

**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

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 III)**

Operations Manual

Volume One

GENERAL DESCRIPTION AND SURVEILLANCE PROCEDURES

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MANUAL ONE

GENERAL DESCRIPTION AND SURVEILLANCE PROCEDURES

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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 (1). 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

Although age-adjusted mortality rates for cardiovascular disease are lower in American Indians than in the U.S. population as a whole, 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. Age-adjusted mortality rates for cerebrovascular disease were similar to U.S. rates for Oklahoma and Pima Indians and higher for Aberdeen Area Indians in 1981-83.

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. The relatively low rates of cardiovascular disease in American Indians as a group obscure both regional differences in heart disease and the high mortality rates from heart disease in younger Indians (those aged 25-44 years). The 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.

The Strong Heart Study was initiated in response to a recommendation by the Subcommittee on Cardiovascular and Cerebrovascular Disease of the Secretary of Health and Human Services Task Force on Black and Minority Health that concluded that information on CVD in American Indians was inadequate.

B. Description of Strong Heart Study Phases I and II

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 from October 1, 1988 to July 31, 1996 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 two components. 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 of resident tribal members (the cohort). During the 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. 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 Phase I 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 Phase II 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 and an echocardiogram 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 SHS has shown that the three groups of American Indians included in the study are not homogenous with respect to cardiovascular disease and its risk factors. Initial data analysis indicate that the prevalence of ECG diagnosed myocardial infarction varies: among non-diabetic participants, southwestern Oklahoma Indians have the highest (5.8%), followed by Sioux Indians in North and South Dakota (4.5%), and the Pima Indians in Arizona have the lowest (2.9%). For diabetic patients, Sioux Indians have highest rate (10.4%), Oklahoma Indians are slightly lower (9.2%), and the Pima Indians have the lowest rate (6.3%).

Preliminary analyses of our data indicate that the prevalence of cardiovascular disease (CVD) risk factors also differs from center to center. Diabetes is high in all groups, but highest among the Pimas in

Arizona (over 65% prevalence). Mean levels of cholesterol in Sioux and Oklahoma Indians are comparable to those for the U.S. (all races) but considerably lower among the Pimas. The prevalence of smoking is high in the Sioux (approximately 50%), low in the Pimas and intermediate in Oklahoma Indians. Hypertension is less prevalent than in the U.S. in all groups, but the prevalence is higher among the Pima and Oklahoma Indians than among the Sioux. A high prevalence of sedentary lifestyle exists in all three groups. Prevalence of obesity is high in all three groups and highest in the Pimas. Genetic admixture was determined by interview: over 90% of Pimas are full blood Indian, less than half of the Sioux are full blood, and seventy-three percent of Oklahoma Indians are full blood.

C. Rationale for Phase III of the Strong Heart Study

The Strong Heart Study is the largest multi-center 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 rates 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. By the time of the Phase III examination, participants will range in age from 53 - 82 years. Data on prevalent CHD showed differences in rates between centers, and the availability of baseline data from the Phase I and II 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. In addition, it will be possible to evaluate changes in risk factors as the cohort ages. 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 risk factors and prevalence of disease.

In Phases I and II, the end-points of interest have been fatal and non-fatal cardiovascular events, and there have been no direct assessments of atherosclerosis. Ultrasound measurements of the carotid arteries will provide the opportunity to assess the relationships of arterial intimal thickness and discrete atherosclerosis to the risk factors previously measured. In addition, the availability of echocardiographic data from Phase II in these same individuals will provide an extremely interesting comparison of cardiac structure and function to the degree of atherosclerosis and arterial dysfunction. This comparison should provide insight into the mechanisms of diabetes-associated CVD. It will be especially important to further investigate the factors that may explain the lower prevalence of coronary heart disease among Arizona participants who in fact have the highest prevalence of diabetes (>65%). Compared to OK and SD/ND, AZ has both lower CHD prevalence and CVD mortality. Of interest is that the reduction in prevalent CHD in AZ compared to the other centers is greater than the reduction in confirmed CVD mortality. The data on cardiac function and carotid atherosclerosis will help to investigate whether AZ participants actually have less atherosclerosis, whether it is manifest in different parts of the vascular tree, or whether traditional

measures such as T-wave abnormalities do not reflect the same disease processes in this population.

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 both Phases I and II. 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 would be most valuable, however, to collect data on risk factors and target organ damage and DNA on large kindreds. This cohort 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 will allow us to communicate the importance of the information that can be gathered from large families. Thus, the SHS will be able to recruit and retain large kindreds from which physiologic measurements can be made and blood samples can be taken for direct genotyping.

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

1. A continuous mortality and morbidity surveillance of the Phase I examination cohort.
2. A second reexamination of the Phase I cohort with an abbreviated personal interview, measurements of carotid intimal thickness, discrete atherosclerosis and arterial function using ultrasound and tonometry, additional laboratory tests, measurement of asthma and carbon monoxide levels in breath, and a repeat of the basic risk factor assessments done in the Phase I and Phase II examinations.
3. An initial study to examine family participants (first degree relatives and grandchildren) of members of the Strong Heart Study. Ten 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 in Phase I. The examination on these individuals will include all components of the Phase III examination plus selected components from the Phase I and II examinations, 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.

Rationales for New Components of Phase III of the Strong Heart Study

1. 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 0.1 mm 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 the relationship between these measures and several CVD risk factors and the presence of diabetes and its complications.

2. *Computerized Electrocardiography -*

The digital acquisition of ECGs, which facilitated ECG handling in Phases I and II, will be used in Phase III to improve characterization of cardiac status in Strong Heart Study participants. Computerized measurements of digital ECGs that have already been recorded and archived or that will be recorded in Phase III, will be used to assess QRS voltage and duration measures of left ventricular (LV) hypertrophy and myocardial infarction and to assess ST/T measures of repolarization indicative of LV hypertrophy or ischemia. In addition, the validity of an approach to computerized performance of Minnesota coding will be tested to determine whether this standard method of diagnostic classification can be made less expensive and time-consuming.

3. *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 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 proposed pilot family study will take the first steps toward achieving that goal.

We will establish a resource of extended families beginning with sib-ships 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 by positional cloning. 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.

4. *Pulmonary Function -*

The daily lability of peak expiratory flow (PEF) is an index of airway hyper-reactivity, the hallmark of asthma. The prevalence and mortality rates of asthma have increased during the last 20 years in developed countries. The actual prevalence of asthma is unknown in the American Indian population. The prevalence of self-reported asthma from the SHS Phase II medical questionnaire was 6% (preliminary data from 3029 exams). The prevalence of asthma symptoms (attacks of wheezing with dyspnea or wheezing during colds) was 17%. The procedures employed during the Phase II exam may have under diagnosed asthma, since spirometry is often normal in persons who have asthma but who are without symptoms at the time of testing. An objective measurement of asthma in a sub-sample of SHS participants would be very helpful in estimating the true asthma prevalence. Airway hyper-reactivity, or excessive airway lability are cardinal features of asthma. The "gold standard" test for airway reactivity is the histamine or methacholine inhalation challenge test. Although this test has been adapted for use in large population surveys, it requires 30-45 minutes and the presence of a physician in the same building. An acceptable alternative is ambulatory monitoring of lung function, where the participant blows into a hand-held spirometer several times each day for two weeks. If the participant has asthma, their early morning PEF (or FEV1) is at least 20% lower when compared with the values from later in the day. New hand-held, battery powered electronic spirometers can store the results, eliminating the need for a written diary. This will provide a feasible way to further explore the prevalence and impact of asthma in the SHS populations.

Cigarette smoking is a very powerful risk factor for CVD. Mis-classification of smoking status can, therefore, reduce the power of many analyses of associations of risk factors with CVD outcomes. It is well known that a percentage of participants in medical research studies misrepresent their smoking status. Moreover, many SHS participants report sporadic smoking or are exposed to smokers at home or at the workplace; thus an objective measure would help to classify their degree of smoking. There are several biochemical methods available to verify smoking status, including blood, urine or salivary samples analyzed for thiocyanate or cotinine levels, and breath carbon monoxide (CO) levels. The primary advantages of breath CO include non-invasiveness, speed (30 seconds) and a very low cost per sample. In addition, it can also detect exposure to CO in environmental tobacco smoke. Such devices have been beneficial in motivating smokers to stop smoking and to promote a smoke-free environment. Limitations include the

relatively short 4-hour half-life of carbon monoxide in the blood and breath, and the occasional high reading in non-smokers exposed to faulty gas heaters in enclosed homes during cold months. However, follow-up of such high levels of CO will be beneficial in detecting the presence of faulty heaters so that corrective action can be taken to prevent lethal CO exposure. The instruments to measure CO in exhaled air cost less than \$1,000. The multi-center Lung Health Study of smoking cessation successfully used the hand-held, battery-powered Vitalograph "BreathCO" to validate smoking status. A similar protocol will be employed to measure expired CO levels in SHS participants in Phase III.

5. *Laboratory Tests -*

The Strong Heart Study investigators, in their planning, have been careful not to repeat laboratory measurements unless they were of interest and it would be reasonable or feasible to assess changes in them over time. Thus, in Examination II, the glucose tolerance test, insulin, fasting lipids, albuminuria, and fibrinogen were repeated; however, apoprotein measurements, apo E phenotype, Lp(a), and Gm allotypes were not. For Examination III the same reasoning was applied. In order to assess progression of glucose intolerance and abnormalities in hemostasis, fasting and post-load glucose, fasting insulin, urinary albumin/creatinine, and fibrinogen and PAI1 will be included. Red blood cell allotypes, Gm allotypes, apo E phenotypes, Lp(a), apo B and A1 will not be re-measured because they would not be expected to change or have measurable changes. HbA1c will not be re-measured because of its high correlation with plasma glucose in our diabetic population. LDL size will be repeated because of the interesting question of how it changes along with triglycerides, insulin and other components of the insulin resistance syndrome. On the other hand, a Chemistry Profile (SMAC 12 including electrolytes, BUN, creatinine, total protein, SGPT, SGOT), which has never been determined on this cohort, will now be included. These basic chemistries will yield data which are generally not available among Indian populations in a standardized way and will assist in the interpretation of a number of CVD risk factors.

Studies have documented 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 by the increased shear stress imposed on the arterial intima by more viscous blood flowing past it. To assess the relevance of these associations to the arterial hypertrophy, dysfunction and atherosclerosis to be detected in SHS Phase III in a cost-effective way, hematocrits will be measured as well as total plasma protein (in the chemistry profile). These two variables are the principal determinants of whole blood viscosity (WBV) and predicted WBV at a shear rate of 208 per sec accurately compared to direct WBV measurements.

By the time of the Phase III examination, based on the death rate observed so far, there should be more than 800 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 homocystine to allow the assessment of this potential risk factor in the Indian population; an assessment of lipoparticle AI:AI-AII, a recent measurement of HDL distribution, which may provide additional information on the relationship between HDL function and coronary disease; a measure of proinsulin which will allow the assessment of pro-insulin's role in CVD and the development of diabetes. 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.

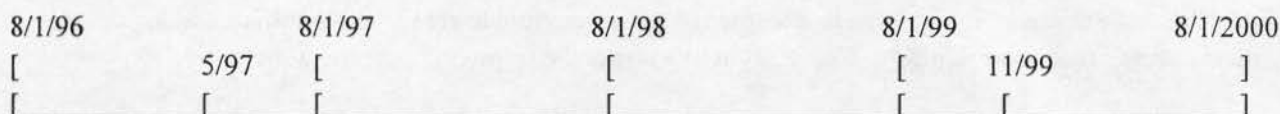
1.2 RESEARCH OBJECTIVES

The Strong Heart Study-III (SHS, Cardiovascular Disease in American Indians Phase III) is to continue the mortality and morbidity surveillance on the original cohort, to follow and re-examine the original cohort of American Indian men and women in three geographic areas, and to initiate a study of the inheritance of risk factors in families. The study will address the following specific aims:

1. To determine mortality rates for CVD and other causes in the original SHS cohort using a standardized methodology.
2. To determine rates of CVD and CVD risk factors in these Indian groups by longitudinal surveillance and a second follow-up examination of the Phase I cohort (ages 53 - 82 years at the Phase III examination).
3. To compare risk factors and their changes over time in the three geographic areas and relate them to different rates of CVD among the three areas.
4. To identify and compare risk factors for CVD among diabetic and non-diabetic participants.
5. To obtain quantitative measures of systemic atherosclerosis and arterial dysfunction using ultrasound studies of the carotid artery and to relate these measures to prevalent CVD and CVD risk factors and to previous echocardiographic measures of cardiac structure and function.
6. To determine whether echocardiographic measures of cardiac structure and function predict incident CVD events and death.
7. To compare the risks of differing manifestations of vascular disease (e.g. CHD, PVD, carotid atherosclerosis, cardiac wall motion abnormalities) among American Indians in the three areas and to determine the risk factor profile associated with each measure of disease.
8. To identify at random in each of the three geographic areas, 10 families with two or more siblings who participated in the original Phase I examination and with approximately 30 adult members aged 18 years and older, in each family; on each family member to perform an examination to measure CVD risk factors; and to conduct preliminary linkage analyses to assess the inheritance of CVD risk factors.

1.3 STUDY DESIGN

Time Line:



-----> mortality & morbidity surveillance until 5/31/99

-----> continue to analyze SHS-II data

-----> development of protocol, manual, data forms and pre-testing

4/97

-----> training and pilot study

5/97

12/97

-----> family examination

1/98

8/99

-----> Phase III examination

-----> data analysis

1.3.1. Surveillance

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

For the cohort 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.

1.3.2. Clinical Examination

- a. Components of the Phase III Clinical Examination for SHS Cohort. These are described on page II-2 of this manual.

The Phase III clinical examination will include a personal interview and a physical examination. 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 Phase I and Phase II. Procedures are described in brief below, with details presented in the manual Volume II.

i. Personal Interview

The following questionnaires will be administered:

- 1) Demographic information
- 2) Health habits
- 3) Medical history
- 4) Dietary survey
- 5) Quality of Life

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
 - ii) Height
 - iii) Waist and hip circumferences
 - iv) Body fat measurement
 - v) Arm circumference
- 2) Examination of the following:
 - i) Pedal pulses
 - ii) Ankle edema
- 3) Blood pressure measurements
- 4) Twelve-lead resting ECG measurement
- 5) Glucose Tolerance Test (GTT)
- 6) Fasting blood samples for measurements of total triglyceride (TG) and cholesterol, LDL and HDL cholesterol, plasma fibrinogen, and PAI-1, and DNA isolation, glucose, creatinine, insulin, and SMA-12 will be obtained.

- 7) Urine will be collected at the beginning of the physical examination for measurement of albumin and creatinine.
- 8) Peripheral sensation will be measured in the right foot by mono-filaments.
- 9) **The following procedures will be added:**
 - i) Echocardiography of the carotid artery (see Manual Volume VI, Special Studies for details).
 - ii) Carbon monoxide in exhaled air will be measured to validate smoking status.
 - iii) Ambulatory pulmonary function (PF) monitoring

b. Components of the Examination for Family Members

The family members will have all the information collected that is described above for the Phase III exam of the cohort, except for the ambulatory PF monitoring. Each center will pilot the family member exam in at least 10 persons and appropriate revisions in the procedure will be made and standardized for use in all three centers for 300 family members age 18 or over at each center. 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. As much of the information as possible that was collected on the original participants will be collected on the family members. The interview will include the following:

- i. Phase I Information: This includes: tribal enrollment, degree of Indian blood, marital status, education/income, use of native language, smoking and alcohol use, medical conditions, reproductive history, and current physical activity.
- ii. Phase II Information includes: history of attending boarding school, respiratory/snoring, cultural factors, risk factor knowledge, quality of life.

1.4 STUDY QUESTIONS

The morbidity and mortality surveillance of the original cohort and the new approaches in Phase III, will provide information that can be used to address multiple questions related to furthering our understanding of the etiologies of CVD and the impact of diabetes on risk. **These questions include:**

1. How have the absolute rates and proportional mortality ratios for CVD and other causes of mortality changed over 10 years (1989-1998) in American Indians in the three centers?
2. What changes in CVD risk factor levels have occurred over time in these study populations, and what are the most important determinants of these changes?
3. What are the relationships between CVD risk factors, clinically manifested CVD, and measures of atherosclerosis (intimal medial thickness and discrete atheromas) within and among centers?
4. Do these relationships differ in individuals with diabetes?
5. What are the explanations for the differences in CHD morbidity and mortality between Indians in the three geographic areas?
6. What are the relationships between cardiac disease as measured by echocardiography and systemic atherosclerosis as estimated from carotid ultrasound studies? Do the relationships between these differ in individuals with diabetes?
7. Do the relationships of CVD risk factors to carotid wall thickness and morphology in American Indians differ from those in previously reported aged-matched cohorts?
8. Does renal dysfunction as measured by albuminuria predict the risk of CVD? How does it relate to abnormalities in the carotid wall?
9. What is the impact of the rapid change in economic status induced by gaming activities in some of the communities on CVD risk factors and quality of life?
10. Can the current family history data collected in Phase I and Phase II of the Strong Heart Study be used to identify groups of related individuals (family members) in the initial cohort?
11. Can families of large size with multiple siblings be successfully recruited, starting with sibships who are current Strong Heart cohort members?
12. There are many interesting questions concerning genetic effects on CVD risk factors in American Indians. The proposed family studies will lay the groundwork for addressing some of these questions:
 - a. Are there genes that have large effects in explaining the low plasma cholesterol levels in American Indians? Can their chromosomal locations be determined?
 - b. Is blood pressure in American Indians influenced by genes whose effects are individually detectable and whose chromosomal locations can be determined?
 - c. Are there detectable genes that influence diabetes susceptibility in American Indians? Can these genes be mapped to specific chromosomal regions?
 - d. Are the amount and distribution of body fat in American Indians influenced by genes with large effects? Can we determine their chromosomal locations?
 - e. Carotid wall intimal-medial thickness (IMT) has been shown to have high heritability in a Hispanic population. Is IMT in American Indians influenced by one or a few genes whose chromosomal locations can be determined?
 - f. Little is known for any population about the genetic mediation of phenotypes related to

- clotting (for example, fibrinogen and PAI-1). Are there genes that have substantial effects on these phenotypes in American Indians, and can they be mapped to specific chromosomal regions?
- g. Is there evidence for heterogeneity among tribes with respect to the genes that influence CVD risk factors?

1.5 STUDY MANAGEMENT

1.5.1 Introduction

The Strong Heart Study Phase III 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. The operations of the study are directed by the Strong Heart Study Phase III Steering Committee, which includes members from each center and the NHLBI Project Manager (see Appendix 2 for the members of Steering Committee). An organizational chart of the Strong Heart Study Phase III is given in Appendix 3. 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 Medical Center under the direction of Dr. Richard Devereux serves as both the ECG Reading Center and the Carotid ultrasound reading center. Peak flow pulmonary function testing results are analyzed at the Coordinating Center under the direction of Dr. Paul Enright. Analysis of the family study genetic component is directed by Dr. Jean MacCluer at the Southwestern Medical Center. SHS-III 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 prepares and distributes a quarterly newsletter to facilitate communication among Study staff. In general, each edition includes: (1) reports from the Program Office, the Coordinating

Center, the Core Laboratory, the ECG Reading Center, Carotid Ultrasound Reading Center, Pulmonary Function Testing Center, and the Steering Committee, (2) a description of the facilities and staff of one field center or central agency, (3) general information on data management and (4) a calendar of 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 will be the major electronic mail facilities to be used by all field centers, the Coordinating Center, Core Laboratory, ECG and Ultrasound Reading Center, Genetic Study Center, and the Program Office. This electronic mail network will allow rapid and efficient communication among centers for messages such as announcements, meeting agendas, abstracts for clearance and acknowledgments of receipt of data.

3. Field Center Visits:

The Program Office and Staff from the Coordinating Center, ECG and Ultrasound 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 Data Forms and Guidelines for Completing Forms

Uniform data entry forms for all information to be collected will be 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 who return for the third phase examination, 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.

Center	Family ID	SHS ID
Arizona	AZxxyyyy	360001 - 36zzzz
Oklahoma	Okxxyyyy	260001 - 26zzzz
South and North Dakota (1)	Dkxxyyyy	160001 - 16zzzz

Where xx : family number.

yyy : 001 - 999 for each family member.

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

(1) The numbering system for the Dakota center is not sequential for the first four families.

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 8. Hospitals where the subject 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 9 and 10, 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 11. 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 will 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 key punch 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-III Operations Manual Volume VII - Data Entry*

1.6.3 Data Transmission -- See *SHS-III Operations Manual Volume VII - Data Entry*

The lab data, ECG data, and ultrasound data will be electronically transmitted to the Coordinating Center, and will be converted to SAS data-sets. 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 PROGRAM

1. Data Collection

Every data form will be checked for completeness by the field staff before entering into computer. Ambiguous or erroneous items will be clarified and corrected. All forms will then be double-entered for the first two months of the study. The Coordinating Center will check the error rates of data entry. If the error rate is less than 0.5% between the two entries, only 10% of the data forms are required to double entry for the following month. The Coordinating Center will continuously monitoring data entry errors for the three field centers. If the error rate raises above 0.5%, all the data will required double entry for the month until the error rate drops below 0.5%. The data entry program will provide a second quality control check. Range and logic checks will be built into the data entry program. The program will refuse to accept such data until the errors are corrected. Computer printouts of data received will be sent to each field center. 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

Biannual quality control site visits will be made to each of the three centers. 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, impedance meter, 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 monitoring of the impedance meter will include checking the battery charge daily before the instrument is used, following the manufacturer's instructions. 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 measurement 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 ankle blood pressure using a Doppler will be made by two observers simultaneously. Duplicate measures of anthropometry (height, weight, waist/hip ratio, and electrical impedance measurements) will be performed by a second observer on a 10% 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 units
- vi) Waist circumferences: 1 cm
- vii) Hip circumferences: 2 cm

Duplicate data for blood pressure, height, and weight 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 and by Doppler 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. Duplicate blood pressures taken by Doppler will be performed quarterly by the supervisor.

2) Laboratory tests

Duplicate blood and urine specimens will be collected on approximately 10% 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 errors 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) Dietary interviews

The dietary consultant, Ms. Ellie Zephier, will conduct field observation during the first three months after the initial training session. Field observation will include evaluation of 1) Introduction and confidentiality statement, 2) mannerism and eye contact, 3) flow of the interview, 4) use of neutral probes, 5) proper use of food models, 6) proper use of the edit system, and 7) review of dietary logs.

The dietary consultant will also review dietary recalls completed the day of observation and provide immediate feedback at the time of the field visit. Questions and concerns will also be discussed during these visits as needed.

Once a month, one interview per dietary interviewer will be taped and reviewed by the dietary consultant for interview quality. After receiving permission from the participant and/or proxy, the interview will be recorded and reviewed by the study coordinator. The dietary consultant will provide written feedback to each interviewer on how to improve interview techniques.

5) Quality control for surveillance data

In the mortality and morbidity surveys, records of every non-injury death and 10% of all morbid events will be sent to a second member of the mortality or morbidity Review Committees. Each physician independently will determine the classification of a cause of death or CVD event, and the Coordinating Center then will compare the results from both physicians. The adjudication process is described in the surveillance section of this manual.

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. Re-certification will occur every six months to ensure accurate and consistent performance.

1.6.6. Statistical Analysis

Major statistical analyses of Phase III data include: 1) determination of mortality rates by cause of death in the SHS Phase I cohort (cohort mortality), 2) estimation of incidence of CVD and other diseases of interest, e.g., diabetes, PVD, and renal disease, in the SHS Phase I cohort, and 3) identification of risk factors that are related to cohort mortality and incidence of CVD and other diseases of interest.

Death rates due to CVD calculated on the basis of death certificates alone will be compared with those based on the confirmation of the Mortality and Morbidity Committee. The center-specific all-cause and CVD mortality rates will be compared to those obtained from the U.S. population, the respective states, and other ethnic groups. Using the mortality data from all three phases of the SHS, we will be able to examine the trends of CVD and all-cause mortality over a 10-year period (1989-1999) in the three Indian populations.

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 the phase III examination, 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 U.S. and in other ethnic populations, and to those obtained in the community mortality survey of the same population. Lifetable analysis techniques will be used to estimate median remaining lifetime.

Data on disease status obtained from the morbidity surveillance and the clinical examination will be used to estimate incidence rates of CVD, diabetes, PVD, renal disease, etc. If the date of diagnosis is unknown, we can estimate a seven-year (baseline is Phase I) cumulative incidence or a three-year (baseline is Phase II) 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.

Statistical analyses to be used to identify risk factors related to mortality and to morbidity include, in the uni-variate analysis, comparisons of cumulative incidence, incidence density, mortality rates, and disease-free time and survival time distributions between "exposure" subgroups. The survival time will be calculated from Phase I examination to the time of death or last-follow-up and the disease-free time will be from 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.

The cumulative incidence between "exposure" sub-groups 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 in Rothman. The distributions of survival time and disease-free time in different "exposure" subgroups can be compared by using the logrank or K-sample tests. The association between categorical risk factors and disease status can be further analyzed by adjusting for possible confounding factors using the Cochran-Mantel-Haenszel test. Trends will be analyzed and summary odds ratios calculated. Continuous risk factors will be categorized and analyzed accordingly in addition to being treated as continuous data.

After the uni-variate and bivariate analyses, selected variables will be included in the Cox's proportional hazards model or logistic regression model depending on whether or not the date of diagnosis is known. The relative importance of individual risk factors will be determined by step-wise procedures. If the changes in a risk factor were not consequences of the event of interest, a Cox model with time-dependent co-variables may be adopted. Recurring events such as hospital-based MI and stroke can also be modeled with Cox's continuous time model using a counting process formulation.

Changes in the means of the risk factors will be assessed graphically and either qualitatively or quantitatively. The patterns of changes across the three phases will also be characterized. For simple comparisons of the means between genders, centers, and other "exposure" groups, the Hotelling T square and multi-variate analysis of variance will be used. The data will be transformed if warranted to stabilize the variance. Adjusted means can be computed using multivariate analysis of covariance.

The longitudinal observations will allow us to assess and model the association of disease outcome with risk factors or the association of a risk factor with other risk factors by utilizing the marginal models. By using the marginal models, we will be able to distinguish changes over time within subjects (aging effects) from differences among individuals in their baseline levels (cohort effects). In the model, age at baseline and change in age from baseline can be included as co-variables. The coefficient for age at baseline is sensitive to cohort effects but that for change in age is not. It is of interest also to examine if, and in what way, these two age coefficients are different.

Another advantage of the longitudinal design is the allowance of addressing questions such as what are the important determinants that are associated with the changes in CVD risk factors (e.g. cholesterol level) over time. Statistically, one can address this question by regressing the cholesterol level on time, the determinant variable and the interaction between the two variables. This marginal model approach was suggested in the recent monograph on analysis of longitudinal data by Diggle et al..

The distribution of the response variable is not required to be Gaussian in a marginal model. The marginal mean is modeled as in cross-sectional studies. The parameters are estimated by a generalized estimating equation, a multi-variate extension of quasi-likelihood. Since the number of subjects is larger than the number of observations per subject, the inference is robust to mis-specification of the covariance structure between observations in the same subject. For continuous dependent variables, the covariance structures will be estimated using the auto-regressive models and one where the co-variances are estimated from the data. For binary response variables, the variance is determined by the mean. Odds ratios and confidence intervals will be estimated for various risk factors. A SAS macro using SAS IML is available to estimate the regression coefficients in marginal models. Further, we may be able to address both the regression objective and the within-subject correlation simultaneously by using the transition (Markov) models, and discuss the correlation among responses for an individual by using random effects models.

1.7 PUBLICATION POLICY

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

Dr. Elisa T. Lee (Chair)
Mr. Richard R. Fabsitz
Dr. Barbara V. Howard
Dr. Thomas K. Welty

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

1.7.1 Submission of a Paper Proposal

I. Proposal

A formal paper proposal must be submitted to the Chair of the P&P Committee at least one week prior to the monthly P&P meeting. 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 (include the phrase "Strong Heart Study" whenever possible)
2. Primary author's name and affiliation
3. Suggested co-authors
4. A detailed outline which includes:
 - a) Introduction (Rationale)
 - b) Methods
 - c) General analysis plan
 - d) Lay summary for the tribes
5. Analysis responsibility (authors or Coordinating Center, CC)

It is assumed that all proposals are submitted with the knowledge of the field center 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, deferral, or disapproval (with reasons)
2. Upon approval, the paper is given an SHS Paper Number
3. The paper may then be given a priority score if analyses are to be done by the Coordinating Center

The decision will be forwarded to the author who submitted the proposal. If the proposal is approved and CC is responsible for the analysis, the author must then submit a "Request for Data Analysis" form (see below) to CC as soon as possible. CC will then assign a statistician to work with the author. The statistician is the CC representative to the writing group.

The P&P Committee will periodically report its decisions to the SHS Steering Committee, and SC may nominate additional co-authors for any papers that have been approved by the P&P Committee.

III. Analysis

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 time table 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 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. The author should then complete a first draft within 4 months and submit it to the P&P Committee for comment (to be returned by the Chair within 1 month).
4. After P&P approval of the first draft, the author then has 3 months to submit the penultimate draft to the P&P Committee for final review (to be returned by the Chair within 1 month).
5. Review by the P&P Committee may result in suggestions which are essentially editorial in nature, in which case the paper is approved and the Chair conveys these suggestions to the author. If the P&P Committee considers the paper to require substantive changes, approval is deferred until the paper is revised in light of the Committee's critique and reviewed further by the Committee.
6. All statistical analyses in the penultimate draft which were performed outside of CC must be verified by CC before finalizing the paper.
7. After P&P approval, the penultimate draft must be submitted by the author to NHLBI (through Mr. Fabsitz) for review (to be returned to the author within 1 month of submission). Simultaneously, the principal investigators should send the penultimate draft to their respective IHS Area IRB and to their tribes for review and approval.
8. After NHLBI approval, the author should submit the final manuscript to a journal, and a copy of the cover letter and the final manuscript should be sent to the P&P Chair.
9. The author should inform the P&P Chair regarding outcome of the journal review process and send a reprint of the published article to the Chair. At least one copy (reprint) of all published papers must be sent to NHLBI (R. Fabsitz). **NOTE:** Papers that are likely to result in press coverage or substantial press/media interest require **notice in advance** to the NHLBI so that the staff and public information office can be prepared.
10. The P&P Chair will maintain a list of published SHS papers and papers in various stages of preparation.
11. 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.
12. 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. Summary of Abstract Approval Process

1. An author submits an abstract proposal (see abbreviated proposal form below) to the P&P Committee Chair.
2. The P&P Chair notifies the author of the committee decision.
3. Abstracts should also be submitted to NHLBI, IHS Area IRBs, and Tribes for approval.
4. Approximately 2 weeks prior to a poster or slide presentation, the author should submit the material for review and comment by one P.I. and two other Steering Committee members, preferably outside of the writing group.
5. Copies of all published abstracts should be sent to the P&P Chair, along with complete citation data, for inclusion in a list of published SHS abstracts.

VI. Examples of Paper and Abstract Proposal Forms

The following two pages display the desired format for paper and abstract proposals submitted to the P&P Committee. These forms will be transmitted electronically to SHS authors by e-mail so that e-mail 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 e-mail, or more traditional means if desired.

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:

Outline of Paper:

- a) Introduction (Rationale)
- b) Methods
- c) General analysis plan
- d) Lay summary for the tribes

Analysis Responsibility: (authors or Coordinating Center)

Note: 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.

Submitted by: (Corresponding author, with address for correspondence)

Date:

STRONG HEART STUDY

ABSTRACT PROPOSAL

Title of Abstract: (include the phrase "Strong Heart Study" whenever possible)

Name of Primary Author:

Author Affiliation:

Co-Authors:

Outline of Abstract:

- a) **Brief rationale**
- b) **General analysis plan**

Analysis Responsibility: (authors or Coordinating Center)

Submitted by: (Corresponding author, with address for correspondence)

Date:

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 _____

STRONG HEART STUDY

SCHEDULE OF DEADLINES FOR REQUESTED DATA ANALYSIS

Paper # _____ Received by Coordinating Center: _____

First author: _____

<u>Item</u>	<u>Date Due</u>	<u>Date Received</u>
Proposal	_____	_____
Outline & Analytic plan	_____	_____
First draft	_____	_____
Second draft	_____	_____
Third draft	_____	_____
Final draft	_____	_____
Date published	_____	

NOTE TO FIRST AUTHOR: Please sign, date, make a copy for your files and return original to the Coordinating Center.

Signature

Date

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: _____

1.8. ANCILLARY STUDIES POLICY

1.8.1 General Policy

To enhance the value of 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 in 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 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 is responsible for obtaining IRB approval from the 3 areas and the national IHS IRBs. In all cases IRB approval is needed if the proposed studies were not mentioned in the original protocol that received IRB approval.

1.8.6 Analysis and Publication of Results of Ancillary Studies

The 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 a confidentiality statement (Appendix 7). In addition the investigator will need to sign a statement that indicates his/her willingness to submit draft manuscripts for approval by the Steering Committee, NHLBI, IHS and the tribes. Manuscripts resulting from ancillary studies will require approval by the Steering Committee and by NHLBI, IHS and the tribes prior to submission for publication or presentation. 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 title and listed as a key word whenever possible. Manuscripts will also contain an appendix listing all Strong Heart Study Principal Investigators as well as other individuals deemed appropriate.

1.8.7 Agreement for Ancillary and Collaborative Investigation

The following agreement must be signed by ancillary and collaborative investigators:

I agree to read and follow the SHS protocol with regard to analysis of Strong Heart Study data I request. I will comply with the SHS policies regarding maintaining data security and will sign a confidentiality statement. I have attached a research protocol describing how I will use these data to better understand cardiovascular and pulmonary diseases in American Indians and how to benefit the health of American Indians.

I agree to submitting a draft report of the results of this analysis for review and approval of the SHS Steering Committee, NHLBI, IHS and the participating tribes. If approval for publication is not granted, I agree not to publish these results.

I understand the SHS Steering Committee will assist me in revising my report in such a way that will make it acceptable for publication. I agree to include one of the SHS Steering Committee members as a co-investigator and a co-author.

Signed: _____

Date: _____

1.8.8 Feedback of Results of Ancillary Studies to Participants

Results of ancillary studies shall be reported to participants and/or their physicians if medically useful. Such reporting should follow standard Strong Heart protocol for notification of participants. A copy of any resultant article should be sent to the Program Office and the participating tribes.

CHAPTER TWO

OVERVIEW OF STRONG HEART STUDY PHASE III MORTALITY AND MORBIDITY SURVEILLANCE

2.1 OBJECTIVES

All surviving participants from the SHS Phase I examination are eligible for morbidity and mortality follow-up in Phase III. 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 2.1 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. Events will be ascertained annually, thus providing on-going and up-to-date information about the cohort, independent of the Phase III examination. Surveillance activities in Phase III will continue until May 31, 1999.

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.

2.2 OVERVIEW OF SURVEILLANCE PROCEDURE

2.2.1 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 III follow-up would begin with those seen earliest in Phase II.

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 and II 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 2.1. 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.

Figure 2.1 Example of Tracking Form

SHS ID:	10xxxx	DOB:	4/27/40
NAME:	Smith, James	DOD:	
SSN:	000-00-0000	SHS-II Exam:	09/20/93
Address:	PO Box 5, Rapid City, SD 57577	SHS-III Exam:	
Home Phone:	(605) 555-5555	IHS Rec #:	000000
Work Phone:	(605) 555-5556		

EVENTS ABSTRACTED: None

Contact Date	Method of Contact	Result	INIT	MI/Stroke Other CVD	Comments
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

NOTES:

Table 2.1 Endpoints

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

I = Incidence

P = Prevalence

S = Surveillance contact

E = Examination, Phase II or Phase III

E* = By interview, with medical record confirmation

For each event, there is a designation as to whether it is an incident or prevalent event and the source(s) through which it will be initially ascertained. Because baseline data for the primary endpoints are available from Phase I, new events ascertained in Phase II will be incident events, and all of the primary endpoints, with the exception of ECG evidence of new myocardial infarction, can be identified both through surveillance contacts and during the Phase II examination. 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 will be prevalent cases. In addition, most of the secondary events will be ascertained only through systematic, uniform examination of participants in Phase II.

Once the Phase III exams begin in 1998, the exam serves as the annual contact for the participant. Otherwise, the participant is contacted again after the Phase III exam to have their annual contact completed. All participants will be contacted within the last six months of morbidity and mortality surveillance that ends 5/31/99. 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.

2.2.2 Specific Surveillance Approaches

Table 2.2 presents the percentage of each SHS center's population who have a telephone and who have a P.O. address.

Table 2.2 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. 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, and the morbidity information for that person will be collected at the time of the Phase III examination.

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.

2.3 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.

2.4 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 2.2.

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 ($\# \text{ abstracted} \div (\# \text{ potential events} - \# \text{ ineligible})$) 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 (usually the Phase II exam date). 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

Site	Cumulative as of:	Target#	Contacted	Participants With Potential Events		Total # of Potential Events		Events Abstracted		Ineligible Events		Packets Forwarded For Review	
				Mort	Morb	Mort	Morb	Mort	Morb	Mort	Morb	Mort	Morb
OK	04/30/97	617	573	27	57	27	101	16	71	0	11	16	45
OK	05/30/97	717	672	28	63	28	116	18	86	0	14	18	53
OK	06/30/97	843	785	30	84	30	141	20	102	0	15	20	67
OK	08/01/97	943	875	30	93	30	163	21	129	0	18	21	77
OK	08/31/97	1140	1021	32	127	32	189	24	148	0	23	24	95
AZ	05/01/97	777	728	51	102	51	210	39	175	0	0	39	84
AZ	06/01/97	883	831	56	116	56	240	44	187	0	3	44	90
AZ	07/01/97	986	924	56	131	56	282	48	239	0	5	48	108
AZ	08/01/97	1086	1021	64	125	64	306	51	270	0	19	51	117
AZ	09/01/97	1191	1120	70	133	70	317	52	293	0	20	52	128
SD	04/30/97	798	798	47	59	47	110	16	76	0	0	16	39
SD	05/30/97	898	898	47	78	47	170	24	136	0	3	24	63
SD	06/30/97	998	998	47	84	47	182	29	172	0	7	29	77
SD	08/01/97	1111	1111	47	106	47	243	35	223	0	20	35	101
SD	09/02/97	1244	1244	49	116	49	267	40	247	0	20	40	112
SHS	04/30/97	2192	2099	125	218	125	421	71	322	0	11	71	168
SHS	05/30/97	2498	2401	131	257	131	526	86	409	0	20	86	206
SHS	06/30/97	2827	2707	133	299	133	605	97	513	0	27	97	252
SHS	07/30/97	3140	3007	141	324	141	712	107	622	0	57	107	295
SHS	08/30/97	3575	3385	151	376	151	773	116	688	0	63	116	335

09/04/97

Figure 2.2 Monthly Surveillance Progress Form

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.

POTENTIAL EVENTS: This is the total number of possible CVD EVENTS (there may be multiple events per participant) and total number of reported deaths (this number will match the number of participant deaths). 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.

INELIGIBLE: This is the total number of potential events, which after medical records review, have been determined NOT to be SHS events.

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.

2.5 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 check lists 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 mortality packet, excluding Dr. Sievers's 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 are identified by the Coordinating Center. In these instances when both reviewers determine the death to be non-CVD but the assigned causes differ, Dr. Sievers's decision will be taken as the cause of death. Those cases in which one of the two reviewers assigns a CVD cause or when there is a discrepancy in type of CVD will be forwarded to Dr. James Howard for adjudication. Dr. Jim Howard will have the results of other two reviewers available to him so that the process in Phase III is consistent with that used in Phase I and II. 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 suspected fatal and non-fatal stroke events are forwarded to Dr. David O. Wiebers at the Mayo Clinic for review by him and his staff after initial review by the first M&M physician. A complete listing of the members of each of the physician review panels is given in 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's coming) and a copy to the M&M contact person at the CC (so they know what's been sent).

Material pertaining to M&M surveillance that is sent to the CC, should not be sent to Dr. Yeh, but rather to: "M&M Surveillance, attn. William Moore".

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

- a. Materials should be 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 should be 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 should be collected before sending the packets off for review.
- d. The CC will provide the reviewers with blank decision forms.
- e. Reviewers should 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.

CHAPTER THREE

MORTALITY SURVEILLANCE

3.1 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 1999, the final year of data acquisition in Phase III, 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.

3.1.1. Detailed Procedures for Mortality Surveillance

a. Cohort Mortality (date of Phase II exam through May 31, 1999)

Of the original 4,549 members of the Phase I cohort, 500 deaths occurred through the end of Phase II exam, and an additional 350-450 deaths are expected to occur before the Phase III examination. Thus, it is estimated that 3,600 to 3,700 surviving individuals will be eligible for Phase III. All members of the Phase I examination cohort, regardless of whether they participated in the Phase II exam, are eligible for ongoing cohort mortality surveillance. Each member of the cohort will be contacted annually during Phase III to determine their 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 Manual).

- 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 (Appendix C) for possible CVD deaths when medical records data is 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.

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 (Appendix 7) 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 stamp the back of the death certificate, add the ID number immediately above the stamp and send only the death certificate to the central nosologist,

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

for coding 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, including Final Decision Form, 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. 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 (Appendix C), and the Photocopy Checklist will be completed. 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. This process is done only for suspected CVD deaths for which there was no terminal hospital admission.
- c. Dr. Sievers will return the completed, including Final Decision Form, injury-related non-CVD mortality packet to the Coordinating Center for data entry. The rest of the mortality packets will be forward 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.

3.1.2 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.

3.1.3 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. 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 are recorded on separate Informant Interview Forms. Up to three (the three best) Informant Interview Forms may be completed for a given event.

3.1.4 Death Occurring Outside 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 to interview an informant. Their local medical charts will also be reviewed.

3.2 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:

3.2.1 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.

3.2.2 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 (I)a. in Section 3.2.1 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.

3.2.3 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 3.3.

3.2.4 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.

3.2.5 Definite Fatal Stroke

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

AND

- (1b) No other disease process or event such as brain tumor, subdural hematoma, subarachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma - according to death certificate, autopsy, hospital records, or physician records

OR

- (2a) History of rapid onset (approximately 48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness

AND

- (2b) Documentation of localizing 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.

3.2.6 Possible Fatal Stroke

- (1) Death certificate with consistent underlying or immediate cause (ICD-9 codes 431-437)

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 localizing neurologic signs (see (1b) above).

3.2.7 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.

3.2.8 Possible Fatal CHF

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

3.2.9 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.

3.3 DEFINITION OF ABNORMAL ECG, ABNORMAL ENZYMES AND PROLONGED CHEST PAIN

3.3.1 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, pacer, etc.)

3.3.2 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:

- 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.

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:

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

3.3.3 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.

3.4 MORTALITY SURVEY FORMS

1. **Mortality Survey Death Certificate Form:** This form codes relevant information directly from the death certificate. Data from the form are entered on computer by the M&M Coordinator at each center and forwarded electronically to the Coordinating Center.

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 that is not due to an intentional or unintentional injury. 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.
6. **Master List of Hospitalizations and Outpatient Visits:** This form 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 out-patient 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 FOUR

MORBIDITY SURVEILLANCE

4.1 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 III examination. Events of interest are those occurring since the SHS-II examination (or Phase I if that was the last contact). Some prior events that were inadvertently missed previously may also be picked up in Phase III.

4.2 SURVEILLANCE EVENTS

Table 2.1 summarizes 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.

4.3 DIAGNOSTIC CRITERIA: NON-FATAL MYOCARDIAL INFARCTION

4.3.1 Definite Non-Fatal MI

Must meet one or more of the following criteria:

1. Evolving diagnostic ECG (defined in Section 3.3.1);

OR

2. Diagnostic ECG and abnormal enzymes (defined in Sections 3.3.1 and 3.3.2);

OR

3. Prolonged cardiac pain (defined in Section 3.3.3) and abnormal enzymes.

4.3.2 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

4.3.3 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)

4.3.4 Possible Coronary Heart Disease

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

4.3.5 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
8. Pacemaker implantation
9. Positive non-coronary angiography
10. Arrhythmia
11. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; otherwise, diagnosis=07)

4.3.6 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. The ECG series for each case will be reviewed independently by three cardiologists. Discrepancies will be adjudicated among the three readers. The series of three ECGs is assigned the highest category for which criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than equivocal is greater than other.

A summary of the diagnostic criteria for hospitalized, non-fatal myocardial infarction used in the Strong Heart Study is given in Table 4.1.

Table 4.1 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

4.4 DIAGNOSTIC CRITERIA: NON-FATAL STROKE

4.4.1 Definite Non-Fatal Stroke:

1. History of rapid onset (approximately 48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness

AND

2. Documentation of localizing 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, sub-arachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma according to hospital records.

4.4.2 Possible Non-Fatal Stroke:

- 1a. History of rapid onset (approximately 48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness,

AND

- 1b. Documentation of localizing 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.

4.4.3 Unequivocal Laboratory Findings:

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 4.2.

Table 4.2 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

4.5 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.

4.6 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 (V₁-V₅); lateral (I, aV_L, V₆); 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.)

4.7 ABNORMAL ENZYME

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.

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:

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

4.8 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.

4.9 PROCEDURE FOR IDENTIFICATION OF INCIDENT AND RECURRENT CASES

Identification of non-fatal CVD events in the SHS cohort will continue in Phase III. Participants will be contacted annually or their IHS records will be reviewed. In addition, at the time of the Phase III examination, individuals will be asked about the occurrence of selected events, including ESRD, since the date of their last examination. 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. Participants reporting any event or procedure will be 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 III 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
- 428 Heart failure
 - 428.0 Congestive heart failure
 - 428.1 Left heart failure
 - 428.9 Heart failure, unspecified
- 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

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 4.3.3) should be arranged in chronological order from earliest to latest.

4.10 MORBIDITY SURVEY FORMS

- 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 of Part B, the reviewer has the opportunity to indicate their 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 will 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 Abstract:** This form is used to capture information on the results of selected tests of cardiac function and for atherosclerosis that may have been done on a SHS participant. This form is completed based on the test report which is photocopied from the medical record. The form is completed by the M&M Coordinator when only a procedure was performed, and by the Morbidity Review physician when the procedure was done in conjunction with an admission that he or she is reviewing.

CHAPTER FIVE

TRAINING & QUALITY CONTROL OF MORTALITY & MORBIDITY SURVEILLANCE

5.1 TRAINING

Interviewers and data abstractors will be centrally trained at the April, 1997, training meeting in Oklahoma. Training will include instructions in reviewing and abstracting of charts and instructions in transcribing of information on death certificates and medical examiner reports. Training will include:

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 will consist 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

5.2 QUALITY CONTROL

5.2.1 Ascertainment of Cause of Death

In the mortality study, mortality packets for non-injury 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. Jim Howard. Disagreement as to non-CVD causes of death will be resolved by using Dr. Sievers' decision.

5.2.2 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 panel members to improve concordance of assignment of type of event.

