as to the underlying and contributory causes of death. The form is completed independently by two reviewers for each death in the SHS cohort. Completed forms are forwarded to the Coordinating Center for data entry and review to identify discrepancies in assigned causes.

SPECIAL COMMENTS:

Assigning Codes for Causes of Death - Section A of the Final Decision Form includes codes for the underlying cause of death (only 1 is allowed) and for up to 2 contributing causes. Codes 01 through 09 are used for CVD and codes 21 through 33 are used for major, non-CVD causes. Code 88 should be used to designate a cause other than those listed, and the exact "other" cause should be printed in the space provided. Code 99 is used to designate death due to indeterminate causes. When a vascular disease was a contributory cause of death, the code associated with a "definite" occurrence should be used, i.e., codes 01, 03, 05 or 07.

The remainder of the form is used to indicate the types of evidence on which the designation of CVD was based. For non-CVD deaths, up to 3 evidence codes are provided to record the type of information on which the decision regarding cause of death was based.

5. **Mortality Survey Packet Checklist:** This form is used by the field staff to organize materials for the mortality packets prior to forwarding the packet to Dr. Sievers for review.

5. **Master List of Hospitalizations and Outpatient Visits:** This form (see Appendix D) is used by the field staff to record both in-patient and out-patient visits for which the medical records need to be reviewed. This would include any event of interest to the SHS or may be used by the centers to keep a log of all hospitalizations or outpatient visits. The intent of the form is to be useful to the field staff for organizing the events that require review for any given participant.

CHAPTER THREE

MORBIDITY SURVEILLANCE

3.1 ELIGIBLE POPULATION

Cardiovascular morbidity will be identified among surviving SHS examination cohort members in the three study areas through annual contacts or review of medical records, and through interviews of the participants at their Phase IV examination of cohort members of the family study. Events of interest are those occurring since the SHS-III examination (or the most recent chart review if that was the last contact). Some prior events that were inadvertently missed may also be picked up in Phase IV.

3.2 SURVEILLANCE EVENTS

Tables 1.1 and 1.2 summarize the primary and secondary CVD endpoints of interest in the SHS. All potentially eligible events will be reviewed whether they were treated on an in-patient or out-patient basis. Outcomes include selected positive tests for atherosclerosis.

Criteria used for defining acute myocardial infarction and stroke have been derived primarily from the International Diagnostic Criteria. The criteria for "diagnostic" cardiac enzymes are those of ARIC and the International Diagnostic Criteria.

3.3 DIAGNOSTIC CRITERIA: NON-FATAL MYOCARDIAL INFARCTION

3.3.1 Definite Non-Fatal MI

Must meet one or more of the following criteria:

1. Evolving diagnostic ECG (defined in Section 2.3.1);

OR

2. Diagnostic ECG and abnormal enzymes (defined in Sections 2.3.1 and 2.3.2);

OR

3. Prolonged cardiac pain (defined in Section 2.3.3) and abnormal enzymes.

3.3.2 Possible Non-Fatal MI

Must meet one or more of the following criteria in the absence of findings that meet the criteria for Definite Non-Fatal MI:

1. Equivocal enzymes and equivocal ECG (with or without pain)
2. Equivocal enzyme and diagnostic ECG (no pain)
3. Abnormal enzymes and other ECG (no pain)
4. Abnormal enzymes and equivocal ECG (no pain)
5. Abnormal enzymes alone (no pain, ECG absent or uncodeable)
6. Prolonged cardiac pain and equivocal enzymes (ECG absent or uncodeable)
7. Prolonged cardiac pain and equivocal ECG (enzymes incomplete)
8. Prolonged cardiac pain and diagnostic ECG (equivocal or incomplete enzymes)
9. Prolonged cardiac pain alone (ECG and enzymes incomplete)
10. Prolonged cardiac pain, "other" ECG, equivocal enzymes
11. Prolonged cardiac pain, "other" ECG, incomplete enzymes

3.3.3 Definite Coronary Heart Disease (CHD)

1. Cardiac cath proven coronary artery disease, *or*
2. PTCA, *or*
3. Coronary artery bypass grafting, *or*
4. Abnormal stress ECG, **and** Abnormal imaging, *or*
5. Positive functional test of ischemia (such as treadmill)

3.3.4 Possible Coronary Heart Disease

Meets some, but not met all, criteria for definite CHD or test results are equivocal.

3.3.5 Other Non-fatal CVD

1. Congestive Heart Failure (CHF)
2. CHF secondary to ESRD (ESRD diagnosis=10)
3. Cardiomyopathy
4. Valvular Heart Disease
5. Left ventricular Hypertrophy
6. Atrial Fibrillation
7. Non-coronary heart surgery or carotid or other vascular surgery (includes procedures for Peripheral Vascular Disease (PVD))
8. Pacemaker implantation
9. Positive non-coronary angiography (includes procedures for PVD)
10. Arrhythmia
11. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; otherwise, diagnosis=07)

3.3.6 End Stage Renal Disease

1. Kidney dialysis
2. Kidney transplantation

3.3.7 ECG Tracings to be Photocopied

The following ECG tracings are to be photocopied:

1. The last ECG obtained prior to this admission.
2. The first ECG recorded after admission or the occurrence of an in-hospital event.
3. The first ECG done each day thereafter, and
4. The last ECG recorded before discharge.

The photocopies of ECGs should be dated according to the date and time the ECG was done, and they should be arranged in chronological order from earliest to latest.

A summary of the diagnostic criteria for hospitalized, non-fatal myocardial infarction used in the Strong Heart Study is given in Table 3.1.

Table 3.1 Summary of Diagnostic Criteria for Hospitalized, Non-Fatal Myocardial Infarction (MI)

Cardiac Pain	ECG Findings	Enzymes	Diagnosis
Present	Evolving Diagnostic ECG	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG	Abnormal	Definite MI
		Equivocal	Possible MI
		Incomplete	Possible MI
		Normal	No MI
	Equivocal ECG	Abnormal	Definite MI
		Equivocal	Possible MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodeable, or other	Abnormal	Definite MI
		Equivocal	Possible MI
		Incomplete	No MI
		Normal	No MI
Not present	Evolving Diagnostic ECG	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG	Abnormal	Definite MI
		Equivocal	Possible MI
		Incomplete	No MI
		Normal	No MI
	Equivocal ECG	Abnormal	Possible MI
		Equivocal	Possible MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodeable, or other	Abnormal	Possible MI
		Equivocal	No MI
		Incomplete	No MI
		Normal	No MI

3.4 DIAGNOSTIC CRITERIA: NON-FATAL STROKE

3.4.1 Definite Non-Fatal Stroke (for definitions of stroke sub-types, see pp. II-40-II-41)

1. History of rapid onset (approximately minutes to hours from onset to time of maximum acute neurologic deficit) of focal neurologic deficit with or without a change in state of consciousness

AND

2. Documentation of focal neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of onset with 24 hours duration of objective physician findings

AND

3. No other disease process or event such as brain tumor, sub-dural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit with or without coma according to hospital records.

3.4.2 Possible Non-Fatal Stroke (for definitions of stroke sub-types, see pp. II-40-II-41)

- 1a. History of rapid onset (approximately minutes to hours from onset to time of maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness,

AND

- 1b. Documentation of focal neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of onset with 24 hours duration of objective physician findings,

OR

- 1c. Discharge diagnoses with consistent primary or secondary codes (ICD-9-CM codes 431, 432, 434, 436, 437),

AND

2. No evidence by unequivocal physician or laboratory findings of any other disease process or event causing focal brain deficit or coma other than cerebral infarction or hemorrhage according to hospital records.

3.4.3 Unequivocal Laboratory Findings (for definitions of stroke sub-types, see pp. II-40-II-41)

1. A computerized axial tomography (CAT) scan showing no definite findings of any disease process or event causing focal brain deficit or coma other than cerebral infarction or hemorrhage,

AND

- 2a. Showing a focal area of decreased or normal attenuation consistent with cerebral infarct,

OR

- 2b. Showing focal increased attenuation consistent with intra-cerebral hemorrhage.

A summary of the diagnostic criteria for hospitalized, non-fatal stroke used in The Strong Heart Study is given in Table 3.2 (for definitions of stroke sub-types, see pp. II-40-II-41).

Table 3.2 Summary of Diagnostic Criteria for Hospitalized, Non-Fatal Stroke

Diagnostic Evidence	Onset/Duration Neuro. Deficit	Other Causes	Diagnosis
Unequivocal physician or laboratory	Rapid/ > 24 hr.	Absent	Definite Stroke
Discharge Diagnoses of Stroke (431, 432, 434, 436, 437)	Rapid/ > 24 hr.	Absent	Possible Stroke
All other combinations			No Stroke

3.5 DEFINITE CHF

Two major or one major and 2 minor criteria must be present concurrently.

Major criteria

- Paroxysmal nocturnal dyspnea or orthopnea
- Neck vein distention
- Rales
- Cardiomegaly
- Acute pulmonary edema
- S₃ gallop
- Increased venous pressure > 16 cm water
- Circulation time \geq 25 seconds
- Hepatojugular reflux

Minor criteria

- Ankle edema
- Night cough
- Dyspnea on exertion
- Hepatomegaly
- Pleural effusion
- Vital capacity reduced by one-third from predicted
- Tachycardia (rate of \geq 120/min)

Major or Minor criterion

Weight loss \geq 4.5 kg in 5 days in response to treatment. No known non-cardiac process leading to massive fluid overload such as renal failure.

Congestive heart failure that occurs secondary to ESRD should be entered as such in item 4.b. but coded as “non-CVD, specify:”, code “10” in part A.

3.6 ABNORMAL ECG

1. Evolving Diagnostic ECG

An evolving pattern on serial ECGs of a diagnostic ECG. (An evolving pattern of changes [appearance or disappearance within lead groups: anterior (V_1 - V_5); lateral (I, aV_L , V_6); or inferior (II, III, aV_F)] establishes the infarct as acute. Two or more ECG recordings during the hospitalization are needed for this classification.)

To qualify as a Q wave, deflection should be at least 0.1 mV (1 mm.) in amplitude.

Possibilities:

- a. No Q wave in one ECG record followed by a record with a diagnostic Q wave.

OR

- b. An equivocal Q wave and no major ST segment depression in one ECG followed by a record with a diagnostic Q wave PLUS a major ST segment depression.

OR

- c. An equivocal Q wave and no ST segment elevation in one ECG record followed by a record with a diagnostic Q wave PLUS ST segment elevation > 1 mm.

OR

- d. An equivocal Q wave and no major T wave inversion in one ECG record followed by a record with a diagnostic Q wave PLUS a major T wave inversion.

OR

- e. No Q wave and no ST Junction depression ≥ 0.5 mm. and flat or down-sloping ST segment depression followed by a record with an equivocal Q wave PLUS ST Junction and flat or down-sloping ST depression of 0.5 mm.

OR

- f. No Q wave and no ST elevation > 1 mm. followed by a record with an equivocal Q wave PLUS ST elevation > 1 mm.

OR

- g. No Q wave and no T wave findings diagnostic of infarction followed by a record with an equivocal Q wave PLUS T wave findings diagnostic of infarction.

2. DIAGNOSTIC ECG WITH Q WAVE
 - a. Diagnostic Q and QS patterns.
3. DIAGNOSTIC ECG WITHOUT Q WAVE
 - a. ST segment elevation PLUS T wave depression indicative of infarction.
(T wave depression cannot be used in the presence of ventricular conduction defects.)
4. EQUIVOCAL ECG WITH Q WAVE
 - a. ECG with Q and QS pattern possibly representing infarction.
5. EQUIVOCAL ECG WITHOUT Q WAVE
 - a. ST junction (J) and segment depression or T wave inversions or ST segment elevations possibly representing infarction.
6. OTHER
 - a. All other findings, including normal.
7. UNCODEABLE ECG
 - a. Missing Leads
 - b. Baseline drift (1 in 20) if it obscures ST-T segment.
 - c. Muscle tremor giving 2 mm. Peak-to-peak oscillation.
 - d. Other technical errors making Q wave measurements impossible.
 - e. Major abnormal QRS conduction patterns (BBB, pacemaker, etc.)

3.7 ABNORMAL ENZYMES

To be able to be used to evaluate an MI, enzymes must have been measured within 1-4 days of admission or onset of acute event, whichever is later.

1. Abnormal Cardiac Enzymes

Enzymes are classed as "abnormal" if any enzyme values recorded meet any of the following criteria:

- 1a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or the CK-MB (heart fraction) is at least twice the upper limits of normal (if hospital uses quantitative criteria) or 10% of the total CK value, and total CK is at least twice the upper limit of normal.

AND

- 1b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.

OR

- 2a) The ratio $LDH_1 : LDH_2 > 1$

AND

- 2b) There is no evidence of hemolytic disease.

OR

- 3a) Total CK and LDH are both at least twice the upper limits of normal. (These increases do not have to occur on the same day.)

AND

- 3b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

OR

- 4) Troponin is ≥ 2 times the upper limit of the normal range used by the lab at which the test was done or it is reported as "abnormal".

2. Equivocal Cardiac Enzyme

Enzymes are classed as "equivocal" if the criteria for abnormal are not met and if:

- 1) Either total CK or total LDH are at least twice the upper limits of normal.

OR

- 2) Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)

OR

- 3) CK-MB= 5-9% of total CK or is "weakly present".

A summary of the enzyme diagnostic criteria, as related to total CK and LDH is given in the following algorithm:

	Twice Upper Limit of Normal	<i>Equivocal</i>	<i>Equivocal</i>	Abnormal
TOTAL LDH	Upper Limit of Normal	Normal	<i>Equivocal</i>	<i>Equivocal</i>
	Normal	Normal	Normal	<i>Equivocal</i>
		Normal	Upper Limit of Normal	Twice Upper Limit of Normal
			TOTAL CK	

3.8 PROLONGED CARDIAC PAIN

Pain having the following characteristics: Occurring anywhere in the anterior chest, left arm or jaw, which may also involve the back, shoulder, right arm, or abdomen on one or both sides and lasting for more than 20 minutes.

3.9 STROKE TYPES (See Petty GW et al. *Stroke* 2000;31:1062-1068 and Broderick JP et al. *Stroke* 1992;23:1250-1256.)

3.9.1 Cerebral Infarction

3.9.1.1. Cardioembolic Stroke

Defined by the presence of one or more major cardiac sources of embolism, or of a condition consistent with a cardioembolic etiology: (1) congestive heart failure at stroke onset; (2) myocardial infarction within 2 months prior to stroke onset; (3) hemodynamically significant mitral valve disease; (4) prosthetic mitral or aortic valve; (5) atrial fibrillation or flutter; (6) cardiomyopathy; (7) congenital heart disease; (8) recent systemic arterial emboli; (9) stroke within 48 hours after coronary artery bypass surgery; (10) stroke within 48 hours after left ventricular aneurysm surgery; (11) stroke related to cardiac catheterization or pacemaker implantation; (12) left ventricular aneurysm; (13) intracardiac thrombus; (14) valvular vegetations; (15) sick sinus syndrome; (16) autopsy evidence of recent myocardial infarction that could be dated at the time of or before the stroke; (17) autopsy evidence of rheumatic heart disease; (18) autopsy or imaging (arteriography, magnetic resonance angiography, computed tomography angiography) evidence of recent systemic arterial emboli that could be dated at the time of or before the stroke; and (19) autopsy or imaging (arteriography, magnetic resonance angiography, computed tomography) evidence of embolic occlusion of an intracerebral vessel with little or no evidence of cervical or intracranial atherosclerotic disease.

3.9.1.2. Atherothrombotic Stroke

Characterized by the presence of occlusion or a $\geq 50\%$ stenosis of a cervicocephalic artery (carotid, vertebral, basilar, middle cerebral, anterior cerebral, or posterior cerebral) supplying the vascular territory of the stroke, as documented by ultrasound, transcranial Doppler, oculopneumoplethysmography, cerebral angiography, magnetic resonance angiography, computed tomography angiography or autopsy.

3.9.1.3. Lacunar Stroke

Classified based on the presence of a clinical syndrome consisting of pure motor stroke, pure sensorimotor stroke, pure sensory stroke, ataxic hemiparesis, or clumsy hand-dysarthria. Brain CT or MRI demonstrates either no lesion to explain the syndrome or a

deep ischemic stroke, ≤ 15 mm in size, in a location consistent with the clinical syndrome.

3.9.1.4. Other, Unknown Infarction

Cerebral infarction defying classification into any of the above categories. This includes cryptogenic infarction, i.e., infarction of uncertain cause despite a thorough evaluation or because the evaluation is incomplete; infarction in the setting of competing potential etiologies (e.g., a 70% ipsilateral carotid stenosis in the presence of left ventricular thrombus); and infarction attributable to uncommon etiologies, such as vasculitis, fibromuscular dysplasia, etc.

3.9.2 Intracerebral (Intraparenchymal) Hemorrhage

The acute onset of focal neurological deficit possibly associated with headache, vomiting, altered level of consciousness, signs of meningeal irritation, or blood stained CSF. If performed, CT, MRI, or autopsy will demonstrate a parenchymal hemorrhage. Rupture of a lesion resulting in parenchymal hemorrhage, which is not associated with hemorrhage into the subarachnoid space, is classified as an intracerebral hemorrhage. Intraparenchymal hemorrhage extending into the subarachnoid space is also classified as an intracerebral hemorrhage.

3.9.3 Subarachnoid Hemorrhage

The abrupt onset of headache, with or without altered consciousness, and with associated signs of meningeal irritation. A focal neurologic deficit may develop acutely or with a delay of hours or days after the other criteria have been present. CT, MRI, CSF examination, or autopsy will show blood in the subarachnoid space. A subarachnoid hemorrhage is one that is confined to the subarachnoid space. Imaging studies or autopsy may show an intraparenchymal hemorrhage that occurred either at or after the onset of primary subarachnoid hemorrhage. Intraparenchymal hemorrhage extending into the subarachnoid space is classified as an intracerebral hemorrhage.

3.9.4 Transient Ischemic Attack

A transient ischemic attack (TIA) is an episode of focal neurological symptoms with abrupt onset and rapid resolution lasting less than 24 hours and due to altered circulation to a limited region of the brain. Transient visual disturbances associated with retinal ischemia will be excluded. Transient symptoms such as syncope, unexplained unconsciousness, dizziness, or wooziness will be excluded unless associated with other symptoms of brainstem ischemia. Symptoms such as vertigo, dysarthria, or diplopia which occur in isolation without other symptoms of brainstem ischemia are excluded. The diagnosis of TIA is a clinical one; results of neuroimaging studies are recorded but do not affect the diagnosis of TIA.

3.10 PROCEDURE FOR IDENTIFICATION OF INCIDENT AND RECURRENT CASES

Identification of non-fatal CVD events in the SHS cohort will continue in Phase IV. Participants will be contacted annually or their IHS records will be reviewed. These events include non-fatal MI or stroke and new diagnoses of congestive heart failure. Persons will also be asked whether certain treatments or diagnostic procedures were done, including cardiac bypass surgery or angioplasty, cardiac catheterization, treadmill testing, and renal dialysis or renal transplant. All participants are asked to sign a consent form for review of their medical records.

Criteria used to define acute MI, stroke, and congestive heart failure in Phase IV are the same as those previously used by the SHS. These criteria were derived primarily from the International Diagnostic Criteria, ARIC, and the Framingham Study and are described in detail previously. The criteria for 'diagnostic' cardiac enzymes used in the SHS are those of ARIC and the International Diagnostic Criteria. All available information concerning the event is reviewed by a member of the SHS Morbidity Review Committee to determine whether the study criteria have been met. Reports of cardiac surgery, angioplasty, cardiac catheterization, and treadmill testing are also validated by review of information obtained from medical records.

The morbidity survey will involve the following steps:

STEP 1: Identification of potentially eligible cases.

In order to identify persons with events that may qualify as incident cases, IHS hospital computerized medical records (PCC, patient care component) or their IHS medical records are reviewed. All screening discharge diagnoses should be reviewed (see below); in addition to tests and procedures of interest to the SHS. Other local hospitals will also be surveyed to obtain discharges for MI or stroke that may be SHS participants. Participants at the clinical examination will also be asked if they had a CVD event of interest since their last SHS examination. Positive answers will be confirmed by chart review. Potential cases will be identified using the following ICD-9 codes. The list of screening codes to be used in reviewing discharge diagnoses is broader than the study event codes in order that cases not be missed.

1. MYOCARDIAL INFARCTION (ICD-9 codes 402, 410-414, 427-428, 518.4)

- 402 Hypertensive heart disease
- 410 Acute myocardial infarction
- 411 Other acute and subacute forms of ischemic heart disease
 - 411.0 Post-myocardial infarction syndrome
 - 411.1 Intermediate coronary syndrome
 - 411.8 Other - includes coronary insufficiency (acute), microinfarct of heart, subendocardial ischemia

- 412 Old myocardial infarction
- 413 Angina pectoris
- 414 Other chronic ischemic heart disease
- 427 Cardiac dysrhythmia

(Participants for whom *three separate admissions* that included atrial fibrillation have already been abstracted and morbidity packets forwarded for review *need NOT have additional, subsequent admissions for atrial fibrillation abstracted*. If they are admitted for other SHS events or procedures, these other events SHOULD be abstracted.)

- 428 Heart failure
 - 428.0 Congestive heart failure
 - 428.1 Left heart failure
 - 428.9 Heart failure, unspecified

(Participants for whom *three separate admissions* that included congestive heart failure have already been abstracted and morbidity packets forwarded for review *need NOT have additional, subsequent admissions for congestive heart failure abstracted*. If they are admitted for other SHS events or procedures, these other events SHOULD be abstracted.)

518.4 Acute edema of lung, unspecified

2. CEREBROVASCULAR DISEASE (ICD-9 430-438)

- 430 Subarachnoid hemorrhage
- 431 Intracerebral hemorrhage
- 432 Other and unspecified intracranial hemorrhage
- 433 Occlusion and stenosis of precerebral arteries - includes embolism, narrowing, obstruction or thrombosis of basilar, carotid, and vertebral arteries
- 434 Occlusion of cerebral arteries
- 435 Transient cerebral ischemia
- 436 Acute, but ill-defined, cerebrovascular disease - includes CVA NOS, Stroke
- 437 Other and ill-defined cerebrovascular disease - includes cerebral atherosclerosis, chronic cerebral ischemia, hypertensive encephalopathy, cerebrovascular disease or lesion not otherwise specified.
- 438 Late effects of cerebrovascular disease

3. *END STAGE RENAL DISEASE (ICD-9 39.95, 54.98, 55.6, 585, 586) (It is only necessary to identify and collect chart information for the FIRST time one of these diagnoses was made.)

- 39.95 Hemodialysis
- 54.98 Peritoneal dialysis
- 55.6 Kidney transplant

585 Chronic renal failure
586 Renal failure, unspecified

4. *CHRONIC VALVULAR HEART DISEASE (ICD-9 394-396, 424.0, 424.1)

394 Diseases of mitral valve
395 Diseases of aortic valve
396 Diseases of mitral and aortic valves
424.0 Mitral valve disorder
424.1 Aortic valve disorder

5. *AORTIC ANEURYSM (ICD-9 441.0-441.9)

6. *PROCEDURES FOR TREATMENT OF PERIPHERAL VASCULAR DISEASE

ICD-9 procedure code 88.48	Peripheral Angiograms
ICD-9 procedure code 39.50	Peripheral Angioplasty
ICD-9 procedure codes 39.25 & 39.29	Peripheral Surgical Revascularization
ICD-9 procedure codes 84.10-84.19	Amputation

* These events were added to the annual surveillance of cohort members in 2003. Retrospective surveillance for incident events only (those occurring since January 1, 2000) was done for these newly added events beginning in summer, 2003.

STEP 2: Confirmation of event occurrence

Because discharge diagnoses may be improperly recorded and a variety of associated codes will be screened, it is important to confirm that one of the events of interest has, in fact, occurred. Information in the record pertaining to the admission by which the potential case was identified (the index admission) should be reviewed. Check the discharge diagnoses listed on the face sheet of the admission and read the discharge summary. If one of the survey events has occurred during the study interval, information about the event will be photocopied from the record. If it is determined that the event is not an eligible SHS event, no information need be collected. Data should be obtained for all events of interest occurring during the study interval.

STEP 3: Medical record data collection

If the index admission is for one of the study events (whether or not it is the first occurrence), an appropriate photocopy checklist for that admission should be completed (Appendix D). If evidence is present suggesting that one or more myocardial infarctions or strokes occurred, a separate medical records abstract and checklist form will be completed for each event. Separate events must have a 28 day period when the patient is discharged from an acute care facility after a previous event. **If the participant is a study death, the abstract of medical records for decedents should also be completed.** If the medical record is not eligible for abstraction, the reason for exclusion (i.e., event occurred outside of the calendar years of the

study, not a study event) should be entered on the master list of hospitalization and outpatient visits.

High resolution photocopies of ECGs taken as evidence of a myocardial infarction during the morbidity survey (see Section 3.3.7) should be arranged in chronological order from earliest to latest.

3.11 MORBIDITY SURVEY FORMS (see Appendix D)

1. **Morbidity Survey Medical Records Abstract and Photocopy Checklist for Non-fatal CVD Events or Procedures:** This form is to be completed for each eligible non-fatal CVD event or procedure, regardless of whether it was treated on an in-patient or out-patient basis. The checklist is used to record all of the relevant types of information that were collected from the medical record. Morbidity packets for each admission are assembled according to this listing.
2. **Morbidity Survey - Decision Form:** This form is completed by members of the Morbidity Review Committee based on information provided from medical records. Part A is used to code the type of event, and Part B is used to indicate on what evidence the decision in Part A was based. In section C the reviewer has the opportunity to indicate his/her clinical impression, even if it does not conform to the SHS criteria for an event. If more than one event occurred during a hospitalization, they can both be recorded on a single form, but the reviewer may have to add his own extra boxes in Section A and be sure to complete the “evidence” Section for each event.
3. **Morbidity Survey - Cardiovascular Test Procedures and Peripheral Vascular Procedures Abstract:** These forms are used to capture information on the results of selected tests of cardiac function and for atherosclerosis (including peripheral vascular disease) that may have been done on a SHS participant. The appropriate form is completed based on the type of test report that is photocopied from the medical record. The form is completed by the Morbidity Review physician.

3.12 ACUTE MYOCARDIAL INFARCTION (AMI) QUALITY OF CARE TOOL AND INSTRUCTIONS (see Appendix E)

1. **AMI Tool. (see Appendix E, pp. E-1 to E-8)** This is an abstraction tool for assessing quality of care for hospitalized acute myocardial infarctions that was developed by the Health Care Financing Administration (HCFA). The SHS Observational Study Monitoring Board has asked SHS to assess quality of care, and HCFA uses this AMI Quality of Care assessment tool on a nationwide basis. Thus, during Phase IV of SHS the Steering Committee hopes to be able to collect sufficient data on the quality of care provided for acute MIs in SHS communities to make comparisons with national data. The SHS investigators found it necessary to modify the tool somewhat to fit the particular circumstances typical of Indian healthcare facilities.
2. **AMI Tool Instructions. (see Appendix E, pp. E-9 to E-57)** This is the instruction manual which was also developed by HCFA and modified by the SHS investigators to reflect the changes made in the tool in adapting it for use in Indian community healthcare facilities.

CHAPTER FOUR

TRAINING & QUALITY CONTROL OF MORTALITY & MORBIDITY SURVEILLANCE

4.1 TRAINING

Interviewers and data abstractors were centrally trained at the January 2001 training meeting in Oklahoma. Training included instructions in reviewing and abstracting of charts and instructions in transcribing of information on death certificates and medical examiner reports. Training included:

1. Adherence to the standardized protocol
2. Techniques for locating information in the charts
3. Dealing with problems encountered in the charts
4. Post-abstraction responsibility for the data

The training sessions consisted of:

1. Explanation of the procedure for abstracting
2. Demonstration by the instructor of abstraction procedures
3. Performance of abstraction by the trainee with instructor observing
4. Abstraction of records by both the trainee and the instructor with verification for completeness, consistency and accuracy

4.2 QUALITY CONTROL

4.2.1 Ascertainment of Cause of Death

In the mortality study, mortality packets for all deaths are sent to a second member of the Mortality Review Committee by the Arizona Center after being reviewed by Dr. Sievers. Each reviewer will independently make a judgment as to the cause of death and fill out a Mortality Survey Final Decision. The Coordinating Center will then compare the results from both reviewers. Discrepancies for CVD deaths will be adjudicated by Dr. James Howard and the Mortality Committee. Disagreement as to non-CVD causes of death will be resolved by using Dr. Sievers' decision.

4.2.2 Review of non-fatal CVD

A 10% sample of non-fatal CVD events will be reviewed by a second member of the Morbidity Review Committee. Disagreement will be discussed among Committee members to improve concordance of assignment of type of event.

RELATED READING

1. Sievers ML. Myocardial infarction among Southwestern American Indians. Ann Int Med 1967;67:800-807.
2. The National Heart, Lung and Blood Institute, ARIC (Atherosclerosis Risk in Communities Study) Manual, 1987.
3. Brown RD, Whisnant JP, Sicks JD, O'Fallon WM, Wiebers DO. Stroke incidence, prevalence, and survival: secular trends in Rochester, Minnesota, through 1989. Stroke 1996;27:373-380.
4. Petty GW, Brown RD Jr, Whisnant JP, Sicks JD, O'Fallon WM, Wiebers DO. Ischemic stroke subtypes: a population-based study of functional outcome, survival, and recurrence. Stroke 2000 May;31(5):1062-8.
5. Broderick JP, Phillips SJ, O'Fallon WM, Frye RL, Whisnant JP. Relationship of cardiac disease to stroke occurrence, recurrence, and mortality. Stroke 1992 Sep;23(9):1250-6.

APPENDIX A

Codes

APPENDIX A -- 1

THE STRONG HEART – FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

Study Communities and Codes

Arizona Community Codes

County	Community Name	Community Code
Maricopa	Co-Op Colony	116
	Gila Crossing	119
	Komatke	124
	Laveen	125
	Lone Butte	127
	Komatke Hts.	799
	Maricope Colony	128
	Lehi	126
	Salt River	132
	Pinal	Santa Cruz
Blackwater		213
Sacaton Flats		230
Sacaton		229
San Tan, Lower		232
San Tan, Upper		233
Stotonic		237
Goodyear (South)		235
Bapchule		212
Casa Blanca		214
Casa Blanca S		215
Casa Blanca W		216
Sacate		228
Sweetwater		240

Dakotas Community Codes

County	Community Name	Community Code
<u>Bennett (Pine Ridge)</u>	Allen	526
	Harrington	527
	Martin	528
	Patricia	529
	Swett	530
	Tuthill	531
	Vetal	532
<u>Benson (Fort Totten)</u>	Leeds	001
	Maddock	002
	Minnewaukan	003
	Brinsmade	100
	Esmond	101
	Crow Hill	356
	Flora	357
	Fort Totten	358
	Knox	359
	Mission	360
	Oberon	361
	St. Michael D	362
	Tokio	363
	Warwick	364
Woodlake Dis	365	
<u>Custer (Pine Ridge)</u>	Buffalo Gap	586
	Custer	587
	Hermosa	588
	Pringle	590
<u>Dawes (Pine Ridge)</u>	Chadron	306
	Crawford	307
<u>Dewey (Eagle Butte)</u>	Agency Dist	605
	Bear Creek/Eagle Butte	606
	Eagle Butte	607
	Firesteel	608
	Four Bear/Swiftbird	609
	Glencross	610
	Green Grass/Eagle Butte	611
	Isabel	612
	Lantry	613
	Laplant/Swiftbird	614
	Marksville/Swiftbird	615
	Moreau River/Whitehorse	616
	Promise/Whitehorse	617
Ridgeview	618	

Dakotas Community Codes (cont.)

County	Community Name	Community Code
<u>Dewey (Eagle Butte)</u> <u>(cont.)</u>	Swiftbird	619
	Swiftbird JC	620
	Timber Lake	621
	Trail City	622
	White Horse	623
	Blackfoot	624
	Parade	625
<u>Eddy (Fort Totten)</u>	New Rockford	102
	Hamar	396
	Sheyenne	397
<u>Fall River (Pine Ridge)</u>	Edgemont	631
	Hot Springs	632
	Igloo	633
	Oelrichs	634
	Oral	635
	Provo	636
	<u>Haakon (Eagle Butte)</u>	Midland
Milesville		601
Philip		602
Hughes	Big Bend	656
	Pierre	657
	Harrold	658
<u>Jackson (Pine Ridge)</u>	Belvidere	661
	Interior/Wanblee	662
	Kadoka/Wanblee	663
	Stamford	664
<u>Jackson (Pine Ridge)</u>	Hisle/Wanblee	846
	Longvalley	847
	Potato Creek	848
	Wanblee	849
<u>Meade (Eagle Butte)</u>	Faith	706
	Howes	707
	Sturgis	708
	Blackhawk	709
	Ft. Meade	710
	Mud Butte	711
	Piedmont	712
<u>Nelson (Fort Totten)</u>	Aneta	103

Dakotas Community Codes (cont.)

County	Community Name	Community Code
<u>Nelson (Fort Totten)</u> <u>(cont.)</u>	Pekin	104
	Dahlen	105
	Lakota	456
	Michigan	457
	Tolna	458
Pennington	Keystone	220
	Yellow Thunder Camp	630
	Ellsworth Air Force Base	631
	Scenic	632
	Wall	633
	Caputa	700
	Box Elder	736
	Hill City	737
	New Underwood	738
	Quinn	739
	Rapid City	740
Sioux Addition (Lakota Homes)	741	
<u>Potter (Eagle Butte)</u>	Gettysburg	751
	Lebanon	771
<u>Ramsey (Fort Totten)</u>	Starkweather	106
	Webster	107
	Churches Ferry	108
	Crary	476
	Devils Lake	477
	Doyon	478
	Lake Wood	479
<u>Shannon (Pine Ridge)</u>	Am Horse Cr/Kyle	771
	Batesland/Allen	772
	Calico	773
	Crazy Horse	774
	Cuny Table	775
	Denby	776
	Grass Creek/Manderson	777
	Kyle	778
	Lake	779
	Lakeside	780
	Manderson	781
	Oglala	782
	Pine Ridge	783
	Porcupine	784
	Red Shirt TA	785
Rockyford/Porcupine	786	

Dakotas Community Codes (cont.)

County	Community Name	Community Code
<u>Shannon (Pine Ridge)</u> <u>(cont.)</u>	Slim Butte	787
	White River	788
	Wolf Creek	789
	Wounded Knee/Manderson	790
	Wakfamni Lk	791
<u>Sheridan (Pine Ridge)</u>	Gordon	336
	Hay Springs	337
	Lakeside	338
	Rushville	339
	Whiteclay	340
<u>Sully (Eagle Butte)</u>	Onida	801
<u>Walworth</u>	Mobridge	841
<u>Ziebach (Eagle Butte)</u>	Bridger	866
	Cherry Creek	867
	Dupree	868
	Glad Valley	869
	Iron Lightin	870
	Red Elm	871
	Red Scaffold	872
	Thunder Butte	873

Oklahoma Community Codes

County	Community Name	Community Code
<u>Beckham</u>	Carter	095
	Delhi	096
	Elk City	097
	Erick	098
	Mayfield	099
	Sayre	100
	Texola	101
<u>Blaine</u>	Canton	104
	Eagle City	105
	Geary	106
	Greenfield	107
	Hitchcock	108
	Homestead	109
	Longdale	110
	Okeene	111
	Southard	112
Watonga	113	
<u>Caddo</u>	Albert	138
	Alfalfa	139
	Anadarko	140
	Apache	141
	Binger	142
	Bridgeport	143
	Carnegie	144
	Cement	145
	Cyril	146
	Eakly	147
	Fort Cobb	148
	Gracemont	149
	Hinton	150
	Hydro	151
	Lookeba	152
	Riverside Bi	153
	Washita	154
<u>Canadian</u>	Concho	158
	Concho Bia S	159
	Calumet	160
	El Reno	161
	Mustang	162
	Piedmont	163
	Union	164
Yukon	165	

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Carter</u>	Ardmore	169
	Carter Semin	170
	Clemscot	171
	Fox	172
	Gene Autry	173
	Graham	174
	Healdton	175
	Lone Grove	176
	Mcman	177
	Milo	178
	Newport	179
	Pooleville	180
	Ratliff City	181
	Springer	182
	Tatums	183
	Tussy	184
	Wilson	185
Wirt	186	
Woodford	187	
<u>Cleveland</u>	Lexington	232
	Moore	233
	Noble	234
	Norman	235
<u>Comanche</u>	Cache	245
	Chattanooga	246
	Elgin	247
	Faxon	248
	Fletcher	249
	Ft. Sill BIA	250
	Geronimo	251
	Indiahoma	252
	Lawton	253
	Medicine Prk	254
	Meers	255
Sterling	256	
<u>Cotton</u>	Devol	260
	Randlett	261
	Temple	262
	Walters	263
<u>Custer</u>	Arapaho	291
	Butler	292
	Clinton	293
	Custer	294

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Custer</u> (cont.)	Moorewood	295
	Thomas	296
	Weatherford	297
<u>Garvin</u>	Foster	350
	Elmore City	351
	Hennepin	352
	Lindsay	353
	Maysville	354
	Paoli	355
	Pauls Valley	356
	Pernell	357
	Stratford	358
	Wynnewood	359
<u>Grady</u>	Alex	363
	Amber	364
	Bradley	365
	Chickasha	366
	Cox City	367
	Minco	368
	Ninnekah	369
	Pocasset	370
	Rush Springs	371
	Tuttle	372
	Verden	373
	<u>Greer</u>	Brinkman
Granite		391
Mangum		392
Reed		393
Willow		394
<u>Harmon</u>	Vinson	395
	Gould	397
	Hollis	398
<u>Jackson</u>	Altus	435
	Blair	436
	Duke	437
	Eldorado	438
	Elmer	439
	Headrick	440
	Martha	441
Olustee	442	

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Jefferson</u>	Addington	446
	Fleetwood	447
	Grady	448
	Hastings	449
	Oscar	450
	Ringling	451
	Ryan	452
	Terral	453
	Waurika	454
<u>Kiowa</u>	Cooperton	495
	Gotebo	496
	Hobart	497
	Lone Wolf	498
	Mountain Prk	499
	Mountain View	500
	Roosevelt	501
	Snyder	502
	<u>Love</u>	Burneyville
Leon		566
Marietta		567
Orr		568
Overbrook		569
Rubottom		570
Thackerville		571
<u>McClain</u>		Blanchard
	Byars	575
	Dibble	576
	Newcastle	577
	Purcell	578
	Rosedale	579
	Washington	580
	Wayne	581
	<u>Murray</u>	Big Canyon
Davis		665
Dougherty		666
Hickory		667
Sulphur		668
<u>Oklahoma</u>		Okla City, Rur
	Arcardia	718
	Bethany	719
	Choctaw	720
	Edmond	721

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Oklahoma</u> <u>(cont.)</u>	Harrah	722
	Jones	723
	Luther	724
	Newalla	725
	Nicoma Park	726
	Okla City, Urb	727
	Spencer	728
	Wheatland	729
	Del City	730
	Midwest City	731
<u>Stephens</u>	Alma	905
	Bray	906
	Comanche	907
	County Line	908
	Duncan	909
	Loco	910
	Marlow	911
	Velma	912
<u>Tillman</u>	Davidson	927
	Frederick	928
	Grandville	929
	Hollister	930
	Loveland	931
	Manitou	932
	Tipton	933
<u>Washita</u>	Bessie	965
	Burns Flat	966
	Canute	967
	Cloud Chief	968
	Colony	969
	Cordell	970
	Corn	971
	Dill City	972
	Foss	973
	Rocky	974
Sentinel	975	

APPENDIX A -- 2

THE STRONG HEART – FAMILY STUDY
 CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

Codes for IHS Facilities by Area and Service Unit

Service Area Code	Service Unit Code	Location Code	Facility Name
<i>Area: Aberdeen</i>			
Service 10	Unit: 00	Non SVC Unit 00	Aberdeen
Service 10	Unit: 09	Rapid City 01	Rapid Ct Gms
10	09	88	R Shirt T Hs
Service 10	Unit: 10	Cheyenne Riv 01	Eagle Butte
10	10	31	Cherry Cr Hs
10	10	33	Red Scaff Hs
10	10	34	Swiftbird Hs
10	10	35	Whitehors Hs
10	10	51	Cherry Cr Hs
10	10	82	Faith
10	10	88	Isabel
Service 10	Unit: 12	Ft. Berthold 00	Berthold
10	12	10	Newtown Fo
10	12	30	Minni – Tohe
10	12	31	Mandaree Hs
10	12	31	Twin Bute Hs
10	12	32	Wh Shield Hs
Service 10	Unit: 13	Ft. Totten 10	Ft. Totten Hc
10	13	51	St. Michaels
Service 10	Unit: 14	Pierre 00	Chamberln Fo
10	14	21	Pierre S – Hc
10	14	30	Ft. Thomps Hs
10	14	31	Low Brule Hs
Service 10	Unit: 15	Pine Ridge 01	Pine R’g Ho
10	15	10	Wanblee Hc
10	15	30	Allen Hs
10	15	31	Kyle Hs
10	15	32	Manderson Hs
10	15	62	Porcupine Sc
10	15	63	Porcupine Ch

Service Area Code	Service Unit Code	Location Code	Facility Name
<i>Area: Aberdeen (cont.)</i>			
Service	Unit:	Rosebud	
10	16	01	Rosebud Hosp
10	16	55	Norris Sc
10	16	59	St. Francis
10	16	61	White River
10	16	90	Parmelee
Service	Unit:	Sisset – Wahpt	
10	17	01	Sisseton Hos
10	17	22	Wahpeton Hc
Service	Unit:	Standing Rock	
10	18	01	Ft. Yates Hos
10	18	10	Mclaughln Hc
10	18	30	Bullhead Hs
10	18	31	Cannonbal Hs
10	18	33	Wakpala Hs
Service	Unit:	Turtle Mount	
10	19	01	Belcourt Hos
Service	Unit:	Omaha – Winneb	
10	20	01	Winnebago Ho
Service	Unit:	Yankton	
10	21	01	Wagner Hosp

Service Area Code	Service Unit Code	Location Code	Facility Name
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Area: Oklahoma

Service	Unit:	Claremore	
50	52	01	Claremore Ho
50	52	14	Miami HI Cen
Service	Unit:	Clinton	
50	53	01	Clinton Hosp
50	53	10	Watonga H. Ct
50	53	11	Concho Hc
Service	Unit:	Kansas	
50	54	10	Holton Hc
50	54	20	Haskell Hc
50	54	30	White Cloud
Service	Unit:	Lawton	
50	55	01	Lawton Hosp
50	55	10	Anadarko Hc
50	55	30	Carnegie Hc
50	55	31	Riverside Hs
Service	Unit:	Pawnee	
50	56	10	Pawhuska Hc
50	56	11	White Eag Hc
50	56	12	Pawnee Hc
50	56	13	Pawnee Benefit Package
Service	Unit:	Shawnee	
50	58	10	Shawnee H Ct
Service	Unit:	Tahlequah	
50	59	01	W.W. Hastings
Service	Unit:	Ada	
50	62	01	Carl Albrt H
50	62	11	Wewoka HI Ct

Area: Oklahoma Tribe/638

Service	Unit:	Claremore	
55	52	02	Creek Nation
55	52	11	Delaware Dhc
55	52	12	Okemah H Ct
55	52	15	Indian Hlth. Res. (Tulsa)
55	52	16	Salina Hlth. Center
55	52	31	Sapulpa Hc
Service	Unit:	Shawnee	
55	58	11	Oklahoma City Clinic
55	58	12	Black Hawk Clinic
Service	Unit:	Tahlequah	
55	59	10	Eufaula Hc

Service Area Code	Service Unit Code	Location Code	Facility Name
<i>Area: Oklahoma Tribe/638 (cont.)</i>			
55	59	11	Sallisaw HC
55	59	12	Dkmartin Hc
Service	Unit:	Talihina	
55	60	01	Talihina Hos
55	60	11	J. Andrsn Hc
55	60	12	Hugo Hl Ct
55	60	13	McAlester Hc
Service	Unit:	Ada	
55	62	10	Tishomingo
55	62	12	Ardmore Hc
Service	Unit:	Eagle Pass	
55	63	00	Eagle Pass

Service Area Code	Service Unit Code	Location Code	Facility Name
<i>Area: Phoenix</i>			
Service 60	Unit: 62	Keams Canyon 01	Keams Canyon
Service 60	Unit: 63	Owyhee 01	Owyhee Hosp
Service 60	Unit: 64	Colorado Riv 01	Parker Hosp
Service 60	Unit: 66	Phoenix 01	Phoenix Ho
60	66	20	Phoenix H S
60	66	30	West End H C
60	66	31	Salt River
60	66	63	Ft. McDowell Hs
60	66	99	Undesig Locs
Service 60	Unit: 67	Sacaton 01	Asacaton Hos
Service 60	Unit: 68	San Carlos 01	San Carlos
Service 60	Unit: 69	Schurz 01	Schurz Hosp
Service 60	Unit: 71	Whiteriver 01	Whiteriver H
Service 60	Unit: 72	Ft. Yuma 01	Ft. Yuma

APPENDIX A -- 3

THE STRONG HEART – FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

Non-IHS Hospitals and Codes

1. *Dakota*

Pine Ridge	
Martin Hospital	10-15-55
Kadoka Hospital	10-15-56
Philip Hospital	10-15-57
Hot Spring VA Hospital	10-15-58
Ft. Meade VA Hospital	10-15-59
Rapid City Regional Hospital	10-15-60
Gordon, Nebraska Hospital	10-15-61
Porcupine Community Clinic	10-15-62
University of Minnesota Hospital	10-15-63
Hot Spring Community Hospital	10-15-64
Fitzsimons Hospital, Denver	10-15-65
Sioux Valley Hospital, Sioux Falls	10-15-66
McKenna Hospital	10-15-67
Ellsworth AFB	10-15-68
Wall Clinic	10-15-69
Rapid City Eye Institute	10-15-70
Minneapolis VA Medical Center	10-15-71
St. Anthony Hospital, Denver	10-15-72
Porter Memorial Hospital	10-15-73
Eagle Butte	
Faith Clinic	10-10-82
Isabel Clinic	10-10-83
St. Mary's Hospital, Pierre	10-10-84
Sacred Heart, Yankton	10-10-85
Mid Dakota, Chamberlain	10-10-86
Med Center One, Bismarck, ND	10-10-87
St. Alexius, Bismarck, ND	10-10-88
Mobridge Hospital	10-10-89
Gettysburg Hospital	10-10-90
Ft. Totten	
Mercy Hospital, Devil's Lake	10-10-60
New Rockford Hospital	10-10-61
United Hospital, Grand Forks	10-10-62
St. Lukes Hospital, Fargo	10-10-63
Fargo VA Hospital	10-10-64

2. *Phoenix*

Desert Samaritan Hospital	60-66-70
Good Samaritan Hospital	60-66-71
Humana Hospital	60-66-72
Jesse Owens Med. Ctr.	60-66-73
John C. Lincoln Hospital	60-66-74
Maricopa Med. Ctr.	60-66-75
Maryvale Samaritan Hospital	60-66-76
Mesa Lutheran Hospital	60-66-77
Phoenix Baptist Hospital	60-66-78
Phoenix Memorial Hospital	60-66-79
St. Luke's Medical Center	60-66-80
Scottsdale Memorial Hospital	60-66-81
St. Joseph's Hospital	60-66-82
Valley Lutheran Hospital	60-66-83
Chandler Community Hospital	60-66-84
NIH	60-66-85
Family Care Clinic in Chandler	60-66-86

3. *Oklahoma*

Anadarko Municipal Hospital	08-01-14
Carnegie Tri-County Municipal Hospital	08-02-14
Comanche County Memorial Hospital	16-01-05
Southwestern Medical Center	16-03-05
Reynolds Army Hospital	16-05-05
Grady Memorial Hospital	26-01-14
Veterans Administration Hospital	55-18-01
State of Oklahoma Teaching Hospitals	55-20-01
Oklahoma Memorial Hospital	55-20-01
Oklahoma Childrens Memorial	55-20-01
Duncan Regional Hospital	69-28-76
Mercy Hospital	55-63-76
South Community	55-63-87
Norman Regional Hospital	14-60-24
St. Anthony Hospital	55-63-78
Baptist Medical Center	55-63-89
Deaconess Hospital	55-63-24
Presbyterian Hospital	55-63-84
Midwest City Memorial Hospital	55-53-29

APPENDIX A -- 4

STRONG HEART – FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

PERSONNEL CODES

Arizona Center

301	Barbara Howard	358	Rachel Peters
303	Jim Howard	359	Tony Dasaro
304	Betty Jarvis	360	Sean McKnight
305	Paula Harper	361	Lenita Fragua
307	Linda Phillips	362	Bernadita (Ditas) Fallis
309	Michael Paidi	363	Brad McCormick
312	Joy Jones	364	Roberta Seepie
313	Matilda Johns	365	Debbie Hockless
314	Helen Johns	366	Lemark Davis
315	Rowena Juan	367	Tamara Brewer
316	Oreen Johns	368	Shannon Begay
317	Angelina Barley	369	Michael Davidson
320	Sonja Antone	370	Nanette Oram
322	Maurice Sievers	371	Virgena Claw-Begay
323	Rosinna Briones	372	Annette Rave
333	Andrea Kriska	373	Caroleen Miles
340	Robert Hanson	374	Erica Boyd
341	Janet Andrews	375	Mary Jackson
342	Joanne Carter	376	Judy King
347	Judy Bergman	377	Sharon Shurtz
352	Bert Lewis	378	Libby Schwartz
354	Melissa Bergman	379	Tonah Kaylor
355	Jean MacCluer	380	Mary Rybka
356	David Robbins	381	Kristen Gonzales
357	Roseanne Lewis	382	Tanya Molina

Dakotas Center

101	Thomas K. Welty	418	Janna Morris
102	Beverly Blake Price	419	Jeanette Ofstad
109	Arliss Keckler	420	Joe Ferber
119	Corbin LeBeau	421	Sarah Lantis
134	Kurt Schweigman	422	Tiffany Dailey
160	Marcia O'Leary	423	Jeffrey A. Henderson
177	Patsy Foote	424	Freda Poor Bear
182	Lillian Brown	425	Earline Shiroma
190	Alan Crawford	426	Arlette Hager
197	Neil Sikes	427	Myra Lohnes
198	Theresa Sikes	428	Maxine Paul
402	Arlene Iron Crow	429	Mabel Rosales
403	Dorothy Rhoades	430	Bonnie High Bull
405	Theresa Wounded Face	431	Cherie Kessler
406	Sue Marion	432	Marlene Poor Bear
407	Misty Tyon	433	Lyle G. Best
408	Jim Galloway	434	Jennifer Richards
410	Brenda Veit	435	Sandra Shot with Arrow
411	Joyce Marshall	436	Mae Keller
412	Marie Kougl Gross	437	DeeAnn Hollenbeck
413	LaVonne Looking Elk	438	Lois Bettelyoun
414	Chris Zahn	439	Fedelia Brown
415	Jay Bad Heart Bull	440	Leola Quiver
416	Wendy Lawrence	441	Helene Gaddie
417	Francine Red Willow	442	Danial Kougl

Oklahoma Center

201	Elisa Lee	227	Tauqeer Ali
202	Linda Cowan	229	Karen Kimbley
204	Jeunliang Yeh	231	Stephanie Gomez
205	Barbi Sanchez	233	Donna Smith
206	Carl Schaefer	234	Nahusheah Rodriguez
207	Debra Gates	239	Imran Ahmed
208	Linda Poolaw	242	Boureima Sambo
209	Wenyu Wang	243	Betty Huckaba
210	Fawn Yeh	250	Richard Devereux
211	Deanna Haener	252	Verna Cable
212	Lee Keesee	254	Jonathan Bella
213	Shannon Proctor	255	Everett Rhoades
214	Ying Zhang	256	Jorge Kizer
215	Leon Kalbfleisch	270	Paul Enright
216	Momotaz Begum	290	Wiebers
217	Dorothea Pendarvis	291	“
218	Aihua Bian	292	“
220	Shabina Hussain	402	Richard Rodeheffer

APPENDIX B

Instructions for Death Certificate Form

and

Informant Interview Form

APPENDIX B -- 1

Instructions for Death Certificate Form

The Death Certificate Form is completed for each eligible death. The purpose of this form is to obtain information on the decedent and information on the informant, coroner/medical examiner, or certifying physician. The ID number has 6 digits; it is the participant's SHS ID. The community code has 3 digits, it is the standard IHS community code.

Item **Instructions**

1. Decedent's name. Enter the first, middle, and last name of the decedent. Begin each name in the left-most box using CAPITAL letters.
2. Death certificate number. This number will be found stamped or typed on the death certificate. If a computer printout is used, it must include this information. Record the number starting in the right-most box. DO NOT add zero to the right of the number.
3. Sex. Record the decedent's sex.
4. Race. Record as is stated.
5. Marital status. Record as listed. If the death certificate just says "not married" or "S", record as "Single".
6. Date of birth. Record as listed on the death certificate.
7. Date of death. Record as listed on the death certificate.
8. Time of death. Convert all time to 24 hour clock and record. Enter unknown as "=" in each field.
9. Location of death. Choose an appropriate answer. Other includes nursing home, another residence, or a non-hospital institution.
10. Autopsy. Record as indicated on the death certificate.
11. Record whether this is a coroner's or medical examiner's case.
12. Interval of onset of symptoms and death. Record the shortest possible category for the immediate cause of death as indicated on the death certificate. If this is missing, DO NOT substitute the interval for another cause. Instantaneous should be recorded as "5 minutes or less".
13. Date abstract completed. Record the date the Death Certificate Form is completed.
14. Code number of abstractor. The field center staff member who has completed this form must enter his/her valid Strong Heart Study code number in this question.

APPENDIX B -- 2

Informant Interview Form Instructions

I. General Instructions

The purpose of the informant interview is to obtain information about possible cardiovascular events in order to classify the cause of death. Informant interviews are very helpful in deaths that occur outside the hospital, especially if no autopsy, coroner, or medical examiner reports are available. *It is important to note that the most useful portion of the interview is that which describes what happened to the person during the last few hours (day) of his or her life. Often these descriptions of the person's symptoms or behaviors are the best indicators of the likely cause of death. Thus, this portion of the interview should be a major focus, as well as questions regarding timing of any symptoms in relation to death.*

The interview with next-of-kin is potentially difficult because of the sensitive nature of a relative's death and the difficulty recalling or understanding the events related to the death. Even if the informant initially claims no knowledge, begin the form to see if the questions can be answered. The person interviewed should be the one with the most information about the circumstances of death. This may not always be the person listed as the informant on the death certificate.

The interviewer should enter the information required on the first page before the contact is made with the informant, though some of the informant data may need to be completed after contact, such as relationship to the decedent. In some cases the informant may change, as in the case where a spouse is to be contacted but the actual informant is a son or daughter. A record of calls should be maintained regarding attempts to contact the informant. The interviewer should record the date and time of each call, any explanatory notes, a result code for each call, and the interviewer's assigned code number. Eight attempts to contact an informant should be made over a two-week period. If no contact is made, attempts can be stopped.

The questionnaire is divided into sections. The first is concerned with the decedent's medical history, including previous hospitalizations, followed by his/her health in the year prior to death. Then the questions address the events immediately surrounding the fatal event, and the symptoms the deceased experienced prior to the event. Then emergency medical care is ascertained, and the information about other potential informants is requested. A detailed, verbatim, description of the circumstances surrounding death is sought. Finally the interviewer answers questions about the reliability of the information obtained during the interview.

Almost all questions have multiple choices for answers; however, if necessary the interviewer can write any additional information or comments that may be important to understanding the response in the margins next to the question. A few questions require the interviewer to write out descriptions of the death or the decedent's state of health as related by the informant. For these questions, the interviewer should write word-for-word (in short phrases,

abbreviating) the response of the informant. For questions asking the informant to specify names, if more than one answer is given, write all responses.

The interviewer needs to know thoroughly the SHS definition of death to complete the interview accurately. "Death" is defined as the point at which the decedent stops breathing on his/her own and never recovers. Thus, the onset of death for someone who is resuscitated or ventilated is the point at which he/she last breathes spontaneously. He/she may recover several times after resuscitation, but the last cessation of breathing is considered "death". Death is not the time "pronounced dead". If someone is "found dead", timing of death may be estimable if the time since last seen alive was short. However, if long, timing of death may be unknown.

The interviewer should be familiar with skip patterns and the nature of each question. Several questions are similar, with only subtle differences. The interviewer must make the distinction clear to the informant. Such questions may sound repetitive and are easier if clarified.

If the informant contradicts a previous answer, probe to clarify and correct the answers.

If the informant says at the start of the interview that he/she does not know anything about the death, coax the informant to start the interview and try to complete it. If the informant is obviously not helpful, gracefully end the interview.

Finally, the interviewer is responsible for reviewing and editing the Informant Interview Form thoroughly following the interview. Review every question and the skip patterns carefully. Every question must be answered unless skip patterns indicate otherwise. The description of the events preceding the death is extremely important for diagnostic purposes. Make sure that the description includes the timing of events and the symptoms experienced.

II. Detailed Instructions for Various Questions

ITEM DESCRIPTIONS

- 1-4 Information on the decedent's name, date of death, and informant should be filled out prior to the informant interview.
- 5 This question asks for the relationship of the informant to the decedent. Make sure not to reverse this: for example, "She was my mother" should be answered "daughter/son". "Other relative" includes aunt, uncle, cousin, in-law, and grandparent.
- 6-8 These questions relate to the decedent's medical history and thus are "*ever*" questions.
- 6 This question refers to chest pain from heart disease at any time before death. Angina or angina pectoris or a heart attack would be considered "yes" responses. Pain in the left arm or shoulder, jaw, or upper abdomen is considered equivalent to chest pain.
- 7 Refer to the list of names for nitroglycerin if informant hesitates. Nitroglycerin is usually administered as a small tablet placed under the tongue but may be taken as a pill, an ointment, or as "skin patch".

- 8 These questions simply ask whether the decedent had ever had any of these cardiac events previously. Mark the appropriate response for each one.

Synonyms for heart attack are "myocardial infarction", "MI", coronary occlusion.

Coronary bypass involves surgery bypassing the blocked coronary arteries with vessels removed from the arm or leg. "Balloon dilation" or "PCTA" are other terms for angioplasty. A cardiac catheterization, coronary angiography, or angiogram for diagnostic purposes without angioplasty should be answered "no".

A stroke is a brain hemorrhage or ischemia (blockage of blood flow) also known as a cerebrovascular attack, cerebral hemorrhage, or blood clot on brain.

These events include the final, fatal event under consideration.

- 9-12 These questions relate to hospitalization and doctor's visits in the year prior to death.
- 13 If decedent was hospitalized more than once or stayed in more than 1 hospital, record the most recent on the form, then list all dates, names, cities and states of other hospitalizations on a separate piece of paper. If exact dates are unknown, fill in month and year. Missing values are indicated by "=" (equal sign) in the appropriate field.
- 14 Refer to any encounter with a physician for any reason in the year preceding death, including final symptoms.
- 15 This should be the most recent visit. If more than one physician was seen, obtain the names and addresses of the two who the respondent thinks would be the most knowledgeable about the decedent.
- 16 Record the name and address of decedent's "usual" physician. If the same as most recently seen, record "same".
- 17 This question refers to any restriction from the decedent's usual day-to-day activities. It excludes the events at death.
- 18 "Being cared for" refers to attendant medical care because of disability or sickness.
- 19 Fill in as much information as is known by informant. If the informant asks why this is needed, explain that it may be important to get additional information from the nursing home, with permission, to understand the cause of death.
- 20 "Present" is defined as being within sight or sound of the deceased at the time of death; for example, Present: lying next to in bed, in next room and could be heard, left decedent alone momentarily. Not present: in another room out of sight and sound, outside out of

sight and sound, left decedent alive and returned after 5 minutes, talked to on phone sometime right before.

- 21 This question asks whether anyone was present at the time of the decedent's death (defined above). If the decedent died in his/her sleep with someone nearby, Question 21 should be answered "yes".
- 22 Mark the shortest interval known to be reliable. If the informant hesitates, read the intervals in order starting with the shortest.

We are primarily interested in acute symptoms, not chronic. Thus, if a person had been generally fatigued for a month and then had chest pain one hour before death, it is the chest pain that was the last episode. Similarly, if someone had a long history of angina but, not having acute pain, suddenly collapsed and stopped breathing, the onset of the final episode was the time of collapse. If the death occurred while sleeping or while someone was within hearing range of decedent, the interval between onset and death is considered to be instantaneous. If the decedent was found dead (no one close enough to see or hear him/her), the onset may be unknown.

Onset of last episode is defined as being at that point in time when new symptoms cause a change in activity. If the symptom is chronic (e.g., longstanding exertional chest pain), there must be a change in severity or frequency. Symptoms might be step-wise (e.g., one chest pain, then a more severe one an hour later). In this case it is the first pain, if it was new and caused a change, that is the onset of the final episode. The final episode for someone who collapses, is revived, and collapses again began at the first collapse. Interviewers will have to probe and define onset specifically for each informant.

- 23-24 The location of the pain or discomfort referred to in Q23 and Q24 is specific. If the pain was experienced at sites other than the chest, left arm or shoulder or jaw, the answer should be "no". If the informant is unsure, but is leaning toward a "yes", then proceed as with a "yes". If the decedent was found dead, most of the answers to the next few questions will be "unknown". In this case, skip quickly through, verifying that the answers are unknown.
- 25 A list of names of "nitroglycerin" preparations is provided in the medication list and should be consulted if informant isn't sure or offers a brand name.
- 26 This is a crucial question for the timing of death. Use the definition provided above for death and onset of the final episode in order to clarify timing. Read the question, wait for response, and mark the shortest interval known to be true. If the informant gave a time interval when answering Question 23, the interviewer may want to preface Q26 stating the time interval and asking for confirmation (e.g., "You mentioned that _____ had chest pains two days before he died. Is that when the chest pain began?").

- 27 This question asks about any symptoms other than pain or discomfort in the chest that started within 3 days of death. Make sure the onset was within 3 days, and that the condition was not longstanding or "usual". Read the list slowly and fill in the appropriate answers.
- 28 Fill in the appropriate response.
- 29 Fill in as much of the information as is known.
- 30 This question asks if there is any person who may be able to provide additional information about the events leading up to the death or the death itself. For example, a spouse may know most about the three days prior to death while a co-worker actually witnessed the death. (Note: If the answer is "yes", an interview will need to be carried out with this individual.)

This section is **very important**, and as much detailed information as possible should be sought.

- 31 Narrative: Write out as close to word-for-word as possible, using short phrases. Probe neutrally for symptoms, order and timing of events, medical care, etc. Record these important items verbatim; try to limit the narrative to the space provided. When describing the events surrounding the death itself, be sure to differentiate between the onset of the last symptoms, the death (recalling definition of death), and being "pronounced dead".
- 32 Close the interview by thanking the informant and repeating how much the quality of our research depends on the cooperation of people like themselves. After closing the interview, fill in the questions about reliability and administrative information.
- If informant is decedent's next of kin and agrees to provide consent for further information, ask him/her to sign the consent form.
- 33 Interviewer evaluates the quality of information provided by the informant.

APPENDIX C

Mortality Surveillance Data Forms

**THE STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

**Mortality Survey
Death Certificate Form**

ID number: Community Code:

Social Security Number: -- --

1. Decedent:
 - a. Last name:
 - b. Middle name:
 - c. First name:
2. Death certificate number: (*State File Number*)
3. Sex: Male 1 Female 2
4. Race/Ethnicity:

American Indian <input type="checkbox"/> 1	Oriental <input type="checkbox"/> 5
Hispanic <input type="checkbox"/> 2	Other <input type="checkbox"/> 8
White <input type="checkbox"/> 3	Unknown <input type="checkbox"/> 9
Black <input type="checkbox"/> 4	
5. Marital status:

Married <input type="checkbox"/> 1	Divorced <input type="checkbox"/> 4
Single <input type="checkbox"/> 2	Widowed <input type="checkbox"/> 5
Separated <input type="checkbox"/> 3	Unknown <input type="checkbox"/> 9
6. Date of birth: / /
mo day yr
7. Date of death: / /
mo day yr
8. Time of death (*24 hour clock*): :
(*If "Death Occurred" is missing use "Death Pronounced"*) hr min
9. Where did the decedent die?

IHS hospital/clinic in study area <input type="checkbox"/> 1	Home <input type="checkbox"/> 4
Non-IHS hospital in study area <input type="checkbox"/> 2	Other <input type="checkbox"/> 5
Hospital out of area <input type="checkbox"/> 3	Location unknown <input type="checkbox"/> 9
10. Was an autopsy performed? Yes 1 No 2 Unknown 9
11. Was this a coroner's or medical examiner's case? Yes 1 No 2 Unknown 9
12. Interval between onset and death (*for immediate cause of death*):

5 min. or less <input type="checkbox"/> 1	1 week or less <input type="checkbox"/> 4
1 hour or less <input type="checkbox"/> 2	1 month or less <input type="checkbox"/> 5
1 day or less <input type="checkbox"/> 3	more than 1 month <input type="checkbox"/> 6
Unknown or not recorded <input type="checkbox"/> 9	
13. Date abstract completed: / /
mo day yr
14. Code number of abstractor completing this form:

**THE STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

**Mortality Survey
Informant Interview Form**

ID number: _____

Social Security Number: _____

A. DECEDENT (filled by study center staff prior to interview)

1. Name: _____
Last
First
Middle

2. Date of death: _____
mo
day
yr

B. INFORMANT (filled by study center staff prior to interview)

3. a. Name: _____
Last
First
Middle

b. Address: _____

c. Telephone: () _____

C. RECORD OF CALLS or HOME VISIT TO COMPLETE INTERVIEW

	DATE (mo/day/yr)	TIME (24 hr clock)	Method of contact	Contact successful	Interview Completed
			1=Phone 2=Home Visit 3=Other	1=Yes 2=No	1=Yes 2=No 9=Refused
1)	_____	_____	_____	_____	_____
2)	_____	_____	_____	_____	_____

D. Person Providing Information (filled by study center staff prior to interview).

4. a. Name: _____
Last
First
Middle

b. Address: _____

c. Telephone: () _____

5. Before we get started, could you please tell me what was your relationship to the deceased?

You are the _____ of the deceased.

These first questions are about his/her medical history.

6. Before his/her final illness, had he/she ever had pains in the chest from heart disease, for example, angina pectoris?

Yes |1 No |2 (*If no, go to Q8*) Unknown |9

7. Did he/she ever take nitroglycerin for this pain?

Yes |1 No |2 Unknown |9

8. Did he/she ever have any of the following medical condition or procedures before his/her final illness?

- | | Yes | No | Unknown |
|---|-----------------------------|-----------------------------|-----------------------------|
| a. heart attack? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| b. stroke? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| c. heart failure? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| d. rheumatic heart disease? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| e. any other heart disease or heart condition | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| If yes, specify: _____ | | | |
| f. coronary bypass surgery (CABBAGE) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| g. coronary angioplasty (balloon angioplasty) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| h. insertion of pace maker (defibrillator) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| i. any other heart surgery? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |

The next few questions are about his/her health in the year prior to death.

9. Was he/she hospitalized... Yes No Unknown

In the year prior to death? |1 |2 |9

In the month prior to death? |1 |2 |9

In the 7 days prior to death? |1 |2 |9

10. Were any hospitalizations for heart attack or chest pain? Yes |1 No |2 Unknown |9

11. Was a hospitalization for heart surgery? Yes |1 No |2 Unknown |9

12. What was the date of the ***last*** hospital admission? |||/||||/||||
(If unknown, draw two lines across the boxes) mo day yr

If the information in questions 13 – 16 is already known to you, skip to Q17.

13. Can you tell me the name and location of the hospital? (*If unknown, check the box.*)

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

14. Was he/she seen by a physician anytime in the year prior to death?

Yes |1 No |2 Unknown |9

15. Can you tell me the name and address of this physician or healthcare facility?

IHS only

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

16. Can you tell me the name and address of his/her usual physician?

If same as Q17, check here.

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

17. Now, think back to about one month before he/she died. At that time, was he/she sick or ill; was his/her activities limited, or was he/she normally active for the most part?

Sick/ill/limited activities |1 Normally active |2 Unknown |9

18. Was he/she being cared for at a nursing home, or at another place at the time of death?

Yes, nursing home |1 No |4

Yes, at home |2 Unknown |9

Yes, other, specify: _____ |3

19. If the decedent was cared by nursing home prior to the death, please tell me the name and location of the nursing home:

a. Name: _____

b. Address: _____

c. Telephone: () _____

20. Were you present when he/she died?

Yes |1 (*Skip to Q23*) No |2 Unknown |9

21. If no, how long before he/she died did you last see him/her?

1 hour or less |1 More than 24 hours |2

24 hours or less |2 Unknown |9

Did anyone see or hear him/her when he/she died?

Yes |1 No |2 Unknown |9

22. How long after he/she was last known to be alive was he/she found dead?

(Enter the shortest interval known to be true)

5 minutes or less |1 More than 24 hours |4

1 hour or less |2 Unknown |9

24 hours or less |3

23. Did he/she experience pain or discomfort in his/her chest, left arm or shoulder or jaw either just before death or within 3 days (72 hours) of death?

Yes |1 No |2 Unknown |9

(If NO or Unknown, skip to Q27)

The next set of questions deal specifically with the last episode (that led to the death) of his/her pain or discomfort. The last episode is defined as starting at the time he/she noticed discomfort that caused him/her to stop or change what he/she was doing.

24. Did his/her last episode of pain or discomfort specifically involve the chest?
 Yes 1 No 2 Unknown 9
25. Did he/she take nitroglycerine because of this last episode of pain or discomfort?
 Yes 1 No 2 Unknown 9
26. How long was it from the beginning of his/her last episode of pain or discomfort to the time he/she stopped breathing on his/her own? *(use the shortest interval known to be true)*
- | | | | |
|--------------------|----------------------------|--------------------|----------------------------|
| 5 minutes or less | <input type="checkbox"/> 1 | 24 hours or less | <input type="checkbox"/> 4 |
| 10 minutes or less | <input type="checkbox"/> 2 | More than 24 hours | <input type="checkbox"/> 5 |
| 1 hour or less | <input type="checkbox"/> 3 | Unknown | <input type="checkbox"/> 9 |
27. Within 3 days of death, or just before he/she died, did any of the following symptoms begin for the first time:
- | | Yes | No | Unknown |
|---|----------------------------|----------------------------|----------------------------|
| a. Shortness of breath? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| b. Dizziness? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| c. Palpitations (pounding in the chest)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| d. Marked or increased fatigue, tiredness, or weakness? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| e. Headache? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| f. Sweating? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| g. Paralysis? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| h. Loss of speech? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| i. Attack of indigestion or nausea or vomiting? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| j. Other? specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |

The next few questions are concerned with emergency medical care he/she may have received just prior to or at the time of death. You may have already given this information in an answer to an earlier question. Since it is important to obtain information specifically on emergency medical care, I hope you don't mind if these questions seem repetitive.

28. Was he/she taken to a hospital? Yes 1 No 2
29. If Yes, could you tell me the name and location of this hospital:
- a. Name: _____
- b. Address: _____
- City/town: _____
- State-Zip: _____
30. Is there someone else whom we could contact, who might know more about the circumstances surrounding his/her death or his/her usual state of health?
 Yes 1 No 2 Unknown 9
(If Yes, complete the front of the second Informant Interview)
31. Finally, I want to ask you to tell me everything about the circumstances surrounding his/her death. Specifically, please tell me what you know of his/her general health, health on the day he/she died, and of the death itself. *(Record summary verbatim)*
-
-

THE STRONG HEART STUDY IV

**Mortality Survey
FINAL DECISION FORM I -- AUTOPSY REPORT FORM**

ID number:

Social Security Number:

1. Decedent's name:

a. Last name:

b. Middle name:

c. First name:

2. Cause of death, choose appropriate one:

01=Definite fatal myocardial infarction

02=Definite sudden death due to coronary heart disease

03=Definite fatal coronary heart disease

04=Possible fatal coronary heart disease

05=Definite fatal stroke

06=Possible fatal stroke

07=Definite fatal congestive heart failure

08=Possible fatal congestive heart failure

09=Other fatal cardiovascular diseases; specify: _____

21=Malignant neoplasm; specify primary site: _____ ICD code

22=Unintentional injury and adverse effects/motor vehicle accident ICD code

23=Unintentional injury and adverse effect/all other

24=Pneumonia and influenza

25=Chronic obstructive pulmonary disease and allied conditions

26=Diabetes mellitus

27=Chronic liver disease and cirrhosis

28=Suicide

29=Homicide and legal intervention

30=Nephritis, nephrotic syndrome and nephrosis

31=ESRD

32=Septicemia

33=HIV/AIDS

88=Other, specify: _____ ICD code

99=Can not be determined. ICD code

Date abstract completed: / /
mo day yr

Code number of abstractor completing this form:

**STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

**PHOTOCOPY CHECKLIST FOR MEDICAL RECORDS REVIEW
MORTALITY SURVEILLANCE -- CVD and NON-CVD**

Admission date: |__|__|/|__|__|/|__|__|__|__|
 mo day yr

ID Number: |__|__|__|__|__|__|

For each hospital admission WITHIN the YEAR prior to death, obtaining photocopies of each of the following sections of the medical history (when available) and assemble them for each admission. Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets)	__ 1	__ 2	__ 9
Admitting History and Physical Exam	__ 1	__ 2	__ 9
Discharge Summary	__ 1	__ 2	__ 9
ECGs (SHS-I and II)	__ 1	__ 2	__ 9
Cardiac Enzyme (including Troponin)	__ 1	__ 2	__ 9
Reports of results of:			
Chest X-ray	__ 1	__ 2	__ 9
Echocardiogram	__ 1	__ 2	__ 9
Angiogram	__ 1	__ 2	__ 9
Exercise tolerance test (Treadmill)	__ 1	__ 2	__ 9
Cardiac catheterization	__ 1	__ 2	__ 9
CT (CAT) scan	__ 1	__ 2	__ 9
MRI	__ 1	__ 2	__ 9
Carotid ultrasound	__ 1	__ 2	__ 9
Lumbar puncture	__ 1	__ 2	__ 9
Creatinine	__ 1	__ 2	__ 9
Liver Function test	__ 1	__ 2	__ 9

**PHOTOCOPY CHECKLIST FOR MEDICAL RECORDS REVIEW
MORTALITY SURVEILLANCE (continued)**

ID Number:		_ _ _ _ _ _ _ _ _		
	YES	NO	DONE, No Report	
Reports of results of: (continued)				
Pathology	_ 1	_ 2	_ 9	
Cultures	_ 1	_ 2	_ 9	
Other Laboratory results, SPECIFY:				
_____	_ 1	_ 2	_ 9	
_____	_ 1	_ 2	_ 9	
_____	_ 1	_ 2	_ 9	
Operative reports:				
Coronary bypass	_ 1	_ 2	_ 9	
Angioplasty	_ 1	_ 2	_ 9	
Swan-Ganz catheterization	_ 1	_ 2	_ 9	
Non-CVD operation	_ 1	_ 2	_ 9	
For terminal Event Only:				
Ambulance report	_ 1	_ 2	_ 9	
ER Admission and Discharge Summary	_ 1	_ 2	_ 9	
Any clinical notes regarding DOA	_ 1	_ 2	_ 9	
Autopsy Report/ Coroner's Report	_ 1	_ 2	_ 9	
From IHS clinic chart (if available), photocopy notes and test results from the most recent visit prior to death	_ 1	_ 2	_ 9	
Abstractor Number			_ _ _ _	
Date abstract completed:			_ _	_ _ _ _
			mo	day yr

**THE STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

Mortality Survey --- Final Decision Form

ID number: |_|_|_|_|_|_|_|_|_|

Date of death: |_|_|/|_|_|/|_|_|_|_| Age at death: |_|_|
mo day yr

	<i>Underlying cause of death</i>	Contributory cause of death	
		1	2
A. Cause of death, choose appropriate one. _ _ 	_ _	_ _	_ _

- 01=Definite fatal myocardial infarction
- 02=Definite sudden death due to coronary heart disease
- 03=Definite fatal coronary heart disease
- 04=Possible fatal coronary heart disease
- 05=Definite fatal stroke
- 06=Possible fatal stroke
- 07=Definite fatal congestive heart failure
- 08=Possible fatal congestive heart failure
- 09=Other fatal cardiovascular diseases

If is Non-CVD death, choose one from the following list and complete the evidence code:

	Evidence Code: (up to 3 Codes)	_ _ _ _ _ _
21=Malignant neoplasm; primary site: _____	01=Pathology Report	
22=Unintentional injury and adverse effects/MVA	02=Clinical Diagnosis only	
23=Unintentional injury and adverse effects/all other	03=Pulmonary function test	
24=Chronic obstructive pulmonary disease and allied conditions	04=Blood glucose test	
25=Pneumonia and influenza	05=Abnormal liver function tests	
26=Diabetes mellitus	06=Abnormal kidney function test	
27=Chronic liver disease and cirrhosis	07=Positive culture (blood or sputum)	
28=Suicide	08=Positive antibody test	
29=Homicide and legal intervention	09=Positive blood test (any type)	
30=Nephritis, nephrotic syndrome and nephrosis	10=Autopsy	
31=ESRD	11=Police/Coroner's investigation	
32=Septicemia	12=Other medical records evidence	
33=HIV/AIDS	Specify: _____	
88=Other, specify: _____		
99=Can not be determined.		

Was the death alcohol related? Yes |_|_| 1 No |_|_| 2 Unknown |_|_| 9

B. Criteria used: (Please check the appropriate boxes)

1. Definite fatal myocardial infarction

- 1)a. Definite MI within 4 weeks of death by criteria: Yes No
- | | | |
|---|----------------------------|----------------------------|
| 1. Evolving diagnostic ECG, <i>and/or</i> | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 2. Diagnostic ECG and abnormal cardiac enzymes, <i>and/or</i> | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 3. Prolonged cardiac pain and abnormal cardiac enzymes | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

OR

- 1)b. Acute MI diagnosed by autopsy

AND

- 2) No known non-atherosclerotic or noncardiac-atherosclerotic condition that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

2. Definite sudden death due to CHD

1. Death witnessed as occurring within 1 hour after the onset of severe cardiac symptoms (prolonged cardiac pain, shortness of breath, fainting) or within 1 hour after the subject was last seen without symptoms.

AND

2. No documentation of acute MI within 4 weeks prior to death.

AND

3. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician report.

3. Definite fatal CHD

- 1. Death certificate with consistent underlying or immediate causes, **AND**
- 2. No documentation of definite acute MI within 4 weeks prior to death, **AND**
- 3. Criteria for sudden death not met (above), **AND**
- 4. No known non-atherosclerotic or noncardiac-atherosclerotic process or event that was probably lethal according to death certificate, autopsy report, hospital records, or physician records,

AND

- 5(a) Previous history of MI according to relative, physician, or hospital records, or definite or possible MI by criteria,
OR
- 5(b) Autopsy reporting severe atherosclerotic-coronary artery disease or old MI without acute MI (50% proximal narrowing of two major vessels or 75% proximal narrowing of one more vessel, if anatomic details given.),
OR
- 5(c) Death occurring greater than 1 and less than or equal to 24 hours after the onset of severe cardiac symptoms or after subject was last seen without symptoms,
OR
- 5(d) Angiogram reporting severe ($\geq 50\%$ narrowing) atherosclerotic coronary artery disease,
OR
- 5(e) Other positive physical signs or lab findings.

4. Possible fatal CHD

- 1. No documentation by criteria of definite acute MI within 4 weeks prior to death, **AND**
- 2. No documentation by criteria of definite sudden death, **AND**
- 3. No documentation by criteria of definite fatal CHD, **AND**
- 4. Death certificate with consistent underlying or immediate cause, **AND**
- 5. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

5. Definite fatal stroke (also complete Section C)
- 1a. Cerebral infarction or hemorrhage diagnosed at autopsy,
AND
 - 1b. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,
- OR**
- 2a. History of rapid onset (approximately minutes to hours from onset to time of maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness,
AND
 - 2b. Focal neurologic deficit within 6 weeks of death documented by unequivocal physician or laboratory findings with 24 hours duration of objective physician findings,
AND
 - 2c. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,
6. Possible (Undocumented) fatal stroke (also complete Section C)
- 1. Death certificate consistent with underlying or immediate cause (ICD-9, code 431-437), but neither autopsy evidence nor adequate pre-terminal documentation of the event,
AND
 - 2. No evidence at autopsy examination of the brain, if performed, of any disease process that could cause focal neurologic signs that would not be connected with cerebral infarction or hemorrhage.
7. Definite fatal congestive heart failure.
- Two major criteria or one major and two minor criteria:
- a. Major criteria
- i. Paroxysmal nocturnal dyspnea or Orthopnea
 - ii. Neck vein distention
 - iii. Rales
 - iv. Cardiomegaly
 - v. Acute pulmonary edema
 - vi. S₃ gallop
 - vii. Increased venous pressure > 16 cm water
 - viii. Circulation time ≥25 seconds
 - ix. Hepatojugular reflux

b. Minor criteria

- i. Ankle edema
- ii. Night cough
- iii. Dyspnea on exertion
- iv. Hepatomegaly
- v. Vital capacity reduced by one third from maximum
- vi. Tachycardia (rate of ≥ 120 /min.)

c. Major or minor criteria

- i. Weight loss > 4.5 kg in 5 days in response to treatment

AND

- d. No known non-cardiac process leading to fluid overload such as renal failure

8. Possible fatal congestive heart failure

- Death certificate or medical records with consistent underlying or immediate cause, but neither autopsy evidence nor adequate pre-terminal documentation of the event.

9. Other fatal cardiovascular diseases

- i. Death certificate or medical records with consistent underlying or immediate cause.

Comment: _____

C. TYPE OF CEREBRAL EVENT:

- | | |
|--------------------------------|--------------------------------|
| 1. Cardioembolic infarction | 5. Other, unknown infarction |
| 2. Subarachnoid hemorrhage | 6. TIA |
| 3. Intraparenchymal hemorrhage | 7. Unknown type stroke |
| 4. Lacunar | 8. Atherothrombotic infarction |

D. Does the diagnosis in Section A (Cause of death) agree with your clinical impression?
1=Yes 2=No

If "No", what is your diagnosis? _____

Why? _____

Reviewer's code:

Date completed: //
mo day yr

Coordinating Center Use Only

Reviewer: First review 1 Second review 2 Third review 3 Adjudication 9

**STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

Mortality Survey Packet Checklist

ID number: |_|_|_|_|_|_|_|_|

- 1. Death Certificate _____
- 2. ICD coded cause of death by nosologist _____
- 3. Autopsy performed Yes |_|
No |_|
- 4. Autopsy report Available |_|
Unavailable |_|
- 5. If autopsy report is available, Autopsy Form (by receiver) _____
- 6. Medical Records Photocopy Checklist _____
- 7. Copy reports as specified _____
- 8. Check if the decedent is eligible for the morbidity survey and proceed as required by the morbidity survey protocol. _____
- 9. Check if tracking form was sent. _____
- 10. Informant Interview Form? _____
- 11. Medical Records Abstract Form, Informant Interview Form, Autopsy Report Form, and Final Decision Form to Dr. Sievers on _____
Date
- 12. Send to Dr. Wiebers if this is a potential stroke case _____
Date
- 13. Was he/she in a nursing home at the time of death? Yes |_| No |_| Unknown |_|
- 14. Was he/she receiving care from a home hospice care program at the time of death?
Yes |_| No |_| Unknown |_|

Code number of SHS staff completing this form |_|_|_|_|

Date completed: |_|_|/|_|_|/|_|_|_|_|
mo day yr

APPENDIX D

Morbidity Surveillance Data Forms

**STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

Master List of Hospitalization and Outpatient Visits

ID number: _____

List all facilities where patient was hospitalized or was an outpatient since date of last SHS contact.

Reason: 1=Heart attack 2=Stroke 3=CHF
 4=Other CVD, please specify (includes PVD and valvular heart disease).
 5=Other non-CVD, please specify.
 6=End Stage Renal Disease (includes kidney dialysis or kidney transplant).

If it is a FATAL event, mark X in the inpatient or outpatient space.

In- patient	Out- patient	Hospital/Clinic	Town/State	Date (mm/dd/yy)	Reason	Abstracted (Y/N)
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						
_____	_____	_____	_____	/ /	_____	_____
Diagnosis: _____						

**THE STRONG HEART STUDY IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

Morbidity Survey

Medical Records Abstract and Photocopy Checklist for Non-Fatal CVD Events or Procedures

ID number:

1. a. Hospital code number

b. Hospital name _____

c. Hospital location _____

d. Medical record number

2. Date of ADMISSION to this hospital or date of this outpatient visit:
 / /
mo day yr

3. Date of discharge:
 / /
mo day yr

4. Was the patient transferred to or from another acute care hospital?
Yes 1 (*be sure information is listed on M&M master list form*) No 2

5. Enter the ICD-9 code numbers for the hospital discharge diagnoses and procedure codes recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. Be sure they are ICD-9 codes. Record diagnoses if no codes are available.

1. • 7. •

2. • 8. •

3. • 9. •

4. • 10. •

5. • 11. •

6. • 12. •

6. Has the participant received a kidney transplant? Yes 1 No 2

If yes, date of first transplant: / /
mo day yr

7. Was the participant receiving kidney dialysis during this hospital or outpatient visit?
Yes 1 No 2

If yes, date dialysis FIRST STARTED: / /
mo day yr

For each hospital admission or outpatient visit, obtain photocopies of each of the following sections of the medical records (when available) and assemble them for each admission. Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets), including Diagnoses	_____	_____	_____
Admitting History and Physical Exam	_____	_____	_____
Discharge Summary	_____	_____	_____
ECGs (see instruction)	_____	_____	_____
Cardiac enzyme report (days 1 to 4)	_____	_____	_____
Neurology Consult Report	_____	_____	_____
Reports of Procedures:			
1. Echocardiogram	_____	_____	_____
2. Coronary angiogram	_____	_____	_____
3. Exercise tolerance test (Treadmill)	_____	_____	_____
4. Cardiac catheterization	_____	_____	_____
5. Coronary bypass	_____	_____	_____
6. Coronary angioplasty	_____	_____	_____
7. Swan-Ganz catheterization	_____	_____	_____
8. Intracoronary or I.V. streptokinase, or TPA reperfusion	_____	_____	_____
9. Aortic balloon pump	_____	_____	_____
10. Radionuclide scan	_____	_____	_____
11. CAT or CT of the head	_____	_____	_____
12. Magnetic Resonance Image (MRI) of the head	_____	_____	_____
13. Carotid ultrasound/Doppler	_____	_____	_____
14. Lumbar puncture	_____	_____	_____
15. Angiography (including vessels in the lower extremities)	_____	_____	_____
16. Peripheral Angioplasty (lower extremity vessel(s))	_____	_____	_____
17. Surgical revascularization of peripheral vessel(s)	_____	_____	_____
18. Amputation	_____	_____	_____
19. Chest X-ray	_____	_____	_____
20. Other, specify: _____	_____	_____	_____

Be sure to include Tracking Sheet in the packet

Code number of SHS staff completing this form |_|_|_|_|

Date completed: |_|_|_|/|_|_|_|/|_|_|_|_|
mo day yr

**THE STRONG HEART STUDY IV
Morbidity Survey --- DECISION FORM**

ID number: |_|_|_|_|_|_|_|

Date of this event: |_|_|/|_|_|/|_|_|_|_|
mo day yr

- A. DIAGNOSIS (enter appropriate code number): |_|_|
- 01. Definite non-fatal myocardial infarction
 - 02. Possible non-fatal myocardial infarction |_|_|
 - 03. Definite non-fatal stroke
 - 04. Possible non-fatal stroke
 - 06. Definite CHD |_|_|
 - 07. Possible CHD (those with some, but not all, criteria or with equivocal criteria for definite CHD)
 - 08. TIA
 - 09. Other CVD, specify: _____ |_|_|
 - 10. Non -CVD, specify: _____ |_|_|
 - 11. ESRD (dialysis or transplant)

B. Criteria used: (Please check one box in each field)

1. MYOCARDIAL INFARCTION

- a. PROLONGED CARDIAC PAIN
 - Present |_|1
 - Absent |_|2
 - b. ECG FINDINGS
 - Evolving diagnostic ECG |_|1
 - Diagnostic ECG |_|2
 - Equivocal ECG |_|3
 - Absent, uncodable, or other |_|9
 - c. CARDIAC ENZYMES
 - Abnormal |_|1
 - Equivocal |_|2
 - Incomplete |_|3
 - Normal |_|4
- i) Troponin-I \geq 2xULN or "abnormal" Yes |_|1 No |_|2 Not done |_|9

COMMENTS: _____

2. STROKE

- a. DIAGNOSTIC EVIDENCE
- Unequivocal physician or laboratory |1
 - Discharge diagnoses of stroke (431, 432, 434, 436, 437) |2
 - Neither of above |9
- b. ONSET/DURATION OF NEUROLOGICAL DEFICIT
- Rapid/ > 24 hours |1
 - Rapid/ < 24 hours |2
 - Protracted/ > 24 hours |3
 - Protracted/ < 24 hours |4
- c. OTHER CAUSES
- Present |1
 - Absent |2
- d. TYPE OF STROKE:
- | | | |
|--------------------------------|--------------------------------|--------------------------|
| 1. Cardioembolic infarction | 5. TIA | <input type="checkbox"/> |
| 2. Subarachnoid hemorrhage | 6. Other, unknown infarction | |
| 3. Intraparenchymal hemorrhage | 7. Unknown type stroke | |
| 4. Lacunar | 8. Atherothrombotic infarction | |

COMMENTS: _____

3. **Definite Coronary Heart Disease (CHD)**
- a. Cardiac cath proven coronary artery disease (1 or more vessels \geq 50% stenosis), *or* |1
 - b. PTCA, *or* |2
 - c. Coronary artery bypass grafting, *or* |3
 - d1. Abnormal stress ECG, **and** |4
 - d2. Abnormal imaging, *or* |5
 - e. Positive functional test of ischemia (such as treadmill) |6

COMMENTS: _____

4. **Other Non-fatal Cardiovascular Disease**

- a. Congestive Heart Failure
- b. CHF secondary to ESRD (diagnosis = 10)
- c. Cardiomyopathy
- d. Valvular Heart Disease
- e. Left Ventricular Hypertrophy
- f. Atrial Fibrillation
- g. Non-coronary heart surgery or carotid or other vascular surgery (does not include procedures for PVD)
- h. Pacemaker implantation
- i. Positive non-coronary angiography (does not include procedures for PVD)
- j. Arrhythmia
- k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides) (diagnosis = 07)
- l. PVD (either peripheral arterial surgical procedures, angiogram or amputation)

COMMENTS: _____

C. Does the diagnosis in Section A (DIAGNOSIS) agree with your clinical impression?
 Yes 1 No 2

If "No", what is your diagnosis? (Diagnosis in A)

Why? _____

Reviewer's code:

Date completed: //
 mo day yr

Coordinating Center Use Only

Deposition: Regular 1 QC 2 Equivocal 3 Adjudication 9

APPENDIX E

Acute Myocardial Infarction (AMI) Tool

and

Instructions

**THE STRONG HEART IV
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

**Acute Myocardial Infarction
(Strong Heart Study Provider Tool)
revised 2/14/2003**

SHS I.D.:

Inclusion:

1) Is Acute Myocardial Infarction confirmed by discharge diagnosis at ANY of the hospitalizations in this series? **The diagnosis may be either principal or secondary; and listed on either the discharge summary or discharge face sheet.**

Yes = Continue **No = STOP**

Which facility(s)?

Initial facility

Principal diagnosis Secondary diagnosis not categorized

First referral facility

Principal diagnosis Secondary diagnosis not categorized

Second referral facility

Principal diagnosis Secondary diagnosis not categorized

2) Is Acute Myocardial Infarction confirmed by enzymes and/or EKG's obtained at ANY of the hospitalizations in this series?

Yes = Continue **No = STOP**

Which facility(s)?

Initial facility

First referral facility

Second referral facility

PLEASE COPY THE FIRST EKG OBTAINED AT EACH ADMISSION IN THIS SERIES.

Complete this form if the above criteria apply to ANY of a continuous series of admissions and transfers. Use information from as many as the FIRST THREE facilities where the patient received care. (If more than 3 facilities.....STOP).

A. Demographics:

A1. SHS # _____

A2. Name _____

A3. Date of Birth: ____ / ____ / ____.

A4. Pay Source, IF KNOWN:(select all that apply):

- Medicare
- Medicaid
- IHS/Tribal facility
- Private Insurance
- Self Pay

A5. Initial Facility Name (or number) _____:

Admission Date: ____ / ____ / ____.

Arrival Time: _____ (Military time, or closest approximation)

Discharge (or Transfer) Date: ____ / ____ / ____.

Discharge (or Transfer) Time: _____ (Military time, or closest approximation)

Was chest pain or clinical suspicion of cardiac disease present at the time of admission to this facility?

- Yes
- No

Was there any indication of unusual delay from the time the patient presented to the facility and when they were first evaluated by a provider?

- Yes
- No

If "NO", skip to A6.

Approximately how long was this delay? _____ hours

A6. First Referral Facility Name (or number) _____:

Admission Date: ____ / ____ / ____.

Arrival Time: _____ (Military time, or closest approximation)

Discharge (or Transfer) Date: ____ / ____ / ____.

Discharge (or Transfer) Time: _____ (Military time, or closest approximation)

Was chest pain or clinical suspicion of cardiac disease present at the time of admission to this facility?

- Yes
- No

A7. Second Referral Facility Name (or number) _____:

Admission Date: ____ / ____ / ____.

Arrival Time: _____ (Military time, or closest approximation)

Discharge (or Transfer) Date: ____ / ____ / ____.

Discharge (or Transfer) Time: _____ (Military time, or closest approximation)

Was chest pain or clinical suspicion of cardiac disease present at the time of admission to this facility?

Yes

No

B. Early Administration of Aspirin:

B1. Did the patient receive aspirin, **FROM ANY FACILITY**, within 24 hours of arrival (either 24 hours before arrival or 24 hours after arrival) to the **FIRST** hospital/health care facility?

Yes

B1A. Date first aspirin received? ____ / ____ / ____.

B1B. Time first aspirin received? (military time) _____ Not Available

B1C. Facility that administered aspirin _____

B1D. Dosage of aspirin administered ____ mg.

B1E. Type of aspirin __ Non-enteric (or Not Known) __ Enteric

No

IF "YES" SKIP TO C1.

Contraindications/Exclusions/Possible Reasons for non-administration

B2. If patient did **NOT** receive aspirin within 24 hours of arrival at the first facility, are any of the following noted in **ANY** medical record during the first 24 hours after the initial admission?

Yes, select at least one of the following:

Allergy/intolerance to aspirin

Bleeding/hemorrhage on admission

History of bleeding/bleeding risk

History of peptic ulcer disease

Chronic liver disease

First platelet count $<100 \times 10^9$ /L

First Hemoglobin $<10\text{g/dL}$ or First Hematocrit $<30\%$

Warfarin prior to arrival

Renal insufficiency (Creatinine $>3\text{mg/dL}$ on admission)

Other reasons given for not prescribing aspirin? _____

No

B3. If patient did **NOT** receive aspirin within 24 hours of arrival at the first facility, did he/she take aspirin 24 hours prior to the initial admission?

Yes

No or Unknown

C. Early Administration of Beta Blockers:

C1. Did the patient receive a beta blocker, **FROM ANY FACILITY**, within 24 hours of arrival to the **FIRST** hospital/health care facility?

Yes

C1A. Date first beta blocker received? ____ / ____ / ____.

C1B. Time first beta blocker received? _____

(Military time, or closest approximation)

C1C. Facility that administered a beta blocker _____

No

IF “YES” SKIP TO D1.

Contraindications/Exclusions/Possible reason beta blockers not administered

C2. If patient did **NOT** receive beta blockers within 24 hours of arrival at the first facility, are any of the following noted in **ANY** medical record during the first 24 hours after the initial admission?

Yes, select at least one of the following:

Allergy/intolerance to beta blockers

First pulse < 60 bpm on arrival and not taking beta blockers prior to arrival

Heart Failure/Pulmonary Edema on arrival

Previous LVEF < 50% or described as severe, moderate or mild dysfunction

Shock (any type) on arrival

First systolic BP < 100 mmHg

Arrival EKG with any of the following indicating heart block

1st degree heart block, PR interval > 240 milliseconds.

2nd/3rd degree heart block

RBBB and left fascicular block (bifascicular block)

History of Chronic Obstructive Pulmonary Disease or asthma

History of Peripheral Vascular Disease

Other reasons given for not prescribing beta blockers? _____

No

D. Timely Reperfusion:

D1. Is this patient eligible for reperfusion?

Yes

Arrival EKG at the FIRST facility with one of the following:

ST elevation in 2 contiguous leads

LBBB

ST segment elevation or injury noted on physician interpretation

and

Onset of chest pain or other AMI symptoms \leq 12 hours prior to arrival at the FIRST health care facility.

Date of onset of symptoms ____ / ____ / ____.

Time of onset of symptoms _____ (Military time, or closest approximation)

No **If “NO”, skip to E1.**

D2. Did the patient receive thrombolytic therapy?

Yes **If “YES”, skip to E1.**

D2A. Date of first thrombolytic ____ / ____ / ____.

D2B. Time first thrombolytic started _____ (military time or closest approximation)

D2C. Facility that administered first thrombolytic _____

No

D3. Did the patient have a revascularization procedure (angioplasty (PTCA) or CABG) within 24 hours of arrival to the referral hospital?

Yes **If “YES”, skip to E1.**

D3A. Date of first revascularization procedure ____ / ____ / ____.

D3B. Time revascularization procedure started _____ (military time or closest approximation)

D3C. Facility that conducted revascularization procedure _____

No

If “Yes” to either D2 or D3, then skip to E1.

Contraindications/Exclusions:

D4. If patient did **NOT** receive thrombolytic therapy during hospitalization at any facility or revascularization procedure within 24 hours of arrival at the first facility, are any of the following noted in **ANY** medical record during the first 24 hours after the initial admission?

Yes, select at least one of the following:

- Bleeding on admission
- History of bleeding/bleeding disorder
- History of peptic ulcer disease
- Chronic liver disease
- Surgery/biopsy within 2 months
- Trauma in past month
- Cardiac arrest within 6 hours prior to arrival
- Bilirubin > 2 mg/dl
- Warfarin prior to arrival
- Stroke (history or current)
- Thrombolysis considered but rejected
- Age > 80 years

Other reasons for not prescribing thrombolytic therapy? _____

No

E: Eligible for Discharge Indicators:

E1. Did the patient expire?

- Yes **If Yes, STOP**
 No

E2. Is discharge status unknown?

- Yes **If Yes, STOP**
 No

THE FOLLOWING SECTIONS APPLY ONLY TO THE FINAL FACILITY PATIENT WAS DISCHARGED FROM

F. Beta Blockers at Discharge:

F1. Was a beta blocker prescribed at discharge?

- Yes **If "YES", skip to G1.**
 No

Contraindications/Exclusions/Possible reasons beta blockers not prescribed:

F2. Are any of the following noted in the medical record of the discharge facility?

- YES, select at least one of the following:
- Allergy/intolerance to beta blockers
 - Pulse < 50 bpm and not taking a beta blocker
 - Heart Failure or Pulmonary Edema (by physical exam, x-ray, or clinical assessment) **and** LVEF < 50% or described as moderate or mild dysfunction
 - LVEF < 30% or described as severe dysfunction
 - Shock
 - Systolic BP < 90 mmHg during hospital stay
 - Last systolic BP < 100 mmHg **and not** on a beta blocker
 - Heart block
 - First degree
 - 2nd/3rd degree
 - Bifascicular (RBBB **and** left fascicular block)
 - Chronic Obstructive Pulmonary Disease or asthma
 - Peripheral Vascular Disease
- Other reasons beta blockers not prescribed? _____
- No

G. Aspirin at Discharge:

G1. Was aspirin prescribed at discharge?

- Yes **If “YES”, skip to H1.**
 No

Contraindications/Exclusions/Possible reasons aspirin not prescribed:

G2. Are any of the following noted in the medical record of the discharge facility?

- Yes, select at least one of the following:
- Allergy/intolerance to aspirin
 - Bleeding/hemorrhage
 - History of bleeding/bleeding risk
 - Chronic liver disease
 - Peptic ulcer disease
 - Platelet count < 100 x 10⁹ /L
 - Hemoglobin < 10 g/dL or Hematocrit < 30 %
 - Treatment with warfarin on discharge
 - Renal insufficiency (Creatinine > 3 mg/dL)
- Other reasons given for not prescribing aspirin? _____
- No

H. ACE Inhibitor at Discharge for Low LVEF (Left Ventricular Ejection Fraction)

H1. Does the patient have an LVEF < 40% or described as severe or moderate dysfunction?

- Yes
 Unknown
 No **If “NO”, skip to I1.**

H2. Was an ACE Inhibitor prescribed at discharge?

- Yes **If “YES”, skip to I1.**
 No

Contraindications/Exclusions:

H3. Are any of the following noted in the medical record of the discharge facility?

- Yes, select at least one of the following:
- Allergy/intolerance to ACE Inhibitor
 - Aortic stenosis
 - Serum Creatinine > 2 mg/dL
 - Last systolic BP < 100 mmHg and not on ACE Inhibitor
- Other reasons given for not prescribing ACE inhibitors? _____
- No

I. Smoking Cessation Counseling:

I1. Is there a history of cigarette use within the year prior to arrival in the medical record of any facility?

Yes

No

If “No”, skip to J1.

I2. Is smoking cessation counseling documented in the medical record of the discharge facility?

Yes

No

J. Screening and treatment of dyslipidemia:

J1. Was a fasting lipid profile obtained at any facility during this series of admissions?

Yes-Results of first test after presenting for care at any facility

LDL cholesterol _____ mg/dl

HDL cholesterol _____ mg/dl

Triglycerides _____ mg/dl

No

J2. What treatment plan for dyslipidemia was documented in the chart at the discharge facility during hospitalization or at the time of discharge?

(Circle all that apply)

A. Dietary counseling

B. Lipid lowering medication

C. Cardiac rehabilitation program

D. None

**Acute Myocardial Infarction (AMI)
Strong Heart Study Instructions - Provider Tool – Revised 12/20/2002**

Data Element	AMI Confirmation Criteria
<p>1. MI confirmed?</p> <p>Question: Is Myocardial Infarction confirmed by discharge diagnosis?</p> <p>Instructions: Select this option if primary discharge diagnosis of any facility in the series indicates the patient was hospitalized with an acute myocardial infarction.</p> <p>No: Select this option if the documentation does not indicate acute myocardial infarction.</p>	<p>Review the discharge diagnoses of all admissions in this continuous series of hospitalizations to determine if any of the admissions have a principal discharge diagnosis of “acute myocardial infarction”. The principal diagnosis is the primary condition affecting the services provided during the hospitalization, and this should be where the MI is recorded. In some facilities a “principal diagnosis” will be listed and “secondary” diagnoses listed separately. If this is the case, please indicate by check mark in the following line, whether the diagnosis was principal or secondary. If there is no designation of principal or secondary, check “not categorized”.</p> <p>Do not consider a particular admission as satisfying this criterion if the diagnosis is listed as:</p> <ul style="list-style-type: none"> *MI listed as secondary diagnosis *Rule out MI *R/O MI
<p>2. MI confirmed?</p> <p>Question: Is Myocardial Infarction confirmed by enzymes and/or EKGs?</p> <p>Instructions: YES: Select this option if enzymes and EKGs</p>	<p>Acute MI confirmed by enzymes (any one of the following)</p> <p>Peak LDH within first 48 hours after arrival > 1.5 times LDH Upper Limits of Normal and LDH-1 on peak LDH > LDH-2 on peak LDH</p> <p>or</p> <p>Peak CK-MB % > 5 (CK and CK-MB within the first 48 hours after arrival)</p> $\frac{\text{Peak CPK-MB unit of measurement}}{\text{CK on peak CK-MB}} \times 100$ <p>or</p> <p>Peak CK-MB (% , index, fraction) > 5% if peak CPK-MB or CK on peak CK-MB is missing</p> <p>or</p> <p>Troponin I within first 48 hours after arrival > Troponin I Upper Limits of Normal or Troponin T within first 48 hours after arrival > Troponin T Upper Limits of Normal ,</p>

Data Element	AMI Confirmation Criteria																					
<p>indicate an acute myocardial infarction.</p> <p>No: Select this option if the documentation does not indicate acute myocardial infarction.</p> <p><u>Note: Please obtain a copy of the admission EKG from EACH facility.</u></p>	<p><u>OR</u></p> <p>At least two of the following:</p> <p>1. Two-fold elevation of Peak CPK (Within the first 48 hours after arrival at the first facility) Peak CPK > 2 times CK-Upper Limits of Normal,</p> <p>or</p> <p>2. Presence of chest pain w/in 48 hrs. prior to arrival at the first facility.</p> <p>or</p> <p>3. Acute MI on EKG:</p> <p>3a. ST elev on any EKG within 6 hrs of arrival at first facility. indicates ST elevation (≥ 1 mm) in 2 contiguous leads Contiguous leads: <table style="margin-left: 40px;"> <tr> <td>I, AVL</td> <td>I, V₄</td> <td>I, V₅</td> <td>I, V₆</td> <td>AVL, V₅</td> <td>AVL, V₆</td> <td>V₁ V₂</td> </tr> <tr> <td>V₂ V₃</td> <td>V₃ V₄</td> <td>V₄ V₅</td> <td>V₅ V₆</td> <td>II, III</td> <td>II, V₆</td> <td>II, AVF</td> </tr> <tr> <td>III, AVF</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table> </p> <p>or</p> <p>3b. EKG interpretation mentions “myocardial infarction (or injury)” on any EKG during this series of hospitalizations, AND there is no history of a myocardial infarct prior (days/weeks/months before) to admission at the first facility (see History and Physicals of all admissions in this series).</p> <p>or</p> <p>3c. New Q waves, or left bundle branch block documented on any EKG within 6 hours of arrival at first facility. New Q-waves on arrival EKG, or left bundle branch block on any EKG within 6 hours of arrival at first facility.</p> <p><u>Complete the AMI Provider Tool if the above criteria apply to ANY of a continuous series of admissions and transfers. Use information from as many as the FIRST THREE facilities where the patient received care. (If more than 3 facilities.....STOP).</u></p>	I, AVL	I, V ₄	I, V ₅	I, V ₆	AVL, V ₅	AVL, V ₆	V ₁ V ₂	V ₂ V ₃	V ₃ V ₄	V ₄ V ₅	V ₅ V ₆	II, III	II, V ₆	II, AVF	III, AVF						
I, AVL	I, V ₄	I, V ₅	I, V ₆	AVL, V ₅	AVL, V ₆	V ₁ V ₂																
V ₂ V ₃	V ₃ V ₄	V ₄ V ₅	V ₅ V ₆	II, III	II, V ₆	II, AVF																
III, AVF																						

DEMOGRAPHICS

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
A1. SHS ID #	What is the SHS ID No.?	List the SHS ID number.	SHS Record		
A2. Name	What is the pt name?	List the name of the patient	Hospital Record		
A3. Date of Birth	What was the patient's date of birth?	Record the patient's date of birth as it appears in the medical record, in the following format MM/DD/YYYY.	SHS Record		
A4. Pay Source	What is the pay source listed for this patient?	<p>Select all that apply:</p> <p>Medicare: Select this option if a payment source is Medicare (T18)</p> <p>Medicaid: Select this option if a pay source is Medicaid (T19)</p> <p>IHS/Tribal-Select this option if one of the facilities is run by a Tribe or IHS</p> <p>Private Health Insurance- Select this option if some of the care was paid for by private health insurance.</p> <p>Self-Pay-Select this option if third party coverage was not available to pay for part of the care provided for the AMI</p>	Face sheet		
A5 through A7. Facility Names and Numbers	What is/are the facility names numbers? (If more than 3 facilities.....STOP).	List all the facilities that provided care for this AMI in chronological order and include admission and discharge dates and times (military time).	Use SHS codes for health care facilities that are listed in the SHS manual.		

A5 through A7. Admission Date	What is the date the patient was admitted to this hospital?	Enter the date in MM/DD/YYYY format. Use the actual date of inpatient admission to acute care.	ER record, history & physical, nursing assessment, surgery or procedure note.		Arrival Date Admit to observation
A5 through A7. Discharge/Transfer Date	What is the date the patient was discharged/transferred from acute care, left against medical advice, or expired?	Enter the date in MM/DD/YYYY format.	Discharge summary, transfer note, nursing discharge note, progress notes, graphic sheet. Physician orders	AMA	

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
B1. Aspirin within 24 hours of arrival at the first health care facility?	Did the patient receive aspirin, FROM ANY FACILITY , within 24 hours of arrival (either 24 hours before arrival or 24 hours after arrival) to the FIRST hospital/ health care facility?	Yes: Select this option if there is documentation that the patient was given aspirin within 24 hours of arrival (either 24 hours before arrival or 24 hours after arrival) at the first health care facility. If Yes, skip to C1. No: Select this option if the patient did not take aspirin within 24 hours of arrival.	ER record, history & physical, nursing admission assessment, Ambulance record/sheet. Also look for documentation that the patient was advised to self-administer aspirin.	(See attached medication sheet for aspirin-containing drugs)	
B1A. Date first aspirin received?	What was the date the first aspirin was received?	Enter the first date the patient received aspirin after arrival to the hospital using MM/DD/YYYY format.			
B1B. Time first aspirin received?	What time was the first aspirin received?	Enter the time the first aspirin was received after arrival to the first health care facility, enter in military time.	Medication records in medical record or ER record.		