RELATED READINGS

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APPENDIX 2

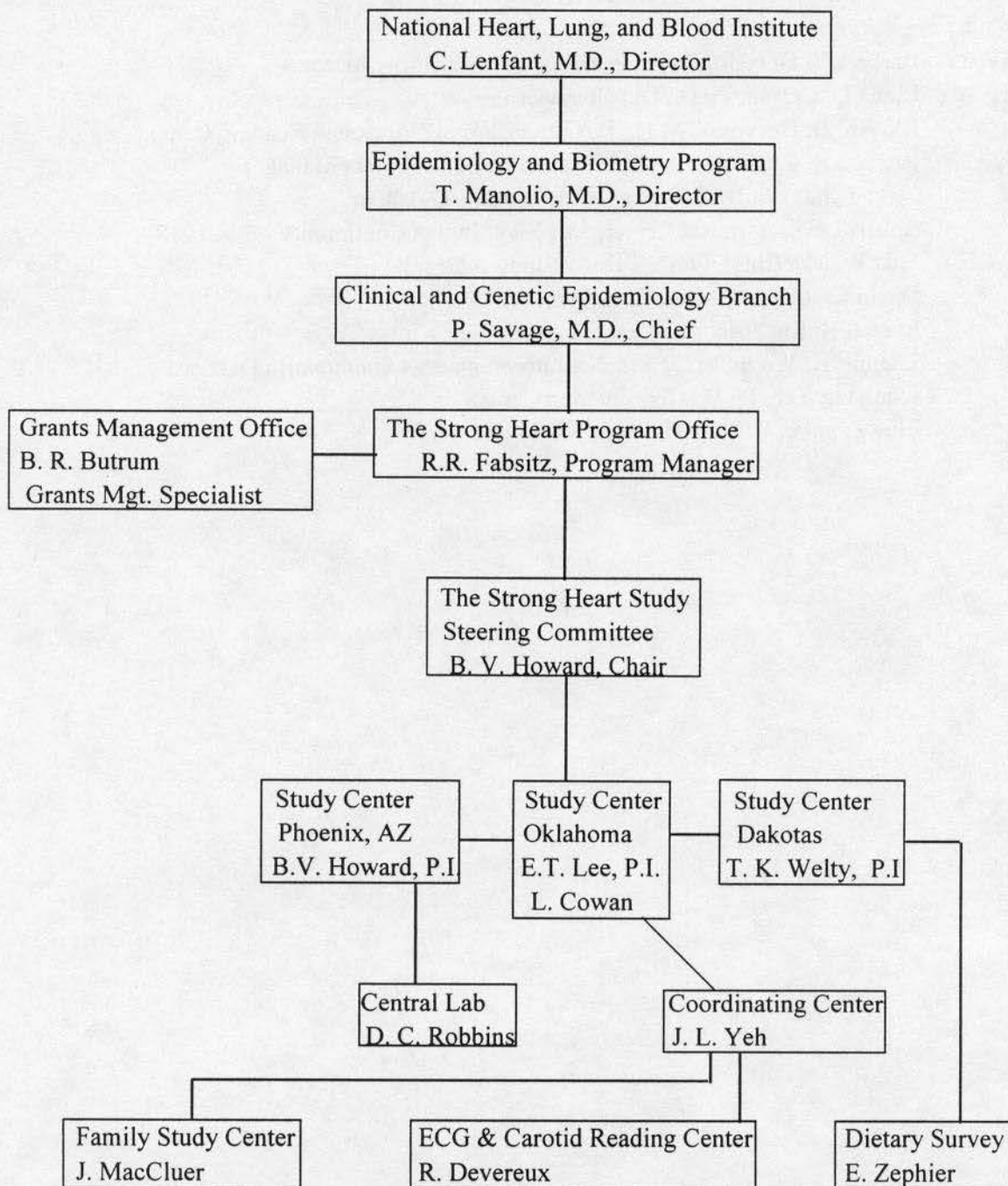
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APPENDIX 3

Organizational Chart of the Strong Heart Study



APPENDIX 4

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THE STRONG HEART STUDY III

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

STUDY COMMUNITIES AND CODES

Arizona Community Codes

County	Community Name	Community Code
<u>Maricopa</u>	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
<u>Pinal</u>	Santa Cruz	231
	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
	Lapland/Swiftbird	614
	Marksville/Swiftbird	615
	Moreau River/Whitehorse	616
	Promise/Whitehorse	617
	Ridgeview	618
	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

Dakotas Community Codes (cont.)

County	Community Name	Community Code
<u>Fall River (Pine Ridge)</u>	Sheyenne	397
	Edgemont	631
	Hot Springs	632
	Igloo	633
	Oelrichs	634
	Oral	635
<u>Haakon (Eagle Butte)</u>	Provo	636
	Midland	600
	Milesville	601
	Philip	602
<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
	Aneta	103
<u>Nelson (Fort Totten)</u>	Pekin	104
	Dahlen	105
	Lakota	456
	Michigan	457
	Tolna	458
	Gettysburg	751
<u>Potter (Eagle Butte)</u>	Lebanon	771
	Starkweather	106
<u>Ramsey (Fort Totten)</u>	Webster	107
	Churches Ferry	108
	Crary	476
	Devils Lake	477
	Doyon	478
	Lake Wood	479
	Am Horse Cr/Kyle	771
	Batesland/Allen	772
<u>Shannon (Pine Ridge)</u>	Calico	773
	Crazy Horse	774
	Cuny Table	775
	Denby	776
	Grass Creek/Manderson	777
	Kyle	778
	Lake	779
	Lakeside	780

Dakotas Community Codes (cont.)

County	Community Name	Community Code
	Manderson	781
	Oglala	782
	Pine Ridge	783
	Porcupine	784
	Red Shirt TA	785
	Rockyford/Porcupine	786
	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>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
	Canton	104
<u>Blaine</u>	Eagle City	105
	Geary	106
	Greenfield	107
	Hitchcock	108
	Homestead	109
	Longdale	110
	Okeene	111
	Southard	112
	Watonga	113
	Albert	138
<u>Caddo</u>	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
	Concho	158
	Concho Bia S	159
	Calumet	160
	El Reno	161
<u>Canadian</u>		

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Carter</u>	Mustang	162
	Piedmont	163
	Union	164
	Yukon	165
	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
<u>Comanche</u>	Norman	235
	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

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Cotton</u>	Sterling	256
	Devol	260
	Randlett	261
	Temple	262
	Walters	263
<u>Custer</u>	Arapaho	291
	Butler	292
	Clinton	293
	Custer	294
	Moorewood	295
	Thomas	296
	Weatherford	297
	Foster	350
<u>Garvin</u>	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
	Pocassett	370
	Rush Springs	371
	Tuttle	372
	Verden	373
<u>Greer</u>	Brinkman	390
	Granite	391
	Mangum	392
	Reed	393
	Willow	394
<u>Harmon</u>	Vinson	395

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Jackson</u>	Gould	397
	Hollis	398
	Altus	435
	Blair	436
	Duke	437
	Eldorado	438
	Elmer	439
	Headrick	440
	Martha	441
	Olustee	442
<u>Jefferson</u>	Addington	446
	Fleetwood	447
	Grady	448
	Hastings	449
	Oscar	450
	Ringling	451
	Ryan	452
	Terral	453
	Waurika	454
	Cooperton	495
<u>Kiowa</u>	Gotebo	496
	Hobart	497
	Lone Wolf	498
	Mountain Prk	499
	Mountain View	500
	Roosevelt	501
	Snyder	502
	Burneyville	565
	Leon	566
	Marietta	567
<u>Love</u>	Orr	568
	Overbrook	569
	Rubottom	570
	Thackerville	571
	Blanchard	574
	Byars	575
	Dibble	576
	Newcastle	577
<u>McClain</u>		

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
<u>Murray</u>	Purcell	578
	Rosedale	579
	Washington	580
	Wayne	581
	Big Canyon	664
	Davis	665
	Dougherty	666
	Hickory	667
<u>Oklahoma</u>	Sulphur	668
	Okla City, Rur	717
	Arcadia	718
	Bethany	719
	Choctaw	720
	Edmond	721
	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

Oklahoma Community Codes (cont.)

County	Community Name	Community Code
	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 9

CODES FOR IHS FACILITIES BY AREA AND SERVICE UNIT

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

Service Area Code	Unit Code	Location Code	Facility Name
Area: Aberdeen (cont.)			
10	15	32	Manderson Hs
10	15	62	Porcupine Sc
10	15	63	Porcupine Ch
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	Unit Code	Location Code	Facility Name
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Area: Oklahoma

Service	Unit:	Claremore	
50	52	01	Claremore Ho
50	52	14	Miami Hl 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 Hl 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 Area Code	Unit Code	Location Code	Facility Name
Service	Unit:	Shawnee	
55	58	11	Oklahoma City Clinic
55	58	12	Black Hawk Clinic
Service	Unit:	Tahlequah	
55	59	10	Eufaula Hc
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

Area: Phoenix

Service	Unit:	Keams Canyon	
60	62	01	Keams Canyon
Service	Unit:	Owyhee	
60	63	01	Owyhee Hosp
Service	Unit:	Colorado Riv	
60	64	01	Parker Hosp
Service	Unit:	Phoenix	
60	66	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	Unit:	Sacaton	
60	67	01	Asacaton Hos
Service	Unit:	San Carlos	
60	68	01	San Carlos
Service	Unit:	Schurz	
60	69	01	Schurz Hosp
Service	Unit:	Whiteriver	
60	71	01	Whiteriver H
Service	Unit:	Ft. Yuma	
60	72	01	Ft. Yuma

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 Hosital, 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 11

PERSONNEL CODES

Arizona Center

301	Barbara Howard	328	Greg Wood
303	Jim Howard	329	Don Warne
304	Betty Jarvis	333	Andrea Kriska
305	Paula Harper	339	Kathleen Quintero
307	Linda Phillips	340	Robert Hanson
309	Michael Paidi	341	Janet Andrews
310	Shinkuro Kataoka	342	Joanne Carter
312	Joy Jones	343	Michael Cyll
313	Matilda Johns	344	Veronica Rhodes
314	Helen Johns	345	Valentine Rodriguez
315	Rowena Juan	346	Wesley Yamada
316	Oreen Johns	347	Judy Bergman
317	Angeline Barley	348	Pamala Daily
320	Sonja Antone	352	Bert Lewis
321	Carmelita Estenson	354	Melissa Bergman
322	Maurice Sievers	356	David Robbins
323	Rosinna Brionnes	357	Roseanne Lewis
327	Daryl Allis		

Dakotas Center

101	Thomas K. Welty	408	Jim Galloway
102	Beverly Blake Price	410	Brenda Veit
109	Arliss Keckler	411	Joyce Marshall
119	Corbin LeBeau	412	Marie Kougl
134	Kurt Schweigman	413	LaVonne Looking Elk
160	Marcia O'Leary	414	Chris Zahn
182	Lillian Brown	415	Jay Bad Heart Bull
190	Alan Crawford	416	Wendy Lawrence
197	Neil Sikes	417	Francine Red Willow
198	Theresa Sikes	418	Janna Morris
402	Arlene Iron Crow	419	Jeanette Ofstad
405	Theresa Wounded Face	420	Joe Ferber
406	Sue Crawford	421	Sarah Lantis
407	Misty Tyon		

Oklahoma Center

201	Elisa Lee	231	Stephanie Gomez
202	Linda Cowan	232	Peng Li
203	Everett Rhoades	234	Kurt Schweigman
204	Jeunliang Yeh	235	Leon Kalbfleisch
206	Carl Schaefer	240	Fawn Yeh
208	Linda Poolaw	241	Wenyu Wang
209	June Eichner	242	Boureima Sambo
211	Chris McGlory	250	Richard Devereux
212	Lee Keesee	261	Melisa French
215	Juanita Cortez	270	Paul Enright
216	Data Manager	271	Dorrie Rhoades
217	Bill Moore	272	Yvette Roubideaux
221	Ying Zhang	290	Weibers
227	Tauqeer Ali	291	"
229	Karen Kimbley	292	"

Oklahoma Center

201	Elisa Lee	214	Lorrie Hollingsworth
202	Linda Cowan		
204	Jeunliang Yeh	217	Bill Moore
205	Oscar T. Go	233	Karita Nichols
208	Linda Poolaw	262	Kamran Rafiq
215	Juanita Cortez		
227	Tauqeer Ali	250	Richard Devereux
229	Karen Kimbley	251	Cheryl Pegus
231	Stephanie Gomez	270	Paul Enright
235	Leon Kalbfleisch		
240	Fawn Yeh	261	Melisa Cozad
241	Wenyu Wang	234	Kurt Schweigman
242	Boureima Sambo		
216	Jocelyn Langevin	290	Weibers
252	Dara Hill	291	"
206	Carl Schaefer	292	"
232	Dinesh Dalbir		
		293	Bennett Goss

APPENDIX B

Instructions for Mortality/morbidity Surveillance Data Forms

APPENDIX 12
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.

<u>Item</u>	<u>Instructions</u>
--------------------	----------------------------

- | | |
|-----|---|
| 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. |

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. 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 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 filled after contact, such as relationship to the decedent. In some cases the informant may change after calling, 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 for the attempts at contacting the informant. The interviewer should put 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 their health in the year prior to date. 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 is asked 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.

Written releases need to be witnessed.

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 usually 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 evaluate the quality of information provided by the informant.

APPENDIX C

Mortality Surveillance Data Forms

THE STRONG HEART STUDY III 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="text"/> 1	Oriental	<input type="text"/> 5
Hispanic	<input type="text"/> 2	Other	<input type="text"/> 8
White	<input type="text"/> 3	Unknown	<input type="text"/> 9
Black	<input type="text"/> 4		
5. Marital status:

Married	<input type="text"/> 1	Divorced	<input type="text"/> 4
Single	<input type="text"/> 2	Widowed	<input type="text"/> 5
Separated	<input type="text"/> 3	Unknown	<input type="text"/> 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="text"/> 1	Home	<input type="text"/> 4
Non-IHS hospital in study area	<input type="text"/> 2	Other	<input type="text"/> 5
Hospital out of area	<input type="text"/> 3	Location unknown	<input type="text"/> 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="text"/> 1	1 week or less	<input type="text"/> 4
1 hour or less	<input type="text"/> 2	1 month or less	<input type="text"/> 5
1 day or less	<input type="text"/> 3	more than 1 month	<input type="text"/> 6
Unknown or not recorded	<input type="text"/> 9		
13. Date abstract completed: / /
mo day yr
14. Code number of abstractor completing this form:

**THE STRONG HEART STUDY III
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 1=Phone 2=Home Visit 3=Other	Contact successful 1=Yes 2=No	Interview Completed 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? ☐1 ☐2 ☐9

b. stroke? ☐1 ☐2 ☐9

c. heart failure? ☐1 ☐2 ☐9

d. rheumatic heart disease? ☐1 ☐2 ☐9

e. any other heart disease or heart condition ☐1 ☐2 ☐9

If yes, specify: _____

f. coronary bypass surgery (CABBAGE) ☐1 ☐2 ☐9

g. coronary angioplasty (balloon angioplasty) ☐1 ☐2 ☐9

h. insertion of pace maker (defibrillator) ☐1 ☐2 ☐9

i. any other heart surgery? ☐1 ☐2 ☐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 or healthcare facility. → |__|
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 Q25**) 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 Q29)

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)*

THE STRONG HEART STUDY III
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 III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
PHOTOCOPY CHECKLIST FOR MEDICAL RECORDS REVIEW
MORTALITY SURVEILLANCE — CVD and NON-CVD

Admission date: |__|_|_|/|__|_|_|/|__|_|_|_|_| ID Number: |__|_|_|_|_|_|_|_|_|

mo day yr

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, but Report Not Available
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	__ 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

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

Mortality Survey — Final Decision Form

ID number: _____

Date of death: _____ mo _____ day _____ yr Age at death: _____

	Underlying cause of death	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: _____
- 22 = Unintentional injury and adverse effects/MVA
- 23 = Unintentional injury and adverse effects/all other
- 24 = Chronic obstructive pulmonary disease
and allied conditions
- 25 = Pneumonia and influenza
- 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

- 01=Pathology Report
 - 02=Clinical Diagnosis only
 - 03=Pulmonary function test
 - 04=Blood glucose test
 - 05=Abnormal liver function tests
 - 06=Abnormal kidney function test
 - 07=Positive culture (blood or sputum)
 - 08=Positive antibody test
 - 09=Positive blood test (any type)
 - 10=Autopsy
 - 11=Police/Coroner=s investigation
 - 12=Other medical records evidence
- Specify: _____

88=Other, specify: _____
99=Cannot 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

- | | Yes | No |
|---|------|------|
| [] 1)a. Definite MI within 4 weeks of death by criteria: | | |
| 1. Evolving diagnostic ECG, and/or | __ 1 | __ 2 |
| 2. Diagnostic ECG and abnormal cardiac enzymes, and/or | __ 1 | __ 2 |
| 3. Prolonged cardiac pain and abnormal cardiac enzymes | __ 1 | __ 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, subarachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma according to death certificate, autopsy, hospital records, or physician records,

OR

- [] 2a. History of rapid onset (approximately 48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness,

AND

- [] 2b. Localized 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, subarachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma according to death certificate, autopsy, hospital records, or physician records,

6. Possible fatal stroke (also complete Section C)

- [] 1. Death certificate with consistent 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 localizing 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 \geq 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 $\geq 120/\text{min.}$)

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. Thrombo-embolic infarction | 5. Other, unknown infarction |
| 2. Subarachnoid hemorrhage | 6. TIA |
| 3. Intraparenchymal hemorrhage | 7. Unknown type stroke |
| 4. Lacunar 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

--	--	--	--	--	--

-

--	--	--	--

|_|mo|_|||_|day|_|||_|yr|_|

APPENDIX D

Morbidity Surveillance Data Forms

**STRONG HEART STUDY III
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. 5=Other non-CVD, please specify.

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 III
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: _____
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. _____ • _____

For each hospital admission, 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, but Report Not Available
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 streptokinase, or TPA reperfusion	_____	_____	_____
9. Intravenous streptokinase, or TPA reperfusion	_____	_____	_____
10. Aortic balloon pump	_____	_____	_____
11. Radionuclide scan	_____	_____	_____
12. Computerized Axis Tomography (CAT or CT) of the head	_____	_____	_____
13. Magnetic Resonance Image (MRI) of the head	_____	_____	_____
14. Carotid ultrasound/Doppler	_____	_____	_____
15. Lumbar puncture	_____	_____	_____
16. Angiography	_____	_____	_____
17. 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 III

Morbidity Survey — DECISION FORM

--	--	--	--	--	--

|_mo_|/|_day_|/|_|_|_|_|_|

-

- | | | |
|--|--|--|
| | | |
|--|--|--|

--	--	--	--

1	2	3
---	---	---

_____1

 $|\underline{\quad}|^2$ $|\underline{\quad}|^2$

13

19

1

$$| \underline{\quad} |^2$$

1.3

_____4

Yes |__|1

No |__|2

Not done |__|9

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. Thrombo-embolic infarction | 5. TIA |
| 2. Subarachnoid hemorrhage | 6. Other, unknown infarction |
| 3. Intraparenchymal hemorrhage | 7. Unknown type stroke |
| 4. Lacunar 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 2 degrees to ESRD (diagnosis = 10) ☐
- c. Cardiomyopathy ☐
- d. Valvular Heart Disease ☐
- e. Left ventricular Hypertrophy ☐
- f. Atrial Fibrillation ☐
- g. Noncoronary heart surgery or carotid or other vascular surgery ☐
- h. Pacemaker implantation ☐
- i. Positive non-coronary angiography ☐
- j. Arrhythmia ☐
- k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides)
(diagnosis = 07) ☐

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

Finding of Valvular Function:

		Yes	No	Uncertain	Unknown
15.	Mitral regurgitation:	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 8	<input type="text"/> 9
16.	Aortic regurgitation:	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 8	<input type="text"/> 9
17.	Was Angioplasty performed?	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 8	<input type="text"/> 9

18. WAS TREADMILL EXERCISE TEST DONE?

Yes |__|1 No (**skip to Q25**) |__|2 Yes, but no report |__|3

19. If YES, When? |__| |__| |__|/|__| |__| |__|/|__| |__| |__| |__| |__|
mo day yr

20. Where: _____ |__| |__| |__| |__| |__| |__|
Hospital/clinic City/State Hospital Code

21. Treadmill ECG:
Normal |___|1 Borderline |___|2 Abnormal |___|3 Inconclusive |___|8 No report |___|9

22.	Maximum heart rate (beats/minute):	999=no report	____ ____ ____
23.	Maximum systolic blood pressure (mmHg):	999=no report	____ ____ ____
24.	Treadmill time (round to nearest whole number minute):	99=no report	____ ____

25. WAS THALLIUM TEST, OR OTHER NUCLEAR IMAGE TEST DONE?

Yes |__|¹

No (*skip to Q29*) |__|²

Yes, but no report |__|³

26. If Yes, when?

|_|mo|_|day|_|yr|_|

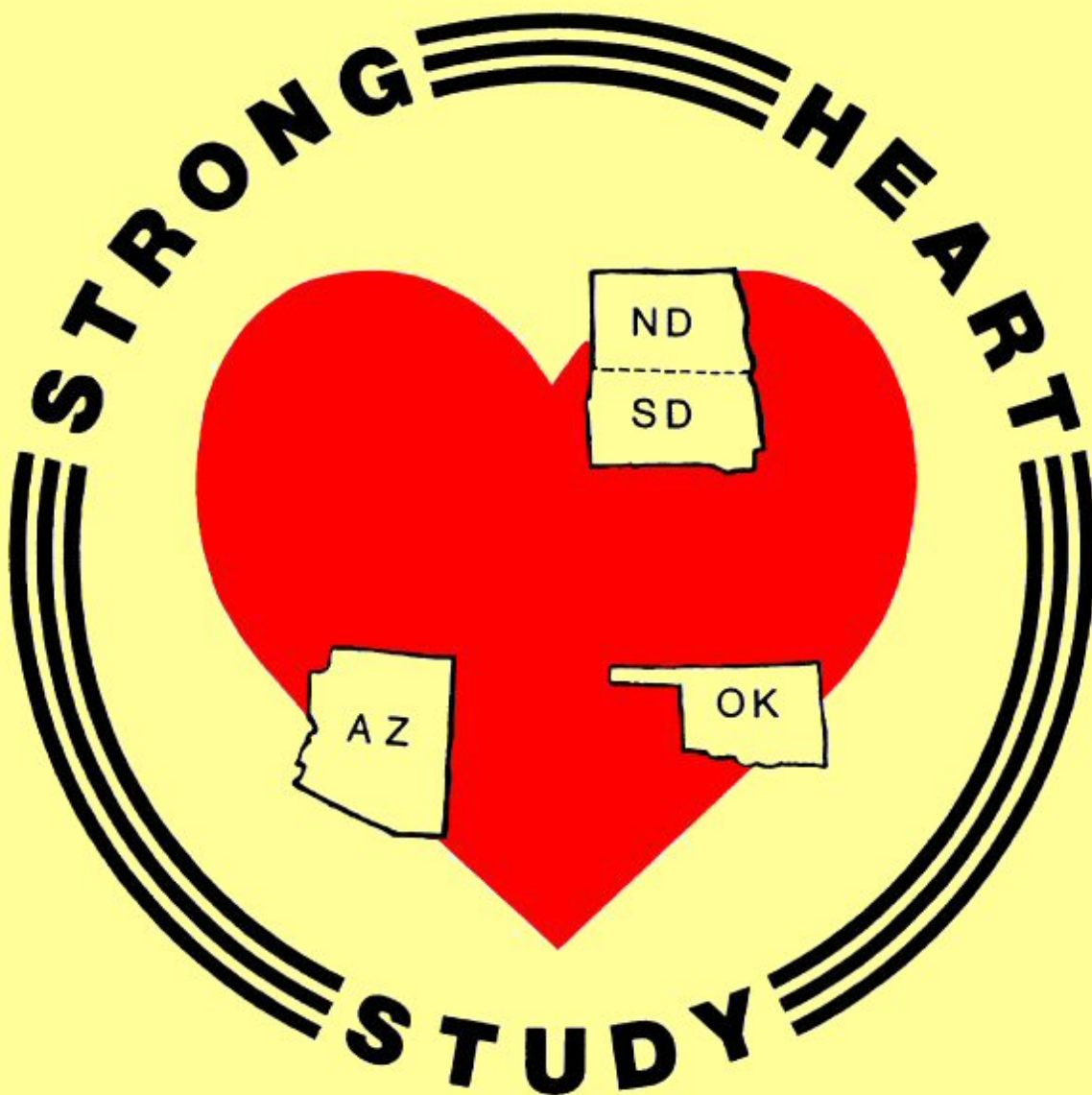
27. Where:

Hospital/clinic City/State Hospital Code

28. Test results: Positive |___|1 Negative |___|2 Equivocal |___|3 No report |___|9

29. Reviewer's code:

30. Date completed: | | mo | / | | day | / | | yr | |



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME TWO

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 III)

Operations Manual
Volume Two
Personal Interview and General Examination

September 8, 1997

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research

University of Oklahoma Health Sciences Center
College of Public Health

P.O. Box 26901
Oklahoma City, OK 73190

VOLUME II

PERSONAL INTERVIEW AND GENERAL EXAMINATION

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Clinical Examination - General

1.1 INTRODUCTION

Tribal members who had resided in one of the study communities for at least 6 months and who were between 45 and 74 years of age during the examination phase were invited to participate in the Phase I physical examination. Persons who were institutionalized were excluded. All those who participated in the Phase I exam are eligible for the Phase II and III exams. 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 and to assess the degree of association between the risk factors and CVD.

The examination will be conducted at local IHS hospitals and clinics. In the Dakotas, it will be performed at the Aberdeen Area IHS hospitals and clinics on three reservations. In Phoenix, the Tribal hospital at Sacaton (GRIC), the Tribal outpatient clinic at Salt River (SRIC) and the outpatient clinical AkChin 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.

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. Appendix A-1 gives an example of the consent form which requires a signature by the participant.

All examinations are performed by trained personnel, nurse practitioners, registered nurses, medical 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, medical students, physician assistants and physicians on the Phase III protocol occurred on April 16-19, 1997 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: income, residence, marital status, number of household members and employment will be determined.
- 2) Health habits: Smoking, alcohol intake and the impact of gaming since casinos have been established in some communities will be assessed.
- 3) Medical history, including Rose questionnaire for angina pectoris and intermittent claudication will be assessed.
- 4) Dietary survey: The 24-hour recall instrument used with the National Health and Nutrition Survey and in Phase II of SHS will be re-administered following procedures utilized by NHANES.
- 5) Quality of Life: The Quality of Life instrument will be the same as in the Phase II using the Rand MOS SF 36 questionnaire.

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 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 and rounded to the nearest unit.
 - 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 measurement are rounded to the nearest unit.

- 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-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) Glucose Tolerance Test (GTT) -- Fasting blood samples will be taken. Participants will be asked to drink 75 gm. glucose solution (Glutol) quickly (within 3 minutes). The participant will be instructed to take specimen container to the bathroom for urine sample. The second blood sample will be obtained at exactly 2 hours±3 minutes post-load. The GTT will be given to all participants, except:
- i) Insulin-requiring diabetic participants.

- ii) Diabetic participants who are on oral agents and the previous record indicated at least two values of random blood glucose above 250 mg/dl, or fasting glucose 225 mg/dl. on the day of the exam by One Touch glucometer.
 - iii) Non-diabetic participants with a fasting glucose of 225 mg/dl. or higher by One Touch glucometer.
- 6) Fasting blood samples for measurements of total triglyceride (TG) and cholesterol, LDL and HDL cholesterol, plasma fibrinogen, and PAI-1, and DNA isolation, glucose, creatinine, insulin, and SMA-12 will be obtained. Only tubes for DNA will be taken from patients who are on renal dialysis or have had a kidney transplant.
- 7) Urine will be collected at the beginning of the physical examination for measurement of albumin and creatinine.
- 8) Peripheral sensation will be measured in the right foot by monofilaments. Both feet will be examined for possible ulcers.
- 9) **The following procedures will be added:**
- i) Echocardiography of the carotid artery: See Volume VI of the Manual for details.
 - ii) Carbon monoxide in exhaled air will be measured to validate smoking status.
 At the beginning of the examination, after fasting blood specimens are obtained, the participants will be asked to take a breath and exhale forcefully into a Vitalograph "BreathCO" meter. The digital reading of CO in ppm is instantaneous. The participants will be asked when their last cigarette was smoked and how many cigarettes were smoked in the last 24 hours. History of exposure to smoke in the environment will also be obtained. CO readings in the range 15 to 50 ppm are most often seen in smokers, readings in the range of 9 to 14 ppm are usually seen with environmental tobacco smoke exposure and readings 0-8 ppm are usually seen in persons who have not been exposed to smoke for 24 hours. The results will be interpreted immediately to the participants who smoke or who are exposed to smoke and they will be advised to quit or cut down on smoking and/or establish a smoke-free environment in their houses or workplaces.

 High readings in persons not exposed to smoke will be referred to IHS Environmental Health Program for follow-up evaluation for faulty heater or vehicle exhausts.
 - iii) Ambulatory pulmonary function (PF) monitoring -- A hybrid nested case-control/cross-sectional design for the study of asthma will include as "cases" all those who reported asthma or asthma symptoms during the Phase II examination, along with an age, gender and tribe-matched control group of

healthy non-smoking participants without respiratory symptoms or cardiopulmonary disease. Approximately 600 cases will be identified and about 200 of controls will be selected. Cases and controls will be asked to perform peak expiratory flow (PEF) measurements using a hand-held battery powered electronic spirometer that can store results for two weeks of testing, eliminating the need for written daily. The participants (cases and controls) will be asked to measure PEF at least twice a day for two weeks. An addressed, stamped, and padded envelope will be provided so that the participants can return the spirometer after two weeks of monitoring. This will be performed using methodology comparable to the Cardiovascular Health Study.

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 since the previous Strong Heart Study examination.

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. The participant will then be instructed to go to the laboratory for blood drawing, to drink the glucose preparation (Glutol), and to obtain the urine specimen. The nurse clinician and other staff will then conduct the personal interview, examination of the lungs, obtain anthropometric measurements, blood pressure, impedance measurement for body fat composition, and ECG measurements. At exactly two hours after the ingestion of the glucose preparation, the participant will have another blood sample drawn for the glucose tolerance test. If the above procedures are not completed before the 2-hour sample is drawn, they may be continued and completed after the participant consumes a light snack. After all the procedures are completed, the participant will receive the payment or sign the payment form and be thanked for his/her participation.

If possible, all of the components, except for the dietary survey 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.

1.2.2 Components of the Examination for Family Members

The family members will have all the information collected that is described above for the Phase III exam of the cohort, except for the ambulatory PF monitoring. Each center will pilot the family member exam in at least 10 persons and appropriate revisions in the procedure will be made and standardized for use in all three centers for 300 family members age 18 or over at each center. 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. As much of the information as

possible that was collected on the original participants will be collected on the family members. The interview will include the following:

- i. Phase II Information: This includes: tribal enrollment, degree of Indian blood, marital status, education/income, use of native language, smoking and alcohol use, medical conditions, reproductive history, and current physical activity.
- ii. Phase II Information includes: history of attending boarding school, respiratory/snoring, cultural factors, risk factor knowledge, quality of life.

1.2.3 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
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

Non-coronary heart surgery or carotid or other vascular surgery

Pacemaker implantation

Bruits by physical examination

Intermittent Claudication by Rose Questionnaire

Positive non-coronary angiography

1.3 RECRUITING

1.3.1 Recruitment Techniques

Recommendations from the Dakotas' Lillian Brown

Always remember that the participant is here on a voluntary basis.

Recruiting participants to the Strong Heart 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 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. 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 casual 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 circadian 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 participants needs when scheduling.

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 like 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.

1.3.2

All individuals who participated in the Phase I exam are eligible for the Phase III clinical examination. Eligible study participants are identified through the Strong Heart Study data base. 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 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 visit to 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;
3. That the volunteer should not take their morning diabetes medication until blood drawing is completed;
4. No tobacco or vigorous activity before the clinic visit;
5. Volunteer should be instructed to wear loose clothing and ladies to wear a skirt and blouse or pants and shirt, rather than a dress

If the participant is related retarded 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 to have the hospital chart for that participant available the morning of the clinic visit. The chart may also be reviewed to see if the participant satisfies the exclusion criteria for the glucose tolerance test.

1.4 PERSONAL INTERVIEW

1.4.1 Components of the Personal Interview

The personal interview is designed to obtain demographic information, medical history, health behavior, acculturation and stress data that are considered important in identifying risk factors for cardiovascular disease. The following questionnaires will be administered during the clinical examination:

1. Personal Interview Form (I and II)
2. Gambling
3. Medical History Form
4. Dietary Form

5. Sleep Habit
6. Quality of Life
7. Respiratory (family study members)
8. Physical Activity (family study members)

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 and the degree of acculturation will be collected by using the Personal Interview Forms (I and II). Medical History Form which consists of questions on medical conditions, medications used and the Rose Questionnaire for angina pectoris and intermittent claudication. These questionnaires are given in Appendix C.

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 has been shown to increase response over self-administered questionnaires. When rapport is established between the interviewer and the interviewee it 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 multi-center study such as the Strong Heart Study. Since the interviewer is known to have a large effect on the quality of the data obtained, therefore 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 Study.

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 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 judgement 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 record the information provided, and to elicit the desired response.
- 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 or clucking. 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 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 (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.
- 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 and comfortable. 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 also 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. 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

While it is generally held that the principles outlined above, which have been derived solely from research into and experience of face-to-face interviewing, 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, each interview and form contains a set of question by question instructions for filling out 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.
- i. Write "refused" beside any question that the respondent refused to answer.

1.4.3 Training & Quality Control of Interviewers

1. Training

Interviewers were centrally trained in April 1997 at the training session in Oklahoma using a standardized procedure for administering each questionnaire. Training included instructions in research interviewing techniques and in completing each form. Interviewer skill training included:

- (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 inter- and intra-interviewer differences, study coordinators will monitor 5% of the interviews done by each interviewer.

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 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

Population studies have always demonstrated a uni-variate association between obesity and CVD. However, in many early studies, the association between obesity and the incidence of CVD did not remain significant in multi-variate analysis, and thus it was thought that obesity was a risk factor solely because of its influence on other risk factors such as blood pressure, plasma lipoproteins and diabetes. More recently, especially in longer term studies, significant independent associations between obesity and the incidence of CVD have been demonstrated.

Although early records are not conclusive, all evidence indicates that obesity among American Indians was rare until the last century. Their farming and hunting life styles 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 role in cardiovascular disease as well as its 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

It has been recently demonstrated that 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 the triad of 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 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 been also 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 multi-variate 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.

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 Mascot Model).

1.5.5 Electrocardiograms

All participants will have a resting electrocardiogram so that evidence for ischemic changes and left ventricular hypertrophy can be determined. The prevalence of such changes will reflect the prevalence in the population studied and can be compared to other population-based studies and among the three sites.

1.5.6. Overview of Laboratory Measurements

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).

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

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.

The relationship 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.

If a Beta Estimate is performed, measurements are made of total plasma cholesterol and triglyceride. HDL is measured after precipitation of LDL and VLDL. LDL is calculated by the Friedewald formula:

$$\text{LDL chol} = \text{Total Chol} - \text{HDL Chol} - (\text{Total TG}/5)$$

This estimate is based on the assumptions that VLDL cholesterol is a minor portion of the total cholesterol, that the majority of the total triglyceride is in VLDL, and that the composition of the VLDL is "normal", that is, VLDL cholesterol is approximately one fifth that of triglyceride.

This method has two advantages:

- (1) Can be performed on plasma that was frozen.
- (2) Requires much less technician time.

The disadvantages are:

- (1) It is inaccurate in individuals with high triglycerides (> 400).
- (2) It is inaccurate in individuals with altered VLDL composition.
- (3) It will not allow the isolation and examination of VLDL composition and relations to ASCVD.

If Beta quantitation is performed, total cholesterol and triglyceride are measured, and HDL cholesterol is measured after precipitation, as in the beta estimate. In addition, VLDL is isolated by ultracentrifugation, and the ratio of cholesterol to triglyceride is measured in VLDL. From this we can directly calculate:

$$\text{LDL-Chol} = \text{Bottom-chol} - \text{HDL-CHOL}$$

$$\text{VLDL-Chol} = \text{Total chol} - \text{Bottom chol}$$

$$\text{VLDL-Triglyceride} = \text{VLDL-Chol} \times [\text{VLDL-TG}/\text{VLDL-Chol}]$$

The advantages are:

- (1) LDL cholesterol is measured directly, not estimated.
- (2) A measure of VLDL composition is obtained.
- (3) VLDL and bottom fractions are available for further apoprotein measurements or for storage.

The disadvantages are:

- (1) The ultracentrifugation is laborious, time consuming and costly.

The Beta quantitation procedure is selected because of the need for accuracy in the measurement of LDL and because it yields a VLDL fraction of particular interest in a population with high prevalence of diabetes. People with diabetes frequently have abnormal composition of VLDL.

2. Glucose Tolerance Test (Glucose and Insulin)

Although it may be argued that 75 gm glucose load is not a measure of glucose disposal that is analogous to carbohydrate ingested during daily meals, it is the standard measure of glucose tolerance which can be compared to other studies, and forms the basis for all the currently used criteria for diagnosis of diabetes. Because of the high prevalence of diabetes in all three centers, and because of the multiple previous studies reporting associations between diabetes and CVD, a glucose tolerance test is essential for the current study. The most simple to perform is one where blood samples are drawn by venipuncture at fasting, and then two hours after ingestion of the glucose. All other fasting blood samples may be obtained at the time of the fasting sample, thus limiting the venipunctures to two.

Glucose concentrations will be measured in both fasting and two hour samples. Blood for this is obtained in tubes containing fluoride to prevent consumption of glucose by WBCs. Previous studies in Phoenix 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. 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, hypertriglyceridemia, 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 relationship to vascular disease and also to blood pressure, triglycerides, 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.

4. Fibrinogen

Disorders of the coagulation system could play a major role in ASCVD. There has been special interest in the role that abnormalities in the clotting system might play in the increased risk for atherosclerosis observed in diabetics. Abnormalities in several factors have been reported to be associated with atherosclerosis. One of the most commonly and easily studied is fibrinogen, and it has been shown to be an independent risk factor for CVD in both nondiabetics and diabetics in the Framingham study.

Fibrinogen has been most commonly measured using a chronometric technique. For this, thrombin is added to plasma to induce clotting, and the clot is quantitated on a fibrometer or automated coagulometer. Since the lab at the MRI does not possess this equipment, measurements will be made by Dr. Russell Tracy at the University of Vermont.

5. DNA

Because CVD is a clinically heterogeneous disorder and involves a complex interaction between genetic and environmental factors, it will probably be explained by a complex polygenic transmission. Recent development in recombinant DNA technology, including using restriction enzymes to identify polymorphisms, are now frequently being used in the study of genetic disorders and may be very helpful in sorting out the genetics of complex diseases such as atherosclerosis. Methods are now available for detecting altered nucleotide sequence in the human genome, which may be used as genetic markers of CVD or risk factors. Certain alterations in DNA sequence may be demonstrated by cleaving genomic DNA with restriction enzymes, hybridizing with cloned DNA probes and by detecting changes in the length of gene fragments by autoradiography. These techniques have allowed the chromosomal mapping of the genes for diseases such as muscular dystrophy and Huntington's chorea.

Although we do not yet have evidence in Indians that CVD shows familial aggregation, there is certainly ample indication in other populations that CVD and several of its risk factors are familial and thus would lend themselves to genetic studies. Although genes for cardiovascular disease have been localized in animals, attention in human studies has been focused on identifying alleles that may be associated or linked with other diseases. Since diabetes, hypertension and altered lipoprotein concentrations are strong risk factors for the development of CVD, attention has been focused on the possibility that abnormalities in

apoprotein or insulin gene loci might be associated with susceptibility to CVD. Mandrup-Poulsen et al. have suggested that a polymorphic region of DNA close to the human insulin gene is a genetic marker for atherosclerosis. Karathanasis et al. have shown that the genes for ApoA-I and apoC-III are physically linked, and that polymorphism of the apoA-I gene is inherited as a trait linked to premature atherosclerosis in one affected family. Ordovas et al. have also shown that the apolipoprotein A-I gene polymorphism was associated with CAD in a study of 88 patients, and was also found in 8 out of 12 kindreds with familial hypoalphalipoproteinemia. Finally, the possible association between NIDDM and arteriosclerosis is further suggested by a recent report of an association between a apoA-I gene polymorphism and susceptibility to NIDDM.

Because of the distinct possibility that the next several years will lead to greatly increased availability of genetic markers and likely specific gene loci with documented association with CVD, it is of interest to study these in the Indian groups to be examined in the current survey. The present study will undoubtedly include many related people and gives the opportunity to identify families for linkage studies. For this reason, it is proposed in the present protocol to isolate and store DNA from lymphocytes of blood sample. This can be easily accomplished in an efficient and economical way and would, therefore, serve as a store for future genetic studies.

1.6 PROCEDURE FOR GLUCOSE TOLERANCE TEST (GTT)

For all subjects, a fasting glucose value will first be obtained by using One-Touch (see Volume III Laboratory Procedure for details). Query subjects as to whether they are a known diabetic. If they are, ask if they take insulin or oral agents.

Note that all diabetic participants taking insulin will be exempted from the glucose tolerance test (GTT). Those diabetics who take oral agents and who have two random glucose values ≥ 250 mg/dl. or any participant with a fasting glucose ≥ 225 mg/dl. by One-Touch will also be EXEMPTED from the GTT. For individuals on renal dialysis or who have had a kidney transplant, blood will be drawn at the time of the examination, if possible.

1. Have the bottle of glucose (Glutol 75g.) and blood drawing equipment ready. Although the Glutol has proved to be very dependable and consistent when its concentration per ml has been measured in numerous samples, the volume supplied per bottle is not consistent. Thus it is necessary to measure both the Glutol and the water into which it will be diluted for each patient. The easiest way to accomplish this is to have a plastic graduated container such as that used for urine collections. The person administering the glucose tolerance test can thus pour 135 ml of Glutol into the measuring container, pour that into the cup supplied to the patient and then measure out 135 ml of water using the same measuring container. The cup containing the diluted Glutol is then ready for the patient. This measuring container can be used for all patients visiting on that day, but it should be discarded at the end of the day and a fresh measuring container used for the next clinic.

2. Ask subject if he/she has been fasting for 12 hours and whether he/she has refrained from smoking and beverages other than water, and record the response on the GTT check list given in Appendix C.
3. Draw fasting blood samples as described in Procedure for Blood Drawing. Record the time of blood collection.
4. Describe the purpose of the GTT to the subject.
5. Ask the subject to drink the glucose solution quickly, within 3 minutes - Record the time the process started on form.
6. Instruct the subject that he/she should not eat, drink or smoke anything until the second blood sample is obtained two hours later.
7. Instruct the subject to take the specimen container to the bathroom for the urine sample - Record the time of urine collection.
8. Place urine sample in the refrigerator.
9. Obtain second blood sample at exactly 2 hours post load - Effort should be made so that the second blood sample is obtained at exactly 2 hrs \pm 3 min. Record the time of collection.

1.7 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 C.

1.7.1 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 (Detecto, model 683-p) 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 lbs.) 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.

Figure 1. Frankfort Plane for Measuring Body Height

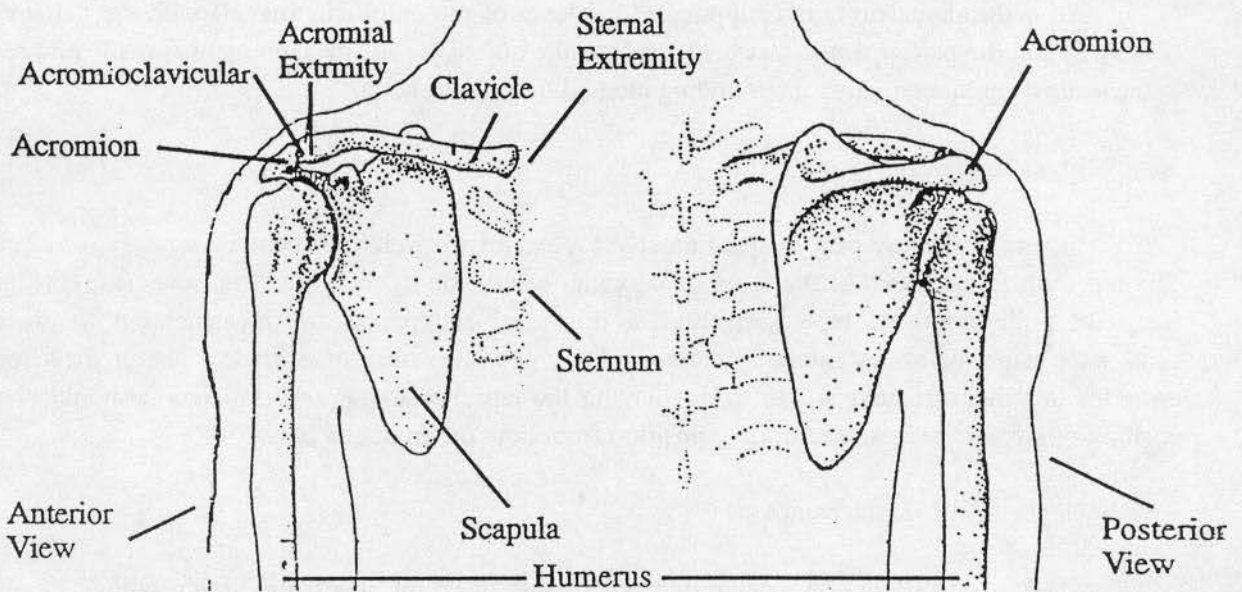


Figure 1 (a). General Description: The **scapulae**, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body. The end of the spine projects as a flattened, expanded process called the **acromion**. This process articulates with the clavicle.

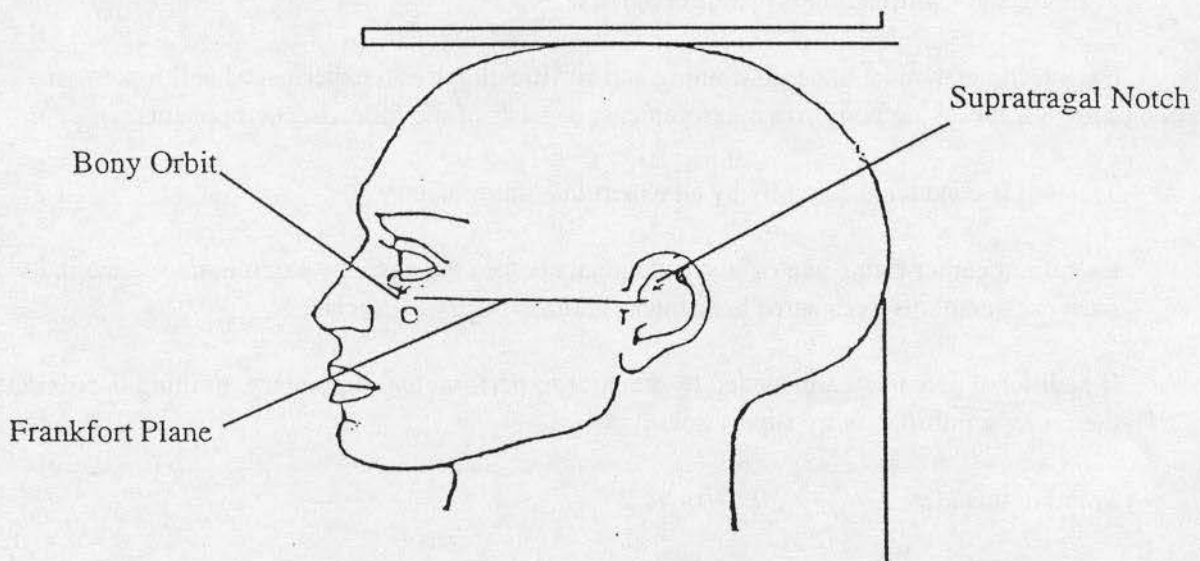


Figure 1 (b). the **Frankfort Plane**: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external ear.

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 acromion 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.

1.7.2 Training and Certification for Anthropometry

Each technician must undergo training and certification by an experienced anthropometrist. The training program for taking body size measurements consists of the following components.

1. Training is conducted centrally by an expert 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 - 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 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 a trained anthropometrist. 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 expert'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 arm, waist and hip measurements must agree within ± 1 cm on each subject.
 - 2) Weight must agree within ± 1 kg. Height within ± 1 cm.

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.

1.7.3 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.

Figure 2. Location of Waist Girth Measurement

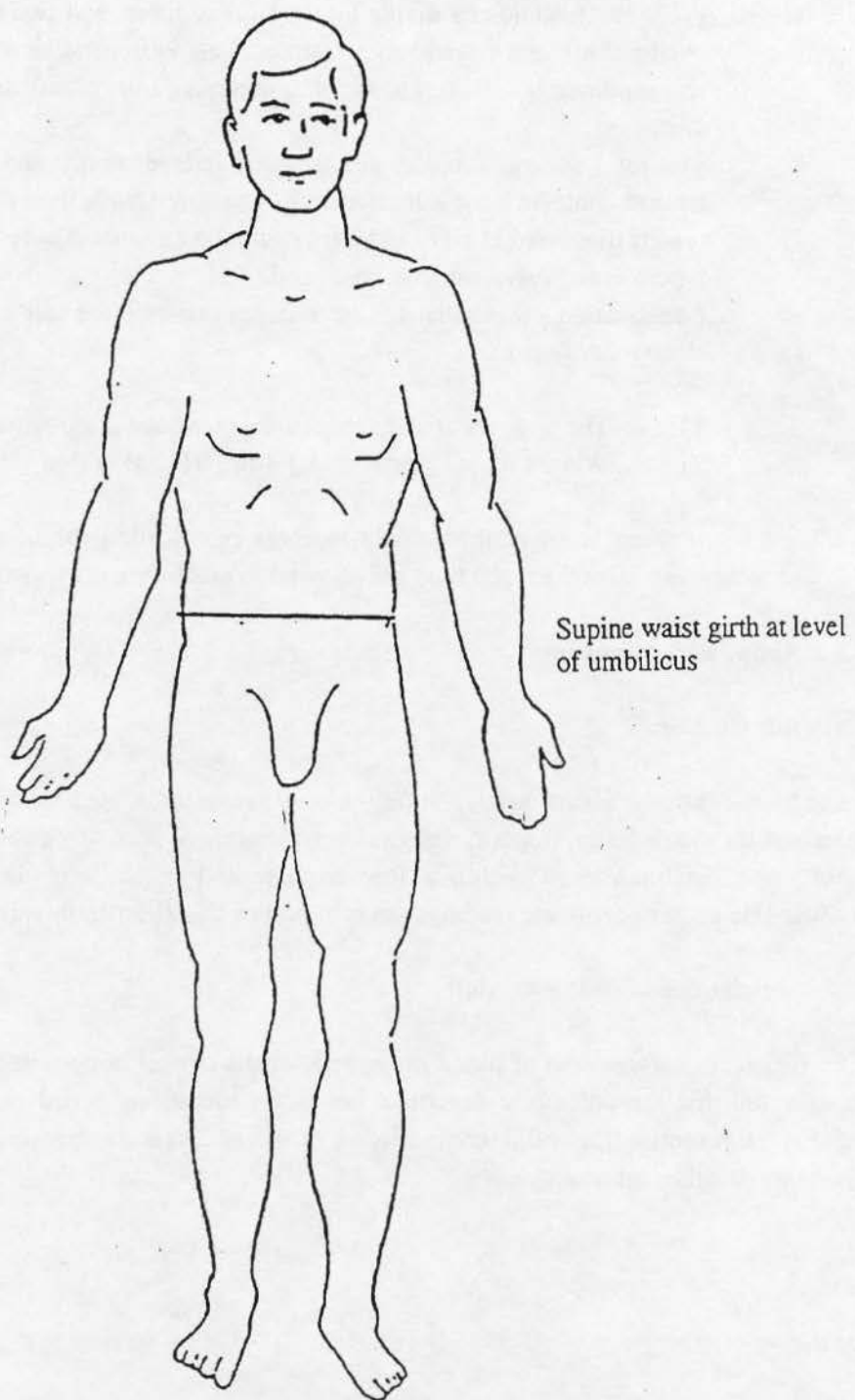
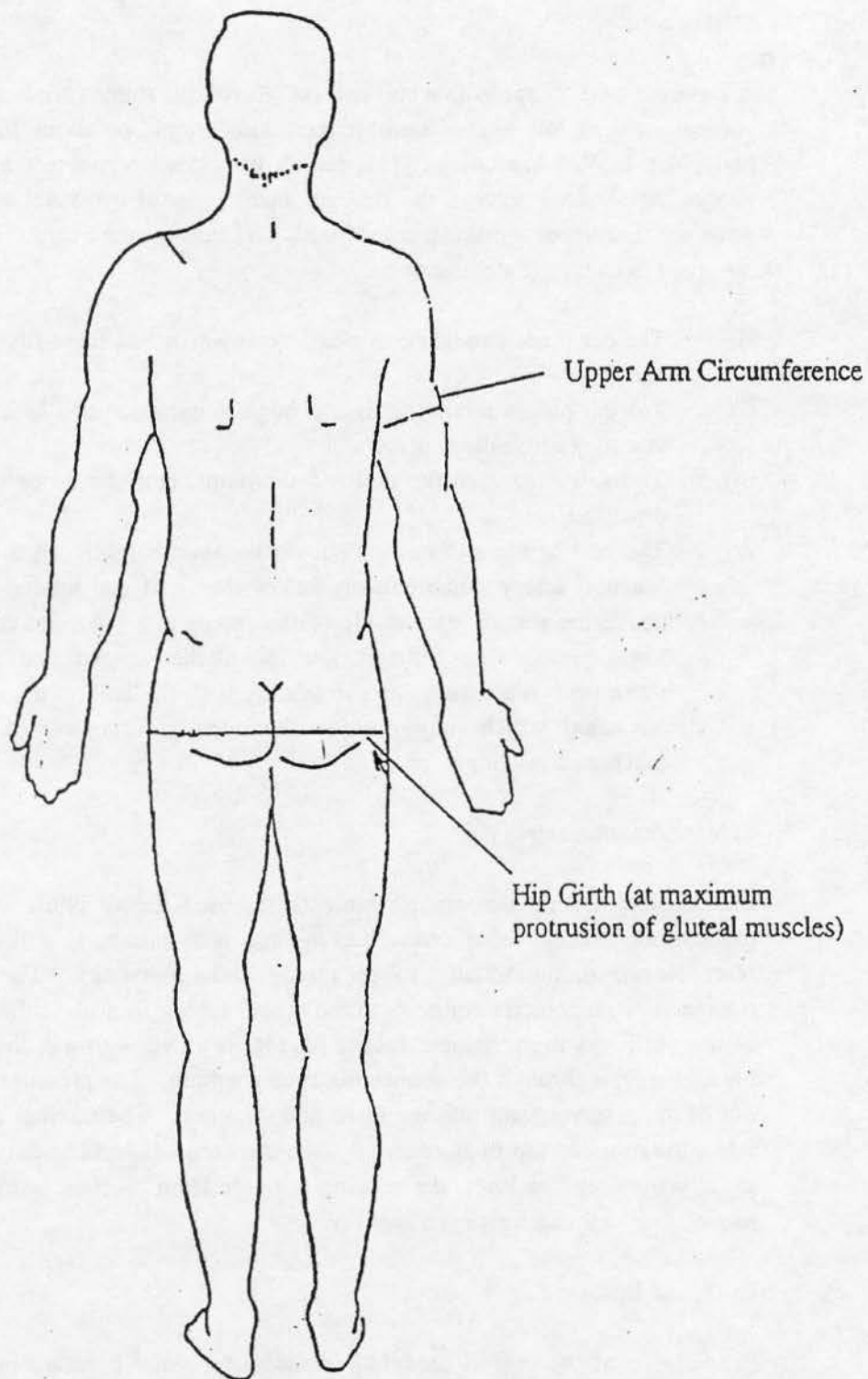


Figure 3. Location of Upper Arm, Hip, and Calf Circumference



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. Earpieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

- i) The ear piece should be directed downwards and forwards into the external ear canal.
- ii) The ear pieces 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 three standardized Baum cuffs available - 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 follow:

Table 1.2 Determination of cuff size based on arm circumference (Mid humeral)

Cuff Size	Arm Circumference
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 alcohol intake and recent physical activity at work and leisure are also recorded.

5. Staff Preparation for Participant Visit

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 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) 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.
- d) 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. Raise the arm for 5 seconds and wait at least 25 seconds before auscultating the blood pressure.
- e) 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.
- 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 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 work station, 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 pressure.

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 video tape. Checklist is used for certifying all persons taking BPs (Appendix A3). Simultaneous BPs will be recorded using a Y stethoscope as described in Appendix A4.

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 A4. 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 and 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 systemic 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 A4 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 A5.

- of: The standard sphygmomanometer is inspected once a month. These inspections include a check
- 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 A6.

1.7.4 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. 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 ankle 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 1/2 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 1/2 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 Mascot Doppler. If no pulse is audible or palpable, then try to use the dorsalis pedal 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.
- d) Take a second blood pressure, and record both blood pressures in the Physical Examination Form. This procedure also applies to the doppler arm blood pressure.
- e) Record the first sound as described above.

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, no systolic measurement should be made in that ankle.

- f) Repeat the procedure for the left leg and record the pressure as soon as the cuff is in the proper position.

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 work station.

1.7.5 Electrocardiogram

1. Basic description

- a) A Marquette Mac-PC (or Mac-12) based system will be used.
- 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 over-read and promptly returned.
- d) All ECGs will be Minnesota coded at Cornell.
- 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" would be conducted of all persons recording ECGs at individual sites by a physician (or other designated person) who would judge the ability of the person being examined to adhere to standard protocol.

2. Minimal Equipment Requirements

- a) A new Mac-PC with modem will be used at each clinic. Mac-12 machines may be used if they are available.
- 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-12 compatible format.

Transmission instructions on Mac-PC and Standardized ECG are given in Volume IV 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. 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. The Minnesota codes will then be added to the ECG data set by the Coordinating Center for data analyses.

Figure 4. Placement of the Blood Pressure Cuff on the Ankle
Step I. Positioning the Lower Leg on the Cuff

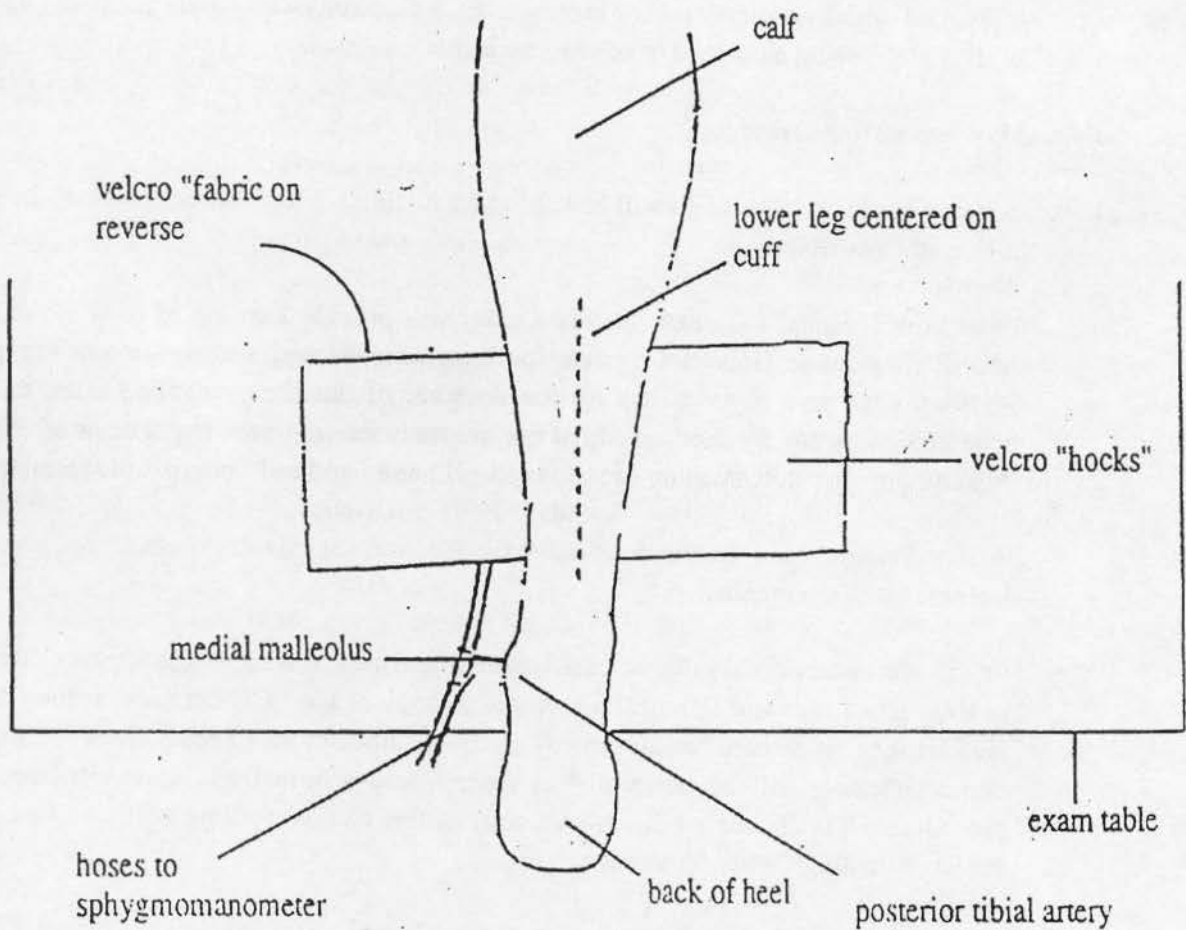
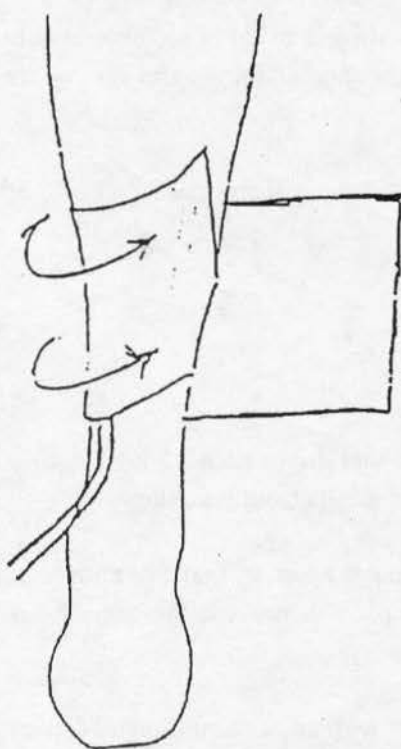


Figure 5 Placement of the Blood Pressure Cuff on the Ankle
Steps II and III: Wrapping and Securing the Cuff

Step 2. Wrap fabric end of the cuff
following contour of ankle



Step 3. Wrap and secure cuff

"ears" about
equal



1.7.6 Impedance Measure

The measurement of body fat is accomplished using the Impedance Meter, Model # B1A101, made by RJL Equipment Company. This involves a small low frequency current which 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, it is proportional to fat free mass.

1. Procedure

- a) Before beginning, explain why you are making the measurement to the subject and check to see that the subject 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 subject 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 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 effect the results).
 - v) Subject'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 electrode at 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

Battery Charging

Unit has rechargeable batteries that must be charged before use. They are charged by plugging instrument in with power switch in off position. Manufacturer suggests charging for 8 hours prior to use. Instrument should not be plugged in longer than 8 hours; damage to batteries may occur.

For our use they suggest the following: Plug unit in first thing in the morning before clinic and at least 15 minutes before the first test. Leave unit plugged in for the duration of each clinic, but have the power on only when testing a patient. At the end of clinic, the meter should indicate high charge (green area).

Checking Instrument

Before testing the first patient, be sure that the cables are not crimped or damaged. Check battery charge using the following procedure. Disconnect power cord. 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.

If resistance is not within this range, the batteries may not be fully charged, or another problem may be present. If charge appears to be low, charge batteries for 8 hours, then retest. If unit is fully charged and resistance is still not acceptable, see Impedance Tech Manual, page 9, for trouble shooting.

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 3%.

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 3%.

In addition, the instructor is responsible for the monitoring of the impedance meter. This includes checking the battery charge daily before the instrument is used, following the instructions in the manual. Further, the instructor should observe individual operators performing impedance measures at least quarterly to verify consistent and proper technique.

1.7.7 Examination of the Pulse

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.

d) Peripheral neuropathy using mono-filaments.

1.7.8 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 were 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 A10.

1.8 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 and, also that the participants receive assistance in securing medical care for any significant medical conditions uncovered during the course of the study exam.

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.

- b) After all laboratory results are completed from the physical examination, a follow-up letter will be mailed to each participant thanking him or her for participation and supplying him/her with basic medical information obtained during the exam. (See example of letter and suggested interpretation in Appendix A7 and A8).
- c) After all results from the medical examination are complete, a form will be generated by the Coordinating Center which will be available to the Indian Health Service for insertion into the patient's medical record. This will contain results of the electrocardiogram, carotid ultrasound measurements of body fat, glucose tolerance test, and blood measurements, which might be of benefit for their future medical care.
- d) In order to insure 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.

2. Referral Levels and Medical Data Review

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 are the levels of referral established for the Medical Data Review.

- a) **Emergency Referral:** The patient is immediately escorted to a physician, 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.
- 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 SHS participants to be seen that day. The participant is provided with an IHS referral form to take to his/her physician and transportation is provided or arranged if needed.

- c) **Urgent Referral:** The participant is urged to see his/her physician within one week and SHS staff makes an appointment for needed follow-up whenever possible.

An IHS referral form is filled out and transportation is arranged if needed.

- d) **Routine Referral:** The participant is asked to see his/her physician within one month, or at first convenient appointment and appointments for the patients are made by the CHRs

or clinic staff. An IHS referral form is filled out and transportation is arranged if needed.

- e) No Referral: The study results are summarized for participant and the participants are advised that the summary of the final results will be mailed to them at a later date.

3. Referral and Review Guidelines for Independent Patient Follow-up

Guidelines for referral are provided in the table below. The SHS nursing 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, judgement is exercised about whether to refer. The standard IHS referral form 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

<u>Emergency Referral</u>	Statement to Participant <i>("Consult M.D. immediately")</i>
SBP \geq 260 mmHg	Your BP is very high
DBP \geq 130 mmHg	Your BP is very high
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
	Use Local IHS Referral Form
<u>Immediate Referral</u>	Statement to Participant <i>("Consult M.D. today")</i>
Fasting One Touch glucose > 400	Your blood sugar is very high
SBP 200-259 mmHg	Your BP is very high
DBP 105-129 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

Carbon monoxide reading > 125

Your carbon monoxide level is very high
(Also refer to IHS Environmental Health)

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
(Use Local IHS Referral Form)

Your symptoms may be important

Other acute, but less severe
symptoms

Your symptoms may be important

Inappropriate medication usage

Taking medication incorrectly
may be dangerousNon-diabetic with a fasting
One Touch glucose of ≥ 200

Your blood sugar is high

Chronic cough, fever, weight
loss, and other symptoms suggestive
of active TB or valley fever

You may have serious problem in your lungs

Carbon monoxide 20-124 for non-smokers
50-124 for smokersYour carbon monoxide level is high
(Also refer to IHS Environmental Health)Carotid ultrasound findings indicate
potential plaque/stenosisYou may have serious problem in your
neck vessel(s)**Routine Referral*****("Consult M.D. within one month or
at first convenient appointment")***

SBP 140-199 mmHg

Your BP is elevated into borderline range. Recommend
that participant confirm blood pressure reading within 2
months

DBP 90-104 mmHg

Your BP is elevated into borderline range. Recommend
that participant confirm blood pressure reading within 2
monthsOld MI (Rose Questionnaire),
previously unrecognized

Your chest pain may be important

Routine Referral

(Continued)

("Consult M.D. within one month or
at first convenient appointment")Neurologic problem (stroke, TIA
findings) > 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
or the ratio of doppler pressure of
ankle/arm < 0.8You may have a problem in your feet.
You should check with your doctorUndiagnosed peripheral neuropathy
(Score 6 or less out of 10)

Your symptoms may be important

Referral after Results Are Available

- 1) Critical values: See next page for critical values of various laboratory results.

Laboratory will call field center. Field follow up is considered an urgent referral. SHS staff should notify participants by phone, home visit, or certified letter and should make an appointment for clinical follow-up within one week whenever possible. SHS staff should help arrange transportation if needed. An IHS referral form is filled out.

- 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 should be filled out and SHS staff should assist participant in making an appointment and arranging transportation for follow-up (see letters and interpretation in Appendix A8).
- 3) Carotid Ultrasound -- the Cornell Reading Center will call the field center if > 50% obstruction is noted on the carotid artery. If the obstruction is $\geq 75\%$, the participant should be immediately referred for follow up. If the obstruction is between 50 and 74%, the participant should have a routine 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.

Strong Heart Study Critical Values for Laboratory Results

<i>Test</i>	<i>Critical Value</i>
Fasting Glucose	≤ 40 <i>or</i> ≥ 400 mg/dl
Total Cholesterol	≥ 300 mg/dl
Total Triglyceride	≥ 1000 mg/dl
Plasma Creatinine	≥ 3.0 mg/dl
Na	≤ 125 <i>or</i> ≥ 150 MEQ/dl
K	≤ 3.0 <i>or</i> ≥ 6.5 MEQ/dl
Ca	≤ 8.0 <i>or</i> ≥ 12.0 mg/dl
PO ₄	≥ 6.0 mg/dl
Total Bilirubin	≥ 4.0 mg/dl
ALK	≥ 400 IU/L
BUN	None
Cl	None
CO ₂	None
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

ECG REFERRAL: ECG Findings Requiring Review by M.D. before Participant leaves the clinic

Would like to review with M.D.,

Call should be made to Reading Center by field staff at (212) 746-4655

- * Acute pattern abnormalities (MI, ischemia)
- * Rhythm disturbances
2nd or 3rd degree block, ventricular tachycardia,
any type of ectopic beat > 6/minute, couplets bigeminy, R on T,
multifocal premature ventricular contractions,
atrial fib/flutter with ventricular rate < 60/min or > 110/min,
sinus bradycardia < 40/min, sinus tachycardia > 110/min, PR interval \geq 0.26 sec.
- * Any other ECG findings, alone or in conjunction with symptoms, causing concern

Other ECG Findings to be reviewed the same day: if possible

QT Prolongation (confirm medications)

ECGs where Routine Referral is usually appropriate

New left bundle branch block
New right bundle branch block
Wolff Parkinson White
Left Ventricular Hypertrophy

Examples of Usually Benign ECGs (always obtain old comparison ECG when available)

Left Axis Deviation/Left Anterior Hemi (Fascicular) Block
Atrial Abnormalities, Intra-ventricular Conduction Delay
Unusual P Wave Axis, Wandering Atrial Pacemaker
S₁ S₂ S₃ Pattern, Old Right Bundle Branch Block
Incomplete Right Bundle Branch Block
ST Elevation compared with Early Re-polarization
First Degree AV Block

Copies of each ECG obtained as part of the Strong Heart Study will be forwarded to either the local clinical director or other identified local clinical personnel, if the participant consents to having results sent to the local IHS facility.

1.9 QUALITY CONTROL

1) Anthropometry and blood pressure

Duplicate measures of arm blood pressure (systolic and diastolic), ankle blood pressure, and anthropometry (height, weight, waist/hip ratio, and electrical impedance measurements) should be performed by a second observer on an approximate 5% randomly selected sample of participants. These data must 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 monthly basis. Criteria for unacceptable differences are as follows:

- 1) Systolic Blood Pressure: 4 mmHg by Y-tube stethoscope
- 2) Diastolic Blood Pressure: 4 mmHg by Y-tube stethoscope
- 3) Height: 1 cm
- 4) Weight: 1.0 Kg
- 5) Waist circumference: 1 cm
- 6) Hip circumference: 2 cm
- 7) Resistance: 15 units

Duplicate data for blood pressure, height, and weight 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 and by Doppler should 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 should be made. All results will be analyzed by the Coordinating Center on a quarterly basis. Duplicate blood pressures taken by Doppler will be performed quarterly by the supervisor.

To maintain accuracy, the scale should be zeroed daily and should be calibrated with a known weight (50 lbs.) every month or whenever the scale is moved. The impedance meter should be calibrated daily, follow manufacturer's instructions. This includes checking the battery charge daily before the instrument is used. The standard sphygmomanometer should be 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, and (iv) condition of all tubing and fittings. Record equipment monitoring on a checklist. The Coordinating Center will compile the data and document staff performance.

2) Laboratory tests

Duplicate blood and urine specimens should 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%, 10%, and 20% will be computed. Correlation coefficients and coefficients of variation will be calculated and technical errors estimated. Poor correlation or unreasonably high technical error will be reported to the Laboratory and the Steering Committee.

3) Personal interview

Personal interviews must be observed monthly by the study coordinator. Problems and errors should be identified using a checklist and corrected immediately.

4) Quality control for surveillance data

See Volume I, Chapter 5, section 5.2 for details.

5) Quality control site visits

Quality control site visits will be scheduled every six months. The site visit team which consists of the Program Manager from NHLBI and representatives from every center will visit each center, observe every component of the study, identify inconsistencies, discrepancies, and other problems, and provide advice for improvement.

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 are trained at each clinic. Re-certification occurs every six months to ensure accurate and consistent performance.

7) Confidentiality and safety of data

All personnel with access to data collected for the study are required to sign a confidentiality pledge. Completed data forms are placed in locked file cabinets at every center and only authorized staff members have access to the data.

APPENDIX A

APPENDIX A - 1(a)
Sample of Individual Consent Form --- Family Study

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

Individual's Consent for Participation in a Research Project

I, _____, voluntarily agree to participate in the study
Subject

entitled: **CARDIOVASCULAR DISEASE IN AMERICAN INDIANS** (The Strong Heart Study Phase III), which is sponsored by the National Heart, Lung, and Blood Institute, under the supervision of Dr. Elisa T. Lee.

1. **PURPOSE:** The purpose of this study is to assess how often heart disease, lung disease, and stroke occur in American Indians and what factors are likely to cause heart or blood vessel disease in American Indians.

2. **DESCRIPTION OF STUDY:** You will be given an examination to identify diseases of the heart or blood vessels. 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. Your exam will be completed in one or possibly 2 visits, will take a total of about 3 to 4 hours, and will include the following:

Physical Exam: The physical examination includes the following procedures: weight, height, and girth measurements (measurements of the arm, waist, and hip), blood pressure, impedance measurement of body fat, an electrocardiogram (ECG), a carotid ultrasound study, a breathing test for asthma, a test to find out the carbon monoxide level in your breath, blood samples, and a urine sample. Some of these procedures are explained below.

Blood Sample: A blood sample (about four ounces or 8 tablespoons) will be taken from your arm by a needle to measure the amount of lipids (fat) and other substances in your blood. A small amount of the blood will be frozen and stored at Medlantic Research Laboratories in Washington, DC for future tests including genetic factors that may be related to heart disease, lung disease, diabetes, stroke, and risk factors for those diseases. Some of these tests may be done by other laboratories. Your blood will be stored until it is no longer of scientific value for studying heart disease and its risks factors at which time it will be disposed of according to standard laboratory procedures. Blood cells will not be cultured, cloned or grown, and the blood will not be used for commercial purposes.

Impedance Measurement of Body Fat: The impedance meter involves putting several electrodes (small suction cups or adhesive pads) on your foot and the back of your hand to measure the amount of fat in your body.

Electrocardiogram: The electrocardiogram is to test whether your heart is working normally. Several electrodes will be placed on your chest with an ointment. This will be sent to Cornell University in New York for reading.

Ultrasound: The carotid ultrasound study uses sound waves to examine your neck artery to determine whether your blood vessel is clogged. This will also be sent to Cornell University in New York for reading.

Blood Pressure: Blood pressure and stiffness of blood vessels will be measured over your wrist using an experimental machine and computer program that have not been approved by the Food and Drug Administration. There are no known risks to you from these measurements. The information from this stiffness measurement will not be used in your medical care. This recording will also be read at Cornell University in New York.

Carbon Monoxide: For measuring the carbon monoxide level in your breath, you simply have to exhale into a small hand-held device. Carbon monoxide levels are high in smokers, those who are exposed to smoke, and people who have faulty furnaces.

Breathing Test: You may be given a breathing test that is designed to detect asthma. You may be asked to blow your breath into a machine called a "spirometer" that measures your lung capacity. You may also be loaned a small hand-held spirometer to take home for two (2) weeks so that you can repeat a breathing test at least three (3) times on the first day and then at least twice a day over the 14 day period.

Finger Stick Blood Sugar Test: A drop of blood will be obtained by pricking your finger to measure your fasting blood sugar (blood glucose) level to see if you can be given a glucose tolerance test.

Glucose Tolerance Test: If you can be given a glucose tolerance test, you will be asked to drink a sweet beverage and two hours later a blood sample (about one teaspoon) will be taken by a needle into your arm to measure how well your body can tolerate the sweet drink. You will not be given the glucose tolerance test if you have a fasting glucose of 225 mg/dl or higher by One Touch glucometer (finger stick blood sugar test), or if you have diabetes and are on insulin, or if you are on oral anti-diabetic agents and have had two glucose measurements 250 mg/dl or higher.

You must not have eaten anything for at least 12 hours prior to the physical examination. At the physical examination, if problems are found that require immediate attention, you will be referred to the Indian Health Service for appropriate care. The Strong Heart Study will not be able to pay for follow-up tests or treatment recommended.

Health Interview: In addition to the physical examination, you will be asked to answer some questions about your diet, smoking and drinking habits, quality of life, gambling, breathing problems, sleep problems, use of any medications, heart disease history, and any other medical problems. You are free to refuse to answer any or all of the questions in the health interview without losing your right to health care or any other benefit to which you are entitled; however, we hope you will answer all of the questions.

3. **PAYMENT:** You will be paid \$25.00 for your participation in the study.

4. **BENEFITS:** If we identify a problem requiring medical attention, you will be referred to the Indian Health Service or your private health care provider for appropriate tests and treatment. The Strong Heart Study will help arrange necessary follow up, but will not pay for recommended tests or treatment. You will be advised how to reduce your risk for heart disease and stroke at the end of your exam. You may request that a copy of your results be sent to your personal physician. There are no other direct benefits to you.

5. **POSSIBLE RISKS:** Possible risks/side effects include discomfort and bruising, bleeding, fainting, and infection from blood drawing. Possible discomfort may occur from the impedance meter and electrocardiogram (ECG) measurement, which includes having electrodes (small suction cups or adhesive pads) placed on your chest when partially unclothed and lying still for approximately ten minutes. These

risks/side effects would not be more than those which could occur in a good routine physical examination. The glucose tolerance test may cause feelings of nausea and requires a finger stick blood sugar test and a second blood sample from an arm vein. If you have any side effects, we ask that you report them to us immediately. If side effects are severe, which is unlikely, you may be removed from this study. The results of the tests done by the Strong Heart Study will be filed in your medical record unless you tell us not to place them there. If your test results from the study are included in your medical record and if you apply for insurance, the results may affect the outcome of your insurance application.

6. **WHY GENETIC TESTS ARE BEING DONE:** The study involves testing of genetic material (DNA) in white blood cells to begin the process of identifying genes that may cause (or protect people from) heart disease, lung disease, stroke or their risk factors. You will not be informed of the results of your analysis since, at this early stage of research, this information will not be diagnostic or characteristic of a specific risk for disease.

7. **IN THE EVENT OF INJURY, INFORMATION CONCERNING MEDICAL TREATMENT AND COMPENSATION:** In the unlikely event of injury, established as a result of your participation in the research, appropriate short-term medical treatment will be provided by the Indian Health Service. Neither the Indian Health Service, the Federal Government, nor the University of Oklahoma Health Sciences Center has provisions for financial compensation in the event of such injury, unless you otherwise qualify for health insurance or other employee benefits. If you have questions about the availability of care, you may contact the Lawton Indian Health Service Hospital at (405) 353-0350 or the Anadarko Indian Health Service Clinics at (405) 247-2458.

8. **FOLLOW-UP:** You will be notified as soon as possible if any life-threatening conditions or situations are identified. Your signed consent form will enable the SHS staff to assist you in obtaining appropriate referrals for such conditions. You will be sent your personal results of the exam when they are available. In addition, you will be sent Strong Heart Study newsletters on a periodic basis to inform you of the results of the study. Study investigators or their colleagues may contact you later for further information about your health or to notify you of test results that are important for your health.

9. **CONFIDENTIALITY:** The information obtained will be treated as confidential, and no personal information or name will be made public in any form. However, the results of the examination and any information in your medical records will be used for statistical analysis to further medical knowledge without disclosing your identity. The results may be reported in medical journals, at medical and research meetings and to your Tribe. Also, any medically important information obtained will be included in your medical record unless you tell us not to place it there. You may request and authorize, by signature, the release of any medically important information to other agencies or persons as you feel appropriate.

10. **SUBJECT ASSURANCES:** You understand that your participation in this study is voluntary. You have not given up any of your legal rights or released any individual or institution from liability for negligence.

YOU MAY STOP PARTICIPATING

This study is designed to examine cardiovascular health in both you and your community. You are free to refuse to answer any or all of the questions in the health interview without losing your right to health care or any other benefit to which you are entitled; however, we hope you will answer all.

You may also withdraw or refuse any part of the exam without losing your right to health care or any other benefit to which you are entitled. However, your cooperation in completing as many of the tests as possible is appreciated and important in learning as much as possible about cardiovascular disease in American Indians.

WE MAY STOP YOUR PARTICIPATION

During the course of the study, you may be asked to stop your participation, if the staff feels that continuing is not in your best interest.

If you have any questions or need to report an adverse effect about the research procedures, you may contact the Principal Investigator, Dr. Elisa Lee, or colleagues by calling (405) 271-3090 during a workday.

If you have any questions about your rights as a research subject, you may take them to the Director of Research Administration, University of Oklahoma Health Sciences Center, Room 121, Library Building, telephone number (405) 271-2090 or to 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.

11. **SIGNATURES:** I have read this informed consent document. I understand its contents, and I freely consent to participate in this study under the conditions described in this document. I understand that I will receive a copy of this signed consent form.

Check all that apply:

_____ I request results of tests that may be important to my health be filed in my Indian Health Service record.

_____ I request that results **NOT** be filed in my Indian Health Service record.

_____ I request that results of tests that may be important to my health be sent to:

Date

Signature of Research Subject

Date

Signature of Witness

Date

Signature of the Principal Investigator

APPENDIX A -- 1(b)
Sample of Individual Consent Form --- Cohort

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

Individual's Consent for Participation in a Research Project

I, _____, voluntarily agree to participate in the study

Subject

entitled: **CARDIOVASCULAR DISEASE IN AMERICAN INDIANS** (The Strong Heart Study Phase III), which is sponsored by the National Heart, Lung, and Blood Institute, under the supervision of Dr. Elisa T. Lee.

1. **PURPOSE:** The purpose of this study is to assess how often heart disease, lung disease, and stroke occur in American Indians and what factors are likely to cause heart or blood vessel disease in American Indians. Starting in 1989, over 4500 American Indians over age 45 in Oklahoma, North and South Dakota, and Arizona participated in the first phase of the Strong Heart Study (SHS). Now, as part of the third examination of this special group of American Indians, 900 family members (300 from Oklahoma) of SHS participants, over the age of 18 years, are being invited to participate in a study of genetic factors that may explain why heart disease and strokes seem to occur more often in some families. We invite you to participate in the Family Study of SHS Phase III.

2. **DESCRIPTION OF STUDY:** You will be given an examination to identify diseases of the heart or blood vessels. 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. Your exam will be completed in one or possibly 2 visits, will take a total of about 3 to 4 hours, and will include the following:

Physical Exam: The physical examination includes the following procedures: weight, height, and girth measurements (measurements of the arm, waist, and hip), blood pressure, impedance measurement of body fat, an electrocardiogram (ECG), a carotid ultrasound study, a breathing test for asthma, a test to find out the carbon monoxide level in your breath, blood samples, and a urine sample. Some of these procedures are explained below.

Blood Sample: A blood sample (about four ounces or 8 tablespoons) will be taken from your arm by a needle to measure the amount of lipids (fat) and other substances in your blood and for genetic testing (DNA from white blood cells). A small amount of the blood will be frozen and stored at Medlantic Research Laboratories in Washington, DC for future tests including genetic factors that may be related to heart disease, lung disease, diabetes, stroke, and risk factors for those diseases. Some of these tests may be done by other laboratories. Your blood will be stored until it is no longer of scientific value for studying heart disease and its risks factors at which time it will be disposed of according to standard laboratory procedures. Blood cells will not be cultured, cloned or grown, and the blood will not be used for commercial purposes.

Impedance Measurement of Body Fat: The impedance meter involves putting several electrodes (small suction cups or adhesive pads) on your foot and the back of your hand to measure the amount of fat in your body.

Electrocardiogram: The electrocardiogram is to test whether your heart is working normally. Several electrodes will be placed on your chest with an ointment. This will be sent to Cornell University in New York for reading.

Ultrasound: The carotid ultrasound study uses sound waves to examine your neck artery to determine whether your blood vessel is clogged. This will also be sent to Cornell University in New York for reading.

Blood Pressure: Blood pressure and stiffness of blood vessels will be measured over your wrist using an experimental machine and computer program that have not been approved by the Food and Drug Administration. There are no known risks to you from these measurements. The information from this stiffness measurement will not be used in your medical care. This recording will also be read at Cornell University in New York.

Carbon Monoxide: For measuring the carbon monoxide level in your breath, you simply have to exhale into a small hand-held device. Carbon monoxide levels are high in smokers, those who are exposed to smoke, and people who have faulty furnaces.

Breathing Test: You may be given a breathing test that is designed to detect asthma. You may be asked to blow your breath into a machine called a "spirometer" that measures your lung capacity. You may also be loaned a small hand-held spirometer to take home for two (2) weeks so that you can repeat a breathing test at least three (3) times on the first day and then at least twice a day over the 14 day period.

Finger Stick Blood Sugar Test: A drop of blood will be obtained by pricking your finger to measure your fasting blood sugar (blood glucose) level to see if you can be given a glucose tolerance test.

Glucose Tolerance Test: If you can be given a glucose tolerance test, you will be asked to drink a sweet beverage and two hours later a blood sample (about one teaspoon) will be taken by a needle into your arm to measure how well your body can tolerate the sweet drink. You will not be given the glucose tolerance test if you have a fasting glucose of 225 mg/dl or higher by One Touch glucometer (finger stick blood sugar test), or if you have diabetes and are on insulin, or if you are on oral anti-diabetic agents and have had two glucose measurements 250 mg/dl or higher.

You must not have eaten anything for at least 12 hours prior to the physical examination. At the physical examination, if problems are found that require immediate attention, you will be referred to the Indian Health Service for appropriate care. The Strong Heart Study will not be able to pay for follow-up tests or treatment recommended.

Health Interview: In addition to the physical examination, you will be asked to answer some questions about family health, family relationships, diet, smoking and drinking habits, quality of life, gambling, exercise activity, breathing problems, sleep problems, use of any medications, heart disease history, and any other medical problems. You are free to refuse to answer any or all of the questions in the health interview without losing your right to health care or any other benefit to which you are entitled; however, we hope you will answer all of the questions.

3. **PAYMENT:** You will be paid \$25.00 for your participation in the study.

4. **BENEFITS:** If we identify a problem requiring medical attention, you will be referred to the Indian Health Service or your private health care provider for appropriate tests and treatment. The Strong Heart Study will help arrange necessary follow up, but will not pay for recommended tests or treatment. You will be advised how to reduce your risk for heart disease and stroke at the end of your exam. You may request that a copy of your results be sent to your personal physician. There are no other direct benefits to you.

5. **POSSIBLE RISKS:** Possible risks/side effects include discomfort and bruising, bleeding, fainting, and infection from blood drawing. Possible discomfort may occur from the impedance meter and electrocardiogram (ECG) measurement, which includes having electrodes (small suction cups or adhesive pads) placed on your chest when partially unclothed and lying still for approximately ten minutes. These risks/side effects would not be more than those which could occur in a good routine physical examination. The glucose tolerance test may cause feelings of nausea and requires a finger stick blood sugar test and a second blood sample from an arm vein. If you have any side effects, we ask that you report them to us immediately. If side effects are severe, which is unlikely, you may be removed from this study. The results of the tests done by the Strong Heart Study will be filed in your medical record unless you tell us not to place them there. If your test results from the study are included in your medical record and if you apply for insurance, the results may affect the outcome of your insurance application.

6. **WHY GENETIC TESTS ARE BEING DONE:** The study involves testing of genetic material (DNA) in white blood cells to begin the process of identifying genes that may cause (or protect people from) heart disease, lung disease, stroke or their risk factors. You will not be informed of the results of your analysis since, at this early stage of research, this information will not be diagnostic or characteristic of a specific risk for disease. The DNA testing for this Family Study will be conducted at the Southwest Foundation for Biomedical Research, San Antonio, Texas under the supervision of Dr. Jean MacCluer.

7. **IN THE EVENT OF INJURY, INFORMATION CONCERNING MEDICAL TREATMENT AND COMPENSATION:** In the unlikely event of injury, established as a result of your participation in the research, appropriate short-term medical treatment will be provided by the Indian Health Service. Neither the Indian Health Service, the Federal Government, nor the University of Oklahoma Health Sciences Center has provisions for financial compensation in the event of such injury, unless you otherwise qualify for health insurance or other employee benefits. If you have questions about the availability of care, you may contact the Lawton Indian Health Service Hospital at (405) 353-0350 or the Anadarko Indian Health Service Clinics at (405) 247-2458.

8. **FOLLOW-UP:** You will be notified as soon as possible if any life-threatening conditions or situations are identified. Your signed consent form will enable the SHS staff to assist you in obtaining appropriate referrals for such conditions. You will be sent your personal results of the exam when they are available. In addition, you will be sent Strong Heart Study newsletters on a periodic basis to inform you of the results of the study. Study investigators or their colleagues may contact you later for further information about your health or to notify you of test results that are important for your health.

9. **CONFIDENTIALITY:** The information obtained will be treated as confidential, and no personal information or name will be made public in any form. However, the results of the examination and any information in your medical records will be used for statistical analysis to further medical knowledge without disclosing your identity. The results may be reported in medical journals, at medical and research meetings and to your Tribe. Also, any medically important information obtained will be included in your medical record unless you tell us not to place it there. You may request and authorize, by signature, the release of any medically important information to other agencies or persons as you feel appropriate.

10. **SUBJECT ASSURANCES:** You understand that your participation in this study is voluntary. You have not given up any of your legal rights or released any individual or institution from liability for negligence.

YOU MAY STOP PARTICIPATING

This study is designed to examine cardiovascular health in both you and your community. You are free to refuse to answer any or all of the questions in the health interview without losing your right to health care or any other benefit to which you are entitled; however, we hope you will answer all.

You may also withdraw or refuse any part of the exam without losing your right to health care or any other benefit to which you are entitled. However, your cooperation in completing as many of the tests as possible is appreciated and important in learning as much as possible about cardiovascular disease in American Indians.

WE MAY STOP YOUR PARTICIPATION

During the course of the study, you may be asked to stop your participation, if the staff feels that continuing is not in your best interest.

If you have any questions or need to report an adverse effect about the research procedures, you may contact the Principal Investigator, Dr. Elisa Lee, or colleagues by calling (405) 271-3090 during a workday.

If you have any questions about your rights as a research subject, you may take them to the Director of Research Administration, University of Oklahoma Health Sciences Center, Room 121, Library Building, telephone number (405) 271-2090 or to 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.

11. **SIGNATURES:** I have read this informed consent document. I understand its contents, and I freely consent to participate in this study under the conditions described in this document. I understand that I will receive a copy of this signed consent form.

Check all that apply:

_____ I request results of tests that may be important to my health be filed in my Indian Health Service record.

_____ I request that results **NOT** be filed in my Indian Health Service record.

_____ I request that results of tests that may be important to my health be sent to:

Date

Signature of Research Subject

Date

Signature of Witness

Date

Signature of the Principal Investigator

Appendix A -- 2(a)
THE STRONG HEART STUDY III
Clinical Examination -- Checklist

Participant's name: _____
Last
First
Middle

ID Number: _____ Date: _____
mo
day
yr

	Items	If done, date and initial	
1.	Consent Form Signed	_____	_____
2.	Medical Release Signed	_____	_____
3.	One Touch blood test, Reading	_____	_____
4.	ProAct/Reflotron (if done), Reading	_____	_____
5.	Fasting blood sample	_____	_____
6.	Glutol	_____	_____
7.	Urine sample	_____	_____
8.	Two-hour blood sample	_____	_____
9.	Personal interview forms	_____	_____
10.	Gambling	_____	_____
11.	Medication	_____	_____
12.	Medical history form	_____	_____
13.	ECG	_____	_____
14.	Impedance measurement	_____	_____
15.	Height and Weight	_____	_____
16.	Abdominal, hip and arm circumference	_____	_____

17.	Sitting blood pressure	_____	_____
18.	Doppler blood pressure	_____	_____
19.	Neuropathy tests	_____	_____
20.	Carbon monoxide	_____	_____
21.	Carotid Ultrasound	_____	_____
22.	Dietary survey	_____	_____
23.	Quality of life questionnaire	_____	_____
24.	Sleep Habit (family members)	_____	_____
25.	Physical Activity (family members)	_____	_____
26.	Payment or payment form		

Appendix A -- 2(b)
STRONG HEART STUDY III
Post Exam Activities

Same Day:

- Process blood specimens
- Review morbidity (chart review at clinic site)
- Stamp patient's clinic chart with SHS exam information
- Add codes: community, tribe, clinic/hospital, medicines
- Edit for missing data
- Transmit ECG's to New York
- Make all but routine referrals
- Complete ultrasound measurements

Later:

- Send carotid ultrasound tapes to reading centers
- Make routine referrals
- File confirmed ECG and ultrasound reports
- Mail letters to patients
- File laboratory findings in patients medical records
- Mail laboratory specimens

Appendix A -- 3
Checklist for Quarterly Observation of BP Technicians

Checklist for Quarterly Observation of BP Technicians and New Employees by BP Supervisor (To be sent quarterly to the Coordinating Center)

BP Technician Code # _____ Observer Code # _____

Date Observed / / (Month/Day/Year)

Instructions: For each item, check "yes" or "no" in the space provided to indicate if the procedure is carried out correctly. Record any comments in the blank line between that item and the next. For certain items specific parts of the procedure which are important are listed separately.