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
B1C Facility that administered aspirin?	What was the name and # of the facility that administered the aspirin?	Enter name and # of facility that administered aspirin.	SHS manual for facility code		
B1D. Dose of aspirin?	What was the dose of aspirin administered?	List the mg dose that was administered or that the patient took themselves	ER record, history & physical, nursing admission assessment, Ambulance record/sheet		
B1E Type of aspirin?	What type of aspirin?	List whether the type was enteric, non-enteric or not known			
B2. Contraindications/ Exclusions/Possible reasons for non-administration	Does the patient have any contraindications to early aspirin therapy?	Yes: Select yes if any of the following are true and select at least one:			
		Allergy/intolerance to aspirin Was there a history of allergy/ sensitivity/ reaction, or intolerance to aspirin prior to arrival?	History & physical, emergency room notes, nursing admission notes, progress notes.	Record only those associated with a reaction to aspirin: Adverse drug event, adverse drug reaction, allergy, anaphylaxis, intolerance, sensitivity.	Documentation which states aspirin caused upset stomach or didn't agree with patient.
		Bleeding/hemorrhage on admission (48 hours prior to arrival or at the time of arrival)	History & physical, ER record, nursing admission notes, progress notes.	GI bleeding: bleeding diverticulum, bleeding from a peptic, gastric, esophageal, or duodenal ulcer, bleeding from colon, blood in vomitus, emesis, or stool, coffee ground emesis, esophageal bleeding varices, hematemesis, hematochezia, heme/guaiac positive vomitus, emesis, or stool,	Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick.

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				Hemoccult/occult positive vomitus, emesis or stool, mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR. GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria. Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma. Pulmonary bleeding: coughing up blood, hemoptysis	
		<p>History of bleeding or bleeding risk: Select this option if there is documentation of a <u>history of</u> bleeding from gastrointestinal (GI) tract (esophagus, stomach, intestine, or colon); the genitourinary (GU) tract (kidneys, bladder, or prostate); the brain, the lungs, or any other bleeding documented other than the exclusions listed.</p>	History & physical, ER record, nursing admission notes, progress notes.	GI bleeding: bleeding diverticulum, bleeding from a peptic, gastric, esophageal, or duodenal ulcer, bleeding from colon, blood in vomitus, emesis, or stool, coffee ground emesis, esophageal bleeding varices, hematemesis, hematochezia, heme/guaiac positive vomitus, emesis, or stool, Hemoccult/occult positive vomitus, emesis	Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick. Easy bruisability

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				or stool, mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR. GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria. Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma. Pulmonary bleeding: coughing up blood, hemoptysis Bleeding disorder: Bleeding diathesis, Bleeding tendency, clotting disorder, factor 8 (VIII) deficiency, factor 9 (IX), hemophilia, ITP (idiopathic thrombocytopenia purpura), prolonged bleeding, Von Willebrand's disease	

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>History of peptic ulcer disease: Select this option when the documentation indicates a <u>history of</u> ulceration of the stomach, esophagus, or duodenum, whether or not they are currently being treated.</p>	<p>History & physical, ER record, nursing admission notes, progress notes.</p>	<p>Duodenal ulcer, esophageal ulcer, gastric ulcer, gastrointestinal (GI) ulcer, peptic ulcer disease (PUD), stomach ulcer, stress ulcer, ulcers.</p>	<p>Decubitus ulcer (skin), digital ulcer (finger/toes), mouth ulcer (aphthous), pressure ulcer (skin), stasis ulcer, ulcerative colitis, ulcer not associated with the upper GI tract.</p>
		<p>Chronic liver disease (History)</p>	<p>History & physical, ER record, nursing admission notes, progress notes.</p>	<p>Hepatic failure, Fulminant hepatic failure, Hepatic encephalopathy, liver failure, cirrhosis, alcoholic cirrhosis, cirrhosis etiology unknown, Cryogenic cirrhosis, primary or secondary biliary cirrhosis.</p>	
		<p>Platelet count < 100 x 10⁹/L Select this option if the patients <u>first</u> platelet count <u>within 24</u> hours of arrival was < 100 x 10⁹/L</p>	<p>Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.</p>	<p>Thrombocyte count</p>	
		<p>First hemoglobin < 10 g/dL or First hematocrit < 30%: Select this option when the patients <u>first</u> hemoglobin <u>within 24 hours</u> of arrival is 10</p>	<p>Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG</p>	<p>Hemoglobin: Hb, Hgb Hematocrit: HCT, Hematocrit, PCV (packed cell volume)</p>	

B. Early Administration of Aspirin

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		g/dL or <u>First hematocrit within 24 hours</u> of arrival is < 30%:	report, respiratory therapy report, emergency room record, progress notes, history & physical.	cell volume)	
		Warfarin prior to arrival: select this option if patient was taking warfarin prior to arrival, or recent use of warfarin.	History & physical, nurse's admission assessment, ER record, progress notes.		
		Renal insufficiency (Creatinine > 3 mg/dL): Select this option if the patient's first creatinine within 24 hours of arrival was > 3 mg/dL	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.	Creat, Creatinine (Cr)	BUN/Creatinine ratio
		No: Select no if none of the above are true.			
B3. Aspirin 24 hours prior to arrival?	If the patient did NOT receive aspirin within 24 hrs of arrival at the first facility, did he/she take aspirin within 24 hrs prior to arrival to the first health care facility?	Yes: Select this option if the patient took aspirin in the 24 hours prior to arrival. No: Select this option if the patient did not take aspirin within the 24 hours prior to arrival at the first health care facility.	ER record, history & physical, nursing admission assessment, Ambulance record/sheet. . Look for documentation that the patient was advised to self-administer aspirin.	This includes self administration at home, or given in ambulance (See attached medication sheet for aspirin synonyms)	

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
C1. Beta Blockers from any facility within 24 hours of arrival at the first health care facility?	Did the patient receive a beta blocker within 24 hours of arrival at the first health care facility?	Yes: Select this option if the patient received a beta blocker in the 24 hours after arrival If Yes, skip to D1. No: Select this option if the patient did not receive a beta blocker in the first 24 hours after arrival.	Medication administration records, emergency room records, IV flow sheets.	(See attached medication sheet for beta blockers)	
C1A. Date first beta blocker received?	What was the date the first beta blocker was received?	Enter the first date the patient received beta blocker after arrival to the health care facility using MM/DD/YYYY format.			
C1B. Time first beta blocker received?	What time was the first beta blocker received?	Enter the time the first beta blocker was received after arrival to the health care facility, enter in military time.	Medication record in medical record or ER record.		
C1C Facility that administered a beta blocker?	What was the name and # of the facility that administered the beta blocker?	Enter the name and # of the facility that administered a beta blocker.	SHS manual facility code list.		
		No: Select this option if none of the above are true.			
C2. Contraindications/ Exclusions/possible reason that beta blockers not administered	Does this patient have any contraindications to early administration of beta blockers	Yes: Select this option if any of the following are true, and select at least one			
		Allergy/intolerance to beta blockers	History & physical, emergency room notes, nursing	Record only those associated with a reaction to beta blocker: Adverse	Documentation which states beta blocker caused upset stomach or didn't agree with

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
			admission notes, progress notes.	drug event, adverse drug reaction, allergy, anaphylaxis, intolerance, sensitivity. (See attached medication sheet for beta blockers)	patient.
		First pulse < 60 bpm and not taking a beta blocker prior to arrival: Select this option if the patient's first pulse within 48 hours of arrival was < 60 bpm, and patient was not taking beta blocker prior to arrival	Emergency room notes, nursing admission notes, History & physical, progress notes, graphic sheets, ICU flow sheets, flow sheets, nursing notes, ER/triage notes	If a range is recorded enter the mid-point, If two values recorded for the same time, and both are higher than 50 record the higher of the two values, if either pulse is lower than 50, abstract the lower value. (See attached medication sheet for beta blockers)	
		Heart failure/pulmonary edema on arrival: Select this option when there is documentation of heart failure/pulmonary edema on arrival to the hospital.	History & physical, Emergency room notes, nursing admission notes, progress notes.	Heart failure/pulmonary edema: Biventricular failure, cardiac decompensation, cardiac failure, cardiomyopathy, congestive heart failure (CHF), edema of the lungs, heart failure (right or left), pulmonary edema, pump failure, ventricular failure, wet lungs.	Heart failure/pulmonary edema: diffuse infiltrate, diffuse interstitial pulmonary edema, edema of the legs (pedal edema), enlarged vessels, fullness of pulmonary vasculature, interstitial edema, interstitial congestion, JVD (jugular venous distention), perihilar vascular congestion, pulmonary vascular congestion, pulmonary vascular engorgement, rales, vascular congestion, venous congestion, volume or fluid overload, x-ray report finding.

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>Previous LVEF < 50 or described as severe, moderate or mild dysfunction.</p>	<p>History & physical, Emergency room notes, nursing admission notes, progress notes.</p>	<p>LVEF: Systolic function is a description of the function of the left ventricle based on how much blood is emptied from the left ventricle during each contraction. Include: contractility, EF Ejection fraction, function, left ventricular ejection fraction, LVEF. Severe dysfunction: Severe, very severe, very low/poor, akinesis, dyskinesia, global akinesis, marked, markedly, poor, severe, very low, very poor, very severe. Mild or moderate dysfunction: Diffuse hypokinesia, global hypokinesia, low, moderate, moderate-severe, moderate to severe, moderately severe, significant, abnormal, compromised, decreased, depressed, diminished, dysfunction, depressed, hypokinesia, impaired, impairment, mild, reduced.</p>	<p>LVEF: Right, atrial or diastolic dysfunction. Local/ localized dysfunction.</p>
		<p>Shock (any type) on arrival. Select this option if the patient</p>	<p>Emergency room notes, procedure note,</p>	<p>The intent is to collect the findings at the time of</p>	<p>Cardiovascular instability, cardioversion/defibrillation,</p>

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		had shock present at the time of arrival	history & physical, physician admission note. Use physician documentation only.	presentation to the hospital. Anaphylactic shock, cardiogenic shock, hypovolemic shock, cardiovascular collapse, intravascular collapse, septic shock, shock, shocky.	electro-convulsive therapy (ECT), electro-shock therapy (EST), hypotension.
		First systolic BP < 100 mm hg: Select this option when the patients first recorded systolic blood pressure within 48 hours of arrival is < 100 mm hg	Emergency room notes, nursing admission notes, History & physical, progress notes, graphic sheets, ICU flow sheets, flow sheets, nursing notes, ER/triage notes	If two blood pressures are recorded at the same time record the blood pressure with the highest systolic reading, if a range is recorded, record the mid-point.	
		Arrival EKG with any of the following indicating heart block: 1st degree heart block, PR interval > 240 milliseconds, 2nd/3rd degree heart block, RBBB and left fascicular block (bifascicular block)	The only acceptable source is the interpretation from the arrival EKG Arrival EKG is the first EKG done within 6 hours prior to or after arrival to the hospital. <u>Note: Please obtain a copy of the admission EKG from EACH facility in the continuous series of admissions.</u>	Arrival EKG is the first EKG done within 6 hours prior to or after arrival to the hospital. 1st degree heart block, PR interval >240 milliseconds (.24 seconds): PR interval measurement is included in the interpretation on 12-lead EKGs. If interval is not shown do not attempt to measure 2nd/3rd degree heart block: 2:1 AV block, 2:1 AV conduction, 2:1 heart block, 3:1 AV block, 3:1	RBBB: Incomplete RBBB, incomplete right bundle branch block, interventricular conduction delay (IVCD), intraventricular conduction delay (IVCD) 2nd/3rd degree heart block: Atrial flutter, first degree heart block (first degree AV block), interventricular conduction delay (IVCD), intraventricular conduction delay (IVCD)

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				AV conduction, 3:1 heart block, atrioventricular block (AV block), atrioventricular dissociation (AV dissociation), AV conduction block, complete heart block, heart block, intermittent HB, mobitz type 1 or 2, second degree AV block, second degree heart block (2 degrees block), third degree atrioventricular block (3 degrees AV block), third degree heart block (3 degrees block), variable HB, Wenckebach	
		<p>Arrival EKG with any of the following indicating heart block: 1st degree heart block, PR interval > 240 milliseconds, 2nd/3rd degree heart block, RBBB and left fascicular block (bifascicular block) Cont.</p>		<p>RBBB: bifascicular block, intermittent RBBB, interventricular conduction delay of RBBB type, intraventricular conduction delay of RBBB type, RBBB, Right Bundle Branch Block, trifascicular block, variable RBBB.</p> <p>Left fascicular block: bifascicular block, intermittent LFB, left anterior fascicular block</p>	

C. Early Administration of Beta Blockers

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				(LAFB), left anterior hemiblock (LAHB), left posterior fascicular block (LPFB), left posterior hemiblock (LPHB), trifascicular block, variable LFB.	
		History of COPD or Asthma	History & physical, Emergency room notes, nursing admission notes, progress notes.	asbestosis, asthma, black lung disease, bronchiectasis, childhood asthma, chronic bronchitis, chronic obstructive airway disease (COAD), emphysema, COLD - must be in capital letters - chronic obstructive lung disease, reactive lung disease, restrictive lung disease.	
		History of Peripheral Vascular Disease (PVD)	Progress notes, emergency room notes, history & physical, nursing admission notes.	Angioplasty to lower extremities, aortic-iliac bypass, arterial insufficiency to legs, claudication, femoral bypass surgery (fem-fem bypass), femoral-popliteal bypass (fem-pop bypass), ischemia of lower extremities, peripheral vascular insufficiency, peripheral vascular disease (PVD).	

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
D1. Eligible for reperfusion?	Is this patient eligible for reperfusion?	<p>Yes: Select this option if both of the following are true:</p> <p>Arrival EKG shows ST elevation in 2 contiguous leads, LBBB or ST segment elevation or injury noted on physician interpretation</p> <p>and</p> <p>Onset of chest pain or other AMI symptoms ≤ 12 hours prior to arrival at FIRST health care facility.</p>	<p>Emergency room notes, History & physical, progress notes, consultants notes, ambulance records, nursing admission assessment, nursing admission notes, nursing progress notes.</p> <p>Arrival EKG: the first EKG completed within 6 hours of arrival.</p>	<p>ST elevation in 2 contiguous leads: ST elevation ≥mm in 2 contiguous leads: Contiguous leads are: I, AVL; I, V₄; I, V₅; I, V₆; AVL, V₅; AVL, V₆; V₁ V₂ (≥2mm) V₂ V₃; (V₂ ≥2mm V₃ ≥1mm) V₃ V₄; V₄ V₅; V₅ V₆; II, III; II, V₆; II, AVF; III, AVF LBBB: intermittent LBBB, interventricular conduction delay of LBBB type, Intraventricular conduction delay of LBBB type, LBBB, Left Bundle Branch Block, Variable LBBB. ST segment elevation: ST 8, ST elevation, ST segment elevation</p>	
		Chest pain/Other AMI symptoms		Chest pain: Onset of angina/ chest pain within 12 hours of arrival, angina, chest discomfort, chest fullness, chest heaviness, chest pain	Chest pain: Arthritic pain, chest wall pain, muscle pain, pain that is determined to be non-cardiac in origin, pleuritic pain, skeletal pain.

D. Timely Reperfusion					
Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				(CP), chest/epigastric: aching, burning, crushing pain, pressure, squeezing, tightening. Heart pain, pain/tightness, retrosternal pain, substernal chest pain Other AMI symptoms: Acute onset of fatigue, weakness, tiredness, lethargy, diaphoresis, dizziness, dyspnea, fainting, loss of consciousness, nausea/vomiting, palpitations, racing of heart, shortness of breath (SOB), sweating.	Other AMI symptoms: cardiac arrest
Date and time of onset of AMI symptoms?	What date and time did the AMI symptoms start?	Enter the date in MM/DD/YYYY format. Enter time in military format.	ER record, ambulance record, Admission history.		
		No: Select this option if both of the above are not true. Stop – go to question E.			
D2. Thrombolytic therapy?	Did the patient receive thrombolytic therapy?	Yes: Select this option if there is evidence that the patient received thrombolytic therapy. If Yes, skip to E1. No: Select this option if there is no documentation that the patient received thrombolytics.	Medication administration record, emergency room records, IV flowsheets	Thrombolytic agents: Abbokinase, abbokinase-open cath, activase, altepase, alteplase, alteplase recombinant, anisoylated plasminogen-strept, anistreplase, APSAC, eminase, kabikinase, kabikinase IV, reteplase, reteplase,	

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				RPA, strepase, streptase, streptokinase, streptotinase, T-PA, tissue plasminogen activase, tissue plasminogen activator, tissue-type plasminogen activa, TPA, TPA drip, urokinase, win-kinase, winkinase.	
D2A. Date of first thrombolytic?	What was the date of the first administration of thrombolytic?	Record the date the first thrombolytic was administered after arrival to the hospital, record date in MM/DD/YYYY format.	Medication administration record, emergency room records, IV flowsheets		
D2B. Time of first thrombolytic?	What time was first thrombolytic initiated?	Record the earliest time thrombolytic therapy initiated, record in military time.	Medication administration record, emergency room records, IV flowsheets		
D2C Facility that administered thrombolytic?	What was the name and # of the facility that administered the thrombolytic?	Record the name and number of the facility that administered the thrombolytic .	SHS facility code list		
D3. Angioplasty (PTCA) within 24 hours of arrival?	Did the patient have a PTCA within 24 hours of arrival to this hospital?	<p>Yes: Select this option if there is documentation that the patient had a percutaneous transluminal coronary angioplasty (PTCA) within 24 hours of arrival to the referral hospital</p> <p>If Yes, skip to E1.</p> <p>No: Select this option if there</p>	Test report, operative report, progress notes, discharge summary	Coronary angioplasty with or without stent placement, coronary artery ablation, coronary artery angioplasty, coronary atherectomy, coronary balloon angioplasty, stent placement	balloon angioplasty of femoral or iliac arteries, percutaneous transluminal angioplasty (PTA) of femoral or iliac artery. Cardiac catheterization without angioplasty/stenting.

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		is no documentation of a PTCA within 24 hours of arrival to the referral hospital.			
D3A. Date of PTCA?	What is the date of the first PTCA?	Record the date of the first PTCA performed during this hospital stay. Record the date in MM/DD/YYYY format.	Test report, operative report, progress notes, discharge summary		
D3B. Time of PTCA?	What time did the first PTCA start?	Record the time first PTCA started in military time.	Test report, operative report, progress notes, discharge summary	Record the start time of the first PTCA in the following priority order: 1. Balloon time 2. Wire insertion time 3. Sheath time (Artery time, cannulation time, Vessel access) 4. Lidocaine injection time (infiltration time, local, local anesthesia, xylocaine injection time) 5. Procedure/case start time (begin time, start time) 6. Time patient arrived in cath lab	
D3C. Facility performing first PTCA?	Name and number of facility performing PTCA	Record name and # of facility performing first PTCA	SHS facility code list		
D4. Contraindications/ Exclusions	Does the patient have any contraindications to reperfusion?	Yes: Select this option if any of the following are true:			

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>Bleeding on admission: Select this option if there is documentation that the patient had bleeding on admission</p>	<p>History & physical, ER record, nursing admission notes, progress notes.</p>	<p>GI bleeding: bleeding diverticulum; bleeding from a peptic, gastric, esophageal, or duodenal ulcer; bleeding from colon, blood in vomitus, emesis, or stool; coffee ground emesis, esophageal bleeding or varices; hematemesis; hematochezia; heme/guaiac positive vomitus/emesis, or stool; Hemoccult/occult positive vomitus/emesis or stool; mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR.</p> <p>GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria.</p> <p>Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma.</p> <p>Pulmonary bleeding: coughing up blood, hemoptysis</p>	<p>Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick.</p>

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>History of bleeding/ bleeding disorder: Select this option if there is documentation that the patient had a history of bleeding or bleeding disorder.</p>	<p>History & physical, ER record, nursing admission notes, progress notes.</p>	<p>GI bleeding: bleeding diverticulum; bleeding from a peptic, gastric, esophageal, or duodenal ulcer; bleeding from colon, blood in vomitus, emesis, or stool; coffee ground emesis, esophageal bleeding or varices; hematemesis; hematochezia; heme/guaiac positive vomitus/emesis, or stool; Hemocult/occult positive vomitus/emesis or stool; mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR.</p> <p>GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria.</p> <p>Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma.</p> <p>Pulmonary bleeding: coughing up blood, hemoptysis</p> <p>Bleeding disorder: Bleeding diathesis, Bleeding tendency,</p>	<p>Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick.</p>

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		History of bleeding/bleeding disorder Cont.		clotting disorder, factor 8 (VIII) deficiency, factor 9 (IX), hemophilia, ITP (idiopathic thrombocytopenia purpura), prolonged bleeding, Von Willebrand's disease	
		History of peptic ulcer disease: Select this option if there is documentation that the patient has a history of peptic ulcer disease.	History & physical, ER record, nursing admission notes, progress notes.	Duodenal ulcer, esophageal ulcer, gastric ulcer, gastrointestinal (GI) ulcer, peptic ulcer disease (PUD), stomach ulcer, stress ulcer, ulcers.	Decubitus ulcer (skin), digital ulcer (finger/toes), mouth ulcer (aphthous), pressure ulcer (skin), stasis ulcer, ulcerative colitis, ulcer not associated with the upper GI tract.
		Chronic liver disease: Select this option if there is documentation that the patient has chronic liver disease.	History & physical, ER record, nursing admission notes, progress notes.	Hepatic failure, Fulminant hepatic failure, Hepatic encephalopathy, liver failure, cirrhosis, alcoholic cirrhosis, cirrhosis etiology unknown, Cryogenic cirrhosis, primary or secondary biliary cirrhosis.	
		Surgery/biopsy within 2 months: Select this option if there is documentation that the patient had surgery/biopsy in the 2 months prior to arrival to the	Physician admission note, progress notes, history & physical, Emergency room notes, Consult notes, nurses notes,	Select yes only if one of the following procedures were performed in the 2 months prior to arrival to the hospital. Procedures include:	Arthroscopy, Cardiac catheterization (cath), diagnostic procedures without biopsy, laparoscopy without lysis of adhesions, orthopedic surgeries of a limb (total hip or

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		hospital.	diagnostic studies/tests, discharge summary.	Abdominal aortic aneurysm (AAA) repair, Aneurysmectomy of the heart, Appendectomy, biopsy, back surgery, bowel surgery, cholecystectomy, coronary artery bypass graft (CABG), cranial surgery, diagnostic procedure with biopsy, gastrectomy, hysterectomy, laparoscopic surgery, laparoscopy with lysis of adhesions, laparotomy, lobectomy, nephrectomy, open heart surgery, pancreatectomy, pelvic surgery, repair of congenital or acquired hear abnormalities, such as septal defect, ventricular septal defect (VSD), atrial septal defect (ASD), scopes requiring biopsy, splenectomy, thoracotomy, valve surgery.	knee replacement, fracture repair, rotator cuff repair), pacemaker insertion, percutaneous transluminal coronary angioplasty (PTCA), scopes without biopsy.
		Trauma in the past month Select this option if there is documentation of an event, in the past month, which could have caused internal injuries	History & physical, Emergency room notes, nursing admission notes, progress notes	Select yes only when the trauma or injury occurred in the month prior to arrival to the hospital. Include: Falls, fractures,	Very minor injuries, such as a small cut or a stubbed toe.

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		(most injuries serious enough to be documented in the medical record should be included).		head trauma/injury, motor vehicle accidents (MVA).	
		Cardiac arrest within 6 hours prior to arrival: Select this option if the patient suffered a cardiac arrest in the 6 hours prior to arrival to the hospital, requiring CPR, cardioversion, defibrillation, or chemical cardioversion.	CPR sheet, Code sheet, Cardiac arrest sheet.	Asystole/cardiac standstill, cardiac arrest, cardiopulmonary resuscitation (CPR), required cardioversion or defibrillation, shocked (to restore cardiac rhythm), ventricular fibrillation (Vfib), Ventricular tachycardia (Vtach),	Atrial fibrillation, DNR, Elective cardioversion, electro convulsive therapy (ECT), pacemaker, sinus tachycardia, shock therapy (EST).
		First bilirubin > 2 mg/dl: Select this option when the first bilirubin recorded in the first 48 hours of hospitalization is > 2 mg/dl	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.	Bili, Bilirubin, Tbili, Tot Bili, Total bilirubin	
		Warfarin prior to arrival: Select this option if there is documentation that the patient was taking warfarin prior to arrival.	History & physical, nurses= admission assessment notes, Emergency record, progress notes.	Taking warfarin (coumadin) prior to hospital, recent use of warfarin.	

D. Timely Reperfusion

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>History or current finding of Stroke: Select this option if there is documentation of a stroke in the past or at the time of arrival</p>	<p>History & physical, emergency room notes, nursing admission notes, progress notes.</p>	<p>Brain infarct, cerebellar infarct, cerebral bleeding/hemorrhage, cerebral infarct, cerebral occlusion, cerebral thrombosis, cerebral vascular accident (CVA), hemorrhagic cerebrovascular accident (CVA), hemorrhagic infarct of the brain, intracerebral bleeding or hemorrhage, intracranial bleeding or hemorrhage, lacunar infarct, multi-infarct dementia, ruptured intracranial aneurysm, stroke, subarachnoid hemorrhage.</p>	<p>Cerebral vascular disease, ministroke, reversible ischemic neurologic deficit (RIND), transient ischemic attack (TIA)</p>
		<p>Thrombolysis considered but rejected: Select this option when there is documentation that a thrombolytic was considered but not used for any reason.</p>	<p>Progress notes, discharge summary, history & physical, emergency room notes. Use physician documentation only.</p>	<p>Any decision documented by a physician not to give thrombolytics. Patient or family refused. Thrombolytic agents include: Abbokinase, abbokinase-open cath, activase, altepase, alteplase, alteplase recombinant, anisoylated plasminogen-strept, anistreplase, APSAC, eminase, kabikinase, kabikinase IV, retavase, reteplase, RPA, strepase, streptase,</p>	

D. Timely Reperfusion					
Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				streptokinase, streptotinase, T-PA, tissue plasminogen activase, tissue plasminogen activator, tissue-type plasminogen activa, TPA, TPA drip, urokinase, win-kinase, winkinase.	
		Age > 80 years: Select this option if the patient is > 80 years of age at the time of admission.	Admission record, ER record, registration form.		
		No: Select no if none of the above are true.			

E. Eligible for Discharge Indicators					
Data Element	Question	Instructions	Recommended Location	Inclusion	Exclusion
E1. Did the patient expire?	Is the patient eligible for discharge indicator after care in one of the health care facilities where care was received for AMI	Yes: Patient expired. If Yes, STOP. No: Patient did not expire.	Discharge summary notes, transfer notes, nursing discharge notes, progress notes, test notes, graphic sheet.		
E2. Is discharge status unknown?		Yes: Select Yes if discharge status is unknown. If Yes, STOP.	Discharge summary notes, transfer notes, nursing discharge		

E. Eligible for Discharge Indicators

Data Element	Question	Instructions	Recommended Location	Inclusion	Exclusion
		No: discharge status is known.	notes, progress notes, test notes, graphic sheet.		

F. Beta Blockers at Discharge

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
F1. Beta Blocker at discharge?	Was a beta blocker prescribed at discharge?	Yes: Select this option if there is documentation that a beta blocker was prescribed at discharge. If Yes, skip to G1. No: Select this option if there is no documentation that a beta blocker was prescribed at discharge.	Physician order sheet, discharge summary, nursing discharge note, transfer sheet.	(See attached medication sheet for beta blockers)	
F2. Contraindications/ Exclusions/ Possible reasons beta blockers were not prescribed.	Does the patient have any contraindications to beta blockers at discharge?	Yes: Select this option if any of the following are true:			
		Allergy/ intolerance to beta blocker	History & physical, emergency room notes, nursing admission notes, progress notes, discharge summary.	Record only those associated with a reaction to beta blocker: Adverse drug event, adverse drug reaction, allergy, anaphylaxis, intolerance, sensitivity. (See attached medication sheet for beta blockers)	Documentation which states beta blocker caused upset stomach or didn't agree with patient.

		<p>Last pulse < 50 bpm and not taking a beta blocker: Select this option if the patients last recorded pulse was < 50 bpm, and not discharged on a beta blocker.</p>	<p>Progress notes, graphic sheet, flow sheets, discharge instructions, nurses= notes, transfer/ DC instruction sheet.</p>	<p>Heart rate, pulse, if a range is documented enter the mid-point. (See attached medication sheet for beta blockers)</p>	
		<p>Heart failure or pulmonary edema and LVEF < 50% or described as moderate or mild dysfunction. Select <u>only</u> if both are present.</p>	<p>History & physical, Emergency room notes, nursing admission notes, progress notes, MUGA scan, echocardiogram (echo), or cardiac catheterization.</p>	<p>Heart failure/pulmonary edema: Biventricular failure, cardiac decompensation, cardiac failure, cardiomyopathy, congestive heart failure (CHF), edema of the lungs, heart failure (right or left), pulmonary edema, pump failure, ventricular failure, wet lungs. LVEF: Systolic function is a description of the function of the left ventricle based on how much blood is emptied from the left ventricle during contraction. Include: contractility, EF Ejection fraction, function, left ventricular function, LVEF. Mild or moderate dysfunction: Diffuse hypokinesia, global hypokinesia, low, moderate, moderate-severe, moderate to severe, moderately severe, significant, abnormal, compromised, decreased, depressed,</p>	<p>Heart failure/pulmonary edema: diffuse infiltrate, diffuse interstitial pulmonary edema, edema of the legs (pedal edema), enlarged vessels, fullness of pulmonary vasculature, interstitial edema, interstitial congestion, JVD (jugular venous distention), perihilar vascular congestion, pulmonary vascular congestion, pulmonary vascular engorgement, rales, vascular congestion, venous congestion, volume or fluid overload, x-ray report finding.</p> <p>LVEF: RIGHT, atrial or diastolic function. Local/ localized function.</p>

				diminished, dysfunction, depressed, hypokinesis, impaired, impairment, mild, reduced.	
		LVEF < 30% or described as severe dysfunction.	History & physical, Emergency room notes, nursing admission notes, progress notes, MUGA scan, echocardiogram (echo), or cardiac catheterization.	Systolic function is a description of the function of the left ventricle based on how much blood is emptied from the left ventricle during contraction. Include: contractility, EF Ejection fraction, function, left ventricular function, LVEF. Severe dysfunction: Severe, very severe, very low/poor, akinesis, dyskinesis, global akinesis, marked, markedly, poor, severe, very low, very poor, very severe.	Right, atrial or diastolic dysfunction. Local/ localized dysfunction.
		Shock: Select this option if the patient had shock any time during the hospital stay.	Progress notes, discharge summary, history & physical, emergency room notes. Use physician documentation only.	Anaphylactic shock, cardiogenic shock, hypovolemic shock, cardiovascular collapse, intravascular collapse, septic shock, shock, shocky.	Cardiovascular instability, cardioversion/defibrillation, electro-convulsive therapy (ECT), electro-shock therapy (EST), hypotension.
		Systolic BP < 90 mm hg during hospital stay: Select this option if any systolic BP during the hospital stay was < 90 mm hg.	Emergency room notes, nursing admission notes, history & physical, progress notes, graphic sheet, ICU flow sheet, flow		

			sheets, discharge instructions, nurses= notes, ER/Triage notes.		
		Last systolic BP < 100 mm hg and not on a beta blocker: Select this option if the patient's last recorded systolic BP was < 100 mm hg AND the patient was not taking a beta blocker.	Progress notes, graphic sheet, flow sheets, discharge instructions, nurses= notes	If two blood pressures are recorded at the same time record the blood pressure with the highest systolic reading, if a range is recorded, record the mid-point.	
		Heart block: 1st degree (From arrival EKG Only), 2nd/3rd degree, or bifascicular block (RBBB and left fascicular block) Note: 1st degree block only acceptable if present on arrival EKG (first EKG done within 6 hours of arrival) All other blocks can be recorded from any EKG during the stay.	EKG report, history & physical, emergency room notes, progress notes.	Arrival EKG is the first EKG done within 6 hours prior to or after arrival to the hospital. 1st degree heart block, PR interval > 240 milliseconds (.24 seconds): PR interval measurement is included in the interpretation on 12-lead EKGs. If interval is not shown do not attempt to measure. 2nd/3rd degree heart block: 2:1 AV block, 2:1 AV conduction, 2:1 heart block, 3:1 AV block, 3:1 AV conduction, 3:1 heart block, atrioventricular block (AV block), atrioventricular dissociation (AV dissociation), AV conduction block, complete heart block, heart block, intermittent HB, mobitz type 1 or 2, second degree AV block,	RBBB: Incomplete RBBB, incomplete right bundle branch block, interventricular conduction delay (IVCD), intraventricular conduction delay (IVCD) 2nd/3rd degree heart block: Atrial flutter, first degree heart block (first degree AV block), interventricular conduction delay (IVCD), intraventricular conduction delay (IVCD)

				second degree heart block (2 degrees block), third degree atrioventricular block (3 degrees AV block), third degree heart block (3 degrees block), variable HB, Wenckebach	
		<p>Heart block: 1st degree, 2nd/3rd degree, or bifascicular block (RBBB and left fascicular block) Cont.</p>		<p>RBBB: bifascicular block, intermittent RBBB, interventricular conduction delay of RBBB type, intraventricular conduction delay of RBBB type, RBBB, Right Bundle Branch Block, trifascicular block, variable RBBB.</p> <p>Left fascicular block: bifascicular block, intermittent LFB, left anterior fascicular block (LAFB), left anterior hemiblock (LAHB), left posterior fascicular block (LPFB), left posterior hemiblock (LPHB), trifascicular block, variable LFB.</p>	
		<p>Chronic obstructive pulmonary disease (COPD) or asthma Select yes if documentation indicates the patient has a history of COPD or asthma.</p>	History & physical, Emergency room notes, nursing admission notes, progress notes.	asbestosis, asthma, black lung disease, bronchiectasis, childhood asthma, chronic bronchitis, chronic obstructive airway disease (COAD), emphysema, COLD -	A cold, acute bronchitis, asbestos exposure, findings of a lung disease on CXR without a clinical history of lung disease, pneumonia, tuberculosis (TB).

				must be in capital letters - chronic obstructive lung disease, reactive lung disease, restrictive lung disease.	
		Peripheral vascular disease (PVD): Select this option if there is documentation of peripheral vascular disease.	Progress notes, emergency room notes, history & physical, nursing admission notes.	Angioplasty to lower extremities, aortic-iliac bypass, arterial insufficiency to legs, claudication, femoral bypass surgery (fem-fem bypass), femoral-popliteal bypass (fem-pop bypass), ischemia of lower extremities, peripheral vascular insufficiency, peripheral vascular disease (PVD).	
		No: Select this option if none of the above are true			

G. Aspirin at Discharge					
Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
G1. Aspirin at discharge?	Was aspirin prescribed at discharge?	Yes: Select this option if there is documentation that aspirin was prescribed at discharge. If Yes, skip to H1. No: Select this option if there is no documentation that aspirin was prescribed at discharge.	Physician order sheet, discharge summary, nursing discharge note, transfer sheet.	(See attached medication sheet for aspirin-containing drugs)	
G2. Contraindications/ Exclusions/Possible reasons aspirin not prescribed at discharge	Does the patient have any contraindications to aspirin at discharge?	Yes: Select this option if any of the following are true:			

G. Aspirin at Discharge

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>Allergy/intolerance to aspirin: Select this option when there is documentation that the patient has a history of intolerance to aspirin or has had a reaction during this hospital stay</p>	<p>History & physical, emergency room notes, nursing admission notes, progress notes, discharge summary.</p>	<p>Record only those associated with a reaction to aspirin: Adverse drug event, adverse drug reaction, allergy, anaphylaxis, intolerance, sensitivity. (See attached medication sheet for aspirin)</p>	<p>Documentation which states aspirin caused upset stomach or didn't agree with patient.</p>
		<p>Bleeding/hemorrhage: Select this option when there is documentation that the patient had bleeding/hemorrhage 48 hours prior to arrival or any time during the hospital stay.</p>	<p>History & physical, emergency room notes, nursing admission notes, progress notes, discharge summary.</p>	<p>GI bleeding: bleeding diverticulum; bleeding from a peptic, gastric, esophageal, or duodenal ulcer; bleeding from colon, blood in vomitus, emesis, or stool; coffee ground emesis; esophageal bleeding or varices, hematemesis, hematochezia, heme/guaiac positive vomitus/emesis, or stool; Hemocult/occult positive vomitus, emesis or stool, mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR. GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria.</p>	<p>Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick.</p>

G. Aspirin at Discharge

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		Bleeding/hemorrhage Cont.		<p>Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma.</p> <p>Pulmonary bleeding: coughing up blood, hemoptysis</p>	
		<p>History of bleeding/ bleeding risk: Select this option if there is documentation of a history of bleeding or bleeding risk.</p>	<p>History & physical, emergency room notes, nursing admission notes, progress notes, discharge summary.</p>	<p>GI bleeding: bleeding diverticulum; bleeding from a peptic, gastric, esophageal, or duodenal ulcer; bleeding from colon, blood in vomitus, emesis, or stool; coffee ground emesis, esophageal bleeding varices, hematemesis, hematochezia, heme/guaiac positive vomitus/emesis, or stool; Hemocult/occult positive vomitus, emesis or stool, mallory-weiss tear, melena, rectal bleeding (BRB) per rectum, BRBPR.</p> <p>GU bleeding: blood in urine, genitourinary (GU) bleeding, hematuria.</p>	<p>Anemia not due to gastrointestinal bleeding, bleeding hemorrhoid, bleeding which occurred as a result of an injury or trauma, chronic anemia, epistaxis, heme positive urine, lab urinalysis report, urine dipstick.</p>

G. Aspirin at Discharge

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>History of bleeding/ bleeding risk Cont.</p>		<p>Intracranial bleeding: cerebral hemorrhage, hemorrhagic CVA, hemorrhagic infarct of the brain, intracerebral bleeding/hemorrhage, ruptured intracranial aneurysm, subarachnoid hemorrhage (SAH), subdural hematoma. Pulmonary bleeding: coughing up blood, hemoptysis Bleeding disorder: Bleeding diathesis, Bleeding tendency, clotting disorder, factor 8 (VIII) deficiency, factor 9 (IX), hemophilia, ITP (idiopathic thrombocytopenia purpura), prolonged bleeding, Von Willebrand's disease</p>	
		<p>Chronic liver disease (History)</p>	<p>History & physical, ER record, nursing admission notes, progress notes.</p>	<p>Hepatic failure, Fulminant hepatic failure, Hepatic encephalopathy, liver failure, cirrhosis, alcoholic cirrhosis, cirrhosis etiology unknown, Cryogenic cirrhosis, primary or secondary biliary cirrhosis.</p>	

G. Aspirin at Discharge

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		Peptic ulcer disease (History)	History & physical, ER record, nursing admission notes, progress notes.	Duodenal ulcer, esophageal ulcer, gastric ulcer, gastrointestinal (GI) ulcer, peptic ulcer disease (PUD), stomach ulcer, stress ulcer, ulcers.	
		Platelet count < 100 x 10⁹/L (First drawn within 24 hours of arrival)	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.	Thrombocyte count	
		Hemoglobin < 10 g/dL, Hematocrit < 30% (First labs drawn within 24 hours of arrival)	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.	Hemoglobin: Hb, Hgb Hematocrit: HCT, Hematocrit, PCV (packed cell volume)	
		Treatment with warfarin on discharge: Select this option if there is documentation that warfarin was prescribed at discharge	Physician order sheet, discharge summary, nursing discharge note, transfer sheet.	Coumadin	

G. Aspirin at Discharge					
Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		<p>Renal insufficiency (Creatinine > 3 mg/dL): Select this option if the patient had a creatinine > 3 mg/dl at any time during the hospital stay.</p>	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical.	Cr, Creat, Creatinine(Cr)	BUN/Creatinine ratio
		<p>No: Select this option if none of the above are true</p>			

H. ACE Inhibitor at Discharge for Low LVEF					
Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
H1. LVEF < 40%?	Does the patient have an LVEF < 40% or described as severe or moderate dysfunction?	<p>Yes: Select this option if there is documentation that the patient has an LVEF < 40% or described as severe or moderate dysfunction.</p> <p>Unknown</p> <p>No: Select this option if the patient's LVEF is greater than or equal to 40%. Stop (go to section I).</p>	History & physical, Emergency room notes, nursing admission notes, progress notes, MUGA scan, echocardiogram (echo), or cardiac catheterization.	LVEF: SYSTOLIC function is a description of the function of the left ventricle based on how much blood is emptied from the left ventricle during contraction. Include: contractility, EF Ejection fraction, function, left ventricular function, LVEF. Mild or moderate dysfunction: Diffuse hypokinesia, global	LVEF: RIGHT, atrial or diastolic function. Local/ localized function.

H. ACE Inhibitor at Discharge for Low LVEF

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
				hypokinesia, low, moderate, moderate-severe, moderate to severe, moderately severe, significant, abnormal, compromised, decreased, depressed, diminished, dysfunction, depressed, hypokinesia, impaired, impairment, mild, reduced. Severe dysfunction: Severe, very severe, very low/poor, akinesia, dyskinesia, global akinesia, marked, markedly, poor, severe, very low, very poor, very severe.	
H2. ACEI at discharge?	Was an ACE Inhibitor prescribed at discharge?	<p>Yes: Select this option if there is documentation that an ACE Inhibitor was prescribed at discharge. If Yes, Stop – go to section I.</p> <p>No: Select this option if there is no documentation that an ACE Inhibitor was prescribed at discharge</p>	Physician order sheet, discharge summary, nursing discharge note, transfer sheet.	(See attached medication sheet for ACE Inhibitors)	
H3. Contraindications/ Exclusions	Does the patient have any contraindications to ACE Inhibitor therapy at discharge?	Yes: Select this option if any of the following are true:			

H. ACE Inhibitor at Discharge for Low LVEF

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		Allergy/intolerance to ACE Inhibitors	History & physical, emergency room notes, nursing admission notes, progress notes, discharge summary.	Record only those associated with a reaction to ACE Inhibitor: Adverse drug event, adverse drug reaction, allergy, anaphylaxis, intolerance, sensitivity. (See attached medication sheet for ACE Inhibitors)	Documentation which states ACE Inhibitor caused upset stomach or didn't agree with patient.
		Aortic stenosis: Select this option if aortic stenosis was noted on the echocardiogram	Test reports, history & physical, emergency room notes, progress notes, discharge summary.	2+, 3+ or 4+ aortic stenosis, aortic stenosis (AS) without mention of degree, aortic valve area < 1.0 square cms, critical aortic stenosis, moderate aortic stenosis, severe aortic stenosis.	1+ aortic stenosis, aortic insufficiency, aortic valve prolapse, aortosclerosis, mild aortic stenosis, subaortic stenosis.
		Serum creatinine > 2 mg/dL: Select this option when the patient had a serum creatinine > 2 mg/dl any time during the hospital stay.	Laboratory report, ICU flow sheet, nursing flow sheet, diabetic flow sheet, graphic sheet, EKG report, respiratory therapy report, emergency room record, progress notes, history & physical	Cr, Creat, Creatinine(Cr)	BUN/Creatinine ratio
		Last systolic BP < 100 mm hg and not discharged on an ACE Inhibitor: Select this option if the patients last recorded systolic BP is < 100	Physician order sheet, discharge summary, nursing discharge sheet, transfer sheet, discharge instruction	If two blood pressures are recorded at the same time record the blood pressure with the highest systolic reading, if a range is	

H. ACE Inhibitor at Discharge for Low LVEF

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
		mm hg and the patient is not discharged on an ACE Inhibitor.	sheet, graphic sheet, nursing notes.	recorded, record the mid-point. (See attached medication sheet for ACE Inhibitors)	
		No: Select this option if none of the above are true.			

I. Smoking Cessation Counseling

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
I1. Cigarette use in the year prior to arrival?	Is there a history of cigarette use within the year prior to arrival?	Yes: select yes if there is documentation that the patient smokes or has smoked in the year prior to arrival. No: Select no when there is no documentation that the patient smoked in the year prior to arrival. If “NO”, skip to J1.	History & physical, emergency room notes, nursing admission notes, progress notes.	+ smoker, + tobacco use, history of cigarette use within one year prior to arrival, History of smoking within one year prior to arrival where the type of product is not identified, History of smoking/tobacco/cigarette use without mention of a time frame.	Chewing tobacco, cigar smoking, illegal drugs (ex. Marijuana), pipe smoker, remote smoker, stopped smoking 1 or more years in the past.
I2. Smoking cessation counseling?	Did the patient receive smoking cessation counseling	Yes: Select this option if there is documentation that the patient was counseled about smoking. No: Select this option if there is no documentation that the patient was counseled about smoking.	Progress notes, discharge summary, history & physical, emergency room notes.	Advised to quit smoking whether or not the patient is a current smoker, shown smoking cessation video, given brochures or handouts on smoking cessation, discharged on smoking cessation aid such as nicoderm or zyban..	

J. Screening and Treatment for Dyslipidemia

Data Element	Question	Instructions	Recommended Location	Synonyms	Exclusion
<p>J1 Lipid profile during hospitalization at the discharge facility?</p> <p>Results of lipid profile</p>	<p>Was a fasting lipid profile obtained at ONE OF THE FACILITIES that provided care for this patient?</p> <p>Results of the first lipid profile obtained on this AMI patient at one of the facilities.</p>	<p>Yes: select yes if there is documentation that a fasting lipid profile was obtained at one of the facilities that provided care for the AMI pt.</p> <p>Record the results of LDL and HDL cholesterol and triglyceride levels in mg/dl</p> <p>No: Select no when there is no documentation that a fasting lipid profile was obtained at any of the facilities for this AMI patient.</p>	<p>History & physical, emergency room notes, nursing admission notes, progress notes, doctors' orders.</p> <p>Laboratory results</p>	<p>LDL cholesterol alone could be considered as yes, since that is the most critical determinate of therapy.</p>	<p>If only total cholesterol was obtained, answer no to this question.</p>
<p>J2. Lipid therapy?</p>	<p>If LDL cholesterol \geq 100 mg/dl, what treatment plan was documented in the chart during hospitalization or at the time of discharge?</p>	<p>Circle all that apply</p> <p>Dietary Counseling-Look for documentation that dietary counseling was provided in the hospital or ordered at the time of discharge. If provided or ordered, circle this choice, if not provided or ordered, don't circle.</p> <p>Lipid lowering medication- Was the patient sent home on lipid lowering medication? If yes, circle this choice; if no don't circle.</p> <p>Cardiac rehabilitation program- Circle this choice if</p>	<p>Progress notes, discharge summary, history & physical, Nurses' notes, doctors' orders.</p> <p>Discharge orders and discharge summary.</p> <p>Doctors' orders, nurses' notes,</p>	<p>(See attached medication sheet for anti-lipemic agents)</p>	

		<p>the patient was referred to a cardiac rehabilitation program after discharge. If no referral made, do not circle.</p> <p>None-Circle this choice if there is no documentation at the discharge facility that any of the above three treatment modalities were recommended or provided.</p>	<p>discharge orders and discharge summary.</p>		
--	--	--	--	--	--

Synonyms/Inclusions for Aspirin:

A	A.S.A.	A	ASA Enteric Coated
A	Acetylsalicylic Acid	A	ASA Enteric Coated Aspirin
A	Acuprin 81	A	ASA GR V
A	Adult Aspirin	A	ASA Rectal
A	Adult Aspirin	A	ASA Supp
A	Amiprin	A	ASA Supp.
A	Andylate	A	ASA Suppository
A	Anisin	A	ASA-Chew
A	Antalgesic	A	ASA-Coated
A	Antrin	A	ASA-EC
A	Antrin Junior	A	ASA/Maalox
A	Apo-ASA	A	ASA/Maalox Buffer
A	Apprin	A	Ascrip
A	Arthrinil	A	Ascriptin
A	Arthritis Pain Formula	A	Ascriptin A/D
A	Arthritis Pain Formula S-C	A	Ascriptin ES
A	Arthritis Pain Formula S/C	A	Ascriptin Extra Strength
A	Arthritis Relief	A	Asparin
A	Arthrotrin	A	Asper-Lox
A	ASA	A	Asper-Lox DS
A	ASA Ent. Coated	A	Asperbuf
A	ASA Enteric Coated	A	Aspercine
A	ASA (Baby)	A	Aspergum
A	ASA (Buffered)	A	Aspir-10
A	ASA (Children's)	A	Aspir-Low
A	ASA (EC)	A	Aspir-Lox
A	ASA (Enteric Coated)	A	Aspir-Lox AD
A	ASA Anteric	A	Aspir-Mox
A	ASA Baby	A	Aspir-Mox IB
A	ASA Baby Chewable	A	Aspir-Trin
A	ASA Baby Coated	A	Aspirin
A	ASA Bayer	A	Aspirin (Baby Aspirin)
A	ASA Bayer Children's	A	Aspirin (Baby)
A	ASA Chewable	A	Aspirin (Bayer Childrens Aspirin)
A	ASA Chewed	A	Aspirin (Bayer)
A	ASA Chewy	A	Aspirin (Children's)
A	ASA Children's	A	Aspirin (Coated)
A	ASA Childs	A	Aspirin (Enteric Coated)
A	ASA Childs	A	Aspirin AC
A	ASA Coated	A	Aspirin Adult
A	ASA Coated Enteric Slow Releas	A	Aspirin Baby
A	ASA Coated Enteric Slow Releas	A	Aspirin Buffer
A	ASA Coated Enteric SR	A	Aspirin Buffered
A	ASA Coated Enteric SR	A	Aspirin Chew
A	ASA EC	A	Aspirin Chewable
A	ASA Enseal	A	Aspirin Chewtab
A	ASA Enteric	A	Aspirin Child

A	Aspirin Child Tabs Chew	A	Aspirin/Buffers
A	Aspirin Children	A	Aspralum
A	Aspirin Children Chewable	A	Aspralum E.B.
A	Aspirin Children's	A	Aspri-Mox
A	Aspirin Childrens	A	Aspricin
A	Aspirin Childs	A	Aspidrox
A	Aspirin Childs	A	Asprimox
A	Aspirin Coated	A	Asprimox E/P
A	Aspirin E.C.	A	Asprimox ID
A	Aspirin EC	A	Asprin
A	Aspirin EC Tab	A	Asprin Childrens
A	Aspirin EC Tab	A	B ASA
A	Aspirin Ecotrin	A	B ASA
A	Aspirin Enseal	A	B. ASA
A	Aspirin Ensea	A	Baby ASA
A	Aspirin Ent Coated	A	Baby ASA
A	Aspirin Enteric	A	Baby ASA (Chewable)
A	Aspirin Enteric Cated Tab	A	Baby Aspirin
A	Aspirin Enteric Coate	A	Baby Aspirin
A	Aspirin Enteric Coated	A	Baby EC ASA
A	Aspirin Enteric-Coat	A	Baby Ecasa
A	Aspirin Enteric-Coated	A	Baby Enteric Coated Aspirin
A	Aspirin For Children	A	Bayer
A	Aspirin Grains	A	Bayer 8-Hour
A	Aspirin Lite-Coat	A	Bayer Adult Aspirin EC
A	Aspirin Low-Strength	A	Bayer ASA
A	Aspirin Maximim Strength	A	Bayer Aspirin
A	Aspirin Plus Antacid	A	Bayer Aspirin EC
A	Aspirin Rectally	A	Bayer Aspirin Maximum
A	Aspirin St Joseph's Baby	A	Bayer Children's
A	Aspirin Supp	A	Bayer Children's Aspirin
A	Aspirin Suppository	A	Bayer Childrens Aspirin
A	Aspirin Tab (Child)	A	Bayer Enteric Coated Aspirin
A	Aspirin Tab (Children's)	A	Bayer Plus
A	Aspirin Tablet Chewable	A	Bayer Supp
A	Aspirin Tablet Chewable	A	Bayer Tab
A	Aspirin Tri-Buffered	A	Bayer Therapy
A	Aspirin W/Aluminum/Magnesium	A	Biobuffer
A	Aspirin W/Antacid	A	Bioteric
A	Aspirin W/Antacid A/D	A	Buff
A	Aspirin With Codeine	A	Buff ASA
A	Aspirin, Enteric	A	Buff Cap
A	Aspirin, Enteric Coated	A	Buff-A
A	Aspirin,Enteric-Coated	A	Buffaprin
A	Aspirin-Baby	A	Buffered Arthritis
A	Aspirin-Baby Chewable	A	Buffered ASA
A	Aspirin-Chewable	A	Buffered Aspirin
A	Aspirin-Coated	A	Buffered Baby ASA
A	Aspirin-For-Arthritis	A	Buffered Baby ASA

A	Bufferin	A	Easa
A	Bufferin Analgesic	A	Easprin
A	Bufferin Arthritis Strength	A	EC ASA
A	Bufferin Tri-Buffered	A	EC Aspirin
A	Bufferine	A	EC Baby ASA
A	Buffex	A	EC-ASA
A	Buffex Sani-Pak	A	Ecaasa
A	Cama	A	Ecasa
A	Chew ASA	A	Ecofair
A	Chew Baby ASA	A	Ecotrin
A	Chewable ASA	A	Ecotrin (Coated Aspirin)
A	Chewable Aspirin	A	Ecotrin (Enteric Coated)
A	Chewable Aspirin	A	Ecotrin ASA
A	Chewable Baby Aspirin	A	Ecotrin Aspirin
A	Child Chew ASA	A	Ecotrin GR V
A	Child's Aspirin	A	Ecotrin Grain
A	Children ASA	A	Ecotrin Grains
A	Children Aspirin	A	Ecotrin Maximum Strength
A	Children's ASA	A	Ecotrin Or Aspirin
A	Children's Aspirin	A	Ecotrin-Coated Aspirin
A	Children's Chewable ASA	A	Ecotrin-Coated Aspirin
A	Children's Chewable Aspirin	A	Ectasa-Orange
A	Childrens ASA	A	Empirin
A	Childrens Aspirin	A	Empirin Aspirin
A	Childrens Chewable ASA	A	Enc ASA
A	Childrens Chewable Sa	A	Encaprin Maximum Strength
A	Childs ASA	A	Encaprin Regular Strength
A	Childs Chewable ASA	A	Encoprin
A	Cild Chew ASA	A	Ent. Coated ASA
A	Coat-A-Prin	A	Entab-650
A	Coated ASA	A	Entaprin
A	Coated Aspirin	A	Entericote
A	Coated Baby Aspirin	A	Enteric Coated Aspirin
A	Coated Baby Aspirin	A	Enteric ASA
A	Coated Low Dose Aspirin	A	Enteric Aspirin
A	Coprin	A	Enteric Coated ASA
A	Cosprin	A	Enteric Coated Aspirin
A	Daily Aspirin	A	Enteric Coated Aspirin Grains
A	Daily Aspirin	A	Enteric Coated Baby ASA
A	Dasprin	A	Enteric Coated Baby Aspirin
A	Dewitt's Aspirin	A	Enteric Coated Baby Aspirin
A	Dewitt's Children's Aspirin	A	Enteric Coated One Aspirin
A	E ASA	A	Enteric Coated Or Buffere
A	E-ASA	A	Enteric Coated Aspirin
A	E-Co-Aspirin	A	Enteric-Coated Aspirin
A	E.C. ASA	A	Enteric-Coated Aspirin
A	E.C. Prin	A	Enteric-Coated Aspirin
A	E.C.ASA	A	Enterically Coated Baby Aspirin
A	Easa	A	Enterin

A	Entrogesic	A	Regular ASA
A	Entrophen	A	Ridiprin
A	Genacote	A	Salagen
A	Gennin	A	Sloprin
A	Genprin	A	Soluable ASA
A	Grain Aspirin	A	Solualde ASA
A	Halfprin	A	Soluble ASA
A	Hipirin	A	Soluble Aspirin
A	Kiddies Aspirin	A	Special Buffered Aspirin
A	Lite Coat Aspirin	A	St. Joseph Aspirin
A	Lite-Coat Aspirin	A	St. Joseph Aspirin Children
A	Litecoat Aspirin	A	St. Joseph Low-Dose Aspirin
A	Magnaprin	A	Stanback Analgesic
A	Maprin	A	Stanback Max Analgesic
A	Maprin A/D	A	Tri Buffered Aspirin
A	Maprin I-B	A	Tri-Buff Aspirin
A	Measurin	A	Tri-Buffered Aspirin
A	Megaprin	A	Tri-Buffered Bufferin
A	Minitab	A	Tribuffered Aspirin
A	Noncoated ASA	A	Trinprin
A	Noncoated ASA	A	TX-Prin
A	Noncoated Aspirin	A	Ud Aspirin
A	Noncoated Aspirin	A	Uni-As Plus
A	Noncoated Aspriin #5	A	Uni-As Plus A/F
A	Noncoated Aspriin #5	A	Uni-Asplus
A	Norwich Aspirin	A	Uni-Asplus A/F
A	One Baby Aspirin	A	Uni-Buff
A	Or-Prin	A	Uni-Buff 3
A	Over Abundance Of ASA	A	Uni-Tren
A	Pain Reliver Super Strength	A	Valumag W/Aspirin Buffered
A	Pediatric Aspirin	A	Verin
A	Poaby ASA	A	Zorprin
A	Quality Aspirin	A	Zorprin SR
A	Reg ASA		
A	Reg ASA		
A	Regular ASA		

ACE Inhibitors

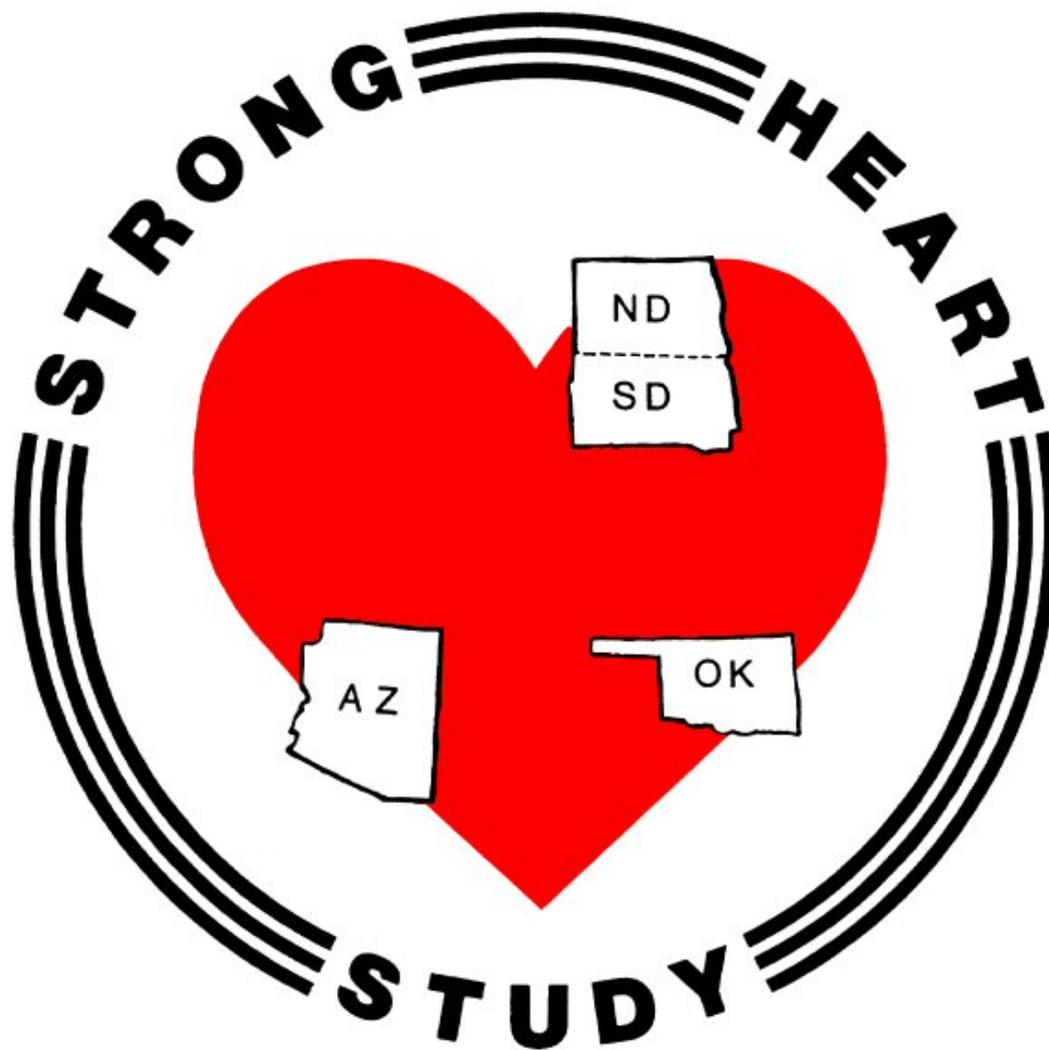
- A Accupril
- A Altace
- A Amlodipine/Benezepril HCL
- A Benazepril
- A Benazepril HCL
- A Capoten
- A Capozide
- A Captopril
- A Enalapril
- A Enalapril maleate
- A Enalapril Maleate HCTZ
- A Enaliprilat
- A Fosinopril
- A Fosinopril sodium
- A Lexel
- A Lisinopril
- A Lisinopril HCTZ
- A Lotensin
- A Lotensin HCT
- A Lotensin HCT
- A Lotrel
- A Mavik
- A Moexipril HCL
- A Monopril
- A Quinapril
- A Quinapril HCL
- A Ramipril
- A Prinivil
- A Prinizide
- A Trandolapril
- A Univasc
- A Vaseretic
- A Vasotec
- A Zestoretic
- A Zestril

Beta Blockers

A	Acebutolol	A	Lopressor
A	Acebutolol HCL	A	Lopressor HCT 100/50
A	Atenolol	A	Lopressor HCT 100/25
A	Atenolol/Chlorthalidone	A	Lopressor HCT 50/25
A	Betabloc	A	Lopressor HCT
A	Betapace	A	Metoprolol
A	Betaxolol	A	Metoprolol succinate
A	Betaxolol HCL	A	Metoprolol Tartate/HCTZ
A	Bisoprolol	A	Metoprolol tartrate
A	Bisoprolol fumarate	A	Nadolol
A	Bisoprolol Fumarate/HCTZ	A	Novanpranol
A	Blocadren	A	Penbutolol
A	Carteolol	A	Penbutolol sulfate
A	Carteolol hydrochloride	A	Pindolol
A	Cartrol	A	Propranolol
A	Corzide	A	Propranolol HCL
A	Corgard	A	Sectral
A	Detensol	A	Sotalol
A	Esmolol	A	Sotalol HCL
A	Esmolol Hydrochloride	A	Tenoretic
A	Inderal	A	Tenormin
A	Inderal LA	A	Timolide
A	Inderide	A	Timolol
A	Inderide LA	A	Timolol maleate
A	Inderide LA	A	Timolol Maleate/HCTZ
A	Kerlone	A	Toprol XL
A	Levatol	A	Visken
A	Levatrol	A	Zebeta
		A	Ziac

Anti-lipemic Agents

Atorvastatin
Atromid-S
Atromids
Baycol
Cerivastatin
Cholestin
Cholestyami
Cholestyram
Cholestyramine
Cholestyram
Cholestyrami
Choloxin
Clofibrate
Colesevelam
Colestid
Colestipol
Colestipolhc
Fenofibrate
Fluvastatin
Gemfibrozil
Lescol
Lipitor
Locholest
Lopid
Lorelco
Lovastatin
Mevacor
Niacin
Niaspan
Nicotinic Acid
Pravachol
Pravastatin
Prevalite
Questran
Questranlight
Simvastatin
Slo-Niacin
Tricor
Welchol
Zocor



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Three

PERSONAL INTERVIEW AND GENERAL EXAMINATION

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Three

PERSONAL INTERVIEW AND GENERAL EXAMINATION

June 1, 2001

For copies, please contact

Strong Heart Study Coordinating Center

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VOLUME III
PERSONAL INTERVIEW AND GENERAL EXAM

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CHAPTER ONE

Clinical Examination - General

1.1 INTRODUCTION

Tribal members who are members of one of the families selected for study and who are at least 15 years of age will be invited to enter the Phase IV exam. Persons who are institutionalized will be excluded. Pregnant women will be examined at least six weeks post partum, and lactating women at least six weeks post partum. All those family members who participated in the Phase III exams and all members of families newly identified in Phase IV are eligible for the Phase IV exam. This component of the study consists of a personal interview, a limited physical examination, and laboratory tests. The objectives are to estimate the prevalence of CVD and its risk factors, to evaluate the heritability of CVD and risk factors through linkage analysis, and, when possible, to assess the degree of association between the risk factors and CVD.

The examination will be conducted at local IHS hospitals, clinics, and tribal community facilities. In the Dakotas, it will be performed at the Aberdeen Area IHS hospitals and private clinics on three reservations. In Phoenix, the Tribal hospital at Sacaton (GRIC), the Tribal outpatient clinic at Salt River (SRIC), the outpatient clinic at AkChin, and various community centers will be the examination sites. In Oklahoma, the IHS hospital in Lawton and the IHS clinic in Anadarko will provide space and facilities for the examination. In some Communities, SHS will need to rent clinic space to perform the examinations, because of lack of space at IHS facilities.

The objectives of the Strong Heart Study and the examination procedures will be explained to the participants, and informed consent will be obtained from each participant. A parental consent form will be obtained in the case of participants under 18 years of age. Appendix A contains the adult consent form and the comparable form for minors that are signed by the participant (and parent in the case of a minor participant) for each of the 3 field centers.

All examinations are performed by trained personnel, nurse practitioners, registered nurses, medical assistants, health profession students, physician assistants or physicians. All examination items are within the scope of training that these providers have received and are usual, if not daily, parts of physical examinations. Detailed descriptions and training are aimed at achieving consistency from examination to examination, and among centers. This is the main goal of this component of the protocol.

The training of the registered nurses, nurse practitioners, health profession students, physician assistants and physicians on the Phase IV protocol occurred on January 29 to February 2, 2001 at the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma and was based on the written protocol. Each Study Center has designated a primary examiner and at least one other person who is available to perform examinations in the absence of this primary person.

Certification requires adequate performance of the components of the examination as validated during training. In case of loss of a center's staff member, a replacement may be trained locally by someone certified in the procedure(s). The same certification requirements as used in the initial training must be met. Quality control focuses on the potential for false positive examinations. Because most participants are healthy, the frequency of abnormal findings is relatively small. The presence of real abnormalities among those with normal examinations is also small (a low false negative rate), and this makes it inefficient to re-examine the many individuals with normal findings. The review of positive findings is part of the medical data review. After the initial training, continuing education includes regular review of the protocol.

1.2 COMPONENTS OF THE CLINICAL EXAMINATION, ENDPOINTS AND RISK FACTORS

1.2.1 Components of the Clinical Examination

The clinical examination has two parts: a personal interview and a physical examination.

1. Personal Interview

The following questionnaires will be administered:

- 1) Demographic information: tribal enrollment, Indian heritage, use of native language, income, education, residence, marital status, number of household members and employment will be determined.
- 2) Health habits: Smoking, alcohol intake.
- 3) Medical history, including reproductive history, respiration/snoring, and Rose questionnaire for angina pectoris and intermittent claudication will be assessed.
- 4) Dietary survey: The Block Food Frequency questionnaire as modified to add foods identified in Phases II and III to be commonly eaten in SHS communities, will be self-administered following instruction by clinic staff.
- 5) Psychosocial information: MOS SF-12, locus of control, cultural factors, and CES-D questionnaires to assess quality of life, depression, and social support. An anger/hostility questionnaire will be optional (it will be administered in the Dakotas).

2. Physical Examination

The physical examination includes the following procedures that were used previously:

- 1) Anthropometric measurements will be made with participants in loose clothing without shoes, and with heavy objects removed from pockets:
 - i) Weight -- The scale will be balanced on a level and firm surface prior to weighing a participant. The participant will stand in the middle of the scale platform, head erect and looking straight ahead. Results will be rounded to the nearest kg.

- ii) Height -- The participant will stand erect on the floor with his back against the vertical mounted ruler, heels together and looking straight ahead. The right angle will be brought down snugly but not tightly on the top of the head so that height can be accurately measured and rounded to the nearest centimeter.
 - iii) Waist and hip circumferences -- For the waist, anthropometric tape will be applied at the level of the navel with the patient supine and breathing quietly. Results will be rounded to the nearest cm. For the hip, the participant will stand erect but relaxed with weight distributed equally over both feet. The measure will be made at the level of maximum protrusion of the hips with the tape kept horizontal. These measurements are rounded to the nearest centimeter.
 - iv) Body fat measurement -- Using an RJL bioelectric impedance meter, resistance and reactance are recorded. Percent body fat will be estimated by the RJL formula based on total body water.
 - v) Arm circumference -- The participant will sit with his right arm hanging freely, with the right hand resting on the right knee. The tape measure will be placed horizontally at the midpoint between the acromium and olecranon. Results will be rounded to the nearest cm. The measure will be used to select the proper size blood pressure cuff.
- 2) Examination of the following:
- i) Pedal pulses – With the participant supine, the presence of posterior tibial (palpating inferior to the medial malleolus of each foot) and dorsalis pedis (palpating superior) pulses will be determined.
 - ii) Ankle edema -- With foot coverings removed, participant will be examined in the supine position. Gentle but firm pressure will be applied along the mid-tibia, anteriorly down to the ankle in each leg. The degree of edema (0-4) will be recorded.
- 3) Blood pressure measurements:
- i) With the participant sitting with right arm on table, the cuff will be connected to a standard manometer and the pulse obliteration pressure will be established and recorded. After five minutes, the cuff will be reconnected and inflated to +30 mm above the obliteration pressure and held constant for 5 seconds. The cuff will be slowly deflated (2 mm/sec) while reading pressures for 1st and 5th phases. Before measurements 2 and 3 are taken, the participant will raise the arm for five seconds. After another 25 seconds with arm on the table, the measurement will be repeated a second and third time. The average of the last two measurements will be used for analysis.
 - ii) Using a Doppler, with the participant supine, right brachial and both ankle systolic pressures will be measured two times.

- 4) Twelve-lead resting ECG measurement -- Using a Marquette Mac-PC or MAC 1200 EKG machine, a 12-lead EKG will be obtained in a standard manner. EKGs will be electronically transmitted to Cornell University, and confirmed interpretations will be transmitted back to the field location to be filed in the participant's medical record. Tracings will be Minnesota coded electronically.
- 5) Fasting blood samples for measurements of total triglyceride (TG) and cholesterol, LDL and HDL cholesterol, LDL size, apolipoproteins AI & B, Lp(a), apo E genotype, plasma fibrinogen, and PAI-1, and DNA isolation, glucose, creatinine, insulin, chemistry profile, and CBC will be obtained. *As a point of clarification, ALL tubes will be taken from patients who are on renal dialysis or have had a kidney transplant.*
- 6) Urine will be collected at the beginning of the physical examination for measurement of albumin and creatinine.
- 7) Ultrasound examination of the carotid artery: See Volume V of the Manual for details.
- 8) Echocardiography: See Volume V of the Manual for details.
- 9) Tonometry of the radial artery: See Volume V of the Manual for details.
- 10) Pedometry will be used to assess physical activity of the participants at home for one week. Each participant will wear an Accusplit Activity meter for 7 days (from waking till going to bed each day), recording daily activity counts in a diary, and returning the diary to the clinic after recording 7 consecutive days of activity.

For those family members returning for reexamination, they will not be asked questions regarding things that do not change, such as Tribal enrollment and Indian heritage. In addition, Apolipoproteins B & AI, Lp(a), apo E genotype, chemistries, and CBC will not be reassessed.

The IHS medical records will also be reviewed to determine whether the participant was hospitalized or received out-patient treatment for ESRD, stroke, myocardial infarction, or other manifestation of CVD.

A checklist to be used for the physical examination and a reminder of post examination activities are given in Appendix A-2 (a) and (b).

The clinical examination will last approximately three hours. The participant will arrive at the clinic fasting in the morning. After registration, a study staff member will explain the study and procedures to the participant, answer questions, if any, and have the consent form signed. A consent form will be signed by parents of all participants under 18 years of age, and participants under 18 years of age will also sign the form indicating their willingness to participate. The participant will then be instructed to go to the laboratory for blood drawing and

to provide a urine specimen. The participant will then be offered a light snack. The nurse clinician and other staff will then conduct the personal interview, obtain anthropometric measurements, blood pressure, impedance measurement for body fat composition, and obtain an echocardiogram, an ultrasound assessment of the carotid artery, radial artery tonometry, and ECG measurements. After all the procedures are completed, the participant will receive payment or sign the payment form and be thanked for his/her participation.

If possible, all of the components, except for the FFQ, psychosocial questionnaire, and echo exams, should be completed in one visit. If an individual leaves before the examination is completed, it must be completed before the study is completed. The personal interview and consent may be completed up to two weeks prior to the physical examination if such arrangements are more convenient. The FFQ and psychosocial questionnaires may be given to the participant to complete before attending the clinic visit. If they are not complete, every effort should be made to have the participant complete them while in the clinic for the rest of the exam.

1.2.2 Endpoints and Risk Factors

A. MORBIDITY EVENT CRITERIA

1. Definite Myocardial Infarction (MI)

Minnesota codes 1.1.x or 1.2.x except 1.26. and 1.28 with no 7.1 or 7.4
or History of MI verified by chart review as definite MI

2. Possible Myocardial Infarction

Minnesota codes 1.3.x, 1.2.6, or 1.2.8 with no 7.1 or 7.4
or History of MI verified by chart review as possible MI

3. Definite Coronary Heart Disease (CHD)

Definite MI,
or Definite CHD verified by chart review to include cardiac cath, proven coronary artery
disease, PTCA, coronary artery bypass grafting, or abnormal stress ECG plus abnormal
imaging (i.e., both must be abnormal),
or Angina Pectoris plus LBBB (7.1.1) or
ST changes (4.1) or
T wave changes (5.1) or
verified possible MI,

4. Possible Coronary Heart Disease

Possible ECG MI (1.3.x, 1.2.6, 1.2.8)
or Angina Pectoris
or Minnesota codes 7.1, 4.1, 4.2, 5.1, 5.2, 7.4
or Unconfirmed history of MI
or Positive functional test of ischemia (such as treadmill) without invasive confirmation
or Possible ECG or imaging in scintigraphic studies (not both).

5. Definite Cardiovascular Disease (CVD)

Definite CHD
or Congestive Heart Failure
or Cardiomyopathy
or Valvular Heart Disease
or Left ventricular Hypertrophy by Echocardiogram
or Left ventricular Hypertrophy by ECG (3.1 or 3.3 plus 4.1-4.3 or 5.1-5.3)
or Ankle Arm Index ≤ 0.8
or Atrial Fibrillation
or Minnesota codes 4.1, 5.1, 6.1, 6.2, 6.8, 7.1, 7.2, 7.4
or Non-coronary heart surgery or carotid or other vascular surgery

or Pacemaker implantation
or Bruits by physical examination
or Intermittent Claudication by Rose Questionnaire
or Positive non-coronary angiography

1.3 RECRUITING

1.3.1 Recruitment Techniques

Always remember that the participant is here on a voluntary basis.

Recruiting participants to the Strong Heart Family Study is more than simply getting the person to come into the clinic for an exam. Their participation in the Study is the result of an ongoing effort of Strong Heart personnel to recognize, establish trust with, and care about the people who take time to participate in the Study. Without our participants, we have no Strong Heart Family Study.

Greet people wherever you see them. Call them by name and make the effort to greet them first.

Take time to be in places like the Tribal Office, Post Office, Hospital and any location where there is a large gathering of people. Talk gently with them about other subjects and then slowly talk with them about Strong Heart participation.

Don't sit in the car and honk the horn when making home visits (**unless you have safety concerns**). Walk to the door and tell them why you are there. Take the initiative to visit with them first and see how they are.

People without a car often feel shut-in and frustrated. It is important to visit with them about a variety of things first before approaching them about participating in the Study.

Sometimes, when possible, it helps to offer a helping hand in things that need to be done, let people know that you recognize them as a person and not only a participant.

Dress casually and never act like you can't be touched with a ten-foot pole.

Enjoy your home visits as most people like someone coming in with a smile. It really helps to enjoy what you do.

Be patient and explain things in a variety of ways so that people will understand what they are being asked to do.

PLEASE always remember that the client is a volunteer. Treat them with courtesy and recognize that they have often gone to a great deal of effort in both time and energy in coming into the clinic to participate.

Recruiting is not a 9 to 5 job. It is important to recognize the people who do it very well and to support them.

Set goals that are clear to all personnel and allow sufficient time for the recruiters to reach them. Everyone should contribute to the recruitment effort.

Recognize the daily rhythms of your community. Some participants are affected more by the community events, seasons and check days than others are. Try to be sensitive to the participant's needs when scheduling.

Let participant know you may not have answers to all questions, but that you will try to find answers **and follow-up**.

Let people know you will provide transportation to and from clinic when necessary.

Give people encouragement, even when they are doing well.

Research Clinic is not a "priority" to some people. Take your time - don't reschedule them continuously.

When approached by people who express interest in the heart study, get names of the person, both parents and grandparents, and tell them you'll see if they fit in one of the family pedigrees.

Be willing to let the participant take part in as much as possible. Although it is ideal to have the participant complete the entire exam at once, it is not always possible. Be willing to adjust your schedule to accommodate the participant.

Regular team meetings are important in setting goals, communicating with team members in a meaningful way, in helping to focus efforts and in supporting the efforts of the personnel. Sometimes personnel can become discouraged when events do not go as they were planned. This does not have to mean that things are going badly. Be aware of staff burn-out and the need to stop and to promote other team members or to give them a helping hand.

There may be times a "potential" participant is going through a personal crisis. Allow them time to deal with it and go back in a couple of weeks, if possible.

1.3.2 Recruitment Instructions

For the Phase IV clinical examination, we will recruit selected individuals who participated in the Phase I exam, and members of their families. Our goal is to recruit large families in which many family members (fathers and mothers of Phase I participants, the participants' children, and other relatives) are willing to participate. Eligible study participants who have large families are being identified through the Strong Heart Study database and a list will be provided to recruiters. Individuals will be contacted in an order convenient for each center. Local publicity campaigns and mailed information will alert participants before participation is requested.

When contacting an eligible participant, the interviewer introduces the Strong Heart Family Study and explains its purpose and importance. A brochure and a letter explaining the

purpose of the study and exam are used for recruitment. The voluntary nature of the study and the confidentiality of the collected data are stressed. If the subject is not at home at the time of the phone call or visit, call backs are made as necessary to meet the individual and schedule the clinic appointment. 100% participation is the goal.

In all areas, the recruiter should wear an identification badge. When scheduling appointments, the recruiter should emphasize the following:

1. That the volunteer should not eat breakfast the morning of the exam and should not eat or drink anything but water after 9:00 p.m. the previous evening;
2. That the volunteer should bring with him/her all medications, which he/she has been prescribed and is currently taking (including any they purchased on their own);
3. That the volunteer should not take their morning diabetes medication until blood drawing is completed;
4. That the volunteer should not use tobacco or engage in vigorous activity before the clinic visit;
5. That the volunteer should wear loose clothing (ladies should wear a skirt and blouse or pants and shirt, rather than a dress).

If the participant is *mentally handicapped* or otherwise mentally incapacitated, a surrogate must accompany him/her to the examination, preferably someone who is very familiar with the medical and family history.

The recruiter schedules the appointment with the clinic for each subject. Whenever possible, eligible members of a single household are scheduled on the same day. The recruiter should also verify name, address, and social security number at the time of the recruiting visit. When possible, participants should be reminded by phone or in person the day prior to the visit.

After the visit appointment is made, the clinic staff should assemble all forms and labels necessary for the exam and arrange *when possible*, to have the hospital chart for that participant available the morning of the clinic visit.

1.3.3 Recruitment Form

The recruitment form (see Appendix B of this volume) will be used to collect information on family members. A form should be completed for each person who is recruited into the Strong Heart Family Study. This means that a form is needed for every family member who participates. The form has several pages. The Strong Heart Family Study ID number should be entered in the upper right corner of each page. In the upper left corner of every page of the form, enter the family number and the household number. If the family is so large that the form does

not have enough spaces for entering information on all family members, please contact Dr. Jean MacCluer or Dr. Kari North in San Antonio. They will provide instructions for collecting the information on additional family members.

Page 1:

On the first row of page 1, enter information about the person being interviewed (the participant). On the following rows, enter information for the participant's mother and her parents and the participant's father and his parents.

Next, enter information about the participant's spouses or partners. You don't need to record information about a spouse or partner unless he/she is the parent of one or more of the participant's children. Enter the first spouse or partner in the row labeled 1, the second in the row labeled 2, and so on.

Next, enter information on the participant's sons and daughters. For each son or daughter, circle 1, 2, 3, or 4, to indicate who is the other parent of the son or daughter. The total number of sons and daughters refers to the total across all pages.

Page 2:

Page 2 provides space to list the participant's brothers and sisters. In the top section, enter information about full brothers and sisters (who share both parents with the participant). The total number of brothers and sisters refers to the total across all pages.

Next, enter information about the parents of the participant's half brothers and half sisters (who share only one parent with the participant). For example, if the participant and her half sister have the same mother but different fathers, enter information for the half sister's father. There is enough room for information on four different parents of half brothers and half sisters.

Next, enter information on the participant's half brothers and half sisters. For each half brother or half sister, circle 1, 2, 3, or 4, to indicate who is the other parent of the half brother or half sister (the parent not shared with the participant). The total number of half brothers and half sisters refers to the total across all pages. *(if the spaces are not sufficient to enter information on the half siblings other parent, use an additional page?)*

Page 3:

Page 3 is a supplement, which may be used to record additional children if there is not enough room on page 1. It is to be used if the participant has more sons and daughters by spouses/partners 1, 2, 3, and 4 than can be recorded on page 1.

Page 4:

Page 4 is a supplement, which may be used if the participant has more than four spouses/partners. The top section provides space to enter information on as many as four additional spouses/partners (numbers 5, 6, 7, or 8).

Next, enter information on the participant's additional sons and daughters by these spouses/partners. For each son or daughter, circle 5, 6, 7, or 8, to indicate who is the other parent of the son or daughter.

Page 5:

Page 5 is a supplement, which may be used to record additional brothers and sisters if there is not enough room on page 2. The total number of brothers and sisters refers to the total across all pages.

Page 6:

Page 6 is a page at the end of the Recruitment or Family Information Form provided for confidential comments. If used, it should be detached from the form and sent immediately to:

Dr. Kari North
Department of Genetics
Southwest Foundation for Biomedical Research
7620 N.W. Loop 410
San Antonio, TX 78227-5301.
Phone: (210) 258-9772
Fax: (210) 670-3317
email: knorth@darwin.sfbr.org

1.4 PERSONAL INTERVIEW

1.4.1 Components of the Personal Interview

The personal interview is designed to obtain demographic information, family history, medical history, health behavior, acculturation and stress data that are considered important in identifying risk factors for cardiovascular disease. The following questionnaires (see forms in Appendix D of this volume) will be administered during the clinical examination (note: diet (item #9) and psychosocial (item #10) forms are self-administered and may be given to the participant up to 2 weeks prior to the exam):

1. Pregnancy/lactation screen
2. Personal Interview Form (I and II)
3. Medical History Form
4. Reproduction and Hormone Use
5. Rose Questionnaire
6. Respiratory
7. Medication Use
8. Family Information Form (see Appendix B)
9. Dietary Form (Food Frequency Questionnaire - FFQ)
10. PSYCHOSOCIAL QUESTIONNAIRES
 - Cultural Factors
 - Quality of Life (SF-12)
 - CES-D
 - Locus of Control
 - Social Support
 - Anger/Hostility - optional
 - Psychosocial Checklist

Personal living habits such as dietary, cigarette smoking and alcohol consumption, and stress have been considered as important risk factors for cardiovascular disease. Data on these factors as well as demographic information will be collected by using the Personal Interview Forms (I and II) and the FFQ. Other pertinent forms are the Medical History Form (questions on medical conditions), the medications form, and the Rose Questionnaire for angina pectoris and intermittent claudication. These questionnaires are included in Appendix D.

1.4.2 Guidelines for Interviewers

1. Introduction

The personal interview is probably one of the most important procedures for data collection in epidemiologic research. The personal interview usually increases response over self-administered questionnaires. Most of the SHS questionnaires are interviewer administered with the exception of the diet (FFQ) and psychosocial forms, which are designed to be self-

administered. The interviewers will need to assist some participants in completely filling out those forms.

When rapport is established between the interviewer and the interviewee, the interview has been shown to be an excellent source of high quality information for epidemiologic research purposes. However, the interviewer must be able to show tact, care, and sensitivity to be effective. Not everyone can become a successful interviewer.

Also, the personal interview can lead to a lack of standardization in the data collected, particularly in a multicenter study such as the Strong Heart Family Study. Since the interviewer is known to have a large effect on the quality of the data obtained, interviewer training is very important. Please read this interviewer's manual frequently, and refer to it as needed during the study. It is also recommended that each Study Coordinator hold monthly interviewer meetings to go over common problems and clear up any questions about the interview procedures and the interview forms in the Strong Heart Family Study. If there are ever questions about the proper procedures for collecting study data, please look to the manual as the authority. If problems are identified, changes will be made to the manual. Therefore, it is important to keep the manual updated and readily available to maintain consistency across centers. Consistency is extremely important if data across the centers in the Strong Heart Family Study are to be used in combined data analyses.

2. Types of Interviews

Structured versus Unstructured Interviews

In an unstructured interview the responses to questions are open-ended, and information given is to be recorded as given. In a structured interview the questions are usually closed, with a specific set of answers provided in the questionnaire.

For the Strong Heart Family Study, we are using both structured and unstructured interviews. The use of structured interviews is the best way to maintain consistency in the data being collected. Interviewer training is important in order to maintain as much consistency in the interviews between study centers as possible.

Because we are using structured and unstructured interviews, we can achieve even more consistency if all interviewers conduct the interviews in a similar way. Therefore, ask each question as it is written. Do not reword the question. Also, ask the questions in the order they are given in the interview form. Hopefully, by following these procedures we can achieve a high degree of consistency in the way the interviews are conducted.

3. Style of the Interview

The interview style is also important and some of the components that are generally considered to be acceptable interview style are listed below. In addition to the components of style listed below, the following interviewer characteristics are also very important: Politeness is very important since we will be asking sensitive questions to strangers, in a situation where they

may be uncomfortable. Sensitivity on the part of the interviewer is also important, in order to know how and when to be more or less assertive in asking for information. Besides these qualities, please develop your style in accordance with these guidelines:

- a. Non-judgmental, non-evaluative style. A large portion of the impression, which the respondent has of the interviewer is based solely on the interviewer's voice and the manner with which the interviewer responds to the respondent's comments. A judgmental or evaluative response would indicate that the interviewer has made a judgment of the relative goodness, appropriateness, effectiveness, or rightness of the respondent's statement. The interviewer should not, in response to the respondent's statements, state what the respondent should or should not do in a given situation. The interviewer's task is simply to ask the question and record the participant's answer.
- b. Non-interpretive style. As above, the interviewer should not use a style that might be considered teaching or preaching. An interpretive response is one which indicates that the interviewer's intent is to teach. We are interested in the respondent's impression of what was happening, not in the interviewer's impression.
- c. Allow for respondent to complete sentences. Do not try to help the respondent by answering the questions for him/her. No matter how slowly the respondent is speaking, putting words in the respondent's mouth or not allowing the respondent to finish thoughts will generally alter the information which the respondent is attempting to give. However, long hesitations may be bridged by asking appropriate questions.
- d. Supportive remarks. Remarks which indicate that the intent of the interviewer is to reassure, to pacify, or to reduce the intensity of the respondent's feelings are appropriate. However, these should be in keeping with local terms and expressions, and should be short so as not to detract from the interview itself.
- e. Probing. This is an important response style which will be discussed further. A probe is a response which indicates that the interviewer's intent is to seek further information, to provoke further discussion along a certain line, or to question the respondent. Direct probes will be specific questions about details of what the respondent said.
- f. Non-directive, or understanding. A typical non-directive response might be "I see". This is the general idea of understanding murmuring. The interviewer might also repeat what the respondent just said. This may prompt the respondent to elaborate.

4. Gain Rapport with the Interviewee before Commencing Interview

The first step in gaining the confidence of the respondent is a straightforward, believable introduction of the interview and the reason for this contact. It may help in gaining rapport with the respondent if you tell him/her a little about yourself, such as where you are from, and your background, etc. If the respondent seems to hesitate or has some questions, the interviewer must be prepared with a more detailed explanation of why the information is needed. Also, if the respondent raises the issue of the confidentiality of the information collected, the interviewer must be prepared to reassure him/her of the precautions taken to respect their privacy.

5. Interviewer Error

We should try to minimize interviewer error during this study. The primary objectives of epidemiologic research are (1) to obtain measurements of exposure and disease variables relevant to the objectives of the study, and (2) to maximize completeness and minimize error in these measurements. The presence of an interviewer may both reduce error and increase error. It may reduce error by increasing the response rate, motivating the subject to respond well and probing to obtain complete data when the responses volunteered fall short of what is desired. The presence of an interviewer may increase error if, by his or her appearance, manner, method of administration of the questionnaire or method of recording of the responses, he or she exerts a qualitative influence on the subject's responses. Possible sources of error in the interview for data collection include (1) conditions of administration (privacy, heat, light, ventilation, freedom from distraction, lack of time, etc.); (2) interaction of the personality, sex or race of the interviewer with that of the subject; and, (3) performance by the interviewer (questioning, prompting and recording of responses).

The following are the common interviewer errors:

- a. Asking errors. Omitting questions or changing the wording of questions. This may be particularly important if the interview is performed in Native language.
- b. Probing errors. Failing to probe when necessary, biased probing, irrelevant probing, inadequate probing, preventing the respondent from saying all he or she wishes to say.
- c. Recording errors. Recording something not said, not recording something said, incorrectly recording response.
- d. Flagrant cheating. Not asking a question but recording a response, recording a response when the respondent does not answer the question asked. These kinds of errors do occur and this has been amply documented by various studies. Cheating has been shown to be more common when the interviewer is in an uncomfortable situation with the interviewee, i.e., he/she is difficult. In such situations the question should still be asked and if the participant refuses to answer the question(s), the refusal should be documented on the form.

6. Circumstances for the Interview

We will not have very much control over the circumstances for the interviews. However the following should be considered in arranging for conducting interviews:

- a. Time. There will be little control over the time of the interviews, since we will have many different interviews to carry out over a short period of time. When possible, the interview should be conducted after the snack has been served, otherwise the interviewee may tend to be somewhat uncomfortable.
- b. Place. The place for the interview should be chosen where there are as few distractions as possible. Try to select a place where the location is quiet, comfortable and private. If it is possible, it is ideal to sit at a table, with the interviewer facing the interviewee, so that the interviewer can organize the papers. Privacy is very important. If the respondent will need to refer to records during the interview, be sure that the records are available before the interview begins.

7. Asking Procedures

In general the rules for asking questions in structured interviews can be summarized as follows:

- a. Questions must be asked according to the instructions for each form and question. Be sure to read and re-read the instructions for each questionnaire you are using, and to ask all the questions in the same way to each person interviewed.
- b. Read the questions exactly as they are worded in the questionnaire. If the question is misunderstood, then it may be repeated, interchanging local terms, if necessary for understanding.
- c. Read each question slowly.
- d. Use correct intonation and emphasis.
- e. Ask the questions in the order that they are presented in the questionnaire.
- f. Ask every question that applies to the respondent (all inapplicable questions will be identified as such by skip instructions in the questionnaire).
- g. Repeat questions IN FULL that are misheard or misunderstood.
- h. Read all linking or transitional statements exactly as they are printed.
- i. Do not add apologies or explanations for questions unless they are printed in the questionnaire.

PROBING: Probes are additional questions asked or statements made by the interviewer when the answer given by a respondent is incomplete or irrelevant. Probing has two major functions: (1) To motivate the respondent to reply more fully; (2) to help the respondent focus on the specific content of the question. It must fulfill these functions without biasing the respondent's answers. However, probes, when they are used, **MUST** be neutral. Probing can introduce bias, such as by summarizing your understanding of the response to the subject when an unclear response has been given, or by offering some alternative interpretations from which the respondent can choose, and this must be guarded against.

The following are **NON-DIRECTIVE** methods of probing:

- a. Repeat the question (RQ). All that may be required to clear up a vague answer may be to repeat the question. You may begin by saying "I am not sure that I understood you, let me just repeat the question so that I can be sure to get your answer right."
- b. The expectant pause. Waiting expectantly will tell the respondent that the interviewer is expecting more information than has been provided.
- c. Repeat the reply. Repeating the reply aloud while recording it may stimulate the respondent to provide more details.
- d. Neutral questions or comments. Various neutral probes may be used for purposes such as clarification, specificity, or completeness: "What do you mean exactly?", "In what way?", "Could you be more specific about that?", "Anything else?", "Can you tell me more about it?"
- e. Interpretation. Make sure that the question was understood, since that may be the reason for incomplete answers. You may need to ask the question again, perhaps substituting some local terms, if there is a problem in interpretation.

FEEDBACK: The provision of feedback by the interviewer to the respondent about his or her performance has been the subject of much research. Some studies have shown that the use of feedback in health-related surveys increased the amount of reporting of most events. Your decision about whether to provide feedback may depend upon the performance of the person you are interviewing and your experience in the benefits of providing feedback.

8. Specific Instructions for Telephone Interviewing

The principles outlined above have been derived solely from research into and experience of face-to-face interviewing. While it is generally believed that these apply to telephone interviewing, the evidence that this is true is very limited. Telephone interviewing is probably not simply the transfer of face-to-face techniques to the telephone. Use of visual cues, such as "show cards", is impossible on the telephone and must be compensated for in questionnaire design. There is evidence that this compensation may lead to response differences. In addition, other non-verbal communication, both from the interviewer to respondent and respondent to interviewer, is absent. The "expectant pause", for example, may be much more difficult to use as

a probe for additional information on the telephone. It is also more difficult for the interviewer to establish the legitimacy of the interview on the telephone and the pace of the interview may be faster (because of the need to keep talking) leading to hurried and, perhaps, less thoughtful responses. On the positive side, the telephone should eliminate non-verbal biasing activity by the interviewer, and may encourage more honest reporting of threatening behaviors. Empirical data, however, have not shown consistent evidence of these effects.

9. Instructions for Recording Responses

In the study manual (Appendix C of this volume), each interview and form contains a set of instructions covering each question in the interview form to clearly describe the information that is being solicited. These instructions should be read carefully and understood before attempting to fill out an interview form.

In addition, see the attached instructions for filling out forms. The following are some additional guidelines for recording responses:

- a. Make sure that you understand each response.
- b. Make sure that the response is adequate.
- c. Do not answer for the respondent (i.e., do not infer a response from an incomplete or inadequate reply).
- d. Begin writing as soon as the respondent begins talking. (The respondent's interest may be held by repeating the response aloud as you are writing).
- e. Use the respondent's own words and record the answers verbatim.
- f. Include everything that pertains to the question's objectives.
- g. Note in the questionnaire the nature and place of each probe used.
- h. Do not erase anything. If a response is wrong, strike it out and enter the correct response above the previous response.
- i. Write "refused/8" beside any question that the respondent refused to answer.

1.4.3 Training & Quality Control of Interviewers

1. Training

Central training for interviewers was conducted at the training session in Oklahoma City (January 29 – February 2, 2001) prior to the start of exams. Interviewers were trained in the use of a standardized procedure for administering each questionnaire. Training included instructions

in research interviewing techniques and in completing each form. Interviewer skill training includes:

- (a) adherence to the standardized protocol
- (b) use of non-judgmental attitudes
- (c) degree and nature of prompting permitted
- (d) dealing with problem interviewing situations
- (e) handling participants' comments and recording relevant information on the note logs
- (f) post-interview responsibility for the data

2. Quality control of interviewers

To insure consistency and accuracy and to minimize interviewer variances, the study coordinator will monitor and tape one interview during the first exam month on interviews conducted by each interviewer. For "new staff", this should be repeated each month until the Coordinator determines that the interviewer has met the standards of the study. Then, new staff members will be observed on a quarterly basis along with the experienced interviewers. Should any interviewer fall short of the required standards, retraining will be required with special attention given to problem areas. If the problem persists, the interviewer will be removed from the task of conducting interviews.

1.5 RATIONALE FOR MEASUREMENTS

1.5.1 Blood Pressure

As blood pressure rises, so does risk of ischemic heart disease and its complications. The range of normal blood pressures is wide. Even within the "normal range", risk increases as the upper limits are approached. Usually, blood pressures are expressed as systolic pressure/diastolic pressure; values. 140/90 mmHg or higher are considered to be hypertensive for adults. Middle-aged persons with a diastolic blood pressure of 90-104 mmHg (so called "mild" hypertension) have a risk of heart attack that is about 70 percent higher than that of persons with a diastolic pressure under 80 mmHg (normal value). Persons with a diastolic blood pressure exceeding 104 mmHg (moderately severe to severe hypertension) have a risk more than twice that of those with a normal value. Hypertension is an especially strong risk factor for stroke, renal disease, and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure.

1.5.2 Measurement of Body Fat

Although early records are not conclusive, all evidence indicates that obesity among American Indians was rare until the last century. Their farming and hunting lifestyles which were associated with high degrees of physical activity and the lack of consistently abundant food sources, probably assured the maintenance of a lean population. However, with the advent of "Westernization" and the reservation system, obesity has increased steadily among all Indian tribes and is now a major health problem. It is thus essential to evaluate the extent of obesity in the individuals in this study in order to ascertain its heritability, role in cardiovascular disease, and relationship to risk factors such as diabetes and hypertension.

In the past, assessment of obesity in population studies was invariably accomplished either by algorithms such as ratios of weight to height, or by measurements of skin folds using calipers. This was because assessment of body composition required either very expensive equipment or time consuming procedures, such as underwater weighing. Within the past few years, instrumentation has become available to allow estimates of body composition from measurements of tetrapolar impedance. This measurement of bioelectrical impedance is quick and easy to perform and has been extensively validated against densitometry. These validations were first performed by Lukaski et. al. and by Roche et. al., in a wide variety of individuals. The conductivity increases in individuals with low percent body fat and the instrumentation calculates the percent body fat utilizing a computerized algorithm.

1.5.3 Anthropometric Measurements

Among obese individuals, the distribution of body fat is related to certain patterns of morbidity. Vague and co-workers have observed that body fat distribution differs among obese individuals, and that obese subjects can be roughly divided into two groups depending on whether accumulation of body fat is subcutaneous and peripheral (referred to as gynecoid or female type obesity) or whether the fat accumulation is central and primarily in the omentum (referred to as central or android obesity). The latter distribution has been shown in a number of

studies to be consistently associated with dyslipidemia, hypertension, insulin resistance, and cardiovascular disease. Most studies have shown that central obesity is a risk factor for coronary artery disease.

No systematic studies of body fat distribution or its heritability have been made among the American Indians. However, visual observations suggest that central obesity is much more prevalent among this racial group.

The quantification of central vs. peripheral obesity is not well standardized. Original studies were done simply by photographs and visual evaluations. This was supplanted by body circumference measurements with investigators generally taking the ratio of the body circumference at the waist to the hip or the thigh as a measure of fat distribution. However, it is clear that the body fat of interest in central obesity is the non-subcutaneous, and therefore, whole body scanning devices are necessary for a precise evaluation of this depot. Nevertheless, it has been shown in a number of population studies that the comparative circumference measurements are an approximation of the body fat distribution and the only practical techniques usable in a field study.

1.5.4 Measurements of Peripheral Vascular Disease

The atherosclerotic process affects vessels in many parts of the body. While the most conspicuous morbidity and mortality arise from coronary atherosclerosis, large vessel peripheral arterial disease (PAD) often results in significant incapacitation of the lower extremities and has also been strongly associated with the incidence of coronary heart disease. Criqui and co-workers have shown that large vessel PAD is strongly and significantly predictive of all cause mortality in both sexes with a relative risk of 4 to 5, and this was independent of other cardiovascular risk factors in a multivariate analysis. Moreover, data from the Framingham study indicate that diabetes was associated with an even greater magnitude of increase of peripheral vascular disease than was coronary heart disease. Little work has been done on PVD in American Indians or the extent of its heritability.

A thorough evaluation of peripheral arterial occlusive disease usually entails both a history and a physical examination including measurements of pulses and segmental blood pressures and then more complex measures such as angiography or sonography. The latter two techniques are both expensive and difficult to apply in a field setting. On the other hand, both Criqui et al and Beach et al have used segmental blood pressures measured by a simple doppler instrument in studies involving hundreds of patients. In addition, the correlation between quantitative velocity measurements and segmental blood pressures with occlusion as measured directly by angiography has been established.

Because of time limitations and economic consideration for purchase of equipment, the following indices of peripheral vascular disease will be made in this study.

1. Rose Questionnaire for intermittent claudication.
2. Palpation of posterior tibial and dorsalis pedis pulses.

3. Measurement of the ratio between blood pressures taken at the antecubital fossa (brachial) and ankle (posterior tibial) using a doppler listening device (Imex Elite 100 Doppler).

1.5.5 Electrocardiograms

All participants will have a resting electrocardiogram so that evidence for ischemic changes and left ventricular hypertrophy can be determined. Heritability of ECG abnormalities can be evaluated and related to their ability to predict CVD.

1.5.6. Overview of Laboratory Measurements

Table 1.1: Definition of Lipoproteins

Class	%Lipid	% Protein	Origin and Function
Chylomicrons	99	1	Intestine; transport of newly absorbed dietary fats; normally not detectable in plasma after a 12-hr fast; creamy layer on top of plasma tube after 12 hrs in the refrigerator.
VLDL, very low density	90	10	Liver; transport of newly synthesized triglycerides to peripheral tissue; lipoprotein approximately 80% of plasma TG is in this fraction
LDL, low density lipoproteins	75	25	Liver; derived from VLDL after the triglycerides have been metabolized; transport of cholesterol; approximately 75% of plasma cholesterol is in this fraction
HDL, high density lipoproteins	45	55	Liver and intestine; transport of cholesterol from peripheral tissues back to the liver

1. Lipoprotein Profile

Lipoprotein Physiology: Lipoproteins are basically spherical particles ranging widely in size and composed of two components: the lipids (or fats) in the core of the particle and the proteins on the surface of the particle. The two types of lipids, which we are interested in measuring as part of the present research, are triglyceride (TG) and cholesterol (CHOL). Depending on the relative amount of these two components and

various associated proteins, different classes of lipoproteins can be defined (Table 1.1 above).

The evidence is overwhelming from both cross-sectional and prospective studies in a wide variety of populations that total and LDL cholesterol are significantly associated with the occurrence of atherosclerotic coronary vascular disease (ASCVD), and the HDL cholesterol has a negative or "protective" effect. There are several lines of evidence that level of lipoprotein lipids and apoproteins are genetically determined.

The relationship of CVD with total triglycerides or VLDL triglycerides has been more controversial. Several population studies have now demonstrated an independent positive association between elevated triglycerides and ASCVD. Triglycerides are also closely linked to obesity, hyperglycemia and low HDL, and are therefore important to measure because of their reflection of these disorders. Some of the ambiguity concerning the associations between triglycerides and coronary vascular disease stems from the possibility that all elevations in triglycerides may not be equal. That is, elevated VLDL with a high proportion of protein, or cholesterol rich VLDL such as that observed in many diabetics may be more atherogenic than large, triglyceride-rich VLDL.

Measurements are made of total plasma cholesterol and triglyceride. HDL is measured after precipitation of LDL and VLDL. In SHS-IV, the LDL cholesterol concentration is estimated by the Friedewald formula for samples with triglycerides ≤ 400 mg/dl (variable name: LDL_EST) and directly measured when triglycerides > 400 mg/dl (variable name: LDL_DIRECT). For data analysis purposes, the two sets of data can be combined into a single LDL cholesterol variable, provided that the above protocol is mentioned in the methods section of potential publications.

LDL Direct Measurement: LDL cholesterol is directly measured by the precipitation of LDL cholesterol with buffered polyanionic reagent while leaving HDL and VLDL in the supernatant solution. The supernatant is then assayed using an enzymatic cholesterol reagent. The difference between the cholesterol value of the supernatant and the untreated specimen is equal to the amount of LDL cholesterol in the sample.

2. Glucose

Diabetes is a well-established, major risk factor for CVD and is very prevalent in the Strong Heart Study population. Impaired glucose tolerance, fasting hyperinsulinemia, and diabetes/obesity have strong genetic components, and the fasting plasma glucose test is a cost-effective test to detect these traits.

Glucose concentrations will be measured in fasting samples, and the diagnostic criteria developed by the ADA will be applied to define NGT, IFG and diabetes. Previous SHS data indicate prevalence rates of DM by ADA criteria are similar to those using OGTT, and that IFG and DM - ADA are similar to IGT and DM - WHO in predicting CVD. Blood for this assay is obtained in tubes containing fluoride to prevent consumption of glucose by WBCs. Previous studies have shown that tubes of blood containing fluoride

can be held on ice for up to four hours before isolating the plasma, and glucose values are stable. Glucose is measured on the Hitachi analyzer using a glucose oxidase technique.

3. Hemoglobin Alc

Hemoglobin Alc will be measured only in those individuals whose fasting plasma glucose ≥ 110 mg/dL. This is the same practice approved under Phase III, and it minimized the expense of measuring HbAlc in normoglycemic individuals. HbAlc may be a better marker of the entire symptom complex of diabetes than glucose values derived from the oral glucose tolerance test. Little et. al. reported that 68% of Pima Indians with impaired glucose tolerance and elevated HbAlc values went on to develop diabetes on follow-up testing 1/6 to 6.1 years later. Inclusion of HbAlc will give an integrated, longitudinal measure of glycemia and allow a better estimate of glucose control. It will also be of practical importance to both participants and field investigators.

4. Insulin

Insulin concentration in blood has been reported in several recent studies to be an independent risk factor for the development of CVD. Although the mechanism of this association has not been established, there are several intriguing possibilities involving its link with insulin resistance, hypertension, dyslipidemia, and thrombosis. The first three factors have been linked in several population studies in individuals with central obesity. However, some studies suggest that these factors are not universally associated. It will thus be of interest to measure fasting insulin concentrations in individuals at the three centers, to evaluate its heritability alone and in relation to blood pressure, triglycerides, body fat, waist/hip ratio and fibrinogen.

Insulin will be measured using an overnight radioimmunoassay developed as a modification of the method of Morgan and Lazarow. It utilizes a double antibody method; both antibodies and labeled insulin can be obtained efficiently from commercial sources. Although no absolute reference plasma pools are available for insulin, we have constructed our own control pools. The assay has proven to be stable over time with a coefficient of variation of 8-10%. One source of error in insulin measurements occurs in some individuals who have been previously treated with insulin, and thus have circulating insulin antibodies. Samples from insulin treated diabetics will be flagged at the time of drawing, so that their data can be separately evaluated.

5. LDL Size

Size of LDL particles can be estimated by gel exclusion electrophoresis. The smaller, faster-migrating LDL is termed the "B" type. It is atherogenic and strongly associated with coronary heart disease. The small dense LDL particle is associated with increased triglyceride and apoB levels, and decreased apoA1 and HDL cholesterol. The small LDL particle is more susceptible to oxidation and this may contribute to its atherogenic potential. A significant proportion of the risk of carrying the type B particle is genetically endowed, and there are important differences between the sexes.

6. Fibrinogen

Fibrinogen is well established as an independent risk factor for prevalent and incident CVD in many populations, and fibrinogen has been shown to be an independent predictor of CVD morbidity in SHS. Fibrinogen was highest in the Arizona participants (and quite high compared to other US populations) and lowest in the Dakota participants, being closely associated with diabetes prevalence. An analysis of the correlates of fibrinogen revealed that the strongest correlate of fibrinogen, by a large margin, was the level of albuminuria, independent of diabetes status. Fibrinogen may be linked to CVD either through its thrombotic or inflammatory properties. Fibrinogen levels have been closely linked to other measures of vascular disease such as ankle-arm blood pressure index, in other populations.

7. PAI-1

Several reports have indicated that PAI-1 may be an independent risk factor for CVD. This is an attractive scenario, because acute increases in PAI-1 have been associated with hypofibrinolytic states, a clinically significant situation requiring anticoagulation. In the Phase II exam, we measured PAI-1 in the cohort, and in the Phase III Strong Heart Study examination, we measured PAI-1 in the family members only.

Concerning PAI-1 levels and their changes over time, the following additional factors may play a role:

- 1) The mechanism for the association of PAI-1 with diabetes is unclear, and might be through insulin levels, lipid changes, and/or inflammation associated with vascular disease (as described above for fibrinogen) because PAI-1, like fibrinogen, is an acute-phase reactant. The triglyceride mechanism is intriguing because the lipid levels in the Arizona group were not as abnormal as might be expected from the diabetes prevalence.
- 2) There is a relatively common genotype (4G---> 5G change in PAI-1 promoter) that has been linked to the cytokine-mediated and insulin regulation of PAI-1. Measuring PAI-1 would allow us to test if changes in PAI-1 levels are modulated by 4G--->5G genotype, among other possible gene variations.

8. Urinary Albumin/Creatinine

Increased concentration of albumin in the urine of diabetic individuals is a strong and independent predictor of all-cause and coronary heart disease mortality. In a study of persons with type 1 diabetes, those who had microalbuminuria had nearly a 200-fold increased risk of cardiovascular disease in the decade following the initial observation compared to those whose urine had normal amounts of albumin. Furthermore, urinary

A/Cr is an independent predictor of CVD in SHS. These findings led to speculation the albumin “leak” in the glomeruli reflects a widespread capillary vasculopathy affecting the heart, eyes and, perhaps, other organs. The appearance of nephropathy may not be a simple consequence of diabetes. Family studies indicate that diabetic nephropathy is more likely to occur among children of parents with nephropathy, families with hypertension, or in siblings of patients with nephropathy. Furthermore, the presence of small, but abnormal amounts of albumin in the urine is predictive of progression to overt nephropathy. It is clear from studies of both types of diabetes that albuminuria clusters among families and several candidate genes have been proposed.

9. CBC and Chemistry Profile

The hematocrit and CBC will be determined locally at each center by standardized automated methods at no laboratory cost. A 12-analyte chemistry profile will be done at the Washington Hospital Center pathology laboratory. Total protein determinations will be used to estimate whole blood viscosity, and hematocrit is related to CVD risk. These relatively simple measurements accurately predict whole blood viscosity (multiple $r=0.78 - 0.92$, at several shear rates). Numerous studies document that increased hematocrit, plasma viscosity, or whole blood viscosity are associated with hypertension and diabetes, and predict subsequent cardiovascular events. One possible mechanism of these associations is the increased shear stress imposed on the arterial intima by more viscous blood flowing past it. The chemistry profile is a cost-efficient group of tests that will be used to assess rates of hepatocellular disease (transaminases, bilirubin), gall bladder/bile duct obstruction (alkaline phosphatase), hyperproteinemia, electrolyte imbalance and hyperuricemia.