Measures arm for correct cuff size	() Yes	() No
Palpates brachial artery	() Yes	() No
Marks pulse point	() Yes	() No
Wraps cuff center of bladder over brachial pulse	() Yes	() No
Instructs on Posture	() Yes	() No
Full five minutes for rest allowed	() Yes	() No
Work station free of excessive noise	() Yes	() No
Finds Pulse obliteration point using standard manometer	() Yes	() No
Calculates peak inflation, standard manometer	() Yes	() No
Places stethoscope in ears	() Yes	() No
Inflates rapidly to peak	() Yes	() No
Counts full 5 seconds with pressure steady	() Yes	() No
Places bell on brachial pulse	() Yes	() No
Deflates cuff 2 mmHg per second	() Yes	() No
Deflates cuff after 2 absent sounds	() Yes	() No
Records readings	() Yes	() No
Disconnects tubes	() Yes	() No
Instructs to hold arm vertical for full 5 seconds	() Yes	() No
Waits at least 30 seconds before proceeding	() Yes	() No
Informs participant of average readings of 2nd and 3rd blood pressure	() Yes	() No

Special Comments: _____

Appendix A -- 4

Recording Simultaneous Blood Pressure Observations On A Volunteer by Two Technicians

Form for Recording Simultaneous Blood Pressure Observations On A Volunteer by Two Technicians

Instructions: Approximately every 4 months, each technician should be part of a pair of technicians who simultaneously measure blood pressure using a Y-tube on a volunteer (not a Strong Heart participant). Each technician should separately record his/her measurements on a standard paper Strong Heart SBP form. The blood pressure supervisor should then transfer the results to this form and calculate the differences between the two sets of measurements. If the difference on any individual measurement is greater than 4 mmHg, or if the averages of the three readings for each technician differ by more than 3 mmHg, the supervisor should indicate the corrective action taken on this form. Any further sets of simultaneous measurements for a given pair should appear on a new form. A copy of each form should be sent to the Coordinating Center.

Technician IDs:	1st ID: _____ 1st Technician	2nd ID: _____ 2nd Technician	Date: _____ Difference
a. Initial Arm Circum-			
1. ference (cm)	_____	_____	_____
b. Initial Cuff Size			
Selected	_____	_____	_____
c. Pulse Obliteration			
Pressure	_____	_____	_____
d. First SBP	_____	_____	_____
e. First DBP	_____	_____	_____
f. Second SBP	_____	_____	_____
g. Second DBP	_____	_____	_____
h. Third SBP	_____	_____	_____
i. Third DBP	_____	_____	_____
j. Average SBP	_____	_____	_____
k. Average DBP	_____	_____	_____

Action taken if differences between technicians exceed limits specified:

Appendix A -- 5
Monthly Log for Sitting Blood Pressure Station

Field Center: Arizona _____ Lawton _____ Anadarko _____
Pine Ridge _____ Eagle Butte _____ Ft. Totten _____
Month _____ Year _____

Monthly Check Procedures:

		Month				
		1	2	3	4	5
1.	Sphygmomanometer:	=====				
	Date of Check	_____	_____	_____	_____	_____
A.	Check Tube for Oxide Dust	_____	_____	_____	_____	_____
B.	Check Cap for Tightness	_____	_____	_____	_____	_____
C.	Check that mercury is at zero with no pressure	_____	_____	_____	_____	_____

List any problems found and corrective action taken:

Procedures performed only if there appear to be problems:

- D. If mercury bounces even though the cap appears tight, remove cap, clean of any mercury beads, and check opening at top of tube for dust

Check Needed and Performed during weeks 1 2 3 4 5
(Circle number of weeks applicable)

- E. If tube appears "dirty" (oxidized mercury) remove cap, tip manometer to retract mercury, run pipe cleaner down, replace cap

Needed and Performed during weeks 1 2 3 4 5

- F. For any other problems contact control center for instructions before proceeding. List the problem encountered, the date, and the actions taken below:

/

2. Measuring tape for arm circumference worn or stretched. Check by holding the zero mark of the tape against the ruler used to measure standing height at the 150 cm mark. If the 30 cm mark on the tape used for arm circumference falls outside the range 119.5 to 120.5 on the standing height ruler, the tape should be replaced.

Month: 1 2 3 4 5

=====

Date of check: _____ _____ _____ _____ _____

Point on height ruler where 30 cm on tape falls

_____ _____ _____ _____ _____

Appendix A -- 6

Maintenance Procedures for Standard Sphygmomanometer

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:
3. The system should be re-inflated until the column rises to 200 mmHg. The tubing should be pinched at various locations to localize the area of the leak. Appropriate replacement of the tubing, cuff, or valve should be performed.
4. 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.
5. 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.

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.

THE STRONG HEART STUDY III
Sample Letter to Participant after Physical Examination

Dear _____:

Thank you very much for taking part in the Strong Heart Study on _____ (date). The final results of your blood tests and other measurements are now available and this letter summarizes the important findings from your visit:

Blood Pressure

Your blood pressure was _____ (less than 140/90 and not taking medication for BP). 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, taking BP medication). This is within the normal range. Continue taking your blood pressure medication as directed by your medical care provider.

Glucose Tolerance (Test for Diabetes)

Your fasting blood sugar was _____ (less than 140) and your 2 hour blood sugar was _____ (less than 140). This is within the desirable range.

Your fasting blood sugar was _____ (less than 140) and your 2 hour blood sugar was _____ (less than 200). These values are slightly high and raise the possibility that you may develop diabetes in the next several years. Weight reduction and exercise may help to prevent you from developing diabetes, so be sure to get advice from a health care provider on what might be helpful to you.

Your fasting blood sugar was _____ (greater than 140) and your 2 hour blood sugar was _____ (greater than 200). These values are above the normal range and suggest that you may have diabetes. Please see your health care provider for advice on appropriate follow-up if you have not already done so.

Your fasting blood sugar was _____ (known diabetic less than 200). On the day of the exam, your fasting blood sugar was under good 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 240). Your fasting blood sugar was higher than the usual target for diabetic patients. See your medical care provider for advice on how to attain better control.

Measurements of Blood Fats (Cholesterol and Triglycerides)

Your blood cholesterol was _____ (less than 200). This is within the desirable range, and we encourage you to maintain a healthy diet so that your cholesterol stays low.

Your blood cholesterol was _____ (200 to 240). This is slightly above the desirable range. We advise you to reduce the fat in your diet and have your cholesterol checked again in 6-months.

Your blood cholesterol was _____ (greater than 240). Your total cholesterol is high and this may cause heart problems. We advise you to reduce the fat in your diet and have your cholesterol checked again in 3 months.

Your blood triglycerides were _____ (less than 200). This is within the desirable range.

Your blood triglycerides were _____ (200-400). This is above the desirable range. We advise you to reduce your amount of calories and alcohol (if you are drinking) and have your triglycerides checked again in three months.

Your blood triglycerides were _____ (>400) This is a high value. You should see your health care provider for follow-up.

Electrocardiogram

We have sent a copy of your ECG (heart tracings) to your physician and he/she will notify you if there are any problems.

Carotid Ultrasound

The sound study done in the artery on your neck showed that fat deposits were present. A change in diet or medication may prevent this from getting worse

The sound study done in the artery on your neck was normal.

Body Fat

During the examination we measured the fat content in your body. The enclosed print out describes the results of this measurement, explains the normal values for your age and gender and suggests exercise programs and calorie recommendations.

Carbon Monoxide in Your Breath

You had _____ parts per million (ppm) of carbon monoxide in your breath. This results indicates:

- 1) You were not exposed to carbon monoxide in the day prior to test (0-8 ppm).

- 2) You may have been exposed to tobacco smoke in the last day (9-14 ppm)
- 3) For smokers -- smoking may have caused you to have a high carbon monoxide level (15-50 ppm).
- 4) For non-smokers > 20 ppm, smoker > 50 ppm -- you may have been exposed to carbon monoxide from a faulty heater or car exhaust. You should have your carbon monoxide level retested and if it is still high, you should request assistance from your local environmental health office to determine if you have a faulty heater or car exhaust.

The results of your tests will be sent to the IHS Hospital or Clinic as part of your hospital record. This will help the doctors take care of you if you get sick and go to the hospital or clinic. If your doctor does not work at the IHS Hospital or Clinic please let us know so we can send your test results to him or her.

We thank you again for participating in the Strong Heart Study. If you have any questions please call Dr. _____ at the _____ Hospital or Clinic or the medical care provider of your choice. You can also reach me at _____.

Sincerely,

SHS

1

Appendix A -- 8

Interpretation of Examination Results and Suggestions

Blood Pressure: If your blood pressure was above 140/90, you should go to clinic to see your health care provider for advice on how to lower it.

Percent Body Fat: If your percent body fat is above the desirable range, you should lose weight. The desirable range is shown on the results.

Body Mass Index is also a measure of obesity. If you are more than 120% of body mass index, you should lose weight.

Physical Exam: The findings listed are those found by the exam done by the nurse practitioner. They will be available in your IHS medical record in case you need further evaluation.

Cigarette use: If you smoke, it is advised that you cut down or preferably quit. Smoking causes heart problems and cancer and you can improve your health by quitting.

Lipids: These are the fats measured in your blood.

Total cholesterol measures both good and bad cholesterol.

Triglycerides are another kind of fat in the blood. Sometimes they are high in diabetic patients who have high blood sugars. If your triglycerides are high, eat less food and drink less alcohol (if you drink) and have your triglycerides checked in 3 months.

HDL cholesterol is the good cholesterol. The higher your HDL cholesterol, the less chance of heart disease.

LDL cholesterol is the bad cholesterol which may cause heart disease if it is high: 130-159 is moderately high, over 160 is very high. Persons who have had a heart attack should lower the LDL cholesterol to 100 or below.

All persons with high LDL should go on a low fat, low cholesterol diet and have a follow-up check-up in several months.

Creatinine measures kidney function. If it is high, you should go to clinic to see a health care provider.

Glucose is blood sugar. Patients with diabetes have high blood sugars.

Fasting glucose 140 or higher = Diabetes

Fasting glucose less than 140 = Normal

Two hour post 75gm glucose load

Some persons were given sugar water to see if they have diabetes. The reading two hours after drinking the sugar means:

Blood glucose 200 or higher	= Diabetes
Blood glucose 140-199	= Impaired glucose tolerance
Blood glucose less than 140	= Normal

People with impaired glucose tolerance are more likely to get diabetes than people with normal levels. Healthy diet, losing weight if you are overweight, and exercise are important ways to prevent or control diabetes.

Urinary albumin-creatinine ratio measures kidney function. If above 30, it indicates there may be some kidney damage.

Glycated hemoglobin reflects the blood sugar over the past 6 weeks.

The levels of glycated hemoglobin are interpreted in diabetic patients as follows:

- Poor control - 9.6% and above
- Fair control - 7.6% - 9.5%
- Good control - 6.0% - 7.5%
- Normal Value - 5.9% and below

**THE STRONG HEART STUDY III
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 immunodeficiency 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 a 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 procedure(s).

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:

Tierno, 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 III
PHYSICIAN REFERRAL FORM FOR DIAGNOSIS OF CONGESTIVE HEART FAILURE

ID Number: _____

While Mr./Ms. _____ 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. Record all that are present when you evaluate the patient.

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 \geq 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 $\geq 120/\text{min}$) _____

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./Ms. _____ 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 QUESTIONNAIRES AND DATA FORMS

Appendix B -- 1
Strong Heart Study III
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 community code from list.

Write in social security number.

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.
- 2 Write down the name of IHS and the non-IHS hospital which subject usually goes. Write in facility with which number is associated.
- 3 Write down the participant's marital status.
- 4 Write down the name of participant's spouse.
- 5 Ask whether her/his spouse also participated in the Strong Heart Study.
- 6a 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.
AZ= Arizona SD= South Dakota
OK= Oklahoma ND= North Dakota

- 7 If residential address is different from the mailing address, write in the residential address following the rules given in item 7a-d.
- 8 Enter complete telephone number of home phone or phone at which subject can be reached during the evenings.
- 9 Enter complete telephone number of work phone or phone at which subject can be reached during the day.
- 10 Ask the participant where does she/he want the Strong Heart Study results sent.

Note: All Personal Interview Forms I should be sent to the Coordinating Center separately for confidentiality.

Personal Interview Form II

A. WEIGHT CONTROL: questions about efforts to lose weight

- 10 Ask whether the participant is satisfied with his/her current weight?
- 11-12 Ask participant whether she/he want to gain or lose weight, and how is he/she doing it.

B. PHYSICAL ACTIVITY

- 13-14 Ask if the participant had any difficulty getting in or out of a bed or chair in Q13. Then, ask if he/she had been confined to bed or chair since last SHS examination because of injury or illness. If the answer is YES, fill in the number of **weeks** confined to bed or chair in Q14a.
- 15 Ask what condition(s) limit the participant's activities and record them.
- 16 Ask participant how often during a typical week that he/she involved in activities required *mild effort* such as walking, gardening, yardwork, fishing, softball, etc..
- 17 Ask participant how often during a typical week that he/she involved in activities required *relative strenuous effort* such as digging, chopping wood, heavy construction, hauling hay, fixing fence, running and other strenuous sports, etc..

C. DENTURE AND EATING PROBLEMS

- 18 Ask participant how many natural teeth he/she still have.
- 19 Ask participant to describe how he/she eat.
- 20 Ask participant to rate his/her ability to chew food.

D FAMILY INCOME

Questions 21-26 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.

- 21 Ask participant whether his/her household income meets his/her family's needs?
- 22 Ask what is the participant's main daily activity(s). Check up to three main activities.
- 23 Ask participant where is his/her source of income. Check all applicable answers.
- 24 Ask participant which source provides the most income from the answers provided in Q23,
- 25 Ask participant, on the average, how many hours per week he/she works for paid job(s).
- 26 Ask participant what is his/her annual household income.
- B. TOBACCO These questions are very important to assess accurately because smoking is a major risk factor for cardiovascular disease.
- 27 This will determine how common ceremonial uses of tobacco is. Ceremonial tobacco use is probably not associated with adverse health effects.
- 27 Determine whether participant currently smokes cigarettes.
- 28 Determine average cigarettes smoked per day, which may have a significant effect on heart diseases and other health problems.
- 29 Ask the participant on the occasions which he/she is most likely to smoke or increase smoking.
- 30 Ask the participant on the occasion he/she increase smoking, how many cigarettes does/did he/she smoke per day.
- 31 Ask the participant whether he/she want to change smoking habit and how.
- 32 Determine when non-smoking participants quit smoking or if they are "never smokers" (smoked less than 100 cigarettes per day)
- 33 Ask the participant whether he/she quit smoking since last SHS exam. If the answer is "YES", ask when and why.
- 34 This question tries to find second-hand smoking. Ask participant, regardless of his/her smoking status, on the average, how many hours does he/she exposed to the smoke of others.

- F. 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.
- 35 Question 35 determines when the individual last had any alcoholic beverage. If the last drink has less than 30 days fill in the box labeled number of days. If the last drink was within the last year, but more than 30 days 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 Q42.
- 36 Question 36 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. Record the type and frequency of drinks in the table.
- 37 Question 37 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.
- 38 Question 38 assess the quantity of average alcohol consumed in a day when participant drinks.
- 39 Ask the participant when he/she drinks more than the usual consumption, how much and how often.
- 40-41 Question 40-41 assess the frequency of binge drink in the past month and the past year, respectively.
- 42 Ask whether the participant use any of the substance for alcohol.
- 43 Question 43 assesses the reliability of the answers responded by the subject. Write down your personnel code number and the date of completion of interview.

Appendix B --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
Ft. McDowell Mohave-Apache Indian Community, Ft McDowell Band of 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
Tlali 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 B -- 3
The Strong Heart Study Phase III
Rationale and Instructions for Assessment of Physical Activity

Physical activity is a very complex behavior that has been measured in a variety of ways (LaPorte, 1985). This complexity can partially be explained by the fact that there are several health-related components of physical activity such as overall caloric expenditure, aerobic intensity, weight bearing activity, flexibility, and strength (Caspersen, 1989). When examining the relation between activity and a disease or condition, it is important to focus on the component(s) of physical activity that is most likely to be associated with the outcome of interest. For this present effort, we are interested in assessing both the total amount of time an individual usually spends participating in physical activities (hours) as well as an estimate of the relative intensity of each activity (in which time spent in each activity is weighted by an estimate of its relative intensity (MET) before summing, resulting in MET-hours). The two components of activity that we will be able to estimate with this information is energy expenditure and aerobic intensity.

The physical activity survey is typically the method of choice for population studies. Reasons for its popularity include its non-reactiveness (lack of alteration of the individual's behavior as a direct result of the assessment technique), practicality (generally determined by cost and participant convenience), applicability (ability to modify the instrument to suit the population in question), and its acceptable accuracy (both reliability and validity) relative to other methods (LaPorte 1985, Montoye, 1984). More objective measurements of energy expenditure, such as the activity monitor, the graded exercise test, or the doubly-labeled water technique, are not practical in most epidemiological studies, but have been used to validate the physical activity questionnaire (LaPorte, 1985, Montoye, 1984).

The survey approaches used to measure physical activity vary from activity diaries to self-administered or interviewer-administered activity questionnaires. The time frame and complexity of the activity questionnaire can range from a single question about usual activity to a recall survey with a time frame of one week, one year, or even over a lifetime (LaPorte, 1985, Montoye, 1984). The advantage of assessing activity using a survey with a short time frame is that the estimate is less likely to suffer from recall bias and is easier to validate. In contrast, assessment over a short time period is less likely to reflect "usual" behavior, as activity levels may vary with season, as a result of an acute health condition, or due to sudden time pressures. Thus, there are good reasons to include activity questionnaires with both a short and long time period of activity assessment in order to obtain the best overall estimate of an individual's activity levels. The questionnaires recommended here include:

1) a modified version of the Pima Indian Questionnaire (or the Modifiable Activity Questionnaire; MAQ) which assesses past year activity as an estimate of "usual activity levels" (Kriska, 1992, 1990) and;

2) a modified version of the Physical Activity Recall (Sallis, 1985) known as the Low Level Physical Activity Recall (LO-PAR; Regensteiner, In Press) which is a seven day activity recall instrument.

Physical activities assessed by questionnaire are usually limited to those activities that require an energy expenditure above that of daily living. The assumption is that the activities of daily living such as bathing, grooming or feeding are similar among most individuals within the population and that accurate

measurement of such typical activities shared by all participants is not feasible or necessary. Likewise, two important components of total energy expenditure, basal metabolic rate, and the thermic effect of food (Ravussin, 1992) are obviously not taken into consideration when assessing activity levels by this method. Therefore, it is clear that the physical activity estimates obtained by activity questionnaire do not reflect **total** energy expenditure for a particular individual. Determination of total energy expenditure can only be obtained by more exact measures of energy expenditure such as the respiratory chamber or the doubly-labeled water technique (Ravussin, 1992). However, the estimates obtained by the activity questionnaire are valuable in relative terms, and can be used to rank individuals or groups of subjects within a population from the least to the most active. The end result is a relative distribution of individuals based upon their reported levels of physical activity that can then be examined in relation to physiological parameters (such as post-load glucose or insulin values) and disease outcome (such as the development of occurrence of NIDDM).

Leisure Versus Occupational Physical Activity Assessment: Although earlier physical activity studies emphasized occupational activity (Morris, 1953; Paffenbarger, 1975) more recent surveys have shifted their focus towards leisure physical activity, due to the decline in the physical activity levels of most occupations in industrialized, developed countries (Powell, 1987). However, occupational activity probably remains of greater importance in areas in which a larger proportion of individuals in the population engage in occupations that are physically demanding. Therefore, occupational activity assessment should be included along with leisure activity as part of the questionnaire design unless the homogeneity of energy expenditure related to occupational activity within the study population is known or can be assumed. Both the PAR and the MAQ include the assessment of occupational activity.

The Modifiable Activity Questionnaire (MAQ): The MAQ (originally the Pima Indian Questionnaire) was designed for easy modification to maximize feasibility and appropriateness of physical activity assessment in a variety of minority populations and age groups (Kriska, 1992). One important feature of this questionnaire is its comprehensiveness in that it assesses current (past year and, if desired, past week) occupational and leisure activities, as well as extreme levels of inactivity due to disability. Another feature is the ability of the questionnaire to weight activities by estimates of their relative intensity. An estimate of the individual's physical activity level is determined over the past year and expressed as hours per week, or alternatively can be weighted by a crude estimate of the metabolic cost of each activity (known in the exercise physiology literature as METs) and expressed as MET-hours per week. A MET is the ratio of the working metabolic rate of an activity divided by the resting metabolic rate. One MET represents the energy expenditure for an individual at rest, whereas a 10 MET activity requires 10 times the resting energy expenditure.

The original version of this activity questionnaire (Kriska, 1990) also assessed historical (over a lifetime) physical activity, which has been used previously for retrospective studies of diabetes and osteoporosis (Kriska, 1988, 1993). The current version of the questionnaire does not include assessment of historical activity (Kriska, 1992), is available in a computer software package (currently in NIH format), and takes about 10 minutes to complete.

The MAQ has been shown to be both reliable and valid (through comparisons with activity monitors, fitness (field) testing, and the doubly-labeled water technique) in adults and adolescents alike (Kriska, 1990; Schultz, 1994; Aaron, 1993). Test-retest reliability of the instrument was shown to be quite good with Spearman rank-order correlations ranging from 0.62 to 0.96 for individuals aged 10-60 yrs (Kriska, 1990). In addition, the past week section of the questionnaire was found to be related to the

Caltrac activity monitor ($\rho=0.62$; $p<0.05$) to the same degree as that found in other similar studies comparing the two measures (Kriska, 1990). Finally, the cross-sectional relationship between reported physical activity levels as determined by this questionnaire and blood glucose, insulin, and obesity have been demonstrated in the Pima Indians as well as other populations (Pereira, 1995; Kriska, 1993; Kriska, Presented Abstract, 1994).

The versatility of the questionnaire is best demonstrated by the fact that modified versions of this questionnaire are being successfully used to estimate physical activity levels in a variety of populations:

- Pima Indian adults (Kriska, 1993, 1992, 1990);
- Pima children (Fontvieille, Kriska, and Ravussin; 1993);
- white and black adolescents (Aaron, Kriska, et al., 1993, 1995);
- populations in the South Pacific and Indian Oceans (Diabetes in the South Pacific: Environmental /Genetic Determinants; P. Zimmet, P.I.; A. Kriska, Co-Investigator);
- Nigerian civil servant workers (Epidemic Hypertension in Nigerian Workers. C. Bunker, P.I.; A. Kriska, Co-Investigator);
- Native Americans from across the country (Cardiovascular Disease in American Indians. B. Howard, E. Lee, and T. Welty, P.I.s);
- Virgin Islanders (E. Tull, P.I.; A. Kriska, Consultant);
- Canadian Indians (B. Zinman and S. Harris, P.I.s; A. Kriska, Collaborator);
- Cherokee Indians (E. Lee, P.I., A. Kriska, Collaborator);
- Natives Indians from Mexico (L. Schultz, PI).

MAQ-Leisure Activity Section: The leisure activity section of the MAQ (Kriska, 1992, 1990) has a format somewhat similar to that used in previously developed activity questionnaires such as the Minnesota Leisure-Time Activity Questionnaire and the Harvard Alumni Survey (Taylor, 1978; Paffenbarger, 1978). Through pilot testing, a list of leisure activities that forms the basis of the leisure activity section of the questionnaire will be developed. It is important that this activity list is both comprehensive and specific to the population(s) in question.

INSTRUCTIONS: The interviewer first reads through the list of activities provided. The participant is instructed to identify all leisure activities from this list in which he/she had participated on at least 10 different occasions over the past year (as the interviewer circles all positive responses). After the list has been read and all of the positive responses have been circled, the interviewer writes down each activity that was circled in the "ACTIVITY" column provided. Estimates of frequency and duration are then obtained for each of these activities. Specifically, for each activity, the months that the activity was performed over the past year (past 12 months) is checked, and then the "AVERAGE # OF TIMES PER MONTH and the AVERAGE # OF MINUTES EACH TIME" is entered in the appropriate columns. Only those activities carried out for a minimum of 10 minutes duration are recorded.

MAQ-Inactivity Section: This activity questionnaire also assesses physical activity at the lower end of the activity curve, i.e., extreme inactivity, since it is possible that the effect of physical activity on glucose intolerance may only be observed at this level in some populations. In addition, the best way to compare subjectively determined physical activity levels between populations may be to examine the percent inactive (or completely sedentary) for each population. The specific questions used to investigate inactivity are provided in the general section of the MAQ (Kriska, 1992, 1990). As an example, the average number of HOURS per DAY usually spent watching television may be a potentially useful index of inactivity (Fontvieille, 1993). Finally, it may be necessary to identify those

individuals who reported that they had been confined to a bed or chair for more than one week over the past year as a result of an illness or injury in order to separate them from the individuals who were physically able to be physically active but chose to be sedentary.

MAQ-Occupational Activity Section: The occupational section of the MAQ is used to determine, for each job held over the past year, the number of hours that the individual participated in physically demanding activities during an average work day (Kriska, 1992, 1990).

The individual is first asked to identify ALL jobs held during the past year for greater than one month (including "occupations" such as homemaker, or being disabled, retired or unemployed). The interviewer will write all of these jobs in the "JOB NAME" column and enter the number of months that the participant had this job(s) over the past year in the "MOS/YR" column. All 12 months of the past year should be accounted for. [Note that "occupations" such as homemaker, retired, unemployed, or being disabled, are only listed during months when no other job is identified.]

Next to each job name, the interviewer enters the "JOB CODE" that best describes the job. Then, for each job entry, the participant answers questions about transportation to and from the job as well as the average job schedule. If the usual form of transportation to and/or from work was either biking (pedal) or walking, the TOTAL amount of time in minutes spent walking or biking to work each day is entered in the "MIN/DAY" column. The participant is asked about the average schedule for that job including the average number of "DAYS/WEEK" and "HOURS/DAY" that he/she works at that specific job.

Finally, the individual is asked to specify the usual number of hours per day at work spent sitting (out of the total number of "HOURS/DAY" the individual reported working). The interviewer enters this number in the "HOURS SITTING" column and then asks the participant to describe the job activities that he/she does when not sitting. The interviewer places a check in the most appropriate activity column based upon the job description given by the participant. The "A" category includes job activities involving sitting, standing still, or slow walking; category "B" includes job activities that require an effort similar to that of continuous walking, while the "C" category includes all those activities with energy demands approaching that of heavy lifting, digging or running. The lists of activities in each column should be modified to include typical job activities for the population in question.

**** Please note:** If the individual reported being a homemaker, retired, unemployed, or being disabled, during all or part of the past year probe for job activities of a normal 8 hour day, 5 day week. In other words, "DAY/WEEK" is automatically "5" and "HOURS/DAY" is "8". Also, since it makes no sense to ask them if they walk or bike to "work", enter a "0" for this question.

MAQ-Questionnaire Calculations: Calculations for obtaining a summary estimate of both leisure and occupational physical activity from the questionnaire are provided below. During the past year, an estimate of the individual's physical-activity level is determined and expressed as either hours per week or MET-hours per week.

Past Year Leisure Activity Calculations

Past Year hours/week = (# of mos checked) x (times/mos) x (minutes/time) ÷ 52 ÷ 60.

The hours/week of all activities are summed to determine the total hours/week over the past year. (Results can also be expressed in $\text{kcal} \cdot \text{kg}^{-1} \cdot \text{wk}^{-1}$ by multiplying hours/week spent in each activity by the estimated MET value as was discussed above.)

Note: Because reported time spent walking for exercise has been found to be unreliable in many populations, it is recommended that the data are analyzed with and without inclusion of this leisure activity.

Past Year Occupational Activity Calculations

1. Past-year moderate activity (calculate only for job entries in which Column "B" is checked):
 $(\text{mos/yr}) \times (4 \text{ weeks/mo}) \times (\text{days/week}) \times (\text{hours/day of moderate activity}) \div 52 = \text{hours/week averaged over the past year}$

where hours/day of moderate activity = (hours/day - hours sitting) + (min/day of walking or pedaling a bike to work $\div 60$).

2. Past-year hard activity (calculate only for job entries in which Column "C" is checked):
 $(\text{mos/yr}) \times (4 \text{ weeks/mo}) \times (\text{days/week}) \times (\text{hours/day} - \text{hours sitting}) \div 52 = \text{hours/week averaged over the past year.}$

3. Combining hours/week of moderate activity and hard activity will provide an overall estimate of the average hours/week above light activity (Column A) during the past year.

4. To express in $\text{kcal} \cdot \text{kg}^{-1} \cdot \text{wk}^{-1}$ instead of hours/week, the moderate-activity category is multiplied by its average estimated MET value of 4 METs and the hard-activity category is multiplied by 7 METs. These can then be summed.

Total Physical Activity Calculations

Total physical activity averaged over the past year = past year leisure hours/week + past year occupational (moderate + hard) hours/week. Similarly, leisure and occupational MET-hours/week can be summed as well.

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Special Tips for Administration of the Modifiable Activity Questionnaire.

Leisure Section:

The interviewer should slowly read through the list of leisure-recreational activities, and ask the participant to identify all activities performed more than 10 times in the last year. (The interviewer will circle the activity number for all positive responses.) The matrix below the Activity List is then used to determine the time spent in each activity. Specifically:

1. All activities identified from this list by the participant are written by the interviewer in the "Activity" column provided.
2. For each activity identified, the interviewer
 - checks off the months of the past year that the activity was performed.
 - enters the "Average # of Times per Month" and the "Average Number of Minutes" the activity was usually performed.

* Please note that any walking or biking in the leisure activity section does **not** include walking or biking to and from work. Walking or biking to and from work will be assessed in the occupational activity section.

Occupational Activity:

The participant is first asked to identify all jobs held during the past year for more than one month. Occupations such as homemaker, retired, or unemployed are also included as well as individuals who are disabled and unable to work.

In the matrix provided, the interviewer will determine the following:

1. Enter the names of all jobs in the "JOB NAME" column. The "occupations" homemaker, disabled, retired or unemployed should only be used if another job was not identified during that month.
2. Enter the number of months the participant performed each job over the past 12 months in the "MOS/YR" column. Account for all months of the year.

For each entry in the JOB NAME column, the interviewer will determine the following information:

3. Enter the "JOB CODE" that best describes the job using the list that appears below the matrix.

4. Identify the usual form of transportation to and from work. If biking or walking is the usual transportation mode, enter the total time spent in the minutes per day (MIN/DAY) column. For homemakers, disabled, retired or unemployed participants, enter a zero for this item.

5. Under the Job Schedule heading, enter the "DAYS/WEEK" and the "HOURS/DAY" the participant usually spent at that job. For homemakers, disabled, retired or unemployed participants, the interviewer should automatically enter "5" in the DAYS/WEEK column and an "8" in the HOURS/DAY column.

6. Out of the total number of HOURS/DAY reported at the job, identify the usual number of hours spent sitting each day and enter in "HRS SITTING" column. Once this is done, the interviewer will ask the participant to identify the job activities that are usually performed when not sitting.

Here the interviewer will note there are three categories of activities listed below the matrix. The interviewer will place a check in the single most appropriate category based upon the verbal job description given by the participant. For example, if the participant was a janitor and reported doing mostly "walking, mopping and sweeping" on the job, a check would be placed in column B.

Note: How about if the activities are not listed? Category A contains activities that involve sitting, standing still, and/or slow walking. Category B includes job activities that require an effort similar to that of continuous walking. The C category contains activities with energy demands approaching heavy lifting, digging, or running. If a participant identifies an activity not on the list, the interviewer will need to make a judgement regarding the most appropriate category.

Modifiable Activity Questionnaire

1. Please circle all activities listed below that you have done more than 10 times in the past year:

Jogging (outdoor, treadmill) 1	Football/Soccer 14	Stair Master 27
Swimming (laps, snorkeling) 2	Racquetball/Handball/Squash 15	Fencing 28
Bicycling (indoor, outdoor) 3	Horseback riding 16	Hiking 29
Softball/Baseball 4	Hunting 17	Tennis 30
Volleyball 5	Fishing 18	Golf 31
Bowling 6	Aerobic Dance/Step Aerobic 19	Canoeing/Rowing/Kayaking 32
Basketball 7	Water Aerobics 20	Water skiing 33
Skating (roller, ice, blading) 8	Dancing(Square,Line,Ballrm) 21	Jumping rope 34
Martial Arts (karate, judo) 9	Gardening or Yardwork 22	Snow skiing (X-country/Nordic trk) 35
Tai Chi 10	Badminton 23	(downhill) 36
Calisthenics/Toning exercises 11	Strength/Weight training 24	Snow shoeing 37
Wood Chopping 12	Rock climbing 25	Yoga 38
Water/coal hauling 13	Scuba Diving 26	Other 39

List each activity that you circled in the "Activity" box below. Check the months you did each activity over the past year (12 months) and then estimate the average amount of time spent in that activity.

Activity	J A N	F E B	M A R	A P R	M A Y	J U N	J U L	A U G	S E P	O C T	N O V	D E C	Average # of Times Per Month	Average # of Minutes Each Time

2. In general, how many HOURS per DAY do you usually spend watching television? _____ hrs
3. Over this past year, have you spent more than one week confined to a bed or chair as a result of an injury, illness or surgery? Yes _____ No _____
If yes, how many weeks over this past year were you confined to a bed or chair? _____ weeks
4. Do you have difficulty doing any of the following activities?
 a. getting in or out of a bed or chair? Yes _____ No _____
 b. walking across a small room without resting? Yes _____ No _____
 c. walking for 10 minutes without resting? Yes _____ No _____
5. Did you ever compete in an individual or team sport (not including any time spent in sports performed during school physical education classes)?
If yes, how many total years did you participate in competitive sports? _____
6. Have you had a job for more than one month over this past year, from last _____ to this _____ ?

List all JOBS that the individual held over the past year for more than one month. Account for all 12 months of the past year. If unemployed/disabled/retired/homemaker/student during all or part of the past year, list as such and probe for job activities of a normal 8 hour day, 5 day week.

						Out of the total # of "Hrs/Day" the individual reported working at this "job", how much of this time was usually spent sitting? Enter this # in "Hrs Sitting" column, then place a check "✓" in the category which best describes their job activities when they were not sitting.			
		Walk or bicycle to/from work	AVERAGE JOB SCHEDULE			Hours spent sitting at work	Check the category that best describes job activities when not sitting		
Job Name	Job Code	Min/Day	Mos/Yr	Day/Wk	Hrs/Day	Hrs Sitting	A	B	C

Category A

(includes all sitting activities)

Sitting
 Standing still w/o heavy lifting
 Light cleaning - ironing, cooking, washing, dusting
 Driving a bus, taxi, tractor
 Jewelry making/weaving
 General office work
 Occasional/short distance walking

Category B

(includes most indoor activities)

Carrying light loads
 Continuous walking
 Heavy cleaning - mopping, sweeping, scrubbing, vacuuming
 Gardening - planting, weeding
 Painting/Plastering
 Plumbing/Welding
 Electrical work
 Sheep herding

Category C

(heavy industrial work, outdoor construction, farming)

Carrying moderate to heavy loads
 Heavy construction
 Farming - hoeing, digging
 - mowing, raking
 Digging ditches, shoveling
 Chopping (ax), sawing wood
 Tree/pole climbing
 Water/coal/wood hauling

JOB CODES

Not employed outside of the home:

1. Student
2. Home Maker
3. Retired
4. Disabled
5. Unemployed

Employed (or volunteer):

6. Armed Services
7. Office worker
8. Non-office Worker

Appendix B -- 4
THE STRONG HEART STUDY PHASE III
Instructions for Phase III Gambling Questionnaire

(Page 8 of the Personal Interview Form 2)

A brief introduction can be made to participants to explain to them that, since more Indian Communities now have casinos and gamblings, we are interested in the possible impact that these activities could have on the health of the communities.

Question 1

Check yes if an individual works, whether part-time or full-time, at a casino or bingo hall.

Question 2

Read the three possible responses. If the participant feels that gambling is neither beneficial nor harmful to his or her community, check no effect.

Question 3

For each of the types of gambling: slot machines, lottery, bingo, or card games, check whether or not the participant has participated within the last year. If the participant has answered yes to any, then estimate whether the frequency is one or more times a week, one or more times a month, or less than once a month. If the participant names something other than slot machines, lottery, bingo, or card games, fill the game in under "other" and indicate the frequency as above.

Question 4

This refers to the amount of money won or lost within the last year.

Question 5

Check yes if the participant has tried to reduce, cutback, or stop gambling. If the answer is yes, ask his/her opinion of whether the attempts have been successful. The response depends on the participant's own opinion. Read the question exactly as written.

Question 6

Refers to the amount of money borrowed to pay living expenses because of money lost in gambling.

Question 7

This attempts to assess the possible influence of gambling on alcohol consumption. The amount of drinks should be filled out for any one gambling session (i.e., evening or afternoon or whole day).

Question 8

This question inquires about the largest amount bet in any single day. It means the total amount wagered that day in any one gambling session.

Appendix B -- 5
THE STRONG HEART STUDY PHASE III
Instructions for Medical History Interview

Before beginning, make certain that the correct study identification number or the subject is entered at the top of the form. Explain to the subject some questions need to be asked about his or her medical history so that we can better evaluate whether or not he/she 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 sequellae 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. All participants in Phase II had gall bladder ultrasound tests done. If gallstones were detected they should have been informed.
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 diet control for their diabetes.
8. Kidney Failure. The interviewer should describe this as kidney failure or if he/she 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.
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.
13. 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. Using the Procedures and Tests Photocopy Check List, obtain the medical record of this procedure (the catheterization report and pictures) and the narrative hospital summary for review by the SHS Morbidity Review Panel. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center. This should not include use of a treadmill for exercise purposes. Show participant a picture of a diagnostic treadmill exercise test.
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. Using the Procedures and Tests Photocopy Check List, obtain the medical record of this procedure (the ECG paper from the test and the report) and the narrative hospital summary for review by the SHS Morbidity Review Panel. If the test included use of thallium, also obtain a copy of the nuclear medicine report. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS

occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center.

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 he/she had a heart attack, ask if there were more than one. Obtain information about each hospitalization and record in (o) below so that medical records can be reviewed for morbid event. Be sure to have participants sign the release forms for non-IHS hospitals, if hospitalizations occurred in the last ten years.
17. If the patient indicates that he/she has had other heart trouble, the interviewer should ask about the symptoms, because of the possibility that it may in fact fit in a, b or c above. If any of these procedures were done since Phase I exam, use the Procedures and Tests Photocopy Check List and obtain a copy of the test or operative report and the narrative hospital summary for review by the SHS Morbidity Review Panel. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center.
18. Stroke. Ask if the patient indicates that he/she has not had a stroke, ask also whether he/she has had any episode where he/she suddenly could not move a part of his/her body for a prolonged period of time. Obtain information about each hospitalization and record in (Question 20) below so that medical records can be reviewed for morbid event. Be sure to have participants sign the release forms for non-IHS hospitals, if hospitalizations occurred in the last ten years.
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.

ACCESS TO CARE. Questions 20-28 were included to assess barriers to care that may prevent Strong Heart Study participants from receiving medical care they need.

20. First part: Check all sources of medical care that participant received in the last five years. Read all the items on the list. If the participant has not received any care in the last five years, check "nowhere". In the right hand column just check **USUAL** source of care.
21. Check all sources of health insurance coverage. Check "none" if the participant has no other coverage.
22. Just check the **most frequent** means that the participant gets to health care.

23. Record the dollar cost (nearest dollar) paid by the participant out of pocket to get to health care. If they drive their own vehicle, use \$ 0.31/mile is a reasonable amount to calculate the cost for a round trip to the usual health care provider. Record "yes" if the CHR or family member provides transportation at no cost to the participant.
24. Record travel time (one way) to their usual source of care using the categories provided.
25. Record if the participant's usual source of medical care needs an appointment for care.
26. Check the appropriate box for waiting time to see the health care provider.
27. If participant can be seen as walk-ins before a scheduled appointment record the time usually required to be seen by a physician or physician's assistant (28a). If participant cannot be seen as a walk-in, record how long it takes to get an appointment (28b).
28. Record the usual cost they have to pay for an office visit out of pocket. For patients receiving care at an IHS or Tribal facility, this would usually be 0.

Appendix B -- 6(a)
The Strong Heart Study Phase III
Instructions for Reproduction and Hormone Use: Women Only
for SHS-I Cohort

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. Ask if the participant's menstrual cycles have stopped.
2. When inquiring about menstrual cycles stopping permanently, this means for more than one year.
- 3-4. If the patient does not know how old she was when they stopped, ask if she remembers what year was the last year that she had a menstrual period. The interviewee 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. By referring to the patients' age and the year in which the periods stopped, then the interviewer can compute the age when they stopped completely.
- 5-7. Use questionnaire as written. If patients are currently taking estrogen pills or birth control pills, be sure they are recorded on the medication history.

Appendix B -- 6(b)
The Strong Heart Study Phase III
Instructions for Reproduction and Hormone Use: Women Only
SHS Family Study -- for SHS Family Members

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).
- 5-7. Ask about use of birth control pills and be sure they are recorded on the medication history if they are currently taking them.
8. When inquiring about menstrual cycles stopping permanently, this means for more than one year.
9. If the patient does not know how old she was when they stopped, ask if she remembers what year was the last year that she had a menstrual period. By referring to the patients' age and the year in which the periods stopped, then the interviewer can compute the age when they stopped completely.
- 10-11. 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.
- 12-14. Use questionnaire as written to obtain information about estrogen use. Be sure to record estrogen as part of the medication history if they are currently taking it.

Appendix B -- 7
The Strong Heart Study Phase III
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

STRONG HEART FAMILY STUDY

Instructions and Recruitment Forms

**STRONG HEART FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

DRAFT - General Instructions for SHS Staff - DRAFT

The purpose of the Strong Heart Family Study is to find genes that influence heart disease risk factors in American Indians. Ten large families, with an average of 30 members each, will be enrolled in the Strong Heart Family Study from each of three centers: Oklahoma, the Dakotas, and Arizona.

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

From the family history forms that were completed for each participant in Strong Heart Study Phase II, preliminary family trees have been constructed by computer. For each center, families have been identified for which:







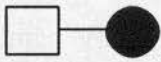
- (1) there is a "core sibship" of at least five full siblings, of whom at least three are Strong Heart Study participants; and
- (2) the SHS participants in the core sibship have a total of at least 12 offspring who are at least 18 years old.

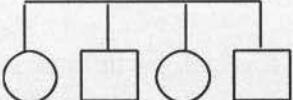
The family trees also indicate which spouses of these siblings are Strong Heart Study participants.

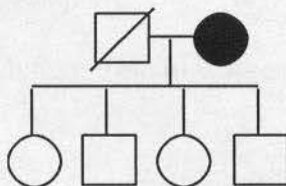
In choosing families for the Family Study, an additional important criterion will be the family's interest in participating. However, as we recruit families, it is important to avoid "ascertainment bias". We want the families in the Family Study to be representative of their communities, and not selected 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 ten families with a total of at least 300 members 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.

We may find that there are many more families and family members interested in participating than we can include in this pilot study. These families can be told that if the pilot study is successful, we hope to be able to expand it to include additional families.

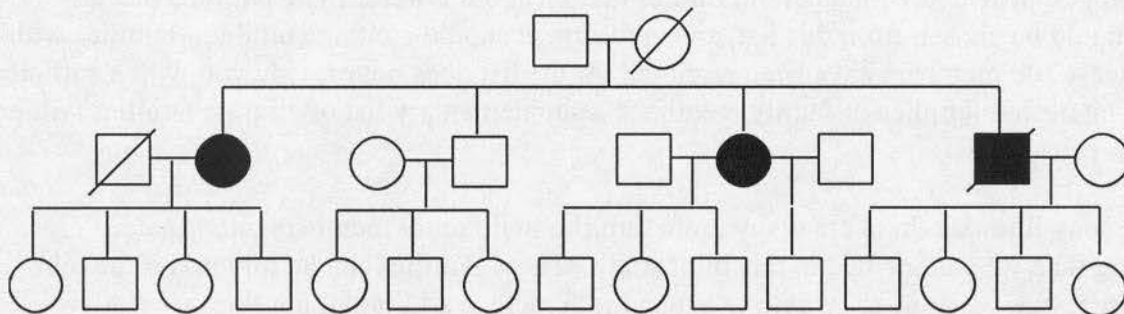
Understanding the Family Tree Diagrams

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 Strong Heart Study participants. Individuals who are no longer living are represented by a diagonal line through a square  or circle . A marriage is represented by a horizontal line (a marriage line) joining a square and a circle . 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 participants. Each of the children is (or was) married. The daughter on the left, a Strong Heart Study participant, has four children. One of her brothers has three children and the other, a Strong Heart Study participant, 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 participants, but we do not know the other parent of each of these offspring, and therefore we don't know whether the offspring are full sibs or half sibs.
- We have no information about the spouses and offspring of the non-SHS sibs of SHS participants.

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 initial family trees. 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 participants, 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.

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 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. Jean MacCluer, 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

Each family targeted as a possible candidate for the Family Study has been identified because it contains a core sibship of at least size five, of whom at least three are Strong Heart Study participants. 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 participants.
- (2) All age-eligible (at least 18 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. 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 Study Participant Interview should be administered. 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 and addresses 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 judgement 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 Study Participant Interview Form

The SHS Family Study Participant Interview consists of five parts. Part I requests general demographic and background information about the participant and his/her family. Parts II to IV request more detailed information about the participant's children, brothers and sisters, and parents, respectively. Part V asks the participant to identify a family contact person who can be asked for additional information. The following conventions should be used for this interview:

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.

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 ☐ next to the symbol for that person on the family tree. Ask which other family members live in the same household and write ☐ next to each of their symbols as well. When you interview the next family member who is **not** in household ☐, write ☐ next to the symbols for that person and everyone

else in his/her household. Continue with additional family members, using ○, ○, and as many additional household numbers as are needed to specify all households in the family. Write the person's household number in the appropriate place on page 1 of the Family Study Participant Interview Form.

Addresses: Addresses of family members are requested 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.

Information on relatives: For recording information on offspring and siblings of the participant, interviewers should use as many sheets labeled "Your Children" and "Your Brothers and Sisters" as needed. These sheets, which are color coded, will be available separately and won't be provided in the Interview 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. Likewise, in recording information about a participant's offspring, you should ask for the name of the other parent of each offspring. And 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.

Tribal affiliation and ethnicity: Questions are included in Part I about the tribal affiliation of the participant and the ethnic background of his/her grandparents. 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 individual participants' degree of Indian ancestry.

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 it 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 Interview 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 page 12 of the SHS Family Study Participant Interview form, detach the page, and send it directly to Dr. MacCluer 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. Jean W. MacCluer
Department of Genetics
Southwest Foundation for
Biomedical Research
For express courier:
7620 N.W. Loop 410
San Antonio, TX 78227-5301

Phone (210) 670-3290
Fax (210) 670-3317
Email jean@darwin.sfbr.org

For U.S. mail:
P.O. Box 760549
San Antonio, TX 78245-0549

THE STRONG HEART STUDY III — FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

GENETICS OF CARDIOVASCULAR DISEASE
FAMILY STUDY PARTICIPANT INTERVIEW

SHS Family Study I.D. SHS. I.D.:

Social Security Number:

Community name: Community Code:

Household Number:

**If there are notes or instructions for Dr. MacCluer on page 16, check here:*

PART 1. YOU AND YOUR FAMILY

1. What is your full name (*Last, first, middle, Jr./Sr., maiden name, nickname*):

Last:

First:

Middle: Jr./Sr.

Maiden

Nickname:

Gender: Male 1 Female 2

Are you an SHS participant? Yes 1 No 2

If Yes, have you changed your name since the SHS -II examination?

Yes 1 No 2

How old are you?
years

What is your date of birth? / /
mo day yr

2. What is your marital status?

(Enter up to 3 options with the most recent one in the left-most box)

1 = Never married

4 = Separated

2 = Currently married

5 = Widowed

3 = Divorced

6 = Adult roommate/partner/significant other

3. If you are currently married or living with someone as if you were married, what is your spouse/partner's name? (If divorced or widowed, draw 2 lines through boxes)

Last: _____

First:

Middle: | | | | | | | | | | | | | | | Jr./Sr. | |

Maiden

Nickname: | | | | | | | | | | | | | | | | | | | |

4. Did he/she also participate in the Strong Heart Study examination?

Yes |__|1 No |__|2 Unsure |__|9

5. What is your current mailing address?

[illegible]

Street/P.O. Box

[illegible]

Reservation/city/town:

County:

State and zip code:

--	--	--	--	--	--	--	--	--

6. What is your residential address? (If different from mailing address)

[illegible]

Street/P.O. Box

[illegible]

Reservation/city/town:

[illegible]

County:

State and Zip code: _____

7. What is your home telephone number?
Or at what telephone number can we
reach you or leave a message?

0= If unlisted

area code

9= If no phone

8. What is your work or other contact telephone number?
0= If same as home phone

0= If same as home phone

area code

9= If not applicable or unknown

Since we are investigating heart disease in the American Indian population, we need to ask about your degree in Indian blood.

9. What do you estimate to be your degree of Indian blood? |_|_|_|/|_|_|

10. Blood quanta:

Please write the name of each tribe in the spaces below, with the largest blood quantum first.

	Tribal Code	Blood quantum
Tribe 1: _____	_ _ _	_ _ _ / _ _
Tribe 2: _____	_ _ _	_ _ _ / _ _
Tribe 3: _____	_ _ _	_ _ _ / _ _
Tribe 4: _____	_ _ _	_ _ _ / _ _
Tribe 5: _____	_ _ _	_ _ _ / _ _
Other ethnic groups: _____		_ _ _ / _ _
_____		_ _ _ / _ _
_____		_ _ _ / _ _
_____		_ _ _ / _ _

11. What is your tribe of enrollment?
Enter name and IHS tribal code: _____ |_|_|_|

12. Now I would like to ask you some questions about your family. How many natural children have you had (including any who are deceased, but not those who are yours by marriage or adoption)? |_|_|_|
of children

13. I would like to ask you some questions about your natural father and mother.

What is your natural father's name? *(Record accurately. Verify spelling)*

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

14. Is he living? Yes | | | 1 No | | | 2 Unsure | | | 9 Unknown | | | 8 *(Go to Q17)*

15. Where was your natural father born?

| | | | | | | | | | | | | | | | | | | | | |

Reservation/county/city/town:

| | | | - | | | | | | | | | | | | | | | | | | | | | |

State Country (if not U.S.):

16. Blood contents of your natural father: *Please write the name of each tribe in the spaces below, with the largest blood content quantum first.*

	Tribal Code	Blood quantum
Tribe 1: _____		/
Tribe 2: _____		/
Tribe 3: _____		/
Tribe 4: _____		/
Tribe 5: _____		/
Other ethnic groups: _____		/
_____		/
_____		/
_____		/

17. What was your natural mother's name? (*Record accurately. Verify spelling*)

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

18. Is she living? Yes | | |1 No | | |2 Unsure | | |9 Unknown | | |8 (*Go to Q21*)

19. Where was your natural mother born?

| | | | | | | | | | | | | | | | | | | | | |
Reservation/county/city/town:

| | | | | | | | | | | | | | | | | | | | | |
State Country (if not U.S.):

20. Blood contents of your natural mother: *Please write the name of each tribe in the spaces below, with the largest blood content quantum first.*

	Tribal Code	Blood quantum
Tribe 1: _____		/
Tribe 2: _____		/
Tribe 3: _____		/
Tribe 4: _____		/
Tribe 5: _____		/
Other ethnic groups: _____		/
_____		/
_____		/
_____		/

21. Now I would like to ask you about your grandparents. To what tribe did each of your grandparents belong? (If grandparent was not Indian, list his/her ethnic background)

Father's father: _____

Father's mother: _____

Mother's father: _____

Mother's mother: _____

22. Where were your grandparents born?

Father's father:

Reservation/county/city/town	state	country
------------------------------	-------	---------

Father's mother:	Reservation/county/city/town	state	country
------------------	------------------------------	-------	---------

Mother's father:	Reservation/county/city/town	state	country
------------------	------------------------------	-------	---------

Mother's mother:	Reservation/county/city/town	state	country
------------------	------------------------------	-------	---------

If person is NOT CURRENTLY married or living with someone as if they were married, skip to Q30.

23. Now I would like to ask about your spouse/partner (*name from Q3*). Where was he/she born?

Reservation/county/city/town	state	country
------------------------------	-------	---------

24. Is he/she also American Indian? Yes |___|1 No |___|2 Unsure |___|9

25. To what tribe/ethnic group does he/she belong? _____

26. What are the names of his/her parents?

Spouse/partner's father (If unknown, leave blank)

Last: | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | Jr./Sr. | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

27. Is he living? Yes |__|1 No |__|2 Unsure |__|9

28. Spouse/partner's mother (If unknown, leave blank)

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | |

Maiden: | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

29. Is she living? Yes |__|1 No |__|2 Unsure |__|9

30. Do you think most of your family members will be willing to participate in this family study?
(Record answer verbatim on lines below)

If "Yes" or "Unsure" → GO TO PART II

If "No" → END INTERVIEW BY THANKING THIS PERSON FOR
THEIR TIME

PART II. YOUR CHILDREN

Now, I would like to get some additional information about your children.

1. Earlier, you told me you have (*number from part 1, Q12*) children. *Pause for reaction.*
Does this include any who may have died and exclude any adopted children?

Record number of children, including those deceased, excluding adoptees: | | |

2. What are the names of your children?

For interviewer: Record names of all children, including those deceased. You may come back later to get the additional information on each child.

(1)

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

Sex: Male | | |1 Female | | |2

Age: | | | | Birthdate: | | |mo | / | | |day | / | | |yr | | |

Living? Yes | | |1 No | | |2 Unsure | | |9 Number of children: | | | |

Address: _____
Number and Street Reservation/city/town/county State and Zip Code

Phone: (| | |) | | | - | | |

Other parent: Father | | |1 Mother | | |2 (*Check one*)

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

Use the additional "Your Children" pages as needed.

PART II. YOUR CHILDREN: ADDITIONAL CHILDREN

CHILD NUMBER Last: First: Middle: Jr./Sr. Nickname: Sex: Male 1 Female 2Age: Birthdate: mo day yrLiving? Yes 1 No 2 Unsure 9 Number of children: Address: Number and Street Reservation/city/town/county State and Zip CodePhone: () - Other parent: Father 1 Mother 2 (Check one)Last: First: Middle: Jr./Sr. Maiden Nickname: *Use additional "Your Children" pages as needed.*

PART III. YOUR BROTHERS AND SISTERS

1. Now I would like to get some information about your brothers and sisters. How many brothers and sisters do you have? You should include any brothers and sisters who may have died and also all of your half-brothers and half-sisters. Do not include any brothers and sisters who are not blood relations.

Record number of brothers and sisters, including those deceased and half-siblings: | | |

2. What are the names of your brothers and sisters?

For interviewer: Record the names of all siblings, including those deceased. You may come back later and get the additional information needed on each individual.

()

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

Sex: Male | | |1 Female | | |2

Age: | | | | Birthdate: | | | | / | | | | / | | | | | |
mo day yr

Living? Yes | | |1 No | | |2 Unsure | | |9 Number of children: | | | |

Address: _____
Number and Street Reservation/city/town/country State and Zip Code

Phone: () -

Parents (if half-sibling): Father | | |1 Mother | | |2 (Check one)

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

Use the additional "Your Brothers and Sisters" pages as needed.

PART III. YOUR BROTHERS AND SISTERS:SIBLING NUMBER Last: First: Middle: Jr./Sr. Maiden Nickname: Sex: Male 1 Female 2Age: Birthdate: mo day yrLiving? Yes 1 No 2 Unsure 9 Number of children: Address: Number and Street Reservation/city/town/county State and Zip CodePhone: () - Parents (if half-sibling): Father 1 Mother 2 (Check one)Last: First: Middle: Jr./Sr. Maiden Nickname: *Use additional "Your Brothers and Sisters" pages as needed.*

PART IV. YOUR PARENTS:

Now I would like to get some additional information about your parents.

1. What is your mother's full name?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

What is/was her birthday?

| | | | | / | | | | | / | | | | |
mo day yr

Is she living? Yes | | | 1 No | | | 2 Unsure | | | 9

Address: _____
Number and Street Reservation/city/town/county State and Zip Code

Phone: () -

2. What is your father's full name?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

What is/was his birthday?

| | | | | / | | | | | / | | | | |
mo day yr

Is he living? Yes | | | 1 No | | | 2 Unsure | | | 9

Address: _____
Number and Street Reservation/city/town/county State and Zip Code

Phone: () -

Now let's return to your mother's side of the family.

3. What is the name of your mother's father?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

4. What is the name of your mother's mother?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

Now, let's go back to your father's side of the family.

5. What is the name of your father's father?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | | Jr./Sr. | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

6. What is the name of your father's mother?

Last: | | | | | | | | | | | | | | | | | | | | | |

First: | | | | | | | | | | | | | | | | | | | | | |

Middle: | | | | | | | | | | | | | | | | | | | | | |

Maiden | | | | | | | | | | | | | | | | | | | | | |

Nickname: | | | | | | | | | | | | | | | | | | | | | |

SHS Family Study I.D. | | | | | | | | | |

SHS. I.D.: | | | | | | | | | |

PART V. FAMILY CONTACT PERSON

In case we wanted to get more information, who in your family knows the most about the other family members?

Name: _____

Address: _____

Phone: () -

How is this person related to you? _____

INTERVIEWER'S SIGNATURE

INTERVIEWER'S ID: | | | | |

DATE

GENETICS OF CARDIOVASCULAR DISEASE

FAMILY STUDY FORM FOR DECEASED FAMILY MEMBERS

Social Security Number: | | | - | | | - | | | | |

- Nickname: | | | | | | | | | | | | | | | | | | | | | |

- | | | | | |
|--|--|--|--|--|
| | | | | |
| | | | | |

THE STRONG HEART STUDY III — FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

GENETICS OF CARDIOVASCULAR DISEASE

SHS Family I.D.

SHS. I.D.:

Participant's name: _____

Notes for Dr. MacCluer:

INTERVIEWER: _____ DATE: _____

Please detach from form and send immediately to:

Dr. Jean W. MacCluer, Department of Genetics, Southwest Foundation for Biomedical Research
7620 N.W. Loop 410, San Antonio, TX 78227-5301
Phone: (210) 670-3290, Fax: (210) 670-3317
E-mail: jean@darwin.sfbr.org

APPENDIX D

STRONG HEART FAMILY STUDY

Questionnaires and Data Forms

**THE STRONG HEART STUDY III — FAMILY STUDY
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: / /
mo day yr

4. What is your marital status? (*Give the most recent status in left-most box*)
Current, 2nd, 3rd

1 = Never married

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 Q8*)

Last

First

Middle

7. Did he/she also participate in the Strong Heart Study examination?

Yes ☐1

No ☐2

8. To which IHS and non-IHS Hospital/Clinic do you usually go? *List the one they go to most often first. Give names and codes.* Do you want your Strong Heart report sent to the named hospitals?

	Hospital	Chart number	IHS 1=yes, 2=no	Hospital Code	Send Report 1=yes, 2=no
a.	_____	_____	_____	_____	_____
b.	_____	_____	_____	_____	_____
c.	_____	_____	_____	_____	_____
d.	_____	_____	_____	_____	_____

9. What is your current mailing address?

a. _____
Street/P.O. Box

b. _____
City/town

c. _____
County

d. State and zip code: _____

10. Is this your residential address? (If different from mailing address)

Yes ☐ 1

No ☐ 2 *if no, what is your current address?*

a. _____
Street/P.O. Box

b. _____
City/town:

c. _____
County:

d. State and Zip code: _____

11. What is your home telephone number?
Or at what telephone number can we
reach you or leave a message?

0= If unlisted

area code

9= If no phone

12. What is your work or other
contact telephone number?
0= If same as home phone

area code

9= If not applicable or unknown

Since we know that years of education may be a risk factor for some diseases, we need to ask about the years of education you have completed.

13. How many years of education have you completed? |_|_|_|

0-12= Vo-tech or years of school (GED = 12)

14= Junior college

16= Bachelors

18= Masters

19= Law degree

20= Doctorate

999= Unknown

Since we are investigating heart disease in the American Indian population, we need to ask about your degree of Indian blood.

14. What do you estimate to be your degree of Indian blood? |_|_|_|/|_|_|_|

15. Blood quantum:

Please write the name of each tribe in the spaces below.

	Tribal Code	Blood quantum
Tribe 1: _____	_ _ _	_ _ _ / _ _ _
Tribe 2: _____	_ _ _	_ _ _ / _ _ _
Tribe 3: _____	_ _ _	_ _ _ / _ _ _
Tribe 4: _____	_ _ _	_ _ _ / _ _ _
Tribe 5: _____	_ _ _	_ _ _ / _ _ _
White — non-Hispanic		_ _ _ / _ _ _
White — Hispanic		_ _ _ / _ _ _
Black.....		_ _ _ / _ _ _
Other, please specify: _____		_ _ _ / _ _ _

16. What is your tribe of enrollment?

Enter name and IHS tribal code: _____

|_|_|_|

**THE STRONG HEART STUDY - PHASE III — FAMILY STUDY
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 (<i>skip to B</i>) | No | ____ 2 | Unknown/unsure | ____ 9 |
|-----|-----------------------------|----|--------|----------------|--------|
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. DENTURE AND EATING PROBLEMS

4. How many natural teeth do you have? All 1 Most 2 Some 3 None 4
5. Describe how you chew your food. (*Please Choose only ONE*):
- I use natural teeth to chew. 1 I use natural teeth with caps/crowns to chew. 2
- I have natural teeth and a denture or partial. I use them both together to chew. 3
- I use dentures to chew. 4 I chew with my gums. 5
6. Rate your ability to chew food (*Please Choose only ONE*) Good 1 Fair 2 Poor 3

C. FAMILY INCOME:

7. Does your household income meet your family's needs?
- Yes |__|1 No |__|2 Unsure |__|9
8. What is your *MAIN* daily activity(s)? (*If more than one, order "1,2..."etc.*) |__| |__| |__|
- Main 2nd 3rd
- | | |
|----------------------------|---------------------------|
| 1 = Caring for Family | 4 = Looking for Work |
| 2 = Working for Pay/Profit | 5 = Retired/Elderly |
| 3 = Going to School | 6 = Other, please specify |

9. Do you receive any income from..? Yes No
- | | | | | | |
|--|----------------------------|----------------------------|-----------------------------|----------------------------|----------------------------|
| 1) Wages/Salary | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 5) Retirement Benefits | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 2) Profits - business | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 6) Social Security Benefits | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 3) Gaming/lottery winnings | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 7) Lease Payment | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 4) Unemployment benefits/
worker's comp/welfare | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 8) Other, specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

10. Of the choices in Question 9, which source provides the most income?
(Choose one: if Missing/Refused/Unknown, code 9) ☐

11. 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)

12. Which of the following categories best describes your annual **household** income from all sources? Please show a list.

Less than 5,000 <input type="checkbox"/> 1	20,000 to 25,000 <input type="checkbox"/> 5	Don't know/not sure <input type="checkbox"/> 9
5,000 to 10,000 <input type="checkbox"/> 2	25,000 to 35,000 <input type="checkbox"/> 6	Refused <input type="checkbox"/> 0
10,000 to 15,000 <input type="checkbox"/> 3	35,000 to 50,000 <input type="checkbox"/> 7	
15,000 to 20,000 <input type="checkbox"/> 4	Over 50,000 <input type="checkbox"/> 8	

D. TOBACCO:

13. During your lifetime have you smoked 100 cigarettes or more total?
Yes ☐1 No ☐2 (skip to SECTION E)

14. How old were you when you first started smoking fairly regularly?
(Indicate age at which you started smoking)
0 = Never smoked regularly 999 = Unknown

15. Do you smoke cigarettes now? Yes ☐1 No ☐2

16. 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?

17. 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) other, specify: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2

18. On the occasions that your smoking increased, how many cigarettes do/did you smoke per day? |_|_|_|_|
19. If you currently smoke, would you like to change your smoking habit? Yes |_|_|1 No |_|_|2
(if No, skip to Q20)
- a) If yes, would you prefer to... Yes No
- | | | |
|--|-------|-------|
| i) Reduce number of cigarettes per day | _ _ 1 | _ _ 2 |
| ii) Switch to lower "tar" or "nicotine" cigarettes | _ _ 1 | _ _ 2 |
| iii) Use nicotine patch/chewing gum | _ _ 1 | _ _ 2 |
| iv) Quit | _ _ 1 | _ _ 2 |
| v) Other, specify: _____ | _ _ 1 | _ _ 2 |
20. Did you quit smoking? Yes |_|_|1 No |_|_|2 *(skip to Section E)*
- 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 | _ _ 1 | _ _ 2 |
| ii) Health concerns | _ _ 1 | _ _ 2 |
| iii) Expenses | _ _ 1 | _ _ 2 |
| iv) Per family pressure | _ _ 1 | _ _ 2 |
| v) Other | _ _ 1 | _ _ 2 |
- specify: _____

E. PASSIVE SMOKING:

21. When you were growing up, did your father or male guardian ever smoke cigarettes regularly?
- | | |
|---|---|
| Yes _ _ 1 | No father/male guardian _ _ 3 |
| No _ _ 2 | Unknown _ _ 9 |
22. When you were growing up, did your mother or female guardian ever smoke cigarettes regularly?
- | | |
|---|---|
| Yes _ _ 1 | No mother/female guardian _ _ 3 |
| No _ _ 2 | Unknown _ _ 9 |
23. Whether or not you smoke, on the average, how many hours a day are you exposed to the smoke of others? |_|_|_|_|
(If none, fill in 0; enter 1 for 30 minutes or more, enter 0 if less than 30 minutes)

F. ALCOHOL:

The next few questions are about the use of beer, wine, or liquor.

PLEASE READ THE FOLLOWING TO THE PARTICIPANT:

"We are asking these questions about alcohol use, because alcohol consumption may be related to heart disease. We want to assure you that this information is strictly confidential. The Strong Heart Study will use this information only to determine to what extent alcohol use is a risk factor for heart disease. This information is analyzed as batches of numbers without any names. Please report your alcohol use as accurately as possible."

24. Have you ever consumed alcoholic beverages?

Yes ☐1 No ☐2 *(this section of the interview is finished, go to Question 31)*

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 31)

25. How many alcoholic drinks do you have in a typical week? *(see chart below)*

One Drink = 12 oz of Beer = 4 oz of Wine = 1 oz of Liquor.

Please choose the type(s) of beverage and write in the Number of Containers under the appropriate volume.

Number of Containers

Type of Drink	Container Size (Ounces)										
	1 shot	1.5 jigger	4 glass	8 tumbler	12 can/btl	16(pt) can	26 fifth	32-34 qt. btl	40 btl	64 (2 gal) jug	128 (gal) jug
Beer	X	X					X			X	X
Wine	X	X							X		
Liquor									X		

26. How many days in a typical month do you have at least one drink?

(Indicate the number of days per month)

27. 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)
28. When you drink more than your usual amount, how many drinks do you have? |_|_|_|
(# Drinks)
- a) How many times in a month? |_|_|_|
(# Times/Month)
29. 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.*) |_|_|_|
30. How many times during the **PAST YEAR** did you have 5 or more drinks on an occasion? (*Enter zero if subject has quit drinking more than one year ago*) |_|_|_|
31. Within the last year, have you ever consumed other substances to get the effects of alcohol, such as...
- | | Yes | No |
|-----------------|-----|-----|
| a. Mouth wash | _ 1 | _ 2 |
| b. Cough syrup | _ 1 | _ 2 |
| c. Lysol | _ 1 | _ 2 |
| d. Hair spray | _ 1 | _ 2 |
| e. Other, _____ | _ 1 | _ 2 |

G. ADMINISTRATIVE INFORMATION:

32. How reliable was the participant in completing the questionnaire?
- Very reliable |_|1 Reliable |_|2 Unreliable |_|3
- Very unreliable |_|4 Uncertain |_|5
33. Did the participant complete the interview?
- Yes, completed the interview |_|1
- No, refused all questions |_|2
34. Interviewer: |_|_|_|
35. Date of interview: |_|_|/|_|_|/|_|_|_|_|
mo day yr

**THE STRONG HEART STUDY - PHASE III — FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

GAMBLING QUESTIONS

SHS Family I.D. SHS. I.D.:

Now we will ask you a few questions about gambling, since more Indian communities have casinos and gambling may have an impact on the health of these communities.

1. Do you work at a casino/bingo hall? Yes |1 No |2
2. Overall, what effects do you think gambling has on the following:
 - a. Tribal government, Beneficial |1 Harmful |2 No effects |3
 - b. Tribal people, Beneficial |1 Harmful |2 No effects |3
 - c. You personally Beneficial |1 Harmful |2 No effects |3
3. What type(s) of gambling have you participated in during the last year?
 - a) Slot machines? Yes |1 No |2
(If Yes, how often. Please check)
|1 1 or more times a week |2 1 or more times a month |3 Less than once a month
 - b) Lottery? Yes |1 No |2
(If Yes, how often. Please check)
|1 1 or more times a week |2 1 or more times a month |3 Less than once a month
 - c) Bingo? Yes |1 No |2
(If Yes, how often. Please check)
|1 1 or more times a week |2 1 or more times a month |3 Less than once a month
 - d) Card games (i.e. poker)? Yes |1 No |2
(If Yes, how often. Please check)
|1 1 or more times a week |2 1 or more times a month |3 Less than once a month
 - e) Other, specify: _____ Yes |1 No |2
(If Yes, how often. Please check)
|1 1 or more times a week |2 1 or more times a month |3 Less than once a month
(Skip to Q9 if person does not gamble)
4. In the past year, have you lost more than you won? Yes |1 No |2
5. In the past year, have you made attempts to control, cut back, or stop gambling? Yes |1 No |2
 - a) If Yes, have your attempts been successful? Yes |1 No |2
6. In the past year, have you had to borrow money to pay basic living expenses (such as food, mortgage/rent), because of gambling losses? Yes |1 No |2
7. When you are gambling, how much alcohol do you drink that day? |
of drinks
8. In the past year, what is the largest amount you have bet on any single day? \$
9. Did the participant complete the interview?
 Yes, completed the interview |1 No, refused all questions |2
10. Interviewer:
11. Date of interview: |/|
mo day yr

**THE STRONG HEART STUDY III — FAMILY STUDY
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 <input type="text"/> 1 No <input type="text"/> 2 Only during pregnancy <input type="text"/> 3 Unknown <input type="text"/> 9
<i>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</i> | <input type="text"/> <input type="text"/> <input type="text"/> |
| | YES NO UNKNOWN | |
| 2. | Arthritis? <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 9 | |
| 3. | Any fractures associated with osteoporosis? <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 9
If YES," where? _____ | |
| 4. | Rheumatic heart disease? <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 9 | |
| 5. | Gallstones? <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 9 | |
| 6. | Cancer, including leukemia and lymphoma? <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 9
If YES," specify type of cancer: _____ | |
| 7. | Diabetes?
Yes <input type="text"/> 1 Impaired glucose tolerance (IGT) <input type="text"/> 2 No <input type="text"/> 3 Unknown <input type="text"/> 9
<i>(if No or Unknown, skip to Q8)</i> | |
| a) | If Yes, do you still have it now?
Yes <input type="text"/> 1 No <input type="text"/> 2 Unknown <input type="text"/> 9 | |
| b) | How old were you when you were first told by a medical person that you had diabetes? <i>Indicate the actual age. Don't know=999</i> | <input type="text"/> <input type="text"/> <input type="text"/> |
| c) | What type of treatment are you taking for your diabetes? <i>(Check appropriate answer)</i> | |
| | YES NO | |
| i) | insulin <input type="text"/> 1 <input type="text"/> 2 | |
| ii) | oral hypoglycemic agent <input type="text"/> 1 <input type="text"/> 2 | |
| iii) | by dietary control <input type="text"/> 1 <input type="text"/> 2 | |
| iv) | by exercise <input type="text"/> 1 <input type="text"/> 2 | |
| v) | do nothing <input type="text"/> 1 <input type="text"/> 2 | |
| vi) | other <input type="text"/> 1 <input type="text"/> 2 | |

YES NO UNKNOWN

8. Has a medical person ever told you that you had kidney failure? ☐1 ☐2 ☐9
- 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

YES NO UNKNOWN

12. **LUNG PROBLEMS**
- a. Emphysema? ☐1 ☐2 ☐9
- b. Hay fever? ☐1 ☐2 ☐9
- c. Chronic bronchitis? ☐1 ☐2 ☐9
- d. Asthma? ☐1 ☐2 ☐9
- If YES" for asthma, do you still have it now? ☐1 ☐2 ☐9

13. Have you had a heart catheterization? Yes ☐1 No ☐2

(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: _____

14. Have you ever had a diagnostic exercise test or Treadmill test to check your heart?

Yes ☐1 No ☐2 Unknown ☐3

- a) If "YES," when and where? / /
mo day yr
hospital/clinic: _____

Has a doctor ever told you that you had any of the following conditions?

(If more than one episode, enter information for the **MOST RECENT**)

15. Heart failure? Yes ☐1 No ☐2 Unknown ☐3

- a) If YES," when and where? / /
mo day yr
hospital/clinic: _____

- b) If YES," do you still have heart failure now? Yes ☐1 No ☐2 Unknown ☐3

16. Heart attack? Yes ☐1 No ☐2 Unknown ☐3

- a) If YES," when and where? / /
mo day yr
hospital/clinic: _____

20. Source of medical care:

In the past 5 years,
have you received
any medical care at:
Yes No

What is your usual source of medical care:
(Check only ONE)

- | | | | | |
|----|--------------------------|----------------------------|----------------------------|--------------------------|
| a) | IHS facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| b) | Tribal facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| c) | Private facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| d) | Private practitioner | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| e) | Traditional healer | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| f) | VA/military facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| g) | Health maint. org. (HMO) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| h) | Other, list _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| i) | Nowhere | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |

21. Do you receive most of your outpatient care in...?

A hospital emergency room |___|1

A clinic	1	2
----------	---	---

A private doctor's office | 3

22. In addition to IHS coverage, what health insurance do you have? (*Check all that apply*)
- | | | | |
|--------------------------|-----------------------------|---------------------------|-----------------------------|
| None | <input type="checkbox"/> 1 | Veteran/military hospital | <input type="checkbox"/> 5 |
| Private health insurance | <input type="checkbox"/> 2 | HMO | <input type="checkbox"/> 6 |
| Medicaid | <input type="checkbox"/> 3 | Other, list _____ | <input type="checkbox"/> 7 |
| Medicare | <input type="checkbox"/> 4 | | |
23. How do you get to your usual healthcare provider? (*Check only one*)
- | | |
|---------------------------------------|-----------------------------|
| Myself | <input type="checkbox"/> 1 |
| Family member | <input type="checkbox"/> 2 |
| Friend | <input type="checkbox"/> 3 |
| Community health representative (CHR) | <input type="checkbox"/> 4 |
| Paid driver | <input type="checkbox"/> 5 |
24. How much does it usually cost, out of pocket, for transportation to your usual healthcare provider? \$ _____
25. On the average, how long does it take you to get to your usual source of medical care?
- | | | | |
|----------------------|-----------------------------|-------------------|-----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
26. Does your usual source of medical care see patients by appointment?
- Yes ☐|1 No ☐|2
27. Once you get to your usual source of medical care, how long do you usually have to wait to see a healthcare provider?
- | | | | |
|----------------------|-----------------------------|-------------------|-----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
28. If you need to be seen before your appointment, can you walk in and be seen?
- Yes ☐|1 (*go to a.*) No ☐|2 (*go to b.*)
- a) As a walk-in, how long does it usually take you to be seen by a physician or a physician's assistant?
- | | | | |
|----------------------|-----------------------------|-------------------|-----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
- b) How long does it usually take you to get an extra appointment?
- | | | | |
|------------------|-----------------------------|-------------------|-----------------------------|
| 2 days or less | <input type="checkbox"/> 1 | 3 to 4 weeks | <input type="checkbox"/> 4 |
| 3 days to 1 week | <input type="checkbox"/> 2 | More than 4 weeks | <input type="checkbox"/> 5 |
| 1 to 2 weeks | <input type="checkbox"/> 3 | | |
29. How much do you have to pay "out-of-pocket" to see your usual healthcare provider for an outpatient visit, **excluding** travel costs? \$ _____

30. Did the participant complete the interview?
- Yes, completed the interview ☐|1 No, refused all questions ☐|2

IS THE PARTICIPANT FEMALE? Yes ☐|1 (*go to next page*) No ☐|2

IF THE PARTICIPANT IS MALE, GO TO ROSE QUESTIONNAIRE

31. Interviewer: _____
32. Date of interview: _____
- mo day yr

THE STRONG HEART STUDY III — 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)
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?
5. Have you ever used birth control pills? Yes |1 No |2 *(go to Q8)*
6. How old were you when you started to use birth control pills?
 Indicate the age in years. 999=unknown
7. 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. Have your menstrual cycles stopped? Yes |1 No |2 *(go to Q12)*
9. If 'YES', have they stopped for 12 months or more? Yes |1 No |2
10. Was your menopause natural or did you have surgery?
 Natural |1 *(go to Q11)* Surgery |2
- a) If **SURGERY**, was only your uterus removed?
 Yes |1 No |2 Unknown |9
11. How old were you when your periods stopped completely?
 Indicate age in years 999=unknown

"ESTROGEN is a female hormone that may be taken after a hysterectomy or menopause."

12. 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 (go to Q15)

- a) If "YES," are you still taking estrogen? Yes ☐1 (go to Q12b) No ☐2

- i) If "No," why did you stop taking estrogen? YES NO UNKNOWN

Caused Bleeding ☐1 ☐2 ☐9

Made breasts tender ☐1 ☐2 ☐9

Made you feel bloated ☐1 ☐2 ☐9

Made you feel "funny," didn't like the way you felt ☐1 ☐2 ☐9

Do not like taking any medicines ☐1 ☐2 ☐9

Too expensive ☐1 ☐2 ☐9

Doctor's advice ☐1 ☐2 ☐9

Concerned about long-term side effects ☐1 ☐2 ☐9

Other _____

- b) Do/Did you use estrogen for YES NO NOT SURE

i) post surgery (hysterectomy and removal of ovaries) ☐1 ☐2 ☐9

ii) relief of menopause symptoms ☐1 ☐2 ☐9

iii) prevent bone loss ☐1 ☐2 ☐9

iv) protect against heart disease ☐1 ☐2 ☐9

v) doctor's advice ☐1 ☐2 ☐9

13. How old were you when you started using estrogen? Indicate age in years.

14. 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)

15. Did the participant complete the interview?

Yes, completed the interview ☐1

No, refused all questions ☐2

16. Interviewer:

17. Date of interview: / /

mo day yr

THE STRONG HEART STUDY III — 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

Carry on | | | 2 (go to Section B)

(Record "stop or slow down" if subject carries on after taking nitroglycerine.)

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

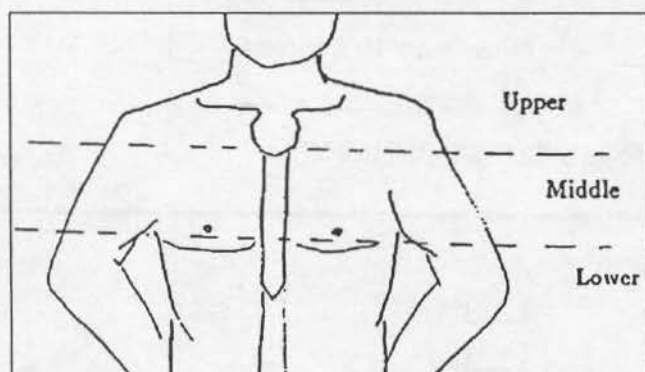
More than 10 minutes | | | 2 (go to Section B)

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)

| | | 1

| | | 2

Sternum (lower)

| | | 1

| | | 2

Left anterior chest

| | | 1

| | | 2

Left arm

| | | 1

| | | 2

Other: _____

| | | 1

| | | 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 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: ☐|1 ☐|2 ☐|3

21. Date of interview: ☐|1 ☐|2 ☐|3 / ☐|4 ☐|5 ☐|6 / ☐|7 ☐|8 ☐|9 ☐|10
mo day yr

**THE STRONG HEART STUDY III — FAMILY STUDY
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
- 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
8. Do you ever have to stop for breath after walking 100 yards (the length of a football field) or after a few minutes on level ground? Yes |1 No |2

9. Are you too breathless to leave the house or
breathless after dressing or undressing? Yes ☐1 No ☐2
10. Did you have any lung trouble before the age of 16? Yes ☐1 No ☐2
11. Have you ever been told you snore? Yes ☐1 No ☐2
-

12. Did the participant complete the interview?

Yes, completed the interview ☐1

No, refused all questions ☐2

13. Interviewer: ☐☐☐☐

14. Date of interview:

☐☐☐mo / ☐☐☐day / ☐☐☐☐☐☐yr

**THE STRONG HEART STUDY III — FAMILY STUDY
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
PHYSICAL EXAMINATION**

SHS Family I.D. | | | | | | | |

SHS. I.D.: | | | | | | | |

I. TOBACCO, CAFFEINE, AND ALCOHOL USE*Before examinations start, check TOBACCO AND CAFFEINE USE*

"Tobacco, alcohol, caffeine and activity levels can change the results of the examinations and laboratory tests we will do today. Because of this, we will ask you a few questions about them."

1. Have you smoked or used chewing tobacco or snuff within the last 4 hours? Yes | | |1 No | | |2 (*skip to Q2*)
 - a) How long ago did you last smoke or last use chewing tobacco or snuff? | | | | |
Specify the lag by hours. # hours
 - b) If less than an hour, specify the minutes. | | | | |
minutes
2. How many alcoholic drinks have you had in the last 24 hours? | | | | |
(0 = None, 999 = Refused) # of drinks
3. Have you done any vigorous physical activity in the last 24 hours? Yes | | |1 No | | |2
4. Have you had any coffee, tea, caffeinated soft drink or chocolate within the last 4 hours?
Yes | | |1 No | | |2 (*skip to Instruction below*)
 - a) How long ago did you last have any coffee, tea, caffeinated soft drink or chocolate? Specify the lag by hours. | | | | |
hours
 - b) If less than an hour, specify the minutes | | | | |
minutes

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. If you *must* use any of these, please tell us that you did before you leave."

II. EXAMINATION OF EXTREMITIES FOR AMPUTATIONS

5. 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"/> _____

III. BLOOD PRESSURE

6. Right arm circumference, measured in centimeters (cm)
Midway between acromium and olecranon
7. Cuff size (arm circumference in brackets)
 Pediatric (under 24cm) ☐1 Large arm (33-41cm) ☐3
 Regular arm (24-32cm) ☐2 Thigh (>41cm) ☐4
8. Pulse obliteration pressure
9. Seated Blood Pressure: **Systolic BP** **Diastolic BP**
- a) First Blood Pressure Measurement
- b) Second Blood Pressure Measurement
- c) Third Blood Pressure Measurement
10. Were the above blood pressures taken from LEFT arm because of missing right arm or some other reason?
 Yes ☐1 Specify: _____ No ☐2
11. Recorder ID (For the SHS staff who took Bps):

IV. GIRTH MEASUREMENT:

	METRIC SYSTEM (centimeters/cm/kg)	BRITISH SYSTEM inches / pounds
12. Height (Standing)	_ _ _ cm	_ _ _ in
13. Weight	_ _ _ kg	_ _ _ lb
14. Hip circumference	_ _ _ cm	_ _ _ in
15. Waist measurement at umbilicus	_ _ _ cm	_ _ _ in

V. PEDAL PULSES AND EDEMA

	PRESENT	ABSENT	MISSING LIMBS	UNABLE TO ASSESS
16. Right posterior tibial pulse	_ 1	_ 2	_ 3	_ 9
17. Right dorsalis pedis pulse	_ 1	_ 2	_ 3	_ 9
18. Left posterior tibial pulse	_ 1	_ 2	_ 3	_ 9
19. Left dorsalis pedis pulse	_ 1	_ 2	_ 3	_ 9
20. Pedal edema	Absent _ 1	Mild _ 2	Marked _ 3	

VI IMPEDANCE MEASUREMENT

21. a) Was impedance taken? Yes |_|1 (*go to b*) No |_|2
if No, due to: Amputation |_|1 Wound/dressing |_|2 Cast |_|3 Refusal |_|9
Go to Question 22
- b) Taken on left side? Yes |_|1 No |_|2 (*go to c*)
If Yes, due to: Amputation |_|1 Wound/dressing |_|2 Cast |_|3 Refusal |_|9
- c) Resistance |_|_|_| d. Reactance |_|_|_|

VII DOPPLER BLOOD PRESSURE

Doppler blood pressure is measured in the posterior tibial artery. If not audible, use dorsalis pedis. Use left arm if left arm was used for standard blood pressure reading.

0 = neither posterior tibial artery nor dorsalis pedis artery was audible.

888 = participant refuses or if blood pressure is not taken for a medical reason or amputation.

999 = unable to obliterate.

- | | Right arm | Right ankle | Left ankle |
|----------------------------|---------------------------------|--|--|
| 22. a) First systolic B.P. | _ _ _ | _ _ _ | _ _ _ |
| b) Second systolic B.P. | _ _ _ | _ _ _ | _ _ _ |
| c) Location | | Posterior tibial _ 1
Dorsalis pedis _ 2 | Posterior tibial _ 1
Dorsalis pedis _ 2 |
| 23. Was an ECG performed? | Yes _ 1 | No _ 2 | |
| 24. Was breath CO done? | Yes _ 1 (<i>go to a</i>) | No _ 2 (<i>go to Q25</i>) | |
| a) Ambient: | _ _ CO[ppm]: _ _ _ | _ _ _ | _ _ _ |
| | Ambient valid entries: -9 to +9 | 1st | 2nd 3rd 4th |
- CO: valid entries Generally 0 to 99 (*usually only the the 1st and 2nd entries will be completed*)

VIII. ADMINISTRATIVE INFORMATION

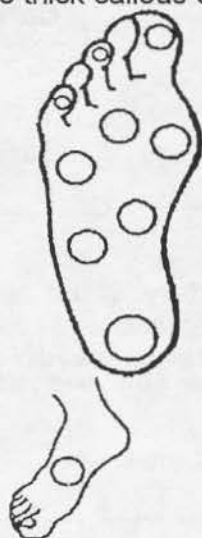
25. Did the participant complete the interview?
 Yes, completed the interview |_|1 No, refused all questions |_|2
26. SHS Code of person completing this form |_|_|_|
27. Date of Examination: |_|_|/|_|_|/|_|_|
 mo day yr

THE STRONG HEART STUDY III — FAMILY STUDY

DIABETIC FOOT SCREEN

SHS Family I.D. SHS. I.D.: IHS Chart Number

1. Is there an ulcer on:
- a) Right foot? Yes 1 No 2
- b) Left foot? Yes 1 No 2
2. Is there a history of foot ulcer? Yes 1 No 2
3. Is either foot numb? Yes 1 No 2
4. Label: Sensory level with a "+" if the participant can feel the 10 gram filament and "-" if he/she cannot feel the 10 g filament. Test each site only once. Testing may not be accurate in areas where thick callous or bunion is present.



	POSITIVE	NEGATIVE
a. Right top	<input type="text"/> 1	<input type="text"/> 2
b. Right large toe	<input type="text"/> 1	<input type="text"/> 2
c. Right middle toe	<input type="text"/> 1	<input type="text"/> 2
d. Right small toe	<input type="text"/> 1	<input type="text"/> 2
e. Right sole front	<input type="text"/> 1	<input type="text"/> 2
f. Right sole right	<input type="text"/> 1	<input type="text"/> 2
g. Right sole left	<input type="text"/> 1	<input type="text"/> 2
h. Right sole back right	<input type="text"/> 1	<input type="text"/> 2
i. Right sole back left	<input type="text"/> 1	<input type="text"/> 2
j. Right heel	<input type="text"/> 1	<input type="text"/> 2

5. Unable to measure due to medical reasons? Yes 1 No 2
(If the right foot has been amputated, conduct exam on the left foot)

6. Measured on left foot? Yes 1 No 2

- a) If "Yes," due to right foot:

Amputation 1 Wound/dressing 2 Cast 3 Refusal 8

7. RESULTS: a. Number of positive answers
- b. Number of sites tested

8. Did the participant complete the interview?

Yes, completed the interview 1

No Foot Exam 2

9. Examined by:

10. Date of Examination:

mo day yr

THE STRONG HEART STUDY III — FAMILY STUDY
GTT 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. Time of collection of urine sample _____:_____
6. Was participant given 75 gram glucose beverage? Yes |1 No |2
 - a) If Yes, Time the 75 gram glucose beverage was consumed _____:_____
 - b) If No, why did participant not have OGTT? *Check the appropriate answer(s)*
 - i) diabetes, on insulin treatment
 - ii) diabetes, on oral agent
 - iii) One Touch > 225 mg/dl
 - iv) refusal to have OGTT done
7. Time of 2-hr blood sample _____:_____
8. If the participant vomited after the glucose beverage was given, check here.

If "Yes," when? (*Indicate the time*): _____

Comments: _____
9. SHS Code of person completing this form
10. Today's Date / /

mo day yr

THE STRONG HEART STUDY III - FAMILY STUDY

RISK FACTOR KNOWLEDGE QUESTIONS

SHS Family I.D. | | | | | | | |

SHS. I.D.: | | | | | | | |

1. How is this questionnaire administered?

By interviewer | | | 1

By self | | | 2

Refused | | | 8

This is a list of things which may or may not affect a person's chances of getting heart disease. After you read each one, answer as to how much you think it affects a person's chances of getting heart disease.

		Does Not Increase Risk	Increases Risk	Don't Know /Not Sure
2.	Cigarette Smoking?	0	1	9
3.	High Cholesterol?	0	1	9
4.	High Blood Pressure?	0	1	9
5.	Diabetes?	0	1	9
6.	Worry, Anxiety, or Stress?	0	1	9
7.	Being very overweight?	0	1	9
8.	Eating a diet high in animal fat? (For example, foods that contain red meat, cheese, butter, lard, etc.)	0	1	9
9.	Family history of heart disease?	0	1	9
10.	Not exercising regularly?	0	1	9

11. Interviewer

| | | | |

12. Date completed

| | | | | / | | | | | / | | | | |
mo day yr

THE STRONG HEART STUDY III — FAMILY STUDY

QUALITY OF LIFE¹

SHS Family I.D. | | | | | | | |

SHS. I.D.: | | | | | | | |

How is this questionnaire administered?

By interviewer | | | 1

By self | | | 2

Refused | | | 8

1. In general, would you say your health is: (Please Check Only One)

Excellent..... | | | 1

Very good..... | | | 2

Good..... | | | 3

Fair..... | | | 4

Poor..... | | | 5

2. Compared to one year ago, how would you rate your health in general, now?

(Please Check Only One)

Much better than one year ago..... | | | 1

Somewhat better than one year ago..... | | | 2

About the same..... | | | 3

Somewhat worse than one year ago..... | | | 4

Much worse than one year ago..... | | | 5

The following items are about activities you might do during a typical day.

Does your health now limit you in these activities? If so, how much?

(Please Circle One Number Per Line)

	Yes, Limited a Lot	Yes Limited a Little	No Not Limited at All
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.....	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.....	1	2	3
5. Lifting or carrying groceries.....	1	2	3
6. Climbing several flights of stairs.....	1	2	3
7. Climbing one flight of stairs.....	1	2	3
8. Bending, kneeling, or stooping.....	1	2	3
9. Walking more than a mile.....	1	2	3
10. Walking several blocks.....	1	2	3
11. Walking one block.....	1	2	3
12. Bathing or dressing yourself.....	1	2	3

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

(Please Check One Answer Per Line)

- | | <u>Yes</u> | <u>No</u> |
|---|----------------------------|----------------------------|
| 13. Cut down on the amount of time you spend on work or other activities..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 14. Accomplish less than you would like..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 15. Were limited in the kind of work or other activities.... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 16. Had difficulty performing the work or other activities (for example, it took extra effort)..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

(Please Check One Answer Per Line)

- | | <u>Yes</u> | <u>No</u> |
|---|----------------------------|----------------------------|
| 17. Cut down on the amount of time you spend on work or other activities..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 18. Accomplish less than you would like..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 19. Didn't do work or other activities as carefully as usual..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

20. During the PAST 4 WEEKS, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups

(Please Check One Answer)

- | | |
|------------------|----------------------------|
| Not at all..... | <input type="checkbox"/> 1 |
| Slightly..... | <input type="checkbox"/> 2 |
| Moderately..... | <input type="checkbox"/> 3 |
| Quite a bit..... | <input type="checkbox"/> 4 |
| Extremely..... | <input type="checkbox"/> 5 |

21. How much BODILY pain have you had during the PAST 4 WEEKS?

(Please Check One Answer)

- | | |
|------------------|----------------------------|
| None..... | <input type="checkbox"/> 1 |
| Very mild..... | <input type="checkbox"/> 2 |
| Mild..... | <input type="checkbox"/> 3 |
| Moderate..... | <input type="checkbox"/> 4 |
| Severe..... | <input type="checkbox"/> 5 |
| Very severe..... | <input type="checkbox"/> 6 |

22. 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..... | <input type="checkbox"/> 1 |
| Slightly..... | <input type="checkbox"/> 2 |
| Moderately..... | <input type="checkbox"/> 3 |
| Quite a bit..... | <input type="checkbox"/> 4 |
| Extremely..... | <input type="checkbox"/> 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 Circle 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
23.	Did you feel full of pep?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
24.	Have you been a very nervous person?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
25.	Have you felt so down in the dumps that nothing could cheer you up?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
26.	Have you felt calm and peaceful?	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
27.	Did you have a lot of energy?....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
28.	Did you feel downhearted and blue?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
29.	Did you feel worn out?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
30.	Have you been a happy person?..	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6
31.	Did you feel tired?.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5	<input type="text"/> 6

32. 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.....	<input type="text"/> 1
Most of the time.....	<input type="text"/> 2
Some of the time.....	<input type="text"/> 3
a Little of the time.....	<input type="text"/> 4
None of the time.....	<input type="text"/> 5

How TRUE or FALSE is each of the following statements?

(Please Circle One Number Per Line)

		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33.	I seem to get sick a little easier than other people.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5
34.	I am as healthy as anybody I know.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5
35.	I expect my health to get worse..	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5
36.	My health is excellent.....	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5

37. Interview conducted in:

English

1

Native language

2 Specify: _____

Other

3 Specify: _____

38. Interviewer

39. Date completed

/ /
mo day yr

STRONG HEART STUDY III — FAMILY STUDY

CULTURAL FACTORS QUESTIONNAIRE

SHS Family I.D. SHS. I.D.:

1. How is this questionnaire administered?

By interviewer |1 By self |2 Refused |8

Traditional Values/Culture:

2. Can you speak your native language?
(interviewer should specify the language)? _____

Yes, fluently |1 Yes, but not fluently |2 No |3 (*Skip to Q4*)

3. How often do you speak your native language ? (Please read options)

Always |1 Almost always |2 Often |3
Seldom |4 Never |5 Not applicable |6

The next several questions are about your own native lifestyle.