10. ApoE Genotype

Apolipoprotein E (ApoE) is a ligand for the LDL receptor. Three apoE genotypes occur in humans, and variations in cholesterol levels and coronary heart disease are associated with the phenotypic patterns. Data from elderly Finnish men showed that the apoE4 gene was a significant predictor of coronary heart disease death. The Framingham Study found that apoE phenotype 4 was significantly associated with coronary heart disease in both sexes, even after adjustment for hypertension, smoking, obesity, diabetes, HDL and LDL cholesterol. Among Strong Heart Study participants, the prevalence of $\epsilon 2$ was significantly lower than among White Americans. LDL cholesterol and apoB concentrations were highest among those with $\epsilon 4$ and lowest among those with $\epsilon 2$. Concentrations of HDL cholesterol and apoA1 were lowest among those with $\epsilon 4$ and highest in $\epsilon 2$. ApoE was significantly related to glucose control in women, but not in men; those with $\epsilon 4$ had higher glucose and HbA1c concentrations.

ApoE Genotype Method: The apoE gene is first amplified by PCR. The amplified product (268 bp) is then exposed to HhaI restriction enzyme and the digestion products separated by agarose or polyacrilamide gel electrophoresis. The DNA fragments are visualized by ethidium bromide staining. ApoE genotype and phenotype methods are in agreement >98% of the time. Blinded duplicates show near-perfect agreement. (Reference: van den Maagdenberg AM, de Knijff P, Stalenhoef AF, Gevers Leuven JA, Havekes LM, Frants RR Apolipoprotein E*3-Leiden allele results from a partial gene duplication in exon 4. *Biochem Biophys Res Commun.* 1989;165:851-7.)

11. ApoB

Apolipoprotein B (apoB) is the major protein component of LDL and is a constituent of chylomicrons, intermediate density lipoproteins and VLDL. Several studies suggest that concentrations of apoB correlate more closely with the risk of ASCVD than routine lipid measurements. ApoB concentrations are independent risk factors for carotid atherosclerosis and silent cerebral infarction in Japanese men. In some studies, multiple regression analysis shows that ApoB levels are significantly and independently associated with angiographically proven carotid atherosclerosis and with premature coronary heart disease.

There is strong evidence for the genetic contribution to the concentrations of apoB. For example, the Bogalusa Heart Study described low ratios of apoA1:apoB among offspring of parents who had coronary heart disease. Similar associations have been described among patients undergoing coronary arteriography at an early age in whom apoB levels show strong familial aggregation. Several studies found evidence that apoB concentrations are influenced by a single gene with large effect. This gene is unlinked to the apoB structural locus. It will be imperative to have reliable measurements of apoB among the Strong Heart Study offspring to perform linkage analyses.

12. ApoA1

Apolipoprotein A1 (apoA1) is a central element in reverse cholesterol transport. Numerous cross-sectional population studies found an inverse relationship between apoA1 levels and coronary heart disease, and it is a regular predictor of CVD in SHS. Octogenarians who are free of coronary heart disease have significantly higher apoA1 levels than age-matched controls with coronary heart disease. As with apoB, genetic factors affect the level of apoA1 and presumably the risk of coronary heart disease. The concentrations of ApoA1 are strongly influenced by the rates of catabolism and synthesis. Prenger et al. reported that a single dominant gene Mendelian model of transmission accounted for variation in apoA1 levels among siblings of patients undergoing cardiac catheterization. The singly locus accounted for 37-49% of variation in observed apoA1 levels.

13. Endothelin-1 and VCAM

The coronary arteries have an active role in the pathogenesis of atherosclerosis and coronary heart disease; they are not simply the passive repositories of injury caused by oxidative stress, dyslipidemia, thrombosis and sheer injury. Both genetic and environmental factors affect the vessel's susceptibility to injury and its response in terms of tone and vascular wall proliferation. Since SHS began, a great deal has been learned about the molecular processes leading to vascular wall injury and its responses to damage.

These responses are regulated by the production and release of a variety of substances including prostacyclins, nitric oxide, cellular adhesion molecules, vasoactive growth

factors and G-protein-coupled receptor agonists including endothelin. There is accumulating in vitro evidence that these factors are essential elements in the acute and long term responses to injury and development of atherosclerotic cardiovascular disease (ASCVD). In addition, vascular responses mediated by nitric oxide are abnormal in established pathological states such as essential hypertension, stroke, atherosclerotic coronary heart disease and heart failure. There is no agreement on a clear relationship or cascade between these factors and the vessel wall. However, it is hypothesized that risk factors for atherosclerosis such as dyslipidemia, hypertension, diabetes and oxidative stress impair nitric oxide bioactivities. Reduced nitric oxide activity may, in turn, adversely affect coronary vasodilation and antithrombotic activities. Reduced synthesis (or intravascular residence time) of nitric oxide also appears to increase inflammation by stimulating the expression of vascular adhesion molecules (e.g., vascular cell adhesion molecule-1 or VCAM-1) for monocytes, and the growth of vascular smooth muscle through the production of local growth factors.

Vascular wall injury also causes production and release of endothelin, a G-protein-coupled-receptor agonist. Endothelin elicits cell growth through production of both autocrine and paracrine factors. In Phase IV of SHS, we will measure endothelin and VCAM-1 in stored Phase I plasma samples. While these factors appear to be elevated in established vascular injury, it is not clear what role they play in pre-clinical or pre-morbid states of ASCVD. Specifically, we will test the hypothesis that VCAM and endothelin are elevated in the blood of individuals who were initially free of clinically apparent ASCVD, but subsequently developed “definite” or “probable” CHD. Our data may allow us to infer that those elevated blood levels of VCAM and endothelin are pre-clinical risk factors for CHD. The practical importance of this may relate to earlier, focused interventions designed to reduce vascular wall injury. These interventions may include ACE inhibitors, estrogen, lipid lowering agents, physical activity, improved diabetic and blood pressure control, and the development and use of new agents such as endothelin or VCAM selective antagonists.

For the case-cohort studies, the control group will be a large random sample of the Phase I examination cohort. Selecting controls in this way will allow them to serve as controls for each of the case groups studied.

VCAM-1 will be measured using a VCAM-specific, commercially available monoclonal solid-phase ELISA kit (R&D Systems, Inc., Minneapolis, MN). Interassay CV is 8.5-10.2% and the sensitivity <2.0 ng/ml. Expected mean human values are ~550 ng/ml with a 2-SD range of 395-714 ng/dl.

Endothelin-1 will be measured using an endothelin-1 specific, commercially available, monoclonal solid-phase EIA kit (R&D Systems, Inc., Minneapolis, MN). Interassay CV is 5.1-6.5 and sensitivity <1.0 pg/ml. Expected mean human values are ~0.6 pg/mL with a 2-SD range of 0.3-0.9 pg/mL.

14. Thyroid-Stimulating Hormone (TSH)

Over the years, several studies have identified hypothyroidism as a stimulus to dyslipidemia and, potentially through that mechanism, coronary atherosclerosis. Since these studies have depended on use of coronary arteriography, an invasive technique with a measurable complication rate, little is known of the relation of thyroid metabolism to atherosclerosis in population-based samples. In addition, it is well known that skeletal muscle relaxation is slowed in the setting of hypothyroidism, but whether this phenomenon occurs in arterial and cardiac muscle is unknown. Preliminary data from SHS reveals that 553/4475 subjects in Phase I were receiving thyroid replacement therapy. This yields a prevalence of treated hypothyroidism of 3.4% vs. a pooled prevalence of 0.5-2% in nationally published studies. We will perform a third-generation TSH assay to be used in Phase IV is a solid-phase chemiluminescence immunometric assay (DPC Immulite Third Generation TSH). The assay is linear between 0.00s and 75 uIU/mL and thus should be useful in detecting hypo-, normal, and hyperthyroid patients.

1.5.7 Measurement of Physical Activity – Pedometry

Pedometer – Activity Monitor

The physical activity questionnaire, in general, is the most common measure of physical activity levels in research studies. However, an activity questionnaire alone may not be the best way to quantify lower intensity, variable frequency, lifestyle activities such as walking (Kriska, 1990; Sallis, 1985). An objective measure of activity will be used to supplement the information collected previously in SHS by an activity questionnaire. The objective measure that we plan to use is the Yamax Accusplit AE120 Activity Meter, a simple, inexpensive, pedometer.

Step monitors are now successfully being used to estimate levels of movement expressed as "daily steps taken throughout the day" and to document activity changes in intervention efforts (Yamanouchi, 1995). However, activity monitors also have their own set of limitations, such as the inability of capturing cycling, swimming and upper body movement. The Yamax Accusplit AE120 step counter will be given to each participant at the time of the clinic visit to wear at home for seven consecutive days. The Yamax Accusplit AE120 Activity Meter is a pocket-sized pedometer that displays the number of steps taken. Verbal/written instructions for the monitors will be presented to the participant with a diary that needs to be completed on the seven days that the monitor is worn (see forms in Appendix D of this volume). The participants will keep the pedometers and will be encouraged to use them to monitor and increase their physical activity levels.

1.6 PHYSICAL EXAMINATION

During the examination, participants wear a gown, or loose fitting clothes that do not impair accurate body measurements and the examination. It is helpful to have them wear large scrub pants to enable the pant legs to be rolled up for the ECG examinations. Shoes and socks are removed for the supine examination and weight and height measurements. The form to be used is given in Appendix D.

1.6.1 Anthropometry

Anthropometry is performed before the clinic snack with the participant's bladder empty. The subject may wear a scrub suit or clothing into the station. Measurements may be taken over the scrub suit or light clothing only. Make sure that the pockets are empty and the belt is removed. Height and weight measurements are not to be taken with the participant wearing shoes.

Measurements, if possible, are taken by a team of two persons (one acting as observer, the other as recorder). If two are available, the first observer takes the measurements, calling out the value of the measurement.

The first observer keeps the measuring instrument in place until the recorder repeats the number. The recorder also checks the examinee's position during the procedure. If a single observer performs the measurements, each should be recorded immediately after they are taken. Values taken are rounded to the nearest unit indicated for each measure. Fractions less than 0.5 will be omitted and fractions greater than or equal to 0.5 will be rounded up to the next higher unit.

1. Height and Weight

a) Standing Body Height

The participant stands erect on the floor or the horizontal platform with his/her back against the vertical mounted ruler, heels together and against the vertical ruler, looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane which includes the lower margin of the bony orbit and the bony socket containing the eye the most forward point in the supratragal notch just above the anterior cartilaginous projections of the external ear) (Figure 1). The right angle is brought down snugly but not tightly on the top of the head. A foot stool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method described above. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and

the metal ruler is mounted perpendicular to the floor). A chart converting centimeters to inches is on the wall or available for use in informing the participant of his/her height in inches.

b) Body Weight

Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Tanita BWB-8005 Adult Digital Scale) with head erect and eyes looking straight ahead. Record the results to the nearest kilogram using the rounding method described above. To maintain accuracy, the scale is zeroed daily and must be calibrated with a known weight (50-lb) every month or whenever the scale is moved. To calibrate the scale, check that the 50-lb weight weighs 50 lbs. after zeroing the scale. Furthermore, the operator should make sure that an adult must weigh 50 lbs. more when standing on the scale holding the weight.

2. Supine Waist (Abdominal) Girth

An anthropometric tape is applied at the level of the umbilicus (navel) with the patient supine (Figure 2) and the participant is instructed to "breathe quietly". The measurement is made and recorded to the nearest centimeter using the rounding method described above.

3. Erect Hip Girth

Instruct the participant to stand erect yet relaxed with weight distributed equally over both feet. The hip girth is measured at the level of maximal protrusion of the gluteal muscles (hips) (Figure 3). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest centimeter using the above rounding method. Only one measurement is made. The greatest source of error for this measurement is due to not having the tape horizontal. Technician(s) should check the position of the tape to assure its correct position from both the front and back.

4. Upper Arm Circumference

The participant sits on a table or stool so that the right arm hangs freely with the right hand resting on the right knee. The observer applies the tape measure horizontally at the midpoint between the acromium and olecranon (Figure 3). Record the measurement to the nearest centimeter using the rounding method described above. This measurement is used to select the proper size blood pressure cuff.

A Novel Products tension tape is used to measure both abdominal and hip girth and the upper arm circumference.

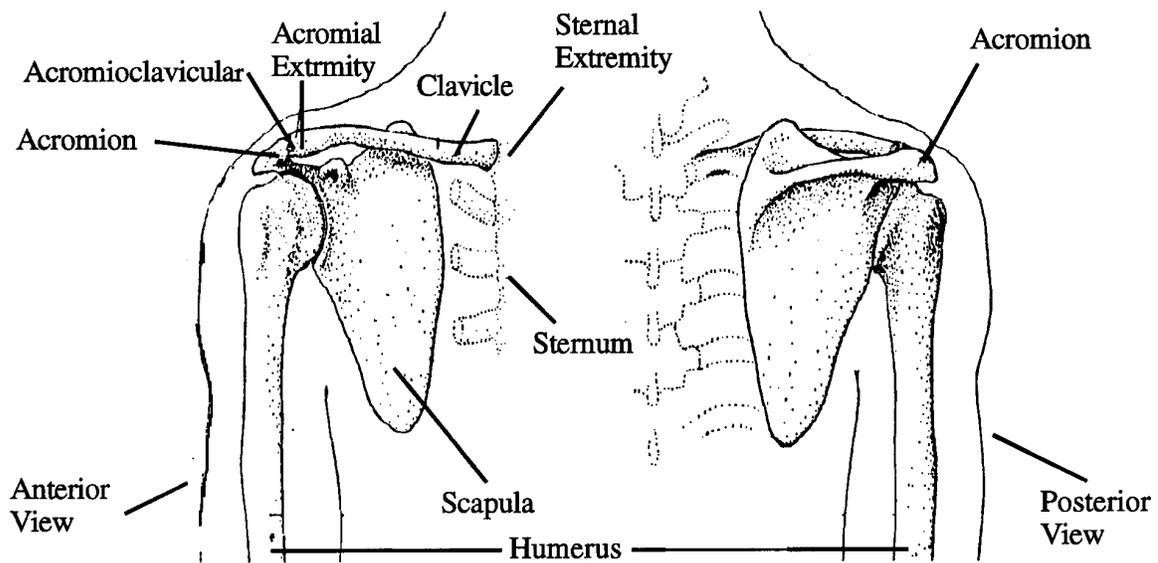


Figure 1 (a). General Description: The **scapulae**, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body. The end of the spine projects as a flattened, expanded process called the **acromion**. This process articulates with the clavicle.

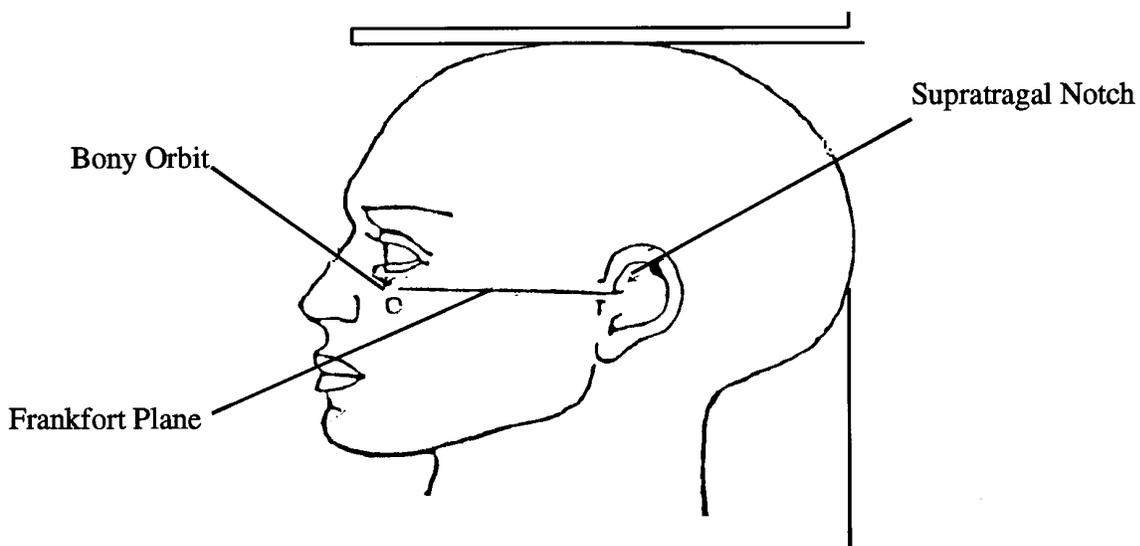


Figure 1 (b). the **Frankfort Plane**: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external ear.

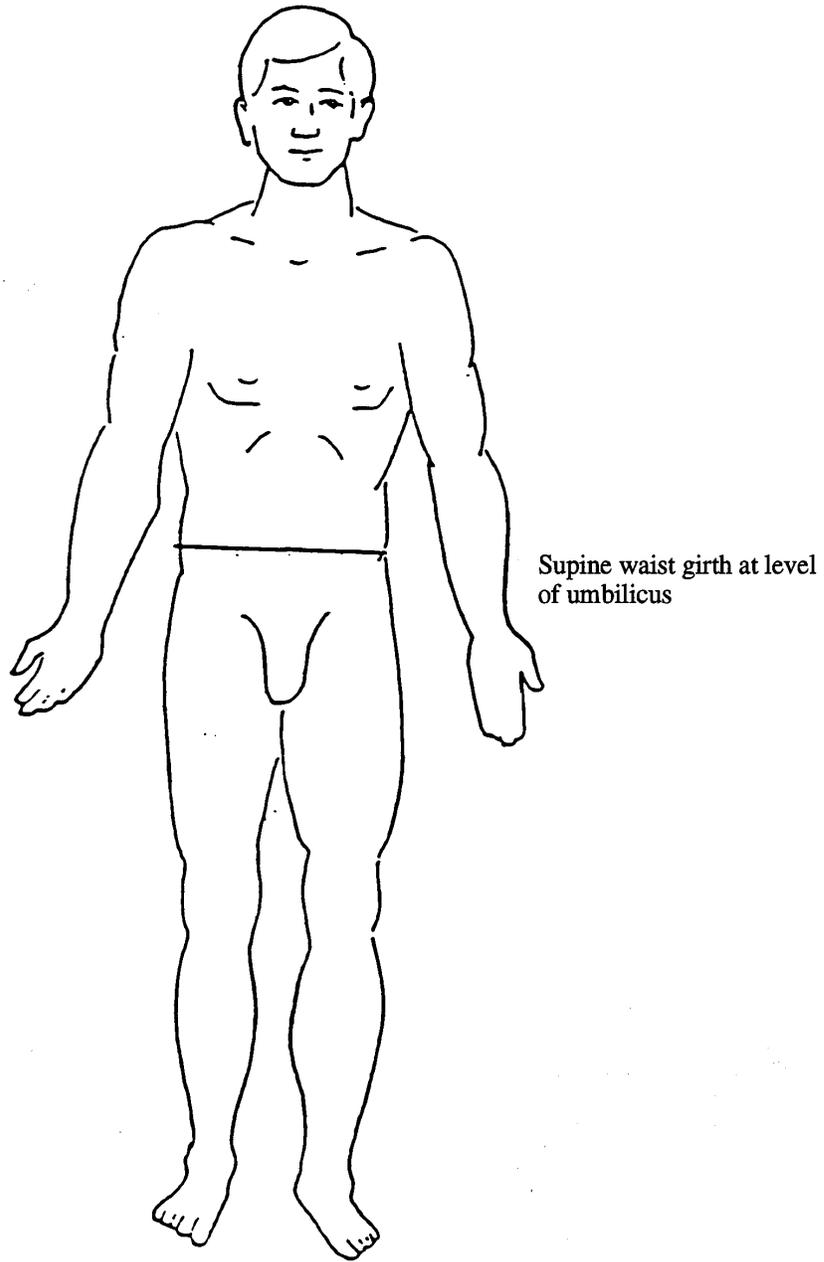


Figure 2. Location of Waist Girth Measurement

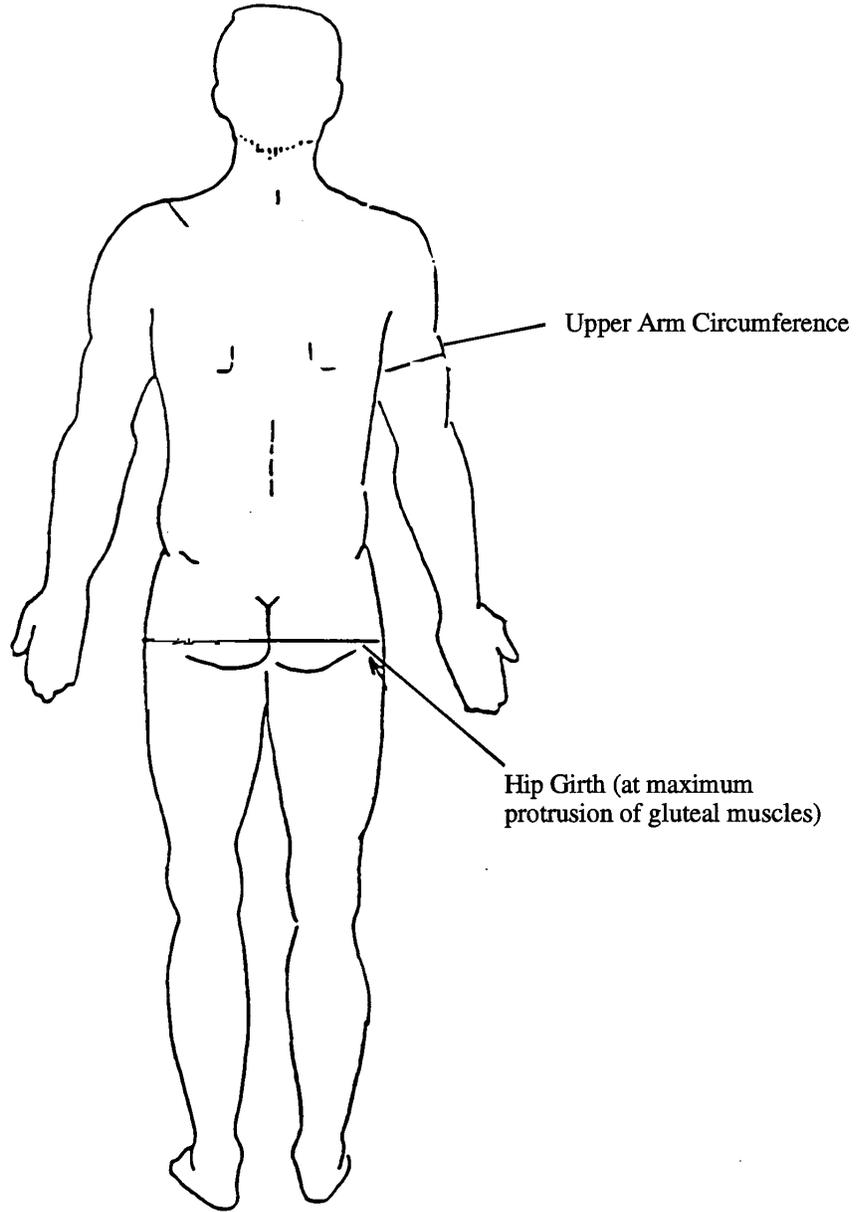


Figure 3. Location of Upper Arm, Hip, and Calf Circumference

1.6.2 Training and Certification for Anthropometry

Each technician must undergo training and certification by staff experienced in anthropometry. The training program for taking body size measurements consists of the following components.

1. Training is conducted centrally by a staff experienced in anthropometry.
2. Each field center trains one or two individuals before the baseline examination. One individual from each center is designated the center's anthropometry supervisor.
3. If additional personnel are needed by a center to perform anthropometry, training is provided by the center's anthropometry supervisor.
4. Training includes:
 - a. Introduction - rationale for body size measurements, overview of technique, expected limits of reproducibility, and pitfalls related to anthropometry.
 - b. Demonstration of technique – the trainer demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as recording of data.
 - c. Practice - technicians divide into groups of three, and two techs perform measurements on the third in a round-robin fashion. This is done under the observation of staff experienced in anthropometry. Differences in technique and clarification of problem areas are discussed.
 - d. Testing - several subjects are assessed independently and blindly by each technician. Each technician's measurements are compared with the trainer's measurements and the results discussed in class. The four subjects examined have four distinctly different body types: lean, obese, athletic, and aged.
 - e. Certification - technicians must measure one or more test subjects and be within certain standards of error:
 - 1) The waist and hip measurements must agree within 2 cm on each subject, and the arm and height measurements must agree within 1 cm.
 - 2) The weight must agree within 1 kg.

If these are met, the subject receives certification for field work. Trainees who have problems are identified, and they are allowed to practice and try again to be certified.

1.6.3 Sitting Blood Pressure

1. Introduction

In the Strong Heart Study, sitting blood pressure is measured in a resting state, using 3 measurements with a Baum mercury sphygmomanometer. Within any one individual, variation in blood pressure is substantial, even within a few minutes and particularly under conditions perceived as stressful. Use of three replicate readings tends to reduce this short-term variation.

2. Standardized Clinic Procedure

Correct measurement of blood pressure is of the utmost importance to the success of this study. It is essential that the procedure described below for measuring blood pressure be followed exactly. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

3. Description of the Equipment

a) Stethoscope

A standard stethoscope with a bell is used. Korotkoff sounds are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10-12 inches from the bell piece to "Y" branching. This length provides optimal acoustical properties and allows the observer to read the sphygmomanometer at eye level and in a comfortable position. Ear pieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

- i) The earpiece should be directed downwards and forwards into the external ear canal.
- ii) The earpieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.
- iii) The valve between the bell and the diaphragm should be turned in the correct direction.
- iv) The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery - immediately below the cuff and medial to the cubital fossa above the medial epicondyle of the radius and posterior to the biceps muscle. Light pressure accentuates the low-pitched sound and avoids compression murmurs. When pressing too heavily with the bell on the artery a murmur can be heard which may prolong the apparent duration of phase 4 and give inaccurate readings.

b) Sphygmomanometers

Standardized Baum mercury instruments are used for all clinic visits. The mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to the rubber tubing from the inflatable rubber bladder of the cuff. As the inflatable rubber bladder is filled with air, the air pressure in the bladder travels through the connecting rubber tubing. The pressure pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., rounded up to the nearest even number.

c) Cuffs and Bulbs

Proper size of the cuff is essential for accurate blood pressure measurement. Study Centers have four standardized Baum cuffs available – pediatric, adult, large adult, and thigh cuff.

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the Strong Heart Study, arm size is measured and the cuff size is selected as follows:

Table 1.2 Determination of cuff size based on arm circumference (Mid humeral)

Cuff Size	Arm Circumference
Pediatric	< 24 cm
Adult	24 to 32 cm
Large Adult	33 to 41 cm
Thigh	> 41 cm

4. Blood Pressure Measurement Instructions

Some of the many extraneous factors influencing blood pressure are controlled by standardizing the measurement technique and the environment in which the measurement is made. Uncontrolled factors, such as time of day, arm circumference, recent use of caffeine, and identity of the observer are recorded, so that they can be taken into account during analysis.

The Strong Heart Study participants are asked to avoid caffeine (tea, coffee, chocolate, and soft drinks), eating, heavy physical activity, smoking and alcohol intake for twelve hours and to refrain from smoking for at least one-half hour prior to the clinic visit. Current drug intake, including medications affecting blood pressure and non-prescription drugs, is recorded on the day of the examination. A detailed history of smoking and alcohol intake are also recorded.

5. Staff Preparation for Measuring Blood Pressure

In relating to the Strong Heart participants, remember that participation in the study is voluntary. Participants are given full explanation and instructions about the preparation for the blood pressure examination and an opportunity for questions. The setting in which blood pressure measurements are made is standardized.

6. Measurement Procedures

The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 minutes to make three blood pressure measurements including the initial five-minute rest. The blood pressure measurements are made early in the clinic visit sequence immediately following the reception and informed consent, and more than 15 minutes after phlebotomy. Once the participant is given instructions and explanations and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

- a) If the participant indicates that there is a medical or postsurgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the data collection form that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.
- b) Seat the participant with the right arm on the table. The bend at the elbow (ante-cubital fossa) should be at heart level. Legs should be uncrossed and head support comfortable. The participant should be able to relax the neck and shoulder muscles as much as possible.
- c) Palpate the brachial artery (just medial to and above the ante-cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery.
- d) Record the time. Allow a five-minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary.
- e) Connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no

longer felt. Deflate and record the pulse obliteration pressure. Have the participant raise measurement arm for 5 seconds and the wait another 25 seconds with the participant's arm on the table before auscultating the blood pressure.

- f) Measurement 1: Connect the cuff to the manometer. Inflate rapidly to the pulse obliteration level + 30 mm. Holding the pressure constant with the bulb, wait 5 seconds. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. If the mercury column falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the **higher number** should be used.
- g) Measurements 2 and 3: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement in step f above and disconnect cuff.

Average blood pressure readings are calculated for the second and third blood pressure readings. Because of the importance of the blood pressure averages, to inform the participant and for the purposes of referral, all arithmetic is done with a calculator.

If for any reason the observer is unable to complete, or has forgotten to complete any portion of the examination (and the participant is gone), draw two horizontal lines through the space(s) on the form. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure workstation, completely deflate the cuff and start over with a replacement reading.

7. Reporting the Blood Pressure Results to the Participant

Using a calculator, average the second and third readings and mention the results to the participant. State clearly the systolic and diastolic pressures.

8. Procedure for changing the peak inflation level

Occasionally the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. The observer immediately deflates the cuff by releasing the thumbscrew and disconnecting the cuff tube. Then have the participant hold the cuff-wrapped arm vertically for five seconds. Proceed with blood pressure measurement, starting at a new peak inflation level, 10 mmHg above the previous level.

9. Sitting Blood Pressure Training and Certification

At each field center a minimum of two clinic staff persons are trained for measuring sitting blood pressure. They need not be health professionals, but they must be trained and certified in the blood pressure measurement technique. Observers should also have experience in relating to people.

The first training session begins with a description and demonstration of the correct blood pressure measurement procedure. Trainees watch the American Heart Association blood pressure instruction videotape. A checklist is used for certifying all persons taking BPs (Appendix A – 3). Simultaneous BPs will be recorded using a Y stethoscope as described in Appendix A – 4.

It is the responsibility of each field center to conduct these procedures and report to the Coordinating Center when the procedures are completed.

Y tube stethoscope observations are made in conjunction with the blood pressure training video during initial training and for quarterly quality control. The trainer has the observer-trainee go through the entire blood pressure measurement procedure using a quality control checklist. The observer and trainer listen with the Y Tube and record the values on separate sheets. Two measurements on one subject are obtained. Measurements by the trainer and the trainee should agree within 4 mmHg on any one reading (systolic or diastolic) and averages should agree within 3 mmHg.

10. Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed centrally and applied at all field centers. These measures include:

- a) recruitment of the most qualified personnel
- b) standardized training and certification
- c) retraining as necessary
- d) observation of data collection by supervisors, using the checklist given in Appendix A – 3. One checklist is used for each technician and mailed to the Coordinating Center each month
- e) frequent staff meetings to provide feedback
- f) editing of data, both manual and by computer
- g) a quality assurance program administered by the Coordinating Center
- h) simultaneous Y Tube observation of each technician by the blood pressure supervisor
- i) equipment maintenance program

11. Technician Training and Quality Control

Blood pressure technicians are trained centrally prior to participant recruitment. New technicians hired after the start of the study are trained locally by the Study Coordinator or a designated "Blood Pressure Supervisor".

The Coordinating Center directs a blood pressure quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure data every 3 months, comparing means for each technician with the values for all technicians, by center. These statistics are adjusted for weight, age and sex of the participants by the use of Z-scores. Arbitrary levels of Z-scores, (which can be modified according to performance) are used to detect possible systematic deviations in blood pressure measurement by individual technicians. Digit preference is also monitored for each technician. The Form for Recording Simultaneous Blood Pressure Observations in Appendix A – 4 will be used.

12. Equipment Maintenance

Each study center is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the nurse clinician, and all staff are instructed to report any real or suspected equipment problems to that person promptly.

All checks, inspections, cleanings and problems indicated are documented and recorded by date in a permanent log. Problems and solutions are also recorded. The local nurse clinician sends a copy of this log monthly to the Coordinating Center. A copy of this log is given in Appendix A – 5.

The standard sphygmomanometer is inspected once a month. These inspections include a check of:

- i) the zero level
- ii) mercury leakage
- iii) manometer column for dirt or mercury oxide deposit
- iv) condition of all tubing and fittings

The equipment is cleaned if inspection indicates it is needed, or at least once a year. Specific maintenance instructions for the standard sphygmomanometer are provided in Appendix A – 6.

1.6.4 Ankle Systolic Blood Pressure

1. Move the participant to the supine position.

Assist the participant in moving to the supine position on the examination table.

2. Apply the blood pressure cuff.

The appropriate ankle blood pressure cuff is applied on the right calf. The same size cuff should be used on the lower leg (calf) as the one used on the arm. In special instances, different cuff size may be used.

At this point, a blood pressure cuff is applied above the ankle of the right leg, as shown in Figure 4 (see below). Place the cuff flat on the table (the surface marked "side to the patient" face up) with the appropriate ankle centered on the cuff. At this time disregard the "over the artery" marker. The lower edge of the cuff (from which the hoses extend) should be approximately 2 to 2.5 inches above the medial malleolus. Following the contour of the lower leg, wrap the end of the cuff with the velcro "fabric" over the ankle, as shown in Figure 5. Note that depending on the degree of tapering in this area, the cuff corner will be offset from parallel toward the knee. Holding the cuff from sliding, wrap the other end over the ankle (step 3 in Figure 5 below), again following the contour of the ankle, and secure the velcro. Check to be sure that the corners of the cuff extending above the upper edge of the cuff are about equal: if one end extends more than the other, loosen the Velcro and adjust the wrap. Next, locate the "over the artery" marker of the cuff, and rotate the cuff so that this line is directly over the posterior tibial artery. The cuff may be rotated more easily by sliding it toward the malleolus, and after alignment, the cuff can be made snug by pulling it up toward the calf. The cuff should conform closely to the shape of the ankle, with the lower edge 2 to 2.5 inches above the malleolus.

The posterior tibial artery is usually palpated as it courses posteriorly to the medial malleolus. Even if the posterior tibial pulse is not palpable, the posterior tibial artery is used as the location for the marker line on the cuff for the "over the artery position". Any kinks in the tubing are removed, and any "tugging" of the tubing on the participant's leg is relieved.

3. Procedure for Measuring Ankle Blood Pressure

- a) Palpate both posterior tibial pulses and mark these locations. Apply ultrasound gel to the posterior tibial areas over the pulse or in the area shown on Figure 4.
- b) Listen for the right posterior tibial pulse using the Imex Elite 100 Doppler. If no pulse is audible or palpable, then try to use the dorsalis pedis pulse for the determination of blood pressure. If no pulse is audible, record zero for ankle blood pressure after the absence of pulses is verified by a second observer.
- c) Inflate cuff to a pressure reading 20 mm higher than the "Peak Pressure" used for the sitting arm pressure (i.e., obliteration plus 50 mmHg) and utilize identical deflation techniques while listening with the Doppler. Record the first sound heard as systolic blood pressure on the physical exam form.
- d) Take a second blood pressure using the same techniques, and record the second blood pressure on the Physical Examination Form.

- e) Repeat this procedure to record the left ankle blood pressure.
- f) Repeat this procedure to record the right brachial blood pressure using the Doppler. The blood pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual. By consulting the participant's Data Form, the observer verifies that the same arm and the same cuff size are used as for the sitting blood pressure readings.

If the participant had his/her sitting blood pressure taken on the right arm earlier in the clinic examination, the cuff is applied on the right arm at this time. The observer then uses the Doppler to record the brachial pressure. The pressure recorded in the right arm is used to calculate the brachial/ankle systolic pressure ratio for both lower extremities.

If it is impossible to obliterate the sounds after increasing the pressure to above 250 mmHg, record 999 on the physical examination form.

The observer now removes all conduction jelly. Socks and a robe or other garments are now replaced, and the participant is escorted to the next workstation.

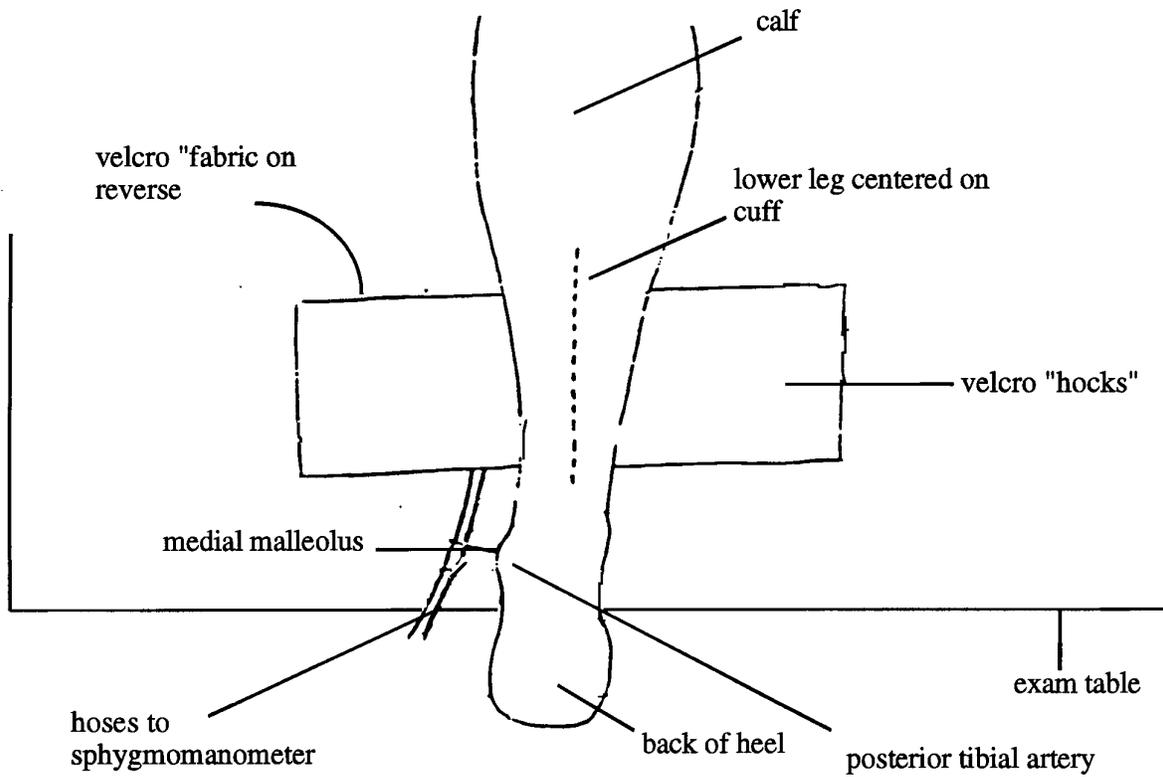


Figure 4. Placement of the blood pressure cuff on the ankle. Step 1 - Positioning the lower leg on the cuff.

Step 2. Wrap fabric end of the cuff following contour of ankle

Step 3. Wrap and secure cuff

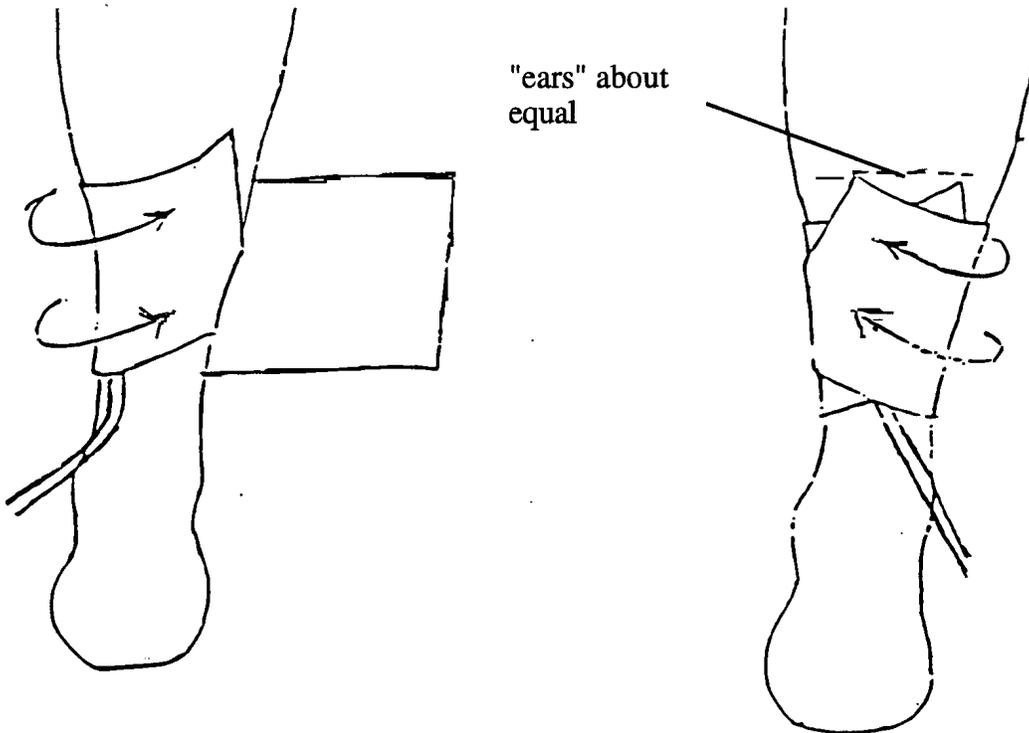


Figure 5. Placement of the blood cuff on the ankle. Step 2 and Step 3: Wrapping and securing the cuff

1.6.5 Electrocardiogram

1. Basic description

- a) A Marquette Mac-PC (or Mac-1200) based system will be used (see Volume VI).
- b) All ECGs will be transmitted centrally to the New York Hospital - Cornell Medical Center in New York electronically by modem.
- c) All ECGs will be read in a standard manner at the ECG Reading Center by Board Certified or Board Eligible Staff Cardiologists and transmitted or mailed back to

the site of origin for clinical correlation or other action, if required. In any case, all ECGs will be overread and promptly returned.

- d) All ECGs will be Minnesota coded at Cornell by computer analysis.
- e) The Strong Heart Study will itself maintain a permanent copy of all cardiograms in its possession to assure "perpetual" availability of the study data for study members.
- f) A standard level of competence must be demanded of our personnel performing ECGs at each site. A "competency exam" will be conducted of all persons recording ECGs at individual sites by a physician (or other designated person) who will judge the ability of the person being examined to adhere to standard protocol.

2. Minimal Equipment Requirements

- a) A Mac-PC with modem (see SHS Phase III Manual, Volume IV) or a Mac-1200 machine (see SHS Phase IV Manual, Volume VI) will be used at each clinic.
- b) New York Hospital - Cornell Medical Center will provide free use of their mainframe MUSE (Marquette Universal System for Electrocardiology) system (except for study hook-up costs and paper costs) for the duration of the study. This system can be accessed 24hrs/day by modem and stores all study cardiograms together or by center. Also, floppy disc downloading can be accomplished to a Mac-1200 compatible format.

Transmission instructions and Standardized ECG are given in Volume VI of the manual.

Procedures will differ at each center concerning how ECG readings are supplied to local physicians and IHS health records. A copy of the ECG obtained at the time of performance, if marked "unconfirmed", can be included in the patients chart that day (if so indicated on the participant's consent form). A clinical reading will be performed at Cornell and returned by reverse transmission procedure WITHIN one week. A hard copy of this clinical reading will also be sent to the Coordinating Center for storage.

All ECGs will be Minnesota coded at Cornell using computer analysis of the ECGs. The Minnesota codes will then be added to the ECG data set by the Coordinating Center for data analyses.

1.6.6 Impedance Measure

The measurement of body fat is accomplished using the Quantum II Impedance Meter made by RJL Equipment Company. This involves a small low frequency current that travels across the body through the extracellular fluids. The measurement of bioelectrical impedance is related to the volume of the conductor and, when expressed as impedance or conductance, is proportional to fat free mass. The participants do not feel anything when this measurement is obtained.

1. Procedure

- a) Before beginning, explain to the participant why you are making the measurement, and check to see that the participant has not exercised vigorously for the past 12-hours and has not consumed alcohol in the past 24-hours. Make sure that the subject is not dehydrated. Record past vigorous exercise or alcohol consumption on the data form.
- b) Before beginning the test, be sure that the subject cable is securely attached to the RJL spectrum, have the participant remove the right shoe and sock and lie down with the right side nearest to the analyzer;
- c) If the examination table is metallic, it must have a foam pad - all of the body must be on the pad.
- d) For best results:
 - i) Use electrodes only once.
 - ii) Legs should be far enough apart so that the thighs do not touch each other. A towel may be used to prevent the legs and thighs from touching.
 - iii) Hands and arms should be far enough apart so that the arms and hands do not touch the torso. A towel can be used to prevent the arms from touching the body.
 - iv) No body parts should be in contact with any external metal (jewelry and pins in bones will not affect the results).
 - v) Participant's skin should be clean, dry and warm to the touch. If the skin is oily, clean it with an alcohol swab before attaching the electrodes.

Prior to the attachment, cut the electrodes in half bisecting the foil tab. The cut edge of the electrode placed on the ankle and wrist should face toward the shoulder and thigh respectively. The cut edge of the other two may face in either direction.

e) Electrode Placement:

- i) Attach the black wires to the foot with the red clip connected to the electrode at the ankle (F1). Attach the red wires to the hand with the red clip connected to electrode at the wrist (H1).
- ii) Put H1 on an imaginary line from the protruding bone of the wrist to bisect the ulnar head; make sure that the cut edge of the electrode is toward the shoulder.
- iii) Put H2 just above the knuckles of the right hand or on any finger; there should be at least 5 cm difference between H1 and H2.
- iv) Put F1 on an imaginary line between the protruding ankle bones to bisect the medial malleolus; make sure that the cut edge of the electrode is toward the thigh.
- v) Put F2 just above the toes of the right foot or on the great toe (there should be 5 cm difference between F1 and F2)

Once the electrodes have been properly attached to the subject, the values for resistance and reactance will appear on the screen. Record these on the results sheet. Make sure that the toggle switch is set on x1.

2. Instructions for Impedance Meter

Checking Instrument

Before testing the first patient, be sure that the cables are not crimped or damaged. Place the Resistance/Reactance switch in the resistance position. Place the switch labeled x1/x10 in the x1 position. Attach the 2 clips from one patient cable to one side of 500 ohm resistor provided.

Attach the two clips from the other cable to the other side of the resistor. Turn power on. Resistance displayed should be between 490 and 510 ohms. If resistance is in this range, proceed with patient testing.

Note: Patient cables are made of silver. Take care not to bend or abuse cables. They should be left plugged into instrument to minimize handling, except when relocating instrument.

3. Quality Control for Impedance Measure

Training for the measurement of body fat using the bioelectric impedance meter was accomplished by an experienced nurse to demonstrate the following steps:

- a. Instructions concerning the use and verification of the machine.
- b. Demonstration by instructor of the procedure.
- c. Practice by the individual operators.
- d. Certification of operators if instructor and operator achieve an impedance measure where resistance and reactance were each within 15 ohms.

For ongoing quality control in each center, one individual will be designated as supervisor of the impedance measures. This individual will assure that each of the other operators of the instruments is re-certified quarterly by having him/her perform an impedance measure on the same individual as the instructor. These should agree within 15 ohms.

In addition, the instructor is responsible for the monitoring of the impedance meter. The instructor should observe individual operators performing impedance measures at least quarterly to verify consistent and proper technique.

1.6.7 Examination of the Pulses

- a) Ankle Edema

The socks or other foot covering are removed. The participant is examined in the supine position. Gentle but firm pressure is applied along the mid-tibia, anteriorly down to the ankle in each leg. Pitting or indentation remaining after pressure is removed constitutes definite edema. The examiner identifies the mid-point between the prominence of the medial malleolus and the inferior border of the patella. Pitting at or above that mid-point is recorded as "marked" edema. Pitting only below that point is recorded as "mild" edema. The degree of edema is based on the extent.

- b) Posterior Tibial Pulse

The examiner palpates inferior to the medial malleolus of each foot. The presence or absence of arterial pulsation is recorded. If in doubt, the examiner compares with the radial pulsation.

- c) Dorsalis Pedis Pulse

The superior aspect of each foot is palpated for the presence or absence of this pulse.

1.6.8 Physical Findings to be Confirmed by a Physician to Assure Presence of CHF

The participants should be referred for evaluation by a physician if these findings are noted so they can be confirmed and evaluated for the presence of congestive heart failure.

Bilateral ankle edema, orthopnea ,or paroxysmal nocturnal dyspnea.

The standard IHS referral form should be used to refer patients with newly observed physical findings described above to an internist or cardiologist so that the diagnosis can be confirmed and the prevalence of congestive heart failure can be determined. In such cases, use the Physician Referral Form for Diagnosis of CHF in Appendix A – 10.

1.7 REFERRAL GUIDELINES

It is the intention of the Strong Heart Study that individuals who participate in the physical examination will be provided both with education and encouragement concerning a healthy life style aimed at preventing cardiovascular disease. If significant medical conditions are uncovered during the course of the study, participants will receive assistance in arranging appointments for medical care. They will also receive assistance arranging transportation for emergent, immediate and urgent referrals.

1. Referral procedure:

- a) All participants reporting for the medical exam will receive appropriate educational materials concerning a heart healthy lifestyle. In addition, the examining personnel, when possible, will endeavor to educate the participants during the exam concerning the importance of risk factor reduction and modifications that the individual might make to improve his/her risk for cardiovascular disease. At the end of the exam, the participant will receive a copy (see Appendix A – 7(a) of this volume) of their BP and glucometer readings, their BMI calculation, and their Acanthosis Nigricans evaluation. The importance of any abnormal findings from the exam and recommendations for referral will be communicated to the participant at this time. For referrals in the emergent, immediate or urgent categories, the participant will be assisted in arranging transportation and appointments. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant’s provider or clinic of choice. For routine referrals, the reason for the referral and information necessitating referral will be given to the participant and a referral letter will be sent to the provider of their choice.
- b) When the clinically useful laboratory results and ECG report have returned, a follow-up letter will be mailed to each participant thanking him or her for participating and supplying him/her with basic medical information obtained during the exam. Any results requiring referral will be pointed out in this letter and a referral letter will also be sent to the provider designated by the participant at the time of their exam. (See example of letter and suggested interpretation in Appendices A – 7(b) and A – 8)
- c) When the carotid ultrasound and echocardiogram reports have returned, a follow-up letter will also be mailed to each participant supplying him/her with basic medical information obtained during the exam. Any results requiring referral will be pointed out in this letter and a referral letter will also be sent to the provider designated by the participant at the time of their exam. (See example of letter and suggested interpretation in Appendices A – 7 and A – 8)
- d) In order to ensure that the patient receives appropriate referral and treatment for significant medical conditions uncovered during the course of the study,

consistent referral levels have been established as described below which will be applied at each center. Communication with the participant will be initiated at the time results indicating Emergent, Urgent and Immediate referrals are made available to the field centers. Communications regarding results indicating routine referrals made be held for short periods of up to two weeks to allow batching of results and somewhat fewer letters.

- e) Before exams begin, the local SHS director will discuss the referral process with the clinical director for the primary IHS clinic for the community. The proposed method of notifying patients regarding referral will be reviewed, and the clinical director's input will be sought as to which individual or office will be receiving referral information. There needs to be a designated provider to accept referrals for participants who do not specify a particular provider at that facility; the provider handling emergency duty for that day would be the most reasonable for Emergent and Immediate referrals. The clinical director should also designate which provider(s) will be responsible for handling Routine and Urgent referrals, and who would assume that responsibility if a particular provider were on leave or otherwise unavailable. The basic plan should be documented in writing and signed by the clinical director and SHS representative.

It is understood that it is the responsibility of SHS to provide referral information to the participants and to the provider or clinic of their choice. Assistance will often be given in arranging an appointment or providing transportation, but further follow-up of missed appointments, secondary referrals to specialty care by the participant's provider will not be the responsibility of SHS.

2. Referral Levels

The Strong Heart Study refers participants using established guidelines for referral. Uniform criteria for referral of participants are implemented at all centers. Emergency, immediate, urgent, and routine referrals are made. Methods for referring participants who have no physician are established with the participant. All referrals are documented on a separate log and copies of the referrals are kept in the Strong Heart Study folders. The following levels of referral are established:

- a) **Emergency Referral:** The patient is immediately escorted to a physician, **or** an emergency squad or an ambulance is summoned.

In such situations study personnel will provide emergency care to the best of their ability and training as appropriate to the emergencies that arise. Findings and measurements indicating referral will also be communicated directly to the emergency staff.

- b) Immediate Referral: The participant is urged to see his/her physician within one day.

The SHS staff notifies the participant's physician or nearest IHS facility and makes appropriate arrangements for the SHS participant to be seen within 24 hours. The participant is provided with an IHS referral form or other written summary to take to his/her physician and transportation is provided or arranged if needed. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant's provider or clinic of choice.

- c) Urgent Referral: The participant is urged to see his/her physician within one week.

SHS staff makes an appointment for needed follow-up whenever possible. An IHS referral form or other written summary is provided to the participant and transportation is arranged if needed. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant's provider or clinic of choice.

- d) Routine Referral: The participant is contacted, and it is suggested that they see their physician or provider within one month, or at the first convenient appointment.

An IHS referral form or other written summary is filled out and sent to the provider of choice. When a group of participants is referred for routine referral by sending a packet of referral materials to a provider or clinic, an individual who will take responsibility for distribution of this material to the proper providers must sign for receipt of the referrals; or alternatively, a certified letter could be sent to the provider or clinic. (Please see 1.d above)

- e) No Referral: At the conclusion of the exam, if there are no findings requiring referral, the participant will be given the results of BP and glucometer readings, BMI calculation and Acanthosis Nigricans evaluation, and advised that they are within acceptable limits. They will also be advised that further results from laboratory tests will be sent to them in the mail, and that results of carotid ultrasound and echocardiograms will be sent to their provider (if so designated in the consent form).

3. Standing orders for nursing or staff referral:

Guidelines for referral are provided in the table below. The SHS nursing staff determines the acuteness of the findings, as well as whether or not the condition is being followed by a physician.

If the participant is aware of and being followed medically for a condition, judgment is exercised about whether to refer. The standard IHS referral form or other written summary is used to provide appropriate clinical information to the health care professional who will evaluate the patient. A copy of this referral will be retained with the research forms to document the referral that was made.

Referral at the time of examination

Emergency Referral

**Statement to Participant
("Consult M.D. immediately")**

SBP \geq 260 mmHg

Your BP is very high

DBP \geq 130 mmHg

Your BP is very high

One Touch glucose $<$ 50

Your blood sugar is very low. Give juice or sugar!

Any finding or symptom suggestive of a life-threatening illness, including evidence of acute MI, unstable angina, or pulmonary edema.

Describe rationale for referral to participant

Immediate Referral

**Statement to Participant
("Consult M.D. today")**

Fasting One Touch glucose $>$ 400

Your blood sugar is very high

SBP 180-259 mmHg

Your BP is very high

DBP 110-129 mmHg

Your BP is very high

Diabetic foot ulcer

Your foot must be seen by a physician

Angina in last day

Your chest pains may be important

Neurologic symptoms in past week

Your symptoms may be important

Other severe symptoms or findings

Your symptoms may be important

Untreated asthma or worsening asthma

You may have a serious problem in your lungs

Carotid ultrasound findings indicate possible >75% obstruction

You may have a serious problem in your neck vessel(s)

Cardiac Echocardiogram indicating significant pericardial effusion or an intracardiac mass

You may have a serious problem with your heart.

Urgent Referral

Statement to Participant
("Consult M.D. within a week")

Angina over 24 hours ago

Your chest pains may be important

Neurologic symptoms, untreated, one week to six months ago

Your symptoms may be important

Suspected congestive heart failure

Your symptoms may be important

Other acute, but less severe symptoms

Your symptoms may be important

Inappropriate medication usage

Taking medication incorrectly may be dangerous

Non-diabetic with a fasting One Touch glucose of ≥ 200
Diabetic with fasting One Touch glucose >300

Your blood sugar is high

Chronic cough, fever, weight loss, and other symptoms suggestive of active TB or valley fever

You may have a serious problem in your lungs

Carotid ultrasound findings indicate possible 50-75% obstruction

You may have serious problem in your neck vessel(s)

Routine Referral

Statement to Participant
("Consult M.D. within one month or at first convenient appointment")

SBP 140-179 mmHg

Your BP is elevated into the borderline range. Recommend that participant confirm blood pressure reading within 1 month

DBP 90-110 mmHg

Your BP is elevated into borderline range. Recommend that participant confirm blood

	pressure reading within 1 month
Non-diabetic with a fasting One Touch glucose of > 130 Diabetic with fasting One Touch glucose >150	Your blood sugar is high
Old MI (Rose Questionnaire), previously unrecognized	Your chest pain may be important
Neurologic problem (stroke, TIA symptoms) > 6 months ago, unrecognized	Your symptoms may be important
Claudication, previously unrecognized	Your leg pain may be important
Both pedal pulses are missing in one extremity and not previously referred <i>or</i> the ratio of doppler pressure of ankle/arm < 0.8	You may have poor blood circulation to your feet. You should check with your doctor

Referral After Lab and Other Test Results Are Available

- 1) Critical values -- See next page for critical values of various laboratory results.

Laboratory will call field center; or use an alternative system involving a verified receipt (e.g., certified Email, FAX with return message confirming). Follow-up will be considered either immediate or urgent as indicated in the list of critical values. For immediate referral, SHS staff should notify participants by phone, or home visit, and (if they can not be reached personally within 4-6 hours) by certified letter. Efforts should continue to contact the participant and discuss results in person. SHS staff should help arrange transportation if needed. An IHS referral form or other written summary is provided.
- 2) Routine report -- Copies of routine results are sent to each participant with an interpretation of results. If the participants have new findings that they have not previously been advised of, such as newly diagnosed diabetes, or cholesterol > 300, an IHS referral form or other written summary should be provided, and SHS staff should assist the participant in making an appointment and arranging transportation for follow-up (see letter in Appendix A – 7 and interpretation in Appendix A – 8).
- 3) Carotid Ultrasound -- The Cornell Reading Center will call the field center (or use an alternate system involving a verified receipt) if > 50% obstruction is noted on the carotid artery. If the obstruction is $\geq 75\%$, the participant should have an

immediate referral (within 24 hours) for follow up. If the obstruction is between 50 and 74%, the participant should have an urgent (within the week) referral. If non-obstructive plaque (< 50%) is detected, the participant should be referred for risk factor assessment and counseling by his/her primary health care provider.

- 4) Echocardiogram -- The Cornell Reading Center will call the field center if there is a significant pericardial effusion, intracardiac mass, or other finding of serious consequence to the participant. Level of referral will depend on the urgency of the condition, as assessed by the reading center and other medical consultants to the field centers.

Strong Heart Study Critical Values for Laboratory Results

<u><i>Test</i></u>	<u><i>Critical Value</i></u>	<u><i>Immediate or Urgent Referral</i></u>
Fasting Glucose	≤ 40 or ≥ 400 mg/dl	Immediate
Total Cholesterol	≥ 300 mg/dl	Urgent
Total Triglyceride	≥ 1000 mg/dl	Urgent
Plasma Creatinine	≥ 3.0 mg/dl	Immediate***
Na	≤ 125 or ≥ 150 meq/dl	Immediate
K	≤ 3.0 or ≥ 6.5 meq/dl	Immediate
Ca	≤ 8.0 or ≥ 12.0 mg/dl	Immediate
PO ₄	≥ 6.0 mg/dl	Urgent
Total Bilirubin	≥ 4.0 mg/dl	Urgent
ALK	≥ 400 IU/L	Urgent
BUN	>40 mg/dl	Immediate***
Cl	None	
CO ₂	<15 meq/L	Immediate
Uric Acid	None	
Mg	None	
AST	None	
ALT	None	
LDH	None	
Total Protein	None	
Albumin	None	
CBC	Local IHS Laboratory critical values for CBC results will be followed	

*** Note: When the field center is aware of End-Stage Renal Disease, or dialysis treatments for the participant, these values can be simply noted as abnormal on the summary sheet to the

participant, with the explanation that we expect these to be abnormal when an individual has ESRD or is on dialysis.

ECG REFERRAL:

a) *ECG findings requiring review by a physician before participant leaves SHS clinic or prompting phone call from ECG Core Lab for emergency referral:*

Call should be made to Reading Center by field staff at (212) 746-4655,

or SHS Dakota Center MDs:

Dr. Lyle Best:	701-246-3884
Dr. Jeff Henderson:	605-355-2401
Dr. Tom Welty:	520-522-9005

or SHS Arizona Center MDs:

Dr. James Galloway:	1-800-777-7522
Dr. W. James Howard:	1-800-564-2536

If unable to obtain consultation from above sources, initiate emergency referral.

- ST segment elevation or depression consistent with acute myocardial infarction or subendocardial ischemia
- 3rd degree AV-block
- ventricular tachycardia
- sustained supraventricular tachycardia with heart rate >135
- any heart rate < 30

b) *ECG findings to be reviewed the same day or prompting phone call from ECG core lab for immediate referral:*

- any heart rate <35 or >135
- atrial fibrillation or atrial flutter with ventricular rate <50 or >110

c) *ECG findings where urgent referral is appropriate:*

- VPC couplets
- 2nd degree AV block
- New left bundle branch block
- New right bundle branch block
- Wolff-Parkinson-White
- Left ventricular hypertrophy
- T-wave inversion consistent with myocardial ischemia
- myocardial infarction of indeterminate age or age undetermined
- QT prolongation

d) *Examples of isolated abnormal ECG findings that do not require referral but can be sent to participant's physician as part of routine report:*

- single ectopic beats of any frequency
- left axis deviation/left anterior hemiblock
- unusual p-wave axis (non-sinus atrial rhythm), wandering atrial pacemaker, av junctional rhythm
- old left or right bundle branch block
- incomplete right bundle branch block (right ventricular conduction delay)
- ST elevation consistent with early repolarization
- 1st degree AV block

1.8 QUALITY ASSURANCE (QC) PROGRAM

A quality control committee oversees the conduct and evaluation of QC procedures. Field center coordinators will be responsible for reviewing all QC data as they become available and following up on any problems that are detected. The QC committee will monitor efficacy of retraining and problem solving.

a. Data collection

Every data form will be checked for completeness at the field center. Ambiguous or erroneous items will be clarified and corrected. The data entry programs generated by the Coordinating Center will provide an additional quality control check by building in range and logic checks. The program will refuse to accept such data until the errors are corrected. During the first two months of examination, all forms will be double entered. After this initial period, 10% of the examinations will be randomly selected for double entry. The Coordinating Center will track the data entry error rates. If the data entry error rate of any field center is greater than 0.5%, that center will have to double enter all the examination data of that month. Computer printouts of inconsistent data items will be sent back to each field center for clarification or correction. Summary statistics such as mean, median, range, maximum and minimum for continuous variables and frequency distributions for categorical variables will be calculated monthly for each center, and data not meeting consistency checks will be flagged. Summary statistics will be generated quarterly to identify any peculiar or unreasonable values. Further verifications will be made and errors corrected.

b. Quality Control site visits

Two quality control site visits will be made to each of the three centers in the first year and one in each year thereafter. The site visit teams will include representatives from the program office at NHLBI and investigators and staff members from each of the centers. Procedures used in the clinical examination will be carefully observed for adherence to protocol. Equipment will be inspected and problems noted. The site visitors then will meet with all the clinic staff to inform them of any observed discrepancies. In addition, a written evaluation, including corrections or improvements needed, will be sent to each center.

c. Quality Control -- Equipment

Other quality control measures will include maintenance of the scale, impedance meter, sphygmomanometer, Doppler, and ECG machine. The scale will be zeroed daily and calibrated with a known weight (50 lbs) every month or whenever the scale is moved. The standard sphygmomanometer will be inspected once a month. These inspections will include checking of the zero level, mercury leakage, manometer column for dirt or mercury oxide deposit, and the condition of all tubing and fittings. Other quality control measures for the blood pressure measurements will include simultaneous Y-tube observation of each technician and frequent staff meetings to provide feedback.

d. Quality Control -- Examination

1) Anthropometry and blood pressure

Duplicate measures of brachial artery blood pressure (systolic and diastolic) simultaneously using a double head stethoscope with two observers will be taken. Duplicate measures of anthropometry (height, weight, waist, and electrical impedance measurements) will be performed by a second observer on a 5% random sample of participants. These data will be sent to the Coordinating Center for monthly analysis. Results of the analysis will be provided to the field centers and the Steering Committee on a quarterly basis. Differences between duplicate measures exceeding the following values will be considered unacceptable:

- i.) Systolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.
- ii.) Diastolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.
- iii.) Height: 1 cm
- iv.) Weight: 1 Kg
- v.) Resistance: 15 ohms
- vi.) Waist circumference: 2 cm
- vii.) Hip circumference: 2 cm
- viii.) Arm circumference: 1 cm

Duplicate data for blood pressure, height, weight, impedance, and waist circumference will be compiled by the Coordinating Center and reported to the clinics and Steering Committee quarterly; in addition, distributions of measurements and digit preference for each staff member will be compiled and repeated quarterly.

Anthropometric measurements and blood pressure by standard sphygmomanometer will be observed and evaluated quarterly by the clinic supervisor. This person will also assure that each of the other operators of the impedance meter is re-certified quarterly by having him/her perform an impedance measure on the same participant as the supervisor. In addition, a simultaneous Y tube observation of each observer by the blood pressure supervisor will be made. All results will be analyzed by the Coordinating Center on a quarterly basis.

2) Laboratory tests

Duplicate blood and urine specimens will be collected on approximately 5% of the participants and sent to the Core Laboratory in a blind fashion. Results obtained for each test will be analyzed monthly by the Coordinating Center for accuracy and consistency. The percent of pairs with differences within 5% and 10% will be computed. Correlation coefficients and technical error rates will be calculated. Poor correlation or unreasonably high technical error will be reported to the Laboratory and the Steering Committee.

3) Personal interview

Personal interviews will be observed monthly by the study coordinator. Problems and errors are identified using a checklist and corrected immediately.

4) Food Frequency Questionnaire (FFQ)

Block FFQ is self-administered; participants will receive guidance in how to fill out the questionnaire. The developer, Block Dietary Data Systems, will provide a specification manual that describes each question. Ellie Zephier, SHS Nutrition Investigator, will use this manual to train the field staffs in how to instruct participants. Those participants who have difficulty will be assisted by trained staff.

5) Certification of technicians

Each center will recruit the most qualified personnel. Clinical staff will be centrally trained and certified before the examination begins and newly hired personnel will be trained at each clinic. Re-certification will occur every six months to ensure accurate and consistent performance.

6) Monitoring of Study progress

The Coordinating Center will work closely with the field centers to monitor recruitment and progress of the examinations. At the beginning of the study, a projected monthly number of participants to be recruited will be generated, and the Coordinating Center will monitor the progress of each field center according to these projected numbers and provide monthly progress reports to the Steering Committee. If the percentage of projected recruitment in a certain field center falls below 80%, the PI and the field coordinator will be informed, so that the efforts can be focused on recruitment. This program proved to be an efficient tool for monitoring the progress of SHS-III and will be continued, and refined if necessary, in Phase IV of SHS. The Coordinating Center will also monitor the number of double entries, QC physical exams, and QC blinded blood samples and report to the Steering Committee monthly.

f. Confidentiality and security of data

All personnel with access to the collected data are required to sign a confidentiality pledge. Completed data forms are placed in locked file cabinets at every center and are accessible by authorized staff members only. At the Coordinating Center, the data are stored on computers that are used exclusively by the Strong Heart Study and are safeguarded by passwords that are known only to authorized personnel. The data are stored on hard disk and four copies of floppy/optical diskettes. Two of the Zip disks/optical diskettes are stored in two different locations other than the Coordinating Center office. All of the disks and diskettes are updated daily.

APPENDIX A

APPENDIX A -- 1

**Consent Forms for
the Arizona Field Center,
the North/South Dakota Field Center,
and
the Oklahoma Field Center
(Adult and Minor Consent/Assent Forms)**

FAMILY STUDY

INFORMATION AND CONSENT FORM (1/17/01)

INSTITUTION: MedStar Research Institute

STUDY NUMBER: 88-8 **PRINCIPAL INVESTIGATOR:** Barbara V. Howard, Ph.D.

STUDY TITLE: Cardiovascular Disease in the Pima Indians. (Strong Heart Study)

INTRODUCTION: We invite you (or your child) to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study. Please read the following material to make sure that you understand this research study. If you have trouble reading this form, one of the staff will read it to you. You should know that: 1) taking part in the study is entirely your choice; 2) you (or your child) might, or might not be personally helped by joining this study, but knowledge will be gained that may help others; 3) you (or your child) may withdraw from the study at any time without losing any benefits which you (or your child) usually have. The kind of study, the benefits, risks, discomforts and other information are found below. If you (or your child) want to join the study, signing this form shows that you have read this Information and Consent Form (or had it read to you), understand what it says, and agree to take part in this research project. We will have an interpreter help you, if you want one. We want you to discuss any questions you have with the staff members before you sign this form.

PURPOSE: This research is to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

HOW YOU WERE PICKED: You (or your child) were asked to take part in the fourth phase of the Strong Heart Study (SHS), because you or one of your relatives joined the first phase of SHS.

PROCEDURE: By joining this study, you (or your child) agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your (your child's) finger and four ounces from your (your child's) arm to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, D.C. for future tests, including gene testing, to learn about

cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. The blood will be stored until it has no more scientific value for studying these problems; then it will be gotten rid of like any other laboratory or clinic that tests your blood. Your blood cells will not be kept growing, cloned, and your blood will not be used for making a profit.

2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your (your child's) arms, legs and chest and connected to an ECG machine. Heart specialists at Cornell University in New York will read this ECG test.
3. **Cardiac and Carotid Ultrasound Study.** These are "pictures" of your heart and of the arteries in your (your child's) neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.
4. **Breathing Tests.** You (or your child) will be asked to blow into an instrument that measures the contents of the air in your lungs.
5. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.
6. **Body composition.** A machine will check how much muscle, fat, and water you (or your child) have in your body by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.
7. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using a machine and computer program that have not currently been approved by the Food and Drug Administration. We know of no risks to you (or your child) from this test of blood vessel stiffness.
8. **Health Questions.** Questions will be asked about many things that can change you (your child's) general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, stress and gambling. Also questions about your family's health, and well being will be asked.

OTHER INFORMATION

1. **POSSIBLE RISKS OF THIS STUDY**
Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You (or your child) may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your (your child's) medical record, and if you (or your child) apply for insurance, the results may make it harder for you (your child) to get insurance. We will normally put your results of the tests done by Strong Heart

Study in your (your child's) IHS record, so that your clinic can use them, but we won't do that, if you don't want this done.

2. **BENEFITS**

If we find a medical problem, you (or your child) will be asked to check with your (your child's) clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You (or your child) will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check ups. You should go to your regular clinic for physical exams, and treatment of any health problems.

3. **WHY GENETIC TESTS ARE BEING DONE**

The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won't get cardiovascular disease; and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you (or your child) personally.

In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5 year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say "for sure" that something new is discovered. For these reasons you will probably NOT be contacted about results of your genetic tests. If a gene is found that would be important to predict your risk for (or help you avoid) heart disease we will contact you and ask, whether you would like to have the results of this gene testing explained to you.

Also, even though we try to be as exact as possible, early research tests like this may not be as dependable as the blood tests you have done at your regular clinic. For this reason, it might be necessary to have a particular gene test done again in a clinical laboratory. The Strong Heart Study would not be able to pay for this extra testing.

If we learn something important from this study, further research may be done after Phase IV is over in 2005. The researchers may contact you then, if we discover something new that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas by Dr. Jean MacCluer and her staff.

4. **CONFIDENTIALITY**

The results collected from this study will not be given to anyone else without your permission. Only study researchers and (by law) some people from the Food and Drug Administration, Indian Health Service Institutional Review Board, and/or the National Heart Lung and Blood Institute, which oversee this project, will be able to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of

the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your (your child's) medical records will be used for statistics to learn about these diseases without letting anyone know your (your child's) name. Names of people who join the study will never be reported in medical journals or at medical meetings. Medically important results will be put in your (your child's) medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics.

5. **RESEARCH-RELATED INJURIES**

It is very unlikely that you (your child) will be injured from joining in this research, but if that happens medical care will be provided by the Indian Health Service or the Gila River Health Care Corporation, if you are eligible for such services.

6. **PAYMENT**

This exam will not cost you (your child) anything. You (your child) will be paid \$40.00 for participating in the examination. If you need to have the exam in two visits, we will divide this into two \$20 payments. The payments are to help with your travel expenses, and to give you something for your (or your child's) time helping this study.

7. **PROBLEMS OR QUESTIONS**

Should any problems or questions come up about this study or any research-related injury, including questions about your (your child's) test results, you should contact the Principal Investigator(s): Dr. Barbara V. Howard (202) 877-6530 and Dr. James Galloway (520) 694-7000 or the Project Coordinator, Betty A. Jarvis, RN. Address: Strong Heart Study – Arizona Center, 1616 E. Indian School Rd. # 250, Phoenix, AZ. 85016 Phone: 602-277-0488

8. **RESEARCH PARTICIPANTS' RIGHTS**

You may contact Dorothy Meyer, CNM, MPH, Chair of the Phoenix Area IHS Institutional Review Board, Phoenix Area Indian Health Service, Two Renaissance Square, 40 N. Central Avenue, Phoenix, AZ 85004. Telephone: (602) 364-5175, about your (your child's) rights as a research participant.

You may also contact Daniel Herr, M.D., Chair, Institutional Review Board, (202)-877-7259.

9. **STOPPING THE STUDY**

You (or your child) may stop at any time or refuse any part of the exam without losing your (your child's) right to health care or any other benefit that you (or your child) normally have. However, we hope you (your child) will finish as many of the tests as possible. During the study, the researchers may ask you (your child) to drop out of the study, if the staff feels it is not in your (your child's) best interest to go on.

10. **FOLLOW-UP**

You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you (or your child) about these conditions. The parts of your exam that are

medically useful will be sent you (your child), when they are available. You (or your child) will also be sent Strong Heart Study newsletters now and then, to tell you (or your child) about results of the study. SHS researchers may contact you for more information about your (your child's) health in the future, or to tell you about test results that are important for your (your child's) health.

11. **CONSENT TO PARTICIPATE**

I have read, or had read to me, this Information and Consent Form, and I have been able to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risks and benefits that I learned about in this Information and Consent Form, I want to join in this research (or have my child join the study). A copy of this Information and Consent Form will be given to me to keep and look back on.

I WANT TO JOIN THE STRONG HEART STUDY – PHASE IV RESEARCH STUDY.

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my (my child's) IHS chart.

I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my (my child's) chart at a different health care provider. Please send to:

I would ____ would not ____ like important genetic test results reported to myself or my clinic providers.

If you need to contact me about results of tests that may be important to my (my child's) health, please use this address (I will let you know if I have a change of address):

PRINTED NAME OF PARTICIPANT

DATE

SIGNATURE OF ADULT PARTICIPANT

DATE

SIGNATURE OF PARENT OR GUARDIAN IF PARTICIPANT IS LESS THAN 18 YEARS OLD.

DATE

In my opinion, the participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

SIGNATURE OF PERSON OBTAINING CONSENT

DATE

ASSENT FORM-1/17/01 STRONG HEART STUDY FAMILY STUDY

The Strong Heart Family Study is research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research. Here are some tests that will be done and some other things that you need to know.

1. **Blood Tests.** We will check how much sugar, cholesterol and other fats are in your blood 12 or more hours after you eat. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. It will be stored in laboratories in Washington, D.C. and San Antonio, Texas until it is no longer needed. Then we will get rid of it.
2. **Electrocardiogram or “ECG”.** This is a tracing of heart waves that will be sent to Cornell University in New York for reading.
3. **Carotid and Cardiac Echo study.** This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.
4. **Urine Test.** Some urine will be taken to find out how the kidneys are working.
5. **Body Composition.** A machine will find out how much muscle, fat, and water is in your body by passing a tiny charge from your hand to your foot. There is no known risk from this test and you won't feel anything.
6. **Physical Examination.** We will check your blood pressure in the arms and legs, your height, weight, waist/hip, arm size and body fat. We know of no risk to you from these tests.
7. **Health interview.** There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, and where you get your health care. You are free to not answer any or all of the questions, but we hope that you will answer them all.

Other information:

1. **Possible risks of joining the study.** Drawing the blood may cause a little pain and sometimes a bruise. Tests that will be done are like in regular medical checkups, and have a low chance of causing problems. If your test results from the study are put in your medical record, and if you apply for insurance, the results may make it harder for you to get insurance.
2. **Benefits.** The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.

3. Why genetic tests are being done. This study does testing on the genes, or DNA in your blood cells. The reason is to find genes that may cause or protect people from heart and lung disease. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will probably NOT be contacted about your personal results.

If we learn something important from this study, more research may be done after Phase IV is over in 2005. The researchers may contact you then, if something new is discovered that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for BioMedical Research, San Antonio, Texas.

4. Payment. This exam will not cost you or your parents anything. You will be paid \$40 for answering the questions having blood drawn, and completing the examination. This money is paid to help with your travel costs and to thank you for the time we have taken.

5. Stopping the study. We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam.

6. Assent to participate. I know the reason for these tests, which tests will be done, and the bad and good things that go with them. By signing this paper, I am saying that I want to be part of this research:

PRINTED NAME OF PARTICIPANT

DATE

MINOR PARTICIPANT'S SIGNATURE

DATE

SIGNATURE OF PARENT OR GUARDIAN

DATE

In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed assent.

SIGNATURE OF PERSON OBTAINING ASSENT

DATE

INFORMATION AND CONSENT FORM

STUDY TITLE: Cardiovascular Disease in Sioux Indians. The Strong Heart Study-Phase IV

PRINCIPAL INVESTIGATOR: Lyle G. Best, M.D.

GRANT RECIPIENT: Missouri Breaks Industries Research, Inc.

INTRODUCTION: We invite you (or your child) to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study. Please read the following material to make sure that you understand this research study. If you have trouble reading this form, one of the staff will read it to you. You should know that: 1) taking part in the study is entirely your choice; 2) you (or your child) might, or might not be personally helped by joining this study, but knowledge will be gained that may help others; 3) you (or your child) may withdraw from the study at any time without losing any benefits which you (or your child) usually have. The kind of study, the benefits, risks, discomforts and other information are found below. If you (or your child) want to join the study, signing this form shows that you have read this Information and Consent Form (or had it read to you), understand what it says, and agree to take part in this research project. We will have an interpreter help you, if you want one. We want you to discuss any questions you have with the staff members before you sign this form.

PURPOSE: This research is to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

HOW YOU WERE PICKED: You (or your child) were asked to take part in the fourth phase of the Strong Heart Study (SHS), because you or one of your relatives joined the first phase of SHS. About 3600 people from the Dakotas, Oklahoma and Arizona will take part in Phase IV of SHS.

PROCEDURE: By joining this study, you (or your child) agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your (your child's) finger and 8 tablespoons from your (your child's) arm to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, D.C. for future tests, including gene testing, to learn about cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. The blood will be stored until it has no more scientific value for studying these problems; then it will be disposed of in the standard way. Your blood cells will not be kept growing, cloned, and your blood will not be used for making a profit.
2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your (your child's) arms, legs and chest and connected to an ECG machine. Heart specialists at Cornell University in New York will read this ECG test.

3. **Cardiac and Carotid Ultrasound Study.** These are "pictures" of your heart and of the arteries in your (your child's) neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.
4. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.
5. **Body fat.** A machine will check how much fat you (or your child) have by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.
6. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using a machine and computer program that have not currently been approved by the Food and Drug Administration. We know of no risks to you (or your child) from this test of blood vessel stiffness.
7. **Health and Family Questions.** Questions will be asked about many things that can change your (your child's) general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, and stress. Also questions about who your family members are, how they are related to you, their health, and well being will be asked.

OTHER INFORMATION

1. **POSSIBLE RISKS OF THIS STUDY**

Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You (or your child) may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your (your child's) medical record, and if you (or your child) apply for insurance, the results may make it harder for you (your child) to get insurance. We will normally put your results of the tests done by Strong Heart Study in your (your child's) IHS record, so that your clinic can use them, but we won't do that, if you don't want this done.

2. **BENEFITS**

If we find a medical problem, you (or your child) will be asked to check with your (your child's) clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You (or your child) will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check ups. You should go to your regular clinic for physical exams, and treatment of any health problems.

3. **WHY GENETIC TESTS ARE BEING DONE**

The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won't get cardiovascular disease; and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These

genetic tests are not likely to help you (or your child) personally.

In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5-year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say “for sure” that something new is discovered. For these reasons you will probably NOT be contacted about results of your genetic tests. If a gene is found that would be important to predict your risk for (or help you avoid) heart disease, we will contact you and ask whether you would like to have the results of this gene testing explained to you.

Also, even though we try to be as exact as possible, early research tests like this may not be as dependable as the blood tests you have done at your regular clinic. For this reason, it might be necessary to have a particular gene test done again in a clinical laboratory. The Strong Heart Study would not be able to pay for this extra testing.

If we learn something important from this study, further research may be done after Phase IV is over in 2005. The researchers may contact you then, if we discover something new that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas or at other laboratories with the approval of the Strong Heart Study researchers.

4. **CONFIDENTIALITY**

Only study researchers and (by law) some people from the Food and Drug Administration, Indian Health Service Institutional Review Board, and/or the National Heart Lung and Blood Institute, which oversee this project, may need to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your (your child's) medical records will be used for statistics to learn about these diseases without letting anyone know your (your child's) name. These statistics will be reported in medical journals, at medical and research meetings and to your Tribe; but the names of people who join the study will never be reported. Medically important results will be put in your (your child's) medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics. A “Certificate of Confidentiality” will be provided by the Department of Health and Human Services, this helps prevent courts and others from obtaining your confidential research information, but there is no way to guarantee that a court could not force our study to reveal some information.

5. **RESEARCH-RELATED INJURIES**

It is very unlikely that you (your child) will be injured from joining in this research, but if that happens the Indian Health Service will provide medical care, if you are eligible for such services. Neither Missouri Breaks Industries Research, Inc., nor the Indian Health Service, nor any person involved with this research project has provisions for financial compensation in the event of such injury.

6. **PAYMENT**

This exam will not cost you (your child) anything. You (your child) will be paid \$25.00 for answering the questions and having blood drawn, and \$20 when you (your child) have the ultrasound tests done. This will probably take two visits. The payments are to help with your travel expenses, and to give you something for your (or your child's) time helping this study. You (your child) will also be given a health promotion gift.

7. **PROBLEMS OR QUESTIONS** Should any problems or questions come up about this study or any research-related injury, including questions about your (your child's) test results, you should contact the Principal Investigator, Dr. Lyle Best or the Project Coordinator, Marcia O'Leary, RN. Address: Strong Heart Study - Dakota Center, P.O. Box 9010, Rapid City, SD 57709. Telephone:(605) 355-2377 or 605-865-3418.
8. **RESEARCH PARTICIPANTS' RIGHTS**
You may contact Dr. Elaine Miller, Chairperson of the Aberdeen Area IHS Institutional Review Board, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Ave SE, Aberdeen, SD 57401 Telephone: (605) 226-7544, about your (your child's) rights as a research participant.
9. **STOPPING THE STUDY**
You (or your child) may stop at any time or refuse any part of the exam without losing your (your child's) right to health care or any other benefit that you (or your child) normally have. However, we hope you (your child) will finish as many of the tests as possible. During the study, the researchers may ask you (your child) to drop out of the study, if the staff feels it is not in your (your child's) best interest to go on.
10. **FOLLOW-UP**
You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you (or your child) about these conditions. The parts of your exam that we think are medically useful will be sent you (your child), when they are available. You (or your child) will also be sent Strong Heart Study newsletters now and then, to tell you (or your child) about results of the study. SHS researchers may contact you for more information about your (your child's) health in the future, or to tell you about test results that are important for your (your child's) health. You may also be contacted in the future by SHS researchers for information about new family members or to clarify family relationships.
11. **RESPONSIBILITY FOR THE STUDY**
The Aberdeen Area Indian Health Service was responsible for Phases I and II, and the Aberdeen Area Tribal Chairmen's Health Board was responsible for Phase III. The Missouri Breaks Research, Inc has taken responsibility for the Strong Heart Family Study (Phase IV) including keeping the research records. Signing this consent form will let Missouri Breaks Research Inc. staff, with professional supervision of the principal investigator, look at the information collected in earlier phases of the study.
12. **CONSENT TO PARTICIPATE**
I have read, or had read to me, this Information and Consent Form, and I have been able to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risks and benefits that I learned about in this Information and Consent

Form, I want to join in this research (or have my child join the study). A copy of this Information and Consent Form will be given to me to keep and look back on.

I WANT TO JOIN THE STRONG HEART STUDY-PHASE IV RESEARCH STUDY.

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my (my child's) IHS chart.

I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my (my child's) chart at a different health care provider. Please send to:

I would ____ would not ____ like important genetic test results reported to myself.

I would ____ would not ____ like important genetic test results reported to my clinic providers.

If you need to contact me about results of tests that may be important to my (my child's) health, please use this address (I will let you know if I have a change of address):

PRINTED NAME OF PARTICIPANT

DATE

SIGNATURE OF ADULT PARTICIPANT

DATE

SIGNATURE OF PARENT OR GUARDIAN IF PARTICIPANT IS LESS THAN 18 YEARS OLD.

DATE

In my opinion, the participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

SIGNATURE OF PERSON OBTAINING CONSENT

DATE

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ASSENT FORM STRONG HEART STUDY FAMILY STUDY

The Strong Heart Study is doing research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research. Here are some tests that will be done and some other things that you need to know.

1. Blood Tests. We will check how much sugar, cholesterol and other fats are in your blood 12 or more hours after you eat. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. It will be stored in laboratories in Washington, D.C. and San Antonio, Texas until it is no longer needed, then it will be disposed of in a standard way.

2. Electrocardiogram or “ECG”. This is a tracing of heart waves that will be sent to Cornell University in New York for reading.

3. Carotid and Cardiac Echo study. This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.

4. Urine Test. Some urine will be taken to find out how the kidneys are working.

5. Body fat. A machine will find out how much fat is in your body by seeing how a very tiny little bit of electricity flows through you. There is no known risk from this test and you won't feel anything.

6. Physical Examination. We will check your blood pressure in the arms and legs (this can cause a mild squeezing feeling), measure your height, weight, waist/hip, arm size and body fat. We know of no risk to you from these tests.

7. Health interview. There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, and where you get your health care. You are free to not answer any or all of the questions, but we hope that you will answer them all.

Other information:

1. Possible risks of joining the study. Drawing the blood may cause a little pain and sometimes a bruise. Tests that will be done are like in regular medical checkups, and have a low chance of causing problems. If results that could be important to your health are found from your tests, we will need to tell both you and your parents because you are not yet of legal age.

2. Benefits. The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.

3. Why genetic tests are being done. This study does testing on the genes, or DNA in your blood cells. The reason is to find genes that may cause or protect people from heart, lung disease and stroke. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will probably NOT be contacted about your personal results.

If we learn something important from this study, more research may be done after Phase IV is over in 2005. The researchers may contact you then, if something new is discovered that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas.

4. Confidentiality. Shortly after we get your samples, your name is replaced by a number, so that even most of the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your medical records will be used for statistics to learn about these diseases without letting anyone know your name. These statistics will be reported in medical journals, at medical and research meetings and to your Tribe; but the names of people who join the study will never be reported. A "Certificate of Confidentiality" will be provided by the Department of Health and Human Services, this helps prevent courts and others from obtaining your confidential research information, but there is no way to guarantee that a court could not force our study to reveal some information.

5. Payment. This exam will not cost you or your parents anything. You will be paid \$25 for answering the questions and having blood drawn, and \$20 when the echo tests are done. This will usually take two visits. This money is paid to help with your travel costs and to thank you for the time we have taken.

6. Stopping the study. We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam.

7. Assent to participate. I know the reason for these tests, which tests will be done, and the bad and good things that go with them. By signing this paper, I am saying that I want to be part of this research:

PRINTED NAME OF PARTICIPANT

DATE

MINOR PARTICIPANT'S SIGNATURE

DATE

SIGNATURE OF PARENT OR GUARDIAN

DATE

In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed assent.

SIGNATURE OF PERSON OBTAINING ASSENT

DATE

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CONSENT FORM
University Of Oklahoma Health Sciences Center
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(The Strong Heart Study Phase IV)
Elisa T. Lee, Ph.D., Principal Investigator

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. If you have trouble reading this consent form, one of the staff will read it to you. Discuss this with your family and friends.

You are being asked to take part in the Strong Heart Family Study because you or one of your relatives participated in the first phase of the Strong Heart Study and because your family is large and your family members are interested in participating.

Why Is This Study Is Being Done?

This research is being done to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

How Many People Will Take Part in the Study?

About **3600** people will take part in this study nationwide. About **1200** of these individuals will participate at this location.

What Is Involved in the Study?

We invite you to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study.

PROCEDURE: By joining this study, you agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your finger and four ounces (8 tablespoons) from your arm by a needle to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, DC and at the Southwest Foundation for Biomedical Research in San Antonio, TX for future tests, including gene testing, to learn about cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. Your blood will be stored until it has no more scientific value for studying heart,

lung, and blood disease; then it will be destroyed. Your blood cells will not be cloned or kept growing, and your blood will not be used for making a profit.

2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your arms, legs and chest and connected to an ECG machine. This ECG test will be read by heart specialists at Cornell University in New York.
3. **Cardiac and Carotid Ultrasound Study.** These are "pictures" of your heart and of the arteries in your neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.
4. **Breathing Tests.** You will be asked to blow into an instrument that measures carbon monoxide. Carbon monoxide levels are high in smokers, people who have to breathe smoke, and people who have bad furnaces.
5. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.
6. **Body fat.** A machine will check how much fat you have by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.
7. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using an experimental computer program that has not currently been approved by the Food and Drug Administration. We know of no risks to you from this test of blood vessel stiffness.
8. **Health and Family Questions.** Questions will be asked about many things that can change your general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, stress and gambling. Also questions about who your family members are, how they are related to you, their health, and well being will be asked.

OTHER INFORMATION

The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won't get cardiovascular disease, and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you personally. In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5-year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say "for sure" that something new is discovered. For these reasons you will NOT be contacted about results of your genetic tests. If we learn something important from this study, further research may be done after Phase IV is over in 2005. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas or at other laboratories with the approval of the Strong Heart Study researchers.

How Long Will I Be in the Study?

The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. You may withdraw from the study at any time without losing any benefits, which you usually have.

What Are the Risks of the Study?

Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your medical record, and if you apply for insurance, the results may make it harder for you to get insurance. We will normally put your results of the tests done by Strong Heart Study in your IHS record, so that your clinic can use them, but we won't do that, if you don't want this done.

Risks of genetic testing: If the genetic tests being done in this study determined that your disease is caused by genetic abnormalities, your family members could face problems in obtaining insurance coverage for this disease, even if they have no symptoms. However, in order to do everything possible to keep this from happening, the results of this test will NOT be given to anyone outside the study staff. This means that it will not be made available to you, your family members, your private physician, your employer, your insurance company, or any other party as allowed by law.

Are There Benefits to Taking Part in the Study?

If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check ups. You should go to your regular clinic for physical exams and treatment of any health problems.

What Other Options Are There?

This is a research study. Research studies involve only individuals who choose to participate, and you are free to choose not to participate.

What About Confidentiality?

Only study researchers and (by law) some people from the Food and Drug Administration, the Institutional Review Boards, and/or the National Heart, Lung and Blood Institute, which oversee this project, may need to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of the staff who run the tests will not have any name connected with your sample. The results of the exam and any information in your medical records will be used for statistics to learn about these diseases without letting anyone know your name. Names of people who join the study will never be reported in medical journals or at medical meetings. Medically important results will be put in your medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics.

What Are the Costs?

This exam will not cost you anything.

Will I Be Paid for Participating in This Study?

You will be paid \$25.00 for answering the questions and having blood drawn, and \$25 when you have the ultrasound tests done. This may take two visits. The payments are to help with your

travel expenses, and to give you something for your time helping this study. You will also be given a health promotion gift.

What If I am Injured or Become Ill While Participating in This Study?

It is very unlikely that you will be injured or become ill from joining in this research, but if that happens medical care will be provided by the Indian Health Service, if you are eligible for such services. Otherwise, emergency medical treatment is available, but you or your insurance company may be expected to pay the usual charge for this treatment. No funds have been set aside by the University of Oklahoma Health Sciences Center, the Indian Health Service, or the National Heart, Lung, and Blood Institute to compensate you in the event of injury. If you have questions about the availability of care, you may contact the Lawton Indian Health Service Hospital at (580) 353-0350 or the Anadarko Indian Health Service Clinics at (580) 247-2458.

What Are My Rights as a Participant?

Taking part in this study is voluntary. You may stop at any time or refuse any part of the exam without losing your right to health care or any other benefit that you normally have. During the study, the researchers may ask you to drop out of the study, if the staff feels it is not in your best interest to go on.

You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you about these conditions. The parts of your exam that we think are medically useful will be sent to you when they are available. You will also be sent Strong Heart Study newsletters periodically, to tell you about results of the study. SHS researchers may contact you for more information about your health in the future, or to tell you about test results that are important for your health. You may also be contacted in the future by SHS researchers for information about new family members or to clarify family relationships.

Whom Do I Call If I Have Questions or Problems?

If you have questions about the study, contact Dr. Elisa Lee or her colleagues at 405-271-3090. For questions about your rights as a research subject, contact Nancy Nisbett, the Director of the Office of Research Administration, at 405-271-2090, or Mr. Samuel M. Hope, Chairperson, Oklahoma City Area IHS Institutional Review Board, Indian Health Service, Five Corporate Plaza, 3625 NW 56th Street, Oklahoma City, OK, 73112, telephone number (405) 951-3829.

Signature:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or institution from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I want to join the Strong Heart Study-Phase IV research study:

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my IHS chart.

I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my chart at a different health care provider. Please send to:

If you need to contact me about results of tests that may be important to my health, please use this address (I will let you know if I have a change of address):

Research Subject: _____ Date: _____

Witness: _____ Date: _____

Person Obtaining Informed Consent: _____ Date: _____

Principal Investigator: _____ Date: _____

SHS Phase IV Family Study, IRB No. 08473, Revised: November 10, 2000

CHILD CONSENT FORM
University Of Oklahoma Health Sciences Center
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(The **Strong Heart Study** Phase IV)
Elisa T. Lee, Ph.D., Principal Investigator

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. If you have trouble reading this consent form, one of the staff will read it to you. Discuss this with your family and friends.

Why Is This Study Is Being Done?

The Strong Heart Study is doing research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research.

What Is Involved in the Study?

Here are some tests that will be done and some other things that you need to know.

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your finger and four ounces (8 tablespoons) from your arm by a needle We will check how much sugar, cholesterol, and other fats are in your blood. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. Your blood will be stored until it has no more scientific value for studying heart, lung, and blood disease; then it will be destroyed.
2. **Electrocardiogram or “ECG”.** This is a tracing of heart waves that will be sent to Cornell University in New York for reading.
3. **Carotid and Cardiac Ultrasound study.** This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.
4. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.
5. **Body fat.** A machine will find out how much fat is in your body by seeing how a very tiny little bit of electricity flows through you. There is no known risk from this test, and you won’t feel anything.
6. **Breathing Tests.** You will be asked to blow into a machine to check for carbon monoxide which is a special gas that can come from smoking or heaters that don’t work right.

7. **Physical Examination.** We will check your blood pressure in the arms and legs, measure your height, weight, waist, arm size and body fat. We know of no risk to you from these tests.
8. **Health interview.** There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, where you get your health care, and gambling. You are free to not answer any or all of the questions.

How Long Will I Be in the Study?

The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam without losing any benefits that you usually have.

What Are the Risks of the Study?

Drawing the blood may cause a little pain and sometimes a bruise. The tests in the exam are similar to those in a regular medical checkup, and have a low chance of causing problems.

Are There Benefits to Taking Part in the Study?

The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.

Other Information

Why genetic tests are being done. This study does testing on the genes, or DNA, in your blood cells. The reason is to find genes that may cause or protect people from heart and lung disease. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will NOT be contacted about your personal results. If we learn something important from this study, more research may be done after Phase IV is over in 2005. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas.

What Other Options Are There?

You are free to choose not to participate.

What Are the Costs?

This exam will not cost you or your parents anything.

Will I Be Paid for Participating in This Study?

You will be paid \$25 for answering the questions and having blood drawn, and \$25 when the ultrasound tests are done. This may take two visits. This money is paid to help with your travel

costs and to thank you for the time we have taken. You will also be given a health promotion gift.

Signature:

Consent to participate. I know the reason for these tests, which tests will be done, and the risks and benefits that go with them. By signing this paper, I am saying that I want to be part of this research:

Minor Participant's Signature: _____ Date: _____

Signature of
Parent or Guardian: _____ Date: _____

Witness: _____ Date: _____

In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

Person Obtaining Consent: _____ Date: _____

Principal Investigator: _____ Date: _____

SHS Phase IV Family Study, IRB No. 08473, Revised: November 10, 2000

Appendix A – 2(a)

**THE STRONG HEART STUDY IV
Clinical Examination – Checklist**

Participant's name: _____

ID Number: _____

Date: _____
 mo day yr

	Items	If done, date and initial	
1.	Consent Form Signed	_____	_____
2.	Pregnancy/lactation screen (if appropriate)	_____	_____
3.	Medical Release Signed	_____	_____
4.	Sample collection checklist	_____	_____
5.	Family information form	_____	_____
6.	Personal interview forms	_____	_____
7.	Medical history form	_____	_____
8.	Reproduction and hormone use (women)	_____	_____
9.	Rose questionnaire	_____	_____
10.	Respiratory questionnaire	_____	_____
11.	Medication checklist	_____	_____
12.	Psychosocial questionnaires checklist	_____	_____
13.	ECG	_____	_____
14.	Impedance measurement	_____	_____
15.	Height and weight	_____	_____
16.	Abdominal, hip, and arm circumference	_____	_____

17.	Sitting blood pressure	_____	_____
18.	Doppler blood pressure	_____	_____
19.	Food Frequency Questionnaire	_____	_____
20.	Carotid ultrasound	_____	_____
21.	Echocardiogram	_____	_____
22.	Radial tonometry	_____	_____
23.	Pedometer diary	_____	_____
24.	Payment or payment form	_____	_____

Appendix A – 2(b)

**THE STRONG HEART STUDY IV
Post Exam Activities**

Same Day:

- Process blood specimens
- Review morbidity (chart review at clinic site)
- Stamp participant's clinic chart with SHS exam information (if so indicated on consent form)
- Add codes: Community, Tribe, clinic/hospital, medicines
- Edit for missing data
- Transmit ECGs to New York
- Make all but routine referrals
- Complete ultrasound and tonometry measurements

Later:

- Send ultrasound tapes to reading center
- Make routine referrals
- File confirmed ECG and ultrasound/tonometry reports
- Mail letters to participants
- File laboratory findings in participant's medical records (if so indicated on consent form)
- Mail laboratory specimens

Appendix A – 3

SHS PHASE IV FAMILY STUDY
Checklist for Blood Pressure

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed ____ / ____ / ____ (Month/Day/Year)

- YES () NO () Provide subject instruction, allowing opportunity for questions.
- YES () NO () Measure right arm for correct cuff size.
- YES () NO () Palpates brachial artery, medial to and above antecubital fossa.
- YES () NO () Marks pulse point.
- YES () NO () Places cuff correctly.
- YES () NO () Leaves subject for 5 minutes rest.
- YES () NO () Subject positioned correctly.
- YES () NO () Provides environment free of excessive noise.
- YES () NO () Finds pulse obliteration point.
- YES () NO () Calculates peak inflation.
- YES () NO () Places stethoscope in ears.
- YES () NO () Inflates cuff rapidly to calculated peak.
- YES () NO () Holds pressure steady for full 5 seconds.
- YES () NO () Places bell on brachial pulse
- YES () NO () Deflates cuff slowly, 2 mmHg per second.
- YES () NO () Deflates cuff rapidly after 2 absent sounds.
- YES () NO () Records readings.
- YES () NO () Disconnects tubes.
- YES () NO () Instructs subject to hold right arm vertical for full five seconds.
- YES () NO () Waits at least 30 seconds before proceeding to 2nd and 3rd readings.
- YES () NO () Average 2nd and 3rd readings, informs subject of average BP.

Comments: _____

Appendix A – 4
SHS PHASE IV FAMILY STUDY
Simultaneous Blood Pressure Observation Form

Quarterly, each technician should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to this form and should calculate the differences between the two sets of measurements. The acceptable margin of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

Technician #1 Code # / Initials _____

Technician #2 Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

	Tech #1	Tech #2	Difference
Arm circumference	_____	_____	_____
Cuff size	_____	_____	_____
Pulse obliteration pressure	_____	_____	_____
SBP #1	_____	_____	_____
DBP #1	_____	_____	_____
SBP #2	_____	_____	_____
DBP #2	_____	_____	_____
SBP #3	_____	_____	_____
DBP #3	_____	_____	_____
Average SBP	_____	_____	_____
Average DBP	_____	_____	_____

Comments: _____

Appendix A – 5(a)
SHS Phase IV Family Study
Quality Control

SPHYGMOMANOMETERS

MONTH	DATE	INIT.	MERCURY LEVEL IS AT ZERO WITH NO PRESSURE	CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHG	CHECK CAP FOR TIGHTNESS	CHECK TUBE FOR OXIDE DUST	COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.
JAN							
FEB							
MAR							
APR							
MAY							
JUN							
JUL							
AUG							
SEP							
OCT							
NOV							
DEC							

Appendix A – 5(b)
SHS Phase IV Family Study
Quality Control

SCALE & MEASUREMENT TAPES

MONTH	DATE	INIT.	PORTABLE SCALE	CALIBRATED WEIGHTS	HEIGHT METAL TAPE 50 cm, 60 cm	MEASURING TAPE, to 30 cm METAL TAPE
JAN						
FEB						
MAR						
APR						
MAY						
JUN						
JUL						
AUG						
SEP						
OCT						
NOV						
DEC						

Appendix A – 6

SHS Phase IV Family Study

MAINTENANCE PROCEDURES FOR STANDARD SPHYGMOMANOMETERS

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting.

1. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, mercury should be added or withdrawn until it does read zero. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.
2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:
 - a) The system should be re-inflated until the column rises to 200 mmHg.
 - b) The tubing should be pinched at various locations to localize the area of the leak.
 - c) Appropriate replacement of the tubing, cuff, or valve should be performed.
3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the silicone rubber, which provides a seat for both ends of the glass tube, should be replaced.
4. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with this instrument. The tube should then be replaced and the zero level rechecked.
5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.

Appendix A – 7(a)

NOTE: THIS LETTER IS TO BE USED ONLY FOR NORMAL RESULTS OR ROUTINE REFERRALS. EMERGENT, IMMEDIATE AND URGENT REFERRALS SHOULD FOLLOW THE GUIDELINES IN SECTION 1.8.

THE STRONG HEART STUDY IV Sample Letter to Participant after Physical Examination

Dear _____:

Thank you very much for taking part in the Strong Heart Study today.

Blood Pressure

When your blood pressure is too high it causes extra “wear and tear” on your heart and blood vessels. Over the years this can lead to hardening of the arteries and then stroke, heart attacks and kidney damage. Doctors have known for many years now that properly controlling blood pressure helps to prevent these medical problems.

Your blood pressure was _____ (less than 140/90 and you do not take medication for your blood pressure). This is within the normal range. It should be checked at least once a year.

Your blood pressure was _____ (greater than 140/90). This is above the normal range. You should make an appointment for follow-up with your medical care provider, since high blood pressure may cause heart problems and stroke.

Your blood pressure was _____ (less than 140/90, and you take blood pressure medicine). This is within the normal range. Continue taking your blood pressure medicine as directed by your medical care provider.

Glucometer test for Diabetes.

Diabetes causes the blood sugar to be too high. Over a long period of time this seems to cause damage to the blood vessels, eyes, kidneys and nerves. We are now quite sure that lowering the blood sugar into the normal range helps to prevent these problems. This glucometer test is very accurate but not as exact as the laboratory test that will be done on the blood sample from your arm. The results from that test will be sent to you later.

Your fasting blood sugar was _____ (less than 130 mg/dl). This is within the desirable range.

Your fasting blood sugar was _____ (more than 130 but less than 200) These values are higher than normal and raise the possibility that you may have diabetes. These results will need to be checked by the sample taken from your arm, but we suggest that you contact your medical provider in the coming week or so to have this result checked sooner than that.

Your fasting blood sugar was _____ (known diabetic, less than 150). On the day of the exam, your fasting blood sugar was probably under adequate control. Be sure to follow the advice of your medical care provider for control of your diabetes.

Your fasting blood sugar was _____ (known diabetic greater than 150 but less than 300). Your fasting blood sugar was not as good as it should be for diabetic patients. We suggest that you see your medical care provider in the coming week or so for advice on how to get better control.

Body Weight and “Body Mass Index” or “BMI”

We have measured your body weight and height. We have done a calculation from these two numbers that give us another number called the “BMI”. This can be compared to the BMI of other people and gives you information about your health risk from obesity.

Your BMI was _____ (less than 25) which is considered normal. We hope you will continue to balance your diet and exercise to maintain this healthy level.

Your BMI was _____ (more than 25 but less than 30) which is higher than normal. We suggest that you think carefully about ways that you can reduce the foods that have a lot of calories and increase the amount of exercise that you do each day. If you want help with planning these changes, we can assist you.

Your BMI was _____ (more than 30 which is definitely higher than normal). We suggest that you let us help you make an appointment to see a dietician that can advise you about ways to change your eating habits. We would also suggest that you discuss with your medical provider ways to increase your exercise.

Acanthosis Nigricans

This is a condition that causes thickening and a slightly darker look to the skin, especially at the back of the neck. This is usually seen in people above their recommended weight and may show that they are becoming resistant to the effects of insulin. People with this condition often go on to develop type II diabetes. If you are able to reduce the calories in your diet, get more exercise and reduce your weight, these changes will often get better or disappear.

During your exam, our staff found NO _____, SOME _____, or DEFINITE _____ acanthosis nigricans.

Smoking

One of the areas that we have asked some questions about today is smoking. While occasionally smoking tobacco as a religious practice probably causes no harm; smoking cigarettes or using other tobacco as a daily habit has many health risks. Most people think of the risk of lung and other cancers, which is very important; but actually the risk of death and

illness from heart disease is a much greater risk from smoking. If you currently smoke, we would like to tell you about some methods that could help you quit.

We hope this information has been helpful. There will be results from your blood tests, ultrasound of the neck blood vessels and ultrasound heart pictures coming back in the next days and weeks. You will be contacted and advised if these tests are normal or abnormal. If there are problems with your results, we will tell you how to get help from your medical providers to take care of your health.

In the meantime, remember these 7 important ways to keep your heart healthy:

- 1) Eat sensibly, keep your weight normal, watch the amount of fat in your diet
- 2) Exercise sensibly, and regularly
- 3) Know that your blood pressure is normal, or work with your provider to control it
- 4) Know that your blood sugar is normal, or work to control it
- 5) If you use tobacco as a habit, please stop
- 6) Abstain from alcohol, or drink in moderation with only one or two drinks per day
- 7) Try to get the rest and relaxation that you need, and enjoy life!

We look forward to working with you to learn more about your health.

Sincerely,

The Strong Heart Staff

Appendix A – 7(b)

NOTE: THIS LETTER (or its ALTERNATE form) IS TO BE USED ONLY FOR NORMAL RESULTS OR ROUTINE REFERRALS. EMERGENT, IMMEDIATE AND URGENT REFERRALS SHOULD FOLLOW THE GUIDELINES IN SECTION 1.8.

**THE STRONG HEART STUDY IV
Sample Letter to Participant Concerning Test Results**

Dear Strong Heart Study participant:

Attached are results of your [**blood tests, or carotid artery ultrasound, or echocardiogram, etc**] study that were done as part of the Strong Heart Study. These results have also been sent to _____ as you requested when you came in for your exam.

ON THE NEXT PAGE YOU WILL FIND A SUMMARY OF THE ABNORMAL RESULTS FROM YOUR TESTS, AND RECOMMENDATIONS ABOUT WHAT SHOULD BE DONE.

If we have suggested that you see your medical provider in the coming week or sooner, we will have also tried to reach you by phone. We would like to help you make arrangements for an appointment or for a ride to the clinic, if that is needed.

If you have any questions about these results, contact your health care provider or the staff at the SHS office in [**Eagle Butte, or Pine Ridge..... at (605) 964-1177etc**]. The attached sheet describes the purpose of each test.

Thank you for your participation in the Strong Heart Study and for helping us learn more about heart disease and strokes in Indian people.

Sincerely,

Principal Investigator
Strong Heart Study

----- **OR, ALTERNATIVELY** -----

substitute the following paragraph for the first paragraph of the above form letter:

“Attached are results of your [**blood tests, or carotid artery ultrasound, or echocardiogram, etc**] study that were done as part of the Strong Heart Study. Honoring your request as stated in your consent form, the attached lab results were NOT sent to the IHS or any other medical facility or healthcare provider. However, it may be in your best interests for you to show your healthcare provider these results during your next visit.”

SUMMARY OF ABNORMAL RESULTS

FOR EXAMPLE:

Cholesterol 229 mg/dl

This is a fatty substance in your blood that may clog arteries if it is too high. Everyone should know his/her cholesterol level. It is best to have your cholesterol below 200 mg/dl. Levels 200-239 mg/dl are moderate risk. Levels 240 mg/dl or higher are high risk. Persons with high levels should eat fewer fatty foods and more foods high in fiber such as cereals, fruits, and vegetables. They may also need medicine to lower their cholesterol.

LDL Cholesterol 166 mg/dl

This is the bad cholesterol that clogs the arteries. It is best to have levels below 130 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. People who have had a heart attack are usually advised to get their levels below 100 mg/dl so that further clogging of arteries is prevented.

CAROTID ULTRASOUND RESULTS

Narrowing less than 50%

These results show that you have a certain amount of hardening of the arteries in the large blood vessels in your neck. These blood vessels supply circulation to the brain. Sometimes clots that form in the neck can travel up into the head to cause stroke. Usually surgery is NOT recommended for people with your level of narrowing, but we do suggest that you are careful to **do things that will prevent this hardening** from getting **worse**. We recommend that you talk with your medical provider about this at your next appointment in the coming month.

Appendix A – 8

THE STRONG HEART STUDY IV INTERPRETATION OF BLOOD TESTS

Cholesterol	This is a fatty substance in your blood that may clog arteries if it is too high. Everyone should know his/her cholesterol level. It is best to have your cholesterol below 200 mg/dl. Levels 200-239 mg/dl are moderate risk. Levels 240 mg/dl or higher are high risk. Persons with high levels should eat fewer fatty foods and more foods high in fiber such as cereals, fruits and vegetables. They may also need medicine to lower their cholesterol.
Triglycerides	This is another type of fat in the blood that may cause problems in the pancreas if it is too high. Levels should be below 250 mg/dl. Levels above 1,000 mg/dl are high risk for pancreas problems. Triglyceride levels may be higher in people with diabetes and if they are, improving the control of blood sugar and avoiding alcohol often can lower the level.
HDL Cholesterol	This form of cholesterol is good in that it may prevent clogging of arteries. Levels below 35 mg/dl are high risk and can be increased by exercise.
LDL Cholesterol	This is the bad cholesterol that clogs the arteries. It is best to have levels below 130 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. People who have diabetes or have had a heart attack are usually advised to get their levels below 100 mg/dl so that further clogging of arteries is prevented.
Calcium	High values (above 10.5 mg/dl) or low values (below 9.1 mg/dl) may indicate problems with diet or how your body handles calcium.
Phosphorus	High values (above 3.7 mg/dl) or low values (below 2.3 mg/dl) may indicate problems with how your body handles phosphorus.
Uric Acid	High levels (above 7.2 mg/dl) are seen in people with gout, a form of arthritis, or other medical problems.
Fasting Glucose	Levels of 126 mg/dl or higher may indicate that you have diabetes and further follow up is needed if you do.
Total Protein	High levels (above 8.0 mg/dl) or low levels (below 6.0 mg/dl) may indicate problems that need further follow up.

BUN High levels (above 20 mg/dl) may indicate kidney problems or dehydration and should be followed up.

Albumin This is a protein in the blood. Low levels (below 3.5 mg/dl) may occur when people have health problems that affect the production of protein in the liver.

Total Bilirubin High levels (above 1.2 mg/dl) occur in people with liver problems and cause people to turn yellow and itch.

Liver Function Tests High values:

ALK Phos	above 100 U/L
LDH	above 180 U/L
AST	above 42 U/L
ALT	above 42 U/L

These test values are high when people have liver disease or other health problems. Sometimes they can go up just by having three or more alcoholic drinks in a day.

Electrolytes	<u>Low Values</u>	<u>High Values</u>
Sodium	below 135 meq/dl	above 147 meq/L
Potassium	below 3.3 meq/L	above 5.5 meq/L
Chloride	below 95 meq/L	above 110 meq/L
CO ₂	below 22 meq/L	above 29 meq/L

These tests measure how well your body is handling salt. Sometimes blood pressure medicines cause electrolytes to become too high or too low, especially potassium.

Creatinine High levels (above 1.2 mg/dl) indicate kidney problems and should be followed up.

CBC Complete Blood Count. This test measures the types of cells you have in your blood. If hemoglobin is less than 14.0 grams (gm) for men or 12.0 grams for women or hematocrit is less than 42% for men or 37% for women, it indicates you are anemic and may need further tests to find out why. If your white blood cells are less than 4.8 thousand or more than 10.8 thousand, you may have an infection or other health problem that affects the white blood cells. If your platelets are below 130 thousand or above 424 thousand, you may need further tests to find out why.

URINE ALBUMIN/CREATININE RESULTS

Less than 30 mg/g

When you have less than 30 mg/g (milligrams per gram) of albumin/creatinine in your urine, this indicates that your kidneys are not leaking protein.

30 to 299 mg/g

When you have greater than 29 mg/g, but less than 300 mg/g of albumin/creatinine in your urine, your kidneys are leaking small amounts of protein. During your next visit to a medical provider, inform them of this lab value. Taking the appropriate medication, changing your diet, exercising on a regular basis, or changing your lifestyle to reduce stress can help maintain normal blood pressure and blood sugar, which in turn protect the kidneys from further damage.

Equal to or greater than 300 mg/g

When you have equal to or greater than 300 mg/g of albumin/creatinine in your urine, this indicates your kidneys are leaking large amounts of protein. If you have not already done so, you should receive a medical evaluation for this problem. Strict adherence to your medical provider's orders concerning the use of medication, change in diet, amount of exercise and/or changes in lifestyle to maintain normal blood pressure and blood sugar values can help protect the kidneys from further damage.

CAROTID ULTRASOUND RESULTS

Narrowing less than 50%

These results show that you have a certain amount of hardening of the arteries in the large blood vessels in your neck. These blood vessels supply circulation to the brain. Sometimes clots that form in the neck can travel up into the head to cause stroke. Usually surgery is NOT recommended for people with your level of narrowing; but we do suggest that you are careful to do the things that make hardening of the arteries less likely. We recommend that you talk with your medical provider about this at your next appointment in the coming month.

Appendix A – 9

THE STRONG HEART STUDY IV INFECTION CONTROL POLICY

Human Immunodeficiency Virus (HIV) and Hepatitis B

INTRODUCTION:

The virus that causes AIDS is a human retro-virus that has been named HIV (human immuno- deficiency virus). The virus primarily infects cells of the T-lymphocyte system, but is also able to infect other cells such as macrophages and those of the central nervous system. The virus destroys the cellular immunity of infected people, leaving them susceptible to a variety of opportunistic diseases.

It has been established that the virus can be transmitted: (1) through sexual contact; (2) through parenteral exposure, including sharing needles and syringes when injecting illicit drugs, transfusion of blood or its components, and infusion of clotting factors concentrates; and (3) through perinatal exposure, probably both transplacental and intra-partum transmission and postpartum transmission.

To date, there is no evidence that the HIV virus can be transmitted by casual social contact, not even among people living in the same household. Recent reports by the CDC suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known.

Hepatitis B virus (HBV) is transmitted in ways similar to HIV.

PURPOSE:

To stress the importance of following recommended precautions to prevent exposure to the AIDS and HBV virus.

PREVENTION:

1. Before initiating work, all bench areas should be cleaned and sanitized daily with an appropriate disinfectant.
2. All laboratory specimens should be treated as if they were contaminated with either HIV or HBV. Any specimens specifically taken from known AIDS or hepatitis patients should be clearly marked as requiring isolation and transported in a leak proof container.
3. Specimens leaking from their containers should be discarded after requesting a replacement. In those cases in which the specimen is not replaceable, the outside of the soiled container should be disinfected with either a 1: 10 sodium hypochlorite solution (household bleach) or

Lysol spray and left standing for at least ten minutes before performing any laboratory procedures).

4. Every laboratorian should wear gloves and be dressed in a laboratory gown or uniform when handling and processing specimens. This will minimize the risk of contamination to exposed body parts or street clothing. Gloves should be worn and disposed of in accordance with the "Gloves (Proper Use and Disposal)" policy. Hands and other skin surfaces should be washed thoroughly and immediately after coming into contact with blood or body fluids.
5. Wear masks, gowns (or aprons), and goggles (or glasses) when there is a possibility that blood or body fluids may splash or splatter on you.
6. All laboratory specimens that must be manipulated before processing (i.e., body fluids to be diluted, caps on tubes of blood to be opened, specimens to be split or transferred, etc.) should be handled cautiously.
7. Centrifuge carriages should be sanitized daily (or after each use if possible HBVs or AIDS specimen is being centrifuged) with a germicide. After weekly use, centrifuge interiors should be sprayed with an appropriate disinfectant.
8. To prevent needle stick injuries, needles should never be recapped, separated from syringes, or otherwise manipulated. Instead, used needles should be placed intact into puncture-resistant containers. The same criteria should be applied to used scalpel blades and any other sharp device that may be contaminated by a patient.
9. To prevent transmission of HIV or HBV, the platform on the finger prick device (Autoclik, etc.) should be changed between patients.
10. Reusable devices, such as tissue grinders, pipettes, etc, should be placed into vesicles containing an appropriate germicide prior to being autoclaved and cleaned.
11. Mouth pipetting of blood or serum or plasma is forbidden for any clinical laboratory procedure. Mechanical pipetting devices are available and must be routinely used.
12. All laboratory specimens and disposables should be discarded in bio-hazard bags and autoclaved prior to final disposition by either incineration or sanitary carting.
13. Accidental spillage of a specimen should be promptly cleaned up with any of the previously mentioned disinfectants. This solution should be freshly prepared and kept in its diluted form no longer than one week.
14. If accidental contamination occurs to an exposed area of the skin, wash first with a good liquid antimicrobial detergent soap (i.e., hibiclens, chlorhexidine gluconate, etc.). Rinse well with water, then apply a 1: 10 dilution of household bleach or 50% isopropyl or ethyl alcohol. Leave preparation on skin surface for at least one minute before final washing with the liquid soap and water.

15. All work bench areas should be cleaned and sanitized with an appropriate germicidal agent at the end of each work shift.
16. Before workers leave the laboratory, all protective clothing should be removed. In addition, all laboratory personnel should wash their hands and arms with an appropriate germicidal detergent soap (i.e., chlorhexidine gluconate with alcohol).

FIRST AID AFTER CONTAMINATION OR LIKELY CONTAMINATION

1. SKIN: Wash the skin well with soap and water.
2. EYES: Flush eyes with water by using the safety eye wash.
3. NEEDLE STICK: Squeeze the affected part gently to somewhat cleanse the wound by bleeding. Cleanse with soap and water.
4. MOUTH: Immediately rinse out the mouth with large amounts of clean water. Do not swallow the water. (mouth pipetting is strictly forbidden)
5. For all incidents:
 - a. Notify the supervisor and report to the Employee Health Unit, or in the event Employee Health is closed, go to the Emergency Room.
 - b. An incident report form must be filed.
 - c. The decision to administer hepatitis immune globulin is made by the Employee Health Unit.
 - d. The hepatitis B surface antigen (HBsag) vaccine HAS BEEN AND IS AVAILABLE to high risk personnel (laboratory, ICU, etc.) All Strong Heart Study personnel who handled blood should receive three dose of hepatitis B vaccine.

REFERENCES:

Tiemo, PM: Preventing Acquisition of Human Immunodeficiency Virus in the Laboratory: Safe Handling of AIDS Specimens. *Laboratory Medicine* 1986; 11: 696-698.

Standard Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture, National Committee for Clinical Laboratory Standards March 1980.

So You're Going to Collect a Blood Specimen, College of American Pathologist, 1980. Rose SL: *Clinical Laboratory Safety Philadelphia, J.B. Lippincott Company, 1984*

Appendix A – 10

**THE STRONG HEART STUDY IV
PHYSICIAN REFERRAL FORM FOR DIAGNOSIS
OF CONGESTIVE HEART FAILURE**

ID Number: _____

While Mr./Mrs. _____ was participating in our examination, it appeared to us that he/she might have congestive heart failure. He/She thus has been referred to you for care. Listed below are the criteria that we are using for the identification of congestive heart failure in our study. We would very much appreciate it if you could complete the form below and send it to us, so that it may assist us in making the diagnosis. Please record all that are present when you evaluate the patient. Thank you.

I. Major Criteria	Present	Absent	Not Evaluated
Paroxysmal nocturnal dyspnea or orthopnea	_____	_____	_____
Neck vein distention	_____	_____	_____
Rales	_____	_____	_____
Cardiomegaly	_____	_____	_____
Acute pulmonary edema	_____	_____	_____
S ₃ gallop	_____	_____	_____
Increased venous pressure > 16 cm of water	_____	_____	_____
Circulation time ≥ 25 seconds	_____	_____	_____
Hepatojugular reflux	_____	_____	_____
II. Minor Criteria	Present	Absent	Not Evaluated
Ankle edema	_____	_____	_____
Night cough	_____	_____	_____
Dyspnea on exertion	_____	_____	_____
Hepatomegaly	_____	_____	_____

Pleural effusion	_____	_____	_____
Vital capacity decrease 1/3 from maximum	_____	_____	_____
Tachycardia (rate of ≥ 120 /min)	_____	_____	_____
III. Major/Minor Criteria	Present	Absent	Not Evaluated
Weight loss 4.5 kg in 5 days in response to treatment	_____	_____	_____
IV. Tests that were performed on this patient	Yes	No	
Echocardiogram	_____	_____	
Chest X-ray	_____	_____	
Measurements of vital capacity	_____	_____	
Measurements of venous pressure	_____	_____	

In your opinion, does Mr./Mrs. _____

have congestive heart failure? **Yes**_____ **No**_____

If **YES**, what is the underlying cause? (Please check the appropriate cause described below)

_____ Valvular heart disease

_____ Atherosclerotic heart disease

_____ Cardiomyopathy

_____ Other. Please specify: _____

What is your specialty/sub-specialty of medical practice?

We thank you very much for your assistance.

Signature

Date

APPENDIX B

Instructions for Recruitment

and

Recruitment Forms

STRONG HEART FAMILY STUDY GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

General Instructions for SHS Staff

The purpose of the Strong Heart Family Study is to find genes that influence heart disease risk factors in American Indians. We already have recruited more than 300 people in large families from each of three field centers, in Oklahoma, the Dakotas, and Arizona. In Phase IV our goal for each field center is to recruit an additional 900 people in large families (an average of 30 or more members each).

Describing the Strong Heart Family Study

The success of the Family Study will depend in part on our ability to explain the study to participants in a way that will make its value clear. The following paragraphs may help:

Heart disease and diabetes are serious health problems for American Indians and for other Americans as well. Medical research has established that both heart disease and diabetes tend to run in families; if you have close relatives with heart disease or diabetes, then you are more likely to develop these diseases yourself.

The reasons why heart disease and diabetes run in families are not well understood. Family members usually live in the same household for at least a part of their lives, and as a result they tend to have similar diets, similar exercise patterns, and similar exposure to smoking. Family members also share the same genes, and we think that some of these genes increase the risk of heart disease and diabetes. Family patterns of heart disease and diabetes probably result from a combination of environment and genes.

The goal of the Strong Heart Family Study is to study the family patterns of heart disease and diabetes in American Indians. We hope to recruit a few large families in your community, including parents, children, and grandchildren. For each participating family, we will draw a family tree. We will give each family member a physical examination and we will ask questions about diet and about other lifestyle factors that we believe are important for heart disease and diabetes. For each person, we will measure traits that are related to risk of heart disease and diabetes (such as cholesterol levels in the blood). All of the information on family members will be coded so that individuals and families can't be identified by name, and confidentiality will be strictly maintained.

We will analyze the family patterns of traits related to heart disease and diabetes, and we will try to determine whether genes influence each trait. If the effects of a gene can be detected, then we will try to pinpoint the location of the gene by studying the DNA obtained from white blood cells. In the long term, we hope to find the genes and determine how they contribute to heart disease and diabetes.

Discovering the genes that contribute to heart disease and diabetes is very important for reducing the burden of these diseases on families and communities. If these genes can

be identified, then new treatments can be developed and new ways of preventing disease can be found. We will also be able to help people to modify their environments so that the effects of harmful genes are lessened. This will lead to a longer life and a better quality of life.

Choosing Families for the Study

Preliminary family trees have been constructed by computer using information from the family history forms that were completed for each participant in Strong Heart Study Phase I, and information gathered by each field center during the pilot family study in Phase III . For each center, families have been identified for which:

- (1) there is a "core sibship" of at least five full siblings, of whom at least three are Strong Heart Study participants; and
- (2) the SHS participants in the core sibship have a total of at least 12 offspring who are at least 18 years old.

The family trees also indicate which spouses of these siblings are Strong Heart Study participants.

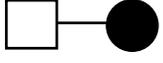
Because we wish to assure that there will be enough large families to meet our recruitment goals in Phase IV, we also have identified numerous large families in each field center that do not quite meet recruitment criteria, for example, families in which the core sibship contains only two Strong Heart Study participants, but in which those participants have at least 12 offspring.

In choosing families for the Family Study, an additional important criterion will be the family's interest in participating. However, as we recruit families, it is important to avoid "ascertainment bias". We want the families in the Family Study to be representative of their communities, and not selected specifically because they have health problems (nor do we want to exclude families simply because they have members with heart disease or diabetes). Sometimes families of patients with heart disease or diabetes are more willing to participate in family studies than are members of the community in general. To minimize possible problems with ascertainment bias, you will be provided with a list of families that meet our criteria. The families that are recruited should be chosen from this list, and recruitment should continue until at least 900 members of large families have been recruited. If the list does not provide you with a sufficient number of interested families or family members, a supplementary list of eligible families will be provided to you by the Southwest Foundation.

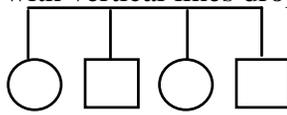
Family Tree Construction

Understanding the Family Tree Diagrams

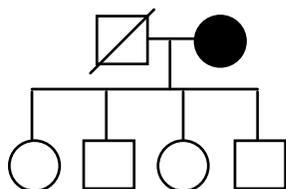
An example of a small family tree is shown at the top of the next page. In a family tree diagram, males are represented by squares  and females by circles . Solid squares  or circles  represent members of the original Strong Heart Study cohort. Individuals who are

no longer living are represented by a diagonal line through a square  or circle . The parents of one or more children are represented by a horizontal line joining a square and a circle . (For the Family Study we need to know the natural parents of each person, but we do not need to know whether those parents are married.)

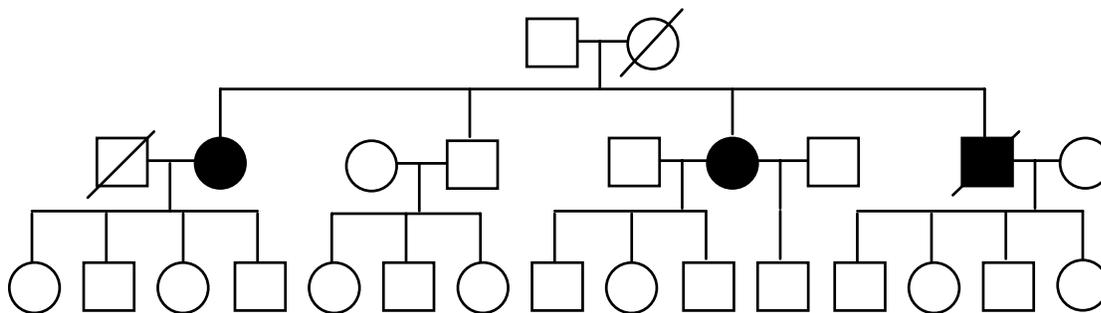
A sibship, which is a group of brothers and sisters who share the same two parents, is represented by another horizontal line, the sibship line, with vertical lines dropping from it to the



squares and circles that represent each of the sibs. A vertical line dropping from the marriage line to the sibship line joins the parents and their children together. The diagram below represents a woman who is a Strong Heart Study participant, her husband who is no longer living, and their four children, two daughters and two sons.



Family tree diagrams can be extended to include additional relatives. The family tree below shows a three generation family with the grandparents in the top generation. They have four children, three of whom are Strong Heart Study cohort members. Each of the children is (or was) married. The daughter on the left, a Strong Heart Study cohort member, has four children. One of her brothers has three children and the other, a Strong Heart Study cohort member, has four. Her sister has been married twice. She has three children by her first husband and one by her second.



Additional information also can be included on the family tree: names, dates of birth, etc. are often written below the symbol representing each family member.

Family Trees Constructed from the Family History Forms

The family trees created from the Family History forms provide some basic information for eligible families. However, some important information is missing because it was not included on the Family History forms. For example,

- We know the names and dates of birth (and death) for the offspring of SHS cohort members, but the Family History Forms do not list the other parent of each of these offspring, and therefore we don't know whether the offspring are full sibs or half sibs.
- The Family History Forms have no information about the spouses and offspring of the non-SHS sibs of SHS cohort members.

The non-SHS members of the families are known only by their names (they have no SHS numbers) and the initial family trees were created by matching names between records. Therefore, we anticipate some mistakes in the family trees created from the Family History Forms. For example,

- If names were misspelled or not clearly written on the Family History Forms, then branches of the family tree may be missed (i.e., some of the relatives are not shown). In some cases, first and last names appear to have been interchanged. In these cases, relatives also are missed.
- In cases in which both a husband and wife are SHS cohort members, the wife (for example) may list six offspring and the husband, only five. We do not know whether the husband's list is incomplete or whether the wife had a child in another marriage.

As discussed below, during the recruitment and interview process, any inaccuracies in the initial family trees should be corrected and missing information should be added.

The Family Informant

We do not know which of the large families that we have identified will be most interested in participating in the Family Study and which family members are living. Before lengthy interviews are conducted with individual family members, the degree to which the families are interested in participating in the Family Study must be determined, and we must begin the process of verifying the accuracy of the family trees. For example, some individuals whom we believe to be full siblings may in fact share only one parent, and thus may be half siblings. An interview with an elder who is knowledgeable about the family (a "family informant") will be the first step in determining which families are likely to be interested and whether the family relationships as we have recorded them are correct.

If the family informant (1) verifies the accuracy of the family tree, and/or provides new information to indicate that the family meets the criteria listed above, and (2) expresses his/her belief that a large number of members of the core sibship and their relatives (at least 30 family members in all) will be interested in participating, then the family will be chosen for the Family Study.

Informed Consent

The first step in interviewing any potential participant is to obtain formal permission to be asked questions about the person and his or her relatives. This is done by giving the person the Informed Consent document (see forms in Appendix A – 1). Each potential participant is asked to read this document, which describes the Strong Heart Study, and then to decide whether or not to take part in the study and a subsequent examination. Each sheet must bear the signature of the interviewer and the participant.

Interviewing the Family Informant

The interview with the family informant will have to be unstructured. The first step is to describe the Family Study briefly to the informant. The next step will be to discuss the computer-generated family tree, describing the meaning of the symbols, and to ask the informant to verify the correctness and completeness of all of the information on it: each name and birth date, family relationships (e.g., whether individuals are full or half siblings), which individuals are no longer living, names of other individuals not included in the family tree (e.g., additional children, parents whose names aren't recorded), etc. As the informant corrects faulty information on the family tree or provides new information, the interviewer should clearly mark the changes directly on the family tree. New symbols should be added for family members who need to be added to the family tree, and if any persons need to be deleted, their symbols and names should be crossed out on the family tree. Any information provided by the informant that should not be shared with other family members (and therefore should not be displayed on revised versions of the family tree) should be clearly marked confidential.

If the information provided by the family informant indicates that the family is not suitable for the Family Study, either because of inappropriate size or structure or because of likely lack of interest, the interviewer should thank the informant for his/her time and terminate the interview.

If, on the basis of the interview, the family remains a good candidate for the Family Study, then the interviewer should ask the informant for addresses of as many family members as possible. This information can set the stage for the recruitment of family members.

Faxing the Revised Family Tree to San Antonio

Immediately after the completion of the family informant interview, the family tree with its hand-entered corrections should be faxed to the Southwest Foundation in San Antonio (Dr. Kari North, fax number: 210-670-3317). Hand-written entries on the family tree must be clearly written so that the fax copies will be readable. A corrected family tree will be generated and immediately faxed back to the center for use in interviews with subsequent family members.

Recruiting Family Members

Please see the Recruiting section of this manual for helpful suggestions on recruiting participants into the Strong Heart Family Study. Most of the families targeted as possible candidates for the Family Study have been identified because (a) they contain a core sibship of at

least size five, of whom at least three are Strong Heart Study participants, and (b) the members of the core sibship have a total of at least 12 offspring. To assure that there will be enough large families to meet our recruitment goals in Phase IV, we also have identified large families in each field center that do not quite meet recruitment criteria, for example, families in which the core sibship contains only two Strong Heart Study participants, but in which those participants have at least 12 offspring.

For families enrolled in the Family Study, every effort should be made to recruit and interview the following family members:

- (1) All members of the core sibship, whether or not they are Strong Heart Study cohort members.
- (2) All age-eligible (at least 15 years of age) offspring of core sibship members.
- (3) All current and (if possible) previous spouses of core sibship members, if these spouses are parents of the offspring listed in (2).
- (4) The parents of the core sibship.
- (5) The parents of spouses of core sibship members, if the spouses are parents of the offspring listed in (2).
- (6) Any age-eligible grandchildren of core sibship members.
- (7) Any spouses of individuals listed in (2), if they are parents of age-eligible offspring.

In other words, the family members to be recruited include the core sibship members, their parents, children, and grandchildren, and any spouses who are parents of these family members. Note that for any person recruited, it is important to get information on both of their parents. Our goal is to recruit at least 30 members per family. It is likely that in order to maintain good rapport with the families, some individuals will have to be enrolled who do not qualify under categories (1) - (7). For example, some family members may want their spouses to participate even though they have no children. These extra family members should be enrolled if the recruiter feels that it is necessary to maintain the good will and cooperation of the family, but such enrollments should not be encouraged.

Interviewing Family Members

For each enrolled family member, the SHS Family Information Form should be administered. A copy of this form is below (Participant Interview forms following p. III B-10). The complete interview should be conducted for the first few family members examined and for any family members who are found to be particularly knowledgeable about their family. As more and more members of the family are interviewed, it will become apparent that some of the information being obtained is repetitive. For example, there is no need to ask each member of a large sibship for the full names of all of their siblings. However it is important that this information be complete and

accurate for every family member, and that it be verified by more than one person. Therefore the interviewer must use judgment in deciding which family members should be given the complete interview and which ones should simply be asked to verify information provided by others and to fill in missing information.

The SHS Family Information Form

The SHS Family Information Form requests information about the participant and his/her family:

Page 1: Information is recorded about the participant, his/her mother and father, all four grandparents, sons and daughters, and the other parent of each son or daughter. There is space for up to four “other parents”.

Page 2: Information is recorded about the participant’s brothers and sisters, half brothers and half sisters (who share only one parent with the participant), and the other (unshared) parent of each half brother and half sister.

Page 3: Information is recorded about additional sons and daughters. This page is used only if there are more sons and daughters than can be recorded on the first page.

Page 4: Information is recorded about additional sons and daughters and the other parent of each son or daughter. This page is used only if there are more than four “other parents”.

Page 5: Information is recorded about additional brothers and sisters. If necessary, add information about additional half brothers and half sisters, and record the other (unshared) parent of each.

Page 6: Information is recorded on the page at the end of the Recruitment or Family Information Form that is provided for confidential comments. If used, it should be detached from the form and sent immediately to Dr. Kari North (see contact information below).

Recruiters should keep a separate record identifying one or more family contact persons who can be asked for additional information.

The following conventions should be used for this interview:

Coding unknown information: If information is unknown, draw two horizontal lines in the space. This indicates that the question has been dealt with.

Names: Whenever full names are requested, the interviewer should enter last, first, and middle names; Jr. or Sr. (if relevant); maiden name for married women; and nickname.

Dates: All dates should be recorded as month/day/year, with year coded as four digits, e.g., December 1, 1996 should be coded as 12/01/1996. The four-digit year is important because birth dates for members of multi-generation families can span more than a century.

Sex: Enter 'M' or 'm' for males. 'F' or 'f' for females.

Date of birth/Current age: If birth date is known, enter month/day/year (separated by /). If only year of birth is known, enter the four-digit year. (Entering all four digits is important!) If only current age is known, enter the age in years.

Birthplace: Birthplace of family members is a useful source of identification, particularly for relatives who are not resident in the area being surveyed, or who are deceased.

Alive: Indicate whether each family member is alive by entering Y for yes (living) and N for no longer living.

Date of death/Age at death: If the death date is known, enter month/day/year (separated by /). If only year of death is known, enter the four-digit year. (Entering all four digits is important!) If only age at death is known, enter the age in years.

Tribal affiliation: Questions are included about the tribal affiliation of the participant and his/her relatives. This information is requested because people of different backgrounds can have different genes, and we want to be certain to take this into account as we look for genes that increase the risk of heart disease. We will not use this information to analyze an individual participant's degree of Indian ancestry.

Household: It is important to know which family members live in the same household because these family members may share certain environmental risk factors. When you interview the first member of a family, assign household number 1 to that person and write ① next to the symbol for that person on the family tree. Ask which other family members live in the same household and write ① next to each of their symbols as well. When you interview the next family member who is **not** in household ①, write ② next to the symbols for that person and everyone else in his/her household. Continue with additional family members, using ③, ④, and as many additional household numbers as are needed to specify all households in the family. Write the household number of the participant (the person indicated as "self") in the appropriate place on each page of the Family Information Form.

Information on relatives: For recording information on offspring and siblings of the participant, interviewers should use as many sheets labeled "Your Sons and Daughters" and "Your Brothers and Sisters" as needed. The extra sheets, which are color coded, will be available separately and won't be provided in the Family Information Form itself. They should be stapled to the back of the Interview Form after the completion of the interview.

Information is requested for some relatives of family members even though these relatives will not be enrolled in the Family Study at this time. This information will be of value in linking families together, and perhaps in the future, in extending the study to more remote relatives. Thus it is important to record the names of (1) parents and grandparents of members of the top generation

(i.e., of the parents of the core sibship); (2) spouses and offspring of members of the bottom generation (i.e., of the offspring of core sibship members); and (3) parents and siblings of spouses of the core sibship members. This information should be sought even for relatives who are no longer living.

Defining relationships: For a family study, it is important to distinguish between full and half siblings, and between biological and adoptive relationships. Therefore when you ask for information about a participant's brothers and sisters, it is important to ask whether the participant and the sibling have the same mother and the same father. If one parent is different, the name of that parent should be recorded in the space provided (Your Half Brothers and Half Sisters Other Parent). On the lines where you have listed the half siblings who have Other Parent #1, circle 1 in the first column. For half siblings who have Other Parent #2, circle 2, etc.

In recording information about a participant's children, you should ask for the name of the other parent of each offspring and record it under Your Children's Other Parent(s). On the lines where you have listed the children of Other Parent #1, circle 1 in the first column. For the children of Other Parent #2, circle 2, etc.

In recording information about a participant's spouse, please allow for the possibility that the participant may have a partner to whom he/she is not married. For the Family Study we need to know the natural parents of each person, but we do not need to know whether those parents are married.

Using the Family Tree as a Visual Aid

As the interviewer is questioning each family member, he/she probably will find it helpful to show the family tree to the participant. An up to date family tree serves as a useful visual aid for both the interviewer and the participant. As in the initial interview with the family informant, any corrections or additional information should be written by hand directly on the family tree and faxed to San Antonio, where the family tree will be redrawn by computer and faxed back to the center.

A Note of Caution

Questions about family relationships should be asked with sensitivity to each family member's background. For example, if a family member is known to be adopted, special care must be taken in phrasing questions about the identity of the person's natural father and mother and about brothers and sisters who are blood relatives. Caution also must be used if the interviewer has information of which the family member is unaware. It is important that the interviewer **review the Family Information Form before the interview** and note any questions that need to be asked with special care (or not asked at all, if that information can be obtained elsewhere).

If there are any sensitive issues (questions that couldn't be asked or information of which family members are unaware) or if there are any uncertainties concerning family relationships, please describe on the last page of the SHS Family Information Form, detach the page, and send it directly to Dr. North at the address shown below. These pages also can be faxed, but please call or email first to be certain that the fax can be retrieved immediately.

Dr. Kari North
Department of Genetics
Southwest Foundation for
Biomedical Research

For express courier:
7620 N.W. Loop 410
San Antonio, TX 78227-5301

Phone (210) 258-9772
Fax (210) 670-3317
Email knorth@darwin.sfbr.org

For U.S. mail:
P.O. Box 760549
San Antonio, TX 78245-0549

Assigning a Permanent ID

Strong Heart Study IDs are assigned to each participant in the Strong Heart Family Study by the SHS field staff in the SHS clinic, when they first enter the study (i.e., when they sign the consent form). The format for the Strong Heart Study IDs is described elsewhere.

Each family member, whether or not they are a participant, also is assigned a permanent Family Study ID number (PID). These codes consist of two capital letters, followed by a two-digit family number and a three-digit sequential number. Thus, AZ01001 is the first person in family 01 in the Arizona field center. Leading zeros are used to keep all codes the same length. Examples of PIDs are as follows:

AZ01001	DA01001	OK01001	
AZ01002	DA01002	OK01002	
AZ01003	DA01003	OK01003	Etc.

Note that

- 1. All Permanent ID Codes must be unique.***
- 2. Each individual may be assigned only one Permanent ID Code.***
- 3. PIDs are needed even for family members who are not examined – even for family members who are not living – because we need to be able to link individuals into families by computer.***
- 4. An individual's PID may not be reassigned when he or she leaves the study, moves to another place, dies, etc.***

Addresses

Addresses of participants are requested on the Personal Interview Form for two reasons: (1) to enable recruiters to contact the family members, and (2) to help us to verify which family members now live in the same household and thus share certain environmental risk factors.

Family # _____

**SHS IV - Family Study
Participant Interview
Page 1**

SHS ID: _____

Household # _____

Family	Last Name	First Name	Middle	Maiden	Sex	DOB/Current Age	Birthplace	*Alive	DOD/Age at Death	Enrolled (Tribe)
Self										
Mother										
Mothers Mom										
Mothers Dad										
Father										
Fathers Mom										
Fathers Dad										
Your childrens other parent(s):										
1										
2										
3										
4										
Your Sons and Daughters: (Total ____)										
1 2 3 4										
1 2 3 4										
1 2 3 4										
1 2 3 4										
1 2 3 4										
1 2 3 4										
1 2 3 4										
1 2 3 4										

*Alive Code: Y, N, U (Unknown)

Family # _____

**SHS IV - Family Study
Participant Interview
Page 4**

SHS ID: _____

Household # _____

	Last Name	First Name	Middle	Maiden	Sex	DOB/Current Age	Birthplace	*Alive	DOD/Age at Death	Enrolled (Tribe)
Your children's other parent(s):										
5										
6										
7										
8										
Your Sons and Daughters:										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										
5 6 7 8										

*Alive Code: Y, N, U (Unknown)

Family # _____

Household # _____

**SHS IV - Family Study
Participant Interview
Page 6**

SHS ID: _____

**STRONG HEART FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

Family Study ID number: _____

SHS ID number: _____

Participant's name: _____

Notes for Drs. MacCluer and North:

INTERVIEWER: _____ DATE: _____

Please detach from form and send immediately to:

Dr. Kari North, Department of Genetics, Southwest Foundation for Biomedical Research, 7620 N.W. Loop 410, San Antonio, TX 78227-5301.
Phone (210) 258-9772, Fax (210) 670-3317, Email knorth@darwin.sfbr.org

APPENDIX C

Instructions for Questionnaires

and

Data Forms

Appendix C -- 1
Strong Heart Study IV
Instructions for the Personal Interview Forms I and II

Subject should be seated comfortably and made to feel welcome during this interview because it is the first form collected and will set the scene for later data collection.

ITEM #	DESCRIPTIONS
=====	

Personal Interview Form I

Study Identification Number should be completely filled in with the number assigned at the time the consent form is completed and subject is registered.

- 1st digit represents the center number (1=SD, 2=OK, 3=AZ).
- 2nd digit should be "0" for all interviewees.
- 3-6 digits will be the consecutive number of the subject interviewed within the center.

Write in social security number.

Write in community code from list.

A. Demographic Information

- 1 Enter last name, left justified.
 Enter first name, left justified.
 Enter middle name, left justified. If no middle name, leave blank.
 Enter nickname or other name being used by friends.
- 2 Check the gender of the participant.
- 3. Fill in the birthday of the participant.
- 4 Write down the participant's current marital status.
- 5 If a female participant has ever married, write down her maiden name.
- 6 Write down the name of a married participant's spouse.
- 7 Write down the name of IHS and the non-IHS hospital which participant usually goes. Write in facility with which number is associated.
- 8a Enter left justified with blank separating number from street name and street name from unit number. If post office box, enter after street address.
- b Enter left justified, city/town or reservation of residence.
- c Enter left justified, county of residence.

- d Enter state of residence as two digit postal abbreviation and postal zip code.
 AZ= Arizona SD= South Dakota
 OK= Oklahoma ND= North Dakota
- 9 If residential address is different from the mailing address, write in the residential address following the rules given in item 9a-d.
- 10 Enter complete telephone number of home phone or phone at which participant can be reached during the evenings.
- 11 Enter complete telephone number of work phone or phone at which participant can be reached during the day.
- 12 Enter number of years of education the participant has received.
- 13 Ask participant, whether she/he is an American Indian by heritage. Fill in the appropriate answer.
- 14 If answer to Q13 is a "Yes", ask the participant what is her/his estimated total amount of Indian heritage. Using fractions, such as 4/4, 3/8, 3/32, etc., to record the response. If participant refuses to answer, record 99/00. If participant does not know the amount, record 88/00.
- 15 Next, ask the participant which tribe she/he is enrolled in. Use the tribal code list to find the appropriate code. If the participant does not know the tribe of enrollment, record 999. If the tribe reported is NOT on the list, record 998.
- 16 If participant is NOT an American Indian, ask which ethnic group she/he belongs to. Check the appropriate box.

Personal Interview Form II

A. WEIGHT CONTROL: questions about efforts to lose weight

- 1 Ask whether the participant is satisfied with her/his current weight?
- 2-3 Ask participant whether she/he want to gain or lose weight, and how is she/he doing it.

B. FAMILY INCOME

Questions 4-7 assess the family income so that the subject's socioeconomic status can be determined. Ask the questions as stated in the questionnaire. Prepare a sheet of income levels to show the participant.

- 4 Ask participant whether her/his household income meets her/his family's needs?
- 5 Ask whether the participant is attending a school.

- 6 Ask participant, on the average, how many hours per week her/his works for paid job(s).
- 7 Ask participant what is her/his annual household income.
- C. TOBACCO: These questions are very important to assess accurately because smoking is a major risk factor for cardiovascular disease.**
- 8 This question will determine the participant is a smoker or not. A person who has smoked less than 100 cigarettes in her/his lifetime is not considered a smoker since the damage caused by smoking is negligible.
- 9 Determine when participant started smoke regularly. Record age in years.
- 10 Ask participant whether she/he quit smoking in the past.
- 10a-b If participant reported she/he quitted smoking, ask when and why.
- 11 Determine average cigarettes smoked per day, which may have a significant effect on heart diseases and other health problems.
- 12 Ask the participant on the occasions which she/he is most likely to smoke or increase smoking. Check ALL the appropriate boxes.
- 13 Ask the participant on the occasion she/he increase smoking, how many cigarettes does/did she/he smoke per day.
- 14 Ask the participant whether she/he is smoking currently.
- 15 Ask the participant whether she/he wants to change smoking habit and how.
- 16 Ask the participant whether she/he uses chewing tobacco or snuff now.
- 17 How often per day does the participant use chewing tobacco or snuff.
- D. PASSIVE SMOKING: This section tries to assess second-hand smoking.**
- 18 Ask the participant when she/he was growing up, did her/his father or male guardian smoke cigarettes regularly.
- 19 Ask the participant when she/he was growing up, did her/his mother or female guardian smoke cigarettes regularly.
- 20 Ask the participant when she/he was growing up, did she/he spend a lot of time with someone smoke cigarettes regularly.
- 21 Ask participant, regardless of her/his smoking status, on the average, how many hours is she/he exposed to the smoke of others.

E. ALCOHOL: Questions related to alcohol consumption are frequently not answered accurately in surveys. Questions included in this questionnaire have been widely used and validated in several national studies.

- 22 Question 22 determines when the individual last had any alcoholic beverage. If the last drink was less than 30 days ago, fill in the box labeled number of days. If the last drink was within the last year, but more than 30 days ago, fill in the number of months. If the last drink was over one year ago, fill in the number of years. If the last drink was one or more years ago, skip to Q29.
- 23 Question 23 assesses the average number of drinks consumed in a typical week. Frequently individuals with severe drinking problems, especially binge drinkers, do not consume alcoholic beverages by the can, glass or shot, but rather drink wine or hard liquor out of a bottle. Remind the participant to use the drinks chart to estimate the number of drinks in a typical week.
- 24 Question 24 will tell you the frequency of alcoholic consumption. Many individuals with severe alcohol problems will only drink on the weekends (i.e., 8 days per month) or at the time of the month when they receive income. Assume 30 days a month.
- 25 Question 25 assesses the quantity of alcohol consumed in a day when participant drinks.
- 26 Ask the participant when she/he drinks more than the usual consumption, how much and how often in a month.
- 27-28 Questions 27 & 28 assess the frequency of binge drinking in the past month and the past year, respectively.

F. PERCEIVED STRESS:

- 29-35 Stress has been associated with the occurrence of CVD in many population studies. Questions 29-35 assess the participant's personal feelings about the degree of stress the SHS participant had in a general sense during the **PAST MONTH**.
- 36 Ask the participant, on the average, how much time she/he watches TV per day.
- 37 Question 37 assesses the reliability of the answers given by the participant. Write down your personnel code number and the date of completion of the interview.

Appendix C -- 2
TRIBAL CODES

Tribe	Code
Absentee-Shawnee tribe of Indians of Oklahoma	141
Agua-Caliente Band of Cahuilla Indians of the Agua-Caliente Indian Reservaton, Palm Springs, CA	263
Ak Chin Indian Comm. of Papago Indians of Maricopa, Ak Chin Reservation, Arizona	360
Alabama and Coushatta Tribes of Texas	223
Alabama-Quassarte Tribal Town of the Creek Nation of Ind. of Oklahoma	266
Alturas Indian Rancheria of Pit River Indians of California	385
Apache Tribe of Oklahoma	231
Arapahoe Tribe of the Wind River Reservation, Wyoming	011
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana - Assiniboine	235
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana - Sioux	276
Augustine Band of Cahuilla Mission Indians of the Augustine Reservation, California	255
Bad River Band of the Lake Superior Tribe of Chippewa Indian of the Bad River Res, WI	243
Barona Capitan Grande Band of Diegueno Mission Indians, Barona Reservation, California	330
Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, CA	412
Bay Mills Indian Comm of the Sault Ste. Marie Band of Chippewa Indian, Bay Mills Reservation, MI	244
Berry Creek Rancheria of Maidu Indians of California	312
Big Bend Rancheria of Pit River Indians of California	380
Big Lagoon Rancheria of Smith River Indians of California	415
Big Pine Band of Owens Valley Paiute Shoshone Indian of the Big Pine Reservation, CA	363

Big Sandy Rancheria of Mono Indians of California	417
Big Valley Rancheria of Pomo & Pit River Indians of California	420
Blackfeet Tribe of the Blackfeet Indian Reservation Montana	015
Blue Lake Rancheria of California	421
Bridgeport Paiute Indian Colony of California	345
Buena Vista Rancheria of MeWuk Indians of California	320
Burns Paiute Indian Colony, Oregon	351
Cabazon Band of Cahuilla Mission Indians of the Cabazon Reservation, California	256
Cachil De He Band of Wintun Indian of the Colusa Indian Community of the Colusa Rancheria, CA	406
Caddo Tribe Indian of Oklahoma	016
Cahto Indian Tribe of the Laytonville Rancheria, California	433
Cahuilla Band of Mission Indians of the Cahuilla Reservation, California	257
Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California	331
Capitan Grande Band of Diegueno Mission Indians of California	332
Cayuga Nation of New York	018
Cedarville Rancheria of Northern Paiute Indians of California	346
Chemehuevi Tribe of the Chemehuevi Reservation, California	021
CherAe Heights Indian Community of the Trinidad Rancheria of California	422
Cherokee Nation of Oklahoma	022
Cheyene-Arapaho Tribes of Oklahoma	012
Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota	277
Chickasaw Nation of Oklahoma	027
Chicken Ranch Rancheria of MeWuk Indians of California	321
Chippewa-Cree Indians of the Rocky Boy Reservation, Montana	042

Chitimacha Tribe of Louisiana	180
Choctaw Nation of Oklahoma	031
Citizen Band of Potawatomi Indian Tribe of Oklahoma	104
Cloverdale Rancheria of Pomo Indians of California	390
Coast Indian Community of Yurok Indians of the Resighini Rancheria, California	408
Cocopah Tribe of Arizona	036
Coeur D'Alene Tribe of the Coeur D'Alene Reservation, Idaho	037
Cold Springs Rancheria of Mono Indians of California	418
CO River Indian Tribes of the CO River Indian Reservation, AZ and CA	269
Comanche Indian Tribe of Oklahoma	039
Confederated Salish & Kootenai Tribes of the Flathead Reservation, Montana	049
Confederated Tribes of the Chehalis Reservation, Washington	020
Confederated Tribes of the Colville Reservation, Washington	038
Confederated Tribes of Coos, Lower Umpqua, and Siuslaw Indians of Oregon	212
Confederated Tribes of the Goshute Reservation, Nevada and Utah	200
Confederated Tribes of the Grand Ronde Community of Oregon	208
Confederated Tribes of the Siletz Reservation, Oregon	183
Confederated Tribes of the Umatilla Reservation, Oregon	164
Confederated Tribes of the Warm Springs Reservation, Oregon	168
Confederated Tribes and Bands of the Yakima Indian Nation of the Yakima Reservation, WA	174
Cortina Rancheria of Wintun Indians of California	407
Coushatta Tribe of Louisiana	181
Covelo Indian Community of the Round Valley Reservation, California	423
Cow Creek Band of Umpqua Indians of Oregon	198

Coyote Valley Band of Pomo Indians Valley Reservation, California	391
Creek Nation of Oklahoma	043
Crow Tribe of Montana	044
Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota	278
Cuyapaipe Community Diegueno Mission Indians of the Cuyapaipe Reservation, CA	333
Death Valley Timbe-Sha Shoshone Band of California	370
Delaware Tribe of Western Oklahoma	046
Spirit Lake Sioux Tribe of the Devils Lake Sioux Reservation, North Dakota	272
Dry Creek Rancheria of Pomo Indians of California	392
Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada	369
Eastern Band of Cherokee Indians of North Carolina	023
Eastern Shawnee Tribe of Oklahoma	142
Elm. Indian Colony of Pomo Indians of the Sulphur Bank Rancheria, California	393
Ely Indian Colony of Nevada	374
Enterprise Rancheria of Maidu Indians of California	313
Flandreau Santee Sioux Tribe of South Dakota	279
Forest County Potawatomi Community of Wisconsin Potawatomi Indians, Wisconsin	378
Fort Belknap Indian Community of the Fort Belknap Reservation of Montana - Assiniboine	236
Fort Belknap Indian Community of the Fort Belknap Reservation of Montana - Gros Ventre	290
Fort Bidwell Indian Community of Paiute Indians of the Fort Bidwell Reservation, CA	347
Fort Independence Indian Community of Paiute Indian of the Fort Independence Res, CA	348
Fort McDermitt Paiute and Shoshone Tribes, Fort McDermitt Indian Reservation, NV	364

Mohave Apache Indian of the Ft. McDowell Indian Reservation, Arizona	234
Fort Mojave Indian Tribe of Arizona	081
Fort Sill Apache Tribe-of-Oklahoma	005
Gay Head Wampanoag Indians of Massachusetts	202
Gila River Pima Maricopa Indian Community of the Gila River Indian Reservation of Arizona	293
Grand Traverse Band of Ottawa and Chippewa Indians of Michigan	196
Greenville Rancheria of Maidu Indians of California	314
Grindstone Indian Rancheria of Wintun-Waitaki Indians of California	435
Hannahville Indian Community Wisconsin Potawatomie Indians of Michigan	379
Havasupai Tribe of the Havasupai Reservation, Arizona	051
Hoh Indian Tribe of the Hoh Indian Reservation, Washington	052
Hoopa Valley Tribe of the Hoopa Valley Reservation, California	053
Hopi Tribe of Arizona	054
Hopland Band of Pomo Indians of the Hopland Rancheria, California	404
Houlton Band of Maliseet Indians of Maine	204
Hualapai Tribe of the Hualapai Indian Reservation, Arizona	055
Inaja Band of Cosmit Mission Indians of the Inaja and Cosmit Reservation, CA	434
Iowa Tribe of Kansas and Nebraska	057
Iowa Tribe of Oklahoma	056
Isleta-del-Sur Pueblo Indians of Texas	222
Jackson Rancheria of MeWuk Indians of California	322
Jamestown Klallam Tribe of Washington	034
Jamul Indian Village of California	424
Jicarilla Apache Tribe of the Jicarilla Apache Indian Reservation, New Mexico	006

Kaibab Band of Paiute Indians, Kaibab Indian Reservation, Arizona	352
Kalispel Indian Community of the Kalispel Indian Reservation, Washington	179
Karuk Tribe of California	216
Kashia Band of Pomo Indians of the Stewarts Points Rancheria, California	394
Kaw Indian Tribe of Oklahoma	058
Keeweenaw Bay Indian Community of the L'Anse, Lac Vieux Desert and Ontonagon Bands of Chippewa Indian of the L'Anse Reservation, Michigan	240
Kialegee Tribal Town of the Creek Indian Nation of Oklahoma	267
Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas	060
Kickapoo Tribe of OK (includes TX Band of Kickapoo Indian)-Oklahoma	059
Kickapoo Tribe of OK (includes TX Band of Kickapoo Indian)-Texas	199
Kiowa Indian Tribe of Oklahoma	062
Klamath Indian Tribe of Oregon	221
Kootenai Tribe of Idaho	063
La Jolla Band of Luiseno Mission Indians of the La Jolla Reservation, California	303
La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California	334
Lac Courte Oreilles Band of Lake Superior Chippewa Indians of the Lac Courte Oreilles Reservation of Michigan	241
Lac du Flambeau Band of Lake Superior Chippewa Indian of the Lac du Flambeau Reservation of WI	246
Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada	353
Lookout Rancheria of Pit River Indians, California	381
Los Coyotes Band of Cahuilla Mission Indians of the Los Coyotes Reservation, CA	258
Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada	354
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota	280
Lower Elwha Tribal Community of the Lower Elwha Reservation, Washington	213

Lower Sioux Indian Community of the MA Mdewakanton Sioux Indian of the Lower Sioux Reservation in MN	281
Lummi Tribe of the Lummi Reservation, Washington	069
Makah Indian Tribe of the Makah Indian Reservation, Washington	071
Manchester Band of Pomo Indians of the Manchester, Pt Arena Rancheria, California	395
Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California	335
Maricopa	888
Mashantucket Peguot Tribe of Connecticut	206
Menominee Indian Tribe of Wisconsin Menominee Indian Reservation, Wisconsin	074
Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California	336
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico	008
Miami Tribe of Oklahoma	076
Miccosukee Tribe of Indians of Florida	077
Middletown Rancheria of Pomo Indians of California	396
MN Chippewa Tribe, MN (six Component Res: Boise Ft Band Nett Lake, Fond du Lac Band, Grand Portage Band, Leech Lake Band, Mille Lac Band, White Earth Band)	242
Mississippi Band of Choctaw Indians, Mississippi	032
Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada	355
Modoc Tribe of Oklahoma	080
Montgomery Creek Rancheria of Pit River Indians of California	382
Mooretown Rancheria of Maidu Indians of California	315
Morongo Band of Cahuilla Mission Indians of the Morongo Reservation, California	259
Muckleshoot Indian Tribe of the Muckleshoot Reservation, Washington	082
Narragansett Indian Tribe of Rhode Island	191

Navajo Tribe of Arizona, New Mexico and Utah	084
Nez Perce Tribe of Idaho, Nez Perce Reservation, Idaho	085
Nisqually Indian Community of the Nisqually Reservation, Washington	086
Nooksack Indian Tribe of Washington	088
Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana	026
Northfork Rancheria of Mono Indians of California	419
Northwestern Band of Shoshone Indians of Utah (Washakie)	220
Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota	282
Omaha Tribe of Nebraska	089
Oneida Nation of New York	090
Oneida Tribe of Indians of WI, Oneida Reservation, Wisconsin	294
Onondaga Nation of New York	217
Osage Tribe of Oklahoma	091
Otoe-Missouria Tribe of Oklahoma	079
Ottawa Tribe of Oklahoma	093
Paiute Indian Tribe of Utah	194
Paiute-Shoshone Indians of the Bishop Comm. of the Bishop Colony, California	365
Paiute-Shoshone Indians of the Fallon Reservation and Colony, Nevada	366
Paiute-Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California	367
Pala Band of Luiseno Mission Indians of the Pala Reservation, California	304
Pascua Yaqui Tribe of Arizona	187
Passamaquoddy Tribe of Maine - Pleasant Point	188
Passamaquoddy Tribe of Maine - Indian Township	189
Pauma Band of Luiseno Mission Indians of the Pauma and Tuima Reservation, CA	305

Pawnee Indian Tribe of Oklahoma	097
Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California	306
Penobscot Tribe of Maine	190
Peoria Tribe of Oklahoma	184
Picayune Rancheria of Chukchansi Indians of California	425
Pinoleville Rancheria of Pomo Indians of California	397
Pit River Indian Tribe, X-L Ranch Reservation, California	383
Poarch Band of Creek Indians of Alabama	207
Ponca Tribe of Indians Oklahoma	102
Port Gamble Indian Community of the Port Gamble Reservation, Washington	214
Potter Valley Rancheria of Pomo Indians of California	403
Prairie Band of Potawatomi Indians of Kansas	105
Prairie Island Indian Community of MN Mdewakanton Sioux Indian of the Prairie Island Reservation, MN	273
Pueblo of Acoma, New Mexico	107
Pueblo of Cochiti, New Mexico	108
Pueblo of Jemez, New Mexico	110
Pueblo of Isleta, New Mexico	109
Pueblo of Laguna, New Mexico	111
Pueblo of Nambe, New Mexico	112
Pueblo of Picuris, New Mexico	113
Pueblo of Pojoaque, New Mexico	100
Pueblo of San Felipe, New Mexico	115
Pueblo of San Juan, New Mexico	117
Pueblo of San Ildefonso, New Mexico	116

Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota	283
Rumsey Indian Rancheria of Wintun Indians of California	172
Sac and Fox Tribe of the Mississippi in Iowa	129
Sac and Fox Tribe of Missouri in Kansas and Nebraska	131
Sac and Fox Tribe of Indians of Oklahoma	130
Saginaw Chippewa Indian Tribe of Missouri, Isabella Reservation, Missouri	245
Salt River Pima-Maricopa Indian Community, of the Salt River Reservation, Arizona	377
San Carlos Apache Tribe of the San Carlos Reservation of Arizona	232
San Manuel Band of Serrano Mission Indians of the San Manuel Reservation, CA	139
San Pasqual Band of Diegueno Indians, San Pasqual Reservation, California	337
Santa Rosa Indian Community of the Santa Rosa Rancheria of California	261
Santa Rosa Band of Cahuilla Mission Indians of the Santa Rosa Reservation, CA	427
Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, CA	033
Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation, CA	338
Santee Sioux Tribe of the Santee Reservation of Nebraska	284
Sauk-Suiattle Indian Tribe	134
Sault Ste. Marie Chippewa Tribe of Chippewa Indians of Michigan	249
Seminole Nation of Oklahoma	137
Seminole Tribe of Florida, Dania, Big Cypress and Brighton Reservation Florida	136
Seneca Nation of New York	138
Seneca-Cayuga Tribe of Oklahoma	019
Shahakopee Mdewakanton Sioux Community of Minnesota (Prior Lake)	274
Sheep Ranch Rancheria of MeWuk Indians of California	323
Sherwood Valley Rancheria of Pomo Indians of California	401
Shingle Springs Band of Miwok Indians Shingle Springs Rancheria (Verona Tract), CA	428

Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation, Washington	185
Shoshone Tribe of the Wind River Reservation, Wyoming	372
Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho	209
Shoshone-Paiute Tribe of the Duck Valley Reservation, Nevada	368
Sisseton-Wahpeton Sioux Tribe of the Lake Traverse Reservation, South Dakota	285
Skokomish Indian Tribe of the Skokomish Reservation, Washington	146
Skull Valley Band of Goshute Indians of Utah	376
Smith River Rancheria of California	429
Soboba Band of Luiseno Mission Indians of the Soboba Reservation, California	308
Sokoagon Chippewa Comm. of the Mole Lake Band of Chippewa Indians, Wisconsin	250
Southern Ute Tribe of the Southern Ute Reservation, Colorado	151
Spokane Tribe of the Spokane Reservation, Washington	152
Squaxin Island Tribe of the Squaxin Island Reservation, Washington	153
St. Croix Chippewa Indians of Wisconsin, St. Croix Reservation, Wisconsin	251
St. Regis Band of Mohawk Indians of New York	182
Standing Rock Sioux Tribe of the Standing Rock Reservations, North and South Dakota	286
Stillaguamish Tribe of Washington	155
Stockbridge-Munsee Community of Mohican Indians of Wisconsin	156
Summit Lake Paiute Tribe of the Summit Lake Reservation, Nevada	357
Suquamish Indian Tribe of Port Madison Reservation, Washington	157
Susanville Indian Rancheria of Paiute, Maidu, Pit River and Washoe Indians of CA	430
Swinomish Indian of the Swinomish Reservation, Washington	158
Sycuan Band of Diegueno Mission Indians of the Sycuan Reservation, California	339
Table Bluff Rancheria of Wiyot Indians of California	431

Table Mountain Rancheria of California	432
Te-Moak Bands of Western Shoshone Indians of Nevada	160
Thlopthlocco Tribal Town of the Creek Indian Nation of Oklahoma	268
Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota - Arikara	010
Three Affiliated Tribes of the Fort Berthold Reservation, ND - Gros Ventre	291
Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota – Mandan	072
Tohono O'odham Nation of Arizona (formerly known as the Papago Tribe of the Sells, Gila Bend and San Xavier Reservation, Arizona)	096
Tonawanda Band of Seneca Indians of New York	192
Tonkawa Tribe of Indians of Oklahoma	161
Tonto Apache Tribe of Arizona	230
Tores-Martinez Band of Cahuilla Mission Indians, Torres-Martinez Reservation, CA	262
Tule River Indian Tribe of the Tule River Indian Reservation, California	162
Tlalip Tribes of the Tulalip Reservation, Washington	163
Tunica-Biloxi Indian Tribe of Louisiana	203
Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California	324
Turtle Mountain Band of Chippewa Indians, Turtle Mountain Indian Reservation, ND	252
Tuscarora Nation of New York	195
Twenty-Nine Palms Band of Luiseno Mission Indians of the Twenty-Nine Palms Reservation, CA	309
United Keetoowah Band of Cherokee Indians, Oklahoma	238
Upper Lake Band of Pomo Indians of Upper Lake Rancheria of California	402
Upper Sioux Indian Community of the Upper Sioux Reservation, Minnesota	287
Upper Skagit Indian Tribe of Washington	145
Ute Indian Tribe of the Uintah and Ouray Reservation, Utah	165
Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico and Utah	166

Utu Utu Gwaiti Paiute Tribe of the Benton Paiute Reservation, California	350
Viejas Baron Long Captain Grande Band of Diegueno Mission Indians, Viejas Reservation.	340
Viejas Group of Capitan Grande Band of Mission Indians of the Viejas Res, CA	413
Walker River Paiute Tribe of the Walker River Reservation, Nevada	358
Washoe Tribe of NV and CA (Carson Colony, Dresslerville and Washoe Ranches)	169
White Mountain Apache Tribe of the Fort Apache Indian Reservation, Arizona	233
Wichita Indian Tribe of Oklahoma	170
Winnebago Tribe of the Winnebago Reservation of Nebraska	171
Winnemucca Indian Colony of Nevada	375
Wisconsin Winnebago Indian Tribe of Wisconsin	295
Wyandotte Tribe of Oklahoma	173
Yankton Sioux Tribe of South Dakota	275
Yavapai-Apache Indian Community of the Camp Verde Reservation, Arizona	009
Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona	175
Yerington Paiute Tribe of the Yerington Colony and Campbell Ranch, Nevada	359
Yomba Shoshone Tribe of the Yomba Reservation, Nevada	373
Yurok Tribe of the Hoopa Valley Reservation, California	410
Zuni Tribe of the Zuni Reservation, New Mexico	124
Alaska Villages	
Ahtna, Inc.	500
Akhiok, Native Village of Akhiok	501
Akiachak, Native Village of Akiachak	502
Akiak Native Community	503
Akutan, Native Village of Akutan	504
Alakanuk, Village of Alakanuk	505
Alatna Village	506
Alegnagik, Village of Alegnagik	507
Aleut Corporation	508
Allakaket Village	509

Appendix C -- 3
THE STRONG HEART STUDY PHASE IV
Instructions for Medical History Interview

Before beginning, make certain that the correct study identification number or the participant is entered at the top of the form. Explain to the participant that some questions need to be asked about her/his medical history so that we can better evaluate whether or not she/he has heart disease or a tendency for heart disease. Stress that the information will be confidential and that their name will never be used in any data analysis.

A. Current Medications

"It is important that we are able to identify all of the pills and medicines that you are now taking. We will talk about each one of the medicines that you brought with you. For each one, we would like to know whether you take it regularly. Don't worry if you forgot to take it when you were supposed to; just tell us as accurately as you can how often you have taken." The interviewer then proceeds to ask about each medicine that the patient brought with him/her, and records for each, the name on the bottle. If the bottle is unlabeled, record the color and shape of the pill and save one of them so that it can be identified in the PDR later. After you have gone through all of the medicines that the patient brought with him/her, then ask "Are there any medicines that you are taking that you forgot to bring", if the answer is yes, record them also in Section A.

B. We would appreciate it if you can give us information about your past medical history.

I am going to ask about a number of medical conditions. Did you ever see a doctor or other health care professional for any of the problems that I am going to mention. (Note to Interviewer: When inquiring about how many years ago, if the patient has trouble remembering, try to ask in what year or how old they were when they had the condition; we can then calculate from their current age or from the current year, the number of years ago and enter it in the appropriate box).

1. High Blood Pressure. For high blood pressure, the interviewer should be alert for those individuals who answer no, who might in fact have been prescribed or taking medication for hypertension. If the patient does not know when the hypertension first began, ask when they first began taking medication for high blood pressure and record that date.
2. Arthritis. The interviewer should also inquire about arthritis.
3. Fractures associated with osteoporosis should be explained as fractures caused by bones getting weak. Such fractures often occur in older people with minor trauma or sometimes with no history of trauma. Back bones (vertebrae) can sometimes collapse (compression fractures) and such fractures are usually caused by osteoporosis when they occur in older people. Record the location of each fractures that you feel is related to osteoporosis.
4. Rheumatic heart disease is a sequela of rheumatic fever and typically stenosis or insufficiency (tightness or leakiness) of the valves of the heart.

5. Gallstones. If participants say they have had gall bladder removed check “yes” because almost all cholecystectomies are done for gallstones.
6. Cancer. The interviewer, when inquiring about cancer should ask about cancer and diseases such as leukemia, lymphoma and tumors of the skin. If they answer yes, record the type of cancer.
7. Diabetes and type of treatment. The interviewer should be alert to individuals who reply no, who are in fact taking oral hypoglycemic agents or insulin. If they have diabetes, ask if they still have it and when they were first told they had diabetes. Also record the type of treatment they are taking. Check “yes” for “do nothing” if they are not taking any medication nor exercising, nor controlling their diet for their diabetes.
8. Kidney Failure. The interviewer should describe this as kidney failure if she/he has been told that their kidneys are not working.
- 9-10. Renal dialysis and transplantation. When inquiring about renal dialysis, the interviewer should also ask if the patient must go two or three times a week to have a machine cleanse their blood. If they have not had a transplant, ask them if they are on the waiting list for a transplant.
11. Cirrhosis of the Liver or Yellow Jaundice. The interviewer should stress that this can occur both because of alcohol and for other reasons as well.

HEART PROBLEMS:

12. Heart catheterization. Ask if patient had any kind of heart catheterization. If “yes”, determine whether they had an angioplasty or other procedure, the date of the procedure and also the hospital where it was done. This should not include use of a treadmill for exercise purposes. Show the participant a picture of a diagnostic treadmill exercise test.
13. Angioplasty (balloon, PCTA, or stent procedure). Ask if the participant ever had an angioplasty procedure. If yes, record when and where.
14. Treadmill test or exercise test to examine the heart. If “yes”, determine the date of the procedure and the hospital where it was done.
15. Heart failure. "That is, did the doctor or health care provider ever tell you that your heart was not working properly?" The necessity to sleep with several pillows (orthopnea) suggests heart failure.
16. Heart Attack. When inquiring about heart attack, this would usually have involved hospitalization, but in some instances, the patient could have been told they had a heart attack in the past on the basis of an electrocardiogram. If the patient indicates that she/he had a heart attack, ask if there were more than one. Obtain information for the most recent ones.
17. If the patient indicates that she/he has had other heart trouble, the interviewer should ask about the symptoms.

18. Stroke. If the participant indicates that she/he has not had a stroke, ask also whether she/he has had any episode where she/he suddenly could not move a part of her/his body for a prolonged period of time.
19. Surgery on chest. Question 19a is designed to ensure that we get accurate information on cardiac surgery so that medical records can be obtained. Use anatomical diagrams if available to help the participants recall the type of surgery they had.

Appendix C -- 4
The Strong Heart Study Phase IV
Instructions for Reproduction and Hormone Use: Women Only

If the patient is a female, explain that we know that in many cases, women appear to be protected from heart disease. Therefore it is necessary for us to ask some questions about their reproductive history, because we are trying to better understand why women appear to have less heart disease.

- 1-4. After inquiring about the number of times pregnant and the number of live births and abortions, the number of live births plus the number of pregnancies lost, should equal the number of times pregnant. (Unless one or more births of twins, etc. occurred).
5. Ask about use of birth control pills and be sure they are recorded on the medication history if they are currently taking them. Ask the participant when she first used birth control pills and for how long.
6. Ask about use of birth control implant. Ask the participant when she first used a birth control implant and for how long.
7. Ask about use of birth control shots, such as Depo Provera. Ask the participant when she first used birth control shots and for how long.
8. Ask when the participant started to have regular menstrual cycles (periods). Record the age in years.
9. Ask the participant whether her menstrual cycles have stopped.
10. If "Yes" go to Q10 and ask her whether the periods stopped more than 12 months.

If "Yes", ask participant her age when her periods stopped completely and the reason menstruation stopped. The interviewer should answer whether the menopause or the cessation of periods occurred naturally or whether it occurred after an operation to remove the womb or uterus.

ESTROGEN AND PROGESTERONE

Use the questionnaire as written. If participants are currently taking estrogen pills other than birth control pills, be sure they are recorded on the medication history.

- 11-15. Use questionnaire as written to obtain information about estrogen use. Record when the participant started to use estrogen, for how long all together, reason(s) for using estrogen, and if progesterone is also being added for use.
- 16-18. Ask the participant whether she is still using estrogen at the time of interview. If not, why?
- 19-22. Ask the participant whether she ever has ever used progesterone alone. If yes, when started and for how long.

Appendix C -- 5
The Strong Heart Study Phase IV
Instructions for Use of the Rose Questionnaire
for Angina and Intermittent Claudication

This questionnaire, originally developed by Rose & Blackburn, has been the mainstay of cardiovascular disease surveys for a number of years. The primary feature of this questionnaire is to have a standardized assessment for the pain associated with angina and intermittent claudication. Since it is well recognized that there can be many other causes for both chest and leg pain, the main objective of the questionnaire is to ask a series of questions so that certain patterns of pain will be assigned positively and others will not be assigned. For this reason, it is important that the questions be asked in the order stated. In addition, during several points of the questionnaire, there is an asterisk if a certain answer is received. The purpose of this asterisk is to assure that the questioner then proceeds to the next section. If an answer is received that has an asterisk, it has been determined that this answer indicates that the pain is not characteristic of either angina or intermittent claudication and thus, it is not necessary to proceed with that section.

The questions are essentially self-explanatory. It is permissible, and in fact advisable, when referring to pain or discomfort in the chest to elaborate to describe this pain as a tightening or crushing feeling that may or may not radiate onto the left arm.

In addition, since this is a standardized questionnaire developed in Britain, phrases such as "carry-on" can also be described as "keep on going" or "continue to walk or climb".

Note that participants who are unable to walk should skip from Question 2 (section A) to Section B. Non-ambulatory participants also can skip to section C.

Appendix C -- 6
The Strong Heart Study Phase IV
Instructions for Use of the Respiratory Questionnaire

- 1-11. These questions are self-explanatory and are part of standard respiratory questionnaires.
12. Lung problems: When inquiring about emphysema, the interviewer should also ask about difficulty in breathing. Participants with a chronic cough should be considered to have chronic bronchitis. If they have asthma, ask if they still have it.

Appendix C -- 7
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

DIRECTIONS TO PARTICIPANTS FOR USING THE ACTIVITY METER
(PEDOMETER)

The Accusplit Activity Meter (pedometer) counts the number of steps taken while walking. You have been requested to wear this meter EVERY DAY for a seven day period from _____ to _____. The pedometer is to be clipped at the waist to your clothes, underwear, or on a belt and worn on the _____ hip and must be kept in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. You can use a belt or elastic strap to keep it in place on your hip. Please DO NOT LET THE PEDOMETER GET WET by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in the morning and to record the pedometer number in your activity record when you take it off at night.

If you have any questions, please contact:

_____ at
_____.

Specific Instructions

1. Every morning, just before you put the pedometer on, push the reset button to read “0”.
2. Record the time you reset the pedometer on the activity record page.
3. *Wear the pedometer all day except for bathing, swimming or in the rain (unless you can keep it dry). If you take it off, record the length of time it was off (minutes or hours) on your activity record page.*
4. At bedtime, take off the pedometer. Record on your activity record page (a) the pedometer number (the number of steps taken), and (b) the time you removed the pedometer.
5. Please do not touch the reset button during the day or you will erase your activity numbers.
6. Wear the pedometer on your dominant hip (right hip for right handed people and left hip for left handed people), keep it upright, and make sure it fits firmly against your body so it does not move around.
7. *Keep the cover closed or it will not record your steps.*
8. The pedometer will not work correctly if it is in a pants, coat, or shirt pocket. It will not work correctly if it is sideways either.
9. Please mail the activity record to us in the self-addressed stamped envelope after you complete your week.
10. Please keep the pedometer as a token of our appreciation of your participation in the Strong Heart Family Study.

Thank you very much for your time and effort!

APPENDIX D

STRONG HEART STUDY

PHASE IV

Questionnaires and Data Forms

**THE STRONG HEART— FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

PERSONAL INTERVIEW FORM I

SHS Family I.D. SHS. I.D.:

Social Security Number:

Community name: _____ Community Code:

A. DEMOGRAPHIC INFORMATION:

1. Your Name:

a. Last:

b. First:

c. Middle:

d. Nickname/Other Name:

2. Gender: Male 1 Female 2

3. Date of Birth: / /

4. What is your marital status?

Current

1 = Never married(Skip to Q. 7)

4 = Separated

2 = Currently married

5 = Widowed

3 = Divorced

6 = Adult roommate/partner/significant other

5. If ever married, what was your maiden name?

6. If married, what is your spouse's name? (if not married, skip to Q7)

Last

First

Middle

**THE STRONG HEART— FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

PERSONAL INTERVIEW FORM II

SHS Family I.D.

SHS. I.D.:

A. WEIGHT SATISFACTION

1. Are you satisfied with your present weight?
 Yes |₁ (*skip to B*) No |₂ Unknown/unsure |₃
2. Do you want to lose or gain weight? Lose |₁ Gain |₂
3. How do you plan to do this? Less More No change
- a) Eating |₁ |₂ |₃
- b) Physical activity |₁ |₂ |₃
- c) Medication Yes |₁ No |₂
- d) Other, specify: _____ Yes |₁ No |₂

B. FAMILY INCOME:

4. Does your household income meet your family's needs?
 Yes |₁ No |₂ Unsure |₃
5. Are you going to school? Yes |₁ No |₂
6. How many hours per week do you work at a job or jobs that pay you a salary or wage? (*Fill in number of hours*)
7. Which of the following categories best describes your annual household income from all sources? *Please show a list.*
- | | | |
|--|--|---|
| Less than 5,000 <input type="text"/> ₁ | 20,000 to 25,000 <input type="text"/> ₅ | Don't know/not sure <input type="text"/> ₉ |
| 5,000 to 10,000 <input type="text"/> ₂ | 25,000 to 35,000 <input type="text"/> ₆ | Refused <input type="text"/> ₀ |
| 10,000 to 15,000 <input type="text"/> ₃ | 35,000 to 50,000 <input type="text"/> ₇ | |
| 15,000 to 20,000 <input type="text"/> ₄ | Over 50,000 <input type="text"/> ₈ | |

C. TOBACCO:

8. During your lifetime have you smoked 100 cigarettes or more total?

Yes 1 No 2 (skip to Q16)

9. How old were you when you first started smoking regularly?

(Indicate age at which you started smoking)

0 = Never smoked regularly 999 = Unknown

10. Did you quit smoking? Yes 1 No 2 (skip to Q11)

a) If you quit, when did you last smoke?

(Just the year, please)

b) What reason(s) did you have for quitting?

Please check all that apply:

Yes

No

i) Doctor's advice

12

ii) Health concerns

12

iii) Expenses

12

iv) Family pressure

12

v) Peer pressure

12

vi) Other

12

specify: _____

11. On the average, how many cigarettes do/did you usually smoke per day?

0= Less than one cigarette per day

a) If less than one cigarette per day, number of cigarettes per month?

12. On which occasions are/were you most likely to smoke, or increase your smoking?
Please read the list and check the appropriate response.
- | | Yes | No |
|------------------------------|----------------------------|----------------------------|
| a) stressful times | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| b) casinos | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| c) wakes/funerals | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| d) when drinking alcohol | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| e) social meetings | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| f) when you have extra money | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| g) bingo | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| h) school | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| i) other, specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
13. On the occasions that your smoking increased, how many total cigarettes do/did you smoke per day?
14. Do you smoke cigarettes now? Yes 1 No 2
(if No, skip to Q16)
15. If you currently smoke, would you like to change your smoking habit?
Yes 1 No 2
(if No, skip to Q16)
- a) If yes, would you prefer to...
- | | Yes | No |
|--|----------------------------|----------------------------|
| i) Reduce number of cigarettes per day | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| ii) Switch to lower "tar" or "nicotine" cigarettes | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| iii) Use nicotine patch/chewing gum/medications | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| iv) Quit | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| v) Other, specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
16. Do you use chewing tobacco/snuff now? Yes 1 No 2

22. Have you ever consumed alcoholic beverages?

Yes 1 No 2 *(this section of the interview is finished, go to Question 29)*

a) If yes, when was your last drink? *(Choose only one)*

1 Within the last week

2 Within the last month

3 Within the last year. Number of months

4 More than a year ago

(If over a year, this section of the interview is finished, please go to Question 29)

23. How many alcoholic drinks do you have in a typical week?

24. How many days in a typical month do you have at least one drink?
(Indicate the number of days per month)

25. On the days when you drink any liquor, beer or wine, about how many drinks do you have, on average? *(Indicate number of drinks per day)*

(# Drinks)

26. When you drink more than your usual amount, how many total drinks do you have?

(# Drinks)

a) How many times in a month?

(# Times/Month)

27. How many times during the **PAST MONTH** did you have 5 or more drinks on an occasion? Indicate times per month. *(Enter zero if subject has quit drinking more than one month ago.)*

28. How many times during the **PAST YEAR** did you have 5 or more drinks on an occasion?

F. PERCEIVED STRESS:

In the past month, how often have you (Q29-35):

Not at all Rarely Sometimes Often Most of the time Not sure

29. been upset because of something
that happened unexpectedly?

1 2 3 4 5 9

30. felt nervous or "stressed"?

1 2 3 4 5 9

- | | Not at all | Rarely | Sometimes | Often | Most of the time | Not sure |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|---|
| 31. dealt with irritating life hassles? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 9 |
| 32. felt that things were going your way? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 9 |
| 33. felt unable to control irritations in your life? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 9 |
| 34. felt that you were on the top of things? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 9 |
| 35. felt difficulties or problems were piling up so high that you could not handle them? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 9 |
| 36. On the average, how much time per day do you watch TV? | | | | | | <input type="text"/> <input type="text"/> <input type="text"/>
hours minutes |

G. ADMINISTRATIVE INFORMATION:

37. How reliable was the participant in completing the questionnaire?
- Very reliable 1 Reliable 2 Unreliable 3
- Very unreliable 4 Uncertain 5
38. Did the participant complete the interview?
- Yes, completed the interview 1
- No, refused all questions 2
39. Interviewer: ||
40. Date of interview: |||||
mo day yr
-

**THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

MEDICAL HISTORY FORM

SHS Family I.D. SHS. I.D.: **B. MEDICAL CONDITIONS:**

*Now I'd like to ask you some questions about medical problems. Has a medical person **EVER** told you that you had any of the following conditions?

1. High blood pressure? Yes 1 No 2 Only during pregnancy 3 Unknown 9

If "YES," how old were you when you were first told by a medical person that you had high blood pressure (for women, not during pregnancy)? Indicate the actual age. Don't know = 999

- | | YES | NO | UNKNOWN |
|--|----------------------------|----------------------------|----------------------------|
| 2. Arthritis? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| 3. Any fractures associated with brittle bone disease or osteoporosis? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |

If YES," where? _____

- | | | | |
|---|----------------------------|----------------------------|----------------------------|
| 4. Rheumatic heart disease? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| 5. Gallstones? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| 6. Cancer, including leukemia and lymphoma? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |

If YES," specify type of cancer: _____

7. Diabetes? Yes 1 No 2 Only during pregnancy 3 Unknown 9
(if No or Unknown, skip to Q8)

- a) How old were you when you were first told by a medical person that you had diabetes? *Indicate the actual age. Don't know=999*

- b) What type of treatment are you taking for your diabetes? *(Check appropriate answer)*

	YES	NO
--	-----	----

- | | | |
|------------|----------------------------|----------------------------|
| i) insulin | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
|------------|----------------------------|----------------------------|

- | | | |
|-----------------------------|----------------------------|----------------------------|
| ii) oral hypoglycemic agent | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
|-----------------------------|----------------------------|----------------------------|

- | | | |
|-------------------------|----------------------------|----------------------------|
| iii) by dietary control | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
|-------------------------|----------------------------|----------------------------|

- | | | | |
|-----|-------------|----------------------------|----------------------------|
| | | YES | NO |
| iv) | by exercise | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| v) | do nothing | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| vi) | other | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

YES NO UNKNOWN

8. Has a medical person ever told you that you had kidney failure? 1 2 9
(if No or Unknown, skip to Q11)

- a) If Yes, are one or both working well now? 1 2 9
- b) How old were you when you were first told by a medical person that you had kidney failure? *Indicate the actual age. Don't know =999*

YES NO UNKNOWN

9. Are you currently on renal dialysis? 1 2 9

10. Have you ever had kidney transplant? 1 2 9

a) If Yes, is the new kidney working well? 1 2 9

b) If No, are you waiting for a kidney transplant? 1 2 9

11. Cirrhosis of the liver? 1 2 9

HEART PROBLEMS:

12. Have you had a heart catheterization? Yes 1 No 2 Unknown 9

(A heart catheterization is a study in which a tube is inserted into the heart through the groin or arm to see how the heart works)

a) If "YES," when and where *(most recent)*?
mo day yr

hospital/clinic: _____

18. Stroke? Yes 1 No 2 Unknown 9

a) If "Yes," when and where? / / / / /

hospital/clinic: _____

19. Have you ever had surgery on your chest? Yes 1 No 2 (skip to Q20)

a) Was it heart surgery? Yes 1 No 2 (skip to Q20)

If "Yes," which surgery have you had?

i) Bypass? Yes 1 No 2

If "Yes," when and where (most recent)? / / / / /

hospital/clinic: _____

ii) Valvular repair/replacement? Yes 1 No 2

If "Yes," when and where (most recent)? / / / / /

hospital/clinic: _____

iii) Pacemaker? Yes 1 No 2

If "Yes," when and where (most recent)? / / / / /

hospital/clinic: _____

iv) Other? Yes 1 No 2

If "Yes," when and where (most recent)? / / / / /

Please specify: _____

hospital/clinic: _____

20. Did the participant complete the interview?
Yes, completed the interview 1

No, some questions refused 2 No, refused all questions 3

IS THE PARTICIPANT FEMALE? Yes 1 (go to next page) No 2

IF THE PARTICIPANT IS **MALE**, GO TO ROSE QUESTIONNAIRE

21. Interviewer:

22. Date of interview:
mo day yr

THE STRONG HEART — FAMILY STUDY

REPRODUCTION AND HORMONE USE (WOMEN ONLY)

SHS Family I.D. SHS. I.D.:

"The following questions are related to your childbearing history and childbearing organs".

(For Q1 - Q4, use 999 for Unknown)

1. How many times have you been pregnant? (gravidity)
(If never pregnant, skip to Q5)
2. How many of your pregnancies resulted in a live birth (parity)?
3. How many living children do you have?
4. How many pregnancies did you lose (including miscarriage or stillbirth)?
5. Have you ever used birth control pills? Yes 1 No 2 Not sure 3
(if NO or NOT SURE, go to Q6)
 - a) Are you still using birth control pills? Yes 1 No 2
 - b) How old were you when you started to use birth control pills?
Indicate the age in years. 999=unknown
 - c) How many years altogether did you use them?
Specify the duration in years. 0=less than 6 months, 1=6-12 months, 999=unknown.
6. Have you ever had a birth control implant (such as Norplant)?

Yes 1 No 2 Not sure 3
(if NO or NOT SURE, go to Q7)

 - a) Are you still using a birth control implant? Yes 1 No 2
 - b) How old were you when you started to use a birth control implant?
Indicate the age in years. 999=unknown, can't remember
 - c) How many years altogether did you use it?
Specify the duration in years. 0=less than 6 months, 1=6-12 months, 999=unknown.
7. Have you ever used birth control shots (such as Depo Provera)?

Yes 1 No 2 Not sure 3
(if NO or NOT SURE, go to Q8)

- S4
- a) Are you still using birth control shots? Yes 1 No 2
- b) How old were you when you started to use birth control shots?
Indicate the age in years. 999=unknown, can't remember
- c) How many years altogether did you use them?
Specify the duration in years. 0=less than 6 months, 1=6-12 months, 999=unknown.
8. How old were you when you started to have regular menstrual cycles (periods)?
Indicate the age in years. 999=unknown
9. Have your menstrual cycles (periods) stopped? Yes 1 No 2 (go to Q11)
10. If 'YES', have they stopped for 12 months or more? Yes 1 No 2 (go to Q11)
- a) How old were you when your periods stopped completely?
Indicate the age in years. 999=unknown, can't remember
- b) Did your periods stop naturally, or because of surgery or hormone use, or for some other reason? Natural 1 (go to Q11)
Surgery 2
Hormonal 3 (go to Q11)
Other, specify: _____ 4 (go to Q11)
- c) If SURGERY, were both of your ovaries removed?
Yes 1 No 2 Unknown 9
- "ESTROGEN and PROGESTERONE are types of female hormones that may be taken for many reasons, including after a hysterectomy or the menopause, to regulate your periods or for other reasons."
11. Except for birth control pills, have you ever taken estrogen - either pills, as a patch or by shot - for any reason? Yes 1 No 2 Not sure 3
(If NO or NOT SURE, go to Q19)
12. How old were you when you started using estrogen? Indicate age in years.
13. How many years altogether did you take estrogen? Specify duration in years.
(If less than 3 months, record 0. If more than 3 months but less than 1 year, record 1)

14. Do/Did you use estrogen for (answer all applicable) YES NO NOT SURE
- a) post surgery (hysterectomy and removal of ovaries) 1 2 3
- b) relief of menopause symptoms 1 2 3
- c) prevent bone loss 1 2 3
- d) protect against heart disease 1 2 3
- e) doctor's advice 1 2 3
- f) other: _____ 1 2 3
15. Do/Did you take progesterone in addition to, or in combination with, your estrogen treatment?
 Yes 1 No 2 Not sure 3
(If NO or NOT SURE, go to Q19)
16. What form of estrogen are you taking? Is it a pill, patch, shot or other type?
 pill 1 patch 2 shot 3 other 4 Not sure 5
17. Are you still taking estrogen? Yes 1 (go to Q19) No 2 (go to Q18)
18. Why did you stop taking estrogen? YES NO UNKNOWN
- a) Caused Bleeding 1 2 3
- b) Made breasts tender 1 2 3
- c) Made you feel bloated 1 2 3
- d) Made you feel "funny," didn't like the way you felt 1 2 3
- e) Do not like taking any medicines 1 2 3

- | | YES | NO | UNKNOWN |
|---|----------------------------|----------------------------|----------------------------|
| f) Too expensive | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| g) Doctor's advice | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| h) Concerned about long-term side effects | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
| i) Other: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 9 |
19. Other than in combination with estrogens, have you ever taken progesterone by itself for any reason?
 Yes 1 No 2 Not sure 3
(if NO or NOT SURE, go to Q23)
20. How old were you when you started using progesterone?
Indicate age in years.
21. How many years altogether did you take progesterone? *Specify duration in years.*
(if less than 3 months, record 0. If more than 3 months but less than 1 year, record 1)
22. Are you still taking progesterone? Yes 1 No 2
-
23. Did the participant complete the interview?
 Yes, completed the interview 1
 No, refused all questions 2
24. Interviewer:
25. Date of interview: / /
mo day yr

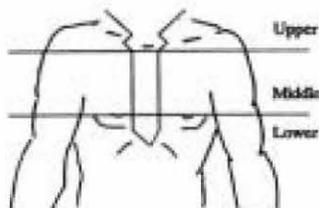
THE STRONG HEART — FAMILY STUDY

ROSE QUESTIONNAIRE FOR ANGINA AND INTERMITTENT CLAUDICATION

SHS Family I.D. SHS. I.D.:

Section A: Chest Pain on Effort

1. Have you ever had any pain or discomfort in your chest? Yes 1 No 2
(go to Section C)
2. Do you get it when you walk uphill, upstairs or hurry? Yes 1
No 2 (go to Section B)
Never hurries or walks uphill or upstairs 3
Unable to walk 4 (go to Section B)
3. Do you get it when you walk at an ordinary pace on the level? Yes 1 No 2
4. What do you do if you get it while you are walking? Stop or slow down 1
(Record "stop or slow down" if subject carries on after taking nitroglycerine.)
Carry on 2 (go to Section B)
5. If you stand still, what happens to it? Relieved 1 Not relieved 2
(go to Section B)
6. How soon? 10 minutes or less 1 More than 10 minutes 2
(go to Section B)
7. Will you show me where it was?
(Record all areas mentioned. Use the diagram below to show the location if participant cannot tell exactly.)
- | | YES | NO |
|---------------------------|----------------------------|----------------------------|
| Sternum (upper or middle) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Sternum (lower) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Left anterior chest | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Left arm | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Other: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |



8. Do you feel it anywhere else? Yes 1 No 2

If "YES," record additional information : _____

Section B: Possible Infarction

9. Have you ever had a severe pain across the front of your chest lasting for half an hour or more? Yes 1 No 2

Section C: Intermittent Claudication

10. Do you get pain in either leg on walking? Yes 1
No 2 (go to Q19)
Unable to walk 3 (go to Q19)

11. Does this pain ever begin when you are standing still or sitting? Yes 1 (go to Q19)
No 2

12. In what part of your leg did you feel it? Pain includes calf/calves 1
Pain does not include calf/calves 2 (go to Q19)

If calves not mentioned, ask: "Anywhere else?" Please specify: _____

13. Do you get it if you walk uphill or hurry? Yes 1
No 2 (go to Q19)
Never hurries or walks uphill 3

14. Do you get it if you walk at an ordinary pace on the level? Yes 1 No 2

15. Does the pain ever disappear while you are walking? Yes 1 (go to Q19) No 2

16. What do you do if you get it when you are walking? Stop or slow down 1
Carry on 2 (go to Q19)

17. What happens to it if you stand still? Relieved 1
Not Relieved 2 (go to Q19)

18. How soon? 10 minutes or less 1 More than 10 minutes 2

END OF ROSE QUESTIONNAIRE

19. Did the participant complete the interview? Yes, completed the interview 1
No, refused all questions 2

20. Interviewer:

21. Date of interview: / /
mo day yr

**THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

RESPIRATORY QUESTIONS

SHS Family I.D.: SHS. I.D.:

1. a) Do you usually have a cough? Yes 1 No 2 (skip to Q3)
- b) Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week? Yes 1 No 2
- c) Do you usually cough at all on getting up, or first thing in the morning? Yes 1 No 2
- d) Do you usually cough like this on most days for 3 consecutive months or more during the year? Yes 1 No 2
- e) How long have you had this cough? /
years months
2. Do you usually bring up phlegm from your chest when you cough?
 Yes 1 No 2
3. Does your chest ever sound wheezy or whistling : Yes No
- a) when you have a cold? 1 2
- b) occasionally apart from colds? 1 2 (go to Q4)
- c) most days? 1 2
- d) most nights? 1 2
4. Have you ever had an attack of wheezing that has made you feel short of breath? Yes 1 No 2
5. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill
 Yes 1
 No 2 (go to Q10)
 Unable to walk 4 (go to Q10)
6. Do you have to walk slower on level ground than people of your age due to breathlessness? Yes 1 No 2
7. Do you ever have to stop for breath when walking at your own pace on level ground? Yes 1 No 2

THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
PHYSICAL EXAMINATION

SHS Family I.D. SHS. I.D.: **I. EXAMINATION OF EXTREMITIES FOR AMPUTATIONS**

1. Are any extremities missing? Yes 1 No 2 (*Skip to next Section*)

If "YES" to amputation, Please code the cause of amputation:

1 = Diabetes

4 = Other, please specify

2 = Trauma

9 = Unknown

3 = Congenital

Extremities	Check if Missing	Cause
a. Right arm	<input type="checkbox"/>	<input type="checkbox"/> _____
b. Right hand	<input type="checkbox"/>	<input type="checkbox"/> _____
c. Right finger(s)	<input type="checkbox"/>	<input type="checkbox"/> _____
d. Left arm	<input type="checkbox"/>	<input type="checkbox"/> _____
e. Left hand	<input type="checkbox"/>	<input type="checkbox"/> _____
f. Left fingers	<input type="checkbox"/>	<input type="checkbox"/> _____
g. Right leg above knee	<input type="checkbox"/>	<input type="checkbox"/> _____
h. Right leg below knee	<input type="checkbox"/>	<input type="checkbox"/> _____
i. Right foot	<input type="checkbox"/>	<input type="checkbox"/> _____
j. Right toe(s)	<input type="checkbox"/>	<input type="checkbox"/> _____
k. Left leg above knee	<input type="checkbox"/>	<input type="checkbox"/> _____
l. Left leg below knee	<input type="checkbox"/>	<input type="checkbox"/> _____
m. Left foot	<input type="checkbox"/>	<input type="checkbox"/> _____
n. Left toe(s)	<input type="checkbox"/>	<input type="checkbox"/> _____

II. BLOOD PRESSURE

2. Right arm circumference, measured in centimeters (cm)
 Midway between acromium and olecranon

3. Cuff size (arm circumference in brackets)

Pediatric (under 24cm) 1Regular arm (24-32cm) 2Large arm (33-41cm) 3Thigh (>41cm) 4

4. Pulse obliteration pressure |_|_|_|
5. Seated Blood Pressure: **Systolic BP** **Diastolic BP**
- a) First Blood Pressure Measurement |_|_|_| |_|_|_|
- b) Second Blood Pressure Measurement |_|_|_| |_|_|_|
- c) Third Blood Pressure Measurement |_|_|_| |_|_|_|
6. Were the above blood pressures taken from RIGHT arm? Yes |_|1
No |_|2
- Specify: _____
7. Recorder ID (For the SHS staff who took BP): |_|_|_|

III. **ANTHROPOMETRIC MEASUREMENTS:**
 (Take off shoes and remove heavy objects from pockets.)

METRIC SYSTEM
 (centimeters/cm/kg)

8. Height (Standing)|_|_|_| cm
9. Weight (Standing)|_|_|_| kg
10. Hip circumference (Standing)|_|_|_| cm
11. Waist measurement at umbilicus (Supine)|_|_|_| cm

IV. **PEDAL PULSES AND EDEMA**

- | | PRESENT | ABSENT | MISSING LIMBS | UNABLE TO ASSESS |
|----------------------------------|-------------|-----------|---------------|------------------|
| 12. Right posterior tibial pulse | _ 1 | _ 2 | _ 3 | _ 9 |
| 13. Right dorsalis pedis pulse | _ 1 | _ 2 | _ 3 | _ 9 |
| 14. Left posterior tibial pulse | _ 1 | _ 2 | _ 3 | _ 9 |
| 15. Left dorsalis pedis pulse | _ 1 | _ 2 | _ 3 | _ 9 |
| 16. Pedal edema | Absent _ 1 | Mild _ 2 | Marked _ 3 | |

VII. ACANTHOSIS NIGRICANS

19. Acanthosis Nigricans in the back of neck: Not Present 0
Grade 1 1
Grade 2 2
Grade 3 3
Grade 4 4

VIII. ADMINISTRATIVE INFORMATION

20. Did the participant complete this examination? Yes, completed the examination 1
No, refused all questions 2
21. SHS Code of person completing this form
22. Date of Examination: / /
mo day yr

**THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

SAMPLE COLLECTION CHECKLIST

SHS Family I.D. SHS. I.D.:

1. Fasting One Touch glucose result. 999= *not done*
2. Is **FASTING** blood sample taken?
- Yes, and participant has been fasting 1
- Yes, but participant has NOT been fasting 2
- No, participant has not been fasting 3
- Other, specify: _____ 4
- No, participant refused 8
3. When was the last time you ate (*use military time*) :
4. Time of collection of fasting samples :
5. Is urine sample taken? Yes 1 (*go to Q7*) No 2
6. If no, why?
- On dialysis 1
- Cannot urinate. 2
- Other, specify: _____ 3
7. Time of collection of urine sample :

8. Blood Samples/Urine Checklist. Check the box(es) if samples were collected

<u>Item</u>	<u>Purpose</u>	<u>Type</u>	<u>Check</u>
One 10 ml SST	Chem Profile, Lipids, Insulin	Serum	<input type="checkbox"/>
One 4.5 ml Lt Blue	PAI-1, Fibrinogen	Plasma	<input type="checkbox"/>
One 7 ml Gray	Fasting glucose	Plasma	<input type="checkbox"/>
One 10 ml Green	Heparin storage	Plasma/Buffy coat	<input type="checkbox"/>
One 10 ml Purple	HbA1c	Whole blood	<input type="checkbox"/>
One 10 ml Purple	DNA	Buffy coat	<input type="checkbox"/>
One 10 ml Purple	LDL size, ApoE	Serum	<input type="checkbox"/>
Urine	Albumin/creatinine	Urine	<input type="checkbox"/>

9. Is this participant also a volunteer for blood/urine QC? Yes 1 No 2

If the participant is NOT a QC volunteer, skip to Q12.

10. QC ID (second digit is "3"):

11. QC samples checklist. Check the box(es) if samples were collected

<u>Item</u>	<u>Purpose</u>	<u>Type</u>	<u>Check</u>
One 10 ml SST	Chem Profile, Lipids, Insulin	Serum	<input type="checkbox"/>
One 4.5 ml Lt Blue	PAI-1, Fibrinogen	Plasma	<input type="checkbox"/>
One 7 ml Gray	Fasting glucose	Plasma	<input type="checkbox"/>
One 10 ml Purple	LDL size, ApoE	Serum	<input type="checkbox"/>
Urine	Albumin/creatinine	Urine	<input type="checkbox"/>

Instructions:

"We ask you not to use any tobacco, caffeine or alcohol until you have completed your visit with us today. We do this so that your test results are not affected by use of these substances."

12. If you did, when and what: _____

13. SHS Code of person completing this form 14. Today's Date / /

THE STRONG HEART— FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
CBC Results

SHS Family I.D. SHS. I.D.:

Each Center's Results May Appear in Different Order, Please Be Careful When Entering the Results

- | | | |
|-----|-----------------------------------|----------------------|
| 1. | WBC ($10^9/L$) | <input type="text"/> |
| 2. | RBC ($10^{12}/L$) | <input type="text"/> |
| 3. | HGB (g/dL) | <input type="text"/> |
| 4. | HCT (%) | <input type="text"/> |
| 5. | MCV (fL) | <input type="text"/> |
| 6. | MCH (pg) | <input type="text"/> |
| 7. | MCHC (g/dL) | <input type="text"/> |
| 8. | RDW (%) | <input type="text"/> |
| 9. | Platelet count (PLT .. $10^9/L$) | <input type="text"/> |
| 10. | MPV (fL) | <input type="text"/> |

DIFFERENTIAL

Each Center's Results May Appear in Different Order, Please Be Careful When Entering the Results

- | | | |
|-----|--|----------------------|
| 11. | NEUT (%) | <input type="text"/> |
| 12. | LYMPH (%) | <input type="text"/> |
| 13. | MONO (%) | <input type="text"/> |
| 14. | EOS (%) | <input type="text"/> |
| 15. | BASO (%) | <input type="text"/> |
| 16. | Code number of person completing this form | <input type="text"/> |

17. Date of data collection

<input type="text"/>							
mo	day	yr					

8. During the PAST 4 WEEKS, how much did pain interfere with your normal work, (including both work outside the home and housework)?

(Please Check One Answer)

- Not at all 1
- Slightly 2
- Moderately 3
- Quite a bit. 4
- Extremely. 5

These questions are about how you feel and how things have been with you during the PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling

How much of the time during the PAST 4 WEEKS....

(Please Check One Number Per Line)

- | | All
of the
Time | Most
of the
Time | a Good
Bit of
the Time | Some
of the
Time | a Little
of the
Time | None
of the
Time |
|---|----------------------------|----------------------------|------------------------------|----------------------------|----------------------------|----------------------------|
| 9. Have you felt calm and peaceful? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 |
| 10. Did you have a lot of energy?.. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 |
| 11. Did you feel downhearted
and blue? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 |

12. DURING the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH or EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

(Please Circle One Number)

- All the time. 1
- Most of the time 2
- Some of the time. 3
- A Little of the time. 4
- None of the time. 5

13. Interviewer/Reviewer: _____

14. Date of interview: _____
mo day yr

**THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

CES-D SCALE

SHS Family I.D. SHS. I.D.:

How is this questionnaire administered? 1=By interviewer 2=By self 8=Refused

Here are some questions (Q2-Q22) about your feelings during the past week. For each of the following statements, please respond as to whether you felt that way: Rarely or Not At All, Some of the time, Often, or Most of the time.

During the past week . . .	Rarely or Not at ALL < 1 day 1	Some 1-2 days 2	Often 3-4 days 3	Most of the Time 5-7 days 4	Not Applicable 9
1. I was bothered by things that don't usually bother me.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
2. I did not feel like eating; my appetite was poor.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
3. I felt that I could not shake the blues even with help from my family or friends.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
4. I felt that I was just as good as other people.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
5. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
6. I felt depressed	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
7. I felt that everything I did was an effort.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
8. I felt hopeful about the future.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
9. I thought my life had been a failure.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
10. I felt fearful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
11. My sleep was restless.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
12. I was happy.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9

For each of the following statements, please respond as to whether you felt that way: Rarely or Not At All, Some of the time, Often, or Most of the time.

During the past week . . .	Rarely or Not at ALL < 1 day 1	Some 1-2 days 2	Often 3-4 days 3	Most of the Time 5-7 days 4	Not Applicable 9
13. I talked less than usual.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
14. I felt lonely.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
15. People were unfriendly.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
16. I enjoyed life.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
17. I had crying spells.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
18. I felt sad.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
19. I felt that people disliked me.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
20. I felt like I couldn't do what I needed to do.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9

For Question 21, please use the following scale: Rarely or Not at ALL < 1 day 1 Some 1-2 days 2 Often 3-4 days 3 Most of the Time 5-7 days 4 Not Applicable 9

21. I have felt depressed or sad in this past year.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 9
22. Interviewer/Reviewer:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
23. Date of interview:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>mo day yr</small>				

THE STRONG HEART STUDY – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MHLC SCALE

SHS Family I.D.

SHS. I.D.:

How was the questionnaire administered? 1=By interviewer 2=By self 8=Refused

Each item below is a belief statement about your medical condition with which you may agree or disagree. Each statement is a scale which ranges from strongly disagree (0) to strongly agree (3). For each item we would like you to write the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you write. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

	Strongly Disagree 0	Disagree 1	Agree 2	Strongly Agree 3
1. If I become sick, I have the power to make myself well again.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
2. Often I feel that no matter what I do, if I am going to get sick, I will get sick.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
3. If I see an excellent doctor regularly, I am less likely to have health problems.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
4. Most things that affect my health happen by accidental happenings.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
5. I can only maintain my health by consulting health professionals.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
6. I am directly responsible for my health.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
7. Other people play a big part in whether I stay healthy or become sick.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
8. Whatever goes wrong with my health is my own fault	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
9. When I am sick, I just have to let nature run its course.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
10. Health professionals keep me healthy.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
11. When I stay healthy, I'm just plain lucky.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3

	Strongly Disagree 0	Disagree 1	Agree 2	Strongly Agree 3
12. My physical well-being depends on how well I take care of myself.	_ 0	_ 1	_ 2	_ 3
13. When I feel ill, I know it is because I have not been taking care of myself properly.	_ 0	_ 1	_ 2	_ 3
14. The type of care I receive from other people is what is responsible for how well I recover from an illness.	_ 0	_ 1	_ 2	_ 3
15. Even when I take care of myself, it's easy to get sick.	_ 0	_ 1	_ 2	_ 3
16. When I become ill, it's a matter of fate.	_ 0	_ 1	_ 2	_ 3
17. I can pretty much stay healthy by taking good care of myself.	_ 0	_ 1	_ 2	_ 3
18. Following doctor's orders to the letter is the best way for me to stay healthy.	_ 0	_ 1	_ 2	_ 3
19. Interviewer/ Reviewer:				_ _ _
20. Date of interview:			_ _ / _ _ / _ _ _ _	
			<small>mo. day yr</small>	

**THE STRONG HEART-FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

SOCIAL SUPPORT

SHS Family I.D. SHS I.D.: How was the questionnaire administered? 1=By interviewer 2=By self 8=Refused

This scale is an assessment of social support, and is made up of a list of statements, which may or may not be true about you. For each statement, check the response that best describes you.

1. How often do you talk on the phone or get together with friends or relatives who do not live with you? . . .
- Every day 5
 A few times a week 4
 A few times a month 3
 Once a month 2
 Less than once a month, or 1
 Never (IF VOL.) 0
- | | NOT MUCH
AT ALL
1 | SOME
2 | A LOT
3 |
|--|----------------------------|----------------------------|----------------------------|
| 2. How much do your friends or relatives really care about you--a lot, some, or not much at all? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| 3. How much do they understand the way you feel about things? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| 4. How much do they appreciate you? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| 5. How much can you rely on them for help if you have a serious problem? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| 6. How much can you talk to them about your worries? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| 7. How much can you relax and be yourself around them? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |

		RARELY NEVER 0	SOMETIMES 1	OFTEN 2
8.	How often do your friends or relatives make too many demands on you--often, sometimes, rarely or never?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
9.	How often do they argue with you?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
10.	How often do they criticize you?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
11.	How often do they let you down when you are counting on them?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
12.	How often do they get on your nerves?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2

		RARELY NEVER 0	SOMETIMES 1	OFTEN 2
13.	How often do they drink or use drugs too much?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2

Among the people you know, is there someone . . .

		NO 0	YES 1
14.	you can go with to play cards, or go to bingo, a powwow, or a community meeting?	<input type="checkbox"/> 0	<input type="checkbox"/> 1
15.	who would lend you money if you needed it in an emergency?	<input type="checkbox"/> 0	<input type="checkbox"/> 1
16.	who would lend you a car or drive you somewhere else if you really needed it?	<input type="checkbox"/> 0	<input type="checkbox"/> 1
17.	you could call who would bail you out if you were arrested and put in jail?	<input type="checkbox"/> 0	<input type="checkbox"/> 1
18.	you could count on to check in on you regularly?	<input type="checkbox"/> 0	<input type="checkbox"/> 1

19.	How isolated do you feel? . . .	
	Very isolated	<input type="checkbox"/> 3
	Somewhat isolated	<input type="checkbox"/> 2
	Not very isolated at all	<input type="checkbox"/> 1

20. How often do you purposefully avoid family gatherings? . . .

- A lot 3
- Sometimes, or 2
- Not very much at all 1

21. Of those family gatherings you go to, how likely are you to leave early? . . .

- Very likely 3
- Somewhat likely, or 2
- Not at all likely 1

22. Interviewer/Reviewer:

--	--	--	--

23. Date of interview:

mo		day		yr							

**THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

SPIELBERGER - AX/COOK MEDLEY SCALE

SHS Family I.D. SHS I.D.: How was the questionnaire administered? 1=By interviewer 2=By self 8=Refused

A number of statements which people have used to describe themselves when they feel angry or furiosus are given below (Q1–Q20). Please read each statement and then indicate how often you feel or act in the manner described when you are angry. This is a measure of your feelings; so there are no right or wrong answers.

	Rarely Or Never 0	Sometimes 1	Often or Always 2	Almost Always 3
When I feel angry....				
1. I control my temper.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
2. I express my anger.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
3. I keep my feelings to myself.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
4. I make threats I don't really mean to carry out.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
5. I withdraw from people when I'm angry.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
6. I give people "the silent treatment" when I'm angry.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
7. I make hurtful remarks to others.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
8. I keep my cool.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
9. I do things like slam doors when I'm angry.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
10. I boil inside, but don't show it.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
11. I argue with others.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
12. I hold grudges that I don't tell anyone about.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3
13. I strike out (emotionally or physically) at whatever makes me angry.	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3

		S15			
		Rarely Or Never	Sometimes	Often or Always	Almost Always
		0	1	2	3
14.	I am more critical of (judge or find fault with) others than I let people know.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
15.	I get angrier than I usually admit.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
16.	I calm down faster than most people.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
17.	I say mean things.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
18.	I am irritated (frustrated, annoyed) much more than people are aware of.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
19.	I lose my temper.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
20.	If someone bothers (frustrates, irritates) me, I am likely to tell him/her.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

These next questions (Q21- Q28) are about how you think about other people. Although we cannot really know what people would think or do unless they tell us, we would like to know your opinion as to whether you think each of the following statements is "True or False". Once again, this is your opinion, so there is no right or wrong answer.

		True	False
		0	1
21.	No one cares much about what happens to me.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
22.	It is safer to trust nobody.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
23.	Most people would lie to get ahead.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
24.	Most people inwardly dislike putting themselves out to help other people.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
25.	Most people will use unfair means to gain an advantage rather than lose it.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
26.	Most people are honest mainly through fear of being caught.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
27.	I often wonder what hidden reason another person may have for doing something nice for me.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
28.	Most people make friends because friends are likely to be useful to them.	<input type="checkbox"/> 0	<input type="checkbox"/> 1
29.	Interviewer/Reviewer:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
30.	Date of interview:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>mo day yr</small>	

**THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

**DIRECTIONS TO PARTICIPANTS FOR USING THE ACTIVITY METER
(PEDOMETER)**

*The Accusplit Activity Meter (pedometer) counts the number of steps taken while walking. You have been requested to wear this meter EVERY DAY for a seven day period from _____ to _____. The pedometer is to be clipped at the waist to your clothes, underwear, or on a belt and worn on the _____ hip and must be kept in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. You can use a belt or elastic strap to keep it in place on your hip. Please **DO NOT LET THE PEDOMETER GET WET** by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to "0" (zero) when you put it on in the morning and to record the pedometer number in your activity record when you take it off at night.*

If you have any questions, please contact:

_____ at

Specific Instructions

1. Every morning, just before you put the pedometer on, push the reset button to read "0".
2. Record the time you reset the pedometer on the activity record page.
3. ***Wear the pedometer all day except for bathing, swimming or in the rain (unless you can keep it dry). If you take it off, record the length of time it was off (minutes or hours) on your activity record page.***
4. At bedtime, take off the pedometer. Record on your activity record page (a) the pedometer number (the number of steps taken), and (b) the time you removed the pedometer.
5. Please do not touch the reset button during the day or you will erase your activity numbers.
6. Wear the pedometer on your dominant hip (right hip for right handed people and left hip for left handed people), keep it upright, and make sure it fits firmly against your body so it does not move around.
7. ***Keep the cover closed or it will not record your steps.***
8. The pedometer will not work correctly if it is in a pants, coat, or shirt pocket. It will not work correctly if it is sideways either.
9. Please mail the activity record to us in the self-addressed stamped envelope after you complete your week.
10. Please keep the pedometer as a token of our appreciation of your participation in the Strong Heart Family Study.

Thank you very much for your time and effort!

SHS Family Study – Cardiovascular Disease in American Indians
 National Heart, Lung, and Blood Institute

ACTIVITY METER SEVEN-DAY RECORD

Name: _____

Strong Heart Study ID No: _____

Family Study ID No: _____

Reminder: Reset the Activity Meter (pedometer) to “0” every morning

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Date							
Day of week							
Time attached							
Meter number at bedtime							
Time removed							
Did you take off the meter for any reason?							
If yes, for how long?							

Complete this question after completing this journal.

Has your physical activity in the past seven (7) days been typical for you compared to your regular activity level? Yes 1 No 2

**THE STRONG HEART STUDY III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

MEDICATION CHECKLIST

SHS Family I.D.

SHS I.D.:

A. MEDICATION RECEPTION:

As you know, the Strong Heart Study will be describing prescription medications that its participants are using. We are particularly interested in medications your doctor prescribed for you that were filled by a pharmacist. These include pills, dermal patches, eyedrops, creams, salves, and injections. The letter you received about this appointment included a plastic medications bag for all your current medications and asked you to bring them to the clinic.

Have you brought that bag with you?

Yes 1

No 2 *(Make arrangements to obtain)*

Took no meds 3 *(Go to Section C)*

Refused 4 *(Cite reasons for refusal in the space below)*

Reasons for refusal: _____ : Go to Section C

B. PRESCRIPTION MEDICATIONS

1. Copy the name of the medication, the strength in milligrams (mg), and the total number of doses prescribed per day, week or month. (Include pills, dermal patches, eye drops, creams, salves, and injections)

2. On the average during the last two weeks, how many of these pills did you take a day/week/month?

Medication Name <i>Print the first 20 letters only. Please print clearly.</i>	Strength (mg) <i>Write the decimal as one of the digits.</i>	Number Prescribed <i>Circle: day, week, month</i>	PRN Medicine?
1 _____	_____	___ D W M	Y N ___ D W M
2 _____	_____	___ D W M	Y N ___ D W M
3 _____	_____	___ D W M	Y N ___ D W M
4 _____	_____	___ D W M	Y N ___ D W M
5 _____	_____	___ D W M	Y N ___ D W M
6 _____	_____	___ D W M	Y N ___ D W M
7 _____	_____	___ D W M	Y N ___ D W M
8 _____	_____	___ D W M	Y N ___ D W M

PRESCRIPTION MEDICATIONS (cont.)