4. How much do you identify yourself with your own native culture?

Not At All |1 A Little |2 Some |3 A Lot |4

5. How much do you identify yourself with non-Indian culture?

Not At All |1 A Little |2 Some |3 A Lot |4

6. How comfortable do you feel in your own native culture?

Not At All |1 A Little |2 Some |3 A Lot |4

7. How comfortable do you feel in the non-Indian culture?

Not At All |1 A Little |2 Some |3 A Lot |4

8. Interviewer

9. Date completed / /
- mo day yr

STRONG HEART STUDY III — FAMILY STUDY

MODIFIABLE ACTIVITY QUESTIONNAIRE

SHS Family I.D. SHS. I.D.: 1. Please check all activities listed below that you have done *more than 10 times* in the past year:

Jogging (outdoor, treadmill).....	<input type="checkbox"/>	1	Football/Soccer.....	<input type="checkbox"/>	13	Stair Master....	<input type="checkbox"/>	25
Swimming (laps, snorkeling).....	<input type="checkbox"/>	2	Racquetball/Handball/Squash..	<input type="checkbox"/>	14	Hiking.....	<input type="checkbox"/>	26
Bicycling (stationary, outdoor).....	<input type="checkbox"/>	3	Horseback riding.....	<input type="checkbox"/>	15	Tennis.....	<input type="checkbox"/>	27
Softball/Baseball.....	<input type="checkbox"/>	4	Hunting.....	<input type="checkbox"/>	16	Golf.....	<input type="checkbox"/>	28
Canoeing/Rowing/Kayaking.....	<input type="checkbox"/>	5	Fishing.....	<input type="checkbox"/>	17	Volleyball.....	<input type="checkbox"/>	29
Snow skiing (Nordic, X-country, dnhill)...	<input type="checkbox"/>	6	Aerobic Dance/Step aerobic....	<input type="checkbox"/>	18	Jumping rope..	<input type="checkbox"/>	30
Strength/Weight training.....	<input type="checkbox"/>	7	Water aerobics.....	<input type="checkbox"/>	19	Bowling.....	<input type="checkbox"/>	31
Skating (roller, ice, blading).....	<input type="checkbox"/>	8	Dancing (Indian).....	<input type="checkbox"/>	20	Snowshoeing..	<input type="checkbox"/>	32
Martial Arts (karate, judo, etc.).....	<input type="checkbox"/>	9	Dancing (square, line, ballroom).	<input type="checkbox"/>	21	Yoga.....	<input type="checkbox"/>	33
Calisthenics/Toning exercises.....	<input type="checkbox"/>	10	Gardening/Yardwork.....	<input type="checkbox"/>	22	Rodeo.....	<input type="checkbox"/>	34
Wood chopping.....	<input type="checkbox"/>	11	Badminton.....	<input type="checkbox"/>	23	Rock climbing.	<input type="checkbox"/>	35
Walking for exercise..... (outdoor, indoor at mall or fitness center/treadmill)	<input type="checkbox"/>	12	Water/coal hauling.....	<input type="checkbox"/>	24	Basketball.....	<input type="checkbox"/>	36

For each activity you checked above, check the months during which you participated in those activities over the past year (12 months), then estimate the average amount of time you spent in each activity

Activity No.	J a n	F e b	M a r	A p r	M a y	J u n	J u l	A u g	S e p	O c t	N o v	D e c	Average of times per month	Average of minutes each time

2. In general, how many *HOURS* per *DAY* do you usually spend watching TV?
of hours

3. Over this past year, have you spent more than one week confined to a bed or chair as a result of an injury, illness or surgery? Yes ☐ 1 No ☐ 2
If "Yes," how many weeks over this past year were you confined to a bed or chair?
of weeks

4. Do you have difficulty doing any of the following activities?
- a. Getting in or out of a bed or chair. Yes ☐ 1 No ☐ 2
- b. Walking across a small room without resting Yes ☐ 1 No ☐ 2
- c. Walking for 10 minutes without resting Yes ☐ 1 No ☐ 2
5. Did you ever compete in an individual or team sport (not including any time spent in sports performed during school physical education classes)? Yes ☐ 1 No ☐ 2
- If "Yes," how many total years did you participate in competitive sports? # of years
6. Have you had a job for more than one month over this past year, from month of last year to month of this year?
- List all jobs that the individual held over the past year, for more than one month. Account for all 12 months of the past year. If unemployment/disabled/retired/homemaker/student during all or part of the past year, list as such and probe for job activities of a normal 8-hour work-day, 5-day, work-week.

Out of the total number of "Hrs/Day," the individual reported working at this "job," how much of this time was usually spent sitting? Enter this number in "Hrs Sitting" col., then place a check (/) in the category which best describes their job activities when they were not sitting.									
Job Name	Job Code	Walk/bicycle to/from work	AVG JOB SCHEDULE			Hrs spent sitting at work	Check the category that best describes job activities when not sitting		
		Min/Day	Mos/Yr	Day/Wk	Hrs/Day	Hrs/Day	A	B	C

Category A

(Includes all sitting activities)

Sitting
 Standing still w/o heavy lifting
 Light cleaning - ironing, cooking, washing dusting
 Driving a bus, taxi, tractor
 Jewelry making/weaving
 General office work
 Occasional/short distance walking

Category B

(includes most indoor activities)

Carrying light loads
 Continuous walking
 Heavy cleaning - mopping, sweeping, scrubbing, vacuuming
 Gardening - planting, weeding
 Painting/Plastering
 Plumbing/Welding
 Electrical work
 Sheep herding

Category C

(heavy industrial work, outdoor construction, farming)

Carrying moderate to heavy loads
 Heavy construction
 Farming - hoeing, digging, mowing, raking
 Digging ditches, shoveling
 Chopping (axe), sawing wood
 Tree/pole climbing
 Water/coal/wood hauling

Job CodesNot employed outside the home:

1. Student 2. Home Maker
 3. Retired 4. Disabled
 5. Unemployed

Employed (or volunteer):

6. Armed Services
 7. Office worker
 8. Non-office worker

Interviewer Date (of interview): / /

THE STRONG HEART STUDY III **CBC Results**

SHS Family Study ID | | | | | | | |

SHS ID number:

| | | | | |

Each Center's Results May Appear in Different Order, Please Be Careful When Entering the Results

- | | | |
|-----|-----------------------------------|---|
| 1. | WBC ($10^9/L$) | . |
| 2. | RBC ($10^{12}/L$) | . |
| 3. | HGB (g/dL) | . |
| 4. | HCT (%) | . |
| 5. | MCV (fL) | . |
| 6. | MCH (pg) | . |
| 7. | MCHC (g/dL) | . |
| 8. | RDW (%) | . |
| 9. | Platelet count (PLT .. $10^9/L$) | |
| 10. | MPV (fL) | . |

DIFFERENTIAL

Each Center's Results May Appear in Different Order, Please Be Careful When Entering the Results

- | | | |
|-----|--|--|
| 11. | NEUT (%) | . |
| 12. | LYMPH (%) | . |
| 13. | MONO (%) | . |
| 14. | EOS (%) | . |
| 15. | BASO (%) | . |
| 16. | Code number of person completing this form | |
| 17. | Date of data collection | / /
mo day yr |

STRONG HEART STUDY III

FAMILY STUDY

Screening for Pregnancy and Lactation
WOMEN ONLYSHS Family Study ID SHS ID number: *Administered to women < 50 years of age at time consent is obtained. It can be self-administered.*

1. Are you pregnant? Yes 1 No 2 Not Sure 9
2. When was your last menstrual period? //
If unknown, leave the boxes blank mo day yr
3. When did your last pregnancy end? //
Never pregnant = 01-01-1001 mo day yr
Currently pregnant = 01-01-1900
4. Are you now breast feeding? Yes 1 No 2
5. If "yes", how long you have been breast feeding (in months)?

Women who think they may be pregnant should not be examined or have blood drawn, because pregnancy changes the blood lipids. Women who think they may be pregnant should be referred for prenatal care. Women can participate in the Family Study six weeks post partum even if they are lactating.

6. Code number of person completing this form
7. Date of data collection //
mo day yr

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

ID number:

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 ☐ 9 (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?

[illegible]

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 only. 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
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

APPENDIX 4 - THE STRONG HEART STUDY III **DIETARY INTAKE - 24-HOUR RECALL**

Participant's ID Number (SHS) <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	Date of Visit <div style="display: flex; justify-content: space-around; align-items: center;"> <div>month / day / year</div> </div>	Social Security Number <div style="display: flex; justify-content: space-around; align-items: center;"> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> </div>	Date of Birth <div style="display: flex; justify-content: space-around; align-items: center;"> <div>month / day / year</div> </div>	Sex: 1=Male <input type="checkbox"/> 2=Female <input type="checkbox"/>
--	--	---	--	--

Participant's Name <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	Initials <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	Intake Day 1=Sun 2=Mon 3=Tue 4=Wed 5=Thu 6=Fri 7=Sat	Interviewer's opinion of information 1=Reliable 2=Unable to recall one or more meals *3=Unreliable for other reasons	Was amount eaten 1=Typical? 2=Considerably less than usual? *3=Considerably more than usual?	Did you take any supplements (vitamins, minerals, etc)? 1=No 2=Yes (If "Yes," describe under <i>Food and Beverage</i> , below)
Interviewer's ID <div style="display: flex; justify-content: space-around; align-items: center;"> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> </div>		<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>

Prepared: 1=At home 2=Restaurant 3=Other	<i>Explain starred (*) items in the COMMENTS space provided below</i>
---	---

Line No.	Time eaten a=a.m., p=p.m.				Salt added in preparation? 1=No, 2=Yes, 9=Unknown	Food and Beverage	amt.	Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>	Complete Description
	Hour	Minute							
01									
02									
03									
04									
05									

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant 3=Other						Participant's ID Number (SHS)			
	Time eaten a=a.m., p=p.m.					Salt added in preparation? 1=No, 2=Yes, 9=Unknown		Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>		
	Hour	Minute				Food and Beverage	amt.		Complete Description	
06										
07										
08										
09										
10										
11										
12										
13										
14										
15										
16										
17										

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant, 3=Other							Participant's ID Number (SHS)								
	Time eaten a=a.m., p=p.m.							Salt added in preparation? 1=No, 2=Yes, 9=Unknown				Was fat added in preparation? 1=No, 2=Yes, 9=Unknown Please note type of fat used, in description				
	Hour		Minute					Food and Beverage		amt.		Complete Description				
06																
07																
08																
09																
10																
11																
12																
13																
14																
15																
16																
17																

COMMENTS (Give line no. when appropriate):

APPENDIX E

STRONG HEART STUDY PHASE-III

Questionnaires and Data Forms

THE STRONG HEART STUDY III CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PERSONAL INTERVIEW FORM I

ID number:

Community name: Community Code:

Social Security Number:

A. DEMOGRAPHIC INFORMATION:

1. Is this still your full name (*Last, First, Middle*)?
Yes ☐ 1 No ☐ 2 (*If No, what is your current name?*)

Last: New Last:

First: New First:

Middle: New Middle:

Nickname/Other Name:

2. To which IHS and non-IHS Hospital/Clinic do you usually go? *List the one they go to most often first. Give names and codes. Do you want your Strong Heart Study report sent to the named hospitals?*

	Hospital	Chart number	IHS 1=yes, 2=no	Hospital Code	Send Report 1=yes, 2=no
a.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

3. What is your marital status?
(*Enter up to 3 options with the most recent one in the left-most box*)

Current 2nd 3rd

- 1= Never married 4 = Separated
2 = Currently married 5 = Widowed
3 = Divorced 6= Adult roommate/partner/significant other

4. If married, what is your husband's/wife's name?
(*if not married, skip to Q6*)

Last

First

Middle

5. Did your husband/wife also participate in the Strong Heart Study examination?

Yes | 1

No | 2

6. Is this your current mailing address?

Yes ☐ No ☐

No 2

(If No, what is your current mailing address?)

- a. Street/PO Box

- b. City/town

- c. County

- d. State and Zip code

7. Is this your residential address? (if different from mailing address)

Yes | 1

No | 2

(If No, What is your current address?)

- a. Street/PO Box

- b. City/town

- c. County

- d. State and zip code

8. What is your home telephone number?

Or at what telephone number can we reach you or leave a message?

area code

0 = Unlisted

9 = No phone

9. What is your work telephone number?

area code

0 = Same as home phone

9 = Not applicable/unknown

**THE STRONG HEART STUDY - PHASE III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

PERSONAL INTERVIEW FORM II

ID number:

A. WEIGHT SATISFACTION

10. Are you satisfied with your present weight?

Yes ☐1 (*skip to Section B*)No ☐2Unknown/unsure ☐9

11. Do you want to lose or gain weight?

Lose ☐1Gain ☐2

12. How do you plan to do this?

a) Eating Less ☐1 More ☐2 No change ☐3b) Physical activity Less ☐1 More ☐2 No change ☐3c) Medication Yes ☐1 No ☐2d) Other, please specify: Yes ☐1 No ☐2**B. PHYSICAL ACTIVITY**

13. Have you had any difficulty getting in or out of a bed or chair?

Yes ☐1 No ☐2

14. Since your last SHS exam have you ever spent any time confined to a bed or chair as a result of an injury or an illness for a period greater than one month?

Yes ☐1 No ☐2

a) If "Yes," how many weeks were you confined to a bed or chair?

15. Do any of the following prevent you from exercising as much as you would like?

*(choose all that apply)*a. Arthritis, or other health conditions Yes ☐1 No ☐2b. Amputation Yes ☐1 No ☐2c. Difficulty breathing Yes ☐1 No ☐2d. Conditions unsafe for walking/exercising Yes ☐1 No ☐2e. No exercise facility available Yes ☐1 No ☐2f. Not interested in exercise Yes ☐1 No ☐2g. Other, please specify: _____ Yes ☐1 No ☐216. Think about physical activities that require a *mild effort* such as walking, gardening, yardwork fishing, softball, ect...During a typical week for you, how much time do you spend performing activities that require a *mild effort*?Rarely ☐1Occasionally ☐2
(1 - 2 times per week)Often ☐3
(3 or more times per week)17. Think about physical activities that are *relatively strenuous* (running and other strenuous sports, digging, chopping wood, heavy construction, hauling hay, fixing fences, etc...).

During a typical week for you, how much time do you spend performing activities that are

relatively strenuous? Rarely ☐1Occasionally ☐2
(1 - 2 times per week)Often ☐3
(3 or more times per week)

C. DENTURE AND EATING PROBLEMS

18. How many natural teeth do you have? All 1 Most 2 Some 3 None 4
19. Describe how you chew your food. (Please *choose only ONE*):
- I use natural teeth to chew. 1 I use natural teeth with caps/crowns to chew. 2
- I have natural teeth and a denture or partial. I use them both together to chew. 3
- I use dentures to chew. 4 I chew with my gums. 5
20. Rate your ability to chew food (Please *choose only ONE*) Good 1 Fair 2 Poor 3

D. FAMILY INCOME:

21. Does your household income meet your family's needs?
- Yes ☐1 No ☐2 Unsure ☐9
22. What is your MAIN daily activity(s)? (Please list three main activities)
- main 2nd 3rd
- 1 = Caring for Family 4 = Looking for Work
2 = Working for Pay/Profit 5 = Retired/elderly
3 = Going to School 6 = Other, specify: _____
23. Do you receive any income from...?
- | | Yes | No |
|---|----------------------------|----------------------------|
| 1) Wages/Salary | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 2) Profits - business | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 3) Winnings from gaming/lottery | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 4) Unemployment benefits/
workmen's comp/welfare | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 5) Retirement benefits | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 6) Social Security benefits | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 7) Lease payment | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 8) Other, specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
24. Of the choices in Question 23, which source provides the most income?
(Please choose only one: If missing/refused/unknown, code 9)
- ☐
25. 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
-
26. Which of the following categories best describes your annual household income from all sources?
(Please check only one)
- | | | | |
|----------------------|----------------------------|----------------------|----------------------------|
| less than \$5,000 | <input type="checkbox"/> 1 | \$25,000 to \$35,000 | <input type="checkbox"/> 6 |
| \$5,000 to \$10,000 | <input type="checkbox"/> 2 | \$35,000 to \$50,000 | <input type="checkbox"/> 7 |
| \$10,000 to \$15,000 | <input type="checkbox"/> 3 | over \$50,000 | <input type="checkbox"/> 8 |
| \$15,000 to \$20,000 | <input type="checkbox"/> 4 | don't know/not sure | <input type="checkbox"/> 9 |
| \$20,000 to \$25,000 | <input type="checkbox"/> 5 | refused | <input type="checkbox"/> 0 |

E. TOBACCO:

27. Do you smoke cigarettes? Yes ☐1 No ☐2 (go to Q32)
28. On the average, how many cigarettes do 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?
29. 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) other, specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
30. On the occasions that your smoking increased, how many cigarettes do/did you smoke per day?
31. Would you like to change your smoking habit? Yes ☐1 No ☐2 (skip to Q32)
- a) If yes, how?
- | | 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 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| iv) Quit | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| v) Other, please specify: _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

CURRENT CIGARETTE SMOKERS SKIP TO Q34

32. During your lifetime have you smoked 100 cigarettes or more total?
 Yes ☐1 No ☐2 (skip to section Q34)
33. Did you quit smoking since your last SHS exam?
 Yes ☐1 No ☐2 (skip to section Q34)
- a) If you quit since your last SHS exam when did you quit? (just the year)
- b) What were the reason(s) you quit? Answer all that apply:
- | | | |
|---------------------------------|--------------------------------|-------------------------------|
| i) Doctor's advice | Yes <input type="checkbox"/> 1 | No <input type="checkbox"/> 2 |
| ii) Health concerns | Yes <input type="checkbox"/> 1 | No <input type="checkbox"/> 2 |
| iii) Expenses | Yes <input type="checkbox"/> 1 | No <input type="checkbox"/> 2 |
| iv) Per family pressure | Yes <input type="checkbox"/> 1 | No <input type="checkbox"/> 2 |
| v) Other, please specify: _____ | Yes <input type="checkbox"/> 1 | No <input type="checkbox"/> 2 |
34. Whether or not you smoke, on the average, how many hours a day are you exposed to the smoke of others?
 (if none, please fill in zero: enter 1 hour if 30 min. or more, enter 0 if less than 30 min.)

F. ALCOHOL:

"The next few questions are about the use of beer, wine, or liquor".

READ THE FOLLOWING TO THE PARTICIPANT:

"We are asking these questions about alcohol use, because alcohol consumption may be related to heart disease. We want to assure you that this information is strictly confidential. The Strong Heart Study will use this information only to determine to what extent alcohol use is a risk factor for heart disease. This information is analyzed as batches of numbers without any names. Please report your alcohol use as accurately as possible."

35. Have you consumed alcoholic beverages since your last SHS exam?
 Yes ☐1 No ☐2 (*this section of the interview is finished, go to Section G*)
- a) If yes, when was your last drink? (*check one box only*)
- ☐1 Within the last week
☐2 Within the last month
☐3 Within the last year. Number of months ago?
☐4 More than a year ago. (*this section of the interview is finished, go to Section G*)
36. How many alcoholic drinks do you have in a typical week? (*see chart below*)
 One Drink = 12 oz of Beer = 4 oz of Wine = 1 oz of Liquor.
 Please choose the type(s) of beverage and write in the Number of Containers under the appropriate volume.

Type of Drink	Container Size (Ounces)										
	1 shot	1.5 jigger	4 glass	8 tumbler	12 can/btl	16(pt) can	26 fifth	32-34 qt. btl	40 btl	64 (2 gal) jug	128 (gal) jug
Beer	X	X					X			X	X
Wine	X	X							X		
Liquor									X		

* Quart = 32 oz, Liter = 33.8 oz

37. How many days in a typical month do you have at least one drink?
 (*indicate the number of days per month*)
38. 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)
39. When you drink more than your usual amount, how many drinks do you have?
 (*# Drinks*)
 a) How many times in a month?
 (# Times/Month)
40. How many times during the **PAST MONTH** did you have 5 or more drinks on an occasion? (*Enter zero if subject has quit drinking more than one month ago.*)
41. How many times during the **PAST YEAR** did you have 5 or more drinks on an occasion? Indicate times per year. (*Enter zero if subject has quit drinking more than one year ago.*)

42. Within the last year, have you ever consumed other substances to get the effects of alcohol, such as...
- | | Yes | No |
|-----------------|----------------------------|----------------------------|
| a. Mouth wash | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| b. Cough syrup | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| c. Lysol | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| d. Hair spray | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| e. Other, _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

G. ADMINISTRATIVE INFORMATION:

43. How reliable was the participant in completing the questionnaire?

Very reliable	<input type="checkbox"/> 1
Reliable	<input type="checkbox"/> 2
Unreliable	<input type="checkbox"/> 3
Very unreliable	<input type="checkbox"/> 4
Uncertain	<input type="checkbox"/> 9

44. Did the participant complete the interview?

Yes, completed the interview	<input type="checkbox"/> 1
No, refused all questions	<input type="checkbox"/> 2

45. Interviewer:

☐ ☐ ☐

44. Date of interview:

☐ ☐ ☐ / ☐ ☐ ☐ / ☐ ☐ ☐

**THE STRONG HEART STUDY - PHASE III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**

GAMBLING QUESTIONS

SHS. I.D.:

Now we will ask you a few questions about gambling, since more Indian communities have casinos and gambling may have an impact on the health of these communities.

1. Do you work at a casino/bingo hall? Yes 1 No 2
2. Overall, what effects do you think gambling has on the following:
 - a. Tribal government, Beneficial 1 Harmful 2 No effects 3
 - b. Tribal people, Beneficial 1 Harmful 2 No effects 3
 - c. You personally Beneficial 1 Harmful 2 No effects 3
3. What type(s) of gambling have you participated in during the last year?
 - a) Slot machines? Yes 1 No 2
(If Yes, how often. Please check)
1 1 or more times a week 2 1 or more times a month 3 Less than once a month
 - b) Lottery? Yes 1 No 2
(If Yes, how often. Please check)
1 1 or more times a week 2 1 or more times a month 3 Less than once a month
 - c) Bingo? Yes 1 No 2
(If Yes, how often. Please check)
1 1 or more times a week 2 1 or more times a month 3 Less than once a month
 - d) Card games (i.e. poker)? Yes 1 No 2
(If Yes, how often. Please check)
1 1 or more times a week 2 1 or more times a month 3 Less than once a month
 - e) Other, specify: _____ Yes 1 No 2
(If Yes, how often. Please check)
1 1 or more times a week 2 1 or more times a month 3 Less than once a month
(skip to Q9 if person does not gamble)
4. In the past year, have you lost more than you won? Yes 1 No 2
5. In the past year, have you made attempts to control, cut back, or stop gambling? Yes 1 No 2
 - a) If Yes, have your attempts been successful? Yes 1 No 2
6. In the past year, have you had to borrow money to pay basic living expenses (such as food, mortgage/rent), because of gambling losses? Yes 1 No 2
7. When you are gambling, how much alcohol do you drink that day?
of drinks
8. In the past year, what is the largest amount you have bet on any single day? \$ _____
9. Did the participant complete the interview?
 Yes, completed the interview 1 No, refused all questions 2
10. Interviewer:
11. Date of interview: / /
mo day yr

**THE STRONG HEART STUDY III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
MEDICAL HISTORY FORM**

ID number:

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="text"/> 1 | <input type="text"/> 2 | <input type="text"/> 9 |
| 3. Any fractures associated with osteoporosis? | <input type="text"/> 1 | <input type="text"/> 2 | <input type="text"/> 9 |
| If YES, where? _____ | | | |
| 4. Rheumatic heart disease? | <input type="text"/> 1 | <input type="text"/> 2 | <input type="text"/> 9 |
| 5. Gallstones? | <input type="text"/> 1 | <input type="text"/> 2 | <input type="text"/> 9 |
| 6. Cancer, including leukemia and lymphoma? | <input type="text"/> 1 | <input type="text"/> 2 | <input type="text"/> 9 |
| If YES, specify type of cancer: _____ | | | |

7. Diabetes? Yes 1 Impaired glucose tolerance (IGT) 2 No 3 Unknown 9
(if No, or Unknown, skip to Q8)

- a) If YES, do you still have it now?

Yes 1 No 2 Unknown 9

- b) 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*

- c) What type of treatment are you taking for your diabetes? (Check appropriate answer)

- | | YES | NO |
|-----------------------------|------------------------|------------------------|
| i) insulin | <input type="text"/> 1 | <input type="text"/> 2 |
| ii) oral hypoglycemic agent | <input type="text"/> 1 | <input type="text"/> 2 |
| iii) by dietary control | <input type="text"/> 1 | <input type="text"/> 2 |
| iv) by exercise | <input type="text"/> 1 | <input type="text"/> 2 |
| v) do nothing | <input type="text"/> 1 | <input type="text"/> 2 |
| vi) other: _____ | <input type="text"/> 1 | <input type="text"/> 2 |

		YES	NO	UNKNOWN
8.	Has a medical person ever told you that you had kidney failure?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
a)	If YES, are one or both working well now?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
b)	How old were you when you were first told by a medical person that you had kidney failure? <i>Indicate the actual age.</i> Don't know = 999			<input type="text"/>
		YES	NO	UNKNOWN
9.	Are you currently on renal dialysis?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
10.	Have you ever had kidney transplant?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
a)	If YES, is the new kidney working well?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
b)	If NO, are you waiting for a kidney transplant?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
11.	Cirrhosis of the liver?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
12.	LUNG PROBLEMS	YES	NO	UNKNOWN
a.	Emphysema?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
b.	Hay fever?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
c.	Chronic bronchitis?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
d.	Asthma?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
	If YES for asthma, do you still have it now?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
13.	Have you had a heart catheterization? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2			
	<i>(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)</i>			
a)	If Yes, when and where? (record the most recent test)	<input type="text"/> mo / <input type="text"/> day / <input type="text"/> yr		
	hospital/clinic: _____			
14.	Have you ever had a diagnostic exercise test or Treadmill test to check your heart?	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	Unknown <input type="checkbox"/> 9
a)	If Yes, when and where? (record the most recent test)	<input type="text"/> mo / <input type="text"/> day / <input type="text"/> yr		
	hospital/clinic: _____			
SINCE your last SHS exam , that is ____ (mo) ____ (yr), has a doctor told you that you had any of the following conditions? <i>(If more than one episode since Exam II, enter information for the MOST RECENT one in the Exam II - Exam III interval)</i>				
15.	Heart failure?	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	Unknown <input type="checkbox"/> 9
a)	If Yes, when and where ?	<input type="text"/> mo / <input type="text"/> day / <input type="text"/> yr		
	hospital/clinic: _____			
b)	If Yes, do you still have heart failure now ?	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	Unknown <input type="checkbox"/> 9
16.	Heart attack?	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	Unknown <input type="checkbox"/> 9
a)	If Yes, when and where ?	<input type="text"/> mo / <input type="text"/> day / <input type="text"/> yr		
	hospital/clinic: _____			

17. Any other heart trouble? Yes ☐1 No ☐2 Unknown ☐9
If Yes, please specify type: _____
a) If Yes, when and where ? mo day yr
hospital/clinic: _____
18. Stroke? Yes ☐1 No ☐2 Unknown ☐9
If Yes, please specify type: _____
a) If Yes, when and where ? mo day yr
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 ? mo day yr
hospital/clinic: _____
ii) Valvular repair/replacement? Yes ☐1 No ☐2
If Yes, when and where ? mo day yr
hospital/clinic: _____
iii) Pacemaker? Yes ☐1 No ☐2
If Yes, when and where ? mo day yr
hospital/clinic: _____
iv) Other? Yes ☐1 No ☐2
Please specify: _____
If Yes, when and where ? mo day yr
hospital/clinic: _____

C. ACCESS TO MEDICAL CARE:

20. Source of medical care:
- | | In the past 5 years,
have you received
any medical care at: | | What is your
usual source of
medical care:
(Check only ONE) |
|-----------------------------|---|----------------------------|--|
| | Yes | No | |
| a) IHS facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| b) Tribal facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| c) Private facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| d) Private practitioner | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| e) Traditional healer | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| f) VA/military facility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| g) Health maint. org. (HMO) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| h) Other, list _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |
| i) Nowhere | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> |

21. In addition to IHS coverage, what health insurance do you have? (*check all that apply*)
- | | | | |
|--------------------------|----------------------------|---------------------------|----------------------------|
| None | <input type="checkbox"/> 1 | Veteran/military hospital | <input type="checkbox"/> 5 |
| Private health insurance | <input type="checkbox"/> 2 | HMO | <input type="checkbox"/> 6 |
| Medicaid | <input type="checkbox"/> 3 | Other, list: _____ | <input type="checkbox"/> 7 |
| Medicare | <input type="checkbox"/> 4 | | |
22. How do you get to your usual healthcare provider? (*check only one*)
- | | | | |
|---------------|----------------------------|---------------------------------------|----------------------------|
| Myself | <input type="checkbox"/> 1 | Community health representative (CHR) | <input type="checkbox"/> 4 |
| Family member | <input type="checkbox"/> 2 | Paid driver | <input type="checkbox"/> 5 |
| Friend | <input type="checkbox"/> 3 | | |
23. How much does it usually cost, out of pocket, for transportation to your usual healthcare provider? \$ _____
24. On the average, how long does it take you to get to your usual source of medical care?
- | | | | |
|----------------------|----------------------------|-------------------|----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
25. Does your usual source of medical care see patients by appointment?
- Yes ☐1 No ☐2
26. Once you get to your usual source of medical care, how long do you usually have to wait to see a healthcare provider?
- | | | | |
|----------------------|----------------------------|-------------------|----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
27. If you need to be seen before your appointment, can you walk in and be seen?
- Yes ☐1 (*go to a*) No ☐2 (*go to b*)
- a) As a walk-in, how long does it usually take you to be seen by a physician or a physician's assistant?
- | | | | |
|----------------------|----------------------------|-------------------|----------------------------|
| Less than 15 minutes | <input type="checkbox"/> 1 | 45 to 60 minutes | <input type="checkbox"/> 4 |
| 15 to 30 minutes | <input type="checkbox"/> 2 | 1 to 2 hours | <input type="checkbox"/> 5 |
| 31 to 45 minutes | <input type="checkbox"/> 3 | More than 2 hours | <input type="checkbox"/> 6 |
- b) How long does it usually take you to get an extra appointment?
- | | | | |
|------------------|----------------------------|-------------------|----------------------------|
| 2 days or less | <input type="checkbox"/> 1 | 3 to 4 weeks | <input type="checkbox"/> 4 |
| 3 days to 1 week | <input type="checkbox"/> 2 | More than 4 weeks | <input type="checkbox"/> 5 |
| 1 to 2 weeks | <input type="checkbox"/> 3 | | |
28. How much do you have to pay "out-of-pocket" to see your usual healthcare provider for an outpatient visit, *excluding* travel costs? \$ _____

29. Did the participant complete the interview?

Yes, completed the interview ☐1

No, refused all questions ☐2

IS THE PARTICIPANT FEMALE? Yes ☐1 (*go to next page*)

No ☐2

IF THE PARTICIPANT IS MALE, GO TO ROSE QUESTIONNAIRE

30. Interviewer: _____

31. Date of interview:

____/____/____
mo day yr

THE STRONG HEART STUDY III
REPRODUCTION AND HORMONE USE (WOMEN ONLY)

ID number: _____

"The following questions are related to your childbearing organs."

1. Have your menstrual cycles stopped? Yes ☐1 No ☐2 (go to Q5)
2. If Yes, has it stopped for more than 12 months? Yes ☐1 No ☐2
3. Was your menopause natural or did you have surgery? Natural ☐1 Surgery ☐2
 a) If **SURGERY**, was **ONLY** your uterus removed? Yes ☐1 No ☐2 Unknown ☐9
4. How old were you when your periods stopped?
 Indicate the age in years. 999 = unknown _____

"ESTROGEN is a female hormone that may be taken after a hysterectomy or menopause."

5. Except for birth control pills, have you ever taken estrogen (either pills, as a patch or by shot) for any reason? (Estrogen is often called premarin: maybe either purplish brown or yellow football shaped pills) Yes ☐1 No ☐2 (Go to Q8)
 a. If Yes, are you still taking estrogen? Yes ☐1 (go to Q5b) No ☐2
 i. If No, why did you stop taking estrogen?
 It caused bleeding? Yes ☐1 No ☐2
 Made breasts tender? Yes ☐1 No ☐2
 Made me feel bloated? Yes ☐1 No ☐2
 Made you "funny," didn't like the way you felt Yes ☐1 No ☐2
 Do not like taking any medications Yes ☐1 No ☐2
 Too expensive Yes ☐1 No ☐2
 Doctor's advice Yes ☐1 No ☐2
 Concern about long term side effects Yes ☐1 No ☐2
 Other: _____ Yes ☐1 No ☐2
 b. Do/Did you use estrogen for...
 i. post surgery (hysterectomy/removal of ovaries) Yes ☐1 No ☐2 Unknown ☐9
 ii. relief of menopause symptoms Yes ☐1 No ☐2 Unknown ☐9
 iii. prevent bone loss Yes ☐1 No ☐2 Unknown ☐9
 iv. protect against heart disease Yes ☐1 No ☐2 Unknown ☐9
 v. doctor's advice Yes ☐1 No ☐2 Unknown ☐9
6. How old were you when you started using estrogen? Indicate the age in years. _____
7. How many years altogether did you take estrogen? Specify the duration in years.
 If less than 3 months, record 0. If more than 3 months but less than 1 year, record 1. _____

8. Does the participant complete the interview?
 Yes, completed the interview ☐1 No, refused all questions ☐2
9. Interviewer: _____
10. Date of interview: _____
 mo day yr

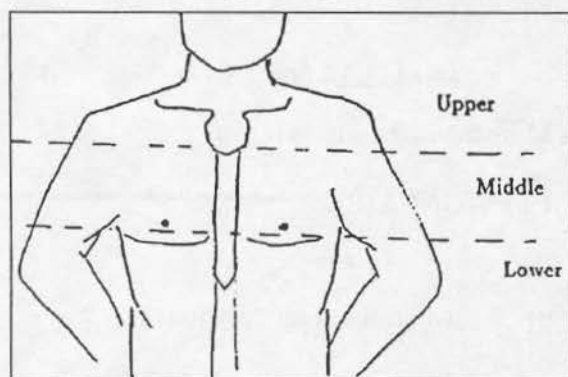
THE STRONG HEART STUDY III

ROSE QUESTIONNAIRE FOR ANGINA AND INTERMITTENT CLAUDICATION

ID number:

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 Carry on 2 (go to Section B)
(Record "stop or slow down" if subject carries on after taking nitroglycerine.)
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.)



- | | | |
|---------------------------|----------------------------|---------------------------|
| Sternum (upper or middle) | Yes <input type="text"/> 1 | No <input type="text"/> 2 |
| Sternum (lower) | Yes <input type="text"/> 1 | No <input type="text"/> 2 |
| Left anterior chest | Yes <input type="text"/> 1 | No <input type="text"/> 2 |
| Left arm | Yes <input type="text"/> 1 | No <input type="text"/> 2 |
| Other: _____ | Yes <input type="text"/> 1 | No <input type="text"/> 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 when you walk uphill, upstairs or hurry?
 Yes ☐1 No ☐2 (go to Q19)
 Never hurries or walks uphill or upstairs ☐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 Question 19) 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. Does 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 STUDY III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
PHYSICAL EXAMINATION**

ID number:

I. TOBACCO, CAFFEINE, AND ALCOHOL USE

Before examinations start, check TOBACCO AND CAFFEINE USE

"Tobacco, alcohol, caffeine and activity levels can change the results of the exams and laboratory tests we will do today. Because of this, we will ask you a few questions about them."

1. Have you smoked or used chewing tobacco or snuff within the last 4 hours?
 - 1= Yes
 - 2= No (*skip to Q2*)
 - a. How long ago did you last smoke or last use chewing tobacco or snuff?

Specify the lag by hours. # hours
 - b. If less than an hour, specify the minutes.

minutes
2. How many alcoholic drinks have you had in the last 24 hours? (*0 = None, 888 = Refused*)
3. Have you done any vigorous physical activity in the last 24 hours? Yes 1 No 2
4. Have you had any coffee, tea, caffeinated soft drink or chocolate within the last 4 hours?
 - Yes 1
 - No 2 (*skip to instructions below*)
 - a. How long ago did you last have any coffee, tea, caffeinated soft drink or chocolate? Specify the lag by hours.

hours
 - b. If less than an hour, specify the minutes

minutes

"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. If you *must* use any of these, please tell us that you did before you leave."

II. EXAMINATION OF EXTREMITIES FOR AMPUTATIONS

5. Are any extremities missing?
 - Yes, 1 *Complete the table on the next page.*
 - No 2 (*skip to Q6*)

If YES to amputation , 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"/> # missing	<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"/> # missing	<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"/> # Missing	<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"/> # Missing	<input type="checkbox"/> _____

III. BLOOD PRESSURE

6. Right arm circumference, measured in centimeters (cm) |_|_|_|
Midway between acromium and olecranon
7. Cuff size (arm circumference in brackets)
 Pediatric (under 24cm) ☐ 1 Large arm (33-41cm) ☐ 3
 Regular arm (24-32cm) ☐ 2 Thigh (>41cm) ☐ 4
8. Pulse obliteration pressure |_|_|_|
9. Seated Blood Pressure:
- | | Systolic BP | Diastolic BP |
|--------------------------------------|-------------------------------|-------------------------------|
| a) First Blood Pressure Measurement | <input type="checkbox"/> _ _ | <input type="checkbox"/> _ _ |
| b) Second Blood Pressure Measurement | <input type="checkbox"/> _ _ | <input type="checkbox"/> _ _ |
| c) Third Blood Pressure Measurement | <input type="checkbox"/> _ _ | <input type="checkbox"/> _ _ |
10. Were the above blood pressures taken from LEFT arm because of missing right arm or some other reason ?
 Yes ☐ 1 No ☐ 2
 If yes, specify: _____
11. Recorder ID (For the SHS staff who took BPs): |_|_|_|

IV. GIRTH MEASUREMENT:

in *METRIC SYSTEM*
(centimeters/cm/kg)

English System
inches / pounds

- | | | | |
|-----|--------------------------------|---|---|
| 12. | Height (Standing) | <input type="text"/> <input type="text"/> <input type="text"/> cm | <input type="text"/> <input type="text"/> <input type="text"/> in |
| 13. | Weight | <input type="text"/> <input type="text"/> <input type="text"/> kg | <input type="text"/> <input type="text"/> <input type="text"/> lb |
| 14. | Hip circumference | <input type="text"/> <input type="text"/> <input type="text"/> cm | <input type="text"/> <input type="text"/> <input type="text"/> in |
| 15. | Waist measurement at umbilicus | <input type="text"/> <input type="text"/> <input type="text"/> cm | <input type="text"/> <input type="text"/> <input type="text"/> in |

V. PEDAL PULSES AND EDEMA

present

absent

missing
limbs

unable
to assess

- | | | | | | |
|-----|---|----------------------------|----------------------------|----------------------------|----------------------------|
| 16. | Right posterior tibial pulse | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| 17. | Right dorsalis pedis pulse | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| 18. | Left posterior tibial pulse | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| 19. | Left dorsalis pedis pulse | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| 20. | Pedal edema <input type="checkbox"/> 1 Absent, <input type="checkbox"/> 2 Mild, <input type="checkbox"/> 3 Marked (<i>above midpoint between malleolus and patella</i>) | | | | |

VI IMPEDANCE MEASUREMENT

21. a) Was impedance taken? Yes ☐1 (go to b) No ☐2
if No, due to: Amputation ☐1 Wound/dressing ☐2 Cast ☐3 Refusal ☐9
Go to Question 22
- b) Taken on left side? Yes ☐1 No ☐2 (go to c)
If Yes, due to: Amputation ☐1 Wound/dressing ☐2 Cast ☐3 Refusal ☐9
- c) Resistance ☐ ☐ ☐ ☐ d. Reactance ☐ ☐ ☐ ☐

VII DOPPLER BLOOD PRESSURE

Doppler blood pressure is measured in the posterior tibial artery. If not audible, use dorsalis pedis.
Use left arm if left arm was used for standard blood pressure reading.

0 = neither posterior tibial artery nor dorsalis pedis artery was audible.
888 = participant refuses or if blood pressure is not taken for a medical reason or amputation.
999 = unable to obliterate.

Right arm

Right ankle

Left ankle

- 22.
- | | | | | |
|----|----------------------|-------|-----------------------------------|-----------------------------------|
| a) | First systolic B.P. | _ _ _ | _ _ _ | _ _ _ |
| b) | Second systolic B.P. | _ _ _ | _ _ _ | _ _ _ |
| c) | Location | | Posterior tibial _ ₁ | Posterior tibial _ ₁ |
| | | | Dorsalis pedis _ ₂ | Dorsalis pedis _ ₂ |

23. Was an ECG performed? Yes | 1 No | 2

VIII BREATH CO

24. Was breath CO done? Yes ☐1 (go to a) No ☐2 (go to Q25)
- a) Ambient: CO[ppm]:
- Ambient valid entries: -9 to +9 1st 2nd 3rd 4th

CO: valid entries Generally 0 to 99 (usually only the the 1st and 2nd entries will be completed)

ADMINISTRATIVE INFORMATION

25. Did the participant complete the interview?
Yes, completed the interview []1 No, refused all questions []2
26. SHS Code of person completing this form [][][]
27. Date of Examination: [][] mo / [][] day / [][] yr

THE STRONG HEART STUDY III

Diabetic Foot Screen

ID number:

IHS Chart Number

1. Is there an ulcer on:
 - a) Right foot? Yes 1 No 2
 - b) Left foot? Yes 1 No 2
2. Is there a history of foot ulcer? Yes 1 No 2
3. Is either foot numb? Yes 1 No 2
4. Label: Sensory level with a "+" if the participant can feel the 10 gram filament and "-" if he/she cannot feel the 10 g filament. Test each site only once. Testing may not be accurate in areas where thick callous or bunion is present.



	POSITIVE	NEGATIVE
a. Right top	<input type="text"/> 1	<input type="text"/> 2
b. Right large toe	<input type="text"/> 1	<input type="text"/> 2
c. Right middle toe	<input type="text"/> 1	<input type="text"/> 2
d. Right small toe	<input type="text"/> 1	<input type="text"/> 2
e. Right sole front	<input type="text"/> 1	<input type="text"/> 2
f. Right sole right	<input type="text"/> 1	<input type="text"/> 2
g. Right sole left	<input type="text"/> 1	<input type="text"/> 2
h. Right sole back right	<input type="text"/> 1	<input type="text"/> 2
i. Right sole back left	<input type="text"/> 1	<input type="text"/> 2
j. Right heel	<input type="text"/> 1	<input type="text"/> 2

5. Unable to measure due to medical reasons? Yes 1 No 2
(If the right foot has been amputated, conduct exam on the left foot)

6. Measured on left foot? Yes 1 No 2

- a. If "Yes," due to right foot:

Amputation 1 Wound/dressing 2 Cast 3 Refusal 8

7. RESULTS:
 - a. Number of positive answers
 - b. Number of sites tested

8. Did the participant complete the exam?
 - Yes, completed the interview 1
 - No foot exam 2

9. Examined by:

10. Date of Examination: mo day yr

THE STRONG HEART STUDY III

GTT CHECKLIST

ID number: Social Security Number: 1. Fasting One Touch glucose result. 999 = *not done* 2. Is **FASTING** blood sample taken?Yes, and participant has been fasting 1Yes, but participant has NOT been fasting 2No, participant has not been fasting 3Other, specify _____ 4No, participant refused 83. When was the last time you ate? (*use military time*) _____:

4. Time of collection of fasting samples _____:

5. Time of collection of urine sample _____:

6. Was participant given 75 gram glucose beverage? Yes 1 No 2

a. If Yes, Time the 75 gram glucose beverage was consumed _____:

b. If No, why did participant not have OGTT? *Check the appropriate answer(s)*i. diabetes, on insulin treatment ii. diabetes, on oral agent iii. One Touch > 225 mg/dl iv. refusal to have OGTT done

7. Time of 2-hr blood sample _____:

8. If the participant vomited after the glucose beverage was given, check here. If "Yes," when? (*Indicate the time*): _____

Comments: _____

9. SHS Code of person completing this form 10. Date samples collected / /
mo day yr

THE STRONG HEART STUDY III

Quality of Life¹

ID number:

Social Security Number:

How is this questionnaire administered?

By interviewer ☐1By self ☐2Refused ☐8

1. In general, would you say your health is:

*(Please check only one)*Excellent..... ☐1Very good..... ☐2Good..... ☐3Fair..... ☐4Poor..... ☐5

2. Compared to one year ago, how would you rate your health in general, now?

*(Please check only one)*Much better than one year ago..... ☐1Somewhat better than one year ago..... ☐2About the same..... ☐3Somewhat worse than one year ago..... ☐4Much worse than one year ago..... ☐5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Please Check One Answer Per Line)

	Yes, Limited a Lot	Yes Limited a Little	No Not Limited at All
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
5. Lifting or carrying groceries.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
6. Climbing several flights of stairs.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
7. Climbing one flight of stairs.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
8. Bending, kneeling, or stooping.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
9. Walking more than a mile.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
10. Walking several blocks.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
11. Walking one block.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
12. Bathing or dressing yourself.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

(Please Check One Answer Per Line)

- | | <u>Yes</u> | <u>No</u> |
|---|----------------------------|----------------------------|
| 13. Cut down on the amount of time you spend on work or other activities..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 14. Accomplish less than you would like..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 15. Were limited in the kind of work or other activities.... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 16. Had difficulty performing the work or other activities (for example, it took extra effort)..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

(Please Check One Answer Per Line)

- | | <u>Yes</u> | <u>No</u> |
|---|----------------------------|----------------------------|
| 17. Cut down on the amount of time you spend on work or other activities..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 18. Accomplish less than you would like..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 19. Didn't do work or other activities as carefully as usual..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

20. During the PAST 4 WEEKS, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Please Check One Answer)

- | | |
|------------------|----------------------------|
| Not at all..... | <input type="checkbox"/> 1 |
| Slightly..... | <input type="checkbox"/> 2 |
| Moderately..... | <input type="checkbox"/> 3 |
| Quite a bit..... | <input type="checkbox"/> 4 |
| Extremely..... | <input type="checkbox"/> 5 |

21. How much BODILY pain have you had during the PAST 4 WEEKS?

(Please Check One Answer)

- | | |
|------------------|----------------------------|
| None..... | <input type="checkbox"/> 1 |
| Very mild..... | <input type="checkbox"/> 2 |
| Mild..... | <input type="checkbox"/> 3 |
| Moderate..... | <input type="checkbox"/> 4 |
| Severe..... | <input type="checkbox"/> 5 |
| Very severe..... | <input type="checkbox"/> 6 |

22. 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..... | <input type="checkbox"/> 1 |
| Slightly..... | <input type="checkbox"/> 2 |
| Moderately..... | <input type="checkbox"/> 3 |
| Quite a bit..... | <input type="checkbox"/> 4 |
| Extremely..... | <input type="checkbox"/> 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 Answer 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
23.	Did you feel full of pep?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
24.	Have you been a very nervous person?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
25.	Have you felt so down in the dumps that nothing could cheer you up?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
26.	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
27.	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
28.	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
29.	Did you feel worn out?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
30.	Have you been a happy person?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
31.	Did you feel tired?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

32. 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 Check One Answer)

All the time.....	<input type="checkbox"/> 1
Most of the time.....	<input type="checkbox"/> 2
Some of the time.....	<input type="checkbox"/> 3
a Little of the time.....	<input type="checkbox"/> 4
None of the time.....	<input type="checkbox"/> 5

How TRUE or FALSE is each of the following statements?