Medication Name <i>Print the first 20 letters only. Please print clearly.</i>	Strength (mg) <i>Write the decimal as one of the digits.</i>	Prescribed <i>Circle: day, week, month</i>	PRN Medicine?
9 _____	_____	___ D W M	Y N ___ D W M
10 _____	_____	___ D W M	Y N ___ D W M
11 _____	_____	___ D W M	Y N ___ D W M
12 _____	_____	___ D W M	Y N ___ D W M
13 _____	_____	___ D W M	Y N ___ D W M
14 _____	_____	___ D W M	Y N ___ D W M
15 _____	_____	___ D W M	Y N ___ D W M

Number unable to transcribe: _____

C. OVER-THE-COUNTER MEDICATIONS

3. Copy the name of the medication, the strength in milligrams (mg), and the total number of doses prescribed per day, week or month. (Include pills, dermal patches, eye drops, creams, salves, and injections)

4. On the average during the last two weeks, how many of these pills did you take a day/week/month?

Medication Name <i>Print the first 20 letters. Please print clearly.</i>	Strength (mg) <i>Write the decimal as one of the digits.</i>	Circle: day week, month
1 _____	_____	___ D W M
2 _____	_____	___ D W M
3 _____	_____	___ D W M
4 _____	_____	___ D W M
5 _____	_____	___ D W M
6 _____	_____	___ D W M
7 _____	_____	___ D W M
8 _____	_____	___ D W M
9 _____	_____	___ D W M

OVER-THE-COUNTER MEDICATIONS (cont.)

Medication Name	Strength (mg)	Circle: day week, month
<i>Print the first 20 letters. Please print clearly.</i>	<i>Write the decimal as one of the digits.</i>	
10 _____	_____	_____ D W M
11 _____	_____	_____ D W M
12 _____	_____	_____ D W M
13 _____	_____	_____ D W M
14 _____	_____	_____ D W M
15 _____	_____	_____ D W M

Comments: _____

5. Interviewer: _____

6. Date of interview: _____
mo day yr

**THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

PHYSICAL EXAMINATION – QC DUPLICATE MEASUREMENT

SHS Family I.D. SHS I.D.: **I. BLOOD PRESSURE**

1. Right arm circumference, measured in CENTIMETERS (cm)
Midway between acromium and olecranon

2. Cuff size (arm circumference in brackets)

Pediatric (under 24cm) 1

Large arm (33-41cm) 3

Regular arm (24-32cm) 2

Thigh (>41cm) 4

3. Pulse obliteration pressure

4. Seated Blood Pressure

	Systolic BP	Diastolic BP
a) First Blood Pressure Measurement	<input type="text"/>	<input type="text"/>

b) Second Blood Pressure Measurement

c) Third Blood Pressure Measurement

5. Were the above blood pressures taken from RIGHT arm? Yes 1 No 2

If no, Why? Amputation 1 Wound/dressing 2 Cast 3 Refusal 4

6. Recorder ID:

During the past year, have you taken any vitamins or minerals regularly, at least once a month?

- No, not regularly Yes, fairly regularly →

(IF YES) WHAT DID YOU TAKE FAIRLY REGULARLY?

VITAMIN TYPE	HOW OFTEN					FOR HOW MANY YEARS?					
	DIDN'T TAKE	A FEW DAYS per MONTH	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY	LESS THAN 1 YR.	1 YEAR	2 YEARS	3-4 YEARS	5-6 YEARS	10+ YEARS
Multiple Vitamins. Did you take...											
Regular Once-A-Day, Centrum, or Thera type	<input type="radio"/>										
Stress-tabs or B-Complex type	<input type="radio"/>										
Antioxidant combination type	<input type="radio"/>										
Single Vitamins (not part of multiple vitamins)											
Vitamin A (not beta-carotene)	<input type="radio"/>										
Beta-carotene	<input type="radio"/>										
Vitamin C	<input type="radio"/>										
Vitamin E	<input type="radio"/>										
Folic acid, folate	<input type="radio"/>										
Calcium, alone or combined with something else	<input type="radio"/>										
Zinc, alone or combined with something else	<input type="radio"/>										
Iron	<input type="radio"/>										
Selenium	<input type="radio"/>										

If you took Once-a-day, Centrum or Thera-type multiple vitamins, did you usually take types that contain minerals, iron, zinc, etc. do not contain minerals don't know

If you took vitamin C or vitamin E:

How many milligrams of vitamin C did you usually take, on the days you took it?
 100 250 500 750 1000 1500 2000 3000+ Don't know

How many IUs of vitamin E did you usually take, on the days you took it?
 100 200 300 400 600 800 1000 2000+ Don't know

Did you take any of these supplements at least once a month?

- Ginkgo Ginseng St. John's Wort Kava Kava Echinacea Melatonin DHEA
 Glucosamine/Chondroitin Something else Didn't take these

The next section is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions to answer for each food:

HOW OFTEN, on average, did you eat the food during the past year?

*Please DO NOT SKIP any foods. Mark "Never" if you didn't eat it.

HOW MUCH did you usually eat of the food?

*Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., ON THE DAYS YOU EAT IT.

*Sometimes we ask "how much" as A, B, C or D. LOOK AT THE ENCLOSED PICTURES. For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat.

(If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.)

*Sometimes we made the "D" column a darker color. This is just to remind you to make sure you really eat that large a serving.

EXAMPLE: This person drank apple juice twice a week, and had one glass each time. Once a week he ate a "C" sized serving of rice (about 1 cup).

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MON.	2-3 TIMES per MON.	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
										How many glasses each time	A	B	D	
Apple juice	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many glasses each time	<input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4				
Rice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much each time	<input type="radio"/> A	<input type="radio"/> B	<input checked="" type="radio"/> C	<input type="radio"/> D



HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME					
										How many glasses on the days you drink it?					
How often do you drink the following beverages?											How many glasses each time				
Tomato juice or V-8 juice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Real 100% orange juice or grapefruit juice, including fresh, frozen or bottled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
When you drink orange juice, how often do you drink a calcium-fortified brand?	<input type="checkbox"/> Usually calcium-fortified <input type="checkbox"/> I don't know <input type="checkbox"/> Sometimes calcium-fortified <input type="checkbox"/> I don't drink orange juice <input type="checkbox"/> Hardly ever calcium-fortified														
Other real fruit juices like apple juice, prune juice, lemonade	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kool-Aid, Hi-C, or other drinks with added vitamin C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drinks with some juice in them, like Sunny Delight, Juice Squeeze	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many bottles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Instant breakfast milkshakes like Carnation, diet shakes like SlimFast, or liquid supplements like Ensure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses or cans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glasses of milk (any kind)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
When you drink glasses of milk, what kind do you usually drink? MARK ONLY ONE:															
<input type="checkbox"/> Whole milk <input type="checkbox"/> Reduced-fat 2% milk <input type="checkbox"/> Low-fat 1% milk <input type="checkbox"/> Non-fat milk <input type="checkbox"/> Rice milk <input type="checkbox"/> Soy milk <input type="checkbox"/> I don't drink milk or soy milk															
HOW OFTEN	NEVER	FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME					
Regular soft drinks, or bottled drinks like Snapple (not diet drinks)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many bottles or cans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Beer or non-alcoholic beer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many bottles or cans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
What kind? MARK ONLY ONE:	<input type="checkbox"/> Regular beer <input type="checkbox"/> Light beer <input type="checkbox"/> Non-alcoholic beer <input type="checkbox"/> I don't drink beer														
Wine or wine coolers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Liquor or mixed drinks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many drinks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Glasses of water, tap or bottled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many glasses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Coffee, regular or decaf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many cups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tea or iced tea (not herb teas)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	How many cups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
What do you usually add to coffee? MARK ONLY ONE:	<input type="checkbox"/> Cream or half & half <input type="checkbox"/> Nondairy creamer <input type="checkbox"/> Milk <input type="checkbox"/> None of these														
What do you usually add to tea? MARK ONLY ONE:	<input type="checkbox"/> Cream or half & half <input type="checkbox"/> Nondairy creamer <input type="checkbox"/> Milk <input type="checkbox"/> None of these														
Do you usually add sugar (or honey) to coffee?	<input type="checkbox"/> No <input type="checkbox"/> Yes		IF YES, how many teaspoons each cup? <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4												
Do you usually add sugar (or honey) to tea?	<input type="checkbox"/> No <input type="checkbox"/> Yes		IF YES, how many teaspoons each cup? <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4												

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PLEASE DO NOT WRITE IN THIS AREA
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HOW OFTEN	NEVER	A FEW	ONCE	2-3	2	3-4	5-6	EVERY DAY	HOW MUCH EACH TIME					
		TIMES	TIMES	TIMES	TIMES	TIMES	TIMES		SEE PORTION SIZE PICTURES FOR A-B-C-D					
		per YEAR	per MONTH	per MONTH	per WEEK	per WEEK	per WEEK							

How often do you eat each of the following fruits, just during the 2-3 months when they are in season?

Raw peaches, apricots, nectarines, while they are in season	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Cantaloupe, in season	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Strawberries, in season	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Watermelon, in season	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Any other fruit in season, like grapes, honeydew, pineapple, kiwi	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							

How often do you eat the following foods all year round? Estimate your average for the whole year.

Bananas	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Apples or pears	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Oranges or tangerines	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Grapefruit	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							

	NEVER	PER YEAR	ONCE PER MONTH	2-3 TIMES PER MONTH	ONCE PER WEEK	TWO PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	EVERY DAY	HOW MUCH EACH TIME				
...s, including egg biscuits or Egg McMuffins (Not egg substitutes)	<input type="radio"/>	How many eggs each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Bacon	<input type="radio"/>	How many pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Breakfast sausage, including sausage biscuits	<input type="radio"/>	How many pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Pancakes, waffles, French toast, Pop Tarts	<input type="radio"/>	How many pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Breakfast bars, granola bars, Power bars	<input type="radio"/>	How many	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Cooked cereals like oatmeal, cream of wheat or grits	<input type="radio"/>	Which bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
High-fiber cereals like All Bran, Raisin Bran, Fruit-n-Fiber	<input type="radio"/>	Which bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								

Which high-fiber cereal do you eat most often? **MARK ONLY ONE:** All Bran or Bran Buds Raisin Bran Fiber One, Fruit-n-Fiber, etc. Something else I don't know I don't eat it

Product 19, Just Right or Total cereal	<input type="radio"/>	Which bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Any other cold cereal, like Corn Flakes, Cheerios, Special K	<input type="radio"/>	Which bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Milk or milk substitutes on cereal	<input type="radio"/>	How many oz. on cereal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
Yogurt or frozen yogurt	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								
...ese, sliced cheese or cheese ...ad, including on sandwiches	<input type="radio"/>	How many slices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>								

When you eat cheese, is it Usually low-fat Sometimes low-fat Hardly ever low-fat Don't know/don't eat

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PLEASE DO NOT WRITE IN THIS AREA



HOW OFTEN	NEVER	A FEW TIMES		2-3 TIMES		2 TIMES		3-4 TIMES		5-6 TIMES		EVERY DAY	HOW MUCH EACH TIME			
		per YEAR	ONCE per MONTH	TIMES per MONTH	ONCE per WEEK	TIMES per WEEK	TIMES per WEEK	TIMES per WEEK	TIMES per WEEK	per WEEK	per WEEK		per WEEK	per DAY	SEE PORTION SIZE PICTURES FOR A-B-C-D	

How often do you eat the following vegetables, including fresh, frozen, canned or in stir-fry, at home or in a restaurant?

Broccoli	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Carrots, or mixed vegetables or stews containing carrots	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Corn	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Green beans or green peas	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Spinach	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Mustard greens, turnip greens, collards	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
French fries, fried potatoes or hash browns	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
White potatoes not fried, incl. boiled, baked, mashed & potato salad	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Sweet potatoes, yams (Not in pie)	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Cole slaw, cabbage	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Green salad	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D										
Salad w tomatoes, including in salad	<input type="radio"/>	How much	<input type="radio"/> 1/4	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2										
Salad dressing	<input type="radio"/>	How many Tbsp.	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4										

Is your salad dressing Usually low-fat Sometimes low-fat Hardly ever low-fat Don't know/don't use

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME				
Any other vegetable, like okra, squash, cooked green peppers	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Refried beans or bean burritos	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Chili with beans (with or without meat)	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Baked beans, black-eye peas, pintos, any other dried beans	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Vegetable stew	<input type="radio"/>	Which Bowl	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Vegetable soup, vegetable beef, chicken vegetable, or tomato soup	<input type="radio"/>	Which Bowl	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Split pea, bean or lentil soup	<input type="radio"/>	Which Bowl	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Any other soup, like chicken noodle, chowder, mushroom, instant soups	<input type="radio"/>	Which Bowl	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Spaghetti, lasagna or other pasta with tomato sauce	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Other cheese dishes without tomato sauce, like macaroni and cheese	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D								
Pizza, including carry-out	<input type="radio"/>	How many slices	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4								

HOW OFTEN	NEVER	A FEW	ONCE	2-3	ONCE	2	3-4	5-6	EVERY	HOW MUCH EACH TIME				
		TIMES	PER	TIMES	PER	TIMES	TIMES	TIMES		DAY	SEE PORTION SIZE PICTURES FOR A-B-C-D			
		PER	PER	PER	PER	PER	PER	PER						
		YEAR	MONTH	MONTH	WEEK	WEEK	WEEK	WEEK						
Do you ever eat chicken, meat or fish? <input type="radio"/> Yes <input type="radio"/> No IF NO, SKIP TO NEXT PAGE														
Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much meat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tacos, burritos, enchiladas, tamales, etc. with meat or chicken	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How do you like beef cooked?	<input type="radio"/> Rare		<input type="radio"/> Medium		<input type="radio"/> Well done		<input type="radio"/> I don't eat beef							
Pork chops, pork roasts, or dinner ham	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When you eat meat, do you	<input type="radio"/> Avoid eating the fat		<input type="radio"/> Sometimes eat the fat		<input type="radio"/> Often eat the fat		<input type="radio"/> I don't eat meat							
Veal, lamb or deer meat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ribs, spareribs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many ribs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liver, including chicken livers or liverwurst	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gizzard, pork neckbones, chillins, pigs feet, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mixed dishes with beef or pork, like stew, corned beef hash, stuffed cabbage, meat dish with noodles	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mixed dishes with chicken, like chicken casserole, chicken & noodles, pot pie or in stir-fry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fried chicken, at home or in a restaurant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	# medium pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chicken or turkey not fried, such as baked, grilled, or on sandwiches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When you eat chicken, do you	<input type="radio"/> Avoid eating the skin		<input type="radio"/> Sometimes eat the skin		<input type="radio"/> Often eat the skin									
HOW OFTEN	NEVER	YEAR	MONTHS	MONTHS	WEEK	WEEK	WEEK	WEEK	EVERY	HOW MUCH EACH TIME				
Oysters	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other shellfish like shrimp, scallops, crabs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tuna, tuna salad, tuna casserole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much of the tuna	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fried fish or fish sandwich, at home or in a restaurant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other fish, not fried	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hot dogs, or sausage like Polish, Italian or chorizos	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are your hot dogs	<input type="radio"/> Usually low-fat		<input type="radio"/> Sometimes low-fat		<input type="radio"/> Hardly ever low-fat		<input type="radio"/> Don't know/don't eat them							
Bologna, sliced ham, turkey lunch meat, other lunch meat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many slices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are your lunch meats	<input type="radio"/> Usually low-fat or turkey		<input type="radio"/> Sometimes low-fat		<input type="radio"/> Hardly ever low-fat									



HOW OFTEN	NEVER	A FEW TIMES PER YEAR	ONCE PER MONTH	2-3 TIMES PER MONTH	ONCE PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
										How much A	B	C	D	
Noodles, macaroni, pasta salad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Tofu, bean curd	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Meat substitutes, such as veggie burgers, Gardenburgers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many patties	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
Chinese food, Thai or other Asian food, not counted above	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Snacks like potato chips, corn chips, popcorn (not pretzels)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Are these snacks <input type="radio"/> Usually low-fat <input type="radio"/> Sometimes low-fat <input type="radio"/> Hardly ever low-fat <input type="radio"/> Don't know/don't eat														
HOW OFTEN	NEVER	FEW TIMES PER YEAR	ONCE PER MONTH	2-3 TIMES PER MONTH	ONCE PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	EVERY DAY	HOW MUCH EACH TIME				
Peanuts, other nuts or seeds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Crackers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Doughnuts, Danish pastry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
Cake, sweet rolls, coffee cake	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Are they <input type="radio"/> Usually low-fat <input type="radio"/> Sometimes low-fat <input type="radio"/> Hardly ever low-fat <input type="radio"/> Don't know/don't eat														
Cookies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many	<input type="radio"/> 1-2	<input type="radio"/> 3-6	<input type="radio"/> 6-7	<input type="radio"/> 8+
Are your cookies <input type="radio"/> Usually low-fat <input type="radio"/> Sometimes low-fat <input type="radio"/> Hardly ever low-fat <input type="radio"/> I don't know/don't eat														
Ice cream, ice milk, ice cream bars	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
Is your ice cream <input type="radio"/> Usually low-fat <input type="radio"/> Sometimes low-fat <input type="radio"/> Hardly ever low-fat <input type="radio"/> I don't know/don't eat														
Pumpkin pie, sweet potato pie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many slices	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
Any other pie or cobbler	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many slices	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
Chocolate candy, candy bars	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many bars	<input type="radio"/> small	<input type="radio"/> medium	<input type="radio"/> large	<input type="radio"/> large
Other candy, not chocolate, like hard candy, caramel, jelly beans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many pieces	<input type="radio"/> 1-2	<input type="radio"/> 3-5	<input type="radio"/> 6-7	<input type="radio"/> 8+



PLEASE DO NOT WRITE IN THIS AREA

HOW OFTEN	NEVER OR A FEW TIMES PER YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	2+ TIMES per DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
										How many each time	How many each time	How many slices each time	How many slices each time	
Biscuits or muffins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Buns, hamburger buns, English muffins, bagels	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dark bread like rye or whole wheat, including in sandwiches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many slices each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
White bread or toast, including French, Italian, or in sandwiches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many slices each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Corn bread, corn muffins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tortillas	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many each time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rice, or dishes made with rice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Margarine (not butter) on bread or on potatoes or vegetables, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many pats (tsp.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Butter (not margarine) on bread or on potatoes or vegetables, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many pats (tsp.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gravy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peanut butter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jelly, jam, or syrup	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mayonnaise, sandwich spreads	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hot sauce, salsa or chile peppers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mustard, soy sauce, steak sauce, barbecue sauce, other sauces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	How many Tbsp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Did you use the pictures to choose your serving size on this form? Yes No I didn't have any pictures.

Would you say your health is Excellent Very good Good Fair Poor

How many times have you gone on a diet? Never 1-2 3-5 6-8 9 or more

Did you ever drink more beer, wine or liquor than you do now? Yes No

How many hours do you watch television or video, per day or per week on average?
 None 1-6 hours/week 1 hour/day 2 hours/day 3 hours/day 4+ hours/day

Do you smoke cigarettes now? No Yes
 IF YES, On the average about how many cigarettes a day do you smoke now?
 1-5 6-14 15-24 25-34 35 or more

What language do you usually speak at home or with friends?
 English Spanish Something else English & something else equally

What is your ethnic group? (MARK ONE OR MORE)
 Hispanic or Latino Black or African American American Indian or Alaska Native
 White, not Hispanic Asian Native Hawaiian or Other Pacific Islander

Thank you very much for filling out this questionnaire. Please take a minute to go back and fill in anything you may have skipped.

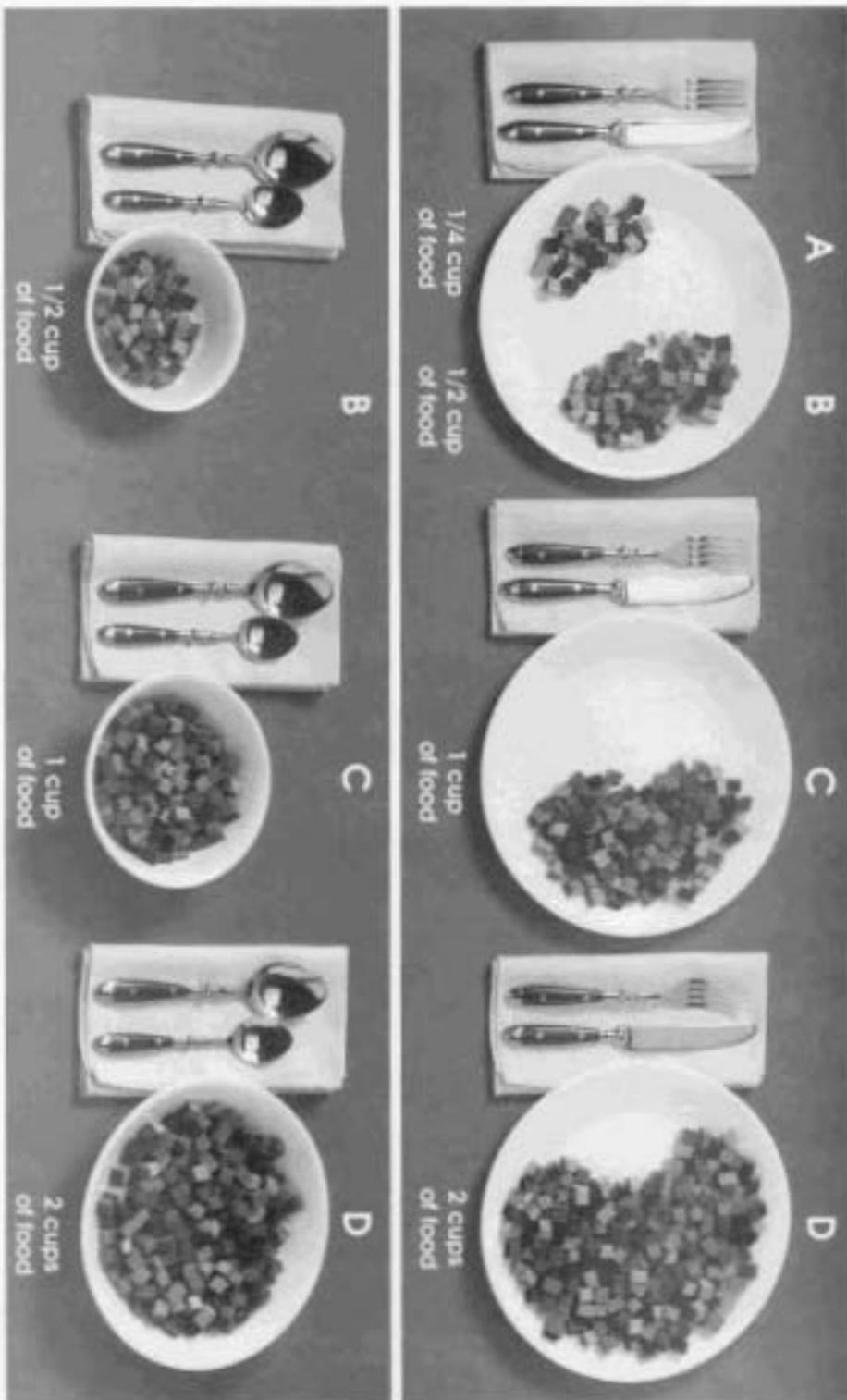
PLEASE DO NOT WRITE IN THIS AREA

95713

FOOD QUESTIONNAIRE
Serving Size Choices

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D: **A** = 1/4 Cup of Food **B** = 1/2 Cup of Food **C** = 1 Cup of Food **D** = 2 Cups of Food



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APPENDIX E

STRONG HEART STUDY

PHASE IV

Derived Variables

DEFINITION OF STUDY VARIABLES

DEFINITION OF AGE, INDIAN HERITAGE, AND INELIGIBILITY

(All the variable names shown here were the SHS-I variables. To derive the same variables for the later phases of examinations, the original variable names may be different, but the algorithm remain the SAME).

1. SEX: PERSONAL INTERVIEW FORM II, Q12
2 (FEMALE) INT2_1='2'
1 (MALE) INT2_1='1'
0/1 (Female/Male) when use numerical 0/1 for modeling.
2. AGE (IN YEARS), Q14 AND DOC IN PERSONAL INTERVIEW FORM II
AGE = (DATE OF EXAM/INTERVIEW) - (DATE OF BIRTH)
= (DOC - INT2_3) / 365.25
3. INDIAN BLOOD QUANTUM (BLOODALL), Q16 AND Q17 IN PERSONAL INTERVIEW II
BLOODALL = (INT2_5 / INT2_6)
= (INT2_8/INT2_9) + (INT2_11/INT2_12) + (INT2_14/INT2_15) +
(INT2_17/INT2_18) + (INT2_20/INT2_21)
4. TRIBE OF ENROLLMENT, Q18 IN PERSONAL INTERVIEW II, INT2_28
5. RESIDENCE, PERSONAL INTERVIEW FORM II
Q39, YEARS LIVING IN INDIAN COUNTRY/RESERVATION: INT2_49
Q41a, YEARS LIVING OUTSIDE INDIAN COUNTRY/RESERVATION:
INT2_51 = AGE - INT2_49
6. INELIGIBILITY:
AGE: < 44.5 YEARS OR > 75.5 YEARS
TRIBE: IF TRIBE OF ENROLLMENT (INT2_28) IS NOT ONE OF THE FOLLOWING
OKLAHOMA: 231 - APACHE
016 - CADDO
039 - COMANCHE
046 - DELAWARE
005 - FT SILL APACHE
062 - KIOWA
170 - WICHITA
DAKOTAS: 282 - OGLALA SIOUX
277 - CHEYENNE RIVER SIOUX
272 - DEVIL'S LAKE SIOUX
OR ANY OTHER SIOUX (276, 279, 280, 281, 283, 284, 274, 285, 286, 287, 275,
278 OR 045) LIVED IN PINE RIDGE, EAGLE BUTTE, AND FT. TOTTEN
AREA.
ARIZONA: 293 - PIMA/MARICOPA IN GILA RIVER INDIAN COMMUNITY
377 - PIMA/MARICOPA IN SALT RIVER INDIAN COMMUNITY
888 - MARICOPA
360 - PAPAGO INDIAN OF MARICOPA IN AK CHIN (OLD CODE = '096')

RESIDENCE: Steering Committee decided not to use this criteria (1-10-92).

IF LIVED LESS THAN 6 MONTHS IN INDIAN COUNTRY/RESERVATION
IN THE PAST YEAR, Q40 AND Q41b

Define Tribal Affiliation (TRIBE, VALUE 1-13)

OKLAHOMA: TRIBE OF ENROLLMENT
ARIZONA & DAKOTAS: TRIBE AND THE COMMUNITY (COMMUNITY CODE, CC) WHERE
THE PARTICIPANT RESIDES

TRIBE WILL BE CLASSIFIED AS MISSING IF TRIBE AND COMMUNITY DO NOT MATCH.

ARIZONA:

CC IN ('126', '132', '133', '377') TRIBE='13' 'SALT RIVER'
CC IN ('096', '96', '211', '209', '360') TRIBE='11' 'AK CHIN-PAPAGO'
The rest of AZ participants: TRIBE='12' 'GILA RIVER'

EXCEPT FOR:

IF IDNO='302017' THEN TRIBE='11'; /* AK CHIN BUT EXAM IN GRIC */
IF IDNO IN ('303335', '303337', '303338', '303341', '303342', '303346', '303369', '303375', '303379',
'303389', '303401', '303413', '303415', '303426', '303429', '303362', '303378', '303406',
'303351', '303527', '303433', '303350') THEN TRIBE='13';
IF IDNO IN ('303258', '303388', '303403') THEN TRIBE='12';
(these were instructed by the AZ PI)

DAKOTAS:

CC IN ('607', '612', '613', '614', '619', '623', '867', '868', '872') TRIBE='01' 'CHEYENNE RIVER'
CC IN ('358', '361', '362', '363', '477') TRIBE='02' '02'='SPIRIT LAKE'
CC IN ('526', '528', '849', '772', '778', '781', '782', '783', '784', '790') TRIBE='03' 'OGALALA SIOUX'

OKLAHOMA (by tribal enrolment, INT2_28):

INT2_28='231' TRIBE='04' 'APACHE'
INT2_28='016' TRIBE='05' 'CADDO'
INT2_28='039' TRIBE='06' 'COMANCHE'
INT2_28='046' TRIBE='07' 'DELAWARE'
INT2_28='005' TRIBE='08' 'FT SILL APACHE'
INT2_28='062' TRIBE='09' 'KIOWA'
INT2_28='170' TRIBE='10' 'WICHITA'

DEFINITION OF DIABETIC STATUS:

I. DIABETES STATUS ACCORDING TO 1985 WHO CRITERIA:

FOR SHS-I (BASELINE) DATA: (DM, value '0', '1', '2', '3', '4', and ' ')

- A. KNOWN DIABETES (DM='4'):
1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:
 - a. ON INSULIN TREATMENT (class code: 682008);
 - b. ON HYPOGLYCEMIC AGENT (class code: 682020);
 - c. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');
- OR**
2. EITHER FASTING BLOOD SUGAR (GLUC_0) \geq 140 OR TWO-HOUR BLOOD SUGAR (GLUC_2) \geq 200 AND WITH MENTIONING ANY HISTORY OF DIABETES IN MEDICAL HISTORY (Q3f, MED25='1' OR '3').
- B. NEW DIABETES (DM='3'):
- EITHER FASTING BLOOD SUGAR (GLUC_0) \geq 140 OR TWO-HOUR BLOOD SUGAR (GLUC_2) \geq 200 AND WITHOUT MENTIONING ANY HISTORY OF DIABETES IN MEDICAL HISTORY (Q3f, MED25='2' OR '9').
- C. IMPAIRED GLUCOSE TOLERANCE (IGT) (DM='2'):
GLUC_0 < 140 AND GLUC_2 BETWEEN 140 AND 199.
- D. NORMAL GLUCOSE TOLERANCE:
1. NGT WITH HISTORY OF DM (DM='1'):
GLUC_0 < 140 AND GLUC_2 < 140 AND WITH A HISTORY OF DIABETES (MED25='1').
 2. TRUE NGT (DM='0'):
GLUC_0 < 140 AND GLUC_2 < 140 AND WITHOUT A HISTORY OF DIABETES (MED25='2').
- E. DIABETIC STATUS UNDETERMINED (DM=' '):
1. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANT WITHOUT MENTIONING OF DIABETES IN THE MEDICAL HISTORY (MED25='2')
 2. RESULTS OF GTT WAS NOT RECEIVED, OR
 3. PARTICIPANT REFUSED GTT AND GLUC_0 WAS NOT SUFFICIENT TO DECIDE THE DIABETIC STATUS.

FOR SHS-I to SHS-III: sXdmwho, value 'NGT', 'IGT', 'DM', and ' ', where NGT are DM='0' or '1'. IGT is DM='2', and DM are DM='3' or '4'.

II. DIABETES STATUS ACCORDING TO 1997 ADA CRITERIA:

sXdmada=(‘DM’, ‘IFG’, AND ‘NFG’)

A. DIABETES:

1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:
 - a. ON INSULIN TREATMENT;
 - b. ON HYPOGLYCEMIC AGENT;
 - c. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');

OR

2. IF FASTING BLOOD SUGAR (GLUC_0) \geq 126

B. IMPAIRED FASTING GLUCOSE TOLERANCE (IFG):
 $110 \leq$ GLUC_0 $<$ 126

C. NORMAL FASTING GLUCOSE TOLERANCE (NFG):

1. NGT WITH HISTORY OF DM: NOT IN (I) AND (II), GLUC_0 $<$ 110 AND NO DM TREATMENT.

D. DIABETIC STATUS UNDETERMINED:
GLUC_0 WAS MISSING.

III. DIABETES STATUS ACCORDING TO 1998 WHO CRITERIA:

A. DIABETES:

1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:

- a. ON INSULIN TREATMENT;
- b. ON HYPOGLYCEMIC AGENT;
- d. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');

OR

2. IF FASTING BLOOD SUGAR (GLUC_0) \geq 126

OR

3. 2-HOUR BLOOD SUGAR (GLUC_2) \geq 200

B. IMPAIRED FASTING GLUCOSE TOLERANCE (IFG):
 $110 \leq$ GLUC_0 $<$ 126

C. IMPAIRED GLUCOSE TOLERANCE (IGT):
GLUC_0 $<$ 126 AND GLUC_2 BETWEEN 140 AND 199.

D. NORMAL FASTING GLUCOSE TOLERANCE (NFG):
GLUC_0 $<$ 110 AND NO DM TREATMENT

E. DIABETIC STATUS UNDETERMINED:
GLUC_0 WAS MISSING.

DEFINITION OF DIABETIC STATUS -- CONT'D

IV. DURATION OF DIABETES, FOR DIABETIC PATIENTS ONLY:

DURATION OF DM VARIES DEPEND ON WHICH DM CRITERIA WAS USING.

IF AGE OF DIABETES WAS DIAGNOSED (Q3f, MED27) WAS KNOWN,
DURATION OF DM = AGE AT EXAM - MED27

IV. DIABETES CONTROL, FOR DIABETIC PATIENTS ONLY:

POOR CONTROL --- HbA1c \geq 9.6% FAIR CONTROL --- HbA1c: 7.6-9.5%
GOOD CONTROL --- HbA1c: 6.0-7.5% NON-DIABETIC --- HbA1c < 6.0%

V. DIABETES TREATMENT, FOR DIABETIC PATIENTS ONLY, MEDICAL HISTORY: (B, I, O, N)

A. BOTH INSULIN AND ORAL AGENT:

TAKING BOTH INSULIN (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008') **AND** HYPOGLYCEMIC AGENT (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682020') AT THE SAME TIME.

B. INSULIN TREATMENT:

TAKING INSULIN CURRENTLY (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008')

C. ORAL AGENT:

TAKING HYPOGLYCEMIC AGENT CURRENTLY (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682020')

DEFINITION OF CORONARY HEART DISEASE:

I. ANGINA PECTORIS - DEFINED BY THE ROSE QUESTIONNAIRE:

ROSEAP=1 (YES): ROSE1='1' AND (ROSE2='1' OR ROSE2='3') AND ROSE4='1' AND
ROSE5='1' AND ROSE6='1' AND (ROSE7A='1' OR ROSE7B='1' OR
(ROSE7C='1' AND ROSE7D='1')), ELSE

ROSEAP=0 (NO)

II. MYOCARDIAL INFARCTION

A. MEDICAL HISTORY

1. HISTORY OF MI: Q31 IN MEDICAL HISTORY QUESTIONNAIRE
MED37='1';
2. POSSIBLE MI FROM ROSE QUESTIONNAIRE: Q9
ROSE9='1'.

B. CLINICAL ABNORMAL ECG: (DR. OOPK)

1. CLINICAL EVIDENCE OF ECG MI --- PANEL DECISION.
2. UNCODEABLE ECG
 - a. MISSING LEADS
 - b. BASELINE DRIFT (1 IN 20) IF IT OBSCURES ST-T SEGMENT.
 - c. MUSCLE TREMOR GIVING 2 MM. PEAK-TO-PEAK OSCILLATION.
 - d. OTHER TECHNICAL ERRORS MAKING Q WAVE MEASUREMENTS IMPOSSIBLE.
 - e. MAJOR ABNORMAL QRS CONDUCTION PATTERNS(BBB, PACER, ETC.)

C. ECG CRITERIA BY MINNESOTA CODE

1. MAJOR ISCHEMIC ABNORMALITIES -
 - a. MAJOR Q-WAVE ABNORMALITIES: 1.1.1 THROUGH 1.1.7.
 - b. STRICT CRITERIA (e.g., THE TECUMSEH STUDY): 1.1.X-1.2.X, 4.1.X, 5.1-5.2, 6.1 OR 7.1.X.
 - c. MINNESOTA DEFINITE MI: 1.1.X OR 1.2.X EXCEPT (1.2.6 OR 1.2.8)
 - d. MINNESOTA POSSIBLE MI: 1.1.X, 1.2.X, OR 1.3.X

2. MINOR ECG ABNORMALITIES - MINOR ST AND T-WAVE CHANGES.
 - a. POOLING PROJECT: 1.1.X-1.2.X, 4.1-4.2, 5.1-5.2, 6.1-6.2, 7.1.X-7.2.X, 7.4, 8.1.X, OR 8.3.X.
 - b. WHITEHALL STUDY: 1.1.X, 1.3.X, 4.1.X-4.4, 5.1-5.3, OR 7.X.

MN CODES	ANTERO-LATERAL	POSTERIOR (INFERIOR)	ANTERIOR	PATTERN
1-1-X	1, 2, 3	1, 2, 4, 5	1, 2, 6, 7	Q AND QS
1-2-X	1, 2, 3, 8	1, 2, 3, 4, 5, 6	1, 2, 7, 8	Q AND QS
1-3-X	1, 3	1, 4, 5, 6	1, 2	Q AND QS
2-X	1, 2, 3, 4, 5			QRS AXIS
3-X	1, 2, 3, 4			HIGH R
4-1-X	1, 2	1, 2	1, 2	ST JUNCTION (J)
4-X	2, 3, 4	2, 3, 4	2, 3, 4	STJ
5-X	1, 2, 3, 4	1, 2, 3, 4	1, 2, 3, 4	T-WAVE
6-X-X	1, 2-1, 2-2, 2-3, 3, 4-1, 4-2, 5, 6, 8			A-V CONDUCTION
7-X-X	1-1, 1-2, 2-1, 2-2, 3, 4, 5, 6, 7, 8			VENTRICULAR CONDUCTION DEF
8-X-X	1-1, 1-2, 1-3, 1-4, 1-5, 2-1, 2-2, 2-3, 2-4, 3-1, 3-2, 3-3, 3-4, 4-1, 4-2, 5-1, 5-2, 6-1, 6-2, 6-3, 6-4, 7, 8, 9			ARRHYTHMIAS
9-X	2	2	2	ST ELEVATION

ECG ABNORMALITIES

(used in Oopik’s paper. Oopik, A.J., Dorogy, M., Devereux, R.B., Yeh, J.L., Okin, P.M., Lee, E.T., Cowan, L., Fabsitz, R.R., Howard, B.V., Welty, T.K. Major Electrocardiographic Abnormalities Among American Indians Aged 45-74 Years (The Strong Heart Study). American Journal of Cardiology, 78:1400-1405, 1996.)

Program: ARVOEKG2.PGM

```

/* *****
** NEXT SECTION DEFINES ECG ENDPOINTS USED BY DR. OOPIK: **
** DMI_E: DEFINITE MN MI, 111, 112, 121-125 OR 127 **
** PMI_E: POSSIBLE MN MI, 13X, 126, 128 **
** VENTRICULAR DEFECT: **
** LBBB: LT BUNDLE BRANCH BLOCK, 71X **
** RBBB: RT BUNDLE BRANCH BLOCK, 72X **
** IVCD: INTRAVENTRICULAR BLOCK, 74 **
** VCDEFECT: ANY VC DEFECT, ANY OF ABOVE, 71, 72, 74 **
** LEFT VENTRICULAR HYPERTROPHY: **
** LVH_NOST: LVH VOLTAGE WITHOUT ST, 31, 33 **
** LVH_MN: LVH VOLTAGE WITH ST, 31, 33, AND (51 OR 52) **
** LVH_CHS: LVH WITH ST-T, 31, 33 AND (51,52,41X,42 OR 43) **
** ISOLATED ST-T: **
** MAJORSTT: ISOLATED MAJOR ST-T, 41X-42, 51, 52 **
** WITHOUT 11-13 3-1, 3-3 **
** MINORST: ISOLATED MINOR ST, 43, 44 **
** WITHOUT 11-13 3-1, 3-3 **
** MINOR_T: ISOLATED MINOR T WAVE, 53, 54 **
** WITHOUT 11-13 3-1, 3-3 **
** ISO_STT: ISOLATED ST-T, ANY OF ABOVE, 41X-44, 51-54, **
** WITHOUT 11-13 3-1, 3-3 **
** STJ_L: LARGE STJ DEPRESSION, >=2.0mm, 41X **
** STJ_S: SMALL STJ DEPRESSION, 1 TO 2.0mm, 42 **
** T-WAVE ITEMS: **
** T_NEGL: LARGE NEGATIVE T, < -5mm, 51 **
** T_NEGS: SMALL NEGATIVE T, -1 TO -5mm, 52 **
** A-V BLOCK: **
** FIRSTAVB: 1ST DEGREE AV BLOCK, 63 **
** SECONDAV: 2ND DEGREE AV BLOCK, 62X **
** AVBLOCK: AV BLOCK, 61, 62X, 63 **
** HEARTRAT: HEART RATE, CONTINUOUS VARIABLE **
** QRSAXIS: QRS VECTOR, CONTINUOUS VARIABLE **
** **
** SHS DEF ECG MI (DMI_S): **
** 11X, 12X EXCEPT (126, 128, 71, OR 74) **
** **
** SHS POS ECG MI (PMI_S): **
** 13X, 126, 128 EXCEPT (71, OR 74) **
** **
***** */

```

D. MORBIDITY EVENT CRITERIA

1. Definite Myocardial Infarction (MI)

Minnesota codes 1.1.x or 1.2.x except 1.26. and 1.28 with no 7.1 or 7.4
History of MI verified by chart review as definite MI

2. Possible Myocardial Infarction

Minnesota codes 1.3.x, 1.2.6, or 1.2.8 with no 7.1 or 7.4
History of MI verified by chart review as possible MI

3. Definite Coronary Heart Disease (CHD)

Definite MI,
Definite CHD verified by chart review to include cardiac cath, proven coronary artery disease, PTCA, coronary artery bypass grafting, or abnormal stress ECG plus abnormal imaging (i.e., both must be abnormal),
Angina Pectoris plus LBBB (7.1.1) or
ST changes (4.1) or
T wave changes (5.1) or
verified possible MI,

4. Possible Coronary Heart Disease

Possible ECG MI (1.3.x, 1.2.6, 1.2.8)
Angina Pectoris
Minnesota codes 7.1, 4.1, 4.2, 5.1, 5.2, 7.4
Unconfirmed history of MI
Positive functional test of ischemia (such as treadmill) without invasive confirmation
Possible ECG or imaging in scintigraphic studies (not both).

5. Definite Cardiovascular Disease (CVD)

Definite CHD
Congestive Heart Failure
Cardiomyopathy
Valvular Heart Disease
Left ventricular Hypertrophy by Echocardiogram
Left ventricular Hypertrophy by ECG (3.1 or 3.3 plus 4.1-4.3 or 5.1-5.3)
Ankle Arm Index ≤ 0.8
Atrial Fibrillation
Minnesota codes 4.1, 5.1, 6.1, 6.2, 6.8, 7.1, 7.2, 7.4
Noncoronary heart surgery or carotid or other vascular surgery
Pacemaker implantation
Bruits by physical examination
Intermittent Claudication by Rose Questionnaire
Positive non-coronary angiography

DEFINE COMPOSITE CVD BY USING M&M SURVEILLANCE AND SHS ECG RESULTS

For fatal event, "deadcode" indicate cause of death. User needs to refer to the **Mortality Survey Final Decision Form** for the meaning and the definition of each of the causes (numerical code). This form, along with other M&M forms can be found in SHS-III Manual Volume I, Appendix C. It is also in the SHS-4 Manual Volume II, Appendix C. This form has not been changed since SHS-III. The variable "deaddate" refers to the date of death. The "deadcode" are:

Cause of Death Code	Event
01	Definite fatal MI
02	Definite sudden death due to CHD
03	Definite fatal CHD
04	Possible fatal CHD
05	Definite fatal stroke
06	Possible fatal stroke
07	Definite fatal CHF
08	Possible fatal CHF
09	Other fatal CVD
10 and after	non-CVD death

For nonfatal events, the user needs to refer to the **Morbidity Survey Decision Form** for definition of each single cause. Since morbid events can reoccur, in this data set, I pulled all the events files together for each single event and selected the earliest one to represent the incident case as well as its date of occurrence. Thus, for nonfatal events, I separated the 9 CVD events in the Decision Form into 8 variables and the date of that specific event. They are:

Decision Diagnosis Code	Event	Variable name
01	Definite non-fatal MI	defmi and defmidt
02	Possible nonfatal MI	posmi and posmidt
03	Definite non-fatal stroke	defstk and defstkdt
04	Possible non-fatal stroke	posstk and posstkdt
06	Definite CHD	defchd and defchddt
07	Possible CHD	poschd and poschddt
08	TIA	shstia and shstiadt
09	Other CVD	othcvd and othcvddt

For SHS ECG MI, we were using MN Codes as:

SHS DEFINITE ECG MI: 11X, 12X EXCEPT (126, 128, 71, OR 74)
(SxDMI_S: x indicate phase, values: Y/N, ECGDATE)

SHS POSSIBLE ECG MI: 13X, 126, 128 EXCEPT (71, OR 74)
(SxPMI_S, values: Y/N)

SHS-I ECG date: ecgdate
SHS-II ECG date: ecgdate2
SHS-III ECG date: ecgdate3 (to be added)

NOTE: In Dr. Howard's Rising Tide paper (Circulation, 1999; 99:2389-2395):

Non-fatal CVD: defmi, defchd, defstk (morbidity decision: 1, 3, 6), and definite ECG MI (s2dmi_s='Y').

Fatal CVD: mortality final decision (01-09).

ALL CVD: combined fatal and non-fatal CVD.

DEFINITION OF HYPERTENSION

I. BLOOD PRESSURE: AVERAGE OF THE LAST TWO SITTING BLOOD PRESSURES FROM PHYSICAL EXAM, Q17, Q18, Q19, AND Q20

SYSTOLIC BLOOD PRESSURE - SBP = (EXAM27 + EXAM29) / 2

DIASTOLIC BLOOD PRESSURE - DBP = (EXAM28 + EXAM30) / 2

MEAN BLOOD PRESSURE - MBP = (2/3 SBP) + (1/3 DBP)

SXsbp, sXdbp

II. HYPERTENSION

A. WHO CRITERIA

SXwhohtn=(‘B’, ‘N’, ‘Y’).

HYPERTENSION (‘Y’):

1. TAKING ANTIHYPERTENSIVE DRUG (MEDICATION CODE='2408')

OR

2. TAKING (DIURETICS ('4028'), OR BETA-BLOCKERS ('1216') OR CARDIAC ('2404') OR VASODILATOR ('2412')) AND HISTORY OF HYPERTENSION (MED19='1')

OR

3. SYSTOLIC BLOOD PRESSURE \geq 160 mmHg

OR

4. DIASTOLIC BLOOD PRESSURE \geq 95 mmHg

BORDERLINE HYPERTENSION (‘B’):

140 mmHg \leq SBP < 160 mmHg OR

90 mmHg \leq DBP < 95 mmHg

NORMOTENSIVE (‘N’):

SBP < 140 AND DBP < 90 AND NO ANTIHYPERTENSIVE TREATMENT.

B. US CRITERIA: *sXushtn=(‘N’, ‘Y’)*.

HYPERTENSION: WHO HYPERTENSION OR BORDERLINE HYPERTENSION

NORMOTENSIVE: SAME AS WHO NORMOTENSIVE.

=====

DEFINITION OF ISOLATED HYPERTENSION:

1. HYPERTENSION: DBP \geq 90 AND SBP \geq 140

2. DIASTOLIC HYPERTENSION: DBP \geq 90 AND SBP < 140

3. ISOLATED SYSTOLIC HYPERTENSION: SBP \geq 140 AND DBP < 90

4. NORMOTENSIVE SBP < 140 AND DBP < 90

=====

HYPERTENSION CONTROL, FOR HYPERTENSIVE PARTICIPANTS ONLY:

1. UNCONTROLLED HYPERTENSION: DBP \geq 90 OR SBP \geq 140

DEFINITION OF RENAL DISEASE:

I. RENAL FUNCTION, PLASMA CREATININE:

A. CATEGORICAL VARIABLE:

1 (RENAL INSUFFICIENCY) PLASMA CREATININE \geq 2.0 mg/dl
0 (NORMAL) PLASMA CREATININE < 2.0 mg/dl

B. CONTINUOUS VARIABLE, ADJUSTED FOR BMI

II. ALBUMINURIA: *sXacr*=(‘1’, ‘2’, ‘3’)

ESTIMATED BY URINARY ALBUMIN - URINARY CREATININE RATIO

3 (MACROALBUMINURIA) ACRATIO \geq 300 mg/g
2 (MICROALBUMINURIA) ACRATIO 30 - 299 mg/g
1 (NORMAL) ACRATIO < 30 mg/g

III. END STAGE RENAL DISEASE (ESRD)

1 (YES)= ON RENAL DIALYSIS, MEDICAL HISTORY FORM, Q4a, MED42='1', OR
HAD KIDNEY TRANSPLANT, MEDICAL HISTORY, Q4b, MED43='1', OR
KIDNEY FAILURE, MEDICAL HISTORY, Q3g, MED29='1'
0 (NO)= NONE OF ABOVE

DEFINITION OF PERIPHERAL VASCULAR DISEASE (PVD)

I. ANKLE-BRACHIAL RATIO (PVD_ABR), PHYSICAL EXAM, Q44, Q45, AND Q46

sXrt_aar and sXlt_aar

RIGHT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ANKLE.

$$\text{RANKBP} = (\text{EXAM66} + \text{EXAM68}) / 2$$

LEFT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF LT ANKLE.

$$\text{LANKBP} = (\text{EXAM70} + \text{EXAM72}) / 2$$

RIGHT ARMBP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ARM.

$$\text{RARMBP} = (\text{EXAM74} + \text{EXAM75}) / 2$$

$$\text{RPVD_ABR} = \text{RANKBP} / \text{RARMBP}$$

$$\text{LPVD_ABR} = \text{LANKBP} / \text{RARMBP}$$

PVD_ABR: (cut-off value may vary depending on investigator)

1 (YES): IF (RPVD_ABR < 0.8) OR (LPVD_ABR < 0.8) OR THE ANKLE DOPPLER BPs WERE NOT AUDIBLE (EXAM70, EXAM72, EXAM74, OR EXAM75 WAS '0')

0 (NO): IF PVD_ABR ≥ 0.8.

(Cut-off point, such as 0.85 or 0.9, may vary according to the investigator).

II. PERIPHERAL OCCLUSION (PERIOCC):

ABSENCE OF DORSALIS PEDIS PULSE **AND** POSTERIOR TIBIAL PULSE ON EITHER FOOT.

(PHYSICAL EXAM Q36-Q39),

PERIOCC=1 (YES): (EXAM58='2' AND EXAM60='2') OR (EXAM59='2' AND EXAM61='2')

PERIOCC=0 (NO): EXAM58='1' AND EXAM59='1' AND EXAM60='1' AND EXAM61='1'

III. PRESENCE OF FEMORAL BRUITS (BRUIT)

(PHYSICAL EXAM Q40-Q41)

BRUIT=1 (YES): EXAM62='1' OR EXAM63='1'

BRUIT=0 (NO): EXAM62='2' AND EXAM63='2'

IV. INTERMITTENT CLAUDICATION (MEDICAL HISTORY - ROSE QUESTIONNAIRE)

ROSEIC=1 (YES): ROSE10='1' AND ROSE11='1' AND ROSE12='1' AND (ROSE13='1' OR ROSE13='3') AND ROSE15='2' AND ROSE16='1' AND ROSE17='1' AND ROSE18='1', ELSE

ROSEIC=0 (NO):

V. COMPOSITE PVD (PVD_COMP)

PVD_COMP 1 (YES): PVD_ABR=1 OR PERIOCC=1 OR BRUIT=1 OR ROSEIC=1

PVD_COMP 0 (NO): PVD_ABR=0 AND PERIOCC=0 AND BRUIT=0 AND ROSEIC=0

DEFINITION OF OBESITY INDICES, PHYSICAL EXAM:

A. BODY MASS INDEX, Q1 AND Q2, (WEIGHT IN KILOGRAM) / (HEIGHT IN METER)²

$$sXBMI = (EXAM94) / (EXAM03/100)^2$$

B. WAIST-HIP RATIO, Q33 AND Q9:

$$sXWHR = EXAM51 / EXAM13$$

C. PERCENT BODY FAT (sXPCTFAT):

(i) PCTFAT is calculated by using Rising's underwater equation as following:

fat-free mass:

$$FFT = 13.74 + 0.25 * (\text{height}^2 / \text{resistance}) + 0.30 * (\text{weight}) - 0.14 * (\text{age}) + 6.18 * (\text{sex})$$

where: height in cm, weight in kg, age in years, sex (0=female, 1=male)

$$\text{fat mass (FM)} = \text{weight} - \text{FFT}$$

$$\text{PCTFAT} = (\text{FM} / \text{weight}) * 100\%$$

RESISTANCE: Q35a IN PHYSICAL EXAM

(ii) following equation was developed by Segal and used by IRAS

$$\text{IF SEX='1' THEN FFM2} = 0.00132 * \text{HT} * \text{HT} - 0.04394 * \text{RESIST} + 0.30520 * \text{WT} - 0.1676 * \text{AGE} + 22.66827; \text{ ELSE}$$

$$\text{IF SEX='0' THEN FFM2} = 0.00108 * \text{HT} * \text{HT} - 0.0209 * \text{RESIST} + 0.23199 * \text{WT} - 0.06777 * \text{AGE} + 14.59453;$$

where FFM2 is fat-free mass

$$\text{PFAT_SG} = \text{ROUND}(100 * (1 - (\text{FFM2} / \text{WT})), .1);$$

(iii) the following equation was revised RJL for general population

$$\text{IF SEX='1' THEN BODYH2O} = \text{EXP}(1.1782 * \text{LOG}(\text{HT}) - 0.5968 * \text{LOG}(\text{RESIST}) + 0.3226 * \text{LOG}(\text{WT})); \text{ ELSE}$$

$$\text{IF SEX='0' THEN BODYH2O} = \text{EXP}(1.2004 * \text{LOG}(\text{HT}) - 0.5529 * \text{LOG}(\text{RESIST}) + 0.2164 * \text{LOG}(\text{WT}));$$

$$\text{FFM3} = \text{BODYH2O} / 0.732;$$

$$\text{FM3} = \text{WT} - \text{FFM3};$$

$$\text{PFAT_RJL} = \text{ROUND}(((\text{FM3} / \text{WT}) * 100), .1);$$

DEFINITION OF RISK FACTORS

1. CIGARETTE SMOKING (PERSONAL INTERVIEW II, Q24-Q29):

A. SMOKING (NEVER, EX-SMOKER, CURRENT)

SXsmoke=(‘E’, ‘N’, ‘Y’)

N (NEVER)	IF INT2_34='2' OR INT2_35=0
E (EX)	IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='2'
Y (CURRENT)	IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='1'
‘ ‘ (UNKNOWN)	NONE OF ABOVE

IF GROUP INTO SMOKER VS NONSMOKER,
(SMOKING=0 OR SMOKING=1) CAN BE COMBINED AS NON-CURRENT
SMOKER;

OR

(SMOKING=1 OR SMOKING=2) CAN BE COMBINED AS EVER SMOKED.

B. SMOKING AMOUNT (FOR SMOKER ONLY):

1. DURATION OF SMOKING: Q29 (INT2_39)
2. AGE STARTED SMOKING:
CURRENT SMOKER: AGE AT EXAM - DURATION OF SMOKING
EX-SMOKER: AGE STOPPED SMOKING (Q27) - DURATION OF SMOKING
3. DAILY SMOKING AMOUNT (Q28): INT2_38
4. TOTAL SMOKING AMOUNT (*sXppy*, PER PACK YEAR):
PPY = (DAILY SMOKING AMOUNT * DURATION OF SMOKING) / 20
= (INT2_38 * INT2_39) / 20

C. OTHER TYPE OF SMOKING: INTERVIEW II, Q30-Q32

0 (NO)	IF (INT2_40='2' AND INT2_41='2' AND INT2_42='2')
1 (YES)	IF (INT2_40='1' OR INT2_41='1' OR INT2_42='1')

D. PASSIVE SMOKING

0 (NO)	IF INT2_33=0
1 (YES)	IF INT2_33 > 0

DAILY EXPOSURE TIME (IN HOURS): INT2_33.

E. PARENTAL SMOKING:

0 (NONE)	(INT2_31=2 OR INT2_31=3) AND (INT2_32=2 OR INT2_32=3)
1 (ONE)	INT2_31=1 OR INT2_32=1
2 (BOTH)	INT2_31=1 AND INT2_32=1

2. EDUCATION: PERSONAL INTERVIEW FORM II, Q15 - INT2_4
- A. CONTINUOUS: $s1edu=INT2_4$ (YEARS)
- B. CATEGORICAL:
- i. THREE CATEGORIES (EDUCAT1):
- | | |
|--|------------------------|
| 1 (LESS THAN HIGH SCHOOL) | $0 \leq INT2_4 < 12$ |
| 2 (HIGH SCHOOL GRADUATE AND/OR SOME COLLEGE) | $12 \leq INT2_4 < 16$ |
| 3 (COLLEGE GRADUATE) | $INT2_4 \geq 16$ |
- ii. FOUR CATEGORIES (EDUCAT2):
- | | |
|--------------------------|---------------------------|
| 1 (LESS THAN NINE YEARS) | $0 \leq INT2_4 \leq 9$ |
| 2 (SOME HIGH SCHOOL) | $10 \leq INT2_4 \leq 12$ |
| 3 (SOME COLLEGE) | $13 \leq INT2_4 \leq 16$ |
| 4 (COLLEGE GRADUATE) | $INT2_4 \geq 16$ |
3. TOTAL DEGREE OF INDIAN BLOOD: INTERVIEW II, Q16
- A. CONTINUOUS: $BLOODALL = (INT2_5 / INT2_6) * 100\%$
- B. CATEGORICAL:
- | | |
|-------------------|----------------------------|
| 0 (LESS THAN 25%) | $0 < BLOODALL < 25\%$ |
| 1 (LESS THAN 50%) | $25 \leq BLOODALL < 50\%$ |
| 2 (50-74.9%) | $50 \leq BLOODALL < 75\%$ |
| 3 (75-99.9%) | $75 \leq BLOODALL < 100\%$ |
| 4 (FULL BLOODED) | $BLOODALL = 100\%$ |
4. INDIAN TRADITION: INTERVIEW II, Q35-Q38
- A. SPEAK NATIVE LANGUAGE, INDYLANG
- | | |
|---------|---|
| 0 (NO) | $INT2_45='3'$ OR $INT2_46='5'$ |
| 1 (YES) | $INT2_45='1'$ OR $'2'$ AND $(INT2_46='1'$ OR $'2'$ OR $'3'$ OR $'4')$ |
- B. USE TRADITIONAL MEDICINE/HERBS, INDYMED
- | | |
|---------|---|
| 0 (NO) | $INT2_47='5'$ OR $'9'$ |
| 1 (YES) | $INT2_47='1'$ OR $'2'$ OR $'3'$ OR $'4'$ |
- C. TRADITIONAL CEREMONIES, INDYCERE
- | | |
|---------|---|
| 0 (NO) | $INT2_48='5'$ OR $'9'$ |
| 1 (YES) | $INT2_48='1'$ OR $'2'$ OR $'3'$ OR $'4'$ |
5. STRESS: INTERVIEW II, Q42-Q46
- A. SLEEP LOSS, Q42, SLEPLOSS
- | | |
|---------|-------------------------|
| 0 (NO) | $INT2_52='1'$ |
| 1 (YES) | $INT2_52='2'$ OR $'3'$ |
- B. STRAIN OR STRESS, Q43, STRAIN
- | | |
|---------|-------------------------|
| 0 (NO) | $INT2_53='1'$ |
| 1 (YES) | $INT2_53='2'$ OR $'3'$ |

- C. OPEN ARGUMENTS, Q44, QUARREL
 0 (NO) INT2_54='1' OR '2'
 1 (YES)INT2_54='3' OR '4' OR '5'
- D. ALCOHOL PROBLEM OF HOUSEHOLD, Q45, HOUSETOH
 0 (NO) INT2_53='1'
 1 (YES)INT2_53='2'
- E. SIZE OF HOUSEHOLD, Q46, HOUSIZE
 1 (SMALL) INT2_54 ≤ 4
 2 (MEDIAN) 4 < INT2_54 < 10
 3 (LARGE) INT2_54 ≥ 10
6. ALCOHOL USE
- A. ALCOHOL DRINKING STATUS, *sXETOH*=(‘0’, ‘1’, ‘2’), Q47-Q48
 0 (NEVER) INT2_57='2'
 1 (EX-DRINKER) INT2_57='1' AND (INT2_59 ≥ 12 OR INT2_60 ≥ 1)
 2 (CURRENT) INT2_57='1' AND INT2_60 = 0
- B. BINGE DRINK
1. DURING THE PAST MONTH, Q52
 0 (NO) 0 ≤ INT2_64 < 5
 1 (YES) INT2_64 ≥ 5
2. DURING THE PAST YEAR, Q53
 0 (NO) 0 ≤ INT2_65 < 5
 1 (YES) INT2_65 ≥ 5
- C. AMOUNT OF ALCOHOL INTAKE
- Average weekly drinking amount: INT2_61 (preferred ETOH variable)
- Average daily drinking amount: INT2_63

7. SOCIOECONOMIC STATUS (SES)
 - A. RECEIVING FEDERAL ASSISTANCE:
 1. FOOD STAMPS / WIC, Q56
0 (NO) INT2_68 = 0
1 (YES)INT2_68 > 0
 2. COMMODITY FOOD, Q57
0 (NO) INT2_69 = 0
1 (YES)INT2_69 > 0
 3. FEDERAL ASSISTANCE, FEDHELP
0 (NO) INT2_68 = 0 AND INT2_69 = 0
1 (YES)INT2_68 > 0 OR INT2_69 > 0
 - B. SES (EDUCATION, FAMILY INCOME, ...)
 1. HOUSEHOLD INCOME, Q58: USE THE CATEGORIES LISTED IN THE QUESTIONNAIRE.

8. FAMILY HISTORY OF DISEASES - PERSONAL INTERVIEW II, FAMILY HISTORY
 - A. CLASSIFICATION:
 1. PARENTAL, FOR RELATIONSHIP CODE 1 AND 2 (FH1 AND FH14)
 2. FIRST DEGREE FULL-BLOOD RELATIVES:
RELATIONSHIP CODE: 1 (MOTHER), 2 (FATHER), 3 (SISTER), 5 (BROTHER), 7 (DAUGHTER), AND 8 (SON).
 3. ALL FIRST DEGREE RELATIVES, ALL CODES.
 - B. DISEASE HISTORY
 1. HEART DISEASE: MI AND HD
 2. CARDIOVASCULAR DISEASE: MI, HD, HBP, CVA
 3. DIABETES: DM
 4. KIDNEY FAILURE: KF
 5. ARTHRITIS: AT
 6. CANCER

9. MEDICAL HISTORY, MEDICAL HISTORY FORM

A. PRESCRIBED MEDICATIONS: USE CATEGORIES IN THE MANUAL (p. 282)

- | | |
|--------------------------------|--------------------------------|
| 1- ANTIHISTAMINE (400) | 2- ANTIBIOTICS (812) |
| 3- ANTINEOPLASTIC RX (1000) | 4- BETA-BLOCKERS (1216) |
| 5- ANTICOAGULANTS (2000) | 6- CARDIAC DRUGS (2404) |
| 7- HYPOLIPIDEMIC (2406) | 8- HYPOTENSIVE (2408) |
| 9- ANALGESIC (2808) | 10- ASPIRIN (280892) |
| 11- ANTICONVULSANTS (2812) | 12- PSYCHOTHERAPY (2816) |
| 13- ADRENALS (6804) | 14- Oral Contraceptives (6812) |
| 15- DIURETICS (4028) | 16- GI DRUGS (5600) |
| 17- MENOPAUSAL ESTROGEN (6816) | 18- INSULIN (682008) |
| 19- SULFONYLUREAS (682020) | 20- THYROID AGENTS (6836) |
| 21- OINTMENTS (8400) | 22- VITAMINS (8800) |
| 23- UNCLASSIFIED (9200) | |

B. HISTORY OF:

1. GALLSTONE, Q3c
0 (NO) MED22='2'
1 (YES)MED22='1'
2. ARTHRITIS, Q3d
0 (NO) MED23='2'
1 (YES)MED23='1'
3. CANCER, Q3e
0 (NO) MED24='2'
1 (YES)MED24='1'
4. KIDNEY FAILURE, Q3g
0 (NO) MED28='2'
1 (YES)MED28='1'
5. EMPHYSEMA, Q3h
0 (NO) MED31='2'
1 (YES)MED31='1'
6. LIVER CIRRHOSIS, Q3i
0 (NO) MED32='2'
1 (YES)MED32='1'
7. RENAL DIALYSIS, Q4a
0 (NO) MED42='2'
1 (YES)MED42='1'
8. KIDNEY TRANSPLANT, Q4b
0 (NO) MED43='2'
1 (YES)MED43='1'

10. REPRODUCTION AND HORMONE USE (FEMALE ONLY), MEDICAL HISTORY

A. REPRODUCTION:

1. TIMES PREGNANT, Q7-1, REPRO1
2. NUMBER OF LIVE BIRTH, Q7-2, REPRO2
3. NUMBER OF LOST PREGNANCIES, Q7-3, REPRO3
4. NUMBER OF LIVING CHILDREN, Q7-4, REPRO4
5. MENOPAUSAL, Q8
0 (NO) REPRO5='2'
1 (YES) REPRO5='1'
6. AGE AT MENOPAUSE, Q9, REPRO6

B. HORMONE USE

1. ORAL CONTRACEPTIVE, Q11
0 (NO) REPRO9='2'
1 (YES) REPRO9='1'
 2. AGE STARTED TO USE OC PILLS, Q12, REPRO10
 3. TOTAL DURATION OF USING OC PILLS, Q13, REPRO11
 4. EVER USE OF ESTROGEN OTHER THAN OC PILLS, Q14
0 (NO) REPRO12='2'
1 (YES) REPRO12='1' OR MEDICATION CODE (Q1a-Q1h)
CONTAINS '6816' (POST MENOPAUSAL ESTROGEN)
 5. AGE STARTED TO USE ESTROGEN, Q15, REPRO13
 6. TOTAL DURATION OF USING ESTROGEN, Q16, REPRO14
-
-

11. PHYSICAL ACTIVITY

WILL CONSULT WITH DR. ANDREA KRISKA

12. LAB DATA

A. LIPID - CONTINUOUS VARIABLE

1. TOTAL TRIGLYCERIDE, ln(TRIG)
2. TOTAL CHOLESTEROL, CHOLEST
3. HDL CHOLESTEROL, HDL_CHOL
4. LDL CHOLESTEROL, LDL_CHOL
5. VLDL TRIGLYCERIDE, VTRIG
6. VLDL CHOLESTEROL, VCHOL
7. RATIOS:
 - i. VCHOL/VTRIG
 - ii. HDL_CHOL/CHOLEST
 - iii. HDL_CHOL/LDL_CHOL
 - iv. APOB/(CHOLEST-HDL_CHOL)
 - v. APOA1/HDL_CHOL
 - vi. APOB/LDL_CHOL

B. APOLIPOPROTEINS: APOA1, APOB

C. GLUCOSE:

1. FASTING BLOOD GLUCOSE, GLUC_0
2. 2-HR BLOOD GLUCOSE, GLUC_2

D. FIBRINOGEN

E. PLASMA INSULIN

F. FIBRINOGEN

G. APO E PHENOTYPE

H. PLASMA CREATININE

I. URINARY ALBUMIN AND CREATININE

J. GLYCATED LDL

CUT POINTS FOR CONTINUOUS VARIABLES:

VARIABLES		LOW (0) NO	MEDIUM (1)	HIGH (2) YES
AGEGP		45-54	55-64	65-74
OBESITY: USING NHANES-II CRITERIA				
In SHS-I:	OBESE (95%)	FEMALE: MALE:	BMI \geq 32.3 BMI \geq 31.3	
	OVERWT (85%)	FEMALE: MALE:	32.3 > BMI \geq 27.8 31.1 > BMI \geq 27.3	
SHS-II and later:	Overweight:		BMI 25-29.9	
	Obesity, level 1:		BMI 30-34.9	
	Obesity, level 2:		BMI 35-39.9	
	Obesity, level 3:		BMI 40-44.9	
	Obesity, level 4:		BMI 45 and above	
OBES_FAT	FEMALE: MALE:	PCTFAT < 41% PCTFAT < 29%		PCTFAT \geq 41% PCTFAT \geq 29%
OBES_WHR (65%)	FEMALE: MALE:	WHR \leq 0.98 WHR \leq 0.96		WHR > 0.98 WHR > 0.96
TOTAL CHOLESTEROL (NCEP GUIDELINE)		CHOLEST < 200 (mg/dl)	CHOLEST 200-239	CHOLEST \geq 240
TOTAL TRIGLYCERIDES 2001 Guideline		TRIG < 250 (mg/dl) TRIG < 200 mg/dl		TRIG \geq 250 TRIG \geq 200
HDL CHOLESTEROL (NCEP GUIDELINE) 2001 Guideline		HDL_CHOL < 35 (mg/dl) HDL_CHOL < 40		HDL_CHOL \geq 35 HDL_CHOL \geq 40
LDL CHOLESTEROL (NCEP GUIDELINE)		LDL_CHOL < 130 (mg/dl)	LDL_CHOL 130-159	LDL_CHOL \geq 160

THE CONTINUOUS VARIABLES MAY ALSO BE ANALYZED BY QUARTILES.

APPENDIX F

STRONG HEART STUDY

PHASE IV

Special Designs and Methods

Nested Case-Control Design:

For the Adiponectin and Thyroid case-control studies

Design: Nested case-control (case-control within an existing longitudinal study) Frequency matching is recommended.

Cases and controls are identified at the same point in time and previous exposure is examined for association with disease. After applying exclusion criteria, cases are selected. From the remaining pool of susceptibles, controls are selected. Controls are matched to cases based on the distribution of diabetes, study center, and gender among randomly selected cases. For instance, if 8% of the cases are women with diabetes from Arizona, then 8% of the controls will also be women with diabetes from Arizona.

Exclusion Criteria:

- prevalent and incident CVD occurring from baseline to phase 2 and CVD cases identified at the phase 2 exam (ECGMI) will be excluded.
 - Prevalent and incident CVD, Fatal and Non-Fatal variables:
 - Deadcodes 1, 2, 3, 4, 7 & 8 (Definite MI, Definite Sudden death due to CHD, Definite and Possible CHD, Definite and Possible CHF)
 - ECG MI identified at phase 1 or phase 2 exam
 - Non-fatal CVD events between phases 1 and 2. (DEFMI and DEFCHD).
- Anyone with renal disease - plasma creatinine level >1.2 mg/dL (from phase 2 lab data)
- Anyone taking thyroid medication (at phase 2)
- Anyone taking glucocorticoid (at phase 2)
- Anyone taking troglitazone (at phase 2)
- Prevalent and incident definite stroke, Fatal and Non-Fatal variables: Deadcodes 05 and 06, and DEFSTK

Matching criteria:

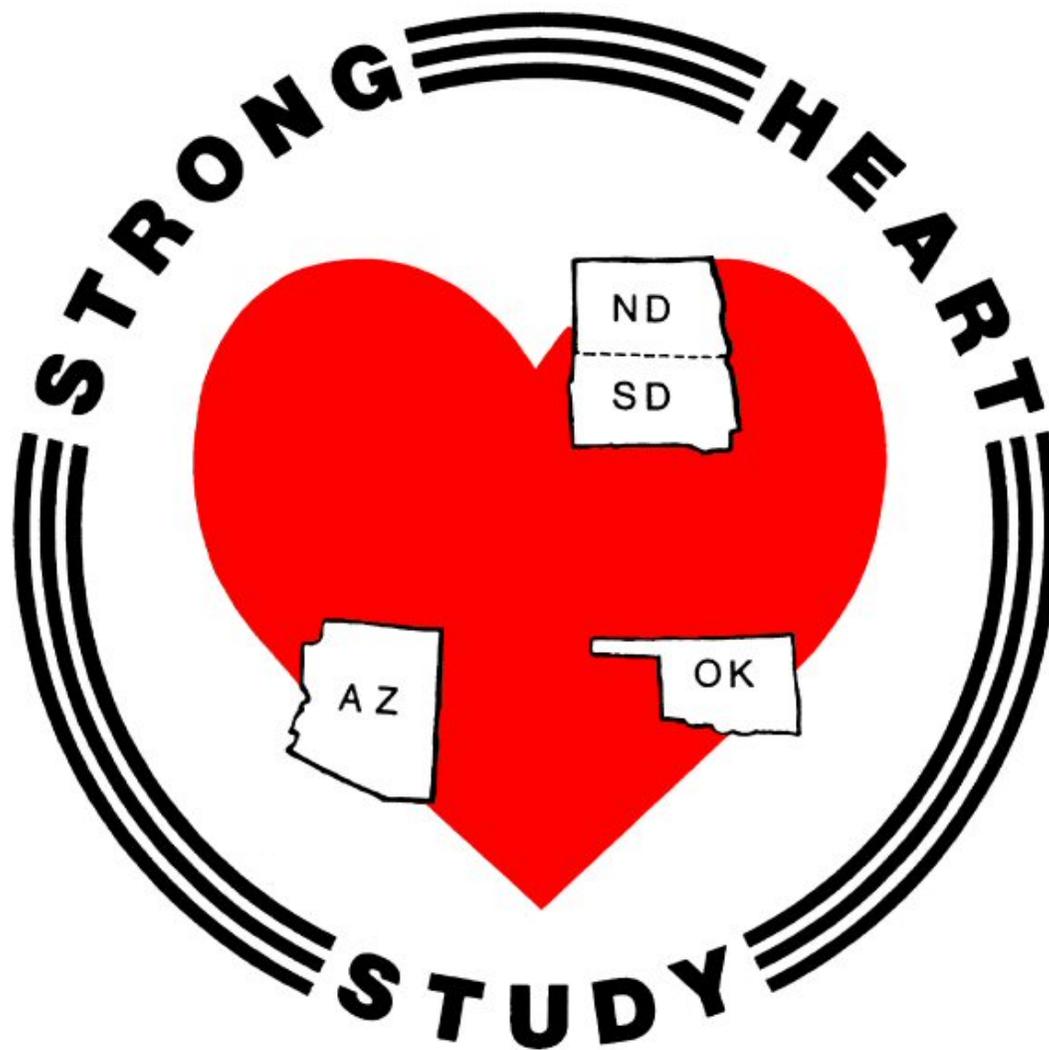
- Gender
- Study site
- Diabetes status (2 groups, diabetes and no diabetes), diabetes defined using ADA criteria: self report or taking oral diabetes medication or taking insulin or FG \geq 126 (at phase 1 or phase 2 exams)

Selection Process:

1. Apply exclusion criteria to phase 2 participants: (Deadcodes 1, 2, 3, 4, 5, 6, 7 & 8, DEFMI, DEFCHD, ECGMI, DEFSTK, plasma creatinine >1.2, taking thyroid meds, glucocorticoid and/or troglitazone). Remove any participant who meets any exclusion criterion.
2. Identify incident CVD cases occurring after phase 2 exam through ALLCVD99: (Deadcodes 1, 2, 3, 4, 7 & 8, not 5 & 6; DEFMI, DEFCHD, and ECGMI-from-phase 3 exam)

3. Remove all incident cases identified in step 2 from the pool of susceptibles at phase 2.
4. Divide the cases into the following 12 categories:
 - 1) Women from AZ with DM
 - 2) Women from OK with DM
 - 3) Women from SD with DM
 - 4) Women from AZ no DM
 - 5) Women from OK no DM
 - 6) Women from SD no DM
 - 7) Men from AZ with DM
 - 8) Men from OK with DM
 - 9) Men from SD with DM
 - 10) Men from AZ no DM
 - 11) Men from OK no DM
 - 12) Men from SD no DM
5. Randomly select 162 cases in as even a distribution as is possible from each of the 12 categories.
6. Select 162 controls from phase 2 participants who remain after the identified cases are removed
7. The distribution of controls should mirror that of the cases.

Proposed and developed by:
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05/23/2002



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Four

LABORATORY MANUAL

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Four

Laboratory Manual

June 01, 2001

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
College of Public Health

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Oklahoma City, OK 73190

VOLUME IV
LABORATORY MANUAL

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STRONG HEART STUDY LABORATORY PROCEDURES

1.0 Safety Precautions, Universal Precautions and Personal Protective Equipment for the Handling of Blood and Working in a Laboratory Setting:

Lab testing in research is important. Your work brings new and important information to the scientific and medical community. The special equipment and skills such as attention to detail, organization and phlebotomy are critical to the success of this project. Your work on this project will probably expose you to a variety of potentially hazardous situations. The following learning modules are designed to help you keep safe on the job.

Each site should have at least one staff member who will be actively involved in this process attend the initial training session. This person, in turn will be responsible for training additional personnel at his/her facility. The training session will cover all procedures related to supplies, equipment, preparation of log sheets, labeling, collection, processing, storage, packing and shipping of specimens.

Throughout the study, a qualified observer should regularly monitor and evaluate the work of those involved in the collection and processing of blood samples. Specific plans should be made to train new staff members at each facility. Training should include a detailed review of the Strong Heart Study laboratory manual as well as supervised practice in the application of the techniques required by the protocol.

This section will provide knowledge to protect you and others. In addition to these instructions, use commonsense on the job every day.

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don't take chances
- Don't operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
- Avoid direct contact with blood, sera or plasma. Cover any scratches or cuts on fingers and hands very carefully and use gloves in the handling of specimens.

- All tubes, containers and other materials exposed to blood must be disposed of in appropriately labeled waste receptacles for biohazardous materials.
- When removing stoppers from vacutainers, use a splash shield to prevent droplets from spraying onto your skin or eyes.
- All samples should be stored in sealed containers or tubes.
- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.
- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.
- Avoid working alone
- Post important phone numbers and emergency numbers prominently
- Know before an accident where to go and what to do
- Know the location of safety showers, eyewashes and fire extinguishers

Module I: Safety Precautions

This module will include the following:

- Provide knowledge to protect you and others.
- Demonstrate common procedures that will be used on the job every day.

Here are some guidelines:

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don't take chances
- Don't operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
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- All samples should be stored in sealed containers or tubes.
- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.
- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.

Emergencies can happen, so be prepared:

- Avoid working alone
- Post important phone numbers and emergency numbers prominently
- Know before an accident where to go and what to do
- Know the location of safety showers, eyewashes and fire extinguishers

Some of the equipment in the areas you will be working is reviewed below:

- **Glassware** like vacutainers can break, causing chemical and cut hazards. Some of the chemicals contained in the vacutainers are EDTA and heparin. Although serious hazards are unlikely if exposed, still follow procedures if an accident occurs. To avoid contact, use the right type of glassware for each job, and discard chipped or cracked vacutainers in an approved receptacle. Don't force anything made of glass.
- **Electrical equipment** always carries the potential of shock or fire. Don't touch it with wet hands or while standing on a wet floor. Report any shocks, and don't attempt to do repairs if you haven't been trained.
- **Centrifuges** and other equipment with moving parts can catch your clothing or open up suddenly, showering you with dangerous material. Keep clothing or long hair away from them. Make sure the load is balanced, the top is locked down, and the equipment has stopped before you open it.

Module II: Personal Protective Equipment

This module will include the following:

- Proper use of protective clothing.
- First-aid instructions

Let protective equipment work for you.

For this aspect of the study, always use assigned protective clothing and

equipment. Always check that it is in good condition before putting it on. For this study the following are required:

- **Goggles or side shield safety glasses** to protect against splashes or flying objects are required any time you are working with specimens or performing phlebotomy.
- **Gloves** must be worn to protect against any chemicals or exposure to samples
- **Long sleeves** are required to the length of your wrist and meet the glove.
- **Lab coats** must be full length and fully buttoned down the front.
- **Sturdy closed toed shoes** are required to cover your feet in case of spills or accidents

If you are exposed to a hazardous substance or samples, take the following actions:

For first-aid instructions, here are some general instructions. You should check with your supervisor for specific instructions at your institution prior to an accident.

- **Eyes:** Flush with water for 15 minutes.
- **Ingestion:** Follow labels and MSDS instructions MSDS is an abbreviation for Materials Safety Data Sheet and is available from the manufacturer for every chemical produced.
- **Skin Contact:** If limited to a small area of the body such as the hands, remove any contaminated gloves or clothing and wash with copious amounts of water. If there is greater exposure, stand under emergency shower and remove contaminated clothing immediately.
- **Inhalation:** Get to fresh air and get prompt medical attention.

Module III: Preventing Exposure to Blood Borne Pathogens:

This module will include the following:

- Universal precautions
- Work practices, including the use of protective clothing that eliminates or minimizes exposure to staff and subjects
- Housekeeping procedures to ensure cleanliness and possible spread of infection
- Hepatitis B vaccinations for employees at risk

- Exposure evaluation and follow-up for exposure incidents
- Hazardous material container warnings such as biohazard labels
- Confidential, accurate employee medical records

Your chance of being directly exposed to bloodborne pathogens on the job is small. But keeping exposure minimal can only succeed if staff use the tools to protect them on the job.

- **Universal Precautions** are your best protection against any risk to exposure. This means all staff must treat all blood, urine, and other potentially infectious body fluids as if they are infected.

All specimens should be regarded as potentially hazardous.

DO:

- Wash hands and exposed skin with soap and water immediately after exposure to infectious materials or after taking off gloves or other personal protective equipment.
- Use antiseptic or cleansers or towelettes only if washing facilities aren't available.
- Minimize splashing, spraying, or spattering of blood or other potentially infectious materials.
- Place contaminated sharps in assigned labeled, puncture-resistant, leak-proof containers.

DON'T:

- Don't shear or break contaminated needles or other sharps, and don't bend, recap, or remove unless specifically instructed.
- Don't keep food, drink, medication or makeup in work areas with exposure potential.
- Don't eat, drink, smoke apply cosmetics or lip balm, or handle contact lenses in work areas with exposure potential.
- Don't pipette or suction anything by mouth.

- **Protective Clothing:**

BEFORE you put on protective clothing, make sure it's in good condition. Don't wear anything that's damaged or does not fit properly.

AFTER tasks in the area are completed, remove all protective clothing before leaving that area. Remove protective clothing in such a manner as to minimize exposure and avoid contamination. Place protective clothing in a specially assigned area or container for decontamination, washing, storage or disposal.

- **Housekeeping:**

Written procedures and a cleaning schedule help keep the workplace free of infection.

- **Cover** equipment and surfaces with plastic wrap, aluminum foil, or impervious absorbent paper. Remove and replace covering that is, or may be, contaminated.

Module IV: Proper Labeling

This module will include the following:

- Correct identification and labeling of containers with biohazardous labels
- Instructions in case of exposure

Proper labeling of containers for regulated waste must be labeled with fluorescent orange or orange-red biohazard warning labels.

Examples in the clinical area or lab are: refrigerators and freezers containing blood and other potentially infectious materials and other containers used to store, transport or ship blood and other potentially infectious materials

Biohazard labels **ARE** required for the following:

- waste containers used for disposal of contaminated needles
- refrigerator or freezer holding blood or other potentially infectious material
- individual specimen containers for storage or shipment zip-lok biohazard bags

Biohazard labels **ARE NOT** required for the following:

- when red bags or red containers are used
- on individual containers or blood of other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal

The risk of exposure is very small and most encounters with an HIV or HBV carrier pose no risk. AIDS and Hepatitis B can be transmitted through:

- Sexual contact
- Shared needles
- Needlestick injuries from infected needles or sharps
- Direct contact between broken or chafed skin and infected body fluids.
- Hepatitis B can also be transmitted through dried blood and contaminated surfaces.

The risk of exposure can not be transmitted by the following:

- Coughing or sneezing
- Touching an infected person
- By using the same equipment, materials, toilets, showers, or water fountains.

Be safe!!! Your employer must make available, free of charge or at a reasonable time and place, the hepatitis B vaccine and vaccination series to all employees at risk. Any booster doses recommended by the US Public Health Service also must be provided. You are not required to participate in a prescreening program to receive the vaccine series. Also, the vaccine can be available at a later time if initially declined. If you choose to not receive the vaccine, your facility will ask you to complete and sign a form stating your refusal. This is required by law.

If you are directly exposed, REPORT IT IMMEDIATELY!!!

An exposure incident is specific to eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance or an employee's duties. A common example of exposure would be a puncture from a used needle.

If exposed, you should contact your supervisor immediately. This allows for

timely medical evaluation and follow up as well as for timely testing of the source. Your facility will provide immediate, confidential assistance and medical evaluation, including a blood test. All information will be treated with the strictest of confidence.

2.0 Sample Collection Instructions:

Personnel involved in sample collection should be highly experienced with vacutainer and butterfly blood collections, and be prepared to handle common problems, such as difficult blood collection and situations such as fainting. The phlebotomist should also be familiar with precautions to avoid exposing themselves to blood and be trained in the following:

- Ideally staff will have cardiopulmonary resuscitation (CPR) certification.
- It is suggested that they read "Collection and Handling of Laboratory Specimens: A Practical Guide"¹ or a similar phlebotomy manual.
- Personnel should wear clean white lab coats (with no blood stains) and maintain a neat appearance. Lab coats will be full length, with long sleeves. Lab coats will be buttoned closed down the full length of the coat.
- Personnel will wear protective eyewear. Safety glasses are required when performing phlebotomy, processing specimens and preparing samples for storage and/or shipment.
- Staff should wear nametags and introduce themselves (if necessary) before a blood draw.
- Long hair and bangs should be pulled back.
- Phlebotomists and assistants should not chew gum or have any food in their mouths during blood draws. Food and drink must never be brought into areas used for blood drawing or processing.
- Staff will attempt no more than three venipunctures on the same subject. After three failed attempts, another person will be asked to try.

Module I: Sample Collection Facilities

This module will include the following:

- Room requirements for sample collection
- Supplies for sample collection

The area in which phlebotomy will occur should be clean and tidy with no evidence of previous blood draws such as used needles, blood stains, etc. A phlebotomy chair should be available for 15-20 minute periods to allow subjects to be seated for 10 minutes prior to a blood draw. If not available within the room, there should be quick access to a bed or examining table and ammonia capsules in case a subject feels faint. Also, there should be easy access to

¹

Slockbower, J.M., and Blumenfeld, T.A., (Eds.). Collection and Handling of Laboratory Specimens: A Practical Guide. Philadelphia: J.B. Lippincott Company, 1983.

emergency equipment in case of cardiac arrest. Ideally, only the participant and phlebotomist (and assistant when needed) are in the room during the procedure.

The room should be set up in advance with basic supplies for blood collection:

- Vacutainer holders/hub
- Vacutainer needles
- Disposable graduated transfer pipettes
- alcohol wipes or swabs
- sterile cotton or 2x2 sterile gauze pads
- band aids
- adhesive tape
- urine collection cups
- disposable latex gloves
- ammonia inhalants
- paper cups
- emesis basin
- tourniquets
- biohazard labels
- biohazard needle disposal boxes
- biohazard bags
- Tube racks or supports
- Waterproof marking pen
- Refrigerator
- Centrifuge
- -70°C Freezer (or lower temperature Freezer than -70°C)

Module II: Sample Collection and Processing

This module will include the following:

- Completion of clinical logs
- Completion of laboratory requisitions
- Demonstration of One-Touch procedure
- Proper labeling of vacutainers and transport tubes
- Venipuncture Instructions
- Posture during blood collection
- Difficult Venipuncture Techniques
- Vacutainers for Sample Collection and Processing Instructions

Sample Collection Logs and Laboratory Requisition Forms

Clinic personnel should carefully review the description of collection requirements to ensure that specimens are collected in the proper order and use the proper technique. Each clinic should set up a blood collection and blood processing notebook or a laboratory log book in advance. It should be located in the blood collection/processing area. This should be a hardbound notebook from which pages cannot be easily removed. Pages should have columns headed for date, visit number, participant name and ID, and room to write "comments" about any problems with blood draws or processing, including hemolysis of samples, etc.

In addition to the logs for the clinical area, it will be necessary to complete a laboratory requisition form for each subject. An example of this form is attached. Proper completion of this form will include the following:

- Subject ID
- Date of Collection
- Under left column marked "Check below to indicate sample was collected" record the number of samples sent

One-Touch Procedure

- 1) Obtain One-Touch reading from a drop of blood obtained by finger stick. Using the blood from the venipuncture procedure below will not provide comparable results since there is a difference between capillary blood (fingerstick) and venous blood values.
- 2) See One-Touch procedure for calibrating the meter and steps to follow in obtaining a glucose reading. (Consult with the operations manual which can be obtained from Lifescan, Inc. 1-800-227-8862) A video and training will be provided at the initial training session. Thereafter, training will be provided on-site. See Appendix of this volume (p. IV - 1-1 below) for additional instructions.

Labeling Collection Tubes and Samples:

Prior to venipuncture, a label showing the date and time of collection and participant ID number should be written by the phlebotomist.

Labels will be provided to the study pre-numbered. Take care to select the correct number depending on whether the samples are being collected from the participant, as a QA sample or for a Courtesy visit.

To properly label vacutainers and shipping vials, the white section of the label must be applied to the tube laterally with the clear end wrapped over the white section of the label after the label is wrapped around the tube.

Module III: Venipuncture Procedure

This module will include the following:

- Correct Venipuncture procedures

Posture During Blood Draws:

A participant should be seated during blood draws. However, if the participant is clearly uncomfortable with the blood drawing situation, because of a previous fainting episode or a fear of fainting, have the participant lie down provided the blood draw can proceed within 10 minutes. This is to ensure that blood is collected before body fluid shifts occur, which could alter plasma concentrations of outcome variables. Therefore, it is desirable that less than **10 minutes** elapse between the participant's lying down and completion of the blood draw.

Difficult Venipunctures:

There will be several common situations in which vascular access may be difficult. These will include but are not limited to the following:

- Palpated vein feels small or rolls.
- Excess subcutaneous tissue and fat lies over veins.
- Participant complains of being stuck more than once on a previous visit (no single staff person will attempt more than three venipunctures on a single participant at a single clinic visit) or has had a bad experience elsewhere.
- Participant has been stuck once already and none of the usual veins are palpable.

All reasonable efforts should be made to collect a blood sample, including use of a 23 gauge needle if that is the only means available to obtain a sample, e.g., in the case of a child or elderly person. If the participant experiences any of the above problems, and is agreeable to a repeat attempt, you may try the following procedure:

- Check back of hand and forearm for venipuncture sites with larger veins.
- Attempt one or more vein dilation methods:

1. Hot pack venipuncture site with a warm, wet towel or apply heating pad for 3-5 minutes.
 2. Have participant hold hand in warm water for 3-5 minutes.
 3. Have participant dangle arm at side with tourniquet in place for one minute.
 4. Use blood pressure cuff as a tourniquet by pumping pressure to 60-80 mm Hg.
 5. Be sure room is not too cool.
-
- 1) Position the participant in comfortable chair in an environment free from distraction.
 - 2) Query the participant about their fasting state. Example: "When was the last time you ate or drank anything except water?" The participant should be fasting for about 12 hours. Record the time since the last food or beverage was consumed. If subject is not fasting, record time and note in comment section what foods or beverages were consumed that morning. Be sure to include any additives like cream, sugar, or artificial sweeteners if a beverage was consumed. Regardless of fasting state, proceed with drawing procedure.
 - 3) Inform the participant about the procedure. Explain the procedure to the participant, e.g., "I will be drawing a blood sample from your arm today. You will probably feel a small prick when I insert the needle."
 - 4) Assemble all materials; have extra tubes within reach.
 - 5) Blood samples will be collected from Strong Heart Study participants using conventional vascular access with a multi-draw Vacutainer (butterfly) needle and collection of the blood sample into Vacutainer tubes.
 - 6) The antecubital site of the left arm will be used as the first choice for venipuncture. The median cubital vein is the one most frequently used. If the venipuncture of this vein is unsuccessful, the cephalic and basilic may be the next appropriate choice, followed by veins on the back of the hand. For known mastectomy participants, avoid use of an arm where there was axillary lymph node dissection.
 - 7) Be sure all necessary supplies and equipment are available and set up in advance. Note visit type and type of Vacutainer tubes required. Label tubes with participant ID# and date and time of collection. Complete all lab forms before specimen collection. Ensure that all necessary equipment is functioning properly.

- 8) Be sure a full length lab coat is worn and buttoned. Wash hands and put on protective gloves.
- 9) Fit luer adapter needle at end of collection set into Vacutainer sleeve and place the first collection tube into sleeve/hub.
- 10) Position participant's arm on the drawing table. Extend the arm toward you, palm up.
- 11) Apply tourniquet 3 inches above a venipuncture site. If it is necessary to apply a tourniquet for preliminary vein selection, release it for two minutes and reapply immediately before entering the vein.
- 12) Pull skin taut 2 inches below site to keep vein from rolling.
- 13) Palpate vein. (A vein feels like an elastic tube and returns when pressure is applied). If the presence of a vein is questionable, remove or loosen the tourniquet. If the structure remains, it probably was not a vein; if it disappears assume it was a vein. Another technique to assist in locating a vein is to moisten the skin with alcohol as it will decrease the friction and may aid in the palpation of a vein. If no vein is felt, try other arm or another site (See section on "Difficult Venipunctures").
- 14) Cleanse skin over vein thoroughly using a circular motion from center to periphery. Wipe alcohol with new 2x2 gauze to dry the area.

**If no radial pulse can be felt,
the tourniquet is too tight.
*Tourniquet must not be in
place more than two minutes.***

DO NOT TOUCH SKIN AFTER CLEANSING.

- 15) With the bevel of the needle in upright position, enter vein. Hold needle in the same direction as vein and at a 15-degree angle to vein. Insert the multidraw needle bevel up, parallel to vein. Use a straight smooth movement through the skin; do not poke around. The needle is sterile; do not touch it while performing venipuncture. If vein rolls, withdraw needle slightly without coming completely out of the arm and try a second attempt. If the vein collapses, remove the needle and tourniquet. Apply slight pressure to the puncture site. Try another site and/or call another staff person to assist. After a new location has been determined, usually the other arm, begin the procedure again. Reapply the tourniquet, possibly have participant open and close the fist, swab areas with alcohol and dry, then reinsert the tube. If there is still no blood, stop the procedure and use techniques in section on "Difficult Venipunctures."

- 16) If the phlebotomy is successful, draw required blood tubes. After blood begins to flow, secure butterfly with a piece of tape and loosen the tourniquet. Place tubes in conditions as specified in the instructions.

If blood does not begin to flow, try the following:

- a) Move the needle slightly in or out.
 - b) Rotate needle slightly or lift needle to move bevel away from the wall of the vein.
 - c) Try another tube.
 - d) Loosen tourniquet; blood flow may be impeded if tourniquet is too tight.
 - e) Be sure to watch for signs of hematoma or swelling from the vein. If there is any indication of hematoma or swelling, immediately remove tourniquet and needle. Place 2x2 gauze over the site, and apply pressure and/or ice pack on site for 5 minutes. If the first attempt to obtain blood is unsuccessful (with the subject's permission) try again on the opposite arm.
The same technician should not attempt a venipuncture more than three times.
- 17) When first tube is filled, remove tube and replace with the next tube. Invert all filled tubes **except SST tubes** 8-10 times and place on ice. **DO NOT** place SST tube on ice.
- 18) Proceed with collection of tubes in this order. Label all tubes:
- | | |
|----------|------------------------------------|
| Fasting: | 1. Red top (SST) tube |
| | 2. Light Blue top (Citrate) tube |
| | 3. Gray top (Sodium fluoride) tube |
| | 4. Green top |
| | 5. Lavender top (EDTA) tube |
- 19) After drawing the last tube, remove the tourniquet. Use clean gauze to apply slight pressure to arm and withdraw needle, then immediately apply pressure to site. Apply gentle pressure to the site.
- 20) Request participant apply pressure at site for 3-5 minutes while leaving the arm straight at the elbow. This is more important than elevating the arm or bending the elbow, which some participants might do automatically.

- 21) Confirm that bleeding has stopped, and apply a pressure bandage at venipuncture site. If bleeding has not stopped, elevate arm and continue to apply pressure until it stops.
- 22) Check preprinted labels and tubes, making sure the ID# and tube designation are correct.
- 23) Dispose of entire needle set-up into a proper biohazard disposal container. *Never try to re-cap a needle since this puts you at risk for a needle puncture.*
- 24) Check site. If blood oozes from the site, have the participant apply pressure to the site 1-2 minutes longer or as long as is necessary, elevating arm above head. Apply Band-Aid.
- 25) Give the participant labeled urine specimen cup and instruct him to void into the container. Inform him/ her where to leave the container.
- 26) Remove gloves, wash hands, and proceed to next participant.

Realize that the participant might be disoriented, embarrassed, or irritable and may need additional attention. Recognize also that this incident will have an impact on future blood drawing, and possible adherence through the study, and must be handled with reassurance. Make a note in the participant's file so that clinic staff will be aware of the situation in the future.

Finish venipuncture following procedures outlined above, if possible. If multiple attempts at venipuncture are unsuccessful, do not reschedule the participant unless both the technician and the participant agree that this is an unusual situation and that there is a high probability of obtaining a sample on the first try at another visit.

Note: If sample is not collected, try to reschedule the visit especially if the technician and participant agree that this is an unusual situation and that is not likely to occur again. If participant does not wish to reschedule, indicate in the comment section on the visit form that the samples were not collected.

If Fainting Episodes Are Experienced:

If participant shows signs of becoming faint (loss of color in the face, unusual sweating on the forehead) or reports feeling dizzy:

- Finish drawing blood if possible but do not proceed if participant is clearly in trouble.
- Remain calm and call for help.
- Have participant lay head on table or move participant into a fully reclined position, if possible.
- Have participant prop feet up on pillow or cushion and elevate participant's legs above her head.
- Continue talking to participant to assess level of consciousness.
- Prevent injuries from possible fall or seizure.
- Have participant lie down for 5-10 minutes after removing the needle; apply pressure on vein.
- Apply cool compress to forehead.
- Use ammonia capsule if needed.
- Keep participant in a reclined position until the subject feels better.
- Taking blood pressure readings to assess recovery may be worthwhile.
- Offer participant water, juice and food after they have recovered.

Urine Sample Collection:

- 1 Containers for routine collection should be clean and hold about 50 ml in volume and must have a tight-fitting lid.
- 2 The participant's privacy should be assured and a clean bathroom available.
- 3 Instruct the participant to perform the following steps:
 - * Remove cap from the labeled container before beginning urination
 - * Void directly into toilet and after stream is steady, pause.
 - * Begin stream again and fill approximately half of the cup.
 - * Finish urinating, firmly place cap on container and return sample to the study person.

General Sample Collection:

Table I: General Instructions for Sample Processing of Blood & Urine Samples

Collection Tube	Test
CBC	CBC's will be done locally. Check with your laboratory for instructions.
1 10-ml SST [chem panel, TSH, lipid panel, insulin] Storage	<ol style="list-style-type: none"> 1. Let stand at room temperature for 20 minutes so blood can clot. If samples cannot be processed within the hour, refrigerate sample or place on ice. 2. Centrifuge at 3000 rpm (1000xG) for 10 minutes 3. Place approximately 1 ml of sample in the appropriate cryovials and label
1 4.5-ml Lt blue [fibrinogen, PAI-1] Storage	<ol style="list-style-type: none"> 1. After collection gently invert 8-10 times 2. <i>This vacutainer must be allowed to fill completely with blood at the time of collection</i> 3. Place on ice or refrigerate immediately after collection 4. Centrifuge at 3000 rpm (1000xG) for 10 minutes 5. Place approximately 1 ml of sample in the appropriate cryovials and label
1 7-ml Gray [Glucose]	<ol style="list-style-type: none"> 1. After collection gently invert 8-10 times 2. Place on ice or refrigerate immediately after collection 3. Centrifuge at 3000 rpm (1000xG) for 10 minutes 4. Place sample in the appropriate cryovial and label
1 10-ml Green [Heparin Storage] [Buffy Coat]	<ol style="list-style-type: none"> 1. After collection gently invert 8-10 times 2. Place on ice or refrigerate immediately after collection 3. Centrifuge at 3000 rpm (1000xG) for 10 minutes 4. Place approximately 1 ml of sample in the appropriate cryovial and label <p>BuffyCoat:</p> <ol style="list-style-type: none"> 5. After all plasma has been removed, there should be about 1/8th inch or plasma remaining on top of the buffy coat. 6. With either a glass or plastic pipette, place the tip of the pipette at the bottom of the small plasma layer just <i>slightly above</i> the buffy coat. Also, rest the pipette against the glass inside edge of the vacutainer tube. 7. Slowly draw up the buffy coat by moving the pipette in a circular motion around the inside of the vacutainer. 8. Remove all of the buffy coat from one tube and place in a 2.0 ml cryovial. Cap cryovial firmly, apply label. 9. With each tube repeat steps 1-4 using a different pipette for each tube. Use a new clean pipet for each tube. Do not mix the buffy coats between cryovials, ie only one buffy coat from one tube per cryovial.

<p>3 10-ml Purple [HemoglobinA1c] (Lp(a), Apo A1&B, E, LDL-size, V-cam, Endothelin-1, hsCRP) Buffy Coat Storage</p>	<ol style="list-style-type: none"> 1. After collection gently invert 8-10 times 2. Place on ice or refrigerate immediately after collection 3. Prior to centrifuging the tubes mix one tube well and pipette approximately one ml of whole blood and place in a 2-ml cryovial. Seal with a clear cap. Re-seal the vacutainer tube. 4. For the vacutainer tube just used and the remaining two vacutainer tubes, centrifuge at 3000 rpm (1000xG) for 10 minutes. 5. Place samples in the appropriate cryovial and label <p>BuffyCoat:</p> <ol style="list-style-type: none"> 6. After all plasma has been removed, there should be about 1/8th inch or plasma remaining on top of the buffy coat. 7. With either a glass or plastic pipette, place the tip of the pipette at the bottom of the small plasma layer just <i>slightly above</i> the buffy coat. Also, rest the pipette against the glass inside edge of the vacutainer tube. 8. Slowly draw up the buffy coat by moving the pipette in a circular motion around the inside of the vacutainer. 9. Remove all of the buffy coat from one tube and place in a 2.0 ml cryovial. 10. Cap cryovial firmly, apply label <p>With each tube repeat steps 1-4 using a different pipette for each tube. Use a new clean pipet for each tube. Do not mix the buffy coats between cryovials, ie only one buffy coat from one tube per cryovial.</p>
<p>Random Urine [Creatinine & Microalbumin] Storage</p>	<ol style="list-style-type: none"> 1. After collection, place on ice or refrigerate immediately after collection. 2. Do not centrifuge. 3. Place the sample in the appropriate cryovials and label.

Table II: Participant Collection Instructions

Collection Tube Type	Tests	Sample Type	Storage/Shipping Requirement	Cryovial Type
CBC will be done at local laboratory. Check with your lab for specific instructions.				
1 10-ml SST	[chem panel, TSH, Lipid panel, 0 HR Insulin] Storage	Serum Serum	Refrigerated Frozen	1 3.0-ml red cap vial 2 2.0-ml red cap vial
1 4.5-ml Lt blue	Fibrinogen PAI-1 Storage	Plasma Plasma Plasma	Frozen Frozen Frozen	1 2.0-ml blue cap vial 1 2.0-ml blue cap vial 1 2.0-ml blue cap vial
7-ml Gray	0 hour (fasting) glucose	Plasma	Frozen	1 2.0-ml orange cap vial
1 10-ml Green	Heparin Storage Buffy Coat	Plasma Buffy Coat Coat	Frozen Frozen	4 2.0-ml green cap vial 1 2.0-ml green cap vial

3 10-ml Purple	HemoglobinA1c	Whole Blood	Frozen	1 2.0-ml clear cap vial
	[Lp(a), Apo A1, B]	Plasma	Frozen	1 2.0-ml purple cap vial
	[LDL-size, ApoE]	Plasma	Frozen	1 2.0-ml purple cap vial
	[V-cam, Endothelin-1]	Plasma	Frozen	1 2.0 ml purple cap vial
	hsCRP	Plasma	Frozen	1 2.0 ml purple cap vial
	EDTA Storage	Plasma	Frozen	8 2.0 ml purple cap vial
	Buffy Coat	Buffy Coat	Frozen	3 2.0 ml purple cap vial
Random Urine	Microalbumin/Creatinine	Urine	Frozen	1 3.0 ml yellow cap vial
	Storage	Urine	Frozen	4 2.0 ml yellow cap vial

Table III: QA Collection Instructions:

Collection Tube Type	Tests	Sample Type	Storage/Shipping Requirement	Cryovial Type
1 10-ml SST	[TSH, Lipids, 0 HR Insulin]	Serum	Frozen	1 3.0 ml red cap vial
1 4.5-ml Lt blue	Fibrinogen PAI-1	Plasma Plasma	Frozen Frozen	1 2.0 ml blue vial 1 2.0 ml blue vial
7-ml Gray	0 hour (fasting) glucose	Plasma	Frozen	1 2.0-ml orange cap vial
1 10-ml Purple	HemoglobinA1c	Whole Blood	Frozen	1 2.0 ml clear cap vial
	[Lp(a), Apo A1, B]	Plasma	Frozen	1 2.0 ml purple cap vial
	[LDL-size, Apo E]	Plasma	Frozen	1 2.0 ml purple cap vial
	HsCRP	Plasma	Frozen	1 2.0 ml purple cap vial
Random Urine	Microalbumin/Creatinine	Urine	Frozen	1 2.0 ml yellow cap vial

Table IV: Courtesy Collection Instructions

Collection Tube Type	Tests	Sample Type	Storage/Shipping Requirement	Cryovial Type
CBC will be done at local laboratory. Check with your lab for specific instructions.				
1 10-ml SST	[chem panel, TSH, Lipid panel, 0 HR Insulin] Storage	Serum Serum	Refrigerated Frozen	1 3.0-ml red cap vial 2 2.0-ml red cap vial
1 4.5-ml Lt blue	Fibrinogen PAI-1 Storage	Plasma Plasma Plasma	Frozen Frozen Frozen	1 2.0-ml blue cap vial 1 2.0-ml blue cap vial 1 2.0-ml blue cap vial
7-ml Gray	0 hour (fasting) glucose	Plasma	Frozen	1 2.0-ml orange cap vial
1 10-ml Green	Heparin Storage Buffy Coat	Plasma Buffy Coat	Frozen Frozen	4 2.0-ml green cap vial 1 2.0-ml green cap vial
3 10-ml Purple	HemoglobinA1c [Lp(a), Apo A1, B] [LDL-size, ApoE] [V-cam, Endothelin-1] hsCRP EDTA Storage Buffy Coat	Whole Blood Plasma Plasma Plasma Plasma Buffy Coat	Frozen Frozen Frozen Frozen Frozen Frozen	1 2.0-ml clear cap vial 1 2.0-ml purple cap vial 1 2.0-ml purple cap vial 1 2.0 ml purple cap vial 2 2.0 ml purple cap vial 8 2.0 ml purple cap vial 3 2.0 ml purple cap vial
Random Urine	Microalbumin/Creatinine Storage	Urine Urine	Frozen Frozen	1 3.0 ml yellow cap vial 4 2.0 ml yellow cap vial

Module IV: Quality Assurance Sample Collection:

As part of the Quality Assurance process of this study, there is a need to assure that all the steps from the time that blood is collected to the time that results are reported are correct. To accomplish this, replication of unknown samples will be necessary by performing blind duplicate testing of samples. Blind duplicate samples, otherwise known as quality assurance (QA) samples, will be obtained from participants as follows:

1. In the first 3 months of the study, collect a blind duplicate sample at a frequency of every 10th participant. After the first 3 months, begin collecting samples at a frequency of every 20th participant.
2. Collect only blind duplicate samples for the tests listed in the table above.
3. In order to label the blind duplicate samples, the numbering system for these QA samples is similar to the Study ID and consists of 6 digits with the first digit corresponding to the center (1-SD, 2-OK, 3-AZ), the second digit will be a "3" to indicate that the sample is a QA and the 4-digit participant ID number. The Coordinating Center should receive at monthly intervals the matching participant ID and corresponding QA for analysis. This list should not be made available to the Core Laboratory.

Processing and Shipping QA samples

These samples should be treated the same as the regular participant samples including being included with the regular shipments with the participant and courtesy samples. DO NOT note the corresponding participant anywhere on the form to go to the lab.

3.0 Sample Storage and Shipment

Module I: Equipment Maintenance

This module will include the following:

- Proper maintenance of equipment

The proper care of equipment promotes the life of any piece of equipment and will reduce the possibility of downtime while waiting for repair. Included in the proper maintenance of equipment is the requirement of taking temperatures of refrigerators and freezers.

- Refrigerators and Freezers

Storage requirements for samples include keeping samples at the proper temperature until samples are shipped. Never store samples in a self-defrost freezer. At each site, there should be a temperature log to record the temperatures of the room, all refrigerators and all freezers that hold samples. By recording and evaluating temperatures each day, you will see temperature fluctuation that is a signal that some part is not working properly and downtime is inevitable. It is also advisable to locate a maintenance/repair company that services your unit in the area before a problem is experienced. If temperatures begin to fluctuate, the repair service should be called in to evaluate the problem. It may be a simple repair like a door seal or it may require ordering a part. In any case, detecting the problem early will give you time to have the repair done while still maintaining samples at proper temperatures. In addition to recording temperatures, all refrigerators and freezers require routine maintenance. Follow manufacturer guidelines.

- Centrifuges

Like refrigerators and freezers, there are many makes and models of centrifuges. Follow manufacturer guidelines for the care of your centrifuge. In addition, locate a service company that can do maintenance and repairs. Find this company before a problem occurs. In addition, once a month the inside bowl of the centrifuge should be cleaned with a disinfectant. Always wear gloves, safety glasses and a lab coat when performing this task.

Module II: Storage Requirements

This module will include the following:

- Proper storage
- Shipping instructions
- Proper packaging of samples
- Proper completion of FedEx airbill
- Notification of shipment to the lab

One important precaution which should always be kept in mind when handling samples is that all blood, **except for the SST tube**, should be cooled (either in the refrigerator or on ice) as soon as the samples are collected. They should be kept cold until processing is complete and samples are properly stored. After the SST tube is completely clotted (20-30 minutes) it should also be kept cool if it can not be processed within the hour. Plasma should be separated from the cells within the hour. Plasma samples should not be allowed to freeze and thaw during any of the handling steps. As noted in Table I on page 18 of this manual.

Module III: Shipping Instructions

Table V: Shipping Instructions for All Visit Types (Participant, QA & Courtesy)

PML = Penn Medical Laboratory
 SFBR = Southwest Foundation for Biomedical Research

Collection Tube Type	Tests	Sample Type	Storage/Shipping Requirement	Lab to Ship to:	Cryovial Type
10-ml SST	[chem panel, TSH, Lipid panel, 0 HR Insulin]	Serum	Refrigerated (Frozen if a QA sample)	PML	1 3.0-ml red cap vial
	Storage	Serum	Frozen	PML	1 2.0-ml red cap vial

4.5-ml Lt blue	Fibrinogen PAI-1 Storage	Plasma Plasma Plasma	Frozen Frozen Frozen	PML PML PML	1 2.0-ml blue cap vial 1 2.0-ml blue cap vial 1 2.0-ml blue cap vial
7-ml gray	0 hour (fasting) glucose	Plasma	Frozen	PML	1 2.0-ml orange cap vial
10-ml green	Heparin Storage Buffy Coats	Plasma Plasma	Frozen Frozen	PML SFBR	3 2.0-ml green cap vial 1 2.0-ml green cap vial
10-ml Purple	HemoglobinA1c	Whole Blood	Frozen	PML	1 2.0-ml clear cap vial
	[LDL-size, ApoE]	Plasma	Frozen	PML	1 2.0-ml purple cap vial
	[Apo A1, B, Lp(a)]	Plasma	Frozen	PML	1 2.0-ml purple cap vial
	[V-cam, Endothelin-1]	Plasma	Frozen	PML	1 2.0 ml purple cap vial
	EDTA Storage	Plasma	Frozen	PML	3 2.0 ml purple cap vial
	Buffy Coat	Buffy Coat	Frozen	SFBR	3 2.0 ml purple cap vial
Random Urine	Microalbumin/Creatinine	Urine	Frozen	PML	1 3.0 ml yellow cap vial
	Storage	Urine	Frozen	PML	2 2.0 ml yellow cap vial

- **Supplies Required for Shipping**

Refrigerated Samples:

- All samples requiring refrigeration must be sent to Penn Medical Laboratory within 48 hours of collection.
- Samples should be sent to Penn medical laboratory within one week for the collection date. Also note laboratory holiday schedules.
- The following supplies are required for shipping refrigerated samples:

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- FedEx Shipping Labels
- Biohazard bags
- 2 Cold packs
- Paper Towels for wrapping Storage Boxes

Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
3/4" Scotch Brand Filament Tape

- **Frozen Samples:**

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- FedEx Shipping Labels
- Biohazard bags
- Dry Ice
- Paper Towels for wrapping Storage Boxes
- Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
- 3/4" Scotch Brand Filament Tape

Note: 20 lbs of dry ice gives some insurance against thawing if the package is delayed a few hours.

- Preparation of Samples for Shipment to Penn Medical Lab for Both Types of Samples:
 - Study laboratory requisitions for each set of samples must accompany each shipment.
 - Each is printed on two-part carbonless form.
 - Keep the last copy for your records and send the original with the samples. When your shipment is received, lab technicians at each laboratory will perform an inventory to be certain that all samples in the box correspond to those indicated on the shipping log. If the lab finds any discrepancies, they will call you to ask for your assistance in identifying extra samples or find lost samples.
- Packing Shipping Containers
 - All samples are to be packed according to DOT regulations and in compliance with shipper's requirements. This includes the following:
 - Label the exterior of all shipping boxes according to the shipper's requirements. Boxes must have dry ice labels with the amount of dry ice marked on the label and orange-red labels with "Perishable" printed
 - Sort specimens to be sent by refrigerated versus frozen and distinguish which lab samples will be sent to Penn Medical Lab or Southwest Research Foundation (See

Table V). After samples are sorted, remove one type of sample at a time (refrigerated versus frozen)

- At the bottom of the shipping box place either two cold packs that have been frozen for at least 24 hours or approximately 20 pounds of dry ice.
- On top of cold packs or dry ice, place packing material, ie chux, styrofoam “peanuts” or newspaper.
- Place samples in biohazard bags with forms in pocket of bag on top of packing
- Check all of the specimens in the box against the Shipping Log Form to be sure there are no transcription errors or missing specimens.
- Add more packing material if there is additional space so samples can not bounce around the box while in shipment.
- If shipment includes dry ice, place "Class 9" (dry ice) labels on the outside of the cardboard shipping carton and record the amount enclosed.
- Place polyfoam lid on box.
- Close cardboard lids.
- With ¾” tape secure the cardboard lid closed.
- Prepare FedEx air bill.
- Samples will be shipped by priority air so that they arrive at the laboratory *WITHIN 24 HOURS*. ONLY SHIP SAMPLES MONDAY through WEDNESDAY.
- Retain a copy of the air bill as a receipt for tracking and auditing purposes.
- The day of shipment, fax (202-877-2378), call 202-877-3596 or email the laboratory to inform them that a package is being sent.
- Please give the following information:
 - Date samples will be shipped
 - The name of the person responsible for shipping the package and a phone number where the call can be returned if needed
 - Number of shipping boxes sent
 - FedEx tracking number

SFBR Laboratories are closed on the following holidays:

Holiday	2000	2001	2002	2003	2004
Labor Day	Monday, September 4	Monday, September 3	Monday, September 2	Monday, September 1	Monday, September 6
Thanksgiving	Thursday, November 23 Friday, November 24	Thursday, November 22 Friday, November 23	Thursday, November 28 Friday, November 29	Thursday, November 27 Friday, November 28	Thursday, November 25 Friday, November 26
Christmas	Friday, December 22 Monday, December 25	Tuesday, December 25 Wednesday, December 26	Wednesday December 25 Thursday December 26	Thursday, December 25 Friday, December 26	Friday, December 22 Monday, December 25
New Years Day	Monday, January 1, 2001	Tuesday, January 1, 2002	Wednesday, January 1, 2003	Thursday, January 1, 2004	Monday, January 3, 2005
Fiesta Friday		Friday, April 27	Friday, April 26	Friday, April 25	Friday, April 23
Memorial Day		Monday, May 28	Monday, May 27	Monday, May 26	Monday, May 31
Independence Day		Wednesday, July 4	Thursday, July 4	Friday, July 4	Monday, July 5

Slockbower, J.M., and Blumenfeld, T.A., (Eds.). Collection and Handling of Laboratory Specimens: A Practical Guide. Philadelphia: J.B. Lippincott Company, 1983.

APPENDIX A

THE STRONG HEART – FAMILY STUDY CARDIOVASCULAR DISEASE IN AMERICAN INDIANS, PHASE IV

The following recommendations are made regarding maintenance and operation of the One Touch glucometer in order to ensure accurate readings of blood glucose.

1. There are 2 types of One Touch equipment (for Home use and for Hospital use). Hospital equipment requires daily QC checks, and this is also required by SHS. Please record the QC in your daily log. Be sure to use only Hospital products including the hospital test strips.
2. Change the battery of the One Touch whenever the message in the display begins to flash repeatedly (e.g., “code-code-code” or “insert-insert-insert”). DO NOT WAIT for the display message saying that the battery needs to be replaced.
3. Change the One Touch test strip holder (platform) when the machine message appears in the display indicating that the holder (platform) must be replaced. After changing the platform, push down on the tongue portion of the machine until it is completely down.
4. Clean the optic eye on the machine daily. Use 10% bleach solution or water only. No alcohol should touch the lens.
5. Using the appropriate button on the One Touch, change the code in the One Touch machine to match the code number on the container of test strips.
6. After removing a test strip, be sure to replace the lid on the test strip container to maintain the cleanliness and integrity of the strips. Store the test strip container in a cool, dry place (the storage temperature should be less than 86°F). High ambient temperatures will quickly ruin the test strips. Make sure to write the date on the vial when it is first opened. Use the strips within 4 months after first opening the vial. Do not use the strips after the expiration date.
7. Use soap and warm water to cleanse the participant’s finger, not alcohol. (One could use a plastic container with cotton balls warmed in some hot water prepared immediately before clinic or have the participant wash his/her hands in warm water.)
8. Turn the One Touch on and then wait for the monitor to display “insert strip”. Insert the test strip into the platform, oriented so that the writing on the strip is visible and the specimen circle is over the optic eye of the One Touch. Once you have inserted the strip, the monitor will display “apply sample”.
9. Use a new or disinfected Penlet II Cap and a sterile lancet OR a disposable lancet, such as the One Step Surgilance lancet. Avoiding “milking” the finger to obtain more

blood, since squeezing the finger can affect the reading.

10. Use a disposable fine tip transfer pipet to obtain the blood. Fill the tip of the pipet with a drop of blood. Avoid creating air bubbles by maintaining even pressure on the pipet bulb.
11. Transfer the drop of blood to the test spot on the One Touch test strip that you have inserted into the One Touch platform.
12. Once you have transferred the blood to the test strip, the One Touch will beep and start a 45-second countdown on the display.
13. After the 45-second countdown, the glucose reading will appear in the display.
14. Record the glucose reading (from the One Touch display) on form S8, Sample Collection Checklist, item #1 (Fasting One Touch glucose result.)
15. Remove the test strip from the One Touch and dispose of it in the proper biohazard container.
16. Complete the rest of the sample collection checklist (form S8).

APPENDIX B

Strong Heart Study DNA and Sample Storage Policy and Procedures

Presented by the SHS Ethics Committee

and adopted by the

SHS Steering Committee

New York City

February 14, 2002

1. Objectives

Penn Medical Laboratory (Washington, DC) is the custodian for plasma, serum, and urine samples of participants in all phases of the Strong Heart Study. Southwest Foundation for Biomedical Research (San Antonio, Texas) is the custodian for DNA samples. Henceforth the term "PML/SWF" will refer to the respective laboratories with regard to either blood or urine derived samples (Penn Medical Laboratory) or DNA samples (Southwest Foundation for Biomedical Research). PML/SWF are charged with inventory and safe storage of these samples under optimal conditions to insure stability of analytes. PML/SWF cannot release these samples unless directed by the Strong Heart Study Steering Committee and under current guidelines of the Indian Health Service, National Heart Lung and Blood Institute and all relevant Institutional Review Boards (Human Use). Samples can be released to foster specific meritorious and ethical research of cardiovascular disease and pulmonary disease and their risk factors as outlined in the Strong Heart Study consent forms. The specific use is subject to scientific review of the Strong Heart Study Steering Committee and the NHLBI. Released samples can only be used for the approved measurements by the designated investigator, and unused samples are to be returned in good condition to the PML/SWF with documented history of the uses of each sample including a log of freeze thaw cycles. Consistent with SHS consent forms, the samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

Policies and procedures described in this document are designed to:

- Release authorized samples only after appropriate review as laid out in Section 4 of this document.
- Release samples after receipt of the signed *Strong Heart Study Sample Use Agreement* (Appendix 1 of this policy).
- Insure sample integrity by keeping the samples in appropriate storage conditions and documenting the history of those storage conditions.
- Insure that the samples are secure and safe from unauthorized use.
- Insure confidentiality of the sample donor in accordance with study guidelines.
- Maintain records of samples stored, removal, freeze thaw cycles, and their placement to insure efficient retrieval.
- Follow procedures to insure that samples are released appropriately and transferred under conditions, which insure sample integrity.

- Maintain records indicating where, when and why samples were released.
- Insure that disposal or destruction of samples is done in accordance both with good laboratory practice and the guidelines of the Strong Heart Study participants.

2. Sample Storage Conditions:

A. Buffy Coats, plasma, urine, serum, and DNA

Samples are stored in airtight, gasketed vials at -70 to -80° C (-20° C for DNA). Vials are filled leaving at least 0.5 cc airspace at the top of each vial. DNA is stored under conditions known to preserve integrity and quality of DNA (i.e. a non-frostless freezer). Vials are marked in indelible ink on freezer-safe labels with Strong Heart Study participant number, date of collection and PML/SWF Sequence number. The freezers are locked and the key is the responsibility of the laboratory supervisor.

B. Database, sample inventory

The laboratory maintains a computerized database containing the following data on each stored sample: date of receipt, condition on receipt, number of vials, approximate volumes of each sample, freezer location, sample type (DNA, buffy coat, serum, plasma, urine, etc.), release date, release destination, release purpose, return date, return volume, freeze thaw cycles logged, misc. notations. PML/SWF will maintain records of freezer temperatures. Temperatures are manually logged on all workdays by the technical staff and reviewed for drift. Periodic maintenance as recommended by the freezer manufacturer will be kept available for inspection. Records of freezer malfunction and maintenance will also be made available.

C. Damaged storage samples

Communication to the Strong Heart Study Steering Committee: At the request of the Steering Committee, PML/SWF will notify the Steering Committee of sample damage evidenced by thawing or breakage of samples. Computerized and paper logs of samples will include such events.

3. Disposal of Samples

Samples will be disposed at the direction of the Steering Committee by routine laboratory methods. Prior to this, a request will be made to appropriate tribes regarding culturally correct methods of disposal of damaged or non-usable samples and the laboratory will make a reasonable attempt to cooperate with those requests. Any procedures used for disposal of samples must be consistent with *Good Laboratory Practice*, and minimize biohazard contamination.

4. Release of samples

A. Procedures for acting on requests. Administrative pathway for release of samples:

Requests are presented in writing to the Strong Heart Study Steering Committee. Requests are judged by their scientific merit², potential benefit to the Indian Communities, and consistency with human use guidelines (as outlined in the signed consent) specific to the Strong Heart Study. Requests for Strong Heart Study samples must be specific. Strong Heart Study samples must not be used for additional measurements unless additional written approval is received from the Strong Heart Study Steering Committee. All uses must be consistent with the participant consent of the Strong Heart Study.

Request for Strong Heart Study samples must be made in writing to the Strong Heart Study Steering Committee and should justify the volume of sample requested and whether previously unused (never thawed) samples are necessary. Requests should be brief and generally follow guidelines used in scientific proposals:

- rationale,
- hypotheses,
- specific aims,
- background,
- methods and
- planned analyses.

Study participants and participating tribes will be notified by the Strong Heart Study Newsletter when new tests are done using stored specimens. The investigators will write articles in the newsletter describing what tests are being done and how they will increase understanding of CVD or pulmonary disease in American Indians. Scientific articles resulting from the laboratory studies of the stored specimens will be reviewed and approved by the SHS publications committee, all participating tribes, by NHBLI and by the Phoenix, Aberdeen and Oklahoma Area IRBs prior to publication.

This policy will not preclude obtaining explicit tribal and/or IRB approvals in the event that ancillary studies are proposed which would require re-contact of participants or other issues that would suggest consultation with appropriate IRBs or tribal governments.

B. Release instructions to PML/SWF:

Written requests to release samples (***Request to Release Samples*** – Appendix 2 of this policy) will be made by the Strong Heart Study Steering Committee after review of scientific merit and ethical considerations. The written request must confirm that

² Scientific merit will include the originality of the research, value to the tribal communities and participants, and quality of the measurements proposed.

all appropriate reviews have been made. Samples to be released must be identified by date or phase of collection, volume or number of vials to be released, shipping destination and contact person, and Strong Heart Study IDs.

PML/SWF will maintain records of requests for a period of 15 years. These records will be made available to the Strong Heart Study sponsor and tribal governments upon request.

C. Technical procedure for releasing samples

Samples are removed from storage only by PML/SWF employees who are trained in safe sample handling. Written logs of the samples requested are used to locate and remove samples. Each sample found is logged onto the table and these data are promptly transferred into the computer database. The removed samples and the list is reviewed by the PML/SWF technical supervisor. Discrepancies are logged and resolved. Samples requested which are not found are logged and investigated to insure consistency between the data base and sample inventory. See ***PML/SWF Sample Request Log*** – Appendix 3 of this policy.

The sample shipment is coordinated with the receiving laboratory to insure safe receipt of the requested samples. The requesting laboratory must acknowledge the receipt and condition of the samples upon arrival. Any discrepancies between the number and amount of samples approved for use by the requested laboratory, and those received, must be reported by the requesting laboratory within one month of receipt of the samples.

SHS Storage Policy Appendix 1

Strong Heart Study Sample Use Agreement

Strong Heart Study release tracking number _____

The release of Strong Heart Study samples is subject to the following policies and procedures. No samples will be released until the investigator agrees to the following policies and procedures approved by the Strong Heart Study Steering Committee:

1. Samples can be released to foster specific meritorious and ethical research as outlined in the Strong Heart Study consent forms. The specific use is subject to prior approved scientific review of the Strong Heart Study Steering Committee and the NHLBI. The laboratory releases samples only after written instructions are received from the Steering Committee.
2. Released samples can only be used for the approved measurements in the specified laboratory and unused samples are to be returned in good condition to PML/SWF with documented history of the uses of each sample including a log of freeze thaw cycles. The investigator must supply PML/SWF with the name, phone number, E-mail address and shipping address of the person responsible for receiving the samples.
3. The samples will be released for a period of ___ days ending on _____(dd/mm/yyyy). At the termination of this period, the investigator must either return the samples to PML/SWF, or request and receive permission from the Strong Heart Study Steering Committee for a specified extension to complete the analyses.
4. Samples must be returned to the PML/SWF with any remaining material at the completion of the approved use period as described above. Samples should be returned in their original containers with the original label. Samples are to be shipped under conditions specified by the Medical or Technical Director of the PML/SWF. Unused samples must not be discarded.
5. Data derived from the use of these samples is the joint property of the Strong Heart Study Steering Committee and the investigator. Publication of the results of these investigations is subject to the policies and prior approval of the Strong Heart Study Publications Committee, the NIH and the appropriate tribal councils.
6. The investigator acknowledges and abides by the informed consent document limiting use of these specimens for the study of cardiovascular and lung diseases and their risk factors and specimens will only be used for those purposes. The samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

I have read the Strong Heart Study Sample Storage policies and understand that the samples must be used only for uses approved in writing by the Strong Heart Study Steering Committee. I agree to abide by the limitations set forth in these policies.

printed name

date

signature

address

address

city, state, zip

phone number

e-mail address

SHS Storage Policy Appendix 2

Request to Release Samples

Date: _____

A request to the Penn Medical Laboratory is made to release the following samples (attach list or table if necessary):

Minimum volume needed for each sample: _____ μ L.

Type of sample: plasma serum buffy coat urine other: _____

OK to use previously thawed samples? Yes No

To:

name of investigator: _____

shipping address: _____

phone contact: _____

E-mail address: _____

Purpose of the Request:

Steering Committee Chair _____
signature date

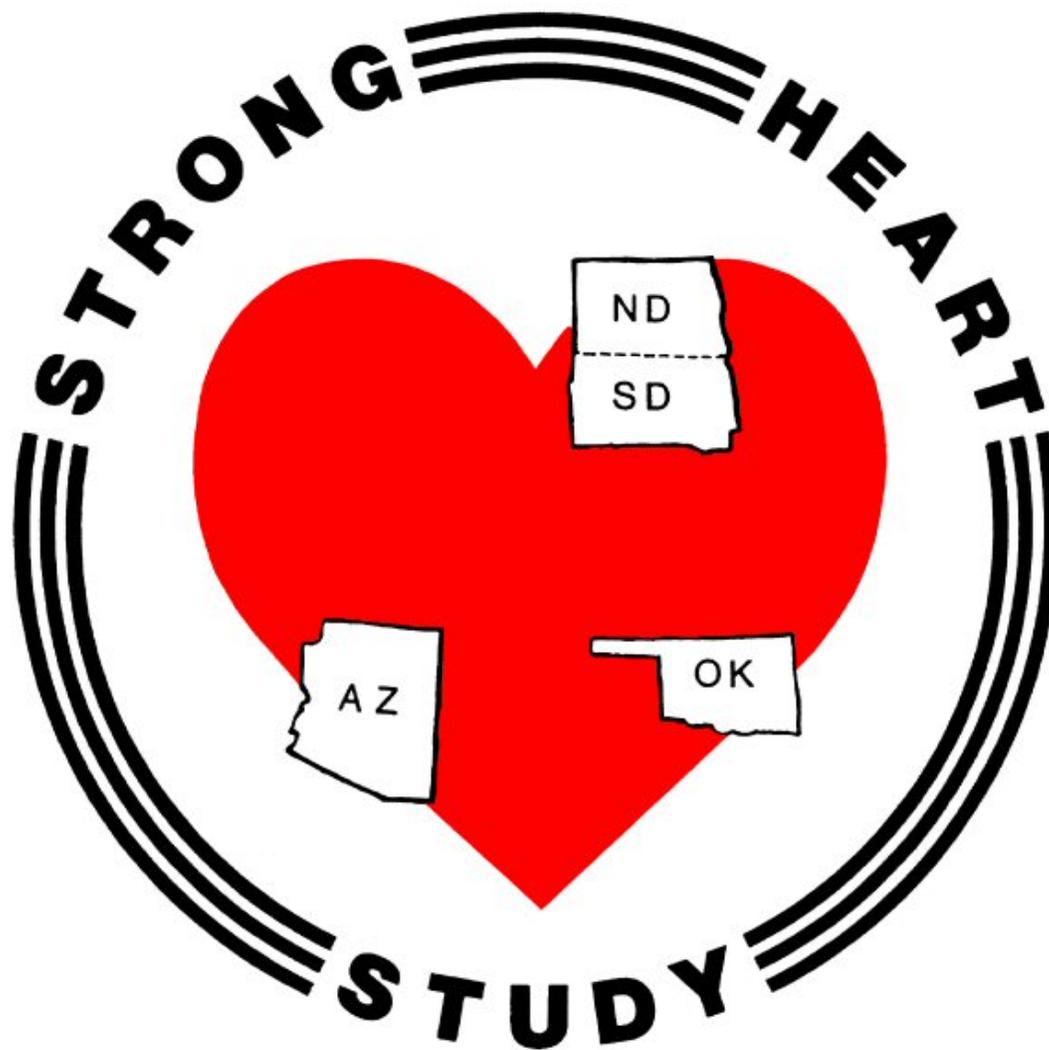
When should the samples be returned to the Penn Medical Laboratory? _____
date

for PML lab use (attach log of sample request v. those actually sent):

samples pulled and shipped on: _____ (mm/dd/yyyy)

technician _____ signature

supervisor _____ signature



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Five

**SPECIAL STUDIES – CAROTID ULTRASOUND,
TONOMETRY, AND ECHOCARDIOGRAPHY**

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Five

**SPECIAL STUDIES - CAROTID ULTRASOUND,
TONOMETRY, AND ECHOCARDIOGRAPHY**

June 01, 2001

For copies, please contact

Strong Heart Study Coordinating Center

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Oklahoma City, OK 73190

VOLUME V

**SPECIAL STUDIES - CAROTID ULTRASOUND,
TONOMETRY, AND ECHOCARDIOGRAPHY**

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STRONG HEART STUDY ULTRASOUND READING CENTER MANUAL OF OPERATIONS

Goals of the Study: Carotid arterial ultrasonography and arterial pressure waveform analysis permit non-invasive assessment of arterial hypertrophy, detection and quantification of atherosclerosis, and estimation of arterial stiffness and hemodynamics. These methods will be used in Phase IV of the Strong Heart Study to accomplish the following specific aims:

1. To assess the heritability and genetic linkage of carotid artery intimal-medial thickness (IMT) and discrete atherosclerotic plaques.
2. To assess the heritability and genetic linkage of measures of arterial stiffness.
3. To determine the separate and joint effects of diabetes mellitus (DM), overweight and hypertension on arterial structure, function and atherosclerosis in individuals ≤ 45 years.
4. To examine the associations of arterial structure, plaque and stiffness with LV structure, systolic and diastolic function, independent of risk factors and clinically-apparent cardiovascular (CV) disease, in a population-based sample of individuals with DM.
5. To assess the prognostic significance of measures of arterial structure and function determined during the 3rd SHS exam.
6. To evaluate change of abnormalities of arterial structure and function in participants in the SHS pilot Family Study over a mean of nearly six years.

Research Design and Methods:

A. Carotid Artery Structure and Atherosclerosis:

Methods will be adapted from those used and refined at Cornell since 1989 and subsequently applied at other sites in multi-center studies (see Table 1). Imaging of both carotid arteries will be performed using Acuson 128 systems equipped with a 7 MHz linear array arterial imaging transducer. B-mode scanning of the right and left extracranial carotid arteries will be done in multiple projections to optimize the detection of discrete atheromata, identified on two-dimensional images as the presence of a discrete plaque at least 50% greater than the surrounding wall within any segment of either carotid artery. Carotid plaque size is quantified by computer-assisted measurement of plaque thickness on two-dimensional frames. The maximum diameter of the plaque is measured along with percent encroachment of the lumen diameter. The severity of stenosis is quantified using standard Doppler techniques. Peak flow velocities in the 1.5 to 2.5 m/sec range are indicative of 50-74% lumen stenosis whereas velocity in excess of 2.5 m/sec is indicative of $\geq 75\%$ stenosis. Two-dimensionally-guided M-mode tracings of both the right and left distal common carotid artery approximately 1 cm proximal to the bulb are obtained to measure carotid wall thicknesses and lumen diameter at end-diastole and peak-systole (maximum diameter).

At the Reading Center, suitable frames for measurement are acquired in real-time from the videotape using a frame-grabber interfaced with a high-resolution video monitor and stored on diskettes (Table 2). Following calibration for depth and time, the end-diastolic wall thickness

(combined intimal-medial thickness of the far wall) and end-diastolic and peak-systolic internal diameters (by continuous tracing of the lumen-intima interface of the near and far walls) are measured on several cycles using electronic calipers and averaged. Measurement of carotid wall thickness is never made at the level of a plaque (infrequent in the common carotid artery).

B. Arterial Pressure Waveform and Compliance Estimates:

Regional compliance characteristics of the carotid artery will be estimated using methods which incorporate carotid artery imaging and central arterial pressure waveforms back-calculated from the radial artery tonometry by means of validated transfer functions. The radial artery waveform is obtained using a high-fidelity solid-state strain-gauge transducer (Millar Instruments, Inc, Houston, TX) which functions as an applanation tonometer.

Arterial stiffness (beta), the inverse of compliance, is estimated according to the formula: **beta = $\ln(P_s/P_d)/[(D_s-D_d)/D_d]$** , where P_s and P_d are peak-systolic and end-diastolic pressures, respectively, D_s and D_d are peak-systolic and end-diastolic dimensions, respectively. Peterson's elastic modulus (E_p), an estimate of vascular stiffness which does not account for differences in distending pressure, is calculated according to the formula: **$E_p = [(P_s-P_d)/(D_s-D_d)] \times D_d$** . Young's modulus (E), which takes into account structural adaptive changes of vessel wall thickness, is calculated according to the formula: **$E = [(P_s-P_d)/(D_s-D_d)] \times (D_d/h)$** , where h is carotid artery wall thickness (intima plus media). The augmentation index, a quantitative measure of the rapidity of wave reflection, will be measured from the arterial pressure waveform. All measurements are calculated on several cycles and averaged.

C. Ultrasonographer Training and Quality Control:

Arterial ultrasonography training, reading procedures and quality-control will be similar to those successfully employed in Phase III of the Strong Heart Study. Sonographers in the geographic locations will be identified and their credentials verified. One week of training will be provided at the Cornell Reading Center. Sonographers will observe the technique for the carotid ultrasound study as performed by a full-time research ultrasonographer. Dr. Roman will demonstrate use of the applanation tonometer. All sonographers will be observed and critiqued in their performance of arterial imaging and in use of the applanation tonometer. Sonographers will complete worksheets at the completion of each study which can subsequently be utilized for written or oral feedback.

Copies of videotapes will be made and kept at the field sites to facilitate feedback and prevent loss of tapes. Initial readings will be performed by the research sonographer and verified by the physician-investigator. The initial and verification readings of the ultrasound studies will be performed in a blinded manner and then merged with demographic descriptors for final quality-control check of extreme values. Measurements will be performed using established in-house custom measurement and database and statistical analysis programs, including computer support from the Clinical Research Center. Data will be electronically transmitted to the Coordinating Center. Clinical alerts, such as high-grade stenoses, will be immediately reviewed and results relayed by FAX immediately to the Field Center.

TABLE 1: CAROTID ULTRASOUND PERFORMANCE PROTOCOL

Instrumentation: Ultrasonographs will be calibrated against a phantom at installation and at regular intervals thereafter. The vascular probe will be set to default with processing curves and a persistence setting optimal for imaging of the carotid artery.

Patient Preparation: Imaging will be performed in a slightly darkened room with the subject in a supine position with slight hyperextension of the neck (a roll under the neck is optional). Electrodes will be placed for a modified three-lead electrocardiogram.

Two-Dimensional Imaging and Doppler Study: Two-dimensional (B-mode) long-axis imaging from multiple planes (posterior, lateral, anterolateral) will be done to maximize detection of discrete plaque. Following identification of the carotid bifurcation, the transducer should be moved caudally to examine the common carotid artery until its origin from the aortic arch (left) or innominate artery (right). Extensive imaging of the bifurcation should be performed given the high predilection for plaque in these regions. Both branch vessels should be scanned in a cephalad direction until their disappearance. If plaque is present, the transducer should be rotated to obtain a cross-sectional image identifying the maximum incursion of the plaque into the lumen. Pulsed Doppler analysis (with angle correction to $\leq 60^\circ$) should be performed to quantify the degree of stenosis.

M-mode Study: Following completion of the two-dimensional scanning protocol, the transducer should be positioned for optimal visualization of the distal common carotid artery perpendicular to the transducer beam (parallel to the linear probe). The M-mode cursor should be placed perpendicular to the long-axis of the distal common carotid artery to intersect the intima-lumen interfaces of both the near and far walls (in an area uninvolved by discrete plaque). Gain settings should be optimized to limit 'blossoming' of the brighter interfaces. Following conversion to a full-screen display, M-mode imaging of the distal common carotid artery should be recorded with particular attention to continuous imaging of the lumen-intima interface of both the near and far walls.

The complete protocol will be videotaped and the procedure will be repeated on the contralateral artery.

TABLE 2: CAROTID IMAGE ANALYSIS PROTOCOL

Reading Center Equipment: The Reading Center is equipped with a personal computer into which a frame-grabber has been inserted and connected to a high-resolution video monitor and professional videocassette recorder. Customized software allows acquisition in real time of two-dimensional or M-mode frames thus bypassing image degradation which might occur were analyses to be performed on stop-frame images.

Review of Videotape: The videotape of each study will be reviewed in its entirety at the Cornell Reading Center. Whenever a plaque is detected, that frame showing maximum diameter of the plaque (either longitudinal or cross-sectional) will be acquired in real time using the frame grabber and stored on a diskette. Suitable frames including M-mode imaging of the both distal common carotid arteries demonstrating continuous tracing of the lumen-intima interfaces of the near and far walls will be acquired in real-time and stored on diskette. The frame number of each image acquired in this context will be recorded on a worksheet.

Measurement Techniques: Measurements will be recorded on a worksheet. Plaque will be graded as present/absent, unilateral/bilateral (including location) and quantified by maximum diameter and percent lumen stenosis (using calibrated electronic calipers). Maximum velocity at the level of a plaque causing significant stenosis will be recorded. Following calibration for depth and time, measurement of the intimal-medial thickness of the far wall will be made on as many cycles as are available on the acquired frame and averaged. Measurements will be obtained at end-diastole (minimum diameter) with the aid of the electrocardiogram. Minimum and maximum diameters will be measured by continuous tracing of the lumen-intima interface of the near and far walls on sequential cycles and averaged.

Data Summary and Transmission: Measurements on the worksheet will be verified by an investigator for faithfulness to the analyzed image and for outlier values before being transferred by diskette for incorporation in the main computer database. Variables to be transmitted will be: plaque (absent/present [unilateral/bilateral]); plaque location(s); plaque diameter(s); percent lumen stenosis; maximal Doppler velocity; right and left end-diastolic intimal-medial thicknesses; mean end-diastolic intimal-medial thickness; right and left minimum and maximum internal diameters; mean minimum and maximum diameters.

TABLE 3: PROCEDURE FOR ARTERIAL APPLANATION TONOMETRY

1. Subject will remain in the supine position following completion of the carotid ultrasound study.
2. Necessary information will be typed into the SphygmoCor system, including subject age, gender, and brachial blood pressure. The brachial systolic and diastolic pressures to be entered here will be calculated by averaging the last 2 of 3 sequential brachial pressure readings made at the end of the echocardiogram procedure (see pp. V-10 to V-11).
3. The applanation tonometer will be positioned over the left radial artery and manipulated to obtain an arterial pressure waveform of an appropriate contour with the highest pulse pressure. Following stabilization of the recording, the space bar on the laptop computer will be pressed and a series of waveforms will be acquired for processing.
4. The data acquired will be stored on diskette and sent to the Cornell Reading Center. Following verification of fidelity of the pressure waveform, the following data will be transferred by diskette for incorporation in the main computer database: central aortic systolic and diastolic blood pressures, augmentation index and estimates of carotid artery compliance (beta, Peterson's elastic modulus, Young's modulus).

Echocardiography

It is the Reading Center principal investigator's experience over many years that the percentage of echocardiograms that are suitable for accurate measurement is enhanced if the examining sonographer makes preliminary measurements on each study and is then provided feedback as to how to improve the suitability of the study for quantitation and the selection of interfaces to measure. To obtain reproducible M-mode measurements of LV structures, dominant lines representing the necessary interfaces should be recorded, and recognized during interpretation, that exhibit continuous motion in the correct pattern for the structure for at least 0.10 second but ideally through the entire cardiac cycle (6, 26, 38).

Echocardiography Performance at Field Centers

Principles: The most important primary echocardiographic measurements and derived variables to assess the heart in an epidemiologic context can be obtained from a relatively simple echo examination (28, 39). Correct orientation of the ultrasound beam and imaging planes to LV structure and blood flow is essential.

The LV resembles an ellipse of rotation that is nearly circular in short-axis views, with a long-axis about twice its minor axis. To measure the LV minor axis accurately it is necessary to orient the echocardiographic plane from the parasternal (or less commonly the subcostal) window to pass perpendicularly through the interventricular septum and posterolateral LV wall at the junction of papillary muscle tips and mitral chordae (Figure 2A). Rotation of the 2-D sector 90° to the short axis projection allows one to measure the true, maximum LV diameter (Figure 2B). If, as is common in older subjects, the best parasternal window is in a low interspace, LV minor-axis dimensions and wall thicknesses should not be measured in the usual fashion, although it may be possible to measure correctly the aortic root and left atrium (Figure 2C). Instead, a higher interspace should be used, which may image only a narrow sector that includes the LV minor axis (Figure 2D). If this is not possible, linear measurements of LV minor axis and wall thicknesses should be made at the correct level and orientation by the leading-edge method from 2-D long-axis views that maximize LV cavity size.

If the 2-D short-axis is correctly oriented, M-mode LV recordings may provide clearer delineation of wall interfaces, and in that case will be used for LV measurements.

A major advantage of 2-D echocardiography is its ability to visualize the LV long-axis and wall segments near the apex. To accomplish this, one must obtain the true (longest) long-axis dimension and visualize the LV walls in approximately orthogonal apical 4- and 2-chamber views. The LV long-axis is commonly foreshortened in the 4-chamber view (Figure 4A), as seen when the transducer is rotated to the 2-chamber view and the LV apex is out of the field of view (Figure 4B). The transducer should then be moved inferolaterally until the LV apex is as nearly centered at the top of the image "fan" in both views as possible (Figures 4C and 4D).

The accuracy of Doppler recordings depends on the ultrasound beam being parallel to the axis of blood flow. Variants of the apical 2- and 4-chamber views should be used to sample LV inflow across the mitral anulus or valve orifice; the apical long-axis should be used to measure systolic flow across the aortic anulus to calculate stroke volume and cardiac output; and sample volume placement between the

inflow and outflow tract to measure isovolumic relaxation time.

Protocol for Echocardiogram Performance

Standardized methods will be employed to obtain high-quality recordings. Echocardiograms will be performed in an area that provides room for the examining table, echocardiograph, etc., and has dimmable lighting to prevent glare on the echocardiograph screen that would interfere with study performance. Participants will change their top for a light gown to permit discrete exposure of the chest wall overlying the parasternal and apical acoustic windows. Disposable ECG lead attachments (set of 3) will be attached to the skin to monitor a single ECG lead for timing purposes. The participant will then lie down and assume a partial left decubitus position (with pillows or a foam-rubber wedge to support the back) with the head of the examining table modestly elevated. The participant's last name, initials, SHS study number and the date and site of recording will be entered so they will be recorded on videotape. Echocardiographic recordings will then be made using procedures outlined in Table 1. Careful performance of this protocol will require 40 minutes of participant's time including the period required to get in and out of a gown and to step from the SHS examining area to and from the adjacent echocardiography area.

TABLE 1
ECHOCARDIOGRAPHIC TECHNIQUES FOR LEFT VENTRICULAR MEASUREMENTS

<u>Instrument Calibration:</u>	Calibrate against phantom at installation and at regular intervals thereafter.
<u>Echocardiographic Performance:</u>	Standardize and record decubitus position. Use mattress cut-out for apical imaging. Record images in held expiration.
<u>Location of Imaging Planes:</u>	
2-Dimensionally guided M-mode:	From short-axis view with correct angulation of short-axis plane defined in long-axis view or in long axis with maximization of left ventricular cavity diameter.
2-Dimensional Echo:	Define correct orientation of short-axis and apical views by use of 90 degree orthogonal planes.
<u>Recognition of Measurable Images:</u>	
M-mode:	Dominant lines with correct motion representing interfaces for at least 0.10 seconds (5mm at standard recording speed).
2-Dimensional Echo:	Visualization of complete interface in motion with continued visualization in stop-frame mode. Do not use "persistence" on the echocardiograph.
<u>Enhancement of Reproducibility:</u>	Use three or more cardiac cycles. Record imaging window location and patient position. For research use readings by two or three investigators.

Modified from Devereux et al (reference 28).

Specific recordings will be made as outlined in Table 2 and the following text: Parasternal

Long-Axis 2-D recordings will be obtained first, with the interspace and degree of left decubitus positioning chosen to allow correctly oriented linear measurements of interventricular septal (IVS), LV internal diameter and posterior wall (PW) dimensions.

TABLE 2
ECHO/DOPPLER SCANNING AND RECORDING SEQUENCE

I. Parasternal Long-Axis Primary View

- A. Two-dimensional echocardiography during quiet respiration: Maximize left ventricular and aortic diameter and record 10 beats on tape.

II. Left Ventricular Imaging:

- A. M-mode cursor perpendicular through left ventricle just below the level of the mitral leaflet tips: Record 10 beats of 2-D update image with M-mode recording, then record at least 10 beats of full-screen M-mode during quiet respiration and attempt at least 5 beats at held-expiration.
- B. Turn 90° into parasternal short-axis view.
- C. Two-dimensional echocardiography at or just above level of papillary muscle tips during quiet respiration: Record 15 beats on tape.
- D. M-mode cursor through the meridian of the left ventricle at level of papillary muscles: Record 10 beats of 2-D update image with M-mode recording and 10 beats of full-screen M-mode recording during quiet respiration on tape. Then attempt at least 5 beats at held-expiration.
- E. Sweep two-dimensional short-axis views superiorly to the mitral valve and aortic valve level. Record 10 beats on tape.

III. M-mode sweep from LV through mitral valve to left atrium/aortic view recorded on videotape.

IV. Aortic Left Atrial Imaging:

- A. Two-dimensional echocardiography in long-axis views during quiet respiration at level of aorta and left atrium with maximization of aortic diameter at the sinuses of Valsalva: 10 beats.
- B. M-mode cursor perpendicular through aorta and left atrium with maximization of aortic diameter by "tilting" medially and laterally of the 2-D imaging plane: Record 10 beats of 2-D update image with M-mode recording, then record 10 beats of full-screen M-mode during quiet respiration.

- C. Color Doppler will be turned on to record 10 beats of a view encompassing the left ventricular outflow tract and left atrium.

V. Apical Four-Chamber View

- A. Two-dimensional echocardiography in quiet respiration. Record at least 10 beats with maximum chamber dimensions and good LV endocardial definition on tape.
- B. Pulsed Doppler transmitral flow recording with sample volume at the mitral anulus leaflet tips during diastole: Using a 2.5 MHz transducer, record 10 beats of 2-D update image with Doppler recording, then record 10 beats of full-screen Doppler during quiet respiration. Repeat the same process moving the sample volume towards the tips of the MV leaflets.
- C. Direct cursor across the base of the anterior mitral leaflet and use pulsed or, if necessary, continuous wave Doppler to record simultaneous LV inflow and outflow patterns for measurement of isovolumic relaxation time.
- D. Move sample volume along left side of interventricular septum to right superior pulmonary vein; record 10 beats of full-screen Doppler of pulmonary vein flow.
- E. Doppler color flow mapping during quiet respiration: Using the 2.5 MHz transducer, turn on color to look for mitral regurgitation: Record 15 beats on tape. while sweeping from the 4- to the 5-chamber view.
- F. Turn approximately 90° into apical two-chamber view.

VI. Apical Two-Chamber and Apical Long-Axis Views

- A. Two-dimensional echocardiography in the true apical two-chamber view during quiet respiration or held expiration: Record 15 beats with maximum LV chamber dimensions and good LV endocardial definition on tape.
- B. Two-dimensional echocardiography in the apical long-axis view during quiet respiration or held expiration: Record 10 beats taking care to include the left ventricle, left atrium, aorta and right ventricle in the image.
- C. Pulse Doppler recording in the apical long-axis view: Record 10 beats of 2-D update image with pulsed Doppler recording at the plane of the aortic valve anulus (hinging points of the aortic cusps), then record 10 beats of full-screen Doppler during quiet respiration.

Left Ventricular Imaging

While recording on VHS tape the imaging plane will be tilted medially and laterally to maximize the LV cavity area in the long-axis view. Gain and dynamic range settings, imaging frequency in mHz,

location of the transition zone and used of harmonic imaging should be adjusted to optimize interface definition. Recordings will then be made of at least 10 cycles of optimally oriented 2-D long-axis views followed by 5 beats in held expiration. The M-mode cursor line will then be optimally oriented in the 2-D long view just basal to the level of the papillary muscle tips; at least 10 cycles of LV M-mode recordings with 2-D update and a second 10 cycles of full-screen M-mode will be made on videotape. If feasible, 5 cycles of full-screen M-mode will be recorded in held expiration. If another imaging window is subsequently recognized to be superior, the primary 2-D view and full-screen M-mode recordings during quiet respiration will be repeated. An attempt will be made to include a period of held expiration in LV recordings unless this interferes with LV visualization. The 2-D imaging plane will be rotated from the chest wall position that permitted optimal long-axis M-mode cursor orientation, approximately 90° to visualize the LV short-axis view, at or just towards the LV base from the visible landmark of the papillary muscle tips. Recordings will then be made as indicated in Table 2.

An M-mode "sweep" will then be made from the LV through the mitral valve to the aorta/left atrium level. At the aorta/left atrium level, 2-D long-axis recording will be resumed, the imaging plane will be manipulated to maximize aortic anular and root diameter, the cursor beam will be oriented through the sinuses of Valsalva at their maximum diameter and M-mode recordings will be made as described in Table 2. Color Doppler will be turned on to record 10 beats of a view encompassing the LV outflow tract and left atrium.

At the completion of these recordings the transducer will be shifted to the apical window, identified by palpating the location of the LV impulse on the chest wall and then moving the transducer inferolaterally until the LV apex is visualized in both 2- and 4-chamber views. Repositioning of subjects may be needed to obtain a good apical acoustic window. When this is accomplished, the 2- and 4-chamber views that maximize LV cavity size will be recorded (at least 10 cycles of each); in the 4-chamber view pulsed Doppler recordings of blood flow velocity at the mitral anulus and mitral leaflet tips will be recorded (Figure 5A)(10 cycles) Color Doppler will then be turned on for another 15 cycles as the imaging plane is swept from the 4- to 5-chamber view, following which pulsed or continuous wave recordings of colored outflow and inflow signals will be made to measure the isovolumic relaxation time. After completion of these recordings, the transducer will be rotated to the apical long-axis view (which visualizes the aortic valve and root as opposed to the 2-chamber view which excludes them in favor of the anterior LV wall) and pulsed Doppler recordings of blood flow at the aortic annular plane (10 cycles) will be performed (Figure 5B).

Brachial Pressure Measurement

At this point the subject will be returned to a supine position without turning up the lights or any other change, and the brachial blood pressure will be measured using the appropriate-size cuff and a mercury sphygmomanometer. The first and fifth Korotkoff sounds (appearance and disappearance of sound) will be used as systolic and diastolic pressures, based on the average of the last two of three sequential determinations.

With the participant remaining in the supine position, the bend of the elbow should be at heart level and the legs should be uncrossed. The participant should be able to relax the neck and shoulder muscles as much as possible. Note: because the participant has been at rest on the examining table, there is no need for the 5-min waiting period used as part of BP measurement during the clinic exam.

The brachial artery is palpated (just medial to and above the ante-cubital fossa), and this location is marked for stethoscope placement. The appropriate size cuff is then wrapped around the participant's arm with the center of the bladder over the artery. Use the arm that is closest to the sonographer. Connect the cuff to a standard mercury manometer and establish the pulse obliteration pressure by slowly inflating the cuff while palpating the radial artery until the pulse is no longer felt. Then, deflate the cuff and record the obliteration pressure. Conversation should be limited but the procedure may be briefly explained to the participant at any time.

For each of the stethoscope BP measurements, the cuff is inflated to +30 mmHg above the obliteration pressure, the pressure is held constant for 5 sec, and then the cuff is slowly deflated (2 mm/sec) while reading pressures for Korotkoff sounds. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. If the mercury column falls in between two scale marks (mmHg) at the time the first or fifth Korotkoff sound is heard, the **higher number** should be recorded. The first sound heard in a series of two sounds is recorded as the systolic blood pressure (phase 1), and the first silence in a series of two silences is recorded as the diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. The sonographer records all 3 of these auscultated BP readings. Using a calculator, average the second and third readings and mention the results to the participant, clearly stating the systolic and diastolic pressures.

If the Korotkoff sounds are heard at the outset of cuff deflation, the peak inflation level used was too low. The cuff should be immediately deflated by releasing the thumbscrew and disconnecting the cuff tube. Make another blood pressure measurement, starting at a peak inflation level, which is 10 mmHg above the previous level.

Once all measurements (carotid ultrasound, echocardiography, and tonometry) have been completed, the ECG leads will then be disconnected and the subject allowed to dress and to go to the SHS clinic or to leave. The technician will then complete the logging information on the unblinded echo performance worksheet (Appendix 2) and on the "blinded" label (without identifiers that would reveal age, gender, blood pressure or body size) for videotape box (Appendix 3) that includes, the subject's initials, SHS participant number, date of performance and sonographer, and prepare the performance area for the next subject. Total technician time for echo performance (30 minutes), initial logging and area preparation will be 40 minutes per subject.

After completion of the day's studies, Field Center technicians will continue the procedure begun during the training period of making preliminary measurements on each study of LV dimensions from 2-D guided M-mode recordings, recording the qualitative normality or abnormality of LV systolic function from 2-D recordings, and noting any clinical abnormalities. The worksheets with preliminary readings (Appendix I) will then be assembled with videotapes for shipment to the Reading Center, preparations (videocassettes, ECG electrodes, gel, etc.) for the next day completed, and the technicians will complete the day by reviewing teaching comments returned from the Reading Center.

Central Coordination and Echocardiogram Reading at The New York Hospital-Cornell Medical Center

The Reading Center is responsible for design of the echocardiogram protocol, training and continuous feedback for quality control of echocardiogram performance by Field Center technicians, central reading of echocardiograms with careful procedures to assure accuracy and reproducibility of data, and on-going analyses (in appropriate conjunction with the Coordinating Center at the University of Oklahoma Health Sciences Center) to assure quality control. The Center will take advantage of procedures and skills developed in this laboratory in performing over 15,000 research echocardiograms in clinical patient groups, defined population samples, and large numbers of family units to study echocardiographic methodology, the heart in hypertension, heritable cardiovascular diseases, valvular heart diseases and a variety of other conditions.

Evaluation of LV Structure

LV measurements will be made by the ASE recommendations, in which measurements are made from leading edge to leading edge, time end-diastolic measurements at the QRS onset. The 2-D parasternal long-axis recordings will be played backward and forward to find the cycle or up to three cycles that maximize(s) the LV cavity area. In this view, septal and PW thicknesses and LV internal dimension will be measured by the leading-edge ASE convention at the level of the papillary muscle tips along an axis perpendicular to the LV walls (40). If the M-mode beam is correctly oriented and demonstrates clearer interfaces than 2-D images, these recordings will be used for linear dimension measurements. This procedure has been used for the past 9 years in the Cornell laboratory, and increases the proportion of subjects with measurable LVs by about 10%. LV mass values by this technique with the ASE correction (9) have proven nearly identical to those from good quality M-mode recordings in the same research subjects in the Cornell laboratory, indicating their interchangeability.

With the parasternal long-axis 2-D view on the monitor, the cycle illustrating the largest LV outflow tract and aortic root diameter will be visualized to measure the aortic annular diameter at the QRS onset between the hinging points of the two visualized aortic cusps, a measurement needed to calculate stroke volume (28). On this same 2-D image the aortic root diameter will be measured by the leading-edge technique at the level of the sinuses of Valsalva as described by Roman et al (41-42), and the videotape will be advanced to end-systole (end of the T wave of the ECG) for measurement of left atrial diameter by the trailing edge to leading edge technique. The choice of the trailing edge of the posterior aortic wall, rather than the leading edge, is based on the fact that a space containing loose connective tissue exists between the aortic and left atrial walls that would otherwise be included in the left atrial diameter measurement.

The videotape will then be advanced to the apical 4- and 2-chamber views and played (several times if necessary) to allow completion by the reader of semi-quantitative scoring of wall motion (from normal to mildly, moderately or severely hypokinetic to akinetic) (40). In addition, a summary impression of global LV systolic function (normal/abnormal/severely depressed) will be made. The videotape will be advanced to the 4-chamber view recording Doppler flow across the mitral annulus. Early and late diastolic flow will be traced by the leading edge (black-white interface) method to measure peak E and A velocities and the E and A time-velocity integrals on the three cycles illustrating the highest velocity. The videotape will then be advanced to the combined recordings of anterior mitral LV inflow and outflow along the midportion of the anterior mitral leaflet to measure the isovolumic relaxation time. The videotape will then be advanced to the apical long-axis view illustrating transaortic

flow and the aortic flow time-velocity interval measured on three cycles by the leading-edge black-white method as described by Dubin et al (30). The recordings of color Doppler flow will be used in conjunction with imaging information to record the presence, etiology and estimated severity of valvular regurgitation or stenosis by established methods (41, 43-44).

Calculation of Derived Variables

After the technician reader has completed accepting or correcting the initial primary measurements of cardiac dimensions, flow patterns and grading of the motion abnormalities, the data will be transferred to the Clinical Research Center computer, where mean values for these measurements will be utilized to calculate derived variables. A second step will merge blood pressure and body size measures for further calculations before range checks and additional physician-investigator verification of primary data.

Linear ASE convention 2-D or M-mode measurements at end-diastole by ASE measurements are used to calculate LV mass by the anatomically validated formula:

$$\text{Left Ventricular Mass} = 0.8(1.04 [(IVS + LVID + PWT)^3 - LVID^3]) + 0.6g$$

Estimates of LV mass by this method were closely related to actual LV weight at necropsy ($r=0.90$, $p<0.001$) in 52 adults (9) showed excellent reproducibility ($RHO=0.93$, $p<0.001$) in a series of 183 hypertensive patients (45) and predicted prognosis in patients with CHF (17).

Overall LV mass is the best measure of myocardial cell size, since the number of cardiac myocytes remains relatively constant after infancy, and is the most sensitive echocardiographic index of LV hypertrophy (24, 27). However, additional useful information is provided by the LV wall thickness/radius ratio, or "relative wall thickness" (RWT). This increases in proportion to chronic elevation of LV systolic pressure due to adaptive LV hypertrophy (46) and adds to LV mass for prediction of complications of hypertension (4). RWT is calculated from M-mode measurements as $2PWT/LVID$ (47); increased LV mass is classified as concentric hypertrophy if RWT is >0.41 and eccentric hypertrophy when RWT is normal (48). If LV relative wall thickness is increased but LV mass is normal, the subject is considered to have "concentric LV remodeling", an LV geometric pattern first described from the Cornell Laboratory (4, 48).

Evaluation of Ventricular Performance and Load

Systolic function of a symmetrically contracting LV, such as occurs with uncomplicated hypertension, diabetes or alcoholism, can be assessed by measurement of the fractional shortening of LVID between end-diastole (d) and end-systole(s):

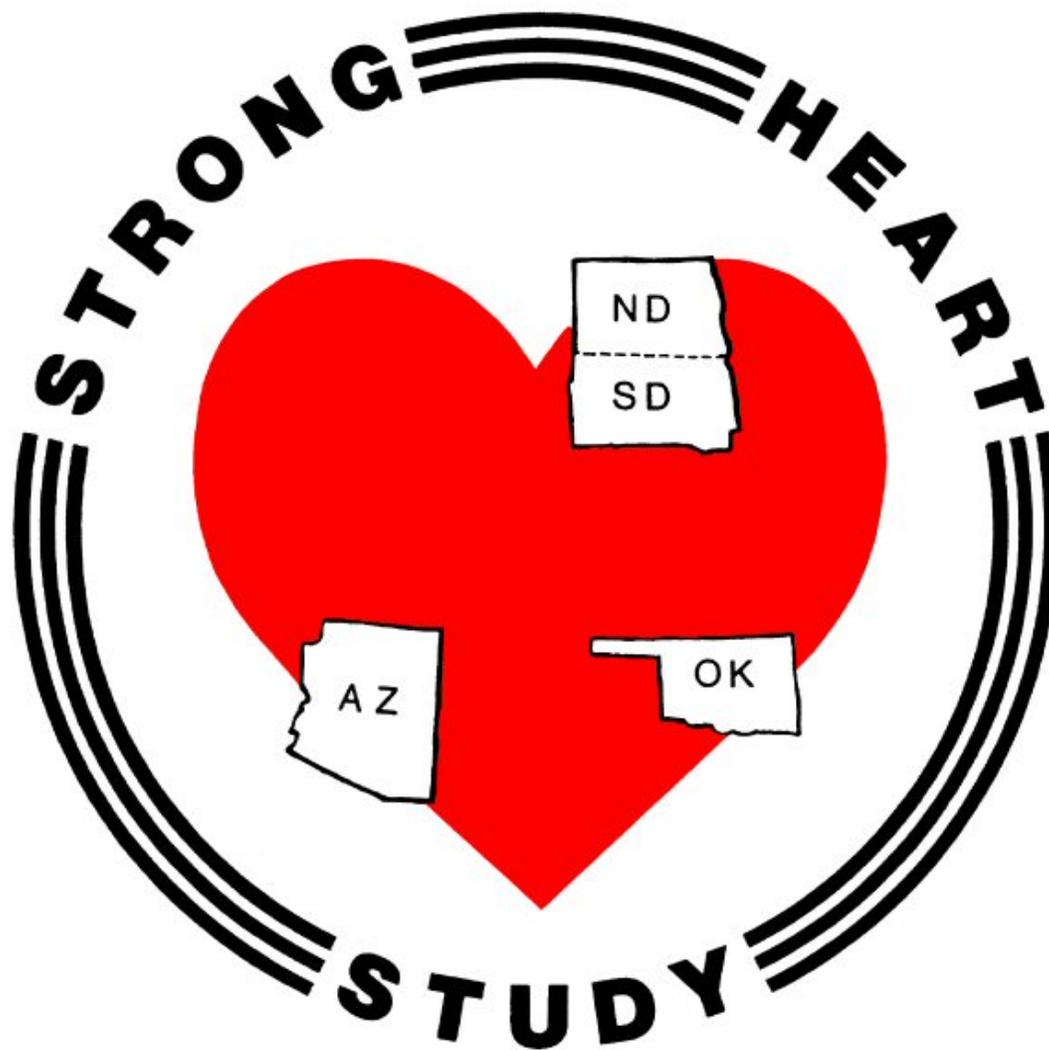
$$\text{Fractional Shortening (\%)} = [(LVIDd - LVIDs) / LVIDd] \times 100$$

If LV wall motion is uniform, fractional shortening is closely correlated with global LV ejection

(EF) (49). Linear dimensions can be used in the Teichholz formula (50) to calculate EF, as has been validated by comparison with angiographic reference studies (51-52). Increased rates of cardiovascular death have been shown to be associated with mildly reduced (40-54%) EF by this method (OR=3.5) and severely reduced (<40%) EFs (OR=6.8, both $p<0.01$) in Strong Heart Study participants.

Because ejection-phase indices of LV performance are highly dependent on afterload, measurement of myocardial afterload is helpful in determining whether or not observed ventricular function reflects normal myocardial contractility. The most direct measure of myocardial afterload is midwall circumferential end-systolic stress (ESS), which can be measured using end-systolic LV measurements by the ASE convention and cuff blood pressure, measured with the subject on the examining table at the end of the echocardiogram, in a catheterization-validated formula (53-54). A close inverse relation exists between LV shortening and ESS in both normal and hypertensive subjects (55-56), which becomes most linear when ESS is plotted on a logarithmic scale (ESS_{10}). Expression of observed midwall shortening as a percent of that predicted for end-systolic stress provides an afterload-independent measure of LV contractile performance. Afterload-corrected midwall shortening is subnormal in patients with congestive cardiomyopathy (57) and in a subset of patients with uncomplicated essential hypertension.

2-D Evaluation of LV Performance will rely primarily on evaluation of LV function by the semi-quantitative scoring system developed by Mayo Clinic investigators (16). This system utilizes parasternal short-axis views at mitral valve and midventricular level, apical 2 and 4-chamber views, and parasternal and apical long-axis views to visualize 6 wall segments in each short-axis plane and 4 segments in the LV apical region. Careful adherence to the described protocol permits scoring of wall motion in all segments in more than 80% of subjects studied under difficult circumstances (portably in a CCU setting) and in well over 90% of subjects in the Strong Heart Study and HyperGEN echocardiographic surveys.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Six

MAC 1200 OPERATOR'S MANUAL

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Six

MAC 1200 Operator's Manual

June 01, 2001

For copies, please contact

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VOLUME VI

MAC 1200 Operator’s Manual

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APPENDIX

Standard ECG Instructions for the Strong Heart Study 1-1

MAC[®] 1200
resting ECG analysis system
Operator's Manual

Version 1.1
227 492 04 GA (USA) Revision D



marquette

A GE Medical Systems Company

The information contained in this manual describes version 1.1 of the MAC® 1200 resting ECG analysis system and reflects software version 5.1.

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Revision History

This manual is subject to the GE Marquette change order service. The revision letter which follows the document part number, changes with every update of the manual.

Part No./ Revision	Date	Comment
227 492 04-A	January 1999	Initial Release
227 492 04-B	March 17, 1999	ECO 061 952
227 492 04-C	May 7, 1999	ECO 062 136
227 492 04-D	October 11, 1999	ECO 062 920

MAC 1200 Option Codes

In addition to the software supplied with the unit, optional programs may be purchased to upgrade the MAC 1200 performance features. In order to use a new option, you need to activate it by entering the option code number (refer to section 9.8 for details). The option codes are entered into the MAC 1200 prior to shipping.

Software package	Functionality	Option Code
MEAS	measurement (measurement of the 10-second resting ECG)	-----
DIAG	interpretation (interpretation of the 10-second resting ECG)	-----
MEMO	memory (storage of a maximum of 40 10-second resting ECGs)	-----
C100	activates the three options MEAS, DIAG, MEMO for a maximum of 100 ECGs	-----
C500	activates the three options MEAS, DIAG, MEMO for a maximum of 500 ECGs	-----
EVAL	activates the three options MEAS, DIAG, MEMO for a maximum of 4 weeks	-----

Serial No:	-----
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Service calls	All products	800-558-7044 (U.S. & Canada) 561-575-5000 (outside U.S.)
	Product support	
	Monitors	800-558-7044 (U.S. & Canada) 561-575-5000 (outside U.S.)
	Cardiology	800-558-5120 (U.S.) 414-355-5000 (outside U.S.)

or contact your local sales and service representative:

Name: _____

Telephone: _____

For other product information please contact one of the offices listed on the next page.

Ordering Supplies and Service Parts

Order supplies (leadwires, electrode paste, thermal paper, etc.) or service parts (circuit boards, cables, software, etc.) and manuals from:

Supplies	GE Marquette Supplies
	2607 North Grandview Blvd.
	Mail Code: SN-471
	Waukesha, WI 53188
	Telephone: 800-558-5102 (U.S. only) 414-521-6856 (outside U.S.)
Service parts	Fax: 800-232-2599 (U.S. only) 414-521-6855 (outside U.S.)

Service parts	GE Marquette Service Parts
	P.O. Box 9100, 100 Marquette Drive
	Jupiter, FL 33468-9100
	Telephone: 800-321-3251 (U.S. only) 561-575-5000 (outside U.S.)
	Fax: 800-421-6841 (U.S. only) 561-575-5050 (outside U.S.)

Have the following information handy before calling:

- part number of the defective part, or
- model and serial number of the equipment,
- part number/name of the assembly where the item is used,
- item name, and
- where applicable, reference designation (eg. R13, S12)

Ordering Manuals When ordering additional operator manuals, be sure to include the software version of the product.

Other Questions or Problems

For additional information contact one of the offices listed below.

Headquarters

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223
USA
Telephone: 414-355-5000
800-558-5120 (U.S. only)
Fax 414-355-3790

Europe

GE Marquette Hellige GmbH
Postfach 60 02 65
D-79032 Freiburg
Germany
Telephone: +49-761-4543-0
Fax: +49-761-4543-233

Australia

Marquette Medical Systems (Australia) Pty Ltd.
Forest Corporate Centre, Suite 7
19 Rodborough Road
Frenchs Forest NSW 2086
Australia
Telephone: (61) (2) 9975-5501
Fax: (61) (2) 9975 5503

Japan

Marquette Medical System, Japan
Waseda Hirai Building, 7th Floor
1-18-9, Nishi-Waseda
Shinjuku-KuTokyo, Japan
Telephone: (81) (3) 3203-1631
Fax: (81) (3) 3202-1626

Hong Kong

Marquette Medical Systems (HK)
26/F, Catic Plaza
8 Causeway Road
Causeway Bay, Hong Kong
Telephone: (852) 2804-2320
Fax: (852) 2804 1776

Southeast Asia

Marquette Electronics (SEA) Pte.
#2 Leng Kee Road
04-04A Thye Hong Centre
Singapore 0315
Telephone: (65) 471-2133
Fax: (65) 471-1540

General Information

- Standards compliance:
 - European Council Directive 93/42/EEC
 - IEC60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment"
 - CISPR11 / EN 55011 "Radio interference emission"
 - IEC 60601, protection class I
 - MDD class IIa
 - UL 2601-1
- The symbol  means: Consult accompanying documents. It indicates points which are of particular importance in the operation of the device.
- The warranty does not cover damage resulting from the use of accessories and consumables from other manufacturers.
- On request GE Marquette will provide a service manual.
- The GE Marquette quality management system complies with the standards EN ISO 9001 and EN 46001.

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1 Intended Use and Functional Description

The MAC 1200 is an ECG acquisition and recording system designed and manufactured by GE Marquette Medical Systems.

- It is intended to be used for resting ECG recording and realtime ECG recording with or without arrhythmia detection.
- It is not intended for use as a vital signs physiological monitor.
- The arrhythmia detection portion of the MAC 1200 is provided to the customer for the convenience of automatic documentation. It is not designed to provide alarms for arrhythmia detection.
- The MAC 1200 offers no diagnostic opinion to the user. Instead it provides analytical statements when configured with the appropriate options.
- It is intended to be used by trained operators under direct physician supervision when ECG records are required.
- It is not suitable for intracardiac application.
- It is designed for continuous operation.
- It is not intended for home use.
- The MAC 1200 is designed as a portable device and can easily be moved from one patient to another or to different locations. It is not intended to be used during patient transport.

Equipped with the standard software, the MAC 1200 supports the following operating modes:

- 12 Lead Mode (acquisition of 12 leads of ECG for a period of 10 seconds),
- 6 Lead Mode (real-time recording of 6 ECG leads), and
- Arrhythmia Mode (continuous ECG analysis for arrhythmias).

The graphics display shows 3 leads at a time.

Resting ECGs can be transferred to the MUSE CV Information System via the RS232 interface.

The device operates from both AC and DC (rechargeable batteries) power sources.

The unit's performance features can be upgraded with the following optional programs:

- MEAS - measurement (measurement of the 10-second resting ECG)
- DIAG - interpretation (interpretation of the 10-second resting ECG)
- MEMO - memory (storage of a maximum of 40 10-second resting ECGs)
- C100 - activates the three options MEAS, DIAG, MEMO for a maximum of 100 ECGs
- CS00 - activates the three options MEAS, DIAG, MEMO for a maximum of 500 ECGs
- EVAL - activates the three options MEAS, DIAG, MEMO for a period of 4 weeks

The MAC 1200 resting ECG analysis system has a setup menu to customize the system parameters.

Patient and user data can be entered for reliable and safe archiving of patient records. The patient name is annotated on each printed report page. All other data is printed on request.



Figure 1-1. MAC 1200

2 Controls and Indicators

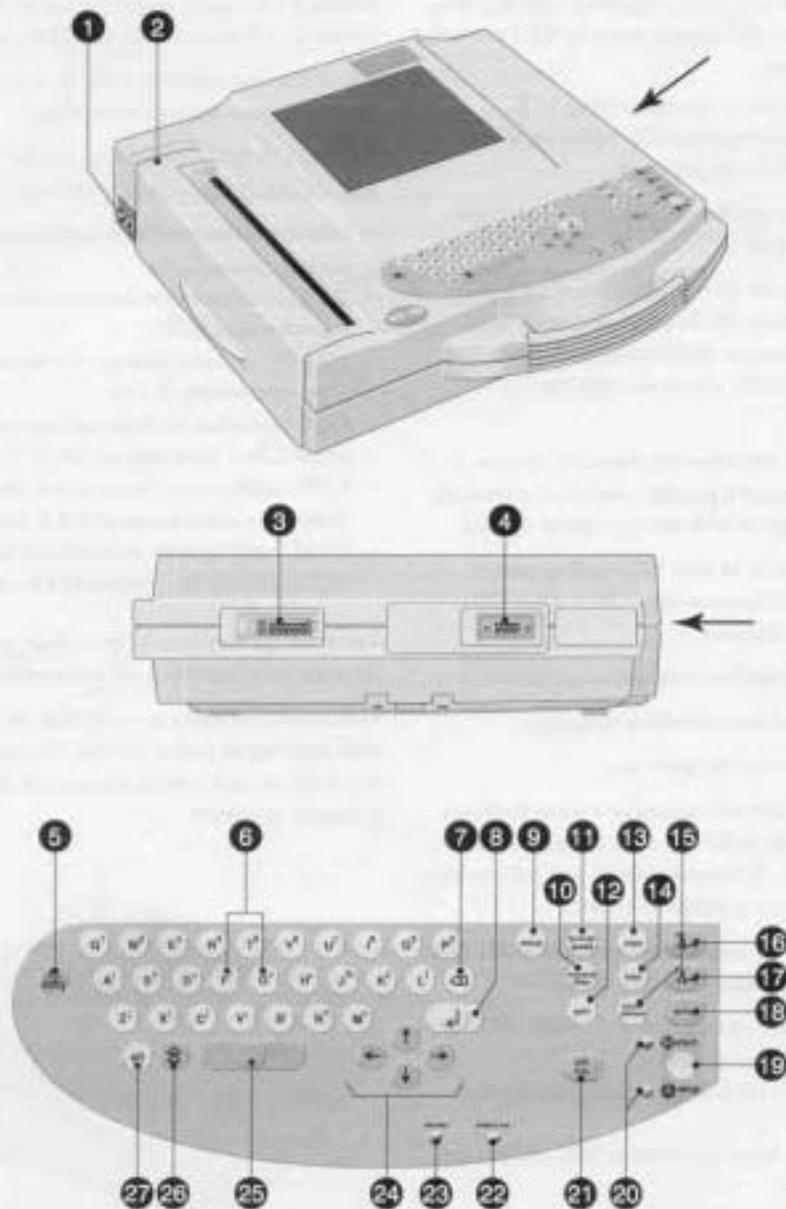


Figure 2-1. Controls and indicators of the MAC 1200 resting ECG analysis system

- | | |
|--|--|
| <ul style="list-style-type: none"> 1 Power input 2 Paper door, windows allow you to check the paper supply 3 Patient cable connector 4 Serial interface (see chapter 13 "Technical Specifications") 5 Power switch (ON/STANDBY) 6 Keys to select a higher or lower HR alarm limit 7 Backspace key (to correct entered data) 8 Confirms entered data (Enter) 9 Displays the setup menu 10 Enables/disables the muscle filter (elimination of muscle artifact) 11 Selects the writer speed (25, 50, 5 mm/s) in 6 Lead Mode and the report formats in 12 Lead Mode 12 Selects the gain (5, 10, 20, 40 mm/mV) 13 Press to print the report or additional copies of the ECG, or to send/receive ECGs | <ul style="list-style-type: none"> 14 Selects the ECG lead in 6 Lead Mode (in 12 Lead Mode, on the display only) 15 Sends ECG to memory/retrieves ECG from memory 16 Selects the 12 Lead Mode 17 Selects the 6 Lead Mode 18 Selects the Arrhythmia Mode 19 Starts/stops the selected operating mode, exits the setup menu and patient data entry 20 Indicators, green: selected mode started, amber: selected mode stopped 21 Enables entry of patient data 22 Indicator is illuminated when battery needs to be charged 23 Indicator is illuminated when unit is connected to the power line 24 Cursor control keys 25 Space bar 26 Shift key 27 Press to access special characters |
|--|--|

Explanation of symbols used on the device

-  Consult accompanying documents
-  Signal input
-  Type CF signal input, highly insulated, defibrillation-proof

-  Start
-  Stop

3 Putting the Device into Operation and Performance Test

3.1 Safety Information

- This manual is an integral part of the device. It should always be kept near the device. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**
- Patient safety, the specified measuring accuracy, and interference-free operation can be guaranteed only if original GE Marquette components are used. The user is responsible for application of accessories from other manufacturers.
- This manual is in conformity with the device specifications and standards on safety of electro-medical equipment valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Hazard is defined as a source of potential injury to a person.

Danger
indicates an imminently hazardous situation which, if not avoided WILL result in death or serious injury.

Warning
indicates a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.

Caution
indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or product/property damage.

- GE Marquette is responsible for the effects on safety, reliability, and performance of the device, only if
 - assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Marquette,
 - the electrical installation of the relevant room complies with the requirements of the appropriate regulations, and
 - the device is used in accordance with the instructions for use.

The safety statements presented in this chapter refer to the equipment in general and, in most cases, apply to all aspects of the device. There are additional safety statements in the other chapters which are specific to the topic described. The order in which safety statements are presented in no way implies order of importance.

DANGERS

EXPLOSION HAZARD — Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

WARNINGS

ACCESSORIES (SUPPLIES) — Use only the original GE Marquette cables. Do not connect other signal sources to the cables. The user is responsible for the use of accessories from other manufacturers.

ACCIDENTAL SPILLS — To avoid electric shock or device malfunction liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.

BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

BEFORE USE — Before using the device, the operator must verify that it is in correct working order and operating condition. For instructions, refer to section 3.2.2 "Performance Check" in this chapter.

CONDUCTIVE CONNECTIONS — Do not allow electrodes to come into contact with conductive parts. The neutral electrode, in particular, must not be connected to earth.

DISCONNECTION FROM MAINS — When disconnecting the system from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device.

MOISTURE CONDENSATION — Devices intended for emergency application must not be stored or transported at temperatures which cause moisture condensation at the application site. Wait until all moisture condensation has evaporated before using the device.

MPSO—The use of a multiple portable socket outlet (MPSO) for a system will result in an enclosure leakage current equal to the sum of all individual earth leakage currents of the system if there is an interruption of the MPSO protective earth conductor. Do not use an additional extension cable with the MPSO as it will increase the chance of the single protective earth conductor interruption.

OPERATOR — The user must have received adequate training in the use of the MAC 1200 and must be capable of applying it properly.

POWER SUPPLY — The device must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect the monitor from the power line and operate it on battery power, if possible.

If the installation of this equipment in the USA will use 240V rather than 120V, the source must be a center-tapped, 240V, single phase circuit.

CAUTIONS

MAINTENANCE — Regular preventive maintenance should be carried out annually, inspections of equipment with measuring functions should be done every two years (refer to chapter 11 "Cleaning, Disinfection and Maintenance").

PERFORMANCE CHECKS — Check the device performance once a month, strictly following the instructions outlined in section 3.2.2 "Performance Check".

POWER REQUIREMENTS — Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source.

VENTILATION REQUIREMENTS — Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

DEFIBRILLATOR PRECAUTIONS — Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

DISPOSAL — Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

ELECTROCAUTERY PRECAUTIONS — To prevent unwanted skin burns, apply electrocautery electrodes as far as possible from all other electrodes, a distance of at least 15 cm/6 in. is recommended.

EMC — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

INTERFACING OTHER EQUIPMENT — Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.

NOTES

- The MAC 1200 is designed to comply with IEC 60601/ EN 60601 requirements. It is Class I equipment/equipment with a built-in rechargeable electrical power source. The device is not suitable for intracardiac use. The device is suitable for continuous operation.
- Choose a location which affords an unobstructed view of the monitor's screen and easy access to the operating controls.
- The MAC 1200 has no additional protection against ingress of water.
- Medical technical equipment such as the MAC 1200 must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
- At the end of its service life; the MAC 1200 and its accessories must be disposed of in compliance with the special waste control regulations for electronic parts. If you have any questions in this matter, please contact GE Marquette Medical Systems.

Literature

- Medical Device Directive 93/42/EEC
- EN 60601-1/1990 + A1: 1993 + A2: 1995: Medical electrical equipment. General requirements for safety
- EN 60601-1-1/9.1994 + A1 12.95: General requirements for safety. Requirements for the safety of medical electrical systems. Requirements for the safety of medical electrical systems.
- EN 60601-2-25/1993: Medical electrical equipment. Part 2: Special requirements for the safety of electrocardiographs.
- IEC Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

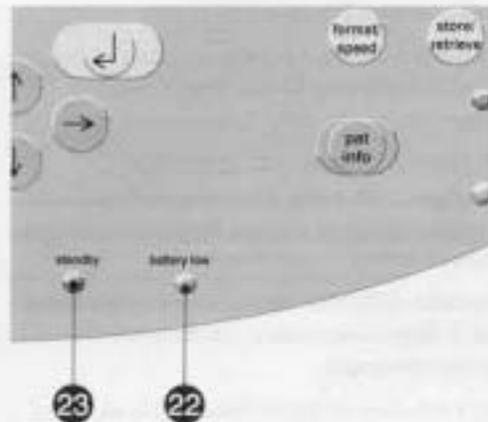


Figure 3-1. Indicators

3.2 Power Supply

The units are powered from the power line or from the rechargeable battery.

The battery charges automatically when the unit is connected to the power line and the **standby** indicator **23** is illuminated (Figure 3-1). It is not necessary to switch on the device for charging. To ensure that the battery is always fully charged, leave the MAC 1200 resting ECG analysis system connected to the power line whenever possible. After 4 hours the battery has regained its full capacity.

The **battery low** indicator **22** is illuminated when battery needs to be charged.

With a full battery, about 50 ECGs (1 page) can be recorded in 12 Lead Mode. When its capacity drops to about 25 recordings, the battery is used up and must be replaced by a service specialist.

Note

To prolong the battery life, discharge the battery at least once per month (by operating the resting ECG analysis system on battery power).

Note

In standby mode, a fully charged battery is drained within approx. 4 hours. Therefore, when operating the device on battery power, be sure to turn it off when it is not in use.

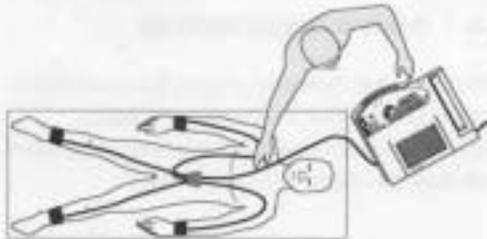


Figure 3-2. Arranging device and couch

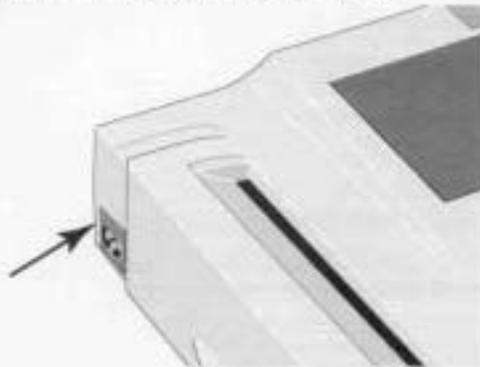


Figure 3-3. AC power input



Figure 3-4. Power switch

Note

- When turning off the MAC 1200 (standby mode), be sure to press the power switch long enough.
- The backlighting of the display switches off automatically when no key is activated for 5 minutes (adjustable).
- Run the full self-test at least once a day to ensure that the device is functioning properly.

3.3 Installation and Mains Connection

Figure 3-2 shows a practical arrangement of patient and recorder. For interference-free operation, it is important that the patient cable and the power cord do not run parallel.

- Using the power cord, connect the device to the power line (Figure -3-1). Use only the original power cord or an equivalent cable.

The **standby** indicator **23** will illuminate.

- Check the paper supply (the window in the paper door allows you to look inside the compartment). If it is necessary to insert a new paper pad, refer to chapter 10 for instructions.

3.4 Performance Check

- Press the power switch to switch on the device (Figure 3-4).

The amber **stop** indicator **20** will illuminate.

After power-up, the resting ECG analysis system runs an automatic self-test. When no problem is detected, it defaults to the 12 Lead Mode. If a malfunction is identified, the display will show an error message "Error...". In this situation, notify service to check and repair the device.

The self-test can be aborted with the **R** button. In this case, the device immediately activates the 12 Lead Mode.

Contrast Adjustment

- To adjust the contrast, simultaneously press **⇧** and the appropriate cursor key:
↑ for more contrast, **↓** for less contrast.

3.5 General Device Settings

The table at left shows the general device settings that can be modified and the system defaults. For instructions on changing the device setup, refer to section 9.5 "General Device Settings".

Parameter	System Defaults	Options
Ordering Physician	empty text box	selection from a list of 10 names
Referring Physician	empty text box	selection from a list of 10 names
Technician	empty text box	selection from a list of 10 names
Institution Name	empty text box	text box (40 chrs)
Cart #	1	1 to 9999
Site #	1	1 to 255
Location	1	1 to 600
Date (dd.mm.yyyy)	current date	
Time (hh:mm)	current time	
Lead Fail Beep	No	Yes
High HR Beep	No	Yes
Lead Labels	AAMI	IEC
Date	mm/dd/yyyy	dd.mm.yyyy
Time	12	24
Units	in, lb	cm, kg
Mains	60 Hz	50 Hz
LCD light off after	5 min.	1 to 99 minutes
Default mode	12 Lead	6 Lead, Arrhythmia
Language	English	English, French, Spanish
Enable password	No	Yes
Test DATA	No	Yes
Restore defaults	No	Yes
Print setup lists	No	Yes

3.6 Connecting External Devices

Via the serial interface, the resting ECG analysis system can be connected to a MUSE CV Information System. These external devices can be connected directly or via a modem. Please contact GE Marquette Application Support for details. Resting ECGs acquired in the 12 Lead Mode as well as the corresponding data can be transferred to these external devices (see section 5.5 "ECG Transmission").

The table below shows the system defaults and all possible adjustments.

For instructions on changing the default setup, refer to section 9.6 "Communication".

Warning

Shock Hazard — *Strictly observe the following warnings. Failure to do so may endanger the lives of the patient, the user and bystanders.*

- *Connecting peripheral devices to the RS232 interface of the resting ECG analysis system creates a medical system. This system must meet the requirements of IEC 60601-1-1.*
- *Use only the original Marquette Hellige connection cables.*
- *All non-medical devices of a system must be connected to the same electric circuit. Devices which are not connected to the same circuit must be electrically isolated (use isolated RS232 interface as per IEC 60601-1).*
- *A PC connected to the resting ECG analysis system should meet the requirements of EN 60601. If it doesn't, it must be set up outside the patient environment. If the PC fulfills the requirements of EN 60950, it must be set up within the medically used area, but outside the patient environment.*
- *Do not connect PCs to the resting ECG analysis system that fulfill neither EN 60601 nor EN 60950.*
- *Modems connected to the resting ECG analysis system must meet the requirements of EN 60950 or UL1950 (all modems recommended by Marquette Hellige meet these requirements). The specific regulations valid in your country must also be observed.
*The modem must be set up within the medically used area, but outside the patient environment.**

Parameter	System defaults	Options
<i>Choices for "Modem → Other"</i>		
		none user-defined MultiTech 19.32 MultiTech 56.6 Elsa 28.8 Elsa 33.6 Elsa 56.6
<i>Choices for "Modem → user-defined"</i>		
telephone init string	AT&FMO&D &Q1VD	
dial string	ATDT	
hangup	+++ATH	
<i>Choices for "Modem → MultiTech 19.32, 56.6, ELSA 28.8, 33.6, 56.6"</i>		
dial mode	tone	pulse
phone		0 to 9 (28 digits)
outside line		0 to 9 (20 digits)

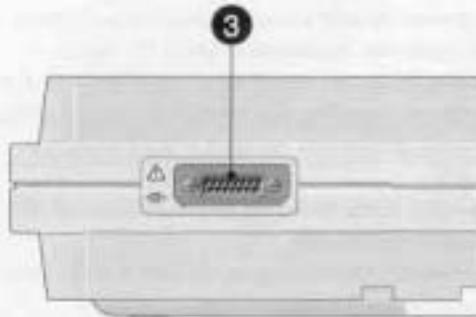


Figure 4-1. ECG signal input

Warning

Shock Hazard — Strictly observe the following warnings. Failure to do so may endanger the lives of the patient, the user and bystanders.

- *For reasons of patient safety, use only the original GE Marquette patient cable. Before connecting the cable to the device, check it for signs of mechanical damage. Do not use a damaged cable.*
- *Ensure that conductive parts (such as the patient, connectors, electrodes, transducers) that are connected to the isolated patient signal input do not come into contact with other grounded, conductive parts. This would bridge the patient's isolation and cancel the protection provided by the isolated input. The neutral electrode, in particular, must not come into contact with ground.*

4 Preparations for ECG Recording

4.1 Connecting the Patient Cable

Use the 10-leadwire patient cable for acquisition of the 12 standard ECG leads.

- Connect the patient cable to connector 3 (Figure 4-1).

Caution

Use only silver-silver chloride electrodes, if the patient may have to be defibrillated. (Refer to chapter 8 "ECG Recording during Defibrillation".)

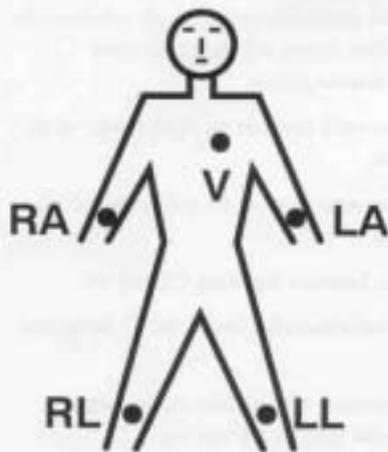


Figure 4-2. Applying limb-lead electrodes

4.2 Applying the Electrodes

Careful application of the electrodes and skin preparation is the key to an interference-free ECG.

4.2.1 Applying Electrodes (Limb Leads)

Refer to the illustration shown in Figure 4-2.

- RA (white) electrode on right arm
- LA (black) electrode on left arm
- LL (red) electrode on left leg
- RL (green) electrode on right leg

Please see Appendix at the end of this volume (pp. VI-Appendix – 1 to 4) for standard ECG instructions for the Strong Heart Study.

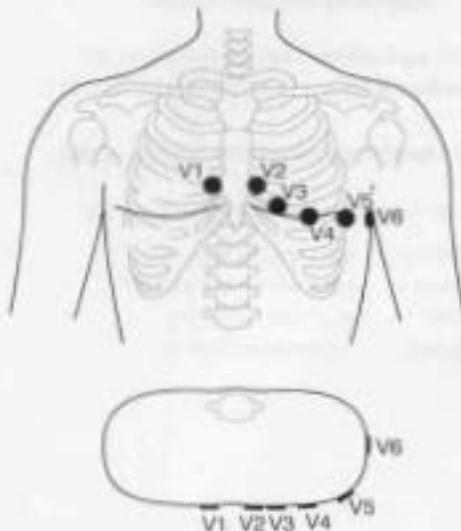


Figure 4-3. Chest electrode placement

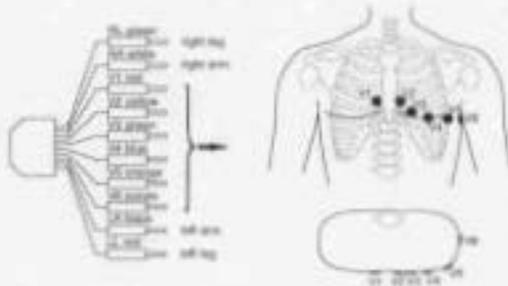


Figure 4-4. Connecting the patient cable
(10-lead cable, standard ECG leads)



Figure 4-5. Arranging the patient cable

4.2.2 Applying Electrodes (Thorax)

- Shave application points, if necessary.

4.2.3 Electrode Placement for Standard Leads (I, II, III, aVR, aVL, aVF, V1-V6)

For acquisition of the standard ECG leads four electrodes must be applied on the limbs and six on the chest. The limb electrodes should be placed above the wrists and ankles. Figure 4-3 shows the chest electrode application points.

- V1 4th intercostal space at the right border of the sternum
- V2 4th intercostal space at the left border of the sternum
- V3 midway between locations V2 and V4
- V4 at the mid-clavicular line in the 5th intercostal space
- V5 at the anterior axillary line on the same horizontal level as V4 and V6
- V6 at the mid-axillary line on the same horizontal level as V4

- Connect the 10-lead patient cable as shown in Figure 4-4.

- Arrange the leadwires and patient cable as shown in Figure 4-5.

4.3 Artifact Due to Poor Electrode Application

The resting ECG analysis system is equipped with state-of-the-art electronic utilities that ensure artifact-free recordings. Among these are the automatic baseline adjustment and the anti-drift system (cubic spline) (ADS).

At the beginning of the recording the automatic baseline adjustment algorithm verifies the incoming signal and adjusts the baseline position accordingly.

During the recording, the anti-drift system (cubic spline) continuously checks the baseline position and returns it to the normal level, if required (Figure 4-6).

For the 6 Lead Mode, the anti-drift system (cubic spline) can be enabled and disabled from the setup menu, in the 12 Lead and Arrhythmia Modes, it is **always** enabled.

When electrodes are not properly applied, these measures may not fully compensate for artifact. High polarization voltages induced by electrodes applied without conductive gel may cause the amplifier to overrange, so that a straight line will be recorded instead of the ECG (see Figure 4-6). The device will then automatically block and return the baseline to its normal position. A baseline is then recorded for approx. 1 second. It is possible to block the amplifiers manually by disconnecting the RL electrode.

On the display this condition is indicated by **** instead of the electrode label (e.g. at **i**, Figure 5-1).

Remedy

- Apply the electrodes according to instructions.
- Do not apply the electrodes on top of clothing.
- Use a contact agent with reusable electrodes (e.g. moistened electrode paper, electrode cream, spray, etc.).
- Wait approx. 10 seconds before initiating a recording. After the 10-second period, the automatic functions are enabled and the polarization voltages have stabilized, provided the electrodes are properly applied. In case of improper electrode application, an error message will appear on the display (RL, LL, LA, LL, V1 to V6).
- If required, the ADS (cubic spline) and the filters (20/40 Hz, 60 Hz) can be disabled to verify the "raw" ECG signal.

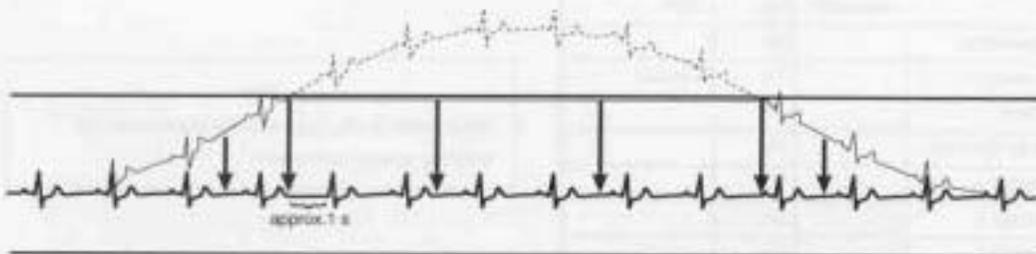


Figure 4-6. Sample recording

Parameter	Factory Default		Options
	adjusted	Menu item displayed	
New Patient	No	Yes	Yes
Last Name		Yes	
First Name		Yes	
Date of Birth	00.00.0000 (mm.dd.yy yy)	Yes	
Patient ID		Yes	
Secondary ID		No	
Pacemaker	No	Yes	Yes
Gender	-	Yes	female, male
Height		No	
Weight		No	
Race	unknown	Yes	other
Systolic BP	0 mmHg	No	
Diastolic BP	0 mmHg	No	
Ordering physician		Yes	selection from a list of 10 names
Referring physician		No	selection from a list of 10 names
Technician ID		Yes	selection from a list of 10 names
Telephone		Yes	
Medication		No	
1.	unknown	No	other
2.	unknown	No	other
Comments		No	
Location #		No	1 to 600
Room		No	
Order Number		No	
Prompt 1		No	
Prompt 2		No	
Prompt 3		No	
Prompt 4		No	

Table 4-1. Patient data entry menu

4.4 Entering Patient Data

It is possible to enter patient data and have them annotated on the recording for easy archiving of patient records.

- Press  to enter the patient data mode.
 - The recorder displays the menu items in a defined order.

In the patient data setup menu (section 9.7 "Patient Data") you determine the items to be included in the menu (In the table at left, the items that appear in the patient data menu in the default setup are marked as "Yes" in the "Menu item displayed" column, the other menu items are marked as "No").
 - To skip a menu item, press  or the cursor key  or .
 - It is not possible to write capital and small letters (do not use the Shift key).
 - For entry of numbers (e.g. date of birth), it is not necessary to press the Shift key.
 - All entries must be confirmed with .
 - Press  or  or  to exit the patient data mode.

The table at left shows the menu items in the correct order. On the display, selected options are shown in brackets. Refer to section 9.7 for details on setting up the patient data menu.

Note

Please refer to the Appendix for instructions on entering special characters.

New patient

yes: existing patient data are deleted
no: entered data can be edited

Last Name / First Name

Enter the patient's last and first names (18 characters maximum each) and confirm entries with .

Date of birth

The slash key  must be entered between month/day/year.

Patient ID / Secondary ID

16 characters maximum each

Pacemaker

Influences the identification of pacer pulses in Arrhythmia Mode. Enable the function ("Yes") when recording the ECG of a pacemaker patient. The recording will then be annotated with the message "Pacemaker Patient".

Gender/Race

If you do not intend to enter all demographic data, select the neutral entries "-" and "unknown".

Height/Weight

Enter the patient's height (in inches) and weight (in pounds). The weight can be entered with one decimal place.

Systolic BP/Diastolic BP

Enter the blood pressure readings in mmHg.

Phone No.

Enter the patient's telephone number.

Ordering Physician / Referring Physician / Technician

When you choose "yes" for "New patient", the default names entered in the General Settings will appear here. When you choose "other", you can pick a name from the list. It is also possible to choose "no".

You can exit the menu with  .

The "Referring Physician" is only relevant if you send ECGs to the MUSE CV Information System. This name will not be annotated on the ECG recording.

Medication

Enter the patient's medications and confirm entries with .

Comments

4 lines of 30 characters each

Location #

ID number of the sending system (3 digits). The default value entered in System Setup will be used, but this value can be changed.

Room

Enter the hospital room number (5 characters maximum).

Order number

Enter order number of the ECG recording, if available (5 characters maximum).

Prompts

Answer the prompts entered in the patient data setup menu (section 9.7).

5 Recording in 12 Lead Mode

Note

Please bear in mind that no automated analysis of ECG signals is completely reliable. Therefore a physician should always overread and reassess the system interpretation before performing patient diagnosis.

5.1 Some Basic Facts

In 12 Lead Mode, 12 leads of ECG are acquired simultaneously for a period of 10 seconds. When initiated with  , ECG acquisition and recording proceed automatically. The system, however, may be set up to start recording only when specific patient data (ID, Secondary ID, name) have been entered (see section 9.7 "Patient Data").

Depending on the implemented software options, the ECG

- is only printed out (options MEAS - measurement -, DIAG - interpretation - not implemented)
- is measured and printed out with the measurement results (with option MEAS - measurement)
- is measured, interpreted (analyzed) and printed out with the interpretative statements (with option DIAG - interpretation)

Units equipped with the optional "Memory" function can save up to 40 resting ECG. These ECGs can be

- printed or
- sent to the MUSE CV Information System (CSI protocol) (see section 5.3 "The Memory Function").

The unit offers different report formats for printout of the ECG. With the system defaults, all 12 leads including the measurement and analysis results will be documented on a single page (see section 5.4 "The Report Formats").

Several system settings can be customized. In this manual they are labeled "configurable".

The following information refers to a unit with the system defaults (see table below). For instructions on changing the system setup, refer to section 9.2 "12 Lead Mode".

Parameter	System defaults	Options
Report sequence	STANDARD	CABRERA
Rhythm leads	II, V1, V5	I, III, aVR, aVL, aVF, V2, V3, V4, V6
Gain	10 mm/mV	"*auto", 5, 20, 40 mm/mV
Report format	4x2.5R1	1x10R12, 2x5R1, 2x5_50, 4x2.5R1, 1x10R3, 4x2.5R3
Detailed results	No	Yes
Muscle filter	No	Yes
Frequency	40 Hz	20 Hz
AC line filter	Yes	No
Manual copy to	EKG	HOST
No. of copies	1	0 to 9
Delete ECG after transm.	No	Yes
Auto save ECG	No	Yes
Use screen, crit.	No	Yes
Suppr. normal st.	No	Yes
Suppr. abnormal st.	No	Yes
Interpretation	Yes	No
Print interpretation	Yes	No
Override function	Yes	No

5.2 Recording

On power up, the unit defaults to the 12 Lead Mode (system defaults) (configurable).

- Before recording the ECG, patient data can be entered (). We recommend to enter the patient's name to annotate it on every report.
- After applying the electrodes, please wait about 10 seconds for the signal to stabilize (stabilization of polarization voltages, see section 4.3 "Artifact Due to Poor Electrode Application"). If you initiate a recording with  immediately after selection of the 12 Lead Mode, a waiting period of 10 to 12 seconds ensues (message "Collecting data").
- Before initiating a recording, check the display for error messages (see table at left). Check all electrodes; if the message persists, there must be a break in the patient cable. Replace the cable with a new one.
- The MAC 1200 continuously saves 10 seconds of the incoming ECG signal.
- The device can be set up to allow a recording only when specific patient data have been entered (last name, first name, ID, 2nd ID, section 9.7 "Patient Data").

When you initiate a recording with  the unit prints the most recent 10 seconds of ECG data and analyzes it. Therefore it is recommended to wait until the patient has been lying relaxed and motionless for about 10 seconds before starting the recording.

RL: right leg electrode disconnected
 RA: right arm electrode disconnected
 LA: left arm electrode disconnected
 LL: left leg electrode disconnected
 V1: chest electrode V1 disconnected
 V2: chest electrode V2 disconnected
 V3: chest electrode V3 disconnected
 V4: chest electrode V4 disconnected
 V5: chest electrode V5 disconnected
 V6: chest electrode V6 disconnected

Messages indicating disconnected electrodes

Note

Please note that filters may suppress diagnostically relevant portions of the signal, because they limit the transmission range. Filters should therefore only be enabled if necessary.

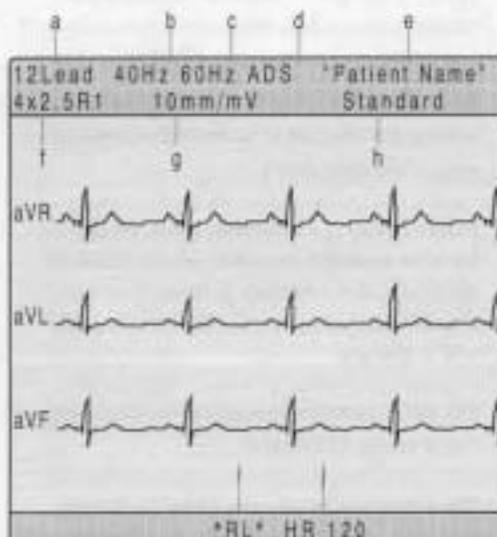


Figure 5-1. 12 Lead mode display

- a Operating mode
- b Muscle filter enabled
- c AC line filter enabled
- d Anti-drift system enabled
- e Patient name
- f Report format or "REC OFF" when no recordings are made
- g Gain 10 mm/mV (automatic gain adjustment off)
- h Report sequence
- i Right leg electrode failure message
- j Heart rate

With the system defaults unchanged, the unit will activate the following functions and settings after power-up:

- the 12 Lead Mode (configurable)
- the Standard report sequence: I, II, III, aVR, aVL, aVF, VI, V2, V3, V4, V5, V6
- rhythm leads II, V1 and V5 (configurable)
- a gain of 10 mm/mV (configurable) (calibration pulse at the beginning of the recording)
- the AC line filter is on (configurable)
- the muscle filter is off (☐) (configurable)
- the anti-drift system (cubic spline) is enabled (wandering baselines are automatically restored to their original position)
- the report format is "4x2.5R1", i.e. 12 leads and all data are printed on one page (configurable)
- the "Detailed results" page (including the median complexes and the ST measurement results) is not printed (configurable)
- pressing (☐) will print one copy of the ECG (configurable)
- units with MEMO option: documented ECGs are not automatically saved (configurable)
- units with MEMO option: after transmission to a host system via the RS232 interface, the ECGs remain stored in the MAC 1200 memory (configurable)
- the "Override Function" is enabled (configurable)
- QTC is calculated with the Bazett formula (only with option MEAS (measurement) or DIAG (interpretation))

All relevant device settings are shown on the display (Figure 5-1).

The display shows 3 leads at a time. With (☐) you can successively display all leads of the report sequence in groups of 3.

- The recording can be stopped with (⏏) (⏏)
- For a description of the different reports, refer to section 5.4 "The Report Formats".

Note

When the unit runs out of paper while printing all stored ECGs (menu item "All stored ECGs - Print"), press   after inserting a new paper pad. Then print the remaining ECGs successively, or restart a printout of all recordings (All stored ECGs - Print).

Memory Program			
All stored ECGs	[Print]	Send	Delete
1	Delete transmitted ECG	2	3
ECG Recording of Walker, John	4	5 (S)	
ECG Recording of Doe, John	6		
ECG Recording of Doe, Jane		7	
ECG Recording of Walker, Jane			

Figure 5-2. ECG identified by patient name

- 1 All stored ECGs will be printed
- 2 All stored ECGs will be transmitted
- 3 All stored ECG will be deleted
- 4 All transmitted ECGs will be deleted
- 5 ECG has been sent (S)
- 6 John Walker's ECG will be printed.
- 7 Select to edit the patient data

Note

With a fully charged battery and the unit turned off, ECGs will remain stored for approx. 4 weeks.

5.3 The Memory Function

Units equipped with the optional MEMO function permit storage of the ECG including patient, measurement and interpretation data with . A message informs the user that ECGs are being saved and indicates the number of stored ECGs (40 max.).

To retrieve an ECG from memory, hold down  and press .

You will see the memory program as shown in Figure 5-2.

The first line refers to all stored ECGs. The Print, Send, and Delete commands following this line will therefore print, send or delete all stored ECGs.

With the command in the line below all ECGs that have been transmitted to another system can be deleted.

The individual ECGs (either identified by name or, if the patient name was not entered, by date and time) follow.

The cursor is positioned at "All stored ECGs [Print]" **1**, which means that all stored ECGs will be printed when you press the  button.

To transmit or delete **all stored** ECGs, position the cursor on "Send" **2** or "Delete" **3** and confirm the command with .

To delete **all sent** ECGs (identified with the letter "S" **5**), position the cursor on field **4** and confirm the command with .

To print, transmit or delete an individual ECG or change the corresponding patient data, position the cursor in the appropriate field (e.g. **6** [Print] or **7** [Change]).

Memory full		
Delete Walker, John	[Yes]	No
Delete Doe, John	Yes	No
Delete Doe, Jane	Yes	No

Figure 5-3. "Memory full" message

Note

- If you intend to print a large number of stored ECGs, we recommend to connect the unit to the power line or to check that the battery is fully charged.
- When you terminate the memory function with  , it is not possible to save the current ECG again.

If you try to save an ECG when the memory is full, you are informed of the memory status and can remove one of the stored ECGs from memory. Use the cursor keys to select the ECG to be deleted. After discarding the ECG, the unit will automatically save the new data (Figure 5-3).

The unit may be set up to automatically save ECGs (without pressing ) and to remove ECGs from memory that were successfully transmitted to a host system (MUSE) (see section 9.2 "12 Lead Mode").

The memory program can be terminated at any time with  .

Note

Observe the safety information given in section 3.6 "Connecting External Devices".

Memory Program				
All stored ECGs				
Print	[Send]	Delete		
Delete transmitted ECG	1			
ECG Recording of Walker, John	2		4 (S)	
Print	Send	Delete	Change	
ECG Recording of Doe, John	3			
Print	Send	Delete	Change	
ECG Recording of Doe, Jane				
Print	Send	Delete	Change	
ECG Recording of Walker, Jane				
Print	Send	Delete	Change	

Figure 5-5. Memory program

- 1 All stored ECGs will be transmitted
- 2 All transmitted ECGs will be deleted
- 3 John Walker's ECG will be transmitted
- 4 ECG has been sent (S)

+-----+	
Phone No.: 4143555000	
+-----+	
Start transmission	[ENTER]
Modify settings	[SETUP]
Cancel	[START/STOP]

Figure 5-6. Transmission menu

5.5 ECG Transmission

Resting ECGs acquired in 12 Lead Mode can be transferred to host systems (e.g. to the MUSE CV Information System (version 004A or higher)). The units can either communicate via modem or directly via a connection cable (see section "Direct Transmission" below).

5.5.1 Transmission via Modem

Depending on the modem model used, the modem **must** be connected either with the 9-pole cable 223 378 01 or with the 25-pole cable 223 378 02.

For transmission of the ECG, the unit must be set up as described in section 9.9 "ECG Transmission via Modem".

After acquisition of the ECG, the transmission is initiated with  (if "Manual copy" is set to "Host" in the setup menu - see section 9.2 "12 Lead Mode").

The recorder is also capable of transmitting stored ECGs (if MEMO option is installed). To retrieve ECGs from memory, hold  down while pressing . You will see the memory menu (Figure 5-5).

- To transmit all stored ECGs in one pass, position the cursor on "All stored ECGs - Send" (1, Figure 5-5), to transmit individual ECGs, position the cursor on the "Send" command of that ECG (e.g. 3, Figure 5-5).

- Confirm the command with .

You will see the transmission menu as shown in Figure 5-6.

- Check the displayed telephone number and press  to initiate the transfer.
- If it is necessary to change the number, press  to display the setup menu.
- With  , the transmission can be stopped.
- ECGs that were successfully transmitted are identified with the letter "S" (for "Sent", 4, Figure 5-5).

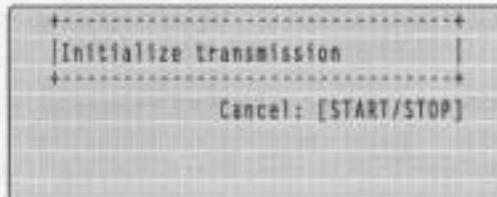


Figure 5-7. Initializing the transmission

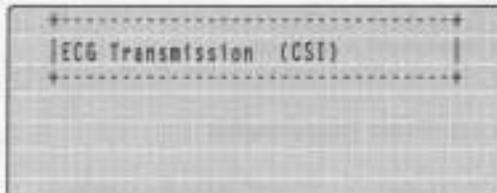


Figure 5-8. Display during ECG transfer

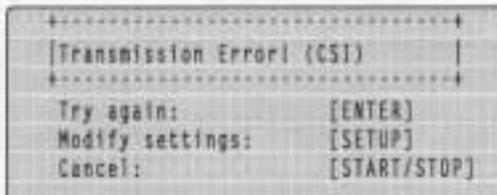


Figure 5-9. Error message

As soon as you initiate the transmission with , the unit will automatically dial the number of the modem at the receiving end and establish a connection (Figure 5-7). Then it will send the ECG (Figure 5-8).

After the transmission, a message on the display indicates the number of successfully transmitted ECGs. As soon as you acknowledge the message with , the 12 Lead Mode acquisition screen appears.

The system identifies ECGs that were successfully sent to the host system with the letter "S" (4, Figure 5-5). All of these ECGs can be deleted with the command "Delete transmitted ECGs" (2, Figure 5-5).

If it is not possible to transmit the ECG (wrong modem setup, modem off), the unit will display an error message, such as "Transmission error! (CSI)" (Figure 5-9).

In this situation you have the following choices:

- you can repeat the transmission with 
- you can change the settings with 
- you can stop the transmission with  .

Modem Error Messages	Cause
Transmission Error! (CSI)	The connection was interrupted due to a fault.
Check interface!	Fault in RS232 interface or modem. Modem may be switched off.
No dial tone!	No dial tone detected.
Busy!	Busy signal detected.
No answer!	No answer at remote end.
No carrier!	Carrier signal lost or not detected.
Check modem setup!	Modem configuration error.

Note

Pacemaker information, telephone number and comments entered in the patient data are not transmitted to MUSE.

Memory Program				
All stored ECGs				
Print	[Send]	Delete		
Delete transmitted ECG	1			
ECG Recording of Walker, John	2	4	[S]	
Print	Send	Delete	Change	
ECG Recording of Doe, John	3			
Print	Send	Delete	Change	
ECG Recording of Doe, Jane				
Print	Send	Delete	Change	
ECG Recording of Walker, Jane				
Print	Send	Delete	Change	

Figure 5-10. Memory program

- 1 All stored ECGs will be transmitted
- 2 All transmitted ECGs will be deleted
- 3 John Walker's ECG will be transmitted
- 4 ECG has been sent (S)

-----+-----
Initialize transmission
-----+-----
Cancel: [START/STOP]

Figure 5-11. Initializing the transmission

5.5.2 Sending Data to a MUSE CV System via Modem

Before sending data to the MUSE CV system, the MAC 1200 automatically logs on to MUSE. Then the data will be transmitted. If the transmission is stopped, the MAC 1200 may take a few seconds before canceling the connection because it has to log off the MUSE system first. Then the communication link with the receiving modem is interrupted and the standard display reappears.

5.5.3 Direct Transmission

The unit must be connected to the PC or to the MUSE CV system by means of the connection cable 223 362 03.

For transmission of the ECG, the unit must be set up as described in section 9.10 "Direct ECG Transmission".

After acquisition of the ECG, the transmission is started with .

The MAC 1200 is also capable of transmitting stored ECGs (if Memory option MEMO is installed).

Activate the memory program by simultaneously pressing  and  (press the  button first and hold it depressed) (Figure 5-10).

- To transmit all stored ECGs in one pass, position the cursor on "All stored ECGs - Send" (1, Figure 5-10), to transmit only one ECG, position the cursor on the "Send" command of that ECG (e.g. 3, Figure 5-10).
- Confirm the command with .

The transmission is first initialized (Figure 5-11), then it starts (Figure 5-12).

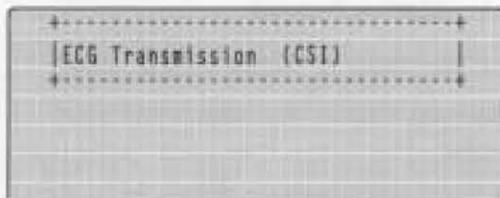


Figure 5-12. Display during ECG transfer

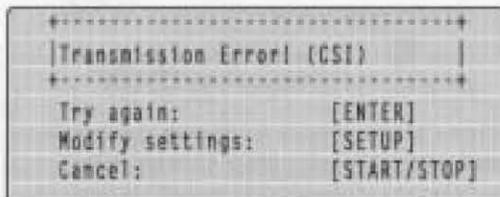


Figure 5-13. Error message

After the transmission, a message on the display indicates the number of successfully transmitted ECGs. As soon as you acknowledge the message with , the 12-Lead Mode acquisition screen appears.

If it is not possible to transmit the ECG (wrong modem setup, modem off), the unit will display an error message, such as "Transmission error! (CSI)" (Figure 5-13).

In this situation you have the following choices:

- you can repeat the transmission with 
- you can change the settings with 
- you can stop the transmission with  .

5.5.4 Direct Transmission of Data to a MUSE CV System

Before sending data to the MUSE CV system, the MAC 1200 automatically logs on to MUSE. Then the data will be transmitted. If the transmission is stopped, the MAC 1200 may take a few seconds before canceling the connection because it has to log off the MUSE system first. Then the standard display reappears.

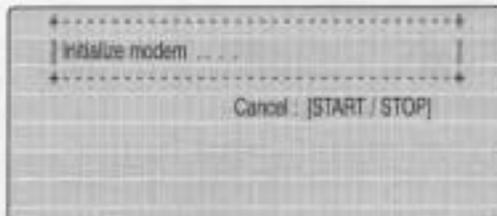


Figure 5-14. Screen display after activation of  and .