(Please Check One Answer Per Line)

		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33.	I seem to get sick a little easier than other people.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
34.	I am as healthy as anybody I know.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
35.	I expect my health to get worse..	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
36.	My health is excellent.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
37.	Interview conducted in:	English	<input type="checkbox"/> 1			
		Native language	<input type="checkbox"/> 2	Specify: _____		
		Other	<input type="checkbox"/> 3	Specify: _____		

38.	Interviewer	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
39.	Date completed	<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"/>
		mo day yr

THE STRONG HEART STUDY III
CBC Results

SHS Family Study ID

SHS ID number:

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"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
mo day yr |

THE STRONG HEART STUDY III
PHYSICAL EXAMINATION — QC DUPLICATE MEASUREMENT

SHS Family Study ID SHS ID number: **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	<input type="text"/>	<input type="text"/>
c) Third Blood Pressure Measurement	<input type="text"/>	<input type="text"/>

5. Were the above blood pressures taken from LEFT arm? Yes 1 No 2

If yes, Why?

6. Recorder ID:

II. GIRTH MEASUREMENT

7. Height (Standing) cm 8. Weight kg

9. Hip circumference cm 10. Waist cm

III. IMPEDANCE MEASUREMENT

11. a) Was impedance taken? Yes ☐ ₁ (go to b) No ☐ ₂
 if NO, due to: Amputation ☐ ₁ Wound/dressing ☐ ₂ Cast ☐ ₃ Refusal ☐ ₈
- b) Taken on left side? Yes ☐ ₁ (go to b) No ☐ ₂
 if NO, due to: Amputation ☐ ₁ Wound/dressing ☐ ₂ Cast ☐ ₃ Refusal ☐ ₈
- c) Resistance d) Reactance

IV. DOPPLER BLOOD PRESSURE

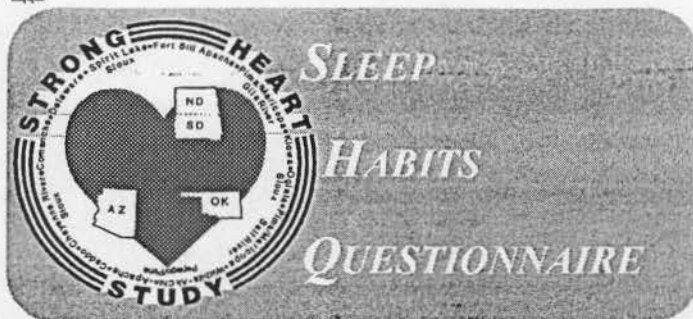
Doppler blood pressure is measured in the posterior tibial artery. If not audible, use dorsalis pedis. Use left arm if it was used for standard blood pressure reading.

0 = neither posterior tibial artery nor dorsalis pedis artery was audible.
 888 = participant refuses or if blood pressure is not taken for a medical reason or amputation.
 999 = unable to obliterate.

12. a) First systolic B.P. Right Arm Right Ankle Left Ankle
- b) Second systolic B.P.
- c) Location: posterior tibial ☐ ₁ posterior tibial ☐ ₁
 dorsalis pedis ☐ ₂ dorsalis pedis ☐ ₂

IV. ADMINISTRATIVE INFORMATION

13. Code number of person completing this form
14. Date of data collection / /
 mo day yr



ID Number: _____

Today's Date: ____ / ____ / ____
mm dd yy

Please complete as thoroughly as possible and to the best of your knowledge.

1. A. At what time do you usually *FALL ASLEEP* on weekdays or work days?

_____ : _____
☐ 1 A.M. (Midnight is 12:00 A.M.)
☐ 2 P.M.

B. At what time do you usually *FALL ASLEEP* on weekends or non-work days?

_____ : _____
☐ 1 A.M. (Midnight is 12:00 A.M.)
☐ 2 P.M.

2. How many minutes does it usually take you to fall asleep at bedtime?

_____ (Number of minutes)

3. A. At what time do you usually *WAKE UP* on weekdays or work days?

_____ : _____
☐ 1 A.M. (Midnight is 12:00 A.M.)
☐ 2 P.M.

B. At what time do you usually *WAKE UP* on weekends or non-work days?

_____ : _____
☐ 1 A.M. (Midnight is 12:00 A.M.)
☐ 2 P.M.

4. How many hours of sleep do you usually get at night (or your primary sleep period on week days or work days)?

_____ (Number of hours)

5. How many hours of sleep do you usually get at night (or your primary sleep period on weekends or non-work days)?

_____ (Number of hours)

6. During a usual week, how many times do you nap for five minutes or more?
(Write in "0" if you take no naps)

_____ (Number of times)

7. Please indicate how often you experience each of the following.
(Please check one box for each item)

	NEVER (0)	RARELY (1/month or less)	SOMETIMES (2 - 4/month)	OFTEN (5 - 15/month)	ALMOST ALWAYS (16 - 30/month)
A. Have trouble falling asleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
B. Wake up during the night and have difficulty getting back to sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
C. Wake up too early and are unable to get back to sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
D. Feel unrested during the day, no matter how many hours of sleep you've had.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
E. Feel excessively (overly) sleepy during the day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
F. Do not get enough sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
G. Take sleeping pills or other medication to help you sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Questions 8 through 16 are about snoring and breathing during sleep. To answer these questions, please consider both what others have told you, AND what you know about yourself.

8. Have you ever snored (now or at any time in the past)?

☐ 1 YES



Go to Question 9

☐ 0 NO

☐ 9 DON'T KNOW

Skip to Question 14
on page 3

9. How often do you snore now? (Please check only one)

- ☐ 0 Do not snore any more —————→ *Skip to Question 13*
- ☐ 1 Rarely - less than one night a week.
- ☐ 2 Sometimes - 1 or 2 nights a week.
- ☐ 3 Frequently - 3 to 5 nights a week.
- ☐ 4 Always or almost always - 6 or 7 nights a week.
- ☐ 9 Don't know.

10. How loud is your snoring? (Please check only one)

- ☐ 1 Only slightly louder than heavy breathing.
- ☐ 2 About as loud as mumbling or talking.
- ☐ 3 Louder than talking.
- ☐ 4 Extremely loud - can be heard through a closed door.
- ☐ 9 Don't know.

11. How many years have you been snoring?

____ _ (Number of years) OR Don't know = 999

12. Is your snoring? (Please check only one)

- ☐ 1 Increasing over time?
- ☐ 2 Decreasing over time?
- ☐ 3 Staying the same?
- ☐ 9 Don't know.

13. Have you ever had surgery as treatment for your snoring?

- ☐ 1 YES ☐ 0 NO

14. Are there times when you stop breathing during your sleep?

- ☐ 1 YES —————→ *Go to Question 15*
- ☐ 0 NO —————→ *Skip to Question 16 on page 4*
- ☐ 9 DON'T KNOW —————→ *Skip to Question 16 on page 4*

15. How often do you have times when you stop breathing during your sleep?

- ☐ 1 Rarely - less than one night a week.
☐ 2 Sometimes - 1 or 2 nights a week.
☐ 3 Frequently - 3 to 5 nights a week.
☐ 4 Always or almost always - 6 or 7 nights a week.
☐ 9 Don't know.

16. A. Have you ever been told by a doctor that you have sleep apnea (a condition in which breathing stops briefly during sleep)?

- ☐ 1 YES
☐ 0 NO
☐ 9 DON'T KNOW
- Skip to Question 17 below

B. Do you sleep with either a pressure mask ("CPAP") or a mouthpiece as treatment for your sleep apnea?

- ☐ 1 YES
☐ 0 NO

C. Have you had surgery as treatment for your sleep apnea?

- ☐ 1 YES
☐ 0 NO

17. Do you usually use oxygen therapy (oxygen delivered by a mask or nasal cannula) During your sleep?

- ☐ 1 YES
☐ 0 NO

18. In the past year, how often, on average, have you been awakened with the following?

	NEVER (0)	RARELY (1/month or less)	SOMETIMES (2 - 4/month)	OFTEN (5 - 15/month)	ALMOST ALWAYS (16 - 30/month)
A. Coughing or wheezing.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
B. Chest pain or tightness.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
C. Shortness of breath.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
D. Sweats or hot flashes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
E. Noise in your surroundings.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
F. Pain in your joints, muscles, or back.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
G. Heartburn or indigestion.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
H. Leg cramps or leg jerks	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I. Need to go to the bathroom.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

19. During the past year, how often have one or more members of your household been in or near the room where you have slept?

☐ 1 NEVER

☐ 2 SOMETIMES

☐ 3 USUALLY

20. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (Please check on box for each situation. If you are never or rarely in the situation, please give your best guess for that situation)

	NO CHANCE	SLIGHT CHANCE	MODERATE CHANCE	HIGH CHANCE
A. Sitting and reading.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
B. Watching television.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
C. Sitting inactive in a public place (such as a theater or meeting)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
D. Riding as a passenger in a car for an hour without a break.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
E. Lying down to rest in the afternoon when circumstances permit.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
F. Sitting and talking to someone.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
G. Sitting quietly after a lunch (without alcohol).	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
H. In a car, while stopped for a few minutes in traffic.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
I. At the dinner table.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
J. While driving.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

Thank you for your participation in the Strong Heart Study's Sleep Habits Survey.

Field Center Use Only

☐ 0 Self-administered

Interviewer administered in:

☐ 1 English

☐ 4 Pima

☐ 2 Spanish

☐ 5 Other, specify: _____

☐ 3 Lakota

☐ 9 Unknown

Interviewer or Reviewer Code: _____ Date: _____ / _____ / _____
month day year

THE STRONG HEART STUDY III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

ID number:

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 ☐ 9 (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?

[illegible]

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?

[illegible][illegible]

5. Interviewer: _____
6. Date of interview: _____
mo. day yr.

APPENDIX 4 - THE STRONG HEART STUDY III **DIETARY INTAKE - 24-HOUR RECALL**

Participant's ID Number (SHS)	Date of Visit month / day / year	Social Security Number [][][][][][][][][]	Date of Birth month / day / year	Sex: 1=Male <input type="checkbox"/> 2=Female <input type="checkbox"/>
-------------------------------	-------------------------------------	---	-------------------------------------	--

Participant's Name	Initials	Intake Day 1=Sun 2=Mon 3=Tue 4=Wed 5=Thu 6=Fri 7=Sat	Interviewer's opinion of information 1=Reliable 2=Unable to recall one or more meals *3=Unreliable for other reasons	Was amount eaten 1=Typical? 2=Considerably less than usual? *3=Considerably more than usual?	Did you take any supplements (vitamins, minerals, etc)? 1=No 2=Yes (If "Yes," describe under <i>Food and Beverage</i> , below)
	Interviewer's ID [][][]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Prepared: 1=At home 2=Restaurant 3=Other	Explain starred (*) items in the <i>COMMENTS</i> space provided below
---	---

Line No.	Time eaten a=a.m., p=p.m.				Salt added in preparation? 1=No, 2=Yes, 9=Unknown	Food and Beverage	amt.	Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>	Complete Description
	Hour	Minute							
01									
02									
03									
04									
05									

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant, 3=Other						Participant's ID Number (SHS)													
	Time eaten a=a.m., p=p.m.						Salt added in preparation? 1=No, 2=Yes, 9=Unknown						Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>							
	Hour		Minute				Food and Beverage			amt.			Complete Description							
06																				
07																				
08																				
09																				
10																				
11																				
12																				
13																				
14																				
15																				
16																				
17																				

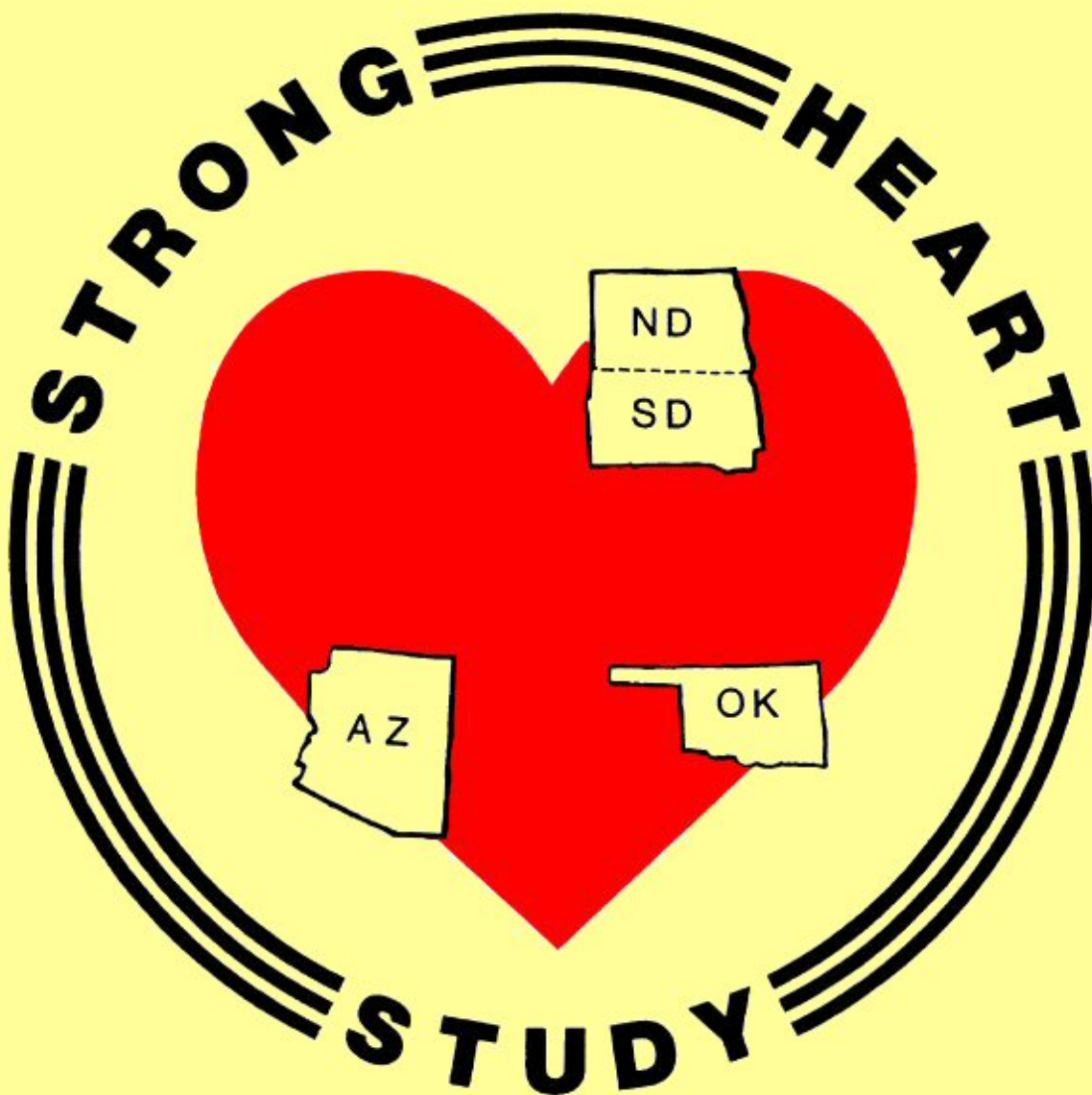
COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant 3=Other						Participant's ID Number (SHS)			
	Time eaten a=a.m., p=p.m.						Salt added in preparation? 1=No, 2=Yes, 9=Unknown		Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>	
	Hour	Minute					Food and Beverage	amt.		Complete Description
06										
07										
08										
09										
10										
11										
12										
13										
14										
15										
16										
17										

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant, 3=Other						Participant's ID Number (SHS)							
	Time eaten a=a.m., p=p.m.						Salt added in preparation? 1=No, 2=Yes, 9=Unknown				Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>			
	Hour	Minute					Food and Beverage		amt.	Complete Description				
06														
07														
08														
09														
10														
11														
12														
13														
14														
15														
16														
17														

COMMENTS (Give line no. when appropriate):



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME THREE

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 III)

Operations Manual

Volume Three

Laboratory Manual

June 1, 1997

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research

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College of Public Health

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VOLUME III
LABORATORY MANUAL

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STRONG HEART STUDY LABORATORY PROCEDURES

1.1 General Precautions for the Handling of Blood:

1. All clinic and laboratory personnel need to take the proper precautions in the handling of blood and body fluids. It is well known that the improper handling of samples from participants with infectious diseases can lead to infection with staff. Many of these diseases can be transmitted by ingestion, contact with mucous membranes of eyes, or inhalation. The most easily transmitted blood borne disease is hepatitis, which makes this a far greater concern than HIV.

All specimens should be regarded as potentially hazardous.

2. To avoid these risks:
 - ▶ 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 Vacutainer™s, 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 clinic and laboratory 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.
3. Clinic personnel will be instructed in the protocol for blood collection and processing procedures as part of a training session held prior to the beginning of the study. Each clinic should have at least one staff member who will be actively involved in this process attend the session. This person, in turn will be responsible for training additional personnel at his/her clinical center. 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, the Clinic Coordinator or another 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.

4. Personnel

Phlebotomists or clinic 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 they 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.
- ▶ They should wear clean white lab coats (with no blood stains) and maintain a neat appearance.
- ▶ They should wear name tags 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.

1.2 Equipment and Supplies:

1. Facilities for Blood Draws

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 emergency equipment in case of cardiac arrest. Ideally, only the participant and phlebotomist (and assistant when needed) are in the room during the procedure.

¹ Stockbower, J.M., and Blumenfeld, T.A., (Eds.). Collection and Handling of Laboratory Specimens: A Practical Guide. Philadelphia: J.B. Lippincott Company, 1983.

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

Specimen Processing

- Tube racks or supports
- Waterproof marking pen
- Refrigerator
- Centrifuge (refrigerated)
- 3/4" Filament Tape (Scotch or equivalent) for sealing Zip-Lok Freezer bags - quart and gallon size
- -20°C Freezer
- Dry Ice
- Crushed Ice

2. Supplies: A description of the various tubes and supplies that will be needed in the study is presented in the two tables provided. Table One is a list of supplies that will be ordered from Penn Medical Laboratory. Do not substitute with other similar products. The second table is a list of supplies that can be ordered from your local vendors with the exception of the SCAT tubes. These must be ordered from the University of Vermont at 802-656-8963.

TABLE 1:

Sarstedt Customer Service: 1-800-257-5101				
Item	Size	Pkg Amount	Material Type	Order Number
2 ml cryovials (no caps)	2-ml	1000/cs	polypropylene	72.609
2 ml cryovial screw caps				
Clear	2-ml cap	1000/cs	polypropylene	65.716
Blue	2-ml cap	1000/cs	polypropylene	65.716.001
Yellow	2-ml cap	1000/cs	polypropylene	65.716.002
Red	2-ml cap	1000/cs	polypropylene	65.716.003
Green	2-ml cap	1000/cs	polypropylene	65.716.005
Purple	2-ml cap	1000/cs	polypropylene	65.716.008
6 ml transport vials (no caps)	6-ml	1000/cs	polypropylene	60.542.530
Clear cap for 6 ml transport tube	6-ml cap	1000/cs	polypropylene	65.176
Red cap for 6 ml transport tube	6-ml cap	1000/cs	polypropylene	65.176.001
Purple cap for 6 ml transport tube	6-ml cap	1000/cs	polypropylene	65.176.007
Sterile, clear screw cap tube round base	6-ml	1000/cs	polypropylene	60.546.002
Transfer Pipet	3.5ml	1000/cs	polypropylene	86.1171
Transfer pipets, sterile	3.5	20/bag	NA	86.1171.020
Cardboard box for 2-ml cryovials	NA	100/cs	NA	95.064.997
Cardboard box for 6-ml cryovials	NA	100/cs	NA	95.064.949
SC Urine Cup (100 ml) w/label	NA	1000/cs	polypropylene	75.562.105

Table 2:

Item	Anticoagulant	Size	Pkg Amount	Order Number
Vacutainer, purple	15%EDTA	3.5-ml	1000/cs	BD-6458
Vacutainer, purple	15%EDTA	10-ml	1000/cs	BD-6457
Vacutainer, red/black (SST)	none	9.5 ml	1000/cs	BD-6510
Vacutainer, light blue	Sodium Citrate	4.5-ml	1000/cs	BD-6579
Vacutainer, gray	Fluoride	3.0-ml	1000/cs	Vacutainer brand #367722
Vacutainer, SCAT	SCAT	4.5-ml	NA	Order from U of Vermont 802-656-8963
Multi-sample needles (butterfly)	NA	21 gauge	200/cs	BD-7251
3 tube mailers for 3-ml EDTA tube	NA	3 space	50/cs	CMS # 282-561, Mfr # 473
Biohazard Specimen Bags	NA	8x10	1000/cs	306-297

Additional Miscellaneous Supplies (order from a local vendor):

glutol (75 gm)

Reusable Vacutainer Hubs/Sleeves (packages of 4 usually come free with each case of tubes)

Adhesive tape

[2x2] Sterile Gauze

Alcohol Wipes

Latex Gloves

Tourniquet

Band-Aids

Needle Disposal Device

=====

1.3 Supplies to Be Prepared Prior to Specimen Collection

Have the appropriate tubes labeled and ready in an ice bucket. For more specific details regarding vacutainer tubes and sample type for each participant type see appendix 1 of this manual.

Family Participant

Cohort Participant

Fasting Sample:

One 9.5-ml Red-Top tube (SST)
One 3-ml Gray-top tube
One 4.5-ml Blue-top tube (Citrate)
One Special tube (SCAT)
Three 10-ml Lavender top tube
Three 3.5-ml Lavender-top tube

Two 9.5-ml Red-top tube (SST)
One 3-ml Gray top tube
One 4.5-ml Blue-top tube (Citrate)
One Special tube (SCAT)
Two 10-ml Lavender-top tube
Two 3.5-ml Lavender top tube

Urine collection for microalbumin
Urine collection for creatinine

Urine collection for microalbumin
Urine collection for creatinine

2-hour Sample:

One 3-ml Gray-top tube

One 3-ml Gray-top tube

Other Supplies:

Adhesive tape
tourniquet
alcohol pads
2x2 gauze pads
Band-Aids
Vacutainer sleeve/hub
Vacutainer needle [21G] (multiple sample)
urine collection cups

Note: Participants exempted from the GTT will not have a 2-hr glucose sample collected.

1.4 Sample Collection

1.4.1 Sample Collection Logs

Clinic personnel should carefully review the description of collection requirements to ensure that specimens are collected in the proper order and using the proper technique. See appendix 2 (a), 2 (b), 2 (c), 2 (d). 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. For each site, a notebook should be set up at each location. This should be a hardbound notebook from which pages cannot be easily removed. Pages should be identified by visit type (Cohort vs Family) and 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.

1.4.2 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.

1.4.3 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 and attached to all sample tubes for the specific visit.

1.4.4 Venipuncture Procedure

- 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 on GTT check list. See appendix 6. 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 has been 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.

If no radial pulse can be felt, the tourniquet is too tight.
Tourniquet must not be in place more than two minutes.

- 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.

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 6-8 times and place on ice.

18) Proceed with collection of tubes in this order:

- Fasting:
- 1. Red top (SST) tube
 - 2. Light Blue top (Citrate) tube
 - 3. Special tube (SCAT)
 - 4. Gray top (Sodium fluoride) tube
 - 5. Lavender top (EDTA) tube

- 2 Hr:
- 1. Gray top (Sodium Fluoride) 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) Record the time the fasting draw is completed on the GTT check list. (See appendix 6.)

22) 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.

- 23) Affix preprinted labels to tubes, making sure the ID# and tube designation are correct.
- 24) 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.*
- 25) 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.
- 26) Serve glucose beverage; instruct subject to consume it within 3 minutes. Record time on GTT check list.
- 27) Give the participant labeled urine specimen cup and instruct him to void into the container. Inform him/ her where to leave the container.
- 28) Remove gloves, wash hands, and proceed to next participant.

1.4.5 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.

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.

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 comments section on the visit form that the samples were not collected.

1.4.6 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.

1.4.7 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. 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 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.

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.

1.4.8 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 both family and cohort members 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 appendix 2(b) and 2 (d).
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 until results for the samples and QA duplicates are reported.

1.4.8 Processing and Shipping QA samples

Appendix 2(b) and 2(d) illustrate the blood and urine processing procedure for QA samples. These samples should be treated the same as the regular participant samples including being included with the regular shipments. See section 1.6 on page 22 and appendix 7 for shipping instructions.

1.5 Sample Processing and Storage

1.5.1 General Rules for Handling Samples for Lipids and Other Lipoprotein Measurements

One important precaution which should always be kept in mind in handling samples for lipids and lipoprotein measurements is that the blood should be cooled (either in the refrigerator or on ice) as soon as the samples are collected, and kept cold until processing is complete and samples are properly stored. Plasma should be separated from the cells within a few hours. Plasma samples should not be allowed to freeze and thaw during any of the handling steps.

1.5.2 Processing of Blood Samples and Urine Sample

The enclosed flipcharts illustrate the blood and urine processing procedure for this protocol. Appendix 2(a) and 2(c) are the checklists for the family and cohort collection logs. Appendix 2(b) and 2(d), are check lists for quality assurance samples which will require a number of additional tubes of blood.

1. Label vials and tubes for each participant according to the flip chart. All tubes are to be labeled before processing is begun.
2. Arrange all of the vacutainers on ice except for the lavender for the CBC, the SST tube for the chemistry profile and the 3.5 ml lavender tube for GM/RBC genetic typing. The lavender tube for the CBC will be tested locally and must be sent to the local laboratory within 24 hours of collection. Please follow any additional instructions provided by those laboratory facilities. The 3.5 ml lavender tubes for genetic typing and glycohemoglobin will not be centrifuged and must remain in the original collection vacutainers. Do not centrifuge any of the 3.5 ml lavender top tubes. **Allow the SST specimen tube to sit vertically for 20 minutes to ensure proper clot formation before centrifugation.**
3. Centrifuge the PAI-1 and SCAT tubes in a refrigerated centrifuge at 4°C for 30 minutes at 3000 rpm ², taking care that the centrifuge is properly balanced. Centrifuge the remaining tubes in a refrigerated centrifuge at 4°C for 10 minutes at 3000 rpm ³.

²Check with the manual for your centrifuge to see which RPM corresponds to a G force of 1000.

³Check with the manual for your centrifuge to see which RPM corresponds to a G force of 1000.

4. During pipetting of the sample, special care should be taken to avoid contact with the buffy coat between the plasma and cells. If the cells or buffy coat are disturbed, do not continue pipetting. Re-centrifuge the sample at 4°C for 10 minutes at 3000 rpm. Note this in the blood processing log book.
5. After centrifuging, place samples in a rack on ice until they can be refrigerated or frozen.
6. To store samples until shipment:

After samples have been collected, place the vacutainers on ice or into refrigeration as soon as possible. DO NOT leave them at room temperature for more than a minute or two.

After samples have been aliquotted into appropriate vials, transfer vials into refrigeration or onto dry ice or freeze at -70°C as soon as possible, i.e., do not leave them at room temperature for more than a minute or two. For screw cap vials, be sure cap is screwed in completely. Generally, follow the volume instructions for each sample. *It is important that vials do not contain excess specimen because expansion or freezing may crack the vial or force the cap off.* It is also undesirable to fill the vial *much less* than its capacity because this provides increased opportunity for sublimation of the sample onto the sides during frozen storage. Be sure that all 2-ml cryovials are properly sealed and stored *upright* for freezing. Do not let samples thaw once they are frozen.

1.5.3 Sample Requirements:

3.5 LAVENDER TOP TUBE FOR CBC

- A. For this phase of the Strong Heart Study, a lavender top tube will be collected for a CBC analysis. Consult the individual testing facilities for specific instructions. All samples must be received and tested within 24 hours of collection.

3.5 LAVENDER TOP TUBE FOR GLYCOHEMOGLOBIN

- A. For this phase of the Strong Heart Study, a 3.5 ml lavender top tube will be collected for a Glycohemoglobin.
- B. Do not centrifuge this sample.
- C. Samples should be sent in the original collection vacutainer tube and placed in the small 3-5 space styrofoam mailer that is also used for the GM and RBC Typing.

D. Ship once a week using priority overnight delivery. Refrigerate until shipment.

[3.5-ML] LAVENDER TOP TUBE FOR GM and RBC TYPING (For Family Study Only)

A. Do not be centrifuge this sample.

B. Place original vacutainer tube in the small 3 space styrofoam packing boxes.

C. Refrigerate samples until shipment.

[10-ML] LAVENDER TOP TUBES (total of 3 for Family, 2 for Cohort participants)

A. Remove stoppers from the two (or three) [10-ml] lavender top tubes.

B. With a fresh, disposable transfer pipet, dispense plasma as follows:

Cohort Samples:

- From the 2 10-ml lavender top tubes, transfer approximately 4-ml of plasma into the 6-ml transport tube marked Beta Estimate. With the same pipet divide all the remaining plasma as follows (approx. 1.0 ml each):

- 2 [2-ml] Cryovials labeled "EDTA Storage"
- 1 [2-ml] Cryovial labeled "Insulin"
- 1 [2-ml] Cryovial labeled "LDL size"
- 1 [2-ml] "Fibrinogen"
- 1 [2-ml] "Fibrinogen Storage"

Penn Medical Laboratory measures *true* triglyceride concentrations. This is the preferred method in diabetic subjects. Sometimes, this results in TG values that are ~5% lower than methods which do not take into account free glycerol.

- Using the plastic purple caps, securely seal the transport and cryovials.

Do not discard the vacutainers yet as you will need to remove the buffy coat as described on page 17 of this manual. Be very careful. Do not to disturb the white cell layer between the plasma and the red cells in the lavender top tubes (leave approximately 0.5 ml of plasma in each vacutainer tube). Discard pipet after completion of this step.

Family Samples:

- Approximately 4-ml is transferred into a transport tube marked Beta Quant. With the same pipet divide all the remaining plasma from the two remaining tubes as follows (approx. 1.0 ml each):
 - 3 [2-ml] Cryovial labeled "EDTA Storage"
 - 1 [2-ml] Cryovial labeled "Insulin"/"Lp(a)"
 - 1 [2-ml] Cryovial labeled "LDL size"/"Apo E"
 - 1 [2-ml] Cryovial labeled "Apo A1 and B"
 - 1 [2-ml] Cryovial labeled "Fibrinogen/storage"
 - Do not discard these tubes and be very careful not to disturb the white cell layer between the plasma and red cells of the lavender top tubes (leave approximately 0.5 ml of plasma in each vacutainer tube). Discard pipet after completion of this step.
- C. Freeze all samples except the 3.5 ml lavender top tube for the CBC, the 3.5 ml lavender top vacutainer tube for GM/RBC genetic testing, the glycohemoglobin and the 6-ml transport tubes for the beta quant./beta estimate and chemistry panel. Do not freeze any 6-ml plasma or whole blood tubes with the exception of the buffy coat. Refrigerate these samples until weekly shipment. Make sure that the caps have been securely closed before placing into storage.
- D. Securely cap and freeze the cryovials as quickly as possible at -70°C. Take care to ensure that the correct color cap is used for each specimen type. Once frozen, the samples are to be kept at -70°C until shipment.
- E. Using a sterile pipet, carefully draw up the buffy coat from the first [10-ml] Lavender top tube and dispense into a prelabeled 6 ml tube labeled "Buffy Ct." The buffy coat is the white layer on top of the red cells. It is rich in white cells. This step is best carried out by positioning the pipet tip slightly above the buffy coat and, while aspirating, carefully moving the tip just over the surface of the buffy coat in a slow swirling motion. The resulting aspirate should contain all of the buffy coat material, plus a small amount of red cells and plasma. When aspirating, try not to let the pipet tip actually touch the buffy coat, or an excess amount of red cells will be drawn up. Similarly, suspending the tip too far above the buffy coat results in too much plasma and too few white cells. This should result in a volume of approximately 1.0-1.5 ml.
- F. Using a fresh sterile pipet for each tube, repeat step E with the remaining 10-ml Lavender top tube(s) for the same participant, pipetting into the same 6-ml tube.

- G. Immediately after the buffy coats have been dispensed into the thinner, taller 6-ml cryovial, and ensure the tube is securely capped, place the cryovial on ice, (or immediately into the freezer.) It is important to ensure that the top of the tube is screwed on tightly, otherwise the "O-ring" seal will leak.
- H. The tube which contains the buffy coat is to be frozen at -70°C as quickly as possible. (The specimens are stable if kept on ice for up to a maximum of 4 hours, if necessary, however, *immediate freezing is preferred*.) Once frozen, the samples are to be kept at -70°C until shipment.
- I. Discard the used pipets and the remaining tubes with the red cells.

BLUE TOP TUBE

- A. Remove the stopper from the tube.
- B. With a fresh transfer pipet, transfer plasma to the [2-ml] Cryovial labelled "PAI-1/storage"
- C. Using blue cap, securely seal the vial.
- D. Freeze the vial as quickly as possible at -70°C . Once frozen, the sample is to be kept at -70°C until shipment.
- E. Discard the pipet and tube with the remaining red cells.

SCAT

- A. Remove the stopper from the tube.
- B. With a fresh transfer the plasma to the [2-ml] Cryovial labelled "SCAT/storage"
- C. Using the green cap, securely seal the vial.
- D. Freeze the vial as quickly as possible at -70°C . Once frozen, the sample is to be kept at -70°C until shipment.
- E. Discard the pipet and tube with the remaining red cells.

RED TOP (SST) TUBE (one for Family, two for Cohort)

- A. Remove the stopper from the tube.
- B. With a fresh transfer pipet, divide the serum between the one 6-ml transport vial labelled "Chem Profile" and the two 2-ml cryovials marked "Serum Storage"
- C. Using the red cap, securely seal the 6-ml transport vial.
- D. Refrigerate the 6 ml transport vials as quickly as possible. Freeze the serum storage vials at -70°C until shipment.
- E. Discard the pipet and tube with the remaining red cells.

GRAY TOP TUBES (0 and 2 hour samples)

- A. Remove the stopper from the fasting 3-ml gray top tube.
- B. With a fresh transfer pipet, divide the plasma between the 2-ml Cryovial labelled "Fasting Gluc".
- C. Using clear caps, securely seal the vial.
- D. Discard the pipet and tube with the remaining red cells.
- E. Remove the stopper from the 2 hour 3-ml gray top tube.
- F. With a fresh transfer pipet, divide the plasma between the 2-ml Cryovial labelled "2 hr Gluc."
- G. Using the clear caps again, securely seal the vial.
- H. Freeze the vials as quickly as possible at -70°C. Once frozen, the samples are to be kept at -70°C until shipment.
- I. Discard the pipets and tubes with the remaining red cells.

URINE SAMPLE

- A. Pour approximately 1.5 ml of the patient's urine sample into each of 2 yellow capped tubes labeled "Microalb/Creat" and "Urine Storage". Discard the

remaining sample.

- B. Securely cap the tubes and freeze at -70°C .
- C. Once frozen, the samples are to be kept at -70°C until shipment.

1.5.5 Sample storage prior to shipping:

Two shipments will be needed for each participant; one for frozen samples and one for refrigerated.

All samples except for the CBC will be sent to Penn Medical Laboratory.

To Ship To Penn Medical Laboratory:

For frozen samples (-70°C) cryovials will be shipped in boxes and shipped every two weeks as follows:

Monday: Dakota
Wednesday: Arizona
Thursday: Oklahoma

This shipment should contain a box of 2-ml cryovials with the following properly labelled tubes:

- * 1 [2-ml] Cryovial labelled "Apo E"/"LDL size"
- * 1 [2-ml] Cryovial labelled "Lp(a)"/"Insulin"
- * 1 [2-ml] Cryovial labelled "Apo A1 and B"
- * 1 [2-ml] Cryovials labelled "SCAT/PAI-1"
- * 1 [2-ml] Urine samples labelled "Microalb/Creat"
- * 1 [2-ml] Cryovials labelled "Fast Gluc"
- * 1 [2-ml] Cryovials labelled "2Hr Gluc"
- * 3 [2-ml] Cryovials for EDTA plasma "EDTA Storage"
- * 2 [2-ml] Cryovials for Serum "Serum Storage"
- * 1 [2-ml] Cryovials labelled "Fibr storage"
- * 1 [2-ml] Cryovials labelled "SCAT/PAI-1 storage"

- * 1 [2-ml] Cryovial labelled "Urine storage"

Boxes for refrigerated samples traveling in the original container will be shipped as follows:

Monday & Wednesday:	Dakota
Monday & Wednesday:	Arizona
Thursday:	Oklahoma

This shipment should contain styrofoam shipping containers which hold 3-5 samples with the following properly labelled 3.5-ml vacutainer tubes:

- 1 [3.5-ml] lavender top vacutainer tube for GM and RBC genetic typing
- 1 [3.5-ml] lavender top vacutainer tube for Glycohemoglobin (HBA1c)

The box(es) for frozen DNA samples to be shipped to Penn Medical Laboratory every two weeks following the above described shipping schedule for each site.

One biohazard bag will be used for the refrigerated (4°C) samples that will be shipped once or twice weekly on Monday, Wednesday and Thursday as previously described and should contain the following properly labelled tubes:

- * 1 [6-ml] Transport vial "Beta Quant or Beta Estimate"
- * 1 [6-ml] Transport vial "Chemistry Profile"

1.6 Shipping Instructions:

1.6.1 Shipping Schedule

There can be two types of specimens sent to the laboratory with each shipment: refrigerated and frozen. The packaging and shipping of these specimens to the laboratory are the responsibility of each clinical center. The procedures described in this section should be followed very carefully to minimize the chances that specimens will be lost, damaged or spoiled in transit.

1. Refrigerated plasma and serum samples

Refrigerated samples are to be shipped once or twice weekly. Ship the samples in approved insulated containers with adequate refrigerant packs (1-2 cold packs) to keep the samples cold. DO NOT FREEZE THESE SAMPLES. Samples should not come in direct contact with refrigerated packs.

The samples are to be sent via airfreight, priority overnight delivery, to the following address for receipt by 10:30 A.M. EST, Monday, Wednesday and Thursday. Do not ship on Fridays, weekends, or the day before a holiday. Ship samples to the following address. See page 27 for a list of observed holidays.

Penn Medical Laboratory
Medlantic Research Institute
108 Irving Street N.W. Annex # 2
Washington, D.C. 20010
(202) 877-5481

2. A Strong Heart Shipping Log Form(s) appendix 3(a) and 3(b) detailing the contents of the package (originating Center, destination, time packed, date shipped, total number of specimens, ID numbers, vial size, color of vial and remarks) will be included.
3. Samples will be mailed by Federal Express overnight *PRIORITY* mail service at scheduled intervals to the laboratory in supplied polyfoam containers with 1-2 refrigerated cold packs or at least 10 lbs. of dry ice.
4. Refrigerated 3.5 ml lavender vacutainer whole blood samples (Family Study Only)

Refrigerated 3.5 ml lavender vacutainer samples are to be shipped weekly. Ship the samples in approved insulated containers with 1-2 refrigerant packs to keep the samples cold. DO NOT FREEZE THESE SAMPLES. SAMPLES ARE NOT TO COME INTO DIRECT CONTACT WITH REFRIGERANT PACKS.

The samples are to be sent via airfreight with the beta quant/beta estimate, glycohemoglobin and chemistry profile, priority overnight delivery, to the following address for receipt by 10:30 A.M. EST, Monday through Friday. Do not ship on Fridays, weekends, or the day before a holiday to:

Penn Medical Laboratory
Medlantic Research Institute
108 Irving Street N.W. Annex #2
Washington, D.C. 20010
(202) 877-5481

5. Frozen samples (plasma and urine)

Frozen samples are to be shipped on dry ice once every 2 weeks. When packing, place at least 10 lbs. of dry ice in the box. Pack tightly and do not add any other packing material.

The samples are to be sent via airfreight, priority overnight delivery, to the following address for receipt by 10:30 A.M. EST, Monday through Friday. Do not ship on Fridays, weekends, or the day before a holiday:

Penn Medical Laboratory
Medlantic Research Institute
108 Irving Street N.W. Annex #2
Washington, D.C. 20010
(202) 877-5481

6. Mailings may be made only on designated days of the week to ensure arrival at the laboratory on a working day. All specimens must be shipped on a Monday, Tuesday and Thursday. This reduces the chance that a lost or delayed shipment will arrive at a laboratory on the weekend when there will be no personnel available to receive it.

1.6.2 Preparation of Specimen Shipping Log Forms:

1. A copy of the shipping log must accompany each shipment. (See attachments 3(a) and 3(b)). Each is printed on two-part carbonless form. Keep the last copy for your records and place the original on top of the Styrofoam container but inside the protective, outer cardboard container. When your shipment is received, lab technicians at Penn Medical 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 finding "lost" samples.
2. A completed shipping slip form should be put into each shipped container. Information required for each participant includes the ID code, the number of plasma tubes, the number of special blood tubes, and the number of blood cell tubes. Place a check mark on the *Frozen Shipment Form* next to the ID number of any participant using insulin.
3. Put the shipping log in a plastic bag and place the bag on top of the insulated lid before closing the outside cardboard box.
4. Upon receipt of the samples by PML, a status check list will be sent back to the PI (or pre-designated individual) by FAX. The condition of the samples received

will be noted on the list, along with any discrepancies between the shipping form and samples actually received.

1.6.3 Supplies Required for Shipping:

The following supplies are required for shipping:

Provided by the Laboratory:

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- Pre-printed vial label
- Pre-printed Federal Express Shipping Labels
- Revco freezer storage

10 lbs of dry ice gives some insurance against thawing if the package is delayed a few hours.

Provided Locally:

- Dry Ice
- Paper Towels for wrapping Storage Boxes
- Zip-Lok plastic bags-quart and gallon size (for Freezer Boxes and Shipping Logs)
- Self-addressed (Clinic Address) envelope
- Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
- 3/4" Scotch Brand Filament Tape

1.6.4 Packing Shipping Containers:

All samples are to be packed according to DOT regulations and in compliance with shipper's requirements. See appendix 7. This includes the following:

- * All samples are to be securely capped and sealed in a transport bag.
- * Shipping containers are to be self contained with sufficient absorbent material surrounding sample bags to absorb any spillage.
- * The exteriors of all packages are to be labelled according to the shipper's requirements.

The safe packaging and shipping of all samples (refrigerated and frozen) are the responsibility of each Clinical Center. Prepare specimens for shipment using the guidelines that follow:

1. Identify the box(es) of specimens that are being sent to the particular laboratory. Check all of the specimens in the box against the Shipping Log Form to be sure

there is no transcription error or missing specimen.

2. The samples are shipped in the type of box designated for each specimen type.
3. Wrap each box in several layers of paper towels or Chux and seal each box in a plastic freezer bag (gallon size). The paper towels/Chux serves as absorbent material in the event that vials are broken or cracked. Place upright in the supplied polyfoam shipping container. For refrigerated specimens, 1-2 refrigerated cold packs should be placed at the bottom of the shipping container. At least 10 pounds of dry ice is necessary to keep the specimens frozen for 48 hours. Be sure that dry ice has been ordered prior to expected shipping date. A layer of dry ice should be placed below each freezer storage box. The boxes may be stacked or placed side by side depending on which size Styrofoam container is used. Stuff any empty space around the boxes tightly with crushed newspaper or Styrofoam chips.
4. The Shipping Log Forms along with a self-addressed envelope should be enclosed in a Zip-Lok bag and taped to the top of the lid of the polyfoam container. A description of the log and instructions for completing it are found below.
5. Place the lid on the polyfoam container and seal with 3/4" filament tape (scotch brand or equivalent).
6. Place the sealed polyfoam container into a cardboard carton and seal the carton with 3/4" filament tape. Place the following preprinted labels on the outside of the cardboard carton.
 - (a) Clinic return address label.
 - (b) "REFRIGERATED" or "KEEP FROZEN," label.
 - (c) "Class 9" (dry ice) label for frozen samples.
 - (d) A preprinted air bill that has been supplied by Federal Express. Federal Express will add the weight and cost to the bill.
- (7) Samples will be shipped by air courier so that they arrive at the laboratory *WITHIN 24 HOURS*. The Federal Express air bill must indicate **overnight priority**. A special account has been established with FEDERAL EXPRESS for mailing study specimens. Once the shipment has been packed and labeled, the clinic must:

Be sure to check the form on the FedEx label that indicates overnight *PRIORITY* shipment to insure arrival at the lab by 10:30 am the next morning.

- (a) Call Federal Express at 800-238-5355 and request a pick-up for an overnight package. Some Clinical Centers may have already established a policy with respect to local pick-ups by Federal Express. Each Clinical Center should inquire as to the policies for daily Federal Express Pick up at their Center.
- (b) Retain the carbon copy of the air bill as a receipt for later auditing by the sponsor.
- (c) ***You must call or fax the laboratory and inform them that a package is being sent.***

Please give the following information:

- the name of the person responsible for shipping the package
- your location
- the Federal Express air bill number

This information will allow the lab to track the package quickly if it does not arrive as planned.

Penn Medical Laboratory is closed on the following holidays:

Labor Day	September 1, 1997
Labor Day	September 7, 1998
Thanksgiving	November 27&28, 1997
Thanksgiving	November 26&27, 1998
Christmas Day	December 25, 1997
Christmas Day	December 25, 1998
New Year Day	January 1, 1998
New Year	January 1, 1999
ML King Day	January 28, 1997
ML King Day	January 19, 1998
President's Day	February 17, 1997
President's Day	February 16, 1998
Memorial Day	May 26, 1997
Memorial Day	May 25, 1998
July 4th Holiday	July 4, 1997
July 4th Holiday	July 4, 1998

If you have any question regarding the status of a shipment contact either Addie Wooden or Marilyn Cadorette at PML. Special shipments for weeks involving a legal holiday are to be coordinated with the laboratory.

Main number: (202) 877-5481

Specimen Processing and Data Management - Addie Wooden : (202) 877-5073

Fax: (202) 877-7342

E-mail: David Robbins, M.D. dcr1@mhg.edu

Marilyn Cadorette mjc1@mhg.edu

APPENDIX 1

THE STRONG HEART STUDY III
Routine Blood and Urine Sample Collection Reference Table

Fasting Samples					
Participant		Test	Sample Type		Transport Vial Type
Family	Cohort				
x	x	CBC	purple top tube	NA	Follow testing center directions
x	x	Chem profile	1(or2)-10 ml Plain SST See flipcharts	3-4 ml serum	1-6 ml red transport vial 2-2 ml red storage cryovials
x	x	PAI-1	1-4.5 ml Lt Blue (Citrate)	1 ml plasma	1-2 ml blue PAI-1/storage cryovial
x	x	SCAT	1-SCAT tube	1 ml plasma	1-2 ml green SCAT/storage cryovial
x	x	Glucose, 0 hour	1-3 ml gray	1 ml plasma	1-2 ml clear cryovial
x		Genetic Testing	1-3.5 ml purple (EDTA)	3.5 ml whole blood	original tube
x	x	Glycohemoglobin (HgbA1c)	1-3.5 ml purple	3.5 ml whole blood	original tube
	x	Beta Estimate (Lipid Profile)	1-10 ml purple (EDTA)	3 ml plasma	1-6 ml purple cryovials 2-2 ml purple storage cryovials
x		Beta Quant	1-10 ml purple (EDTA)	4-5 ml plasma	1-6 ml purple transport vial 2-2 ml purple storage cryovial
x x x	x x	Insulin LDL size Lp(a)	1-10 ml purple (EDTA)	Place 1-1.5 ml in each cryovial	Follow directions on flipcharts
x x x	x	Apo E Apo A1 &B Fibrinogen	1-10 ml purple (EDTA)	Place 1-1.5 ml in each cryovial	Follow directions on flipcharts
x	x	DNA	Collect buffy coat from the 2/3 10 ml purple EDTA tubes	buffy coat 3 10-ml purple	1- 6 ml clear cryovial
Two Hour Sample					
Participant		Test	Sample Type		Transport Vial Type
Family	Cohort				
x	x	Glucose, 2 hour	1-3 ml gray	1 ml plasma	1 - 2 ml clear cryovial
Urine Samples					
Participant		Test	Sample Type		
Family	Cohort				
x	x	Microalbumin & Creatinine	1 2-ml yellow cryovial for urine microalbumin and creatinine 1 2-ml yellow cryovial for storage		

APPENDIX 2 (a)
THE STRONG HEART STUDY III

Family Routine Blood and Urine Sample Collection List

Penn Medical Laboratory
108 Irving St, NW
Annex # 2
Washington, DC 20010

(Check to be sure that the patient is fasting for at least 12 hours, if possible.)