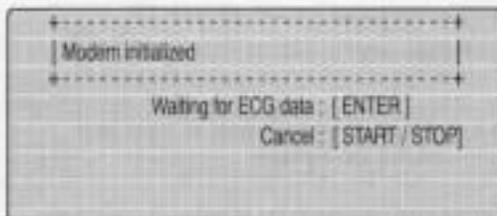


Figure 5-15. Screen display after modem initialization.

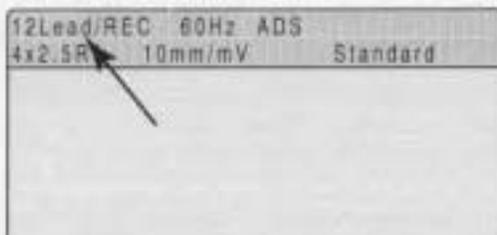


Figure 5-16. Unit is ready to receive data

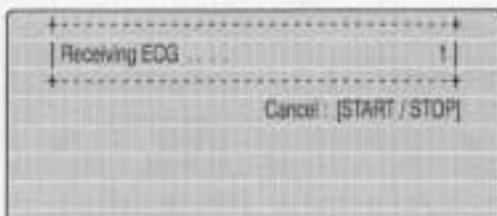


Figure 5-17. Unit is receiving ECG 1

5.5.5 Receiving Data with the CSI Communication Protocol

(see also chapter 13 "Technical Specifications")

Receiving ECGs is only possible in the 12Lead Mode.

- Use the key combination  and  to display the screen for receiving ECGs (Figure 5-14). The connected modem is automatically initialized. The procedure can be aborted with  .
- Press  to enable the "receive data" mode. The procedure can be aborted with  .

When you have enabled the "receive data" mode, the standard screen display of the 12 Lead Mode displays. The message "12Lead/REC" indicates that the unit is ready to receive data (Figure 5-16).

ECGs can be recorded in the 12 Lead Mode even while the unit is in the "receive data" mode.

A message displays on the screen when the unit is receiving data (Figure 5-17). The reception can be aborted with  .

The ECG which has just been received is processed for the printout. The report is printed in the selected format. Multiple ECGs are received and printed one after the other.

After printout of the last ECG, the "receive data" mode is automatically disabled. The mode is also disabled when you select another operating mode.

The following information is annotated in the bottom line of each report:

- the sender
- the software version and analysis program version used at the sending unit (e.g. "ACQ-DEV: M1200 V5.1M12i 12SL V1.13).

5.5.6 Cart to Cart Communication

Via modem, ECG data can be transmitted between two MAC 1200 units or between a MAC 1200 and any ECG recorder using the CSI protocol (see sections 5.5.1 and 5.5.2).

5.5.7 Modem Setup (for Modem --> other)

If you prefer to use another modem than the standard models listed in the setup menu (MultiTech, Elsa), you will have to enter a few parameters required for communication between the MAC 1200 and the modem.

For the AT commands which your modem understands, please refer to the modem user instructions. Three command sequences have to be entered in all, each of which defines a specific modem operating state:

1. the modem is initialized (init string)
2. a communication link is established (dial string)
3. the communication is terminated (hangup string)

These three strings are entered in the modem setup menu (see section 3.6 "Connecting External Devices").

The example below shows the command strings for the MultiTech ZDX modem.

1. AT Command for Modem Initialization

AT prefix that precedes every command line
 &F fetch factory configuration (loads the factory configuration from ROM into the active configuration memory (RAM))
 MO speaker is always off
 &DO ignore DTR status transition
 &QI standard AT result code
 VO digit result codes selected (0 to 999)

- Init string: AT&FMO&DO&:QIVO

2. AT Command for Establishing a Communication Link

Example of a dial string for a modem connected to a branch (PBX system) and dialing a modem via the public telephone network, using the touch tone mode.

AT prefix that precedes every command line
 DT touch tone dial mode
 xxx after DT, enter the characters for access to the public telephone network (e.g. 0 0)
 W W, placed after a number, tells the modem in a PBX system to wait for the dial tone of an outside telephone line
 - dial string: ATDT0W

3. AT Command for Termination of the Communication

The communication is terminated in two steps.

First of all, the MAC 1200 sends an escape command to return from the on-line state to the command state. Then the hangup command follows:

+++ escape command
 AT prefix that precedes every command line
 H hangup command
 - hangup string: +++ATH

5.6 Brief Operating Instructions - 12 Lead Mode

- Switch on the unit and wait for self-test to end
- Apply electrodes to patient
- Enter patient data - 
- Check device settings
 - report sequence
 - report format
 - AC line filter
 - override function
 - 12SL interpretation configuration
- Modify device settings, if required - 
- Wait for patient to lie motionless and for the unit to collect 10 seconds of ECG data
- Check that no lead failure message is displayed
- Start recording with 

6 Recording in 6 Lead Mode

6.1 Some Basic Facts

In 6 Lead Mode, the system acquires 6 leads of ECG in realtime. Recordings are started and stopped with . Some of the system settings can be customized. They are labeled with "configurable".

The following information refers to a unit with the system defaults (see table below). For instructions on changing the device setup, refer to section 9.3 "6 Lead Mode".

Parameter	System defaults	Options
Report sequence	STANDARD	CABRERA, SEQ.NO.4
Gain	10 mm/mV	**auto*, 5, 20, 40 mm/mV
Speed	25 mm/s	5, 50 mm/s
Muscle filter	No	Yes
Filter frequ.	40 Hz	20 Hz
AC line filter	Yes	No
Anti-drift system	No	Yes
Start at queue mark	No	Yes

6.2 Recording

After switching on the unit, press  to select the 6 Lead Mode.

- Before recording the ECG, patient data can be entered with . We recommend to enter the patient's name to annotate it on each page.

Note

In 6 Lead Mode, messages indicating disconnected electrodes are annotated on the recording, e.g. Lead fail VI.

- Before initiating a recording, check the display for error messages (see table below). Check all electrodes; if the message persists, there must be a break in the patient cable. Replace the cable with a new one.

**RI*:* right leg electrode disconnected
**RA*:* right arm electrode disconnected
**LA*:* left arm electrode disconnected
**LL*:* left leg electrode disconnected
**VI*:* chest electrode V1 disconnected
**V2*:* chest electrode V2 disconnected
**V3*:* chest electrode V3 disconnected
**V4*:* chest electrode V4 disconnected
**V5*:* chest electrode V5 disconnected
**V6*:* chest electrode V6 disconnected

Messages indicating disconnected electrodes

Note

- Please note that filters may suppress diagnostically relevant portions of the signal, because they limit the transmission range. Filters should therefore only be enabled if necessary.
- Before and during the recording, the second set of 6 leads can be selected with the  key.

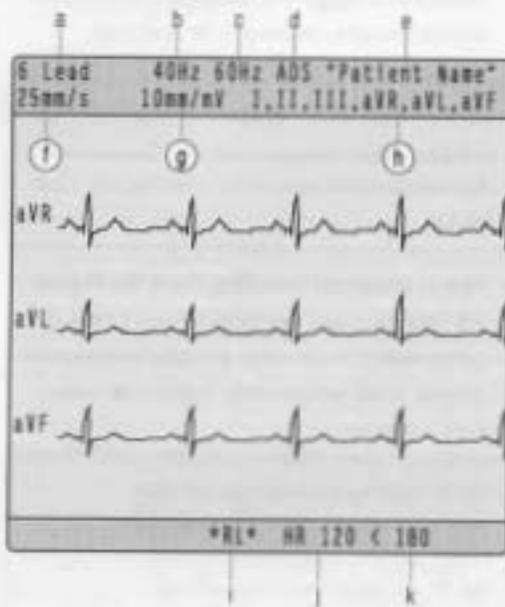


Figure 6-1. 6 Lead mode display

- a Operating mode
- b Muscle filter enabled
- c AC line filter enabled
- d Anti-drift system enabled
- e Patient name
- f Writer speed
- g Gain 10 mm/mV (automatic gain adjustment off)
- h Report sequence
- i Right leg electrode failure message
- j Heart rate
- k Heart rate limit (adjustable)

- The recording is started and stopped with 

With the system defaults, the MAC 1200 will activate the following functions and settings:

- the standard report sequence: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, also available: CABRERA, SEQ. NR. 4 (custom report sequence)
- a gain of 10 mm/mV (configurable) (calibration pulse at the beginning of the recording. The unit can be set up to automatically adapt the gain to the ECG signal (see section 9.3 "6 Lead Mode"). Also, the gain setting can be changed with  (5, 10, 20 and 40 mm/mV).
- the AC line filter is enabled
- the muscle filter is disabled
- the anti-drift system (cubic spline) is disabled (configurable)
- the writer prints at a speed of 25 mm/s, the speed can be changed with 
- Pressing  will output the patient data after the ECG recording.
- The unit will not advance the paper to the beginning of a new page each time a recording is initiated (configurable)

All relevant device settings are shown on the display (Figure 6-1).

- If you change the writer speed, lead group or any filter settings during a recording, the unit will briefly stop.
- With  you advance to the next group of 6 leads of the selected report sequence.

- With  / , you toggle between the two lead sets (3 each) on the display that belong to the recorded group.
- When the anti-drift system is enabled, there will be a short delay before the recording starts. The ECG will then be recorded with a delay of 2.2 s.

The heart rate limit is automatically calculated from the date of birth (WHO 100% = 220 - age). When the date of birth is not entered, the unit will set the limit at 180 bpm. This value can be changed with  and  (in steps of 5 bpm). The minimum value for the heart rate limit is 30 bpm.

6.3 Brief Operating Instructions - 6 Lead Mode

- Switch on the unit and wait for self-test to end
- Apply electrodes to patient
- Select the 6 Lead Mode - 
- Enter patient data - 
- Check device settings
 - report sequence
 - AC line filter
 - ADS (cubic spline)
 - heart rate alarm limits
- Modify device settings, if required - 
- Watch ECG on display
- Check that no lead failure message is displayed
- Start recording with 
- Proceed to the next group of 6 leads with 
- Change the writer speed with 
- Switch on muscle filter with 
- Stop the recording with 
- Print patient data with 

7 Arrhythmia Mode

7.1 Some Basic Facts

In Arrhythmia Mode, the MAC 1200 continuously scans the ECG for arrhythmias.

From six simultaneously acquired leads, the MAC 1200 automatically selects the two that provide the best signal for analysis.

When the analysis algorithm detects an arrhythmia, the event is recorded with "context" (Figure 7-1). The length of the recording varies with the duration of the event episode. In the setup menu (section 9.4 "Arrhythmia Mode") you determine the conditions for a recording:

- the recorder starts each time it detects a single-beat event - all
- the recorder starts each time it detects an event different from the previous event - unequal
- the recorder does not start at all - no.

Some of the system settings can be customized. They are labeled with "configurable". The following information refers to a unit with the system defaults (see table at left). For instructions on changing the system setup, refer to section 9.4 "Arrhythmia Mode".



Figure 7-1. Event recording

Note

After starting the program, press **MEMO** to select a continuous recording with a speed of 5 mm/s (configurable). If the unit identifies an arrhythmic event, it will automatically switch to the fast paper speed. With the same key **MEMO**, the trend recording can be stopped. The unit can be set up to automatically start a trend recording when the Arrhythmia Mode is initiated.

Parameter	System defaults	Options
Report sequence	STD_C (chest leads V1 through V6)	STD_RED (I, II, III, V2, V4, V6) STD_LI (I, II, III, aVR, aVL, aVF) CABR_LI (aVL, I, -aVR, II, aVF, III) HIGH_C (V1 through V6)
Gain	10 mm/mV	"*auto", 5, 20, 40 mm/mV
Muscle filter	No	Yes
Frequency	40 Hz	20 Hz
AC line filter	Yes	No
Trend rec.	No	Yes
Arrhythmia data	unequal	all, no
Episodes	chron.	prio, ventr., no

RL: right leg electrode disconnected
 RA: right arm electrode disconnected
 LA: left arm electrode disconnected
 LL: left leg electrode disconnected
 V1: chest electrode V1 disconnected
 V2: chest electrode V2 disconnected
 V3: chest electrode V3 disconnected
 V4: chest electrode V4 disconnected
 V5: chest electrode V5 disconnected
 V6: chest electrode V6 disconnected

Messages indicating disconnected electrodes

Note

- With , a single-page recording can be initiated after program start.
- Please note that filters may suppress diagnostically relevant portions of the signal, because they limit the transmission range. Filters should therefore only be enabled if necessary.
- For proper functioning of the ECG analysis algorithm, pacemaker patients must be identified in the patient data: Pacemaker – yes (section 4.3 “Entering Patient Data”).

7.2 Recording

- After switching on the unit, press  to select the Arrhythmia Mode.
- Before recording the ECG, patient data can be entered (). We recommend to enter the patient's name to annotate it on each page.
- Before initiating a recording, check the display for error messages (see table at left). Check all electrodes: if the message persists, there must be a break in the patient cable. Replace the cable with a new one.
- The recording is started and stopped with the  key.

Upon program start, the unit records 6 leads of ECG (1 page). During the following learn phase, the analysis algorithm learns the patient's typical QRS complex. After the learn phase, the recorder prints a report where the QRS complexes acquired in the learn phase are labeled "L," and the complex found to be the patient's typical complex is labeled "QRS1." Having completed the learn phase, the MAC 1200 is ready to identify arrhythmias.

With the system defaults, the MAC 1200 will activate the following functions and settings:

- the STD_C report sequence V1 through V6 (configurable)
- a gain of 10 mm/mV (configurable) (calibration pulse at the beginning of the recording. The unit can be set up to automatically adapt the gain to the ECG signal (*auto))
- the AC line filter is enabled (configurable)
- the muscle filter is disabled (configurable)

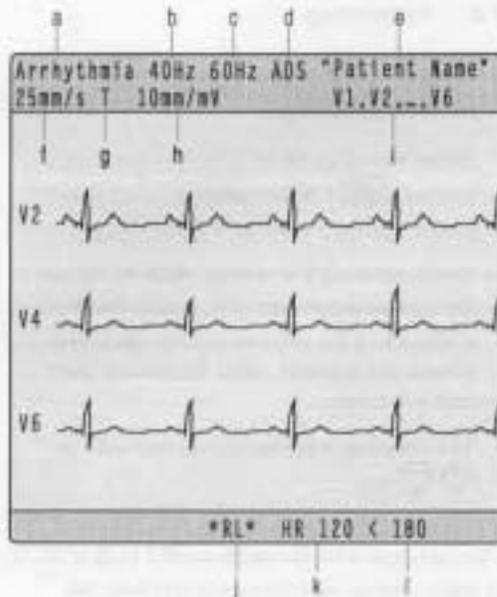


Figure 7-2. Arrhythmia mode display

- a Operating mode
- b Muscle filter enabled
- c AC line filter enabled
- d Anti-drift system enabled
- e Patient name
- f Writer speed (event episodes)
- g Trending enabled
- h Gain
- i Report sequence
- j Right leg electrode failure message
- k Heart rate
- l Heart rate limit

Note

The letter A on a recording indicates the presence of artifact which does not allow the algorithm to identify arrhythmias. Causes include wandering baselines. The anti-drift system largely prevents these disturbances. Still you should check the electrodes and leadwires.

- the anti-drift system is enabled
- the automatic baseline adjustment is enabled
- the slow trend recording is disabled (configurable)
- event episodes are recorded at a speed of 25 mm/s
- the unit documents all events that are different from the previous event (configurable). You can set up the unit to document all events or no event at all.

All relevant device settings are shown on the display (Figure 7-2).

The arrhythmia codes annotated on the recording are explained in table 7-1 (next page).

The heart rate limit is automatically calculated from the date of birth (WHO 100% = 220 · age). When the date of birth is not entered, the unit will set the limit at 180 bpm. This value can be changed with and (in steps of 5 bpm). The minimum value for the heart rate limit is 30 bpm.

Final Report

The arrhythmia recording can be stopped with .

The final report can then be printed with . The final report consists of

- the patient ID sheet (with all patient data as well as with all analyzed QRS complexes, type and number of detected events and the analysis duration in tabular form) and
- the episodes (3 sheets max. with 2 episodes each).

7.3 Brief Operating Instructions - Arrhythmia Mode

Arrhythmic Events

- asystole, limit value	ASYSTO
- ventricular fibrillation/flutter	VFIB
- ventricular tachycardia (>3 PVCs)	VTAC
- ventricular run (3 PVCs)	RUN
- ventricular couplet (2 PVCs)	CPLT
- pause of 2 missed beats	PAU2
- pause of 1 missed beat	PAU1
- early PVC	EPVC
- ventricular bigeminy	VBIG
- new form (e.g. intermittent bundle branch block)	NF
- multiform PVCs	MULT
- supraventricular arrhythmia	SVAR
- paroxysmal supraventricular tachycardia	PSVT
- tachycardia	TACH
- bradycardia	BRAD
- pacemaker malfunction	PERR
- ventricular escape beat	ESC
- premature ventricular contraction	PVC
- premature supraventricular contraction	PSVC
- aberrant beat	ABR
- pacemaker capture	PCAP
- pause (>1.5 times the normal RR interval)	TL
- absolute pause, limit value	PAUA
- artifact	A
- learn phase	L
- learned QRS complex	QRSL

Table 7-1. Arrhythmia codes

- Switch on the unit and wait for self-test to end
- Apply electrodes to patient
- Select the Arrhythmia Mode - 
- Enter patient data - 
- Check device settings
 - report sequence
 - AC line filter
 - trend recordings
 - episodes
 - heart rate alarm limits
- Modify device settings, if required - 
- Check that no lead failure message is displayed
- Start recording with 
- Switch on muscle filter with 
- Stop the recording with 
- Print patient data with 

8 ECGs of Pacemaker Patients / ECG Recording during Defibrillation

8.1 Recording ECGs of Pacemaker Patients

Due to the slow paper speed it is not possible to display pacer pulses directly on the ECG recording. At a paper speed of 50 mm/s and a pulse duration of 0.5 ms, the width of the recorded pacer pulse would be only 0.025 mm.

For this reason the recorder reduces the pulse amplitude and expands the pulse width, so that the pacer pulse is easier to identify. The MAC 1200 records the pulse with the correct polarity, with a width of 5 ms and with the same amplitude in all leads (depending on the polarity of the pacer pulse in leads I and II, the pacer pulse in lead III may be suppressed). The amplitude of the reverse current may differ from lead to lead. Figure 8-1 shows an ECG recording with pacer pulses.



Figure 8-1. ECG recording with pacer pulses

Warning

Incorrect HR, No HR Alarm — If several adverse conditions exist at once, the possibility that the pacer pulses are interpreted (and counted) as QRS complexes should be considered. At the same time, however, QRS complexes might be suppressed in certain situations. Therefore, pacemaker patients should always be watched closely.

8.2 ECG Recording During Defibrillation

The patient signal input is defibrillation-proof so it is not necessary to remove the ECG electrodes before defibrillating the patient. However, when using stainless steel or silver electrodes, the defibrillator discharge current may cause complete polarization at the electrode/skin interface. This condition may prevent ECG signal acquisition for several minutes. With silver/silver chloride electrodes, this will not happen.

Set the MAC 1200 to 6 Lead Mode when you may have to defibrillate the patient while recording the ECG, and disable the anti-drift system as this would cause a 2 second signal delay (section 9.3 "6 Lead Mode").

If electrodes made of other materials are used, disconnect the patient cable from the recorder while the shock is applied.

Warning

- *Equipment Damage — For reasons of patient safety, use only the original GE Marquette patient cable. Before connecting the cable to the device, check it for signs of mechanical damage. Do not use a damaged cable.*
- *Patient Hazard, Delayed ECG Display — Use silver/silver chloride electrodes for ECG signal acquisition, if the patient may have to be defibrillated.*
- *Shock Hazard — The patient signal input of the recorder is protected against damage resulting from defibrillation shocks. Nevertheless, extreme care should be exercised when defibrillators are used on a patient connected to other devices while a shock is released. During defibrillation, do not touch the patient, the electrodes or the leadwires.*

Note

Observe the safety information of the defibrillator.

9 System Setup

9.1 Some Basic Facts

- Press  to display the setup menu.

The setup menu with the following options will appear:

- Operating mode: 12 Lead (6 Lead, Arrhythmia)
- General Settings
- Communication
- Patient Data Setup
- Option Code

At "Operating mode", you will always see the currently selected mode. So be sure to select the appropriate mode before entering the setup menu.

- To access the menu options, position the bar cursor on the option with the cursor keys and confirm the selection with .

The operating steps to select a setting are always the same:

- Using the cursor keys  and , you select the option, then you confirm the selection with .

The cursor will move to the next menu item.

- Individual items can be skipped with  or .
- Press   to exit the setup mode.

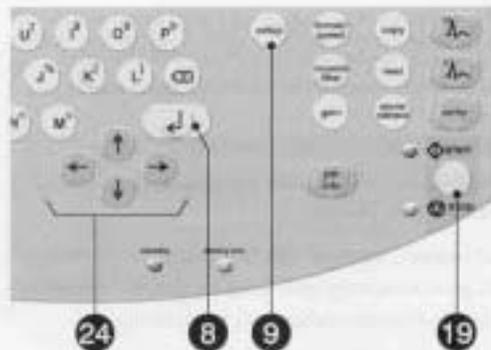


Figure 9-1. System setup keys

9.2 12 Lead Mode

- Use the cursor keys to position the bar cursor on "12 Lead" and confirm the selection with .

The setup menu for automatic 12 lead recording will appear.

The angular brackets [] denote the system defaults.

Report sequence

[STANDARD] (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
 CABRERA (aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6)

Rhythm leads

Any three of the available ECG leads can be selected as rhythm leads. They are printed with report formats 4x2.5R3 and 1x10R3. Formats 2x5R1 and 4x2.5R1 will show only the first of the rhythm leads.

Gain

5, [10], 20, 40 mm/mV, *auto

Report format

For an overview of the available report formats, refer to section 5.4 "The Report Formats". The default format is 4x2.5R1.

Detailed results

The "Detailed results" page will be printed, yes/[no] (section 5.4 "The Report Formats", only available with option MEAS or DIAG).

Muscle filter/AC line filter

Elimination of muscle artifact and AC line interference.

Default: muscle filter [No], AC line filter [Yes]

Note

Please note that filters may suppress diagnostically relevant portions of the signal, because they limit the transmission range. Filters should therefore only be enabled if necessary.

Filter frequency

Cut-off frequency of the muscle filter ([40 Hz], 20 Hz).

The frequency range is indicated in the lower margin of the recording strip.

"0.08 - 40 Hz" (40-Hz muscle filter enabled)

"0.08 - 20 Hz" (20-Hz muscle filter enabled)

"0.08 - 150 Hz" (muscle filter off).

Manual copy to

When the  key is pressed, the unit will print a copy of the ECG [EKG] or send the ECG to a HOST system (MUSE CV Information System).

No. of copies

If you do not want to print the ECG, but only collect data, select "0" (message on display "REC OFF"). When a number greater than 1 is selected, multiple copies of the reports will be printed. Default: [1]

Autosave ECG (only with MEMO option)

After report generation, the ECG will or will not be automatically saved to the internal memory (yes, [no]).

Delete ECG after Transmission

(only with MEMO option)

ECGs that were successfully sent to a host system via the RS232 interface will be cleared from the recorder memory (yes, [no]).

If this menu item is set to "yes" and ECGs have already been sent from the recorder memory, these ECGs will be deleted after the next transmission of a stored ECG.

Configuration of the 12SL Interpretation**Use screening criteria**

The screening criteria can be enabled or disabled.

Default: [disabled]

Suppress "normal" statement

If you select 'Yes', the interpretation statement "normal ECG" will not be shown.

Suppress "abnormal" statement

If you select 'Yes', the interpretation statement "abnormal ECG" will not be shown.

Interpretation

Default: [Yes]. If you select 'No', 12 SL interpretation results will not be generated nor shown.

Print Interpretation

Only available if "Interpretation" is set to "Yes".

Default: [Yes]. The interpretative statements are printed on the reports. When you select "No", the interpretation will not be printed, but it can be sent to the MUSE CV Information System.

Override function

When this function is enabled [yes], the recorder will print in 12 Lead Mode, even when not all electrodes are applied or do not supply a good signal.

When electrodes are disconnected, a message informing the user of poor signal quality will be printed on the recording.

Furthermore, systems with interpretation capability will print a message indicating that the measurement results and interpretation may be incorrect.

9.3 6 Lead Mode

- Use the cursor keys to position the bar cursor on "6 Lead" and confirm the selection with .

The setup menu for continuous recording of 6 leads will appear.

Report sequence

- [STANDARD] (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
- CABRERA (aVL, I, -aVR, II, aVF, III, VI, V2, V3, V4, V5, V6)
- SEQ. NO. 4 (here, users can define a custom report sequence):
 - Position the cursor on "SEQ. NO. 4".
 - Press .

The display shown in Figure 9-2 will appear.

Report sequence	SEQ. NO. 4	
	lead	label
Channel 1:	I	I
Channel 2:	II	II
Channel 3:	III	III

Figure 9-2. Creating a custom report sequence

- Press .

The cursor will move to the position for entry of the lead in channel 1. Follow these steps, if you wish to record aVR in channel 1, for instance:

- Enter AVR and confirm the entry with .

The cursor moves to the position for entry of the lead designation. AVR appears there as well.

- If you wish to enter another designation, you can overwrite the default name (4 characters max.).
- Confirm your entry with  and repeat the above steps for channel 2, etc.

You can write over "SEQ. NO. 4" if you wish to enter another name for the report sequence.

Gain

auto, 5, [10], 20, 40 mm/mV; with ""auto", the unit will automatically determine the appropriate gain setting for the 6 simultaneous leads.

Speed

Changes the writer speed. Default: [25 mm/s]

Muscle filter/AC line filter

Elimination of muscle artifact and AC line interference

Default: muscle filter [No], AC line filter [Yes]

Filter frequency

Cut-off frequency of the muscle filter ([40 Hz], 20 Hz).

The frequency range is indicated in the lower margin of the recording strip.

0.08 - 40 Hz (40-Hz muscle filter enabled)

0.08 - 20 Hz (20-Hz muscle filter enabled)

0.08 - 150 Hz (muscle filter off).

Anti-drift system (ADS) (cubic spline)

In case of wandering baselines, the anti-drift system restores the baseline to its original position (signal delay with ADS approx. 2 s). Default: [No]

Start at queue mark

Before each recording, the recorder advances the paper to the beginning of a new page (yes, [no]).

9.4 Arrhythmia Mode

- Use the cursor keys to position the bar cursor on "Arrhythmia" and confirm the selection with .

The arrhythmia mode menu will appear.

Report sequence

[STD_C]: V1, V2, V3, V4, V5, V6
 STD_RED: I, II, III, V2, V4, V6
 STD_LI: I, II, III, aVR, aVL, aVF
 CABR_LI: aVL, I, aVR, II, aVF, III
 HIGH_C: V1', V2', V3', V4', V5', V6'

(C = chest leads, RED = reduced number of leads, LI = limb leads)

Gain

auto, 5, [10], 20, 40 mm/mV; with ""auto", the unit will automatically determine the gain setting.

Muscle filter/AC line filter

Elimination of muscle artifact and AC line interference

Default: muscle filter [No], AC line filter [Yes]

Filter frequency

Cut-off frequency of the muscle filter ([40 Hz], 20 Hz).

The frequency range is indicated in the lower margin of the recording strip.

"0.08 - 40 Hz" (40-Hz muscle filter enabled)

"0.08 - 20 Hz" (20-Hz muscle filter enabled)

"0.08 -100 Hz" (muscle filter off).

Trend rec.

The slow trend recording of 5 mm/s automatically begins at program start ([no]/yes).

Arrhythmia data

The recorder will document arrhythmias in the following situations:

- each time an arrhythmia occurs
- each time an arrhythmia occurs that is different from the preceding event
- arrhythmias are not documented all, [unequal], no.

Episodes

Final report includes episode report, with episodes listed by one of the following criteria

- in chronological order
 - according to priorities (see table 7-1)
 - ventricular beats only
 - no episodes
- [chron.], prio., ventr., no

9.5 General Device Settings

Ordering / Referring Physician / Technician

In the field at left, you see the last name of the physician or technician selected as the default name. When selecting "other", a menu displays where you can enter up to 10 names (2-digit ID number, first name, last name). The default name (and ID) is automatically selected at power-up.

The "Referring Physician" is only relevant if you send ECGs to the MUSE CV system. This name will not be annotated on the ECG recording. Press the   key to exit the menu.

Institution Name

The name entered here will be printed on each report page.

Cart

Enter any number between 1 and 9999 to identify the cart (local system). The cart # entered here is the default number that appears in "Patient Data".

Default: [1]

Site

Enter any number between 1 and 255 to identify the MUSE CV Information System to which the ECGs will be sent. The site # entered here is the default number that appears in "Patient Data".

Default: [1]

Location

Enter any number between 1 and 600 to identify the location of the sending system. The location # entered here is the default number that appears in "Patient Data".

Default: [1]

Date/Time

Enter date and time (enter 4 digits for the year).

Lead fail beep

Indicates when electrodes are not properly applied or disconnected (yes/[no]).

High HR beep

An audible signal sounds when the heart rate exceeds a limit value (yes/[no]) (only in 6 Lead and Arrhythmia Modes). The limit value (220 - age) can be changed manually.

Lead labels

[AAMI] codes: RA, LA, RL, LL, V1 to V6 or IEC codes: R, L, F, N, C1 to C6

Date

Format: [month/day/year] or day.month.year

Time

Time format [12] hours (am/pm) or 24 hours

Units

Units of measurement for the patient's height and weight: [in/lb] or cm/kg

Mains

AC line frequency (USA [60 Hz], Europe 50 Hz)

LCD light off after

If operating controls are not activated within the selected period of time the display backlighting automatically switches off (system default [5 min], adjustment range 1 to 99 min).

Default mode

This is the operating mode the unit defaults to after power-up: [12 Lead], 6 Lead, Arrhythmia

Language

Select the language for user interface and printouts.

Enable password protection

Select "yes" to protect the setup menu with a password. You will be asked to enter a password and to repeat it. The password protection is then active. To change the password (only possible when password protection is active)

- select menu item "Enable password"
- enter the old password
- enter the new password
- repeat the new password

Test DATA

Used for demonstration purposes (yes). It must be set to [no] for proper clinical use.

Restore defaults

Selecting "Yes" will restore the default setup (including the defaults of the three operating modes).

The resting ECG analysis system must be switched off (standby) and on again for the new settings to become effective.

Print Setup Lists

Selecting "yes" will display a menu with all available setup lists.

- all lists
- System Setup / Communication / External Devices / Patient Data Setup
- 12 Lead
- 6 Lead
- Arrhythmia

9.6 Communication**Protocol**

The recorder offers two communication protocols: "CSI" (Client Server Interface) and A5.

The CSI protocol supports the transfer of resting ECGs from the resting ECG analysis system to a MUSE CV system.

With the "A5" protocol, the 10-second resting ECG can be transmitted to CardioSys and CardioSoft.

Baud rate (HOST)

Transmission rate for the selected protocol. We recommend the default setting of [19200 baud].

Modem

Select the modem type. You can choose among the standard modems MultiTech (MT 19.32, 56.6), Elsa 28.8, Elsa 33.6, Elsa 56.6 and a user-defined modem.

When using one of the standard modems, all you have to enter is

- the dial mode (pulse or tone, depending on your telephone network)
- the telephone number (28 digits max.)
- the number to access the public telephone network (e.g. "0").

For a user-defined modem, enter

- the telephone number (28 digits max.)
- the init string (20 characters max.) (see modem operator's manual)
- the dial string (20 characters max.) (see modem operator's manual)
- the hangup mode (20 characters max.) (see modem operator's manual)



The **master password** overriding all other passwords is

SYSTEM

Use this password if you cannot remember your own password.

9.7 Patient Data

The patient data menu can be set up to meet individual requirements. If you do not want to enter blood pressure readings, for instance, you can remove the corresponding prompts:

- Use the cursor keys to position the bar cursor on "Setup Patient Data" and confirm the selection with .

The patient data setup menu will appear.

- Select "no" for prompts that you want to remove from the dialog.

Items - Last name
- First name
- Date of birth
- Patient ID

cannot be removed.

Items - Height
- Weight
- Diastolic BP
- Systolic BP
- Referring Physician
- Medication
- Comments
- ID required
- Secondary ID
- Secondary ID required
- Last name required
- First name required
- Extra Questions
(Prompt 1 through Prompt 4)

are disabled. They can be enabled from the patient data setup menu.

"Required" Data Fields

If, for one of the data fields

- ID required
- 2nd ID required
- Last name required
- First name required

you choose "yes", an ECG can be recorded in 12 Lead Mode only if the corresponding patient data is entered.

Prompt 1 to 4

You can enter any text here (10 characters max.). When you have entered the text, you can select the format of the response field. There is a choice of 3 formats:

- alphanumeric field (17 characters max.)
- only numbers (9 numbers max.)
- yes or no

- To exit the menu, press  .

9.8 Option Code

In this menu you enter the option codes to enable a number of optional software functions. The respective option becomes active after you have entered the code number. The code numbers are listed on the option code sheet supplied with the different software options.

- In the setup menu, position the bar cursor on "Option Code" and confirm the selection with .

The option code menu appears. There is a choice of 6 options:

MEAS: measurement of the 10-second resting ECG
 DIAG: measurement and interpretation of the 10-second resting ECG
 MEMO: program for storage of up to 40 resting ECGs
 C100: activates the three options MEAS, DIAG, MEMO for a maximum of 100 ECGs
 C500: activates the three options MEAS, DIAG, MEMO for a maximum of 500 ECGs
 EVAL: activates the three options MEAS, DIAG, MEMO for a maximum of 4 weeks

- Position the bar cursor on the option you wish to activate.
- Enter the 12-digit code number from the keyboard and confirm the entry with .

The unit will accept the entered number only if it corresponds to the unit's serial number. The serial number is indicated at the top of the menu (Ser.No. = xxxxxxxx). This number must be the same as printed on the nameplate (back of the device).

When you enter the code number for DIAG and MEMO, the fields for C100, C500 and EVAL will disappear.

- Exit the menu with  .

9.9 ECG Transmission via Modem

- Select the 12 Lead Mode and press .
- Press  to display the setup menu for the 12 Lead Mode.
- Use the cursor keys to position the bar cursor on "Manual copy to HOST" and confirm the selection with  ([HOST]).
- Press   to clear the setup menu.
- Use the cursor keys to position the bar cursor on "Communication" and confirm the selection with .

Selecting the Communication Protocol

- Using the cursor keys, position the bar cursor on "Protocol". Select the protocol CSL to send data to a MUSE CV system, or select A5 if you will send data to CardioSys/CardioSoft.
- Use the cursor keys to position the bar cursor on "Modem, other" and confirm the selection with .
- Choose the modem you use from the list and confirm the selection with . If your modem is not included in the list, select "other" and enter the required modem commands (see also "Modem Setup" in section 5.5).
- When you have selected a standard modem, position the bar cursor on "Dial mode" and select the appropriate mode.
- Enter the telephone number of the receiving modem and the number to access the public telephone network and terminate the setup with  .

9.10 Direct ECG Transmission

- Select the 12 Lead Mode and press .
- Press  to display the setup menu for the 12 Lead Mode.
- Use the cursor keys to position the bar cursor on "Manual copy to HOST" and confirm the selection with  ([HOST]).
- Press   to clear the setup menu.
- Use the cursor keys to position the bar cursor on "Communication" and confirm the selection with .
- Select the same baud rate as at the receiving modem (9600, 19200, 38400, 57600).

Selecting the Communication Protocol

- Using the cursor keys, position the bar cursor on "Protocol".
Select the protocol CSI to send data to a MUSE CV system, or select A5 if you will send data to CardioSys/CardioSoft.
- Use the cursor keys to position the bar cursor on "Modem, none" and confirm the selection with .



Figure 10-1. Opening the paper compartment door



Figure 10-2. Inserting the new Z-fold pad



Figure 10-3. Guiding the leading paper edge over the guide roller



Figure 10-4. Closing the paper compartment door

10 Loading Chart Paper

- Switch on the recorder.
- Pull up the handle of the paper door and fold it out (Figure 10-1).
- Remove the cardboard backing of the previous paper pad.

- Remove the cardboard from the top of the new pad and place the pad, including the cardboard backing at the bottom and with the arrow pointing towards the unit, into the paper compartment (Figure 10-2).

- Pull the top sheet out of the compartment and guide it around the guide roller (Figure 10-3).

- Holding the leading edge of the paper in place between the two markers on the recorder, close the paper door (Figure 10-4). Ensure that it locks into place on both sides.

When inserting an already started Z-fold pad, the grid side must face up and the first fold must point towards the paper compartment.

Note

- Having inserted a new paper pad, be sure to acknowledge the "end of paper" message with , not with   
- When closing the paper door, take care that it locks into place on both sides.
- There is a window in the paper door that allows you to look inside the compartment and check the paper supply.
- Use only the original HELLIGE CONTRAST® chart paper or the GE Marquette thermal paper with precise marks or holes. This paper has a special coating that prevents
 - contamination and debris collecting on the printhead and
 - electrostatic build up.
- Furthermore, the thermosensitive layer and the printhead characteristics are exactly matched. Using other paper may result in recordings of poor quality. Moreover, the printhead may wear out prematurely. Use of other paper voids the warranty.

End-of-Paper Indication

A stripe marks the last 10 pages of the Z-fold pad.

When the writer runs out of paper during a recording, it will emit an audio signal and displays the message "End of paper or paper jam, if OK, press



- Insert a new paper pad and acknowledge the message with .

Aging Stability

The standard ECG writer paper CONTRAST® is designed to guarantee full contrast for a period between 3 and 5 years if it is handled as described below before and after recording:

- Store the paper in suitable rooms at a temperature between 18° and 24° and a relative humidity between 40 % and 60 %.
- Avoid direct contact of the paper with
 - carbon and carbonless forms
 - chart papers and adhesives containing tributyl phosphate, dibutyl phthalate, or any other organic solvents
 - document protectors, envelopes, and sheet separators containing plasticizers.

Caution: The above components may also be found in recycled papers.

 - solvents or solvent-based products containing alcohols, ketones, esters, or other substances from this chemical group.
- We recommend archiving ECG recordings on our ECG filing cards only (P/N 217 043 03).
- If longer storage periods are required, we suggest using our ARCHIVIST 30 chart paper (image legibility up to 30 years) or other image storage technologies.

A stripe marks the last 10 pages of the Z-fold pad.

11 Cleaning, Disinfection and Maintenance

11.1 Cleaning and Disinfecting the Recorder Housing

Warning

Before cleaning or disinfecting the device, disconnect it from the power line.

- Clean the recorder housing with a moist cloth. Do not let liquid enter the device. All cleaning agents and disinfectants that contain alcohol and are commonly used in hospitals are suitable, but do not use disinfectants on a phenol base or peroxide compounds.

11.2 Cleaning and Disinfecting the Patient Cable

- Disconnect the cable from the recorder before cleaning or disinfecting it. When disconnecting the cable, be sure to pull on the connector, not on the cable.
- **Clean** the cable by rubbing it down with a cloth moistened with soap water. Use a disinfectant for **disinfection**. Do not immerse the cable in liquid.

11.3 Cleaning and Disinfecting the Electrodes

In addition to the information given in this manual, observe the instructions for use of the respective electrode types.

- Discard disposable adhesive electrodes immediately after use to prevent that they are reused.
- Clean reusable electrodes immediately after removing them from the patient.
- Peel off the adhesive foil before cleaning the electrodes (residue of the adhesive can be removed with benzine).
- Then use warm water and a small brush to clean the electrodes of cream or gel. Do not use pointed or sharp objects for cleaning.
- Disinfect the electrodes with alcohol-free disinfectant. Ensure that connectors and sockets do not become wet.
- The only approved sterilization method is gas sterilization. Frequently sterilizing the electrodes with ethylene oxide gas reduces the life of the plastic material.

11.4 Maintenance

Checks before each use

Before each use, visually inspect the device, the leads and electrodes for signs of mechanical damage.

If you detect damages or impaired functions that may adversely affect the safety of the patient or user, do not use the device before it has been repaired.

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of the MAC 1200 units, Technical Inspections should be carried out on an annual basis.

These checks should be performed by persons with adequate training and experience.

The checks can be carried out by GE Marquette within the framework of a service contract. The inspections include the following checks:

- Visually inspect the device and the accessories for signs of mechanical damage that may impair the device functions.
- Check that the device labeling relevant for safety is legible.
- Run a performance test as described in the operator's manual.
- Measure the resistance of the protective earth conductor and the equivalent leakage current per your national regulations.

The device does not require any other maintenance.

Disposal at the End of Its Service Life

Note

At the end of their service life, the device described in this manual and its accessories must be disposed of in compliance with the applicable local waste control regulations. If you have questions regarding the disposal of the product or of accessories, please contact GE Marquette or its representatives.

12 Troubleshooting

Symptom	Cause	Remedy
Periodic superimposition of AC line interference (60 Hz) (Figure 12-1)	interference from the power line	Ground bed, verify position of the leadwires, switch on AC line filter
Superimposition of irregular AC line interference (Figure 12-2)	Muscle artifact caused by patient movements, hiccup, coughing	The patient should be warm enough and resting comfortably (place cushions under arms and knees). Comfort patient or distract patient's attention, enable muscle filter (20 Hz / 40 Hz), if necessary.
The printed date and time are incorrect	Built-in lithium battery is depleted. The battery has a life of approx. 5 years	Notify service to check and/or replace battery
The green standby indicator 23 does not light up, although the recorder is connected to the power line	Defective AC power adapter or fuse	Notify service to check and/or replace fuse
The recorder does not write over the entire paper width	Paper compartment not properly closed	Paper door must lock into place on both sides
In 12 Lead Mode, the recorder does not stop and continues to feed paper. This does not happen in 6 Lead Mode.	The paper pad was inserted the wrong way round so the recorder cannot detect the cue mark	Insert the paper pad as instructed
Recorder does not start after activation of the   key, or the recording is aborted.	Unit operated on battery power: battery discharged	Connect recorder to the power line. After a few minutes, the recorder is able to resume operation. Always connect recorder to the power line when the battery low indicator 22 lights up. The battery capacity depends on age, temperature and charge level (chapter 3 "Putting the Recorder into Operation").
No recording in 12 Lead Mode	Failure of at least one electrode	Check all electrodes or enable Override function (section 9.2 "12 Lead Mode").
Paper jam		Open paper compartment and removed jammed sheet, place beginning of paper between the marks, close paper compartment and press  .



Figure 12-1. Regular AC line interference

Note

In the presence of very strong AC line interference in all leads, the thermal printhead may interrupt the recording. Activate the AC line filter (60 Hz) in these situations.



Figure 12-2. Irregular AC interference

13 Technical Specifications

Recording

Direct recording of waveforms and alphanumeric characters with rectangular coordinates by means of thermal-array printhead printing on thermosensitive paper.

- 3 or 6 recording channels, or 12 in 12 Lead Mode, overlapping
- baseline pitch 3 channels: 62 mm (arrhythmia)
6 channels: 31 mm (6 Lead)
12 channels: 16 mm (12 Lead.)
- writing width 200 mm max.
- annotation of recorder settings, date, time and entered patient name in the margin of the recording strip
- with appropriate software, documentation of analysis results in the respective operating mode
- resolution of the recording:

vertical	8 dots/mm
horizontal	25 µm at 25 mm/s

Printer paper

HELLIGE CONTRAST® Z-fold pad , 150 pages per pad, equivalent to a chart length of approx. 45 m

paper width: 8.5 inch

sheet length: 11 inch

To prevent damage to the printhead use only the original HELLIGE CONTRAST® paper or the GE Marquette thermal paper with queue holes or marks.

Paper transport

- paper speed
5-25-50 mm/s, key selectable
error limits at 25 and 50 mm/s, typ. ±1%
at 5 mm/s, ±10% max.
- At paper end, the recorder emits an audio signal and stops recording
the last pages of the pad bear a colored stripe in the lower margin

Membrane keypad

Pushbuttons with tactile feedback

- function keys for all routine operations
- alphanumeric keyboard for entry of text

Display

graphics display with 24 x 40 characters, contrast adjustment

resolution of 320 x 240 pixels with display backlighting

Indicators (LEDs)

For mains power, battery status and start/stop function

Automatic functions

They assist and facilitate operation by

- automatic control of lead selection, paper feed, calibration (configurable)
- report formatting (configurable)
- automatic baseline adjustment
- anti-drift system (cubic spline) compensating for polarization voltage fluctuations (configurable)

Detection of pacer pulses

- pulse length between 0.1 and 2.5 ms
- pacer pulse marker independent of pulse polarity
- pulse amplitude between ± 5 mV and ± 700 mV

Heart rate indication

derivation of the heart rate from all ECG signals

- display range between 30 and 300 bpm
- display update with every heart beat, maximum every 2 seconds

Signal inputs

isolated patient signal input, IEC type CF, high-voltage protection for all lead connections and neutral electrode, interference compensation via neutral electrode, monitoring for open leads

- electrode connections for RA, LA, LL, LA, V1 to V6
- input impedance for differential signals between any two electrode connections > 10 M Ω at 10 Hz
- input impedance for common-mode signals referred to neutral electrode > 50 M Ω up to 60 Hz
- dynamic range for differential signals between any two electrode connections for AC voltage ± 10 mV, for superimposed DC voltage (polarization voltage) ± 600 mV
- dynamic range for common-mode signals referred to neutral electrode ± 1 V, referred to chassis 263 V AC (rms)
- quiescent input current via any electrode connection for 1 k Ω termination referred to neutral electrode < 50 nA
- patient leakage current (rms values) according to IEC, class CF: in normal condition < 10 μ A,

in single-fault condition (e.g. patient in contact with line voltage) < 20 μ A

- non-destructive range for lead-electrode connections and the neutral electrode connection referred to neutral electrode ± 50 V, referred to chassis ± 1500 V
- pulse voltage resistance of all lead electrode connections and of the neutral electrode connection referred to chassis (either polarity, e.g. defibrillation) 5000 V
- monitoring of each electrode for open leads: RA, LA, LL, RL, V1, V2, V3, V4, V5, V6
audio signal at printer start

Data interface

one serial RS232 interface for exchange of data with suitable external devices and software handshake

RS232 interface (standard V.24 interface):

- input voltage range: ± 15 V max.
- output voltage range ± 5 V min.
- interface protected from electrostatic discharge for ± 10 kV max.

Transfer of ECGs with the CSI protocol between the MAC 1200 and the following units

MUSE CVIS	SW version 004A and later
MAC 5000	SW version 001B and later
MAC VU	SW version 002A and later
MAC 1200	SW version V5.01 and later

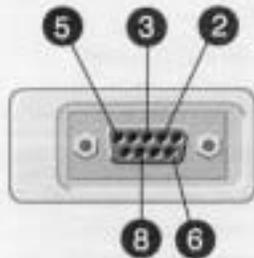
Receiving data with the CSI communication protocol from the following units

CardioSmart	SW version V4.21 and later
CardioSmart ST	SW version V4.21 and later

Sending ECGs to the following units with the A5 protocol

CardioSys / CardioSoft SW version V1.0 and later

Pin assignment of data port



- 2 RXDE
- 3 TXDE
- 5 circuit reference
- 6 modem supply
- 8 remote start

Remote start (hardware)

Paper feed via remote control connection (depending on selected operating mode). External make contact referred to chassis via circuit reference:

- source impedance $R_s < 300 \Omega$
- contact dwell $> 100 \text{ ms}$
- non-destructive load $\pm 10 \text{ V}$
- ESD interface protection up to $\pm 10 \text{ kV}$

Signal Transmission

Patient input to recording

After lead formation and digitization simultaneous transmission of all electrode signals to the digital processing system; muscle filter, AC filter, pacing pulse identification, automatic or manual sensitivity adjustment, automatic baseline adjustment and drift compensation by means of the anti-drift system (A.D.S.) can be enabled or disabled simultaneously for all channels; digital output of processed signals via thermal-array printhead.

- low cut-off frequency (-3 dB limits) 0.08 Hz, equivalent to a time constant of 2.04 s
- high cut-off frequency (3 dB limits) operating mode: 12 Lead, 6 Lead 150 Hz (IEC/AHA) operating mode: Arrhy 100 Hz (IEC)
- signal sampling rate: 1000/s
- resolution, referred to the input 5 μV

- output rate to recorder 2000/s
- for all leads, gain adjustment in four steps: 40-20-10-5 mm/mV
- with active muscle filter (low-pass characteristic) 3-dB drop of the amplitude frequency response at approx. 40 or 20 Hz
- with active AC line filter detection and compensation of periodic 50 or 60 Hz frequency components (depending on recorder model) attenuation $>40 \text{ dB}$
- non-linear distortion below values specified in IEC and AHA recommendations
- coincidence error limits between any two channels $\pm 0.5 \text{ mm}$
- detection of pacer pulses in V2 or other V leads and marking in all channels for signals referred to patient input: duration $\approx 0.1 \text{ ms}$, amplitude $> 5 \text{ mV}$
- noise in the signal transmission path below values specified in IEC and AHA requirements: $\leq 2.5 \mu\text{V rms}$
- common-mode rejection for 50 or 60-Hz signals (depending on recorder model) with AC filter switched on $>140 \text{ dB}$

ECG calibration

automatic recording of a defined voltage step, valid for all channels

- calibration voltage, referred to ECG signal input: 1 mV
calibration pulse width on recording depends on paper speed
25 mm/s 5 mm
50 mm/s 10 mm
5 mm/s 1 mm

Automatic ECG gain adjustment

The gain automatically adapts to the incoming signal. The maximum amplitude of the lead group or of all leads determines the gain setting.

- automatic adjustment range 5 to 40 mm/mV
- amplitude range (6 channels) 18 to 31 mm

Baseline

automatic adjustment of the baseline to the optimal recording range, in dependence of the signal amplitude

Anti-drift system (ADS) (cubic spline)

automatic compensation of baseline fluctuations caused by polarization voltage fluctuations at the lead electrodes (delay in recording: 4.2 s)

ECG storage

in 12 Lead Mode, storage of up to 40 ECGs

- stored ECGs can be deleted (individually or all in one pass), printed, transferred, and patient data can be edited
- when memory is full user is informed of the possible actions

Blocking

rapid charge reversal of the coupling capacitors in the preamplifiers after electrode application, ensures that the baseline is quickly restored to its original position after overranging

Electrode monitoring

audible and visual indication on the LCD of disconnected electrodes or line break; each single electrode is monitored

Text input

patient and user data as well as comments can be entered via the panel keyboard and are annotated on the recording strip

Copy function

after ECG recording in 12 Lead Mode, copies of the ECG can be printed from memory and/or transferred to a MUSE CV system (configurable)

Test

automatic performance test upon power up, including verification of the signal path starting at the signal input

stored test ECG data for demonstration of the device functions

Power supply

from the power line or from a built-in rechargeable battery, automatic switchover; automatic battery charging during line-power operation from integrated AC adapter module

Mains operation

- instrument design in protection class I according to IEC 60601-1
- Rated voltage range 95 to 240 V
- operating voltage range 85 to 264 V, 49 to 65 Hz
- rated current: 0.2 to 0.6 A
- fuse 2 x T1.25A, 5x20
- typical power consumption

battery charging	14 W
------------------	------
- max. power consumption 29 W

Battery operation

- type: nickel-cadmium
- rated battery voltage 18 V

- rated battery capacity 1.3 Ah
- fully charged battery sufficient for up to 50 12 Lead Mode, 1-page ECGs, if unit is only switched on to record the ECGs
- battery charge time approx. 4 hours (min. charge time for one 12 Lead Mode ECG: 10 minutes)
- battery life approx. 2 to 3 years, replacement by service only
- lithium battery for built-in clock, battery life approx. 5 years, replacement by service only

Operational readiness

After successful self-test, approx. 10 s after power-up

Operating position

horizontal

Environment

Operation

- temperature between 50 and 104 °F
- relative humidity between 25 and 95%
- atmospheric pressure between 700 and 1060 hPa

Transport and storage

- temperature between -22 and +140 °F (including battery)
- relative humidity between 25 and 95%
- atmospheric pressure between 500 and 1060 hPa

Recorder dimensions

- width 14.5 in.
- height 3.7 in.
- depth 12.6 in. (incl. handle)

Weight

- approx. 12.3 lb (with battery)

Appendix

Entering Special Characters

The following special characters can be entered by means of the appropriate keystroke combination.

character **keystroke combination**

\\	Alt + Q	Ð	Alt + A
@	Alt + W	Æ	Alt + J
#	Alt + E	Z	Alt + T, then Z
\$	Alt + R	Š	Alt + T, then S
&	Alt + Y	ı	Alt + X
ı	Alt + D		
—	Alt + F		
Ç	Alt + G		
Å	Alt + K		
Ü	Alt + L		
İ	Alt + N		
Ş	Alt + C		
ˆ	Alt + V		
Ø	Alt + B		
Ö	Alt + N		
Ä	Alt + M		
Á	Alt + I, then A		
É	Alt + I, then E		
Í	Alt + I, then I		
Ó	Alt + I, then O		
Û	Alt + I, then U		
Å	Alt + O, then A (enter È, Ì, Ö, Ù in the same manner)		
Ä	Alt + P, then A (enter È, Ì, Ö, Ù in the same manner)		
ÿ	Alt + U, then Y (enter Ì, Ä, Ö, Ù in the same manner)		
Ä	Alt + H, then A (enter Š, Ö in the same manner)		

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APPENDIX

STANDARD ECG INSTRUCTIONS FOR THE STRONG HEART STUDY

1. ELECTROCARDIOGRAM (ECG)

1.1 Introduction

A standard supine 12-lead resting ECG is recorded during the clinic exam of the Strong Heart Family Study.

1.2 Procedure for Recording ECG

The standard electrocardiograph for the Strong Heart Study is the MAC 1200 or the MAC PC by GE Marquette Medical Systems, Inc. The standard configuration for the MAC 1200 is shown in this section. The standard configuration for the MAC PC can be found in the SHS Phase III Manual, Volume IV. A 12-lead resting ECG tracing is obtained consisting of 2.5 seconds of each of the leads simultaneously (I, II, III, aV_R, aV_L, aV_F, V₁-V₆) with a 10 second lead Rhythm Strip.

1.3 Electrode Position Measuring and Marking

Because it is essential for the study to be able to compare this ECG with other participant ECG records, a uniform procedure for electrode placement and skin preparation is required. The method and procedure for standardizing locations are outlined below.

The participant, stripped to the waist, is instructed to lie on the recording bed with arms relaxed at the sides. The individual is asked to avoid movements, which may cause errors in marking the electrode locations, but encouraged to converse with the technician. Prior experience with electrocardiograms is discussed, as is the purpose of the ECG recording. The participant should be told this is a research ECG to be used for statistical analysis later in the study. However, it can also be used by the clinic physician for general diagnostic purposes, and a copy can be sent to the individual's private physician.

For best electrode/skin interface, place the electrodes on the skin at least 2-3 minutes before taking the ECG. Patient information can be entered in the MAC 1200 during this time.

A good felt tip pen is used to mark the six chest electrode positions. It is extremely important that care be taken to locate these positions accurately. Therefore, the procedure given below must be meticulously followed. Electrode positions in women with large, pendulous breasts must be determined in relation to the anatomic points

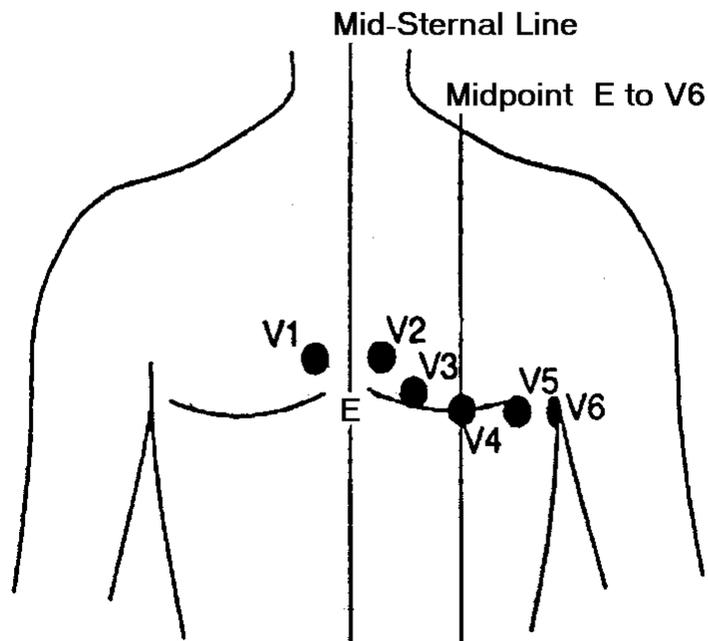
described below – as for all participants. The electrodes must then be placed on top of the breast (in the correct position).

1.3.1 Chest Leads (see Figure below)

1. Electrode V₂

Locate the sternal angle and second left rib between the index and middle fingers of your right hand. Count down to the fourth rib and identify the fourth intercostal space below it. Locate V₂ in the fourth intercostal space immediately to the left of the sternal border.

Figure



2. Electrode V₁

Locate the electrode V₁ in the fourth intercostal space at the right sternal border. This should be at the same level as V₂ and immediately to the right of the sternum.

3. Anterior 5th Interspace Marker (E Point)

Identify the fifth rib and fifth intercostal space below V_2 by counting down ribs as described for V_2 . Follow this space horizontally to the midsternal line and mark this point. This is the “E” point (see E in Figure above).

4. Electrode V_6

Locate the V_6 electrode at the same level as the E point in the midaxillary line (straight down from the center of the armpit). If breast tissue is over the V_6 area, mark the V_6 location on the breast. Do not attempt to move the breast in order to mark V_6 on the chest wall, unless doing so is absolutely necessary to achieve a better anatomic position.

5. Electrode V_4

Electrode V_4 is located using the E- V_6 Halfpoint Method. Using the medical tape measure used in anthropometry, measure the distance between the E point and the V_6 marking. The tape should be resting lightly on the skin, not pressing into the flesh. The E and V_6 marks should be clearly seen. Place electrode V_4 midway between E and V_6 .

6. Electrode V_3

Using the medical tape measure employed in #5, mark the location of electrode V_3 midway between the locations of V_2 and V_4 .

7. Electrode V_5

Using the medical tape measure again, mark the location of electrode V_5 midway between the locations of V_4 and V_6 .

1.3.2 Limb Leads (see Figure 4-2 on p. VI-21 and Figure 4-5 on p. VI-22)

Locate electrode LL on the left ankle (inside)

Locate electrode RL on the right ankle (inside)

Locate electrode LA on the left wrist (inside)

Locate electrode RA on the right wrist (inside)

(The electrodes on the right limbs should be placed at same approximate location as the corresponding left limb electrodes)

1.4 Skin Preparation

Skin preparation is undertaken only in the presence of observed technical problems due to poor electrode contact. As a first step, it may be sufficient to rub the skin lightly with an alcohol wipe, a tongue depressor, or a piece of gauze to produce reddening. If this does not resolve the problem, then:

1. With the participant's consent, remove any excess hair from each electrode site on the chest using a shaver.
2. At each electrode location in turn, the outer horny layer of the epidermis is removed by gentle dermal abrasion with a piece of gauze. Only three passes (in the form of an asterisk) at each site using light pressure are required.

If the skin preparation has removed the felt pen marking at any of the electrode sites, these are accurately re-established by carefully repeating the procedure described above in section 1.3 Electrode Position Measuring and Marking. It is important that the electrode sites be marked using the exact technique described.

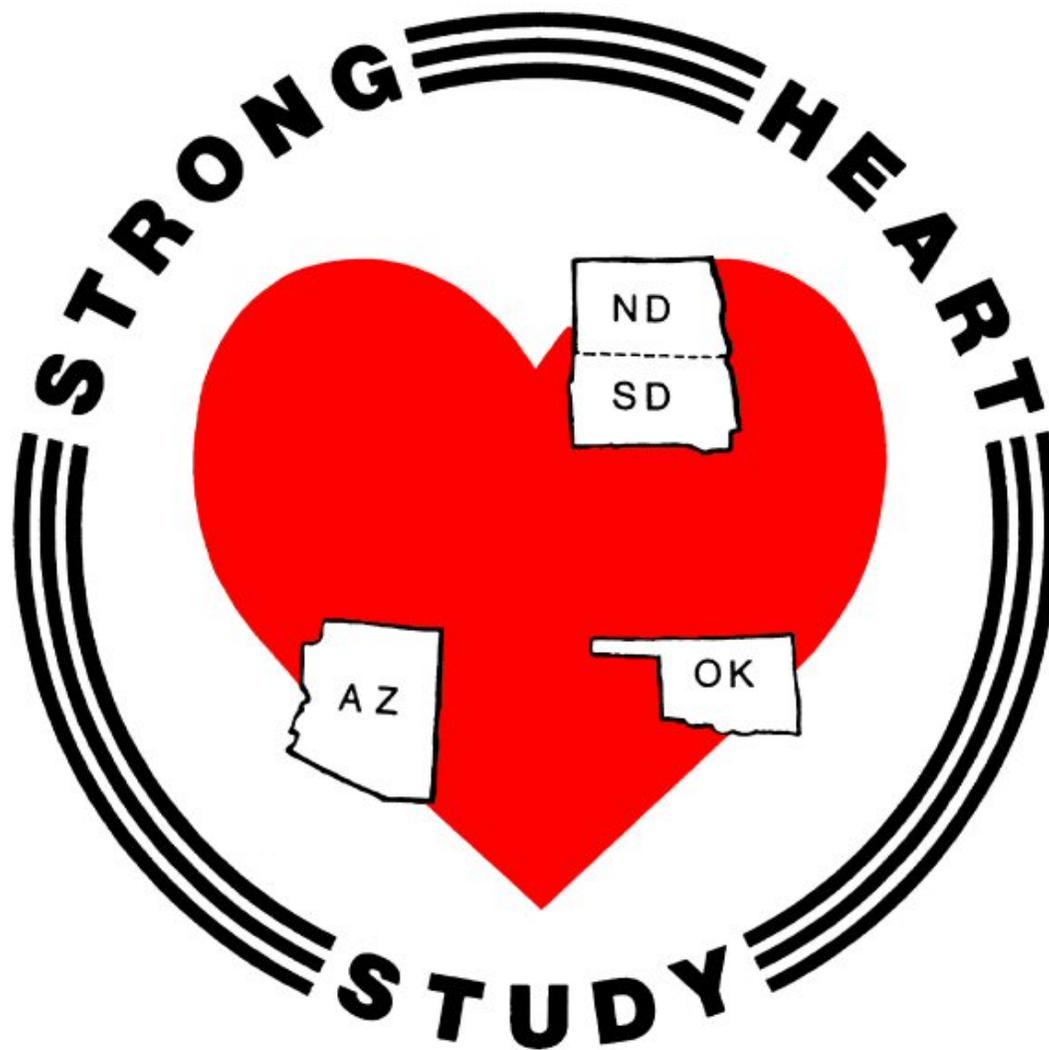
1.5 Application of Electrodes

Disposable electrodes are used in the Strong Heart Study. Adapters are used with the lead wires to connect the "banana" plug from the MAC 1200 lead wire to the disposable electrode via a clip.

When placing each electrode, avoid overlap of gel from one electrode to the next. The clip should be attached so that it touches only the silver ends of the electrode.

Center the four limb electrodes on the inside of the wrist or ankle with the tabs for the clips pointing toward the head. Center the six chest electrodes on the chest markings with the tabs pointing down. Do not let the electrodes overlap or touch each other, if possible.

Clip the appropriate lead wire to each electrode (see Figure 4-4 on p. VI-22). Do not pull or jerk tangled wires. To untangle wires, disconnect lead wires from electrodes.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Seven

DATA ENTRY

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual

Volume Seven

DATA ENTRY

June 01, 2001

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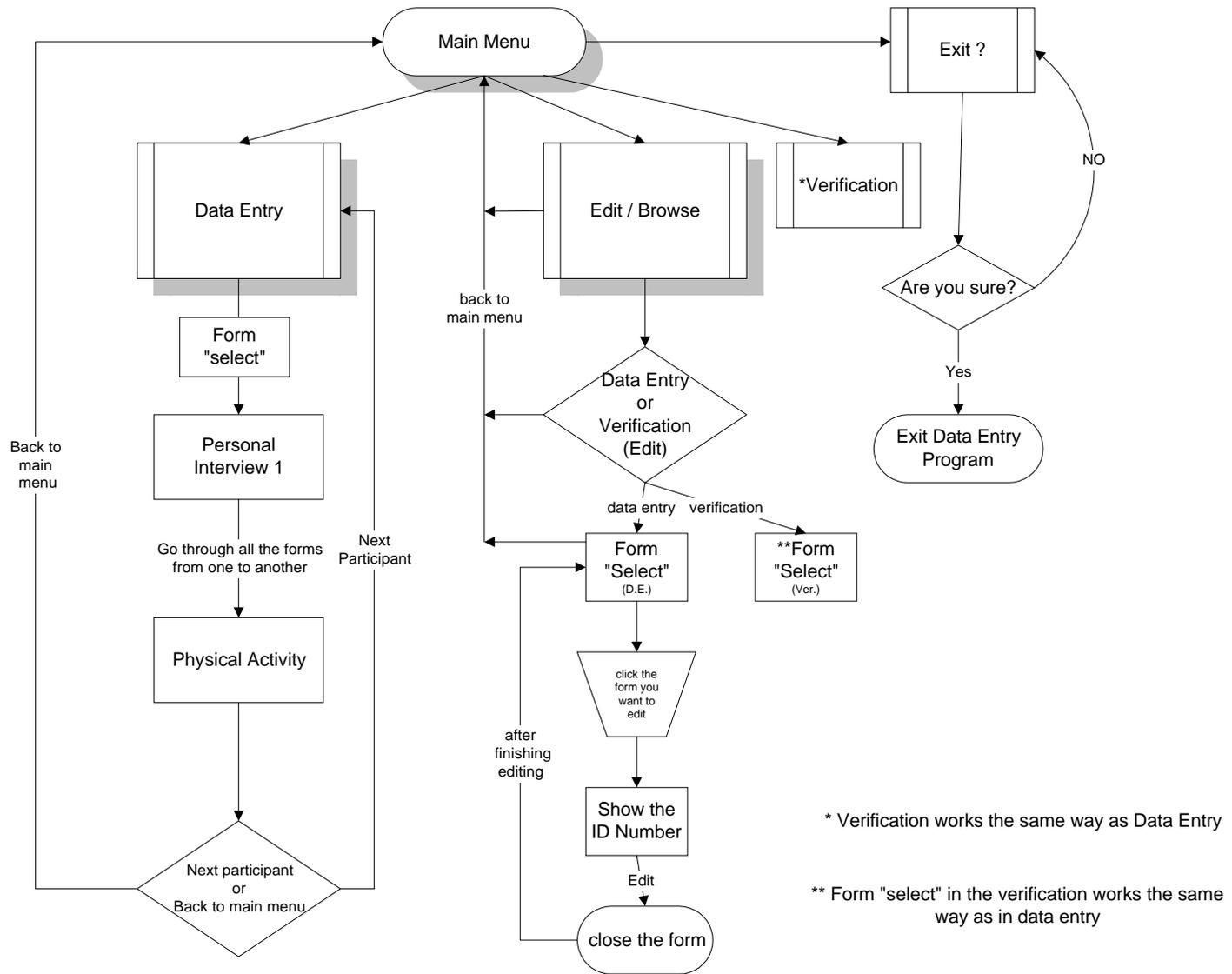
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VOLUME VII
DATA ENTRY

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DATA ENTRY FLOWCHART

Introduction

This manual was developed to assist data entry personnel understand and use the programs developed for Phase IV of the Strong Heart Study. The following topics will be discussed: data entry/verification, editing data, correcting data entry errors, data entry codes, and data clean-up.

Before You Start

Before entering data, the data entry operator should screen each participant's folder. This includes putting the forms in numerical order and skimming each form to make sure it has been filled out properly. If you find errors, contact the interviewer and correct them before you enter the data. Performing these preliminary steps will make the data entry process more efficient and less tedious. If you should have complications when using the data entry program, contact the Coordinating Center.

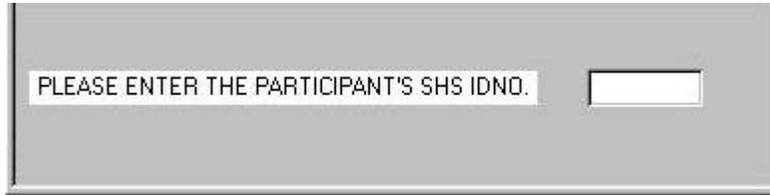
Getting Started

To get started, double click the Strong Heart Data Entry icon in Windows '98 or 2000, then click the "Connect" button in the Terminal Services program window that will pop up. Once you enter your Username and Password to log in to the session, the following menu will appear (Main Menu) (**Note: See pages VII-10 to VII-12 for medications data entry instructions.**):



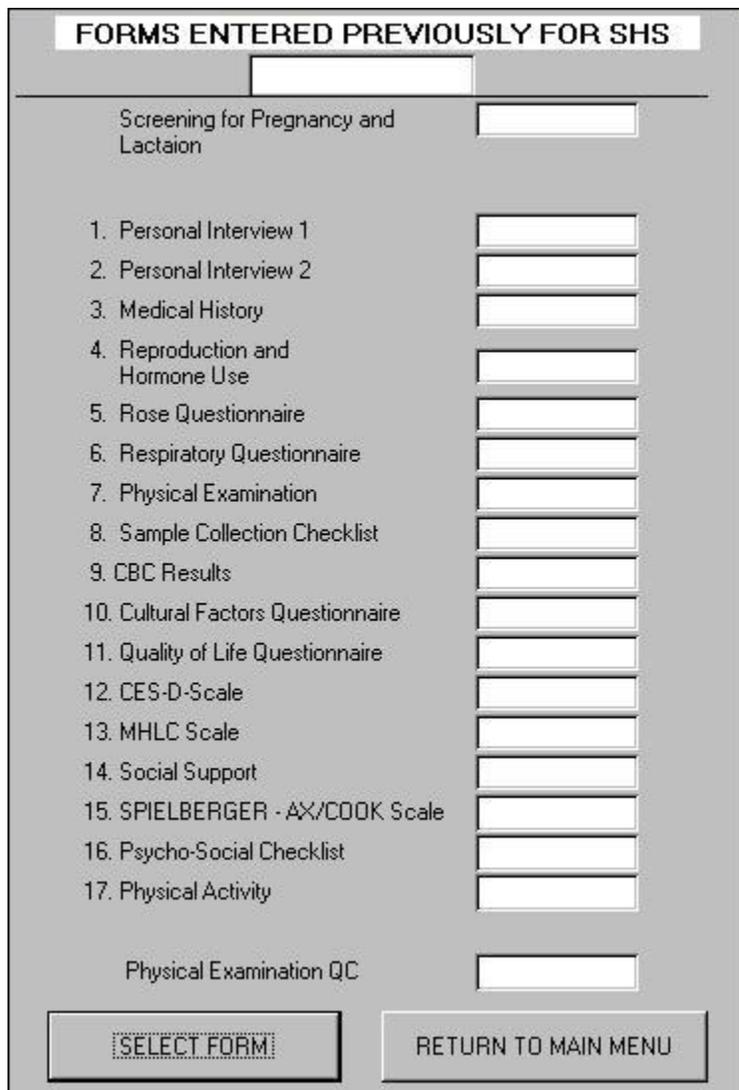
Data Entry

When one selects 'Data Entry', The following input box will appear:



A rectangular box with a grey background and a thin black border. Inside, the text "PLEASE ENTER THE PARTICIPANT'S SHS IDNO." is displayed in a white rectangular area. To the right of this text is a small, empty white input field.

After entering an ID number and pressing the 'Enter' key, another screen will appear:



A screen titled "FORMS ENTERED PREVIOUSLY FOR SHS" with a grey background. At the top, there is a white input field for an ID number. Below this is a list of 17 forms, each with a corresponding input field to its right. The forms listed are:

- Screening for Pregnancy and Lactaion
- 1. Personal Interview 1
- 2. Personal Interview 2
- 3. Medical History
- 4. Reproduction and Hormone Use
- 5. Rose Questionnaire
- 6. Respiratory Questionnaire
- 7. Physical Examination
- 8. Sample Collection Checklist
- 9. CBC Results
- 10. Cultural Factors Questionnaire
- 11. Quality of Life Questionnaire
- 12. CES-D-Scale
- 13. MHLC Scale
- 14. Social Support
- 15. SPIELBERGER - AX/COOK Scale
- 16. Psycho-Social Checklist
- 17. Physical Activity

At the bottom of the list is "Physical Examination QC" with an input field. At the very bottom, there are two buttons: "SELECT FORM" and "RETURN TO MAIN MENU".

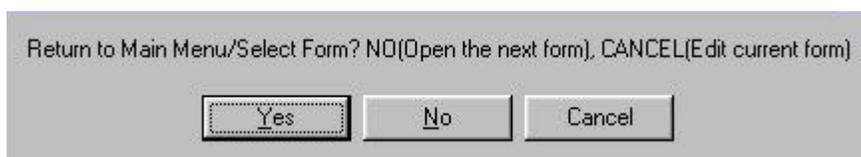
If a date is displayed in the right hand column, that form

has already been entered for that participant. This will help you keep track of which data have already been entered for a participant. Personal Interview Form 1 must be entered first in order for the data entry date(s) to appear in the right hand column.

To proceed, left click the button labeled 'SELECT FORM'. You will see a screen like the one below. This is called the Select Form:



To begin entering data, left click Personal Interview Form One. After you exit the last field, a message box will appear asking you if you would like to open the next form.



If you select 'No', the next form, Personal Interview Two, will be opened and Personal Interview Form 1 will be closed. If you select 'Yes', the cursor will go back to the 'Main Menu/Select Form' as shown below. If you select 'Cancel', you will remain in Personal Interview Form One. For all subsequent forms, the same message box will appear prompting you for the next form.

Please select one of the following:

<input type="checkbox"/>	1	Back to Select Forms and choose form for the same participant
<input type="checkbox"/>	2	Back to Main Menu

After exiting from the last field of the last form (Physical Activity), a message box like the following will appear:

You just finished this participant!
Do you want to

<input type="checkbox"/>	1	Go back to the main menu?
<input type="checkbox"/>	2	Enter the next participant?

If you want to enter the Screening for Pregnancy and Lactation form, close the current form and click the button on the Select form

Verification

The process of entering data for 'Verification' is identical to 'Data Entry'. Since the data entry screens are also identical, we have placed a red colored 'V' in the upper left hand corner to help you differentiate between the two.

Edit/Browse

In order to edit data, you must select 'Edit/Browse' from the Main Menu. After selecting this button, another screen will appear asking you to select which database you would like to edit:

Please select one of the following:

- 1 Edit First Entry
- 2 Edit Verification
- 3 Back to Main Menu

Once the database you want to edit/browse is selected, the Select Form (page 4) will appear. Choose the form you wish to edit/browse. Once you have made your selection, the form will open and the data entered for the specific participant will be displayed.

After you have finished making corrections, **you must close the form manually**. You can go to the menu bar, **left** click the button, and close the form. After you close the form, you will return to the Select Form.

Making Corrections

In order to produce a data entry program that is user friendly and selective about the data entered, skip patterns and message boxes have been added. Unfortunately, the same features that are intended to help the data entry operator can be a source of frustration when one is trying to correct errors, unless you follow these suggestions.

We will discuss two different situations. A data entry error noticed **BEFORE** exiting the field, and a data entry error noticed **AFTER** exiting the field in question.

1) Error noticed **BEFORE** exiting the field.

Solution: Use the backspace key to remove the error and enter the correct value.

2) Error noticed **AFTER** exiting the field.

Solution: We suggest that you use the mouse to reenter the field with the mistake. If you can see the field, place the I-bar in the field and **left** click. Make your correction and continue with the rest of the form. If, after exiting the field that contains the error, the Data Entry program moves to the next page, use the mouse to move the scroll bar (located on the right hand side of the screen) up until you see the field you wish to correct. **Left** click in the field and make your correction.

When attempting to reenter a field that contains an error, this message box may appear:



This means that you are trying to leave a field that requires an entry. First, select 'OK' on the message box. Then, respond to the question, but **DO NOT PRESS 'ENTER'**. Now you can use the mouse to reenter the field with the error and correct it.

If you notice an error after the form is closed, make a note of it and correct it after completing all of the forms for that participant.

Data Entry Codes

In some cases, the participant responding to a question may not know the answer or refuse to answer the question. Some questions have these options listed while others do not. For those that do not, the **interviewer** should indicate these responses by putting a question mark for unknown or drawing two lines through the box for refused. Since the data entry program will not allow the operator to use these symbols, we have developed codes which can be used instead. It was not possible to use the same code for every type of field (e.g. Text, Numeric, etc.), but we tried to make the codes as consistent as possible. Finally, if a question is not answered and there is no indication that the participant did not know or refused, we classify this as missing. The following is a list of data entry codes by variable type.

Text variables (Questions which have options listed or are not quantitative):

7 = Missing
8 = Refused
9 = Unknown

Numeric variables (Questions requesting quantitative information such as measurement data):

777 = Missing
888 = Refused
999 = Unknown

Time variables (Questions requesting the time of an event):

00:07 = Missing
00:08 = Refused
00:09 = Unknown

Date variables (Questions requesting the date of an event):

01/01/1007 = Missing
01/01/1008 = Refused
01/01/1009 = Unknown

Note: if only the year is known use: 06/30/year
if only month and year are known use: month/15/year

Currency variables (Questions requesting a dollar amount):

\$777.00 = Missing
\$888.00 = Refused
\$999.00 = Unknown

If you are not sure which variable type you are working with, leave the field empty and press 'ENTER'. This will cause a message box to appear telling you that the field cannot be left blank, but it will also tell you what codes are appropriate for

that field. Select 'OK' and enter the appropriate response.

Guidelines for Data Entry and Verification

To reduce the likelihood that a data entry error will be repeated during verification, data entry and verification should not be done by the same person. We understand that this is not possible at all field sites. If the same person is performing both data entry and verification, here are two suggestions:

- 1) For a specific participant, do data entry and verification at least a day apart.

OR

- 2) If both data entry and verification must be entered on the same day and you have data for more than one participant:
 - i) Do data entry for all of the participants, then
 - ii) Do verification for all of the participants in the same order that data entry was performed.

Data Clean-Up

Data will be stored at the CC as it is entered (form-by-form), so there will be no need for separate backup or transmission procedures at the FC computers. Opportunities to edit previously entered data through the online Data Entry program will be limited, as CC staff will "sweep" all raw data on a weekly basis, Mondays before 12:00 Noon Central Time -- moving them from the online entry database into first-stage cleaning (see below).

The CC will be responsible for identifying: missing forms, orphan records (records which do not belong to any participant according to the SHS ID number listed on the form), incomplete forms, discrepancies between 'Data Entry' and 'Verification', and values which appear to be unreasonable. The field sites will be responsible for providing information to the CC so that the aforementioned problems can be rectified.

Data clean-up will occur in two stages.

Stage One: Raw data are examined at the CC. Incomplete items and discrepancies between 'Enter' and 'Verify' are listed and sent to the field via fax. Field centers will fax copies of the form with correct information circled and all confidential information

marked off and participant ID number written on it within five working days. The CC will make corrections to the database.

Stage Two: Statistical checks will be performed to identify unreasonable values. These items will be listed and sent to the field. Field personnel will perform verification of the suspect data. A response (fax, as detailed under stage one) is expected within five working days.

Upon completion of both stages, cleaned records will be appended to the Main Database. Please note that the Main Database will be used to perform analyses for reports and publications. Therefore, if a field site were to identify any data entry errors after data clean-up has been completed, they must notify the CC promptly.

In cases where there are many data entry errors found in stage one of data clean-up, the CC may request that changes to a specific record be made at the field and said records be re-entered through the online Data Entry program.

If You Have Questions

So that your questions may be answered efficiently, please address your queries to the following personnel:

Data Entry Programs	- Dr. Fawn Yeh
Data Clean-Up	- Ms. Debra Gates
Forms	- Dr. Jeunliang Yeh
Data Entry Online Server Logins, or Terminal Services (FC computer) client program	- Mr. Leon Kalbfleisch

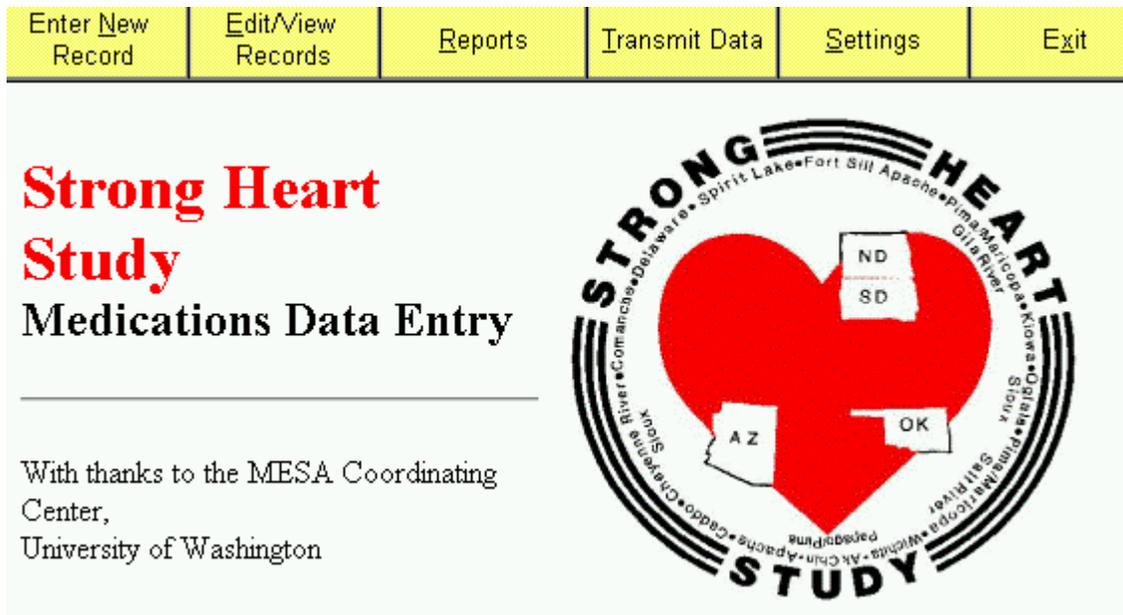
Note: See the following pages (pp. VII-10 to VII-12) for instructions regarding data entry for medications.

Medication Data Entry

In order to enter the medication data, you must select 'Medication Program' from the Main Menu. **See additional instructions on the following pages.**



Double click the 'Medication Program' button several times and wait about 20 seconds, another screen will appear showing Strong Heart Study Medications Data Entry System. You can select different options (Enter New Record, Edit/View Records, and Exit) by clicking on different buttons (see top of this screen).



Additional instructions from the Coordinating Center:

1. Please ignore the "Reports", "Transmit Data", and "Settings" buttons. This Medication Data Entry program was modified from the MESA study for the SHS to use. These buttons are specifically for MESA. Don't even click any of them. If you accidentally hit any of these buttons and cause some error messages to pop-up, don't panic, just get out of the program and start over again.
2. You have to find the Interviewer's code and interview date on the third page of the data form. Type both of them in the boxes. Do not neglect the interview date. If you don't type it in, the program will automatically assign the date you enter this form as the interview day.
3. You have to count the total number of medications that the participant was taking. This number includes both prescribed and over the counter (OTC) medications. The program will use this number to cross check the number of medications you are entering. If at the end, the program tells you the number of medications you entered does not match the number you claimed, check the total that you entered. If the entry is correct, you can tell the program to change this number to match the entries.
4. When entering the medication name, type in the first few letters. You will see the medication menu scroll down to match the drug name you are typing. Click the dose that matches the strength listed on the paper form. If you cannot find the correct strength, choose "---" if it appears in the list. Otherwise, choose the closest dose. You may ask if this will affect the medication codes assigned for this particular drug. If it is indeed the same drug with a different package, different strength, or different commercial brand, it will have a different NDC code, but the Class Code will always be the same. In the SHS we are primarily using Class Code to determine treatment, so it is perfectly O.K. to do so.
5. If you cannot find a match, first, check the spelling with your Field Coordinator. If you decide the spelling is correct and still cannot find a match, go ahead and click "add" to complete the data entry. Keep a log of these "unmatched" medications and send the log to the CC once a month. The CC will check with MESA investigators in Seattle to solve the problem.
6. Please do not type the medication name too fast, especially when you have a long drug name. The program only identifies

the first thirteen characters of the drug name. If you type too fast, the pointer will roll back to the top of the menu as if it cannot find a match, and you will have to re-type the medication name.

7. Put a check in the correct box to indicate if this is an over-the-counter (OTC) medication. The next three boxes are for entering the number of doses taken in what time period; check the "PRN" box only if the medication is taken "as needed". Then click the Update button. This will add the medication to the list on the right hand side. Now repeat this process for all the remaining medications listed on the form. When you have entered all medications, click the "Done" button. This will save your entries and return you to the main menu screen.
8. Since we are using a program developed by MESA, we cannot change the contents or format of the program, Thus, we can not make the Medications Program match our other data entry programs and data forms. Please bear this with us in this regard.

Enter Record			
Your ID:	Date Keyed:	Interviewer ID:	Date Form Initiated:
<input type="text"/>	<input type="text" value="11/29/2001"/>	<input type="text"/>	<input type="text" value="11/29/2001"/>
Participant ID:	<input type="text"/>	Visit:	<input type="text" value="1"/>
Comment:	<input type="text"/>		
List All Meds?		Number of Meds	
<input type="radio"/> Yes	<input type="radio"/> Took None	To Enter:	<input type="text" value="0"/>
<input checked="" type="radio"/> No	<input type="radio"/> Refused	Unable:	<input type="text" value="0"/>
Specify Reason for Refusal:			
<input type="text"/>			
<input type="button" value="Enter Medications"/>		<input type="button" value="Cancel"/>	<input type="button" value="Save and Close"/>
<div style="background-color: #cccccc; height: 50px;"></div>			

"Your ID" = data entry person's code number.

"Date Keyed" = should default to the current date and can be skipped.

"Interviewer ID" = interviewer's code number from page three of the medications form.

"Date Form Initiated" = Date of Interview, from page three of the medications form.

"Participant ID" = SHS ID number.

Ignore "Visit" as we are not using this.

"Comment" = use to record comments from page three of medications forms, specifically to record use of any home remedies.

"List All Meds" = should be either Yes or Took None in most cases.

"Number of Meds" = enter the total number of medications to be entered, both prescription and non-prescription.

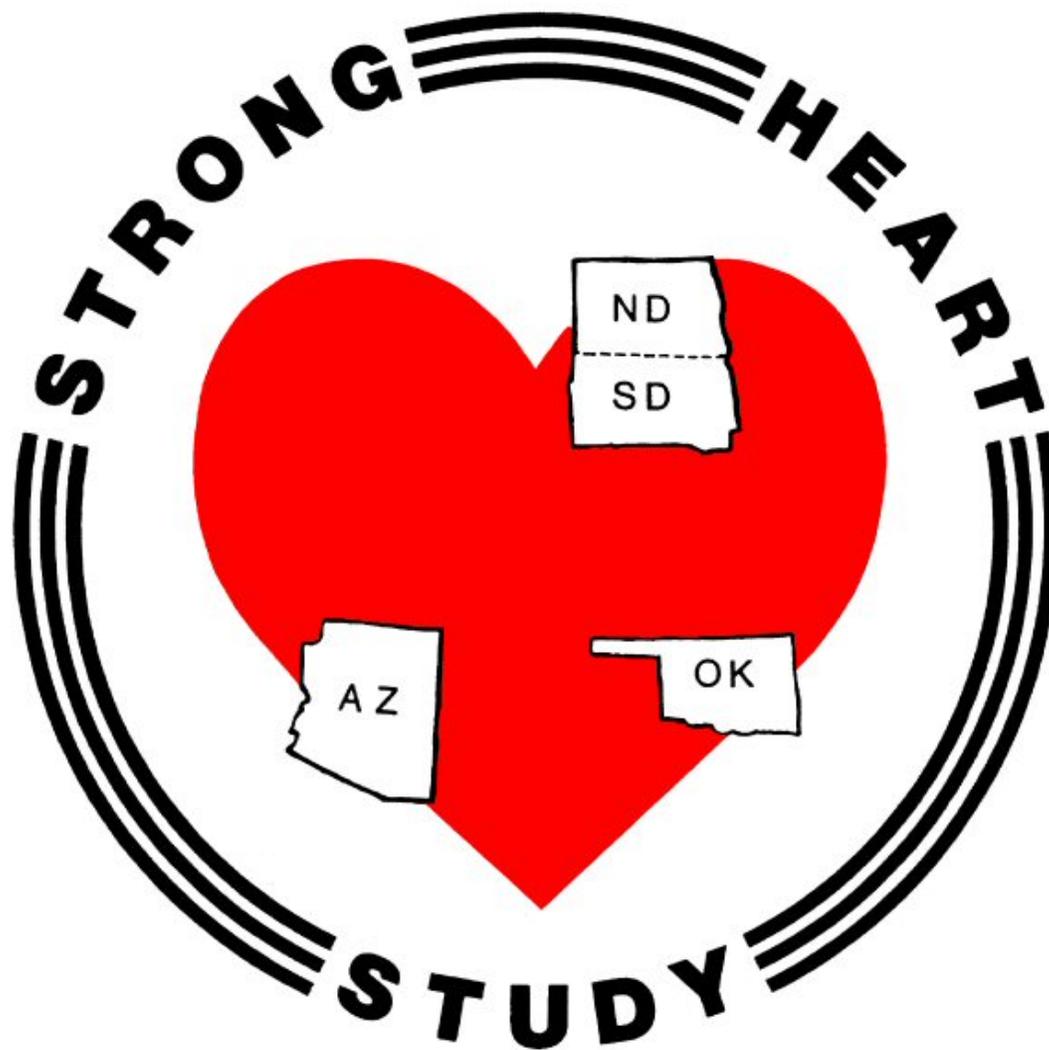
"Specify Reason for Refusal" = if participant refuses to provide medications information, enter reason here.

Click on "Enter Medications" to get the screen to list medications.

Enter Medications																					
Participant	Visit 1																				
Medication: <input type="text"/>	<table border="1"> <thead> <tr> <th>Medication</th> <th>Dose</th> </tr> </thead> <tbody> <tr><td> </td><td> </td></tr> </tbody> </table>	Medication	Dose																		
Medication		Dose																			
Dose: <input type="text"/>																					
OTC: <input type="checkbox"/> PRN: <input type="checkbox"/>																					
Taken/Period: <input type="text"/>																					
Rx/Period: <input type="text"/>																					
<input type="button" value="Add"/>																					
<input type="button" value="Reset"/>																					
<input type="button" value="Cancel"/>																					
<input type="button" value="Done"/>																					
<input type="text"/>																					

"Medication" = name of medication.
 "Dose" = strength of medication.
 "OTC" = check this if medication is non-prescription.
 "PRN" = check this if medication is to be taken on an "as needed" basis.
 "Taken/Period" = amount of medication participant has taken in what period of time, i.e., 1/day.
 "Rx/Period" = prescribed amount of medication participant is to take in what period of time, i.e., 1/day.

Click on "Add" after each medication has been entered. When all medications have been entered, click "Done". This will return you to the main menu where you can add another participant's records. When you are finished with all records to be entered in a session, click on "Save and Close", then click "Exit" in the top right corner to quit the program.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Eight

PSYCHOSOCIAL QUESTIONNAIRES

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Eight

PSYCHOSOCIAL QUESTIONNAIRES

June 01, 2001

For copies, please contact

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VOLUME VIII
PSYCHOSOCIAL QUESTIONNAIRES

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1. RATIONALE FOR PSYCHOSOCIAL QUESTIONNAIRES

Studies of Psychosocial Factors

Over the last twenty years, scientists and clinicians alike have been looking at the relationship between psychosocial factors and health outcome. To date, there has been increasing recognition among the medical community that psychosocial factors (e.g., hostility, anger, stress, depression and social isolation) contribute to many forms of disease. One of the most well documented areas in this research has been in the associations between psychosocial variables and cardiovascular disease.

The idea that psychosocial variables could affect health is not a new concept. In 1628, while describing the circulatory system, William Harvey noted that emotions affect the heart. William Osler, often described as the father of internal medicine, described the typical heart disease patient as “a keen and ambitious man, the indicator of whose engine is always at full speed ahead.” (Clay, 2001). Since then, our knowledge of the effects of psychosocial variables and disease outcome has increased considerably. In recent years, it has been found that the personality trait of cynical hostility predisposes individuals for cardiovascular disease. Depression and social support factors are related to outcomes after the onset of heart disease and several intervention studies have shown efficacy in psychosocial intervention improving both the outcome and the quality of life of individuals suffering from heart disease (Clay, 2001). While some of these psychosocial factors appear to be environmentally created, others appear to have a genetic component. Eysenck (1982) concluded through the study of twins separated at birth, “that genetic factors contribute something like two-thirds of the variance in major personality dimensions”. Loehlin and his colleagues followed 400 children who were brought up in either biological or adoptive families and concluded adopted children primarily resembled their biological parents in personality characteristics, even though they had never been in contact (Loehlin, Willerman, & Horn, 1987). These implications both in health outcome and genetic implications justify the use of psychosocial instruments in Phase IV of the Strong Heart Study. The Strong Heart Study provides a rare opportunity to continue to look at how these factors contribute to both the physical and psychological outcomes of an American Indian population.

The forms are designed to be self-administered, but SHS Staff should check all the forms for completeness and ask questions that have not been answered. The following questionnaires are administered to all Phase IV SHS participants: Cultural Factors Questionnaire; Quality of Life – SF-12; CES-D depression scale; Multidimensional Health Locus of Control (MHLC); and Social Support. The Spielberger-Ax/Cook Medley Scale on anger and hostility is an optional form, but will definitely be administered in the Dakota Center.

References:

Clay, R. A. (2001). Research to the heart of the matter. *Monitor on Psychology*, 32, 1, 42-45.

Eysenck, H. J. (1982). *Personality Genetics and Behavior*. New York: Praeger.

Loehlin, J. C., Willerman, L., & Horn, J. M. (1987). Personality resemblance in adoptive families: A ten-year follow-up. *Journal of Personality and Social Psychology*, 53, 961-969.

2. RATIONALE AND INSTRUCTIONS FOR THE CULTURAL FACTORS QUESTIONNAIRE

The terms “cultural factors” and “acculturation” are difficult to define and assess in epidemiologic studies. In the Strong Heart Study, we have had many discussions about the impact of traditional American Indian culture on heart disease and health problems. We have also discussed the dramatic changes that have occurred when younger generations lose many of the old cultural beliefs, values, and traditions and adopt Western beliefs, values, and traditions. This process is usually considered to be one of “acculturation”. The SHS considered many instruments to assess this transition so that we can determine its impact on health and disease. In the interest of simplicity and because there is no universally accepted instrument for this purpose, the cultural factors survey has been used in Phases II, III, and IV of the study. Chani Phillips developed the cultural factors questionnaire used in Phase II. The questionnaire used in Phase II was simplified for Phases III and IV. A brief rationale for inclusion of these questions follows.

There seems to be universal agreement that fluency in native languages is a very objective measure of how well people have retained their culture. Questions 1-3 assess the ability to speak the language and the fluency in the language. Questions 4-7 are self assessments of how well connected the participants feel with tribal tradition and culture and with non-Indian culture.

See Form S10, Volume 3, Appendix D.

REFERENCES

Language

Marin F, Sabogal F, Marin B, et al. Development of a short acculturation scale for Hispanics. *Hispanic Journal of Behavioral Sciences*. 1989; 8 (2): 183-205.

Han P, Hagel J, Welty T, Leonardson G. Cultural factors associated with health risk behavior among Cheyenne River Sioux Indians. *American Indian and Alaska Native Mental Health Research Journal*. 1994; 5: 15-29.

Cultural Identification

Oetting ER & Beauvais F. Orthogonal identification theory: The cultural identification of minority adolescents. *International Journal of Addictions*. 1991; 23 (5A&6A): 655-685.

Cultural Identification Questions from:

Denver Indian Social Health Survey. Denver Indian Health and Family Services. Denver, CO.

3. QUALITY OF LIFE - SF-12 Form

The SF-12 Health Survey Questionnaire will be used in Phase IV of the Strong Heart Study to replace the SF-36, which was used for the past two examinations (Phases II and III). The main reason for using the SF-12 instead of the SF-36 is to save time by using this shorter version of the Health Survey questionnaire. The SF-12 version generates two summary measures, physical health and mental health, describing health-related quality of life. These two summary scores, the physical component (PCS-12) and the mental component (MCS-12) outcome scores, are compatible to those generated by the SF-36 and have been validated in various populations.

See Form S11, Volume 3, Appendix D.

4. CENTER FOR EPIDEMIOLOGICAL STUDIES DEPRESSION SCALE (CES-D)

Depression and Health A vast research literature exists establishing to varying extents the relationship between depression and health. Measurements of depression can be useful to assess the association of depressive symptoms with health risk behavior, prevalence and incidence of cardiovascular disease, and also to evaluate the effect of health status or CHD on mood states.

Assessment of Depression The Center for Epidemiologic Studies of Depression Scale (CES-D) scale was originally developed as a general screening measure for depression (Radloff, 1977). It is a 20-item self-report instrument designed by the Center for Epidemiologic Studies to measure current level of depressive symptomatology, and especially depressive affect. The items were chosen (from 5 previously used depression scales) to represent all major components of depressive symptomatology. These include: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, loss of appetite, sleep disturbance, and psychomotor retardation. Items are rated on a 4-point scale indicating the degree of their occurrence during the last week. The scales range from “rarely or not at all” to “most of the time.” The scale can distinguish between clinical groups and general community groups. Although it is usually scored continuously, there are various cutoff scores for clinical depression, with reasonable associations between cutoff scores and a clinical diagnosis (Beals et al, 1991).

CES-D Utilized by Similar Studies The CES-D is the standard scale used in numerous large scale studies including the Honolulu Heart Program, the Inter-Tribal Heart Project (Menominee, Red Lake & White Earth), Cardia, and the Stanford Coronary Prevention Project.

Reliability and Validity The CES-D has been found to both adequate test-retest reliability, and internal consistency. The internal reliability (Cronbach’s Alpha) of the CES-D is .89.

Administration Designed for self-administration, or interview format.

Scoring Twenty items are rated on a 4 point likert scale, ranging from “rarely, or not at all” scored as 1, to “most of the time” scored as 4. Four items are reversed when scored: #'s 5, 9, 13, and 17 so that 1 and 2 scores are changed to 4 and 3 respectively (and vice versa). Item scores are then summed for a total depression score (the higher the score, the greater the depression). Item #21 is not a part of the CES-D scale, and so should be scored separately.

Score Interpretation Upon completion of the survey, a staff member will sum the item scores, taking into account the reverse scored items. If the total score of items # 1-20 is above the CES-D cutoff score for indication of depression, the staff member is to ask the participant if they are interested in a referral for follow-up. The staff member then notes in the chart that the verbal offer of a referral had been given to the participant.

Assessment of Depression by Strong Heart Study In Phase II, about 400 SHS participants in Oklahoma and the Dakotas were administered the CES-D questionnaire. In Phase III, all SHS participants in Oklahoma and SHS participants from the Spirit Lake Tribe were administered the CES-

D. Analysis of data from one of the Dakota Center Tribes showed that males and females were similar on psychological, health-related, and cultural behaviors (Plaud et al, 1998). Family history of diabetes was associated with depression (Plaud et al, 1997). Further analyses of the results of SHS data on depression are planned.

See Form S12, Volume 3, Appendix D.

References

Beals J, Manson SP, Keane EM, & Dick RW. Factorial structure of the Center for Epidemiological Studies-Depression scale among American Indian College students. *Psychological Assessment: A Journal of Consulting and Clinical Psychology*. 1991; 3: 623-627.

Plaud JJ, Schweigman K, Welty TK. Health and depression among American Indians: Psychosocial data from the Strong Heart Study Phase II. *International Journal of Rehabilitation and Health*. 1997; 3:51-59.

Plaud JJ, Schweigman K, Welty TK. Health-related and cultural gender differences in an aging Northern Plains Indian Population. *Journal of Clinical Geropsychology*. 1998; 4:111-118.

Radloff L. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychosocial Measurement*. 1977; 1: 385-401.

5. Multidimensional Health Locus of Control Scale (MHLC)

Health Locus of Control

The construct of Health Locus of Control was derived from the Social Learning Theory developed by Rotter in 1966. This theory states that an individual learns on the basis of his or her history of reinforcement. Health Locus of Control (HLC) is the degree to which individuals believe that their health is controlled by internal or external factors. Whether a person is internal or external is based on a series of statements. The statements are scored and summed to determine whether the individual has internal or external health beliefs.

There have been multiple studies done that have suggested that HLOC can play a major role in health outcome. Individuals who have a more internal HLOC perceive that they retain power over health related rewards and are prone to obtain proper nutrition, exercise, rest, stress reduction, and to adopt prevention/ enhancement strategies to maintain/ improve the state of their health. Those who have a more external HLOC believe that chance, god, or doctors, etc., control their health; they are liable to exhibit behaviors which are less action oriented (more reaction oriented). This can be especially important in diseases that have a strong behavioral component such as diabetes or heart disease.

The MHLC scale has three subscales designed to measure the construct of HLOC.

- Internal HLC (IHLC) is the extent to which one believes that internal factors are responsible for health/illness.
- Powerful Others HLC (PHLC) is the belief that one's health is determined by powerful others.
- Chance HLC (CHLC) measures the extent to which one believes that health illness is a matter of fate, luck or chance.

Reliability & Validity

The MHLC subscales have been shown to be reliable in many studies. They have been shown to have Cronbach alphas in the .60-75 range and test-retest stability coefficients ranging from .60 - .70. The MHLC scale is widely considered to be the instrument of choice when measuring the construct HLC.

Administration

This scale was designed for self-administration, or in interview format. Each item is to be answered on a 4 point Likert scale where "Strongly Disagree" is 0, "Disagree" is 1, "Agree" is 2, and "Strongly Agree" is 3.

Scoring

The score on each subscale is the sum of the values for each item on the subscale. All of the subscales are independent of one another, so there is no such thing as a “total” MHLC score. The items for the three subscales are as follows:

Internal:	1, 6, 8, 12, 13, 17
Chance:	2, 4, 9, 11, 15, 16
Powerful Others	3, 5, 7, 10, 14, 18

See Form S13, Volume 3, Appendix D.

References

Wallston KA, Wallston BS, & DeVellis R. Development of the multidimensional health locus of control (MHLC) scales. *Health Education Monographs*. 1978; 6(2):160-170.

6. SOCIAL SUPPORT

Definition of Social Support

Definitions of social support include objective and subjective elements of social support from the ability to gain tangible (instrumental) support from friends (such as a car ride), to appraisal or advice and also emotional support. Cobb emphasizes that the individual believes he/she is esteemed, cared for and loved and belongs to a network that fosters communication and mutual obligation.

Early Work on Social Support

Some of the early work on social support focused on communities in transition. Cassel notes that individuals involved in rapid change of culture or stress (change in social support) may be more susceptible to disease. One study by Cassel and Tyroler noted that 1st generation workers who moved from rural communities had more health problems than second generation workers, who they theorized were not so much in transition and were more familiar with life in a factory town. Marmot, studying Japanese men and controlling for usual cardiovascular risk factors, noted that 5/6 measures of social assimilation with western culture correlated with increased prevalence of CHD (controlling also for culture of upbringing). However, there were some limitations with this study as it was cross-sectional. Bruhn, Phillips and Wolf noted members of a community of Roseto, Pennsylvania in the years 1955-1965 had low rates of CVD compared to other surrounding communities; these lower rates of CVD were felt to be related to differences in communities and social cohesion; it was predicted that loosening of family ties and community cohesion would be accompanied by an increase in CVD - and this is exactly what happened.

Given the social disruption endured by American Indian tribes over the last few hundred years, it would not be surprising that changes in social support/culture may contribute to health problems. However there are few such studies examining the relationship between social support and health in American Indians. A number have addressed the issues in non-Indians, indicating a correlation of social support to later CVD or mortality.

Social Support and Mortality

Berkman and Syme examined mortality in 6928 people in the Alameda county study. They used a social network index based on general categories of marriage, contacts, church membership, and membership in other groups and weighted questions to form an index score. The age adjusted relative (mortality) risk for those who had the fewest social connections (based on their social network index score) was 2.3 for men and 2.8 for women.

House and workers in 1982 in the Tecumseh study (N=2554) looked at different types of social contacts and assessed overall mortality. They prospectively examined categories of social contact, involvement in organizations, social activities, and passive solitary pursuits. Results controlled for age, CAD, FEV1 and smoking and appeared significant primarily in men, with

protective factors being, marriage, frequency of meeting of volunteer organizations, and frequency of attending social activities-sporting events/lectures.

Orth-Gomer and others (1987) in Sweden used a social interaction index, which encompassed frequency and type of visits with family members, friends, neighbors and coworkers to prospectively assess mortality and CVD mortality in 17,433 people. Controlling for age, smoking, exercise and chronic illness yielded a risk estimate of 1.36 ($p=.024$) for increased mortality with a low social interaction score; when, instead of chronic illness in the model, cardiovascular disease was controlled for instead, it yielded a similar risk estimate of 1.37 with $p=.07$.

Kaplan and workers (1998) studied 13,301 people from North Karelia, Kuopio and Eastern Finland using a social connections index that yielded a score and included categories of marital status, frequency of visiting friends/relatives, # homes visited, meetings, clubs, with the dependent variable being all cause death or CVD/IHD. Adjusting for age, geographic location, cholesterol, blood pressure, BMI, smoking, family history of CVD, urban/rural and education, and comparing the lowest quintile to all others, all-cause death revealed an OR of 2.0, death from CVD an OR of 1.8, and IHD an OR of 1.72.

Hanson and others in studying "Men born in 1914 in Malmo Sweden" examined an $N=621$ with univariate results indicating an elevated mortality risk in three categories: adequacy of social support, availability of emotional support and marital status but not for material or informational support, adequacy of emotional support, adequacy of social influence, contact frequency or social anchorage.

In an HMO study of 2603 that examined mortality along with incidence of disease, Vogt and others used a tool that evaluated social network scope, the size of the network, and frequency of contact. Adjusting for age, sex, SES, smoking, subjective health at baseline, they found that decreased mortality was strongly associated with network scope and different network domains, i.e., different types of relationships; also, size of network and frequency of contact were significantly associated with decreased risk. When examining IHD, network scope was correlated with decreased risk but otherwise none of the social support measures correlated with rates of IHD, HTN, CA, or CVA. The author suggested social networks might be more important in supporting recovery than in preventing incidence of new disease.

Penninx and workers evaluated more varied types of social support in longitudinal study of mortality that included: structural support networks, and functional receipt of social support (including two subcategories, one of instrumental social support-help with meals, chores, rides etc. and one of emotional support received-how often during the previous year they talked to a network member about personal experiences and feelings). Also, perceived support-sense of loneliness was measured. With an $N=2829$, and adjusting for age, sex, education, specific diseases, physical limitation, self rated health, alcohol and smoking, they found that high instrumental support actually predicted a higher risk of mortality; those with emotional support had about 1/2 the risk of dying and those with the highest levels of loneliness had 1.89 higher risk of death.

These results suggest that social networks or types of social contacts seem to be important in relation to health, and that instrumental support (loans, car rides) may not be a major contributor to ameliorating health risks. Furthermore, perceived emotional support may also play an important role in mediating the reduced risk of mortality in some studies.

Recommendations for a social support scale for Phase IV of the SHS

In phase II of the SHS, a social support scale, the interpersonal support evaluation list (ISEL), was piloted in about 500 participants. Initial analyses showed elements of convergent/divergent validity and good reliability coefficients; however, on further analysis, it did not break down into the expected factors of tangible, appraisal, belonging and self-esteem. This is concerning, as others have noted that when using psychological tests in other cultures, a similar factor structure across cultures is a necessary but not sufficient component of validity. However, the Strong Heart Study – ISEL was a shortened version of the original and some items were altered, which conceivably might account for the lack of expected factors. Given this, we examined other alternatives.

Dr. Jan Beals, a colleague of Dr. Spero Manson from the National Center for American Indian and Native Alaska Mental Health Research, suggested a series of social support questions from the American Indian Service Utilization, Psychiatric Epidemiology, Risk and Protective Factors Project (AI-SUPERPFP).

The social support questions for AI-SUPERPFP were derived from two sources: the National Comorbidity Study (NCS; Kessler et al., 1994) and the American Indian Vietnam Veterans Project (AIVVP). The NCS measures were selected, in large part, so that one could compare data to that of a national sample. The AIVVP measures, on the other hand, are more reflective of an integrated quantitative/qualitative approach to measure.

The SHS Psychosocial Committee felt that AI-SUPERPFP questions 32-47 would provide the most appropriate assessment of social support for the SHS Family Study. The questions encompass various types of social support, including what appears to include perceived emotional support, social networks, tangible and negative social support. Negative social support may be contributory to poor health outcomes in many Indian communities. Analyses in a family study may include hierarchical linear modeling analyses where one can differentiate the impact of social support of the individual and family levels -- examining their impact on outcomes, along with structural equation methods to model the common variance and unique variances from different levels of analysis to examine family/environmental contributions.

See Form S14, Volume 3, Appendix D.

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7. ANGER/HOSTILITY

Spielberger -Ax/Cook Medley Scale

(This form is optional, but will definitely be used in the Dakota Center)

Definitions of Anger and Hostility Anger is defined as “an emotional state that consists of feelings that vary in intensity, from mild irritation or annoyance to fury and rage” (Spielberger et al 1985). Spielberger also suggested the closely related construct of hostility. Hostility’s central feature is a complex set of negative attitudes towards others, such as distrust. These attitudes are intertwined with emotions such as cynicism, resentment, vengeance, and alienation, which tend to have complex cognitive features, thereby differentiating them from emotions such as anger, which are definable more in terms of affect.

History of Anger and Hostility in Health Research The Type-A behavior pattern has received much attention since it was identified by Friedman and Rosenman (1974). The idea that psychologically related factors could be risk factors for various health outcomes was not completely new, but Type A behavior made sense to many people. Who among us does not know someone who meets the criteria for “Type A behavior” and worry somewhat about their health? An expert review panel convened by the National Institute of Health (NIH) asserted that Type A behavior is an independent risk factor for the development of coronary heart disease equivalent in power to smoking or hypertension (Review Panel 1981).

As the traits of Type A behavior were broken down, anger and hostility were shown to be major risk factors for coronary heart disease (Dembroski and Costa 1987, Spielberg and London 1982, and Williams 1989, and his colleagues Barefoot, Dahlstrom, & Williams, 1983, Williams et al., 1988, Williams et al., 1980). Williams (1980) measured Type A behavior and hostility in a group of heart patients. Findings were that the hostility levels were better predictors of coronary blockage than the overall Type A behavioral pattern. These findings have been extended in three other studies (Barefoot, Dahlstrom, & Williams, 1983; Barefoot et al. 1987; & Shekelle et al. 1983), all indicating that hostility scores predicted both coronary heart disease morbidity and total mortality. Also, in a meta-analysis of studies on type A behavior, Matthews (1988) concludes that hostility is a reliable predictor of events of coronary heart disease in population-based prospective studies. Correctional studies and reanalysis of the two major prospective studies, the WCGS and MRFIT, found significant relationships between clinical ratings of the potential for hostility and coronary artery disease (CAD) and CHD endpoints in the absence of significant relationships between global Type A and disease endpoints. (Matthews et al., 1977; Shekelle et al., 1985; Hecker et al., 1988; Dembroski et al., 1989).

Numerous studies have pointed to anger and hostility as playing a significant role in mortality from coronary heart disease (CHD) as well as mortality from all causes (Barefoot, Dahlstrom & Williams, 1983; Helmers, Posluszny & Krantz, 1994; Miller, Smith, Turner, Guijarro & Hallet, 1996; Siegman & Smith, 1994). Also, research has shown that mortality rates from all causes are higher for individuals scoring high on hostility (Barefoot et al., 1983; Miller et al., 1996). As such it is clear that anger and hostility play an important role in physical health. Unfortunately, most of this research has been conducted on Caucasian, middle aged men. There is very little published research found across different genders, ages or cultures.

Anger and hostility will be measured in the Dakota Center (and in the other two centers, if opting to do so) during Phase IV of the Strong Heart Study in order to determine how these traits affect health outcomes in Northern Plains Indians (and in the Tribes in Oklahoma and Arizona, if used in those field centers) using the Spielberger Anger Expression Scale and the brief Cook Medley Hostility Scale. These instruments can both be administered in under two minutes, either by interview or self-administration. Both of these instruments have been used with Native populations in previous studies and are known to have stable reliability and validity characteristics. The potential findings could be useful to both mental health and medical providers working with this population in developing interventions that could improve the overall quality of life for the proposed population.

Administration: Can be self-administered or in a interview format. If a participant asks for clarification, the response should be that there are no right or wrong answers and they should answer it the best they can.

Scoring: The scoring of the Spielberger -AX/Cook Medley Scale is broken into several steps. This instrument is actually a combination of two separate instruments. Items 1 - 20 are from the Spielberger - AX which are designed to measure the construct of anger, while items 21-28 are the Cook-Medley scale.

The AX scales yields three scales: an Anger Expression score based on all 20 items, and scores for the 8-item Anger-In and Anger-Out subscales. Some of the AX items are worded in a manner such that a high rating indicates that anger is frequently expressed. Other items are worded so that a high rating indicates that anger is experienced but not expressed.

In calculating the AX total score, the score weights for items on which high ratings indicate the expression of anger correspond to the direct score. For items on which high ratings indicate that anger is not expressed, the scoring weights are reversed, i.e., the scores for responses marked 1, 2, 3, or 4, are changed to 4, 3, 2, & 1 respectively. To obtain the AX-Total score, simply sum the weighted scores for all 20 items, making sure to take the direction of scoring into account. In calculating the AX-Total score, the 9 directly scored items and the 11 reversed scored items are:

Directly scored items: 2, 4, 7, 9, 11, 13, 17, 19, 20
Reversed scored items: 1, 3, 5, 6, 8, 10, 12, 14, 15, 16, 18

The Anger-In and Anger-Out scores are obtained by summing the weighted scores for the 8 items that comprise each subscale. The scoring weight for each item corresponds to the number circled on the answer sheet; all 8 items are scored directly in calculating the subscale scores. The items which comprise the AX subscales are:

Anger-In: 3, 5, 6, 10, 12, 14, 15, 18
Anger-Out: 2, 7, 9, 11, 13, 17, 19, 20

The range of possible scores on the AX-Total can vary from a minimum of 20 to a maximum of 80. The range of possible scores on the Anger-In and Anger-Out subscales can vary from a minimum of 8 to maximum of 32.

Items 21-28 comprise the Cook Medley scale (HO). These items are to be answered true (1), false (0) or don't know (N/A, if the participant is not willing to answer the question). The score on the scale is the total number of items marked true (indicating hostile direction).

See Form S15, Volume 3, Appendix D.

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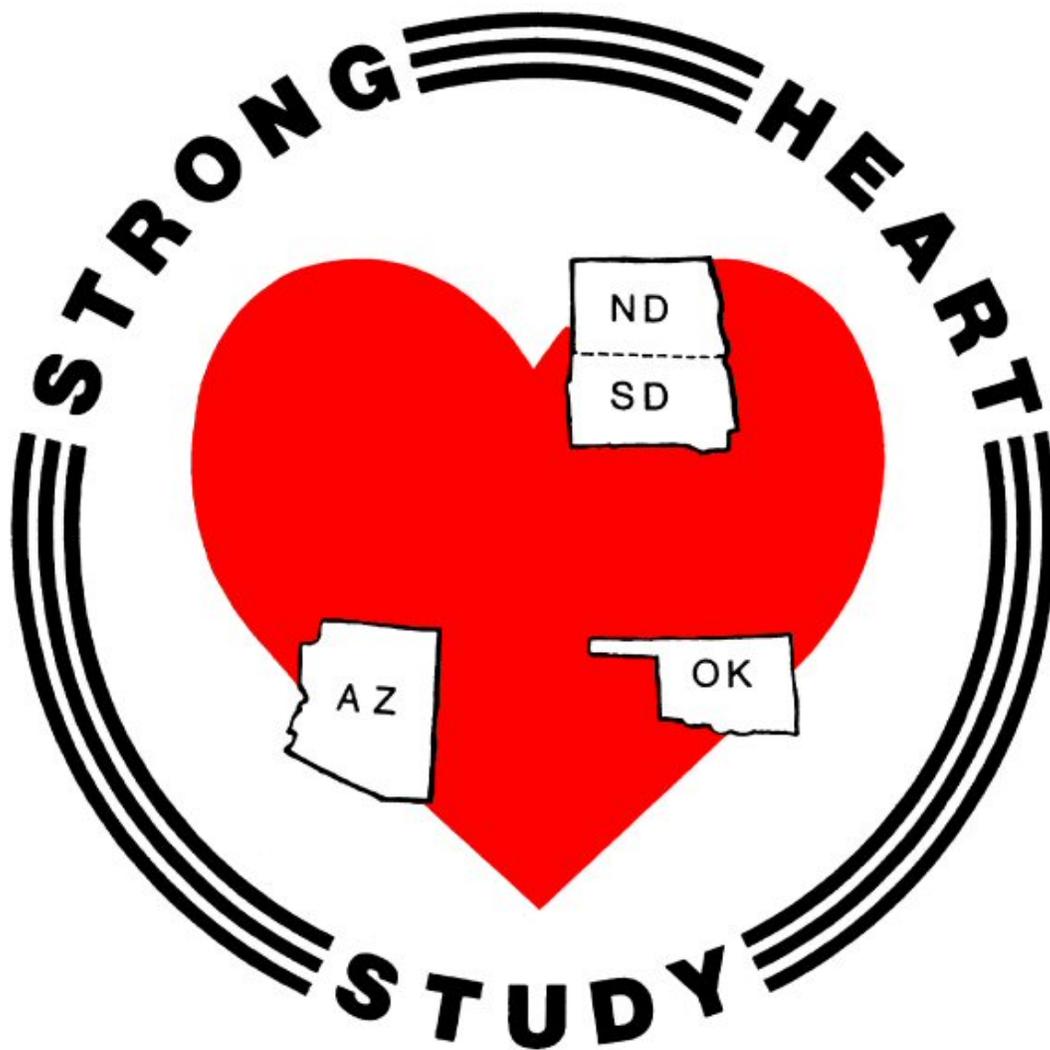
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8. PSYCHOSOCIAL FACTORS QUESTIONNAIRES CHECKLIST

Reason for Incomplete Psychosocial Instruments Form

Rationale: There has been some concern that the administration of psychosocial questionnaires during Phase IV will make participants uncomfortable, or not be understood, or stress the time resources of the Strong Heart Study field staff. This form is to be completed for all participants in regard to their completion of the battery of psychosocial questionnaires, in order to improve understanding of the barriers to doing this type of research in the field with American Indians.

See Form S16, Volume 3, Appendix D.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Nine

BLOCK FOOD FREQUENCY QUESTIONNAIRE

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual

Volume Nine

BLOCK FOOD FREQUENCY QUESTIONNAIRE

June 01, 2001

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
College of Public Health

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Oklahoma City, OK 73190

VOLUME IX
BLOCK FOOD FREQUENCY QUESTIONNAIRE

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Food Frequency Questionnaire

INTERVIEWER INSTRUCTIONS FOR THE BLOCK 98 QUESTIONNAIRE[©]

Copyright: Block Dietary Data Systems
2634 LeConte Ave
Berkeley, CA 94709
Phone or fax: 510-704-8514

Food Frequency Questionnaire

Mechanics

- Use # 2 pencil** To ensure that the scanner reads correctly, the questionnaire must be completed using a #2 pencil. A hard pencil may produce too light a mark, and may be scanned as missing.
- No other marks on the questionnaire** Comments or notes should not be written on the questionnaire, as they may confuse the scanner. Comments must be on a separate page.
- Bubble completely** Fill in the answer bubbles completely. Do not simply make a checkmark or an 'X' over the bubble.
- One bubble per answer** Never mark two bubbles for the same answer -- both will be lost as an error.
- No staples** Staples would have to be removed, and if inadvertently not removed would damage the scanner. Marks left by staples can interfere with the scanner reading of tracking marks, booklet number marks or page number marks, and necessitate someone copying over the entire questionnaire.
- No extra pages** Do not insert any extra pages or papers with notes on them into the booklet, or attach yellow stickies. If not noticed prior to scanning, they might interfere with the scanning.
- No folds** Do not fold the questionnaire.
- No 3-hole punch** Holes might interfere with the scanning process.

General Instructions

- Introducing the Food Questionnaire** Provide a transition from the other parts of the questionnaire to the Food Questionnaire section, with a phrase such as the following: "Now I'd like to ask you some questions about the foods you usually eat." Do not use phrases that include the word "diet", as some respondents may think we mean "dieting", rather than simply their usual food habits. Do not spend too much time at this initial introduction.

Read questions as written

The words are not optional. Do not paraphrase. Do not omit any words. For example, "in season" is an essential part of the prompt for the foods in which it is used. Some foods that may be unfamiliar to you are being marketed nationally; do not omit them. If the respondent interrupts you with an answer before you have finished the entire question, continue on reading the question; there may be foods at the end of the list that the respondent didn't realize were to be included.

Respondent questions

If respondent asks a question for clarification, and you know the answer because it is in this manual, you may give her the answer; it is not necessary to reread the entire question. For example, in the general question "How often do you use fat or oil, to fry ,stir fry....?": If respondent asks, "Does that include butter I put on bread?" you may answer "No, just fat you may use to, stir-fry...", without rereading the whole question.

Introducing the Food List

Read the introduction to the food list, on page 2. *"The next section is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions to answer for each food. 1. **HOW OFTEN**, on average, did you eat the food during the past year?"* After the last sentence you should point to the questionnaire, and prompt, "is it 'Never', 'A few times per year', 'Once per month', '2-3 times per month', 'Once per week', '2 times per week', '3-4 times per week', '5-6 times per week', or 'Every day'."

Continuing with the introduction, read the next section: *"How much did you usually eat of the food?"*

* *Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., **ON THE DAYS YOU EAT IT.***

* *Sometimes we ask "how much" as A, B, C, or D. **LOOK AT THE ENCLOSED PICTURES.**"* At this point, you should hand them the page of portion size pictures, and continue with the introduction: *"For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat."*

The respondent can use either the plates or the bowls to choose her serving size, but generally, she should refer to the bowl pictures for foods that are usually eaten in bowls (breakfast cereal, soups...), and the plate pictures for foods that are usually eaten on plates. Note that there is no 'A' bowl. Finally, if you refer to the portions as A, B, C, or D, it will encourage the respondent to refer to them that way, thus speeding up the process.

Foods not on the food list

The food list represents the most important nutrient sources in most people's diets. It does not and is not intended to include all possible foods that people ever eat. Thus, it is likely that some foods that a person eats will not be on the list. Do not attempt to force unmentioned foods into categories by guessing at their similarity.

Instructions About the Frequency Part of the Food Questions

Importance of frequency Although portion size improves the accuracy of the nutrient estimates, the interviewer should be aware that frequency of consumption is much more important than exact portion size in determining long-term usual intake.

Frequency categories Note the frequency categories at the top of the columns. On most pages these are also repeated at the bottom of the columns, to help guide the eye. Be careful to mark the right column, since being off by a column can make a big difference in the nutrient estimate.

Although you will ask the question in an open-ended way ("How often do you eat..."), encourage the respondent to give her answers in terms of one of the predefined categories. Respondents easily get the idea, and will quickly learn to give answers in the categories shown.

The categories are not the same all the way through the questionnaire -- the categories on the final page of the questionnaire go up to "2+ times per day". When you get to this section, make the respondent aware of this change. You might say something like *"for the foods on the final page of the questionnaire you can answer as much as "2 or more times per day"*.

Should I read all the response categories? In this Food Questionnaire, the answers are all in categories, such as "Less than once per week", "1-2 per week", ... "4+ per day". In most cases it is not necessary to read the response categories every time, although you may do so if the respondent is hesitating or unclear. Instead, you will first show the respondent an example of the type of categories you will be using to record her answers. Then, you will simply ask the question in an open-ended way, wait for a response (such as "5 times a week"), and record it in the appropriate category.

Wording of the frequency questions It is not necessary to say "How often do you eat" for every food. You can repeat the introductory phrase from time to time, but most often you should just read the next food, without the "How often...." This will make the interview go a little faster, be less boring, and perhaps encourage the respondent to pick up the pace. Similarly, avoid repetitively saying "(name of food). How often do you eat that?" It is okay to say that occasionally to vary the wording and pace, but not for every food. Do not, however, just say "Do you eat ..."; this unnecessarily lengthens the interview, because then if the respondent says 'yes' you still have to ask the "How often" question.

2+ per day categories

Remember to remind the respondent of the different categories when you come to "Biscuits/muffins" on the last page. For those frequency pages in which 2+/day and higher are possible answers: If the respondent says "Every day", at least the first time he/she does that you should probe, "Would that be once a day or 2+ times a day?" You don't need to do that probe every time, if it appears that the respondent understands that "2+ times a day" is one of the possibilities.

How often vs. How many

There is a potential confusion between how often and how many, particularly for the fruits. Make sure to keep them separate for the respondent. For example, when you ask 'bananas', some respondents may say "I eat two a week"; this could lead to double-counting if you marked '2/wk', then asked 'how many' and she said '2'. So if respondent is answering fruits as "I eat two a week", explain that you will ask "How many each time" in a subsequent question; right now, you want her to tell you 'how often' per week, meaning "how many days", not how many bananas per week.

Always get the frequency ("How often") before asking about portion size ("How much" or "How many"). While the respondent is thinking about her answer to "How often", do not interrupt with any mention of portion size. Do not point to the portion size pictures until after you know her answer to "How often".

Seasonality

A few foods say specifically "in season". The respondent should give the frequency with which that food is consumed, **just in the few-month period when it is in season**. All other foods require an estimate of average year-round frequency of consumption. If the respondent eats some of these "year-round" items more in one season than another, the reported frequency should still be a rough average over the whole year. For example, if respondent says "I eat apples 3-4 times a week now that they're in season", you should say something like, "Please try to estimate how often that would average out to over the whole year."

If the respondent mentions seasonality for items that do not already say "in season", ask her to average her intake over the whole year. For example, if she says "I eat apples 3-4 times a week now that they're in season", you should say something like, "Please try to estimate how often that would average out to over the whole year."

If the respondent is unable to do the conversion herself, then the interviewer may use the following chart to estimate for her.

Average use in season	Conversion	Average year round use
Every day	Shift 3 columns to the left	Twice per week
5-6 times per week	Shift 3 columns to the left	Once per week

3-4 time per week	Shift 3 columns to the left	2-3 times per month
2 times per week	Shift 2 columns to the left	2-3 times per month
Once per week	Shift 2 columns to the left	Once per month
2-3 times per month	Shift 2 columns to the left	A few times per year
Once per month	Shift 1 column to the left	A few times per year
A few times per year	Shift 1 column to the left	Never
Never	No change	Never

Buying in bulk

Some respondents will say something like "I buy a gallon and then drink it until I'm done with it", and then doesn't drink it so frequently for the subsequent time period. Again, you should ask her to try to average her intake over the whole year. Something like, "Please estimate how many glasses per day or per week you think you drink, on average over the whole year."

Items with more than one food

For example, "Fresh apples or pears". Do not try to get separate estimates of either frequency or portion size for the two foods. Just ask the respondent to answer their frequency for that group of foods. And don't worry about the two foods having different sizes; just ask the respondent to pick the woodblock model that best approximates how much he/she usually eats of that group of foods.

Frequency answers that overlap the response categories

If the respondent answers with a range that does not fit exactly into one of the available categories, ask the respondent to choose which of the available categories is closer to how often she uses that item. For example, look at the "general questions" on page 1 of the Questionnaire. Suppose you ask the respondent, "How often do you use fat or oil to fry or stir-fry?", and she answers "four or five times a week." You would then say, "Would it be closer to "3-4 times per week" or "5-6 times per week"?"

"Never" frequency

Use the "Never" column for any foods either literally never eaten, or eaten by the respondent less than once per year. They will be counted as zero.

Frequency answers with different wording

Apply common sense. "Less than once a year" or "3-4 times in my life": code it as "Never" without further probing. "A couple of times a month": code as "2-3 per month" without further probing. If respondent answers "Rarely" or "Hardly ever", ask "Would that be less than once per year?"; if respondent indicates 'yes', code as "Never".

Instructions about the Portion Size Part of the Food Questions

- Portion size is EASY in this interview** You only ask portion size if respondent eats the food once per week or more often. Ask the portion size before moving on to frequency of the next food.
- You don't worry about converting to half cups, ounces, etc. You just mark the bubble corresponding the respondent's portion size choice:
- "A" = 1st bubble
 - "B" = 2nd bubble
 - "C" = 3rd bubble
 - "D" = 4th bubble
- Wording of the portion size questions** It is not necessary to make a full sentence out of the portion size section each time. I.e., do not say, for every food, "When you have ..., about how much/many do you have each time?" For the "how manys", just say "How many teaspoons", etc. For the "How much"s, you can say "How much each time?" and point to the pictures; or, after a while, just say "A, B, C or D?"; or you can say "Which bowl?"
- "XXL"** If the respondent says that his/her usual portion is larger than the largest model (which corresponds to the fourth bubble), record the answer as the fourth bubble.
- How important is portion size?** Although portion size will definitely improve the accuracy of the answers, you should not permit the respondent to spend undue time on the portion size answers. This section should move along quite quickly, with a breezy "How many" or "A, B, C or D?"
- Note on Beverage "portion sizes"** The portion size part of the beverages section is designed to capture the *number* of glasses, bottles, cans, etc. that the respondent usually drinks, on the days she drinks the beverage. Rather than asking an additional question about *the size* of the beverage that the respondent drinks, to simplify administration of the questionnaire the nutrient analysis of the beverage section assumes standard sizes for glass, bottles, cans, etc. An 8 oz. portion size is assumed for the following beverages: tomato/V8 juice, 100% juices, all other fruit juices, Hi-C, breakfast shakes, milk, water. A 12 oz. portion size is assumed for the following beverages: soft drinks, beer. A 6 oz. portion size is assumed for wine. A 9 oz. portion size is assumed for coffee and tea.
- These portion sizes are provided as clarification for you, the interviewer, so that you will be able to answer questions if the respondent asks. The interviewer does not need to offer the respondent this information, but if she asks, you may respond to questions, using the information provided here.

Correct wording for asking the portion size questions

Each food has a correct wording for asking the portion size question ("how many", "how much" etc), and a recommended portion size model to use. The correct wording is given in the column just preceding the portion size bubbles. The cue about the correct wording is in the words underneath the portion size bubbles.

SUMMARY OF HOW TO ASK PORTION SIZE

What is under the
portion size bubbles:

How to ask the question:

A number

Ask "HOW MANY?" and get an answer in number of items.

A-B-C-D

Ask "HOW MUCH?" and get an answer as A-B-C-D referring to the pictures.

“How many” questions Ask "How many each time" or sometimes just "How many". Use the unit that is the name of the food (e.g., 'bananas') or that is shown in the "Portion Size" column (e.g., 'slices', 'teaspoons', 'bowls'). Code response according to respondent's answer ("1", "2", "3", etc). For example, examine "Bananas": ask portion size in an open-ended way, as "How many, each time?" You then record the answer in the appropriate bubble, "1/2", "1", "2". If the number reported is larger than shown for any of the bubbles, use the fourth bubble. Occasionally, "How many" is awkward; so for "Cantaloupe", it would be "Do you eat 1/8, 1/4 or 1/2 a cantaloupe each time?"

Acceptable phraseology:

"How many bananas, each time?"

"How many, each time?"

"How many, on the days you eat them?"

“How much” questions Ask "How **much** each time, A, B, C or D?", or just "A, B, C or D?", or "Which picture, A, B, C or D?" Code A-B-C-D as 1st bubble, 2nd bubble, 3rd bubble, 4th bubble, without any kind of conversion, calculation or interpretation.

For example, examine "Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins": In the "How Much" section, you see "A,B,C,D". For these foods, indicate the portion size pictures and ask the respondent to choose the picture closest to her usual portion. Again, **the respondent may use either the plates or the bowls to give his/her answer.**

Acceptable phraseology:

"How much each time? A, B, C or D?"

"Which of these pictures is closest to your usual portion?"

"Which picture is closest to the amount you usually eat"

Eventually, you could say simply "A, B, C or D?"

Q by Q (question by question) -- Introduction

Page 1

Respondent ID Number	The ID number must always be filled in . This is the only way it will be possible to connect the nutrient estimates with the right individual.
Today's date	The date the questionnaire is completed
Sex	Sex should not be omitted . The analysis program will use it to evaluate reasonableness of nutrient estimates.
Breast feeding	This is not used by the nutrient analysis program, but may be useful as a categorical variable.
Age	Age must always be filled in, and bubbled in . The analysis program uses it to evaluate reasonableness of nutrient estimates.
Weight	This is not used in the nutrient analysis calculations. However, if printed output is requested, it is reported in the printed output, and advice on desirable weight may be generated. The bubbles should be filled in, not just written in at the top.
Height	This is not used in the nutrient analysis calculations. However, if printed output is requested, it is reported in the printed output, and advice on desirable weight may be generated. The bubbles should be filled in, not just written in at the top. Note that the first bubble is for height in feet, and the second bubble is for inches. In case of "1/2 inch", round down.
Name	This item will not be entered into the database. They are not scanned by the scanner.

Summary questions

These questions are used by the program to compare and if necessary adjust some of the food list responses.

Servings of Vegetables and Fruit

Servings of vegetables, fruit: This doesn't mean 'how many different kinds'. It doesn't refer to 'seconds': for that, they would mark a 'D' in the main food list. Here, we mean how many times it shows up on your plate during the day. So green beans with lunch and squash with dinner would be 2/day; green beans with lunch and green beans with dinner would be 2/day; nothing with lunch and both squash and green beans with dinner would be 2/day.

Salad and potatoes are excluded from these questions simply to clarify which foods we are asking about.

Acceptable answers to respondent questions:

Q: "Do you mean different kinds of vegetables (fruits, cereals)?"

A: "**No, just how often you eat vegetables of any kind.**"

Q: "Should I count second helpings as two servings?"

A: "**No, this is just how often you eat vegetables of any kind.**"

Q: "Give me an example of how to count them up."

A: "**If you usually have some fruit with breakfast and some fruit for a snack, that would be twice a day.**"

Q: "**What if I have a big salad with lots of stuff in it?**"

A: The key is whether it would be enough of any one vegetable that they would include it in their main food list answer. For example, suppose their salad sometimes includes as much as 1/2 cup of broccoli; in the main food list, they would/should think of all times they have broccoli, including the quite substantial portion they have in big salads, and include that in their "Broccoli" answer. Therefore, if their salad contains a large enough amount of a vegetable to have been counted as a serving on the main food list, it should be so counted here.

Cold cereal

Frequency with which respondent eats any cold cereal. This question will be used to adjust the frequencies of the specific cereal questions on page 4 of the questionnaire.

Fat or oil in cooking

Frequency of fat or oil in cooking: Note that fat or oil use is in fry, stirfry or simmer; does not include fat used in baking. Also does not include oil used on salad, and does not include butter/margarine used on bread.

"What kinds of fat...."

Ask this question only if respondent's answer to the previous question on fat or oil was "once per week" or more often. Put some emphasis on "kinds" of fat, so the respondent understand that you are asking a different question. Do not read "Mark only one or two." Do not read the response categories. Leave it open-ended, and then fill in the appropriate box to fit the subject's answer. If respondent names only one, mark only one without further probing. If she names two, mark two. If she names more than two kinds of fats/oils, ask her which two she uses most often.

If she states, in answer to this question, "I do not use it", go back and clarify her answer to the previous question, which was "How often do you use fat or oil to fry...?"

Safflower oil or peanut oil can be marked under "Corn oil, vegetable oil".

"Crisco" refers to Crisco shortening. If subject specifies Crisco oil, mark it under "vegetable oil".

Sesame oil: If respondent reports "sesame oil", ask if she uses it in large quantities such as 1-2 tablespoons; if so, code as vegetable oil. If she only uses a few drops for flavoring, do not code as oil at all.

Page 2

During past year, ... vitamins?

If "No, not regularly" (at least once a week), they may skip to the diet instructions in the middle of the page.

**(If yes)
what...?
Multiple
vitamins**

There are three different multiple vitamin types. "Regular once-a-day, Centrum or Thera" is one type, "Stress Tabs or B-Complex" is a second type, and "Antioxidant combination type" is a third type. They should not two or more types unless they in fact do take two or more different types of multiple vitamins.

What is a "Regular once-a-day..."? Multiple vitamins typically contain all of the vitamins (A, B1, B2, C, D, E and others) and often contain minerals (iron, zinc, calcium and others). One-a-Day, Theragran, Centrum, Centrum Silver, and any local brand (e.g., Safeway Multivits) counts here. The key characteristic is that it contains many different vitamins; it is thought to be a sort of all-round supplement, covering all the bases at least at a basic level. The fact that it does contain A, C and E does not make it an "Antioxidant combination", if it contains other things besides those vitamins.

What is a "Stress tab or B-Complex type"? These will have "stress", or "B-Complex", or "High-B" in the name. They all have B vitamins at levels substantially higher than the RDA.

What is an "Antioxidant combination"? The most common antioxidant vitamins are A, C, E and beta-carotene. If a pill contains two or more of these and not other vitamins like B vitamins, iron, etc., count it as an antioxidant combination. The respondent should not double-count the vitamins taken, however. If respondent takes a multiple vitamin but is not sure what it is, only that it has several things in it, then it should be counted as a "Regular Once-a-Day", and nothing should be marked in the "Antioxidant combination" line. Both of these multiple vitamin types should be marked only if respondent in fact takes two different types of multiple vitamins, one that is a One-a-day type and one that is an Antioxidant Combination type.

**Single
Vitamins**

In general, these are supplements where each pill contains only the one vitamin or mineral. Thus, it is important to note that we are asking here about single supplements, that are not part of multiple vitamins.

An exception: Occasionally a pill may contain just two minerals, such as calcium & zinc. Since we don't have a place for "multiple minerals", it is okay for respondent to record the frequency of consumption under both "calcium" and "zinc" separately.

For Vitamin A, it is important to note that this is "not beta-carotene". Many respondents have learned that vitamin A and beta-carotene are in some way related. However, the "Vitamin A" line is asking specifically about preformed vitamin A, also known as retinol. If they take vitamin A as beta-carotene, they should mark their frequency only under the beta-carotene line.

Contain minerals?

This need only be filled in if respondent takes multiple vitamins. (If respondent doesn't know, the program will assume "with minerals", since that is 80% of the market.)

Vitamin C or E, What milligrams?

This need only be filled in if respondent takes vitamin C or E as single supplements (not part of multiple vitamins). These are the commonly available pill sizes. Note that this refers to the total milligrams in the day, on the days respondent takes it. It is not milligrams in a pill, or milligrams in each dose.

Botanical supplements

These are not included in the nutrient analysis. However, the results returned to the researcher do indicate whether the supplement was reported as having been taken at least once a month.

Introducing the Main Food List

Read the introduction to the food list, on page 2. "*The next section is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions to answer for each food. 1. **HOW OFTEN**, on average, did you eat the food during the past year?" After the last sentence you should point to the questionnaire, and prompt, "is it 'Never', 'A few times per year', 'Once per month', '2-3 times per month', 'Once per week', '2 times per week', '3-4 times per week', '5-6 times per week', or Every day'."*

Continuing with the introduction, read the next section: "*How much did you usually eat of the food?*

* *Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., **ON THE DAYS YOU EAT IT.***

* *Sometimes we ask "how much" as A, B, C, or D. **LOOK AT THE ENCLOSED PICTURES.**" At this point, you should hand them the page of portion size pictures, and continue with the introduction: "*For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat.*"*

The respondent can use either the plates or the bowls to choose her serving size, but generally, she should refer to the bowl pictures for foods that are usually eaten in bowls (breakfast cereal, soups...), and the plate pictures for foods that are usually eaten on plates. Note that there is no 'A' bowl. Finally, if you refer to the portions as A, B, C, or D, it will encourage the respondent to refer to them that way, thus speeding up the process.

The **time frame** that it covers is "the past year or so". This is deliberately a little vague, because it is not expected that anyone could remember exactly what they ate during exactly the past year. The idea is just to get a usual pattern -- their current diet at this point in their life. Some people raise the objection, "Oh, I can't even remember what I ate yesterday; how could anyone answer what they ate in the past year?" If respondents have this concern, it's important to make clear to them that the idea is not to remember, but to think about their usual pattern of frequency. For example, they don't have to remember how many times they had eggs in the past year. Instead, what they can tell you with reasonable accuracy is, "Oh, I have eggs about twice a week."

For some items, people may indicate that they have changed their habits in the past year. In that case, ask "Do you expect that this is a lasting change?" If the new habit appears to be lasting and stable, she should report on the new pattern rather than the former pattern.

In all the examples given below for foods, you should not probe for information about any of the clarifications discussed here. These are provided as clarification for you, the interviewer, so that you will be able to answer questions if the respondent asks.

Read the questions exactly as written. Do not re-word, or leave things out. But you may respond to questions, using the information provided here.

Q by Q -- Beverages

Tomato or V8 juice	Any tomato juice, including Clamato, etc.
Real 100% Orange juice or grapefruit juice	Canned, bottled, frozen or fresh. Do <u>not</u> include fruit <u>drinks</u> , or any drink that is not 100% orange or grapefruit juice. (Sunny Delight is not 100% juice.)
When you drink orange juice...	The program will use the answer to this question to choose the type of orange juice to use for the frequency of orange juice reported above.
Other real fruit juices, ...	Canned, bottled, frozen or fresh. Other 100% real fruit <u>juices</u> (not 'drinks') could be included here, such as lemonade.
Kool-Aid, Hi-C or other drinks with added vitamin C	Include any drinks, whether real fruit juice or not, if they contain added vitamin C. Most forms of Kool-Aid do now contain added vitamin C. Include Sunny Delight here.

Drinks with some juice in them, like Sunny Delight

Instant breakfast... Ensure

Include any meal supplement or replacement, such as Boost or Ensure; any dieting milkshake, such as Sege or Slim-Fast; or Instant Breakfast milkshakes like Carnation.

Glasses of milk...

This applies to glasses of milk, not to milk added to coffee or cereal. Be careful that respondents do not double-count the milk they may have added to their Carnation Instant Breakfast.

When you drink...

The program will use the answer here to choose the kind of milk to apply to the frequency of glasses of milk reported in the previous item. This answer applies to glasses of milk, not to milk added to coffee or cereal. If they drink more than one type of milk, ask them to choose the one they drink most often.

Regular soft drinks...

Any soft drink that is not artificially sweetened. Includes cola, ginger ale, pepper types, orange or grape soda, etc., or sugar-sweetened bottled water. If the respondent buys large bottles of soft drink (such as the standard 64 oz. bottle) and then drinks it in cups or glasses, then the interviewer may suggest that the respondent choose from the ABCD cup models. The interviewer should code an "A" in the "<1 can/bot", a "B" in the "<1 can/bot", a "C" in the "12 oz can/bot", and a "D" in the "16 oz can/bot".

Beer

Bottles, glasses, cans, or draft, all varieties. If respondent drinks nonalcoholic beer, do not include it in this response, but include it in the open-ended section at the end of the questionnaire. Portion size asks what size can or bottle they usually drink.

What kind of beer?

The program will use the answer to this question to choose the type of beer to use for the frequency of beer reported above.

Wine...

All forms, including champagne, spritzers. If respondent drinks nonalcoholic wine, do not include it in this response, but include it in the open-ended section at the end of the questionnaire.

Liquor...

Include all forms, including whisky, scotch, gin, etc. Note that "How many glasses or drinks" is reported in the "how often" section. In the portion size section, respondent should report the amount of alcohol (number of shots) used in each glass. Note here that portion size is not asked -- a standard portion size will be assumed.

Coffee...

Include caffeinated or decaffeinated, brewed or instant.

Tea...

Any form of regular tea or iced tea. Exclude herbal teas.

- What do you usually add to coffee?** Choose the type that is *usually* added to coffee. If the respondent uses more than one type, have her pick the one she uses most often.
- What do you usually add to tea?** Choose the type that is *usually* added to tea. If the respondent uses more than one type, have her pick the one she uses most often.
- Do you usually add sugar or honey to coffee?** Refers to only real sugar or honey, not sugar substitutes. Fill in the Yes/No question. If 'Yes', also fill in the number of teaspoons.
- Do you usually add sugar or honey to tea?** Refers to only real sugar or honey, not sugar substitutes. Fill in the Yes/No question. If 'Yes', also fill in the number of teaspoons.

Q by Q -- Fruits

In this section, the number of times per month or week refers to number of days per month or week. For example, the respondent eats bananas on about two days a week. Then, the portion size section provides the location where the respondent can tell you how many pieces of that fruit she eats, on the days she eats them.

Seasonality: Among the fruits, 5 of the items refer to food intake "in season", and the other 5 items refer to intake "year round". If any of these "year-round" foods are eaten more in one season than another, ask respondent for her best estimate of a year-round average. "Raw peaches..." are "in season". It is essential to read the "in season", and respondent should report the frequency with which that fruit is eaten when it is in season (refer to the "seasonality" section above for a detailed discussion). Do not probe for length of season.

Jams and jellies should not be counted as servings of fruit. Fruit in yogurt does not count as servings of fruit.

- Raw peaches, apricots, nectarines, in season** Any type. Report frequency only for the few months when they are "in season". The frequency section gets at "how often", not how many peaches per week. Get number of days first; then in portion size get "How many" each time. If she seems to be answering peaches per week, clarify and first get 'how often', then under portion size get 'how many each time'. Be careful, for this item and all other items that come in units, that you do not double-count or triple-count: that is, be careful that she doesn't say "2 a week", (which you would record in the "2/wk" column), and then say '2' for how many each time. That would calculate out as four peaches a week instead of two.

Cantaloupe, in season	The focus here is on cantaloupe. Other melons should be counted only if they are deep orange like cantaloupe. Do not include honeydew or other non-orange melons. Report frequency only for the few months when they are "in season".
Strawberries, in season	Fresh only. Report frequency only for the few months when they are "in season".
Any other fruit in season, like grapes... in season	Any other fresh fruit. Report frequency only for the few months when they are "in season".
Bananas	All kinds, all sizes.
Apples or pears	All kinds, all sizes; includes pears, or Asian pears. Discourage respondents from trying to do math, adding up separately their apples and their pears. An intuitive average is fine.
Oranges or tangerines	All kinds, all sizes; includes tangerines, tangelos, mandarin oranges. (Orange juice is a later item.) If respondent <u>only</u> uses oranges to make juice, tell her to wait and count that as orange juice. If she sometimes eats them as oranges and sometimes as juice, just get frequency of 'as oranges' in the fruit section, and then later get the 'as juice' in the juice section.
Grapefruit	All kinds, all sizes.
Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins	Frequency is average year-round frequency of consumption.

Q by Q -- Breakfast items, dairy

Eggs, including egg biscuits or Egg McMuffins (not egg substitutes)	Include real eggs when eaten as eggs, including scrambled, boiled, fried, or on sandwiches. Also, include deviled, or egg salad or quiche(which is mainly egg). Do not count eggs used in cooking, such as in cakes, custards, etc. Do not count Egg Beaters, egg substitutes, or if only egg whites are eaten. The main point is the cholesterol, so if they scramble, for example, one egg yolk and two egg whites, just count the number of yolks. See caution under "Bananas" above, about care in recording the answers to the "How often" and "How many" questions.
Bacon	Includes when eaten at any time, including BLT sandwiches, not just with breakfast.

Breakfast sausage, including sausage biscuits	This includes breakfast-type items, but not sandwich-type cold-cuts, not main-meal items like Italian or Polish sausage, and not hot-dog type sausages like German hot dogs. Turkey sausage may be included here.
Pancakes, waffles, French toast, Pop Tarts	With or without butter or syrup. Syrup will be added automatically.
Breakfast bars, granola bars, power bars	These do <u>not</u> have to be eaten for breakfast.
Cooked cereals like oatmeal, cream of wheat or grits	This refers to all cooked cereals, including cream of wheat, cream of rice, and less common types like kasha, as well as those mentioned.
High-fiber cereals like All Bran, Raisin Bran, or Fruit-n-Fiber	This item may include any higher-fiber cereals, including the very-high-fiber cereals like All-Bran and the moderately high-fiber cereals like "Fruit-n-Fiber". Any cereal with the words "bran" or "fiber" in their titles may be included here. Note that the cereals should be counted even if they are eaten as a snack rather than a breakfast cereal, and regardless of whether they are eaten with milk.
Which high-fiber cereal...	The program will use the answer to this question to choose the type of high-fiber cereal to use for the frequency of the cereal reported above.
Product 19, Just Right or Total	This item includes only these three cereals. These cereals contain 100% of the RDA (Recommended Dietary Allowance) for several nutrients.
Any other cold cereal,...	This item refers to all other cold cereals , like corn flakes, rice krispies, Special K, or Frosted Flakes, etc.

Milk or milk substitutes on cereal Ask about milk on cereal only if cereal is eaten. Ask the question just like any other, "how often do you use...", if the respondent eats cereal; do not just assume that the frequency will be the same as the frequency of cereal. (Some people eat cereal plain, as a snack.)

Frequency: For most people, this will be the number of days per week or month that they eat any kind of cereal with milk. Some respondents may say "every time". Do not code this as 'every day'. Rather, look back at her cereal frequencies and remind her of how often she said she eats cereal; then ask her, "So, about how often do you use milk on cereal, per week?"

Yogurt, frozen yogurt Include all varieties, with or without fruit, regular or low-fat, sweetened or artificially sweetened. Do not code the fruit in yogurt separately as fruit.

Cheese, sliced cheese, or cheese spread, including on sandwiches Include all types, regular or low-fat, hard cheese or soft cheese, natural or processed, including cream cheese. This refers specifically to cheese eaten as cheese. It should not include cheese eaten in lasagna, pizza, etc. Those foods will come later. For the nutrient calculations, a regular or low-fat item on the database will be selected for the calculations, depending on the respondent's answer to the following question on use of regular or low-fat items.

When you eat cheese, ... "Cheese" here refers specifically to cheese by itself, not as part of pizza, lasagna, etc. The program will use the answer to this question to choose the fat content of the cheese whose frequency was reported above.

Q by Q -- Vegetables

When starting the vegetable page, be sure to read the introductory sentence at the top, so that they know to include frozen, canned, etc. All vegetables consumed, whether fresh, frozen, canned or in stir-fry, should be included here if the amount equals at least the 'A' size portion picture. Vegetable soups and vegetable or vegetable-beef stew are separate items, and the vegetables from those items should not be reported separately under the particular vegetable. Small "incidental" amounts that may be included in salads or mixed dishes should not be reported separately under the particular vegetable, unless the amount is equal to at least a half cup. Most of the vegetables must be answered in terms of the portion size pictures; do not let them answer in ounces.

Broccoli Includes cooked or raw. Includes items from salads only if the amount comes to at least the size of a half cup, and then only the frequency that this vegetable itself is actually eaten, not just the frequency that salad may be eaten.

Carrots, or mixed vegetables or stews containing carrots	Includes cooked or raw. Include items from salads only if the amount comes to at least the size of a half cup, and then only the frequency that this vegetable itself is actually eaten, not just the frequency that salad may be eaten. Also includes carrots eaten in mixed dishes such as soup or stew, as those items are captured elsewhere.
Corn	Fresh, frozen or canned. As with year-round fruits, ask the respondent to estimate a year-round average, if eaten more in season. Remember that people may eat corn on the cob when it is in season, but eat canned or frozen corn during the rest of the year. One ear of corn equals approximately a "B" or medium serving.
Green beans	Green beans refers to canned, frozen, fresh, or in salad bars, but <u>not</u> to dried-type peas like black-eye peas, split peas. Green peas (canned, frozen, fresh, or in salad bars) may also be counted in this category.
Spinach	Includes cooked or raw. Spinach salad should be recorded here, not under salad.
Mustard greens, turnip greens, collards	This refers specifically to the dark-green, strong-flavored greens. Beet greens, for example, may be counted here. However, lighter-green leafy vegetables such as celery tops should not be counted here.
French fries, fried potatoes, hash browns	Include home or restaurant fries, and "home fries".
White potatoes not fried...	Include all forms of potatoes except fried. Do not include potatoes eaten in soups or stews, as those are captured elsewhere.
Sweet potatoes, yams	All types. Do not include the sweet potatoes eaten in pies; that question is asked later.
Cole slaw, cabbage	Includes raw or cooked cabbage, including Chinese cabbage, and cole slaw whether homemade or from a restaurant.
Green salad	Includes all kinds of green salad that include some lettuce, whether mostly of iceberg lettuce or of other types of lettuce, and regardless of whether other vegetables are sometimes eaten in it. Spinach salad should be recorded under "spinach", and should not be double-counted here.
Raw tomatoes	Includes tomatoes eaten in alone or in salad <u>Does not include</u> tomato sauces, which are captured under 'spaghetti', etc. Does not include the tomatoes in tomato or vegetable soups, which are captured under that item. The portion size refers to 1/4, 1/2... of a medium tomato.

Salad dressing	All types, creamy or not, including oil & vinegar. Program will assign a regular or low-fat type depending on respondent's answer to the "How often low-fat" question that follows.
Is your salad dressing...	The program will use the answer to this question to choose the fat content of the salad dressing whose frequency was reported above.
Any other vegetable...	Includes any vegetable not already mentioned.
Refried beans or bean burritos	Burritos which have both meat and beans should be recorded here.
Chili with beans	With or without meat.
Baked beans, black-eyed peas...	This includes all dried-type beans, regardless of whether they're mentioned here or not, such as navy beans, red beans, etc. Do not include pea or bean soups; these are asked later
Vegetable stew	Any type of vegetable stew, canned or home-made.
Vegetable soup...	Any type of vegetable soup that has a lot of carrots, or has a tomato base.
Split pea, bean or lentil soups	Any type of pea, bean or lentil soups may be counted here.
Any other soup...	This is the catch-all for all other forms of soup, whether creamed or not.
Spaghetti... <u>with tomato sauce</u>	This item should include only those pasta dishes that are eaten with tomato sauce. It can include mixed pasta items such as raviolis. The defining characteristic is the tomato sauce. When asking this question, emphasize the words "with tomato sauce".
Cheese dishes <u>without tomato sauce...</u>	This item should <u>not</u> include any pasta dishes that are eaten with tomato sauce. Therefore, you must be careful to correctly say " <u>without</u> tomato sauce", not "with". This includes only dishes that commonly have a fair amount of cheese, such as macaroni and cheese, certain Mexican dishes that have a lot of cheese, Welsh rarebit, etc. Incidental sprinkle cheese often used on spaghetti does not make it count as a cheese dish. Cheese sandwiches should be counted in the earlier 'cheese' item, where number of slices can be indicated.
Pizza...	All forms, all sizes, all toppings.

Q by Q -- Meats and main dishes

Hamburgers, cheeseburgers, meat loaf...	All sizes, at home or in a restaurant. Does not include the ground beef used in spaghetti, lasagna or pizza. Only hamburgers, etc. made with beef are to be included here. Turkey burger should not be coded here, but should be included under "chicken or turkey, roasted or broiled".
Tacos, burritos, enchiladas...	Includes beef burritos, tacos, enchiladas, tamales, or other similar dishes, whether with meat or chicken. Bean burritos should be included in the previous section, under "refried beans or bean burritos".
Beef steaks, roasts, pot roasts...	Fresh, in frozen dinners, or on sandwiches. Do not include beef eaten as ground beef.
How do you like your beef cooked	This is not used by the nutrient analysis program, but may be a useful variable.
Pork...	Do not include pork-based lunch meats.
When you eat meat...	The program will use the answer to this question to choose the fat content of the meats whose frequency was reported above.
Veal, lamb, or deer meat	This item includes these three types of meat, or any other 'game' meat (not fowl).
Ribs, spareribs	Any type, any size
Liver...	All forms.
Gizzard, pork neckbones, chitlins, pigs feet, etc.	This item includes the listed foods as well as any other organ meats.
Mixed dishes with beef or pork...	Include any mixed dish with beef, pork, veal or lamb. Do not double-count beef stew reported earlier for the vegetable stew item. Mixed dishes with chicken is a later item.
Mixed dishes with chicken...	Includes any mixed dish with chicken.
Fried chicken...	All parts of a chicken are included (wings, thighs, breast, etc.) provided they are fried. Include McNuggets, etc.

Chicken or turkey not fried...	Include turkey burgers here, but not chicken/turkey eaten as part of a mixed dish.
When you eat chicken...	The program will use the answer to this question to choose the fat content of the chicken whose frequency was reported above.
Oysters	Any form, plain or in stew or soup.
Other shellfish...	All forms, including clams, mussels, squid, oysters.
Tuna...	All forms of tuna, light meat or dark, in oil or in water, straight or in a casserole. Portion size, however, refers to the amount of tuna, and should not include any noodles, etc., eaten with it.
Fried fish...	Home-fried or restaurant, fast food. All types of fish.
Other fish, not fried	All other fish, after excluding fried, tuna or shellfish.
Hot dogs...	All forms, including chicken/turkey.
Are your hot dogs ...	The program will use the answer to this question to choose the fat content of the hot dogs and dinner sausage whose frequency was reported above.
Bologna...	Lunch meats, all types. Ham refers to slices as for sandwiches; ham eaten as a roast or as the entree for a main meal should be reported under "pork". Do not include small amounts eaten on pizza, etc.
Are your lunch meats ...	The program will use the answer to this question to choose the fat content of the lunch meats whose frequency was reported above.
Noodles, macaroni, Pasta salad	This item includes all other pasta dishes that do not contain substantial tomato sauce or substantial cheese. This could include, for example, pasta with white clam sauce (not red), or pesto sauce.
Tofu, bean curd	Refers to "fresh" tofu such as is normally served in Chinese restaurants, or bought in the refrigerator section of supermarkets. Includes all consumption, whether at home or in a restaurant. Count "vegetarian hot dogs" under the next item, "meat substitutes made from soy". Includes only regular tofu, <u>not</u> including fermented or dry, spiced, or koritofu.
Meat substitutes, such as ...	This includes all dishes made with a soy-based meat substitute, such as veggie-burgers made from soy, or tofu hot dogs. This is not just veggieburgers, but veggieburgers <u>made from soy</u> .

Q by Q --Snacks

Snacks, like potato chips...	These should be reported here even if respondent reports eating only low-salt or low-fat varieties. Exclude items here only if respondent eats <u>only</u> air-popped popcorn.
Are these snacks...	The program will use the answer to this question to choose the fat content of the snacks whose frequency was reported above. This question should be answered based on the type of salty snack he or she eats most often.
Peanuts, other nuts and seeds	Any nuts, including walnuts, etc., or seeds such as sunflower.
Crackers	Saltines, or any other crackers
Doughnuts, Danish pastry	This is intended to capture full-fat types of doughnuts and pastries. If they eat a low-fat kind of pastry such as Entenmann's coffee cake, they should report it in the next item.
Cakes, sweet rolls...	All kinds of cakes or coffee cakes, home-made or packaged, including snack cakes.
Are they...	The program will use the answer to this question to choose the fat content of the cakes/pastries whose frequency was reported above. If respondent usually eats low-fat cakes (such as Entenmann's) but eats regular-fat varieties of other foods in the item above, this question should be answered based on the food he or she eats most often.
Cookies	All kinds, all sizes. Since cookies can vary widely in size, the portion size is best recorded in terms of the wood blocks. They may push them into shapes to help them estimate.
Are your cookies...	The program will use the answer to this question to choose the fat content of the cookies whose frequency was reported above.
Ice cream...	All forms including ice cream bars, fast-food milkshakes, etc.
Is your ice cream...	The program will use the answer to this question to choose the fat content of the ice cream whose frequency was reported above. Again, this question should be answered based on the type of ice cream he or she eats most often.
Pumpkin pie...	Include pies or puddings made with pumpkin or sweet potato. However, do not double-count the frequency of sweet potato reported in an earlier item.

- Any other pies...** All forms, fruit-filled or not. Include fast-food pies.
- Chocolate candy, candy bars** Only chocolate-covered or chocolate-based candy and candy bars should be included here. The point is the chocolate, not just any candy.
- Other candy...** Any sugar-based non-chocolate candy.

Q by Q --Breads, etc

Point out the different frequency categories to the respondent. For foods on this page, a response of "every day" always needs to be probed to determine whether the food is eaten once a day or more often. Then, it is important to phrase the serving size question as "How many each time". For example, if the respondent answers that she eats bread twice a day, the portion size should refer to how many slices she eats on each of those times. Suppose she eats bread "twice a day", and has two slices each time; you would record "2+ per day" as her frequency, and "2" as her portion size. (If she is more comfortable telling you she eats four slices per day, it is okay to record "every day" and then "4". But it is important to be careful that you do not accidentally record "2+ per day" for frequency and "4" for portion, as that would give her eight slices per day rather than four.)

If the respondent eats bread "twice per day", but has a different portion size each time, she may have difficulty coding her consumption correctly. The easiest way to handle may be for you to convert her frequency of consumption to "every day", and then code the portion size as the total number of pieces consumed each day. For example, if the respondent eats two slices of bread for lunch and one slice of bread for dinner, you may code this as "Every day", and "3 slices".

- Biscuits or muffins...** Biscuits include homemade or from fast food places such as Kentucky Fried Chicken, McDonalds. Muffins include kinds such as bran muffins, blueberry muffins, etc., but do not include English muffins, which should be included under 'Rolls,...', below.
- Rolls, Hamburger buns, English muffins, bagels** All types, all sizes. Note that these items come as two halves. Therefore, if they only eat 1/2 a bagel, etc., the portion size should be marked as "1/2". Only a whole bagel, English muffin, hamburger bun, etc., should be marked as "1".
- Dark bread...** Includes whole wheat, rye, pumpernickel, or other dark breads. In reporting portion size, the response is in "slices". Include bread eaten in sandwiches.
- White bread...** White, French, Italian, etc., all forms. In reporting portion size, the response is in "slices". Include bread eaten in sandwiches.

Cornbread...	Includes cornbread, corn muffins, hush puppies.
Tortillas	Includes flour and corn tortillas. Portion size is in number of tortillas each time .
Rice, or dishes ...	This includes not only rice eaten by itself, but also as fried rice, Rice-a-roni, beans-n-rice, rice pudding, etc.
Margarine on bread or potatoes...	All forms, on bread or added to vegetables at the table. A "pat" is about one teaspoonful.
Butter on bread or potatoes...	All forms, on bread or added to vegetables at the table. A "pat" is about one teaspoonful.
Gravy	Include meat gravies or packaged varieties.
Peanut butter	Other nut butters may also be included in this item.
Mayonnaise, sandwich spreads	All types
Catsup, salsa...	All kinds of tomato-based condiments.
Mustard, soy sauce...	Any other type of sauce, not already captured above.

Concluding Questions

The last eight questions are not used by the nutrient calculations, and thus may be omitted without harm **to the nutrient calculations**. However, they are important aids in understanding the results, and their presence on the same file will often aid in interpretation.

Did you use the pictures: This question may be filled in by the interviewer when the questionnaire is interview-administered.

Self-assessed health status: This simple question has been shown in numerous studies to be a powerful predictor of subsequent morbidity and mortality. It appears to be even more powerful a predictor than such objective measures as medical conditions, or physician examination.

Repeated weight loss: In addition to being individually implicated in cardiovascular disease, this behavior alters metabolism and thus the relationship between energy intake and resulting body weight.

Hours watching television or video: This question may be useful as a stand-in for questions on respondent's level of physical activity

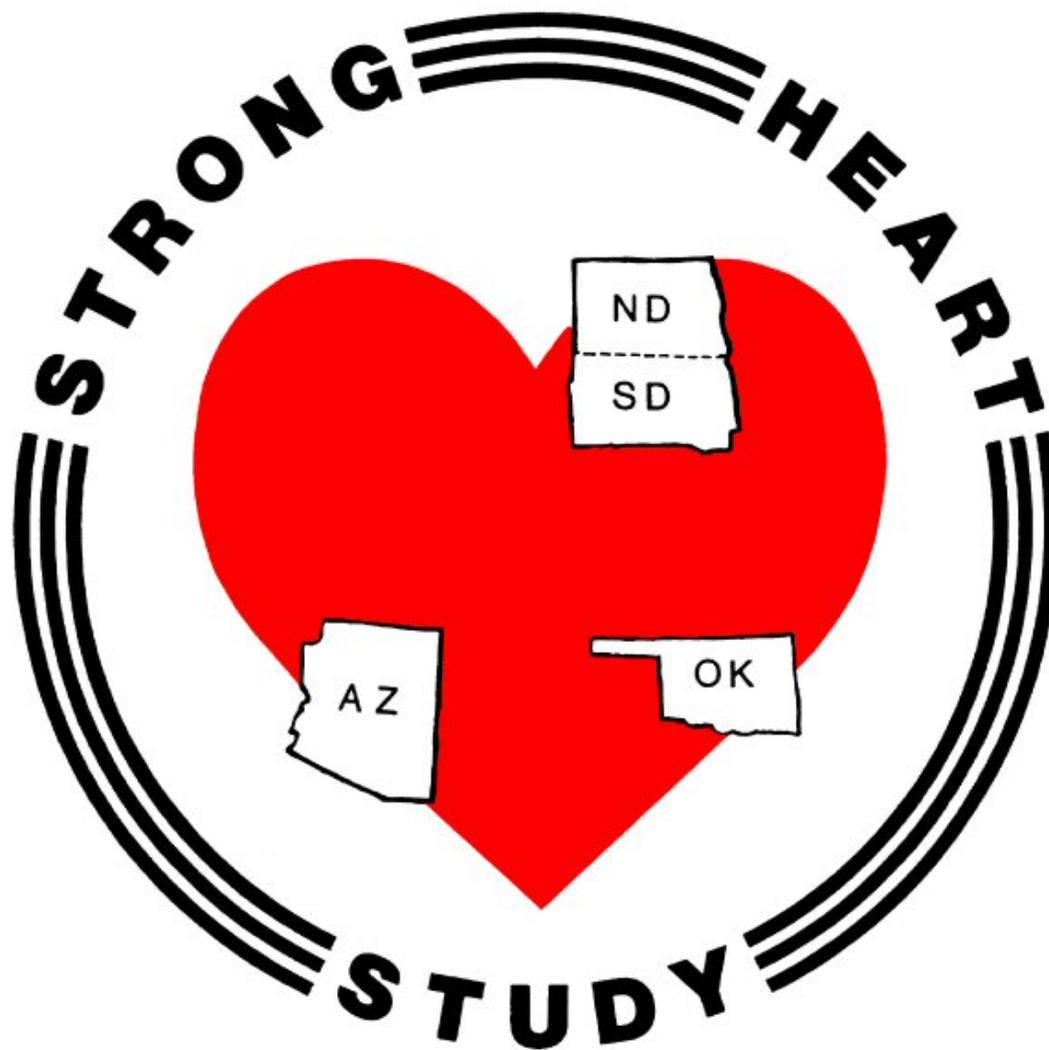
Smoking: Current smoking is not only a risk factor for most health conditions, but it reduces plasma levels of many nutrients, and alters the relationship between intake and tissue level. Thus, even validation studies are poorly interpretable without this question.

Language spoken: This may provide clues to the respondent's ability to self-administer this or other questionnaires. In addition, if unusual nutrient estimates are observed, this may serve to indicate that the food list on the questionnaire was not quite appropriate for this respondent's ethnicity.

Ethnicity: Similar rationale as for language.

ADDITIONAL FOODS (LAST PAGE OF QUESTIONNAIRE)

SPAM	Spam or Spam lite. Any canned luncheon meat.
MENUDO	Tripe, hominy, tomato, onion, chili powder.
POZOLE	Wheat kernels, boiled with tepary beans.
GUYSAVA	Traditional food made from roasted ground corn.
RED OR GREEN CHILI	Beef chuck or stewing beef cooked with chili or jalapeno.
INDIAN TACO salsa.	Frybread, ground beef, beans, cheese, lettuce, tomato, Any combination of the above foods.
FRYBREAD	Any frybread, whether baking powder or yeast dough.
CORN TORTILLA	Tortilla made from corn.
FLOUR TORTILLA	Tortilla made from flour.



FAMILY STUDY

**Cardiovascular Disease in American Indians
(Phase IV)**

Operations Manual - Volume Ten

TRAINING MANUAL

**THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

THE STRONG HEART STUDY

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual

Volume Ten

TRAINING MANUAL

July 01, 2002

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
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VOLUME X
TRAINING MANUAL

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STRONG HEART STUDY

PHASE IV

FAMILY STUDY

TRAINING MANUAL

SHS IV – Cardiovascular Disease in American Indians, Phase IV – Family Study

STAFF TRAINING AND CERTIFICATION CHECKLIST

Trainee Name _____

Task	Date of Certification	Initial
Anthropometry		
Hip		
Waist		
Arm		
Height		
Weight		
Blood Pressures		
Diet - FFQ		
Doppler Blood Pressures		
ECG		
Edema		
Impedance		
Morbidity & Mortality Surveillance		
Pedal Pulses		
Pedometer		
Personal Interview		

SHS Phase IV Family Study
Quality Control Documentation

Trainee Name _____

Activity	QC						
Date							
Consent Form							
Personal Interviews							
Diet FFQ							
Anthropometry							
ECG							
Sitting Blood Pressures							
Impedance Doppler Blood Pressures							
Edema and Pedal Pulses							
Pedometer							

INTERVIEWS

Interview Procedures

In general the rules for asking questions in structured interviews can be summarized as follows:

- a. Questions must be asked according to the instructions for each form and question. Be sure to read and re-read the instructions for each questionnaire you are using, and to ask all the questions in the same way to each person interviewed.
- b. Read the questions exactly as they are worded in the questionnaire. If the question is misunderstood, then it may be repeated, interchanging local terms, if necessary for understanding.
- c. Read each question slowly.
- d. Use correct intonation and emphasis.
- e. Ask the questions in the order that they are presented in the questionnaire.
- f. Ask every question that applies to the respondent (all inapplicable questions will be identified as such by skip instructions in the questionnaire).
- g. Repeat questions IN FULL that are misheard or misunderstood.
- h. Read all linking or transitional statements exactly as they are printed.
- i. Do not add apologies or explanations for questions unless they are printed in the questionnaire.

PROBING: Probes are additional questions asked or statements made by the interviewer when the answer given by a respondent is incomplete or irrelevant. Probing has two major functions: (1) To motivate the respondent to reply more fully; (2) to help the respondent focus on the specific content of the question. It must fulfill these functions without biasing the respondent's answers. However, probes, when they are used, **MUST** be neutral. Probing can introduce bias, such as by summarizing your understanding of the response to the subject when an unclear response has been given, or by offering some alternative interpretations from which the respondent can choose, and this must be guarded against.

The following are NON-DIRECTIVE methods of probing:

- a. Repeat the question (RQ). All that may be required to clear up a vague answer may be to repeat the question. You may begin by saying "I am not sure that I understood you, let me just repeat the question so that I can be sure to get your answer right."
- b. The expectant pause. Waiting expectantly will tell the respondent that the

- c. interviewer is expecting more information than has been provided. Repeat the reply. Repeating the reply aloud while recording it may stimulate the respondent to provide more details.
- d. Neutral questions or comments. Various neutral probes may be used for purposes such as clarification, specificity, or completeness: "What do you mean exactly?", "In what way?", "Could you be more specific about that?", "Anything else?", "Can you tell me more about it?"
- e. Interpretation. Make sure that the question was understood, since that may be the reason for incomplete answers. You may need to ask the question again, perhaps substituting some local terms, if there is a problem in interpretation.

FEEDBACK: The provision of feedback by the interviewer to the respondent about his or her performance has been the subject of much research. Some studies have shown that the use of feedback in health-related surveys increased the amount of reporting of most events. Your decision about whether to provide feedback may depend upon the performance of the person you are interviewing and your experience in the benefits of providing feedback.

Common Interviewer Errors

We should try to minimize interviewer error during this study. The primary objectives of epidemiologic research are (1) to obtain measurements of exposure and disease variables relevant to the objectives of the study, and (2) to maximize completeness and minimize error in these measurements. The presence of an interviewer may both reduce error and increase error. It may reduce error by increasing the response rate, motivating the subject to respond well and probing to obtain complete data when the responses volunteered fall short of what is desired. The presence of an interviewer may increase error if, by his or her appearance, manner, method of administration of the questionnaire or method of recording of the responses, he or she exerts a qualitative influence on the subject's responses. Possible sources of error in the interview for data collection include (1) conditions of administration (privacy, heat, light, ventilation, freedom from distraction, lack of time, etc.); (2) interaction of the personality, sex or race of the interviewer with that of the subject; and, (3) performance by the interviewer (questioning, prompting and recording of responses).

The following are the common interviewer errors:

- a. Asking errors. Omitting questions or changing the wording of questions. This may be particularly important if the interview is performed in Native language.
- b. Probing errors. Failing to probe when necessary, biased probing, irrelevant probing, inadequate probing, preventing the respondent from saying all he or she wishes to say.
- c. Recording errors. Recording something not said, not recording something said,

incorrectly recording response.

- d. **Flagrant cheating.** Not asking a question but recording a response, recording a response when the respondent does not answer the question asked. These kinds of errors do occur and this has been amply documented by various studies. Cheating has been shown to be more common when the interviewer is in an uncomfortable situation with the interviewee, i.e., he/she is difficult. In such situations the question should still be asked and if the participant refuses to answer the question(s), the refusal should be documented on the form.

SHS Phase IV Family Study

Training and Quality Assurance

PERSONAL INTERVIEWS

Training

Interviewers will be trained using a standardized procedure for administering each questionnaire. Training will include instructions in research interviewing techniques and in completing each form. Interviewer skill training will include:

- a) adherence to the standardized protocol
- b) use of non-judgmental attitudes
- c) degree and nature of prompting
- d) appropriate problem solving
- e) proper handling of participants' comments and documenting relevant information on logs
- f) post interview responsibilities

Quality Assurance

To assure consistency and accuracy and minimize interviewer variances, the study coordinator will monitor and tape one interview during the first exam month on interviews conducted by each interviewer. For "new staff," this should be repeated each month until the Coordinator determines that the interviewer has met the standards of the study. Then, new staff members will be observed on a quarterly basis along with experienced interviewers. Should any interviewer fall short of the required standards, retraining will be required with special attention given to the problem areas. If the problem persists, the interviewer will be removed from the task of conducting interviews.

SHS PHASE IV FAMILY STUDY

Checklist for Personal Interviews

The Study Coordinator will observe and tape one interview during the first exam month on interviews conducted by each interviewer and record the results below. As each procedure is carried out, indicate if it is correct by checking the "yes" or "no" column. Suggestions and comments can be written in the space provided. Quarterly observation will be followed after interviewers are certified and have demonstrated the standards of the study have been met.

Interviewer code# _____

Date observed _____

Observer code# _____

- | | | |
|--|-----------|----------|
| Establishes correct environment (for privacy and participant comfort). | Yes _____ | No _____ |
| Uses proper introduction of questionnaire and self (purpose of form/data). | Yes _____ | No _____ |
| Reassures participant: confidential _____ voluntary _____ can skip Q's _____ | Yes _____ | No _____ |
| Reads questions exactly as written, slowly, distinctly, in a neutral tone with no omissions or rewording. | Yes _____ | No _____ |
| Reads questions in correct order following skip patterns when required. | Yes _____ | No _____ |
| Conducts interview in understandable language for participant. If in native language, uses correct translations. | Yes _____ | No _____ |
| Repeats questions in full that are misheard or misunderstood. | Yes _____ | No _____ |
| Uses neutral probes non-directively and appropriately (using pauses, repeating answers, giving ranges, etc.) | Yes _____ | No _____ |
| Handles problem solving situations with proper interventions. (This includes participants' questions.) | Yes _____ | No _____ |
| Remains nonjudgmental throughout interview. | Yes _____ | No _____ |
| Records answers correctly on forms. Edit forms before participant leaves clinic for any corrections. | Yes _____ | No _____ |
| Provides closure with participant (including expression of appreciation). | Yes _____ | No _____ |

Comments: _____

ANTHROPOMETRY

Procedure for Measuring Height, Weight, Waist and Hip Circumferences

1. Height and Weight

a) Standing Body Height

The participant stands erect on the floor or the horizontal platform with his/her back against the vertical mounted ruler, heels together and against the vertical ruler, looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane which includes the lower margin of the bony orbit and the bony socket containing the eye the most forward point in the supratragal notch just above the anterior cartilaginous projections of the external ear) (Figure 1). The right angle is brought down snugly but not tightly on the top of the head. A foot stool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and the metal ruler is mounted perpendicular to the floor). A chart converting centimeters to inches is on the wall or available for use in informing the participant of his/her height in inches.

b) Body Weight

Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Tanita BWB-8005 Adult Digital Scale) with head erect and eyes looking straight ahead. Record the results to the nearest kilogram using the rounding method. To maintain accuracy, the scale is zeroed daily and must be calibrated with a known weight (50-lb) every month or whenever the scale is moved. To calibrate the scale, check that the 50-lb weight weighs 50 lbs. after zeroing the scale. Furthermore, the operator should make sure that an adult must weigh 50 lbs. more when standing on the scale holding the weight.

2. Supine Waist (Abdominal) Girth

An anthropometric tape is applied at the level of the umbilicus (navel) with the patient supine (Figure 2) and the participant is instructed to "breathe quietly". The measurement is made and recorded to the nearest centimeter using the rounding method.

3. Erect Hip Girth

Instruct the participant to stand erect yet relaxed with weight distributed equally over both feet. The hip girth is measured at the level of maximal protrusion of the gluteal muscles (hips) (Figure 3). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest centimeter using the rounding method. Only one measurement is made. The greatest source of error for this measurement is due to not having the tape horizontal. Technician(s) should check the position of the tape to assure its correct position from both the front and back.

4. Upper Arm Circumference

The participant sits on a table or stool so that the right arm hangs freely with the right hand resting on the right knee. The observer applies the tape measure horizontally at the midpoint between the acromium and olecranon (Figure 3). Record the measurement to the nearest centimeter using the rounding method. This measurement is used to select the proper size blood pressure cuff.

A Novel Products tension tape is used to measure both abdominal and hip girth and the upper arm circumference.

Figure 1. Frankfort Plane for Measuring Body Height

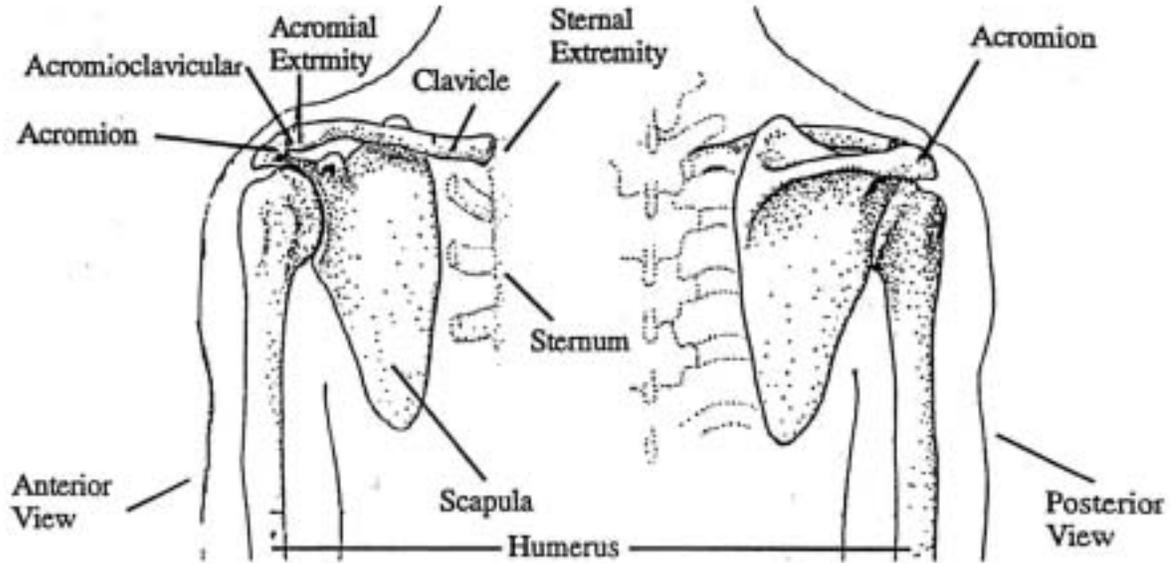


Figure 1 (a). General Description: The scapulae, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body. The end of the spine projects as a flattened, expanded process called the acromion. This process articulates with the clavicle.

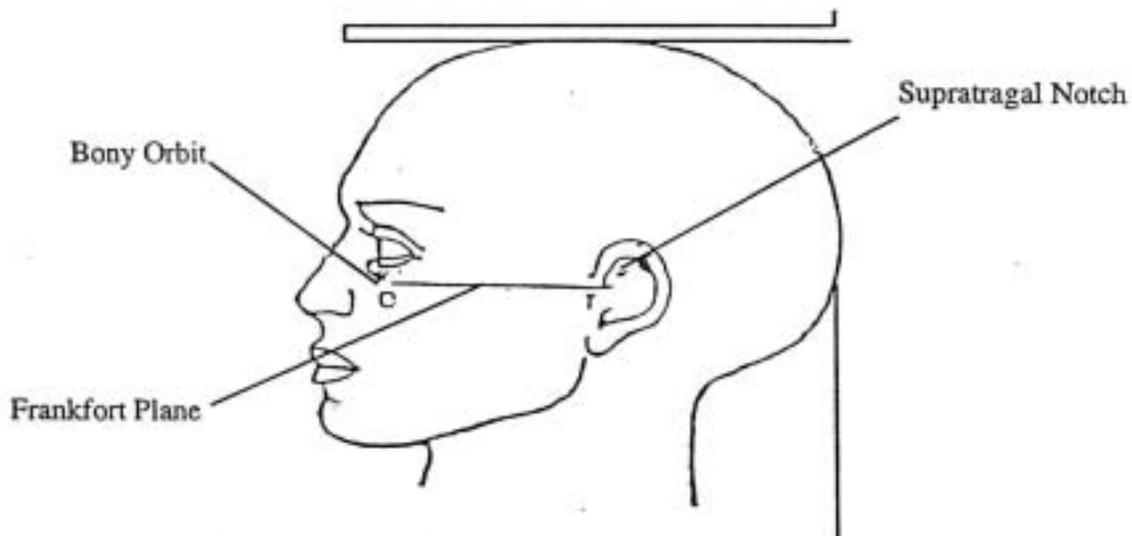


Figure 1 (b). the Frankfort Plane: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external ear.

Figure 2. Location of Waist Girth Measurement

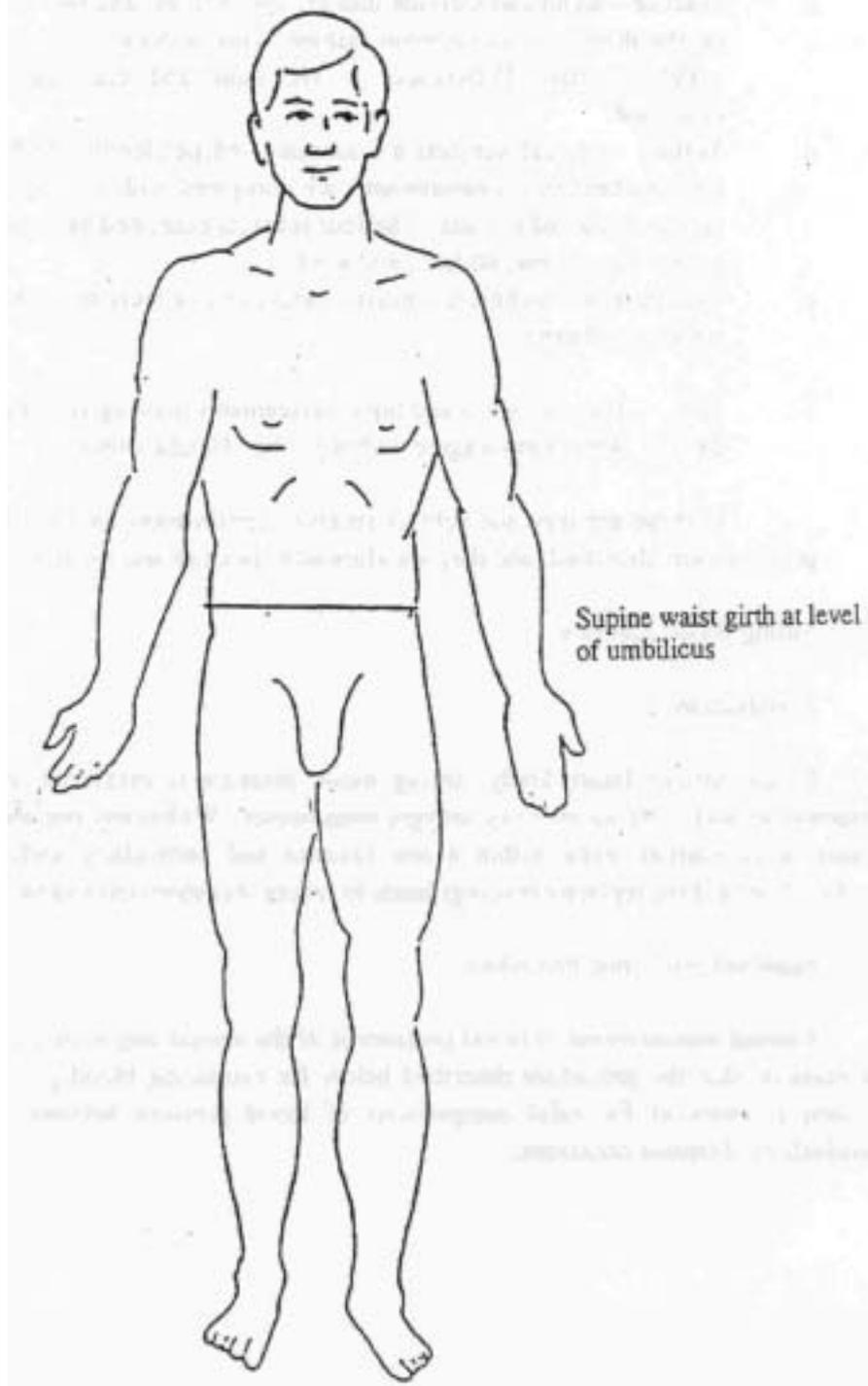
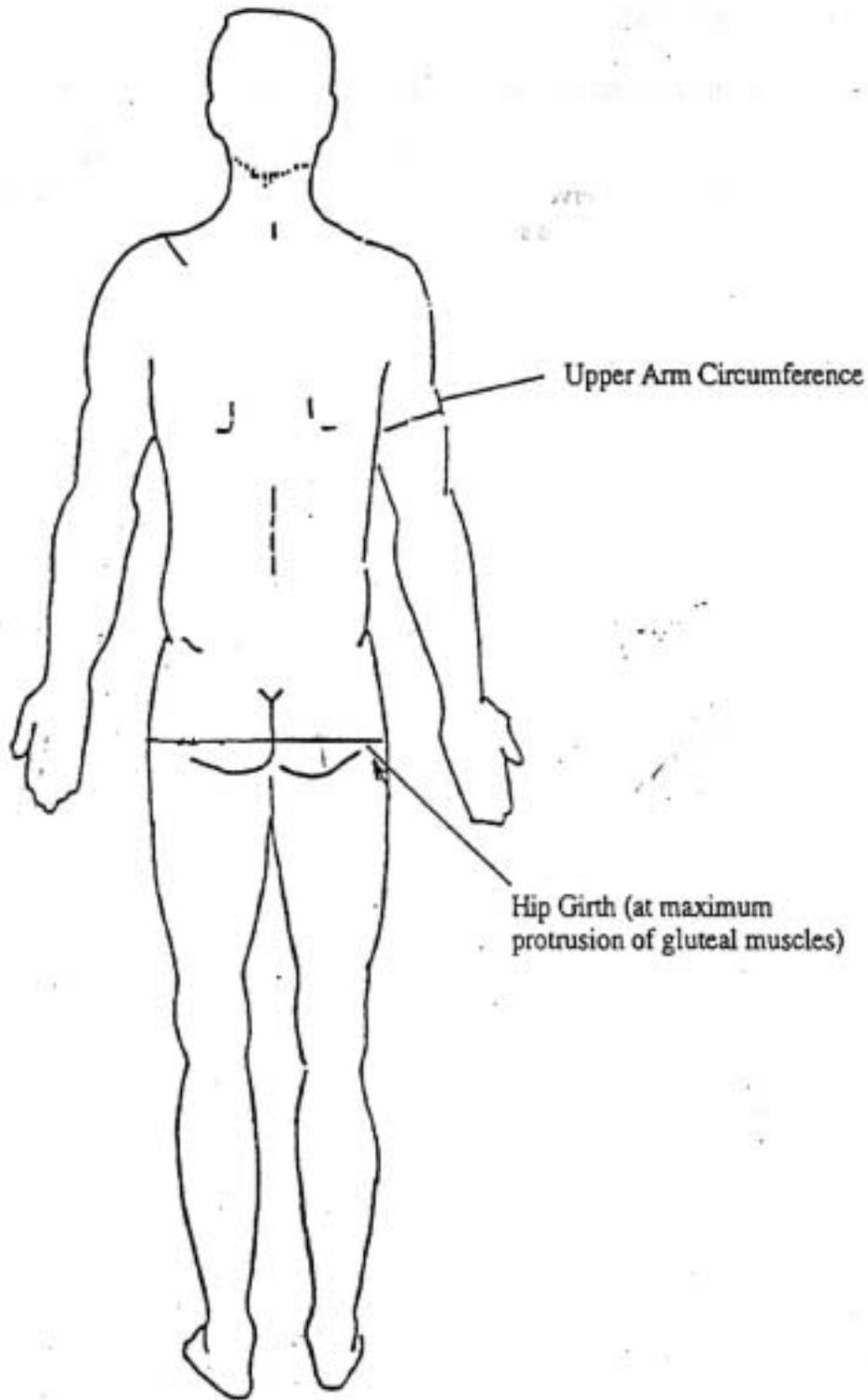


Figure 3. Location of Upper Arm, Hip, and Calf Circumference



SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

ANTHROPOMETRY

Training

Technician skill training will include:

- a) Introduction - rationale for body size measurements
 - overview of technique
 - expected limits of reproducibility
 - pitfalls related to anthropometry
- b) Demonstration - an expert demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as how to record the data.
- c) Practice - techs perform measurements on each other or on a volunteer under the observation of an experienced anthropometrist. Differences in technique and clarification of problems are discussed.
- d) Testing - several subjects are assessed independently and blindly by each technician. The subjects should be from four distinctly different body type groups: lean, obese, athletic, and aged. Each tech's measurements are compared with the expert's measurements and the results are discussed with the tech.
- e) Certification - technicians must measure one or more test subjects and be within the standards of error:
 - 1) The waist and hip measurements must agree within two cm on each subject, and the arm and height measurements must agree within one cm.
 - 2) The weight must agree within one kg.

Quality Assurance.

To insure consistency and accuracy, study coordinators will monitor technicians quarterly.

Observation should include proper technique and accuracy within the standards of error listed above.

SHS PHASE IV FAMILY STUDY

Checklist for Anthropometry

The Study Coordinator will observe each technician quarterly. If each procedure is carried out correctly, indicate so by checking the "YES" space. Results of measurements should be within standard of error:

- The waist and hip measurements must agree within two cm on each subject, and the arm and height measurements must agree within one cm.
- The weight must agree within 1 kg.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

- YES () NO () Tech instructs subject to remove shoes for height and weight.
 YES () NO () Tech positions subject appropriately for height measurement.
 YES () NO () Tech balances and zeroes the scale before subject is weighed.
 YES () NO () Subject is weighed accurately to the nearest kg by the tech.
 YES () NO () Hip girth is measured accurately with the tape measure placed horizontally around the maximal protrusion of the gluteal muscles.
 YES () NO () Tech measures arm circumference accurately, rounding to the nearest cm.
 YES () NO () Tech correctly positions subject for waist measurement.
 YES () NO () Measure of waist taken correctly, tape position at umbilicus.

	Technician	Observer	Difference
Height	_____	_____	_____
Weight	_____	_____	_____
Hip	_____	_____	_____
Arm	_____	_____	_____
Waist	_____	_____	_____

ECG

SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

STANDARD ECG

Training

Technician skill training will include:

- a) procedure for recording baseline ECG
- b) electrode position measuring and marking
- c) chest lead placement
- d) limb lead placement
- e) skin preparation
- f) application of electrodes
- g) recording the 12 - lead ECG

Standard ECG instruction follows this section and is found in the SHS Phase IV MANUAL.

Quality Assurance.

The study coordinator will monitor the ECG technicians quarterly to insure accurate and consistent examinations. Observation should include evaluation of all the criteria listed above and should be recorded on the Checklist for ECGs.

SHS PHASE IV FAMILY STUDY

Checklist for ECGs

The study coordinator will monitor ECG technicians quarterly to assure consistent, accurate examinations. If each procedure is carried out correctly, indicate so by checking the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

- YES () NO () Subject is instructed to disrobe to the waist, lay supine in a relaxed position and to avoid movement during recording.
- YES () NO () Chest electrodes are positioned correctly.
- YES () NO () Limb electrodes are positioned correctly.
- YES () NO () Skin preparation is used for poor electrode adhesion
- YES () NO () Electrodes left in place 2-3 minutes before recording.
- YES () NO () Subject information correctly entered into MAC PC.
- YES () NO () Appropriate recording of ECG performed.
- YES () NO () Recording repeated if artifact on tracing, subject encouraged to relax.

Comments: _____

BLOOD PRESSURES

Procedures for Taking Blood Pressures

1. Determine Cuffs

Proper size of the cuff is essential for accurate blood pressure measurement. Study Centers have four standardized Baum cuffs available - pediatric, adult, large adult, and thigh cuff.

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the Strong Heart Study, arm size is measured and the cuff size is selected as follows:

Table 1.2 Determination of cuff size based on arm circumference (Mid humeral)

Cuff Size	Arm Circumference
Pediatric	< 24 cm
Adult	24 to 32 cm
Large Adult	33 to 41 cm
Thigh	>41 cm

2. Measurement Procedures

The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 minutes to make three blood pressure measurements including the initial five-minute rest. The blood pressure measurements are made early in the clinic visit sequence immediately following the reception and informed consent, and more than 15 minutes after phlebotomy.

Once the participant is given instructions and explanations and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

- a) If the participant indicates that there is a medical or postsurgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the data collection form that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.
- b) Seat the participant with the right arm on the table. The bend at the elbow (ante-cubital fossa) should be at heart level. Legs should be uncrossed and head support comfortable. The participant should be able to relax the neck and shoulder muscles as much as possible.
- c) Palpate the brachial artery (just medial to and above the ante-cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five-minute wait.

- d) Record the time. Allow a five-minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary.
- e) Connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no longer felt. Deflate and record the pulse obliteration pressure. Have the participant raise measurement arm for five seconds and then wait another 25 seconds with the participant's arm on the table.
- f) Measurement 1: Connect the cuff to the manometer. Inflate rapidly to the pulse obliteration level + 30 mm. Holding the pressure constant with the bulb, wait 5 seconds. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. If the mercury column falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the **higher number** should be used.
- g) Measurements 2 and 3: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement in step f above and disconnect cuff.

To assure accuracy, the second and third blood pressure readings are averaged using a calculator.

If for any reason the observer is unable to complete, or has forgotten to complete any portion of the examination (and the participant is gone), draw two horizontal lines through the space(s) on the form. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure workstation, completely deflate the cuff and start over with a replacement reading.

3. Procedure for changing the peak inflation level

Occasionally the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. The observer immediately deflates the cuff by releasing the thumbscrew and disconnecting the cuff tube. Then have the participant hold the cuff-wrapped arm vertically for five seconds. Proceed with blood pressure measurement, starting at a new peak inflation level, 10 mmHg above the previous level.

SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

BLOOD PRESSURE MEASUREMENT

Training

Skill training will include:

- a) Patient instruction, allowing opportunity for questions
- b) Measure right arm for correct cuff size
- c) Palpate brachial artery, medial to and above antecubital fossa
- d) Mark pulse point
- e) Wrap cuff, center of bladder over brachial pulse
- f) Leave subject for five minutes of rest
- g) Position subject, instruct subject on posture (sit upright with right arm bent at elbow, legs uncrossed)
- h) Allow full five minutes for rest
- i) Environment free of excessive noise
- j) Find pulse obliteration point using standard manometer
- k) Calculate peak inflation, 30 mmHg above pulse obliteration point
- l) Place stethoscope in ears
- m) Inflate cuff rapidly to calculated peak
- n) Count full five seconds with pressure steady
- o) Place bell on brachial pulse
- p) Deflate cuff slowly, 2 mmHg per second
- q) Deflate cuff rapidly after 2 absent sounds
- r) Record reading
- s) Disconnect tubes
- t) Instruct subject to hold right arm vertical for full five seconds
- u) Wait at least 30 seconds before proceeding to 2nd and 3rd readings
- v) Average 2nd and 3rd readings, inform subject of average BP

Quality Assurance.

To insure consistent and accurate measurements, the study coordinator will observe technicians quarterly. They should demonstrate proper technique as listed above. The study coordinator should record his/her observations and comments on the BP checklist. Also, quarterly, each tech should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to the Simultaneous BP Observation Form and should calculate the differences between the two sets of measurements. The standard of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

SHS PHASE IV FAMILY STUDY

Checklist for Blood Pressure

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

- YES () NO () Provide subject instruction, allowing opportunity for questions.
- YES () NO () Measure right arm for correct cuff size.
- YES () NO () Palpates brachial artery, medial to and above antecubital fossa.
- YES () NO () Marks pulse point.
- YES () NO () Places cuff correctly.
- YES () NO () Leaves subject for 5 minutes rest.
- YES () NO () Subject positioned correctly.
- YES () NO () Provides environment free of excessive noise.
- YES () NO () Finds pulse obliteration point.
- YES () NO () Calculates peak inflation.
- YES () NO () Places stethoscope in ears.
- YES () NO () Inflates cuff rapidly to calculated peak.
- YES () NO () Holds pressure steady for full 5 seconds.
- YES () NO () Places bell on brachial pulse
- YES () NO () Deflates cuff slowly, 2 mmHg per second.
- YES () NO () Deflates cuff rapidly after 2 absent sounds.
- YES () NO () Records readings.
- YES () NO () Disconnects tubes.
- YES () NO () Instructs subject to hold right arm vertical for full five seconds.
- YES () NO () Waits at least 30 seconds before proceeding to 2nd and 3rd readings.
- YES () NO () Average 2nd and 3rd readings, informs subject of average BP.

Comments: _____

SHS PHASE IV FAMILY STUDY

Simultaneous Blood Pressure Observation Form

Quarterly, each technician should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to this form and should calculate the differences between the two sets of measurements. The acceptable margin of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

Technician #1 Code # / Initials _____

Technician #2 Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

	Tech #1	Tech #2	Difference
Arm circumference	_____	_____	_____
Cuff size	_____	_____	_____
Pulse obliteration pressure	_____	_____	_____
SBP #1	_____	_____	_____
DBP #1	_____	_____	_____
SBP #2	_____	_____	_____
DBP #2	_____	_____	_____
SBP #3	_____	_____	_____
DBP #3	_____	_____	_____
Average SBP	_____	_____	_____
Average DBP	_____	_____	_____

Comments: _____

PEDAL PULSES AND EDEMA

Examination of Edema and Pedal Pulses

1. Ankle Edema

The socks or other foot covering are removed. The participant is examined in the supine position. Gentle but firm pressure is applied along the mid-tibia, anteriorly down to the ankle in each leg. Pitting or indentation remaining after pressure is removed constitutes definite edema. The examiner identifies the mid-point between the prominence of the medial malleolus and the inferior border of the patella. Pitting at or above that mid-point is recorded as "marked" edema. Pitting only below that point is recorded as "mild" edema. The degree of edema is based on the extent.

2. Posterior Tibial Pulse

The examiner palpates inferior to the medial malleolus of each foot. The presence or absence of arterial pulsation is recorded. If in doubt, the examiner compares with the radial pulsation.

3. Dorsalis Pedis Pulse

The superior aspect of each foot is palpated for the presence or absence of this pulse.

SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

EXAMINATION OF PEDAL PULSES AND EDEMA

Training

Technician instruction will include:

- a) rationale for exams
- b) visualization and palpation of lower extremities for edema
- c) palpation of posterior tibial pulses
- d) palpation of dorsalis pedis pulses

Quality Assurance

Observation of technicians should be done quarterly. Evaluation should include all of the criteria listed above and should be recorded on the Q. A. Checklist.

SHS PHASE IV FAMILY STUDY

Checklist for Pedal Pulses and Edema

Observation of technicians should be performed quarterly. If each step in the list below is carried out correctly, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

YES () NO () Positions subject supine.

YES () NO () Examines and palpates lower extremities for edema.

YES () NO () Records status of edema.

YES () NO () Palpates posterior tibial pulses, bilaterally.
(Posterior and inferior to the medial malleolus)

YES () NO () Palpates dorsalis pedis pulses, bilaterally.
(Superior aspect of each foot)

YES () NO () Records presence or absence of pulses.

Comments: _____

IMPEDANCE

Procedure for Impedance Measure

The measurement of body fat is accomplished using the Quantum II Impedance Meter, made by RJL Equipment Company. This involves a small low frequency current that travels across the body through the extracellular fluids. The measurement of bioelectrical impedance is related to the volume of the conductor and, when expressed as impedance or conductance, is proportional to fat free mass. The participants do not feel anything when this measurement is obtained.

1. Explain to the participant why you are making the measurement.
2. Before beginning the test, be sure that the subject cable is securely attached to the RJL spectrum, have the participant remove the right shoe and sock and lie down with the right side nearest to the analyzer;
3. If the examination table is metallic, it must have a foam pad - all of the body must be on the pad.
4. For best results:
 - i) Use electrodes only once.
 - ii) Legs should be far enough apart so that the thighs do not touch each other. A towel may be used to prevent the legs and thighs from touching.
 - iii) Hands and arms should be far enough apart so that the arms and hands do not touch the torso. A towel can be used to prevent the arms from touching the body.
 - iv) No body parts should be in contact with any external metal (jewelry and pins in bones will not affect the results).
 - v) Participant's skin should be clean, dry and warm to the touch. If the skin is oily, clean it with an alcohol swab before attaching the electrodes.

Prior to the attachment, cut the electrodes in half bisecting the foil tab. The cut edge of the electrode placed on the ankle and wrist should face toward the shoulder and thigh respectively. The cut edge of the other two may face in either direction.

4. Electrode Placement:
 - i) Attach the black wires to the foot with the red clip connected to the electrode at the ankle (F1). Attach the red wires to the hand with the red clip connected to electrode at the wrist (H1).
 - ii) Put H1 on an imaginary line from the protruding bone of the wrist to bisect the ulnar

head; make sure that the cut edge of the electrode is toward the shoulder.

- iii) Put H2 just above the knuckles of the right hand or on any finger; there should be at least 5 cm difference between H1 and H2.
- iv) Put F1 on an imaginary line between the protruding ankle bones to bisect the medial malleolus; make sure that the cut edge of the electrode is toward the thigh.
- v) Put F2 just above the toes of the right foot or on the great toe (there should be 5 cm difference between F1 and F2)

Once the electrodes have been properly attached to the subject, the values for resistance and reactance will appear on the screen. Record these on the results sheet. Make sure that the toggle switch is set on x1.

SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

IMPEDANCE

Training

Technician instruction will include:

- a) rationale for body composition estimate measurement
- b) use of equipment and supplies needed
- c) explanation to subject
- d) positioning of subject
- e) electrode placement
- f) recording of resistance and reactance results

The complete, detailed procedure is located in the SHS PHASE IV MANUAL.

Quality Assurance

An individual at each study center will be designated as the supervisor of the impedance measures. The supervisor will assure that each of the other operators of the instruments is re-certified quarterly by having him/her perform an impedance measure on the same subject as the supervisor. The observation of the operators should include evaluation of all criteria listed above and should be recorded on the Checklist for Impedance. The measurement results should agree within 15 ohms.

SHS PHASE IV FAMILY STUDY

Checklist for Impedance

The Impedance supervisor will monitor each of the other operators of the instrument quarterly. The observation of the operators should include the following criteria. If performed accurately, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

- YES () NO () Explains procedure to subject.
- YES () NO () Questions subject about recent exercise and alcohol consumption.
- YES () NO () Asks subject to remove right shoe and sock.
- YES () NO () Positions subject supine, with right side nearest to analyzer.
- YES () NO () Assures that there is no skin to skin contact at axillas, thighs, abdomen.
- YES () NO () Assures that arms are placed to subject's side without hands touching anything.
- YES () NO () Electrodes placed correctly.
- YES () NO () Leads connected correctly.
- YES () NO () Records resistance and reactance.

Comments: _____

DOPPLER BP

Using Doppler to Measure Ankle Systolic Blood Pressure

1. Move the Participant to the Supine Position

Assist the participant in moving to the supine position on the examination table.

2. Applying the Blood Pressure Cuff

The appropriate ankle blood pressure cuff is applied on the right calf. The same size cuff should be used on the lower leg (calf) as the one used on the arm. In special instances, different cuff size may be used.

At this point, a blood pressure cuff is applied above the ankle of the right leg, as shown in Figure 4. Place the cuff flat on the table (the surface marked "side to the patient" face up) with the appropriate ankle centered on the cuff. At this time disregard the "over the artery" marker. The lower edge of the cuff (from which the hoses extend) should be approximately 2 to 2.5 inches above the medial malleolus. Following the contour of the lower leg, wrap the end of the cuff with the velcro "fabric" over the ankle, as shown in Figure 5. Note that depending on the degree of tapering in this area, the cuff corner will be offset from parallel toward the knee. Holding the cuff from sliding, wrap the other end over the ankle (step III in Figure 5), again following the contour of the ankle, and secure the velcro. Check to be sure that the corners of the cuff extending above the upper edge of the cuff are about equal: if one end extends more than the other, loosen the Velcro and adjust the wrap. Next, locate the "over the artery" marker of the cuff, and rotate the cuff so that this line is directly over the posterior tibial artery. The cuff may be rotated more easily by sliding it toward the malleolus, and after alignment, the cuff can be made snug by pulling it up toward the calf. The cuff should conform closely to the shape of the ankle, with the lower edge 2 to 2.5 inches above the malleolus.

The posterior tibial artery is usually palpated as it courses posteriorly to the medial malleolus. Even if the posterior tibial pulse is not palpable, the posterior tibial artery is used as the location for the marker line on the cuff for the "over the artery position". Any kinks in the tubing are removed, and any "tugging" of the tubing on the participant's leg is relieved.

3. Procedure for Measuring Ankle Blood Pressure

- a) Palpate posterior tibial pulse and mark these locations. Apply ultrasound gel to the posterior tibial area over the pulse or in the area shown on Figure 4.
- b) Listen for the pulse using the Imex Elite 100 Doppler. If no pulse is audible or palpable, then try to use the dorsalis pedis pulse for the determination of blood pressure. If no pulse is audible, record zero for ankle blood pressure after the absence of pulse is verified by a second observer.
- c) Inflate cuff to a pressure reading 20 mm higher than the "Peak Pressure" used for the sitting arm pressure (i.e., obliteration plus 50 mmHg) and utilize identical deflation techniques while listening with the Doppler. Record the first sound heard as systolic

blood pressure on the physical exam form.

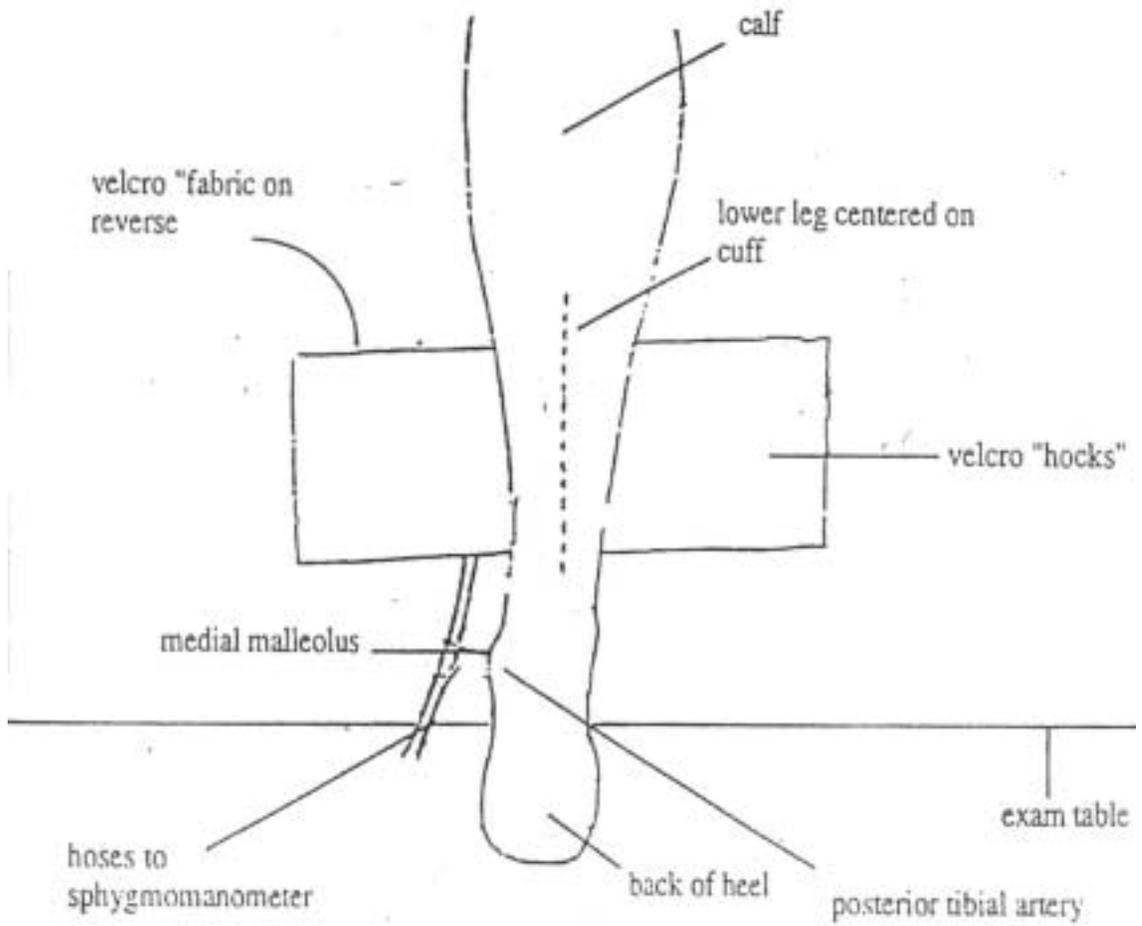
- d) Take a second blood pressure using the same techniques, and record the second blood pressure on the Physical Examination Form.
- e) Repeat this procedure to record the left ankle blood pressure.
- f) Repeat this procedure to record the right brachial blood pressure using the Doppler. The blood pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual. By consulting the participant's Data Form, the observer verifies that the same arm and the same cuff size are used as for the sitting blood pressure readings.

If the participant had his/her sitting blood pressure taken on the right arm earlier in the clinic examination, the cuff is applied on the right arm at this time. The observer then uses the Doppler to record the brachial pressure. The pressure recorded in the right arm is used to calculate the ankle/brachial systolic pressure ratio for both lower extremities.

If it is impossible to obliterate the sounds after increasing the pressure to above 250 mmHg, record 999 on the physical examination form.

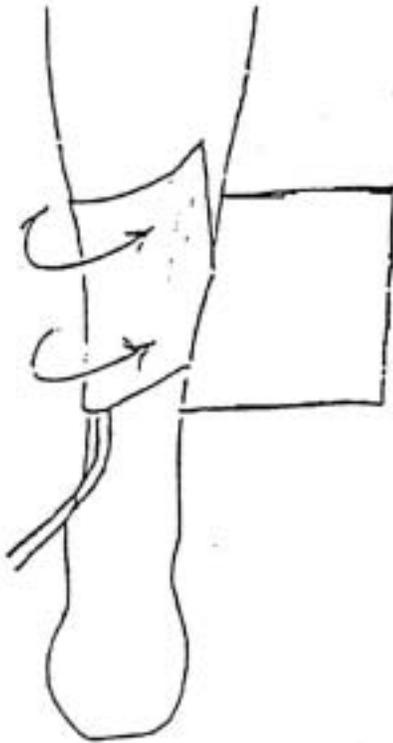
The observer now removes all conduction jelly. Socks and a robe or other garments are now replaced, and the participant is escorted to the next workstation.

Figure 4. Placement of the Blood Pressure Cuff on the Ankle
Step I. Positioning the Lower Leg on the Cuff



**Figure 5 Placement of the Blood Pressure Cuff on the Ankle
Steps II and III: Wrapping and Securing the Cuff**

Step 2. Wrap fabric end of the cuff
following contour of ankle



Step 3. Wrap and secure cuff

"ears" about
equal



SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

DOPPLER BLOOD PRESSURE

Training

Technician instruction will include:

- a) rationale for ankle systolic blood pressure
- b) explanation to subject
- c) positioning of subject
- d) blood pressure cuff size selection
- e) application of cuff - right ankle, left ankle, right arm
- f) palpation of pulse, marking location, application of ultrasound gel
- g) listening for pulse using IMEX Elite 100 DOPPLER
- h) cuff inflation to peak pressure (50 mmHg higher than pulse obliteration pressure of sitting right arm measurement)
- i) recording of the first pulse sound
- j) repeat for a second pressure
- k) perform on right ankle, left ankle, and right arm (if sitting BP was taken on the right arm)

Quality Assurance

Observation of technicians will be done quarterly by the Study Coordinator. Performance by the tech should include all of the criteria listed above, the evaluation should be recorded on the checklist for Doppler Blood Pressures. The tech's results should be within 4 mmHg of the coordinator's pressure results.

SHS PHASE IV FAMILY STUDY

Checklist for Doppler Blood Pressures

The Study Coordinator will observe technicians quarterly. Performance by the technician should include the following steps. If each step is completed correctly, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

- YES () NO () Explains procedure to subject.
- YES () NO () Positions subject, supine.
- YES () NO () Selects appropriate cuff size.
- YES () NO () Applies cuff correctly, right ankle, left ankle, right arm.
- YES () NO () Palpates pulse, marks location, and applies ultrasound gel.
- YES () NO () Listens for pulse using IMEX Elite 100 DOPPLER.
- YES () NO () Inflates cuff to calculated peak pressure.
- YES () NO () Records the first pulse sound..
- YES () NO () Repeats for second pressure.
- YES () NO () Performs on right ankle, left ankle, and right arm (if sitting BP was taken on right arm).

Comments: _____

	Technician	Observer	Difference
Right Ankle	_____	_____	_____
Left Ankle	_____	_____	_____
Right Arm	_____	_____	_____

DIGIWALKER PEDOMETER

DIRECTIONS TO PARTICIPANTS FOR USING THE PEDOMETER

The Accusplit Activity Meter (pedometer) counts the number of steps taken while walking. You have been requested to wear this meter EVERY DAY for a seven day period from

(the day after exam) to (the seventh days of wearing). The pedometer is to be

clipped at the waist to your clothes, underwear, or on a belt and worn on the _____ hip and must be kept in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. You can use a belt or elastic strap to keep it in place on your hip. Please **DO NOT LET THE PEDOMETER GET WET** by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in the morning and to record the pedometer number in your activity record when you take it off at night.

If you have any questions, please contact:

_____ at _____.

Specific Instructions

1. Every morning, just before you put the pedometer on, push the reset button to read “0”.
2. Record the time you reset the pedometer on the activity record page.
3. Wear the pedometer all day except for bathing, swimming or in the rain (unless you can keep it dry). If you take it off, record the length of time it was off (minutes or hours) on your activity record page.
4. At bedtime, take off the pedometer. Record on your activity record page (a) the pedometer number (the number of steps taken), and (b) the time you removed the pedometer.
5. Please do not touch the reset button during the day or you will erase your activity numbers.
6. Wear the pedometer on your dominant hip (right hip for right handed people and left hip for left handed people), keep it upright, and make sure it fits firmly against your body so it does not move around.
7. Keep the cover closed or it will not record your steps.
8. The pedometer will not work correctly if it is in a pants, coat, or shirt pocket. It will not work correctly if it is sideways either.
9. Please mail the activity record to us in the self-addressed stamped envelope after you complete your week.
10. Please keep the pedometer as a token of our appreciation of your participation in the Strong Heart Family Study.

Thank you very much for your time and effort!

SHS PHASE IV FAMILY STUDY

Checklist for Digiwalker Pedometer

Technicians should be observed quarterly administering the pedometer instructions. If each item below is carried out correctly, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

Instructs participant with the following information:

- | | |
|----------------|--|
| YES () NO () | Explains purpose of pedometer measurement. |
| YES () NO () | Must wear for seven days. |
| YES () NO () | Push the reset button every AM to read "0". |
| YES () NO () | Record the current time on the activity record page. |
| YES () NO () | Keep the pedometer on all day. Record length of time if taken off. |
| YES () NO () | Do not get the pedometer wet. |
| YES () NO () | Remove pedometer and record meter number on activity record page. |
| YES () NO () | Record the time removed on activity page record. |
| YES () NO () | Do not touch the button during the day. |
| YES () NO () | Wear the pedometer firmly on dominant hip. |
| YES () NO () | Keep the cover closed. |
| YES () NO () | Do not wear in pocket or sideways. |
| YES () NO () | Mail the record or arrange for pick up. |

Comments: _____

STRONG HEART STUDY

PHASE IV

FAMILY STUDY

Quality Control - Equipment

SHS Phase IV Family Study

ARIZONA FIELD CENTER

DAKOTA FIELD CENTER

OKLAHOMA FIELD CENTER

EQUIPMENT – QUALITY ASSURANCE CHECKLIST

Device	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
ECG												
IMPEDANCE												
BLOOD SUGAR METER												
SPHYGMO- MANOMETER												
MEASURING TAPES												
SCALE												

IMPEDANCE

ONE TOUCH

SHS Phase IV Family Study

QUALITY CONTROL LOG

Glucose Controls will remain stable until manufacturer's date or "opened" expiration date, whichever comes first.

Low Level Control Solution Lot# _____ Date Opened _____ Opened Exp. _____ Manufacturer's Exp. _____
 Normal Level Control Solution Lot# _____ Date Opened _____ Opened Exp. _____ Manufacturer's Exp. _____
 High Level Control Solution Lot# _____ Date Opened _____ Opened Exp. _____ Manufacturer's Exp. _____

Date	Time	Init.	Test Strip			Low Level Control				Normal Level Control				High Level Control				Corrective Action if Applicable		
			Lot #	Code #	Exp.	Accep Range	Actual Value	Mean	W/in Range Y/N	Accep Range	Actual Value	Mean	W/in Range Y/N	Accep Range	Actual Value	Mean	W/in Range Y/N			
								-/+ Mean				-/+ Mean								

SPHYGMOMANOMETER

SHS Phase IV Family Study

MAINTENANCE PROCEDURES FOR STANDARD SPHYGMOMANOMETERS

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting.

1. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, mercury should be added or withdrawn until it does read zero. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.
2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:
 - a) The system should be re-inflated until the column rises to 200 mmHg.
 - b) The tubing should be pinched at various locations to localize the area of the leak.
 - c) Appropriate replacement of the tubing, cuff, or valve should be performed.
3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the silicone rubber, which provides a seat for both ends of the glass tube, should be replaced.
4. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with this instrument. The tube should then be replaced and the zero level rechecked.
5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.

SHS Phase IV Family Study

Quality Control

SPHYGMOMANOMETERS

MONTH	DATE	INIT.	MERCURY LEVEL IS AT ZERO WITH NO PRESSURE	CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHg	CHECK CAP FOR TIGHTNESS	CHECK TUBE FOR OXIDE DUST	COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.
JAN							
FEB							
MAR							
APR							
MAY							
JUN							
JUL							
AUG							
SEP							
OCT							
NOV							
DEC							

SCALE/TAPE

SHS Phase IV Family Study

Quality Control

SCALE & MEASUREMENT TAPES

MONTH	DATE	INIT.	PORTABLE SCALE	CALIBRATED WEIGHTS	MEASURING TAPE, to 30 cm METAL TAPE
JAN					
FEB					
MAR					
APR					
MAY					
JUN					
JUL					
AUG					
SEP					
OCT					
NOV					
DEC					