Participant ID No.:				Today's Date: (mm/dd/yy)	
Send the following specimens to Penn Medical Lab. Questions? Call 202-877-5073 or 202-877-5481.					
Check below to indicate sample was collected	Collection Type	Test	Sample Type	Transfer Vial Type	Refrigerated or Frozen
Fasting Blood Samples:					
	1-10 ml SST	Chem Profile Storage	3 ml Serum 1 ml Serum	1 6-ml red transport vial 2 2-ml red cryovial	Refrigerated Frozen
	1-4.5 ml Lt blue	PAI-1/Storage	1-1.5 ml Plasma	1 2-ml blue cryovial	Frozen
	1 SCAT tube	SCAT/Storage	1 -1.5 ml Plasma	1 2-ml green cryovial	Frozen
	1-3 ml gray	0 hour (fasting) glucose	1 ml Plasma	1 2-ml clear cryovial	Frozen
	1-3.5 ml purple	CBC	Whole Blood	Send in original tube	Refrigerated
	1-3.5 ml purple	Genetic Testing	Whole Blood	Send in original tube	Refrigerated
	1-3.5 ml purple	Glycohemoglobin	Whole Blood	Send in original tube	Refrigerated
	1-10 ml purple	2 hr Beta Quant Storage DNA*	3-4 ml Plasma 1 ml plasma Buffy Coat	1 6-ml purple transport vial 2 2-ml purple cryovial 1 6-ml clear transport tube	Refrigerated Frozen Frozen
	1-10 ml purple	Lp(a)/Insulin LDL size/Apo E Fibrinogen DNA*	Place 1-1.5 ml in each cryovial Buffy Coat	Follow directions on flipcharts 1 6-ml clear transport tube	Frozen Frozen
	1-10 ml purple	Apo A1& B Storage DNA*	Place 1-1.5 ml in each cryovial Buffy Coat	Follow directions on flipcharts 1 6-ml clear transport tube	Frozen Frozen
Urine Samples:					
	Random Urine	Microalbumin/Creatinine Storage	Urine Urine	1 2-ml yellow cryovial 1 2-ml yellow cryovial	Frozen Frozen
Two Hour Samples:					
	1-3 ml gray	2 hour glucose	Plasma	1 2-ml clear cryovial	Frozen

* Buffy Coat from the EDTA tubes should be combined in one 6 ml clear cryovial.

APPENDIX 2 (b)
THE STRONG HEART STUDY III

Family-QA Routine Blood and Urine Sample Collection List

Penn Medical Laboratory
108 Irving St, NW
Annex # 2
Washington, DC 20010

(Check to be sure that the patient is fasting for at least 12 hours, if possible.)

Participant ID No.:				Today's Date: (mm/dd/yy)	
Send the following specimens to Penn Medical Lab. Questions? Call 202-877-5073 or 202-877-5481.					
Check below to indicate sample was collected	Collection Type	Test	Sample Type	Transfer Vial Type	Refrigerated or Frozen
Fasting Blood Samples:					
	1-3 ml gray	0 hour (fasting) glucose	1 ml Plasma	1 2-ml clear cryovial	Frozen
	1-10 ml purple	Fibrinogen Insulin LDL size Lp(a)	Place 1-1.5 ml in each cryovial	Follow directions on flipcharts	Frozen
	1-1ml purple	Apo E Apo A1& B	Place 1-1.5 ml in each cryovial	Follow directions on flipcharts	Frozen
Urine Samples:					
	Random Urine	Microalbumin/Creatinine	Urine	1 2-ml yellow cryovial	Frozen Frozen

Appendix 2 (c)
THE STRONG HEART STUDY III

Cohort Routine Blood and Urine Sample Collection

Penn Medical Laboratory
108 Irving St, NW
Annex # 2
Washington, D.C. 20010

(Check to be sure that the patient is fasting for at least 12 hours, if possible.)

Participant ID No.:	Today's Date: (mm/dd/yy)
---------------------	--------------------------

Send the following specimens to Penn Medical Lab. Questions? Call 202-877-5073 or 202-877-5481.

Check below to indicate sample was collected	Collection Type	Test	Sample Type	Transfer Vial Type	Fresh or Frozen
--	-----------------	------	-------------	--------------------	-----------------

Blood Samples:

	1-10 ml SST	Chem Profile	Serum	1 6-ml red transport vial 2 2-ml red cryovial	Refrigerate Frozen
	1-4.5 ml Lt blue	PAI-1/Storage	Plasma	1-2 ml blue cap cryovial	Frozen
	1- SCAT	SCAT/Storage	Plasma	1 2-ml green cap cryovial	Frozen
	1-3 ml gray	0 hour (fasting) glucose	Plasma	1 2-ml clear cap cryovial	Frozen
	1- 3.5 ml purple	CBC	Whole Blood	Original Tube	Refrigerate
	1- 3.5 ml purple	Glycohemoglobin (HgbA1c)	Whole Blood	Original Tube	Refrigerate
	1-10 ml purple	Beta Estimate Storage DNA*	3-4 ml plasma Place 1-1.5 ml in each cryovial Buffy Coat	1 6-ml purple transport vial Follow directions on flipcharts	Refrigerate Frozen Frozen
	1-10 ml purple	Fibrinogen Insulin LDL size Storage Sample DNA*	Place 1-1.5 ml in each cryovial Buffy Coat	Follow directions on flipcharts	Frozen Frozen Frozen Frozen Frozen

Urine Samples:

	Random Urine	Microalbumin/Creatinine Urine storage	Urine	1 2-ml yellow cap cryovial 1 2-ml yellow cap cryovial	Frozen Frozen
--	--------------	--	-------	--	------------------

Two Hour Samples:

	1-3 ml gray	2 hour glucose	Plasma	1 2-ml clear cap cryovial	Frozen
--	-------------	----------------	--------	---------------------------	--------

* Buffy Coat from the EDTA tubes should be combined in one 4 ml purple cryovial.

Appendix 2 (d)

THE STRONG HEART STUDY III

Cohort-QA Routine Blood and Urine Sample Collection

Penn Medical Laboratory

108 Irving St, NW

Annex # 2

Washington, D.C. 20010

(Check to be sure that the patient is fasting for at least 12 hours, if possible.)

Participant ID No.:	Today's Date: (mm/dd/yy)
---------------------	--------------------------

Send the following specimens to Penn Medical Lab. Questions? Call 202-877-5073 or 202-877-5481.

Check below to indicate sample was collected	Collection Type	Test	Sample Type	Transfer Vial Type	Fresh or Frozen
Blood Samples:					
	1-SCAT	SCAT/storage	Plasma	1-2 ml green cap cryovial	Frozen
	1--4.5 Lt blue	PAI-1 Storage	Plasma	1-2 ml blue cap cryovial	Frozen
	1-10 ml purple	Beta Estimate	Plasma	1 6-ml purple transport vial	Refrige
	1-3 ml purple	Glycohemoglobin	Whole Blood	1 6-ml clear cap transport vial	Refrigerate

STRONG HEART STUDY
FAMILY COLD SAMPLE SHIPPING LOG

[illegible]

APPENDIX 3(b)

***STRONG HEART STUDY
COHORT COLD SAMPLE SHIPPING LOG***

[illegible]

Appendix 4(a)
STRONG HEART III STUDY

FAMILY FROZEN SAMPLE SHIPPING LOG

Federal Express Air Bill #:		Date & Time Shipped:						Date & Time Rec'd at PML:			Rec'd and Processed at PML by:		
Subject #:		Gluc 1 hr :	Gluc 2 hr :	Lp(a) /Insulin:	Apo E /LDL size:	Apo A1&B:	Fibrinogen	Ur Micro alb/Creat:	Storage- Serum	Storage - PAI-1	Storage- SCAT	Storage- EDTA	Storage-urine:
Date of Collection:	Site Comments:			Lab Sequence Label Here:				Spec Condition: N I L H A N PML Comments:					
Subject #:		Gluc 1 hr:	Gluc 2 hr:	Lp(a) /Insulin	Apo E /LDL size:	Apo A1&B:	Fibrinogen	Ur Micro alb/Creat:	Storage- Serum:	Storage - PAI-1:	Storage- SCAT:	Storage- EDTA:	Storage-urine
Date of Collection:	Site Comments:			Lab Sequence Label Here:				Spec Condition: N I L H A N PML Comments:					
Subject #:		Gluc 1 hr:	Gluc 2 hr:	Lp(a) / Insulin:	Apo E /LDL size:	Apo A1&B:	Fibrinogen	Ur Micro alb/Creat :	Storage- Serum	Storage- PAI-1	Storage- SCAT:	Storage- EDTA:	Storage-urine
Date of Collection:	Site Comments:			Lab Sequence Label Here:				Spec Condition: N I L H A N PML Comments:					
Subject #:		Gluc - 1 hr:	Gluc - 2 hr:	Lp(a) /Insulin:	Apo E /LDL size:	Apo A1&B:	Fibrinogen	Ur Microalb/ Creat:	Storage- Serum	Storage-PAI- 1	Storage- SCAT:	Storage- EDTA:	Storage-urine
Date of Collection:	Site Comments:			Lab Sequence Label Here:				Spec Condition: N I L H A N PML Comments:					

Appendix 4(b)
STRONG HEART III STUDY

COHORT FROZEN SAMPLE SHIPPING LOG

Federal Express Air Bill #:				Date & Time Shipped:				Date & Time Rec'd at Penn Medical Laboratory:				Rec'd and Processed at PML by:			
Subject #:	Gluc - 1 hr:	Gluc - 2 hr:	Insulin:	LDL size:	Fibrinogen	UrMicro alb/ Creat:	Storage-Serum	Storage-PAI-1	Storage-SCAT	Storage-EDTA:	Storage-Fibrinogen	Storage-urine:			
Date of Collection:		Site Comments:		Lab Sequence Label Here:			Spec Condition: N I L H A N PML Comments:								
Subject #:	Gluc - 1 hr:	Gluc - 2 hr:	Insulin:	LDL size:	Fibrinogen	Ur Micro alb/ Creat:	Storage-Serum	Storage-PAI-1	Storage-SCAT	Storage-EDTA	Storage-Fibrinogen	Storage-urine:			
Date of Collection:		Site Comments:		Lab Sequence Label Here:			Spec Condition: N I L H A N PML Comments:								
Subject #:	Gluc - 1 hr:	Gluc - 2 hr:	Insulin:	LDL size:	Fibrinogen	Ur Micro alb/Creat:	Storage-Serum	Storage-PAI-1	Storage-SCAT	Storage-EDTA	Storage-Fibrinogen	Storage-urine:			
Date of Collection:		Site Comments:		Lab Sequence Label Here:			Spec Condition: N I L H A N PML Comments:								
Subject #:	Gluc - 1 hr:	Gluc - 2 hr:	Insulin:	LDL size:	Fibrinogen	Ur Micro alb/Creat:	Storage-Serum	Storage-PAI-1	Storage-SCAT	Storage-EDTA	Storage-Fibrinogen	Storage-urine:			
Date of Collection:		Site Comments:		Lab Sequence Label Here:			Spec Condition: N I L H A N PML Comments:								

STRONG HEART STUDY

[illegible]

Appendix 6
The Strong Heart Study III
GTT Checklist

Family Cohort (circle one of the above)	Participant ID:	Today's Date:
Answer the following questions:		
<p>1. Record One Touch glucose result: (999= test not performed)</p> <p>2. Is the FASTING blood sample taken? (Answer one of the following)</p> <p>2a. Yes, and the participant has been fasting.</p> <p>2b. Yes, but participant has NOT been fasting.</p> <p>2c. No, participant is on renal dialysis.</p> <p>2d. No, participant has had a kidney transplant.</p> <p>2e. No, participant has not been fasting.</p> <p>2f. No, participant refused.</p> <p>2g. Other, please specify below:</p> <p>_____</p> <p>_____</p> <p>3. When was the last time you ate (use military time)</p>		<p>1. _____</p> <p>2. _____</p> <p>2a. _____</p> <p>2b. _____</p> <p>2c. _____</p> <p>2d. _____</p> <p>2e. _____</p> <p>2f. _____</p> <p>2g. _____</p> <p>3. _____</p>

Appendix 7

FEDERAL EXPRESS SHIPPING REQUIREMENTS

Worldwide, there has been a significant increase in diagnostic shipments. These include, but are not limited to, human or animal materials such as excreta, secreta, blood and its components, tissue and tissue fluids being shipped for the purpose of diagnosis.



FedEx has set the following packaging standards to ensure the safe transport of all Blood Urine Diagnostic (B.U.D.) specimens containing fluids and/or bodily samples. (Federal government agency regulations may also govern these shipments.)

1. FedEx requires that the shippers of all blood, urine and other liquid diagnostic specimens and environmental samples such as soil and water, package such items to include the following essentials:
 - a. Water tight primary receptacle
 - b. Water tight secondary packaging

Examples are:

 - sealed plastic bag
 - sealed Styrofoam container (1" thick minimum)
2. Absorbent material must be placed between the primary receptacle and the secondary receptacle. If multiple primary receptacles are placed in a secondary package, they must be individually wrapped to ensure that contact between them is protected. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles of untested specimens. It is the responsibility of the shipper to ensure adequate absorbent material is used.

Suggested Absorbent Materials

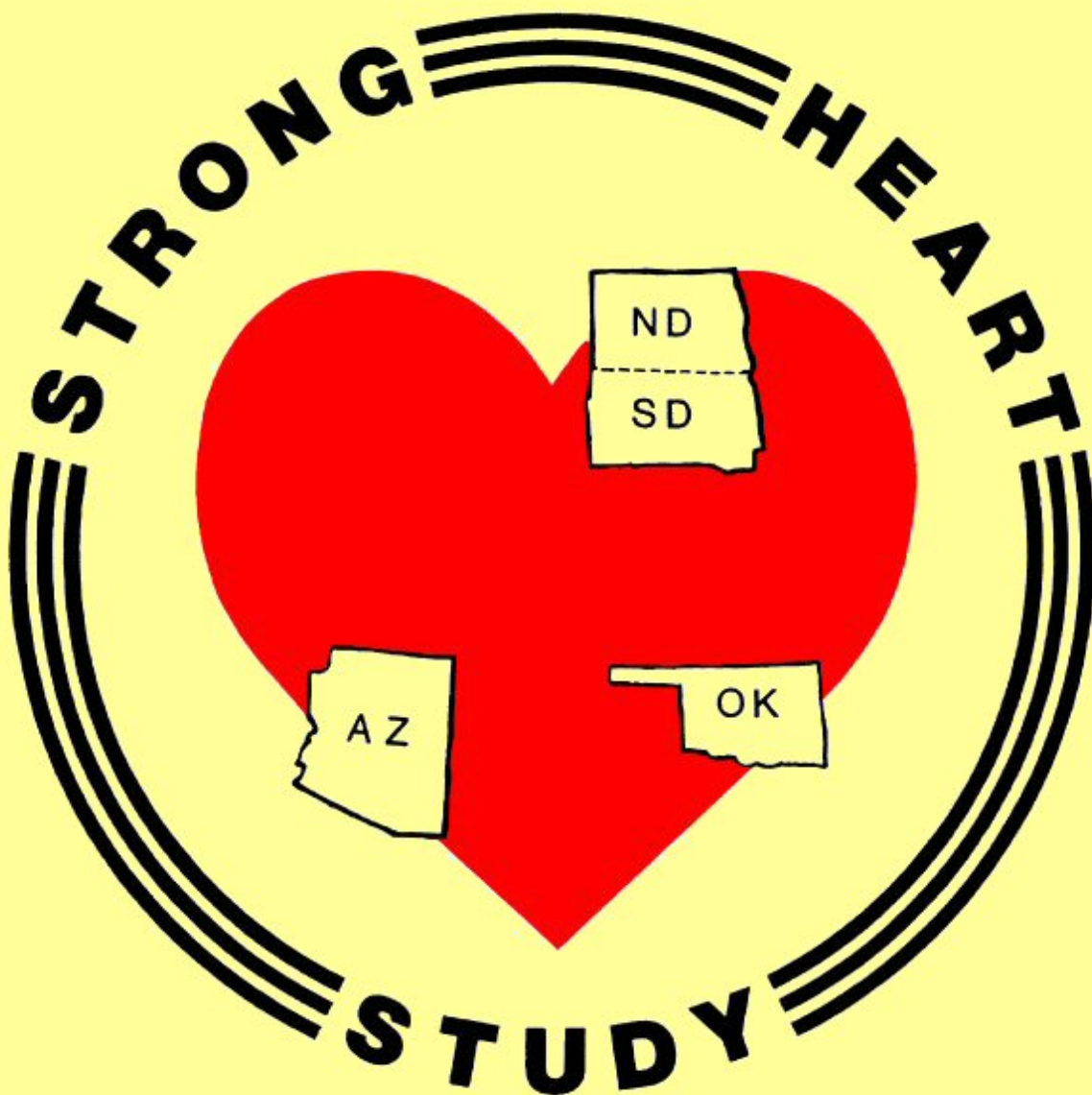
- a. Granular Absorbent (vermiculite or kitty litter)
- b. Super Absorbent Packet
- c. Paper Towels
- d. Cellulose Wadding
- e. Cotton Balls

3. Sturdy outer packaging made of corrugated fiberboard, wood, metal, or rigid plastic must be used. Styrofoam, plastic bags and paper envelopes are unacceptable outer packaging. The minimum acceptable size is 7" x 4" x 2".

Suggested Outer Packaging

- a. Corrugated Fiberboard
- b. Wood
- c. Rigid Coolers
- d. Rigid Plastic Containers

Remember: FedEx will refuse to accept packages not meeting these requirements. Consult the Occupational Safety and Health Administration (OSHA) regulations to determine if your commodity requires the Biohazard Label.



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME FOUR

MARQUETTE MAC PC SETUP

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

THE STRONG HEART STUDY
Cardiovascular Disease in American Indians
(Phase III)

Operations Manual
Volume Four
Marquette MAC PC Setup

June 1, 1997

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research

University of Oklahoma Health Sciences Center
College of Public Health

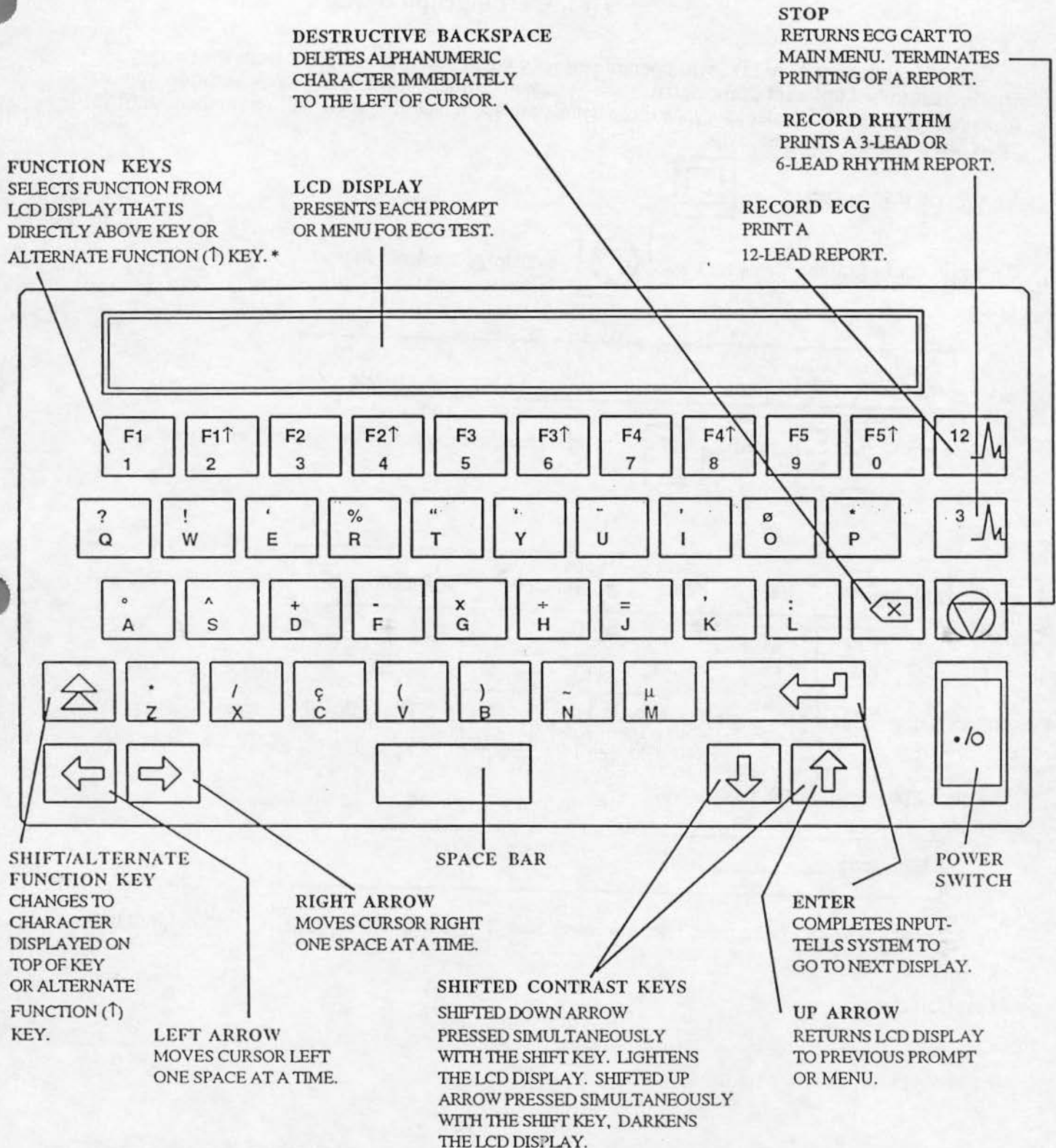
P.O. Box 26901
Oklahoma City, OK 73190

VOLUME IV
ECG SETUP AND INSTRUCTIONS

Table of Contents

1	Marquette MAC PC Setup	1
a.	Cardiograph Setup	2
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1. MAC PC Setup



* FOR MOST FUNCTION KEY USES, PRESSING EITHER THE NORMAL OR THE ALTERNATE FUNCTION (↑) KEY PRODUCES THE SAME RESULTS.

1(a). Cardiograph Setup

Although your MAC PC will operate perfectly when you first receive it from the factory, you'll want to 'set up' a lot of the details such as date and time, the name of your institution, types of reports you want printed, etc. Once these details are set, the cardiograph will retain them until you change the details again.

To turn on Power , press



To begin cardiograph setup, press



to display the *Main Menu*:

↑Task	V1 + II + V5			
PatInfo	Rhythm	25mm/s	10mm/mV	100Hz

Next, press



and



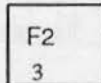
at the same time to display the System Functions

menu:

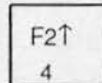
System Functions				
Storage	Setup	Diag	RevXmit	Monitor

F2 2	F2↑ 4
---------	----------

Select Setup (F2) by pressing either



or



. The following display will appear if

a Level 1 password has been entered:

Password: _____

Press keys "L" and "1" (numeric one, not lowercase "l"), then press



to display the

first Cart Setup menu:

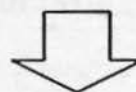
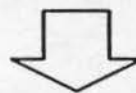
<div> <div>Dat/Tim</div> <div>Phone</div> <div>Cart Setup</div> <div>LdGrps</div> <div>Reports</div> <div>More</div> </div>									
F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6	F4 7	F4↑ 8	F5 9	F5↑ 0

Step A

Step B

Step C

Step D



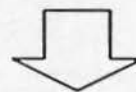
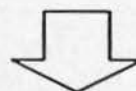
<div> <div>Modem</div> <div>Passwds</div> <div>Cart Setup</div> <div>Misc</div> <div>Defaults</div> <div>More</div> </div>									
F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6	F4 7	F4↑ 8	F5 9	F5↑ 0

Step E

Step F

Step G

Step H



<div> <div>Timeout</div> <div>RS232</div> <div>Cart Setup</div> <div>Monitor</div> <div>More</div> </div>					
F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6

Step I

Step J

Step K

Each of the above steps is explained in the following pages.

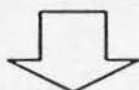
<u>Step</u>	<u>Contents</u>
A.	Date/Time
B.	Phone
C.	Lead Groups
D.	Report Formats
E.	Auto Dial
F.	Passwords
G.	Miscellaneous
H.	Defaults
I.	Timeout

Step A: Date and Time Setup


Date	Date and Time Setup
	Time

Press Backspace-Delete to erase.

F1	F1↑
1	2

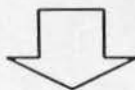


Today's Date (DD-MM-YY):	
DD=Day, MM=Month Name, YY=Year	


Type day + dash + month + dash + year and press 

Date	Date and Time Setup
	Time

F2	F1↑
1	2



Time (HH-MM):	
HH=Hour, MM=Minute (24 Hr Clock)	

Type hour + dash + minute and press 

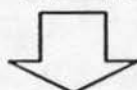
Date	Date and Time Setup
	Time

Press  to return to the Main Menu.

Step B: Phone Setup

Cart Setup				
Dat/Tim	Phone	LdGrps	Reports	More

F2 3	F2↑ 4
---------	----------



Phone Number	
0 - 9 # * = ,	9=12127464699

Some universities need 8 to get off campus, you need 9 or nothing. "=" gives a pause for off-campus dial tone. "1" is for long distance. The rest is the New York Hospital-Cornell Medical Center access number.

Type phone number. Then press



Cart Setup				
Modem	Passwds	Misc	Defaults	More

Press



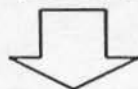
Main Menu.

to return to the

Step C: Lead Groups-Rhythm Leads Setup

Lead Groups			
Rhythm	Standrd	RMR	4 x 2.5

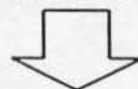
F1 1	F1↑ 2
---------	----------



Group:				
AutoRhm	Group1	Group2	Group3	Group4

F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6	F4 7	F4↑ 8
---------	----------	---------	----------	---------	----------	---------	----------

F5 9	F5↑ 0
---------	----------




These should never need to be changed.


Select a group. The previously chosen leads will appear. Then press



Number of Rhythm Leads :		3
3	6	

Select the number of rhythm leads you want on writer reports. Then press 

F1	F1↑	F2	F2↑
1	2	3	4

Select 1 of 12 available leads for each of the 3 or 6 rhythm channels; press  after each selection. In the example below, the displays for the 12 available leads are shown for channel 1:

Ch 1: V1	II	III	More
I			



Ch 2: II	II	III	More
I			




Ch 3: V5	II	III	More
I			



After selecting a lead for each of the channels, the following will appear:

	Lead Groups		
Rhythm	Standrd	RMR	4 x 2.5

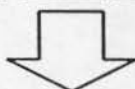
Press  to return to the Main Menu.

Step D: Report Formats Setup

Report Formats for:	
Confrmd	Unconf

Do not configure confirmed. Press F2 for unconfirmed.

F1	F1↑	F2	F2↑
1	2	3	4



For each of the following LCDs press either F1 keys for "YES", F2 keys for "NO"; and press

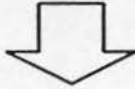


to store the report information.

Suppress Orig Rpt Interpretation:			NO
Yes	No		

Clinic choice here. Marquette interpretation may be printed on ECG.

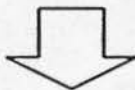
F1	F1↑	F2	F2↑
1	2	3	4



Suppress Copy Interpretation:			NO
Yes	No		

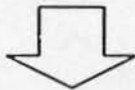
Phoenix enters F1 or F2 for "YES".

F1	F1↑	F2	F2↑
1	2	3	4



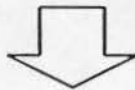
Suppress Text Page:			NO
Yes	No		

F1	F1↑	F2	F2↑
1	2	3	4



Rhythm and Morphology Report (RMR):			NO
Yes	No		

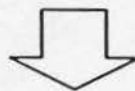
F1	F1↑	F2	F2↑
1	2	3	4



(1)

1 Complex / Lead:			NO
Yes	No		

F1	F1↑	F2	F2↑
1	2	3	4



(2) Automatic Rhythm (1x10): NO
 Yes No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------



(3) 12 Lead (4x2.5): YES
 Yes No

This is the ONLY format to be printed.

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------



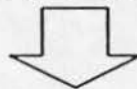
(4) Separate Text Page for 4x2.5: NO
 Yes No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------



(5) 1 Page 4x2.5 with Rhythm: NO
 Yes No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------



12 Lead (2x5): NO
 Yes No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

12 Lead (2x10): NO
 Yes No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------


12 Lead (4x10):	NO
Yes	No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

12 Lead (2x5 at 50mm/s):	NO
Yes	No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

Report Formats for:
Confrmd Unconf

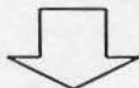
When you return to the start, press  to return to the *Main Menu*.

From here, Press "RETURN" key.

Step E: Modem Setup -- Auto Dial

Modem	Cart Setup			
	Passwds	Misc	Defaults	More

F1 1	F1↑ 2
---------	----------



Speaker On:	Dialing Only
Dial	Always

F1 1	or	F2 3
---------	----	---------

Dialing: Auto Dial
Manual Auto

F2 3	F2↑ 4
---------	----------

Dialing Format: Touch Tone
Pulse T Tone

Or "PULSE", may vary by site.

F1 1	or	F2 3
---------	----	---------

Dial Tone Required:	YES
Yes	No

F1	or	F2↑
1		4

Dial Tone Time: 1s
1s 2s

F1	or	F2↑
1		4

Modem Transmit Power Level: -9dBm
-6dBm -7dBm -8dBm -9dBm More

F1	F1↑	F2	F2↑	F3	F3↑	F4	F4↑	F5	F5↑
1	2	3	4	5	6	7	8	9	0

Transmit Synch Time: 148.3 ms
800ms 220ms 148.3ms 90ms More

F1	F1↑	F2	F2↑	F3	F3↑	F4	F4↑	F5	F5↑
1	2	3	4	5	6	7	8	9	0

Answer Tone Frequency:	2025 Hz
2025hz 2100Hz	

F1	F1↑	F2	F2↑
1	2	3	4

Answer Tone Wait (in seconds): 180
5 - 600

Step F: Password Setup

Modem	Cart Setup			
	Passwds	Misc	Defaults	More

F2	F2↑
3	4



Level 1	System Passwords
	Level 2

F1	F1↑	F2	F2↑
1	2	3	4


Passwords are preset as L1 for Level 1 as all aspects of programmability.


Step G: Miscellaneous Setup

Modem	Cart Setup Passwds	Misc	Defaults	More
-------	-----------------------	------	----------	------

F2
3

F2↑
4



For each of the following prompts, type in an appropriate response or press a function (F) key. Then press  to store that information.

Line Frequency:	60 Hz
60 Hz	50 Hz

F1
1

F1↑
2

F2
3

F2↑
4

Cart ID:
0 - 255

The Cart ID is site specific:

Phoenix MAC PC	= 43
Phoenix MAC 12	= 44
Oklahoma MAC PC 1	= 48 (Lawton)
Oklahoma MAC PC 2	= 49 (Anadarko)
Rapid City:	Eagle Butte = 59
	Pine Ridge = 60
	Fort Totten = 61

Site ID: 3
1 - 255

Institution Name: Strong Heart Study
Up to 40 characters

Number of Patient ID Digits: 11
1 - 12

Height / Weight:		cm/kg
in /lb	cm/kg	

This may be omitted in the SHS.

F1	F1↑	F2	F2↑
1	2	3	4

Input Patient Age As :		DOB
DOB	Years	

= Date Of Birth.

F1	F1↑	F2	F2↑
1	2	3	4

Ask Blood Pressure Questions:		NO
Yes	No	

NO

F1	F1↑	F2	F2↑
1	2	3	4

Ask Options Question:		NO
Yes	No	

NO

F1	F1↑	F2	F2↑
1	2	3	4

Suppress Normal Statement:		NO
Yes	No	

NO

F1	F1↑	F2	F2↑
1	2	3	4

Suppress Border & Abnormal Statement:		NO
Yes	No	

NO

F1	F1↑	F2	F2↑
1	2	3	4

ECGs to Store/Transmit:		All ECGs
All	Abnormal	

ALL

F1	F1↑	F2	F2↑
1	2	3	4

Delete ECGs After Transmission:		SAVE
Save	Delete	

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

SAVE. It is very important to change this to SAVE. By default the machine deletes ECGs as soon as they are transmitted, without waiting for confirmation from Cornell.

Store/Transmit Control: Store	
Store	Transmit

Store

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

Power Up Speed:	25mm/s
25mm/s	50mm/s

25mm/s

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

Power Up Filter:	100 Hz
40 Hz	100 Hz

100 Hz

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

Screening Criteria:	NO
Yes	No

NO

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

Baseline Roll Filter:	.16 Hz
.01Hz	.02Hz .16Hz .32Hz

.16 Hz

F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6
---------	----------	---------	----------	---------	----------

QC Baseline Drift:	NO
Yes	No

NO

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------

QC Muscle Tremor:		NO	
Yes	No		

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------


NO. Press  to

return to the *Main Menu*.

Step H: Defaults Setup

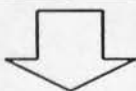
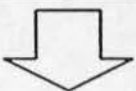
Cart Setup				
Modem	Passwds	Misc	Defaults	More


F4 7	F4↑ 8
---------	----------



Are you Sure???	
yes	No

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------



Never say yes to return original factory setup defaults, because that will set the machine to delete ECGs after transmission.


Return LCD to the following display.

Return the MAC PC to its original factory setup defaults.
Any setup changes that you made will be lost..

Setup I: Timeout Setup

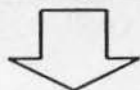
Cart Setup				
Modem	Passwds	Misc	Defaults	More

F5 9	F5↑ 0
---------	----------



Timeout	Cart Setup	Monitor More
	RS232	

F1 1	F1↑ 2
---------	----------



Automatic Timeout (minutes):					10
1	5	10	30	none(ac)	

This saves the battery.

F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6	F4 7	F4↑ 8	F5 9	F5↑ 0
---------	----------	---------	----------	---------	----------	---------	----------	---------	----------

Select F1 to set a 1-minute timeout, F2 to set a 5-minute timeout, F3 to set a 10-minute timeout, F4 to set a 30-minute timeout, or F5 to set an indefinite timeout length.


“Timeout” is the amount of time it takes for the LCD to go blank when the MAC PC is not being used.

If the “none(ac)” is selected, the timeout length will be indefinite only if a power module is attached to the MAC PC and the battery status (section 12) message indicates “OK” or “FULL.” Otherwise, if a power module is NOT attached, then the timeout length will be set to 10 minutes.


Timeout	Cart Setup	Monitor	More
	RS232		

Press  to return to the *Main Menu*.

1(b). Taking a resting ECG Entering Patient Information

Note: It is NOT necessary to enter any patient information in order to take a resting ECG. You can record an ECG at any time -- if the *Main Menu* is displayed by just pressing 12 . If you do not enter the patient's name and identification number, the patient will be identified by the date and time when the ECG was taken.

Note: When a patient's age is entered and the patient is 15 years old or less, then a pediatric 12SL analysis is performed on the ECG data. However, if NO age is entered, then the MAC PC will always performed an adult analysis.

If the Main Menu is not already displayed, then press  to return to it:

↑Task V1 + II + V5

PatInfo Rhythm 25mm/s 10mm/mv 100Hz

Hit either F1 or F1↑.

F1

1

F1↑

2

Next, press either F1 or F1↑ to select PatInfo (F1). One of the following two prompts will appear:

Patient Last name:
A to Z, Space.

Enter names.

OR

New Patient:
Yes No

This won't show up if the machine was just turned on. Hit either F1 button if it is a new person. Hit either F2 button if you want to correct an entry and/or take another ECG on the same person.

Patient First Name:
A to Z, 0 to 9, Space.

Patient ID:
Digits 0 to 9.


This is actually an 11 digit ID. Enter five (5) 0 followed by six (6) digits Strong Heart Study ID.

Referred By :
(Physician Name)

Skip over




Location Number:
0 to 99


Skip over 

Room Number:
Any 5 characters


This is the interviewer #.
Enter your SHS code here.

Date of Birth (DD - MM -- YY)
DD = Day, MM=Month, YY=Year


To type dash press 

and  at the same
time. MM=letters of month
(JAN, FEB, ...,etc.) YY=
Year (89, 90, etc.)

Height: (in cm)

Skip over 

Weight: (in kg)

Skip over 

Sex:
Male Female

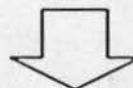
Indicate Sex. Hit either F1
F2.

Race:
Cauc Black Oriental Hisp More

Choose "More". Hit either
F5.

F5
9

F5↑
0

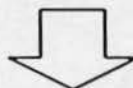


Race:
Unknown Indian

Choose "Indian". Hit either
F3.

F3
5

F3↑
6




Medication:
none Unknown Add Scroll

If on CARDIAC medication
enter either F4. Find medi-
cation and enter. (This is
not part of Strong Heart
Study essential information)

F4
7

F4↑
8



The MAC PC is now ready to take a 12-lead ECG. Press  to start.

Fault Detection Procedures

Should problems with noise or drift be encountered, electrodes are replaced. The following is a guide for determining which electrodes may be faulty. The underlined electrodes are the predominant determinants of the appropriate lead and therefore are most likely to be the faulty electrodes for a given lead. After adjustment or replacement of suspect electrodes, the electrocardiograph should be able to record 10 seconds of good data.

Lead Affected Possible Faulty Electrode

I	RL, RA, LA
II	RL, RA, LL
III	RL, LA, LL
aV _R	RL, RA, LL, LA
aV _L	RL, LL, RA, LA
aV _F	RL, LL, RA, LA
V ₁	RL, LL, RA, LA, V ₁
V ₂	RL, LL, RA, LA, V ₂
V ₃	RL, LL, RA, LA, V ₃
V ₄	RL, LL, RA, LA, V ₄
V ₅	RL, LL, RA, LA, V ₅
V ₆	RL, LL, RA, LA, V ₆

Self-Evaluation of Technical Performance

This section allows technicians to monitor their own ECG technique. It is intended to help technicians who are having difficulty meeting the quality standards set by the ECG Reading Center. These data are not intended to be collected by the study.

The technician examines the ECG tracing to estimate the noise level and baseline drift. Based on the requirements of the Minnesota Code, acceptable and unacceptable levels of noise and baseline drift have been established. These levels are scored using the following table:

Noise Grade	Overall (mm)	Beat-to-beat Drift (mm)	Quality Drift (mm)
1	< .25	< 1	< 1
2	< .50	< 2	< 1.5
3	< 1	< 3	< 2
4	< 2	< 4	< 3
5	> 2	> 4	> 3

The grade levels given in this table are related to the ability of the analysis program to achieve the required accuracy. Quality Grade 5 is unacceptable. ECGs of Quality Grade 5 must be deleted from the machine's memory and retaken immediately.

1. First, the tracing is examined for obvious errors such as right arm/left arm and other common lead misplacement (see Figure 4, negative p-waves in I indicate lead switch). These ECGs must be deleted from the machine's memory and retaken immediately.
2. The Quality Grade for noise is obtained by measuring the noises level ss vertical peak-to-peak values in terms of number of small paper divisions (smallest grid squares). Note that recording sensitivity is 1 mV per centimeter, (one small paper division = 1 mm = 0.1 mV). A noise level of more than 2 small paper divisions (> 0.2 mV peak to peak) is unacceptable (Figure 5).
3. The Quality Grade for overall drift is obtained by searching each of the 12-leads for the maximum and minimum baseline levels within that lead (as determined by the PR and/or TP segments) over the 10 second recording and measuring the vertical distance between them. A distance of more than 4 small paper divisions is unacceptable (Figure 6).
4. The Quality Grade for beat-to-beat drift is determined by searching for the pair of successive QRS complexes having the largest amplitude difference (vertical distance) between successive PR segments. A difference of more than 3 small paper divisions (> 0.3 mV) indicates an unacceptable record (Figure 7).

Improvement in technical quality will indeed result if the prescribed procedure for electrode position marking, electrode and skin preparation, electrode replacement and equipment use are carefully followed. Baseline drift problems, which are essentially caused by poor electrode-skin contact are particularly easy to remedy, as is 60-cycle interference.

Sixty-cycle interference is characterized by perfectly regular fine oscillations occurring at the rate of sixty per second (Figure 8).

Electrical equipment of any kind may be the source of AC interference on an ECG in all leads or only certain ones. Check quality of skin preparation and electrode contact. Check leadwires and resecure attachment of the alligator clip to the electrode. Make sure participant does not touch any metal part of the bed or other equipment. Proximity to a wall with hidden wiring or a partially broken cable may also cause this problem.

Muscle Tremor causes irregular oscillations of low amplitude and varying rapidity superimposed upon the ECG waveform (Figure 9). Muscle tremor is the involuntary muscle activity of a participant whose state is tense, apprehensive, or uncomfortable. This is why a clear explanation of the electrocardiogram test and reassurance are necessary for the participant. The participant is asked if the temperature of the room is too low for her/him and is covered with a blanket if so.

Original Hard Copy Record

The original 12-lead ECG record is filed at the field center. If the clinic needs a second "original" ECG, it can be printed from the machine's memory anytime before deletion of the ECG. The first hard copy ECGs are read locally by clinic physicians for notification and referral if needed. The records are then placed in participants' local data files. Double-check that this participant is correctly identified.

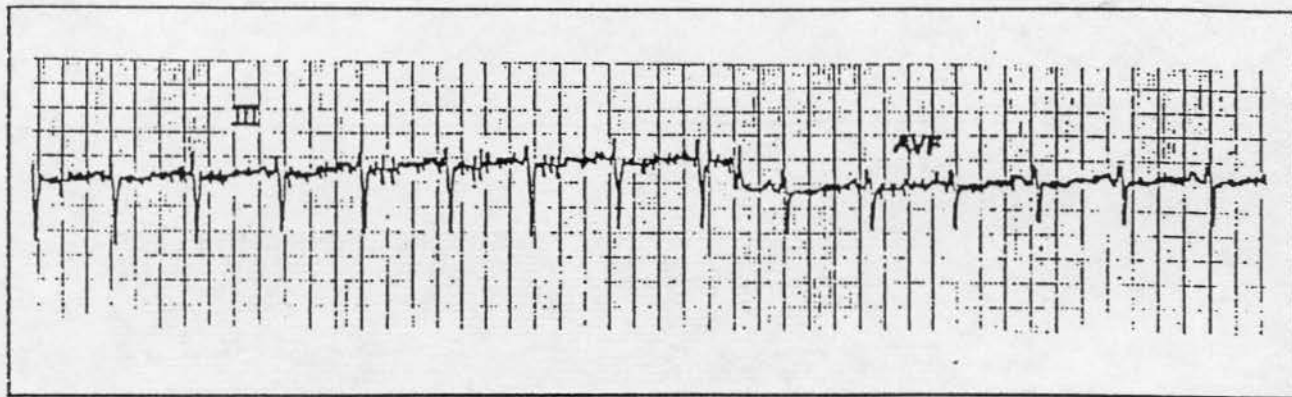


Figure 5. Unacceptable Noise Level

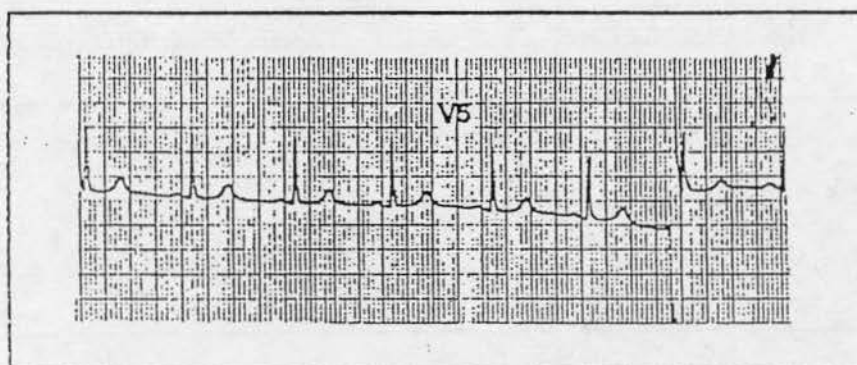


Figure 6. Unacceptable Overall Baseline Drift

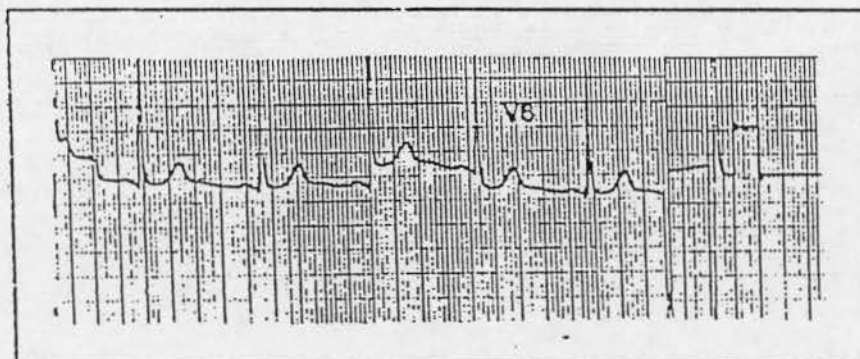


Figure 7. Unacceptable Beat-to-Beat Baseline Drift

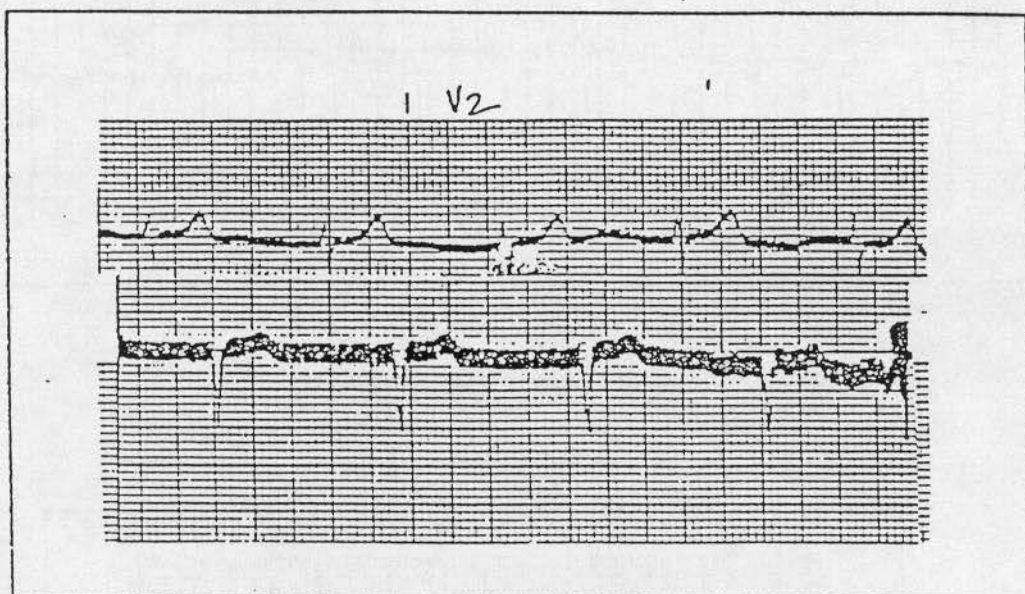


Figure 8. Sixty-Cycle Interference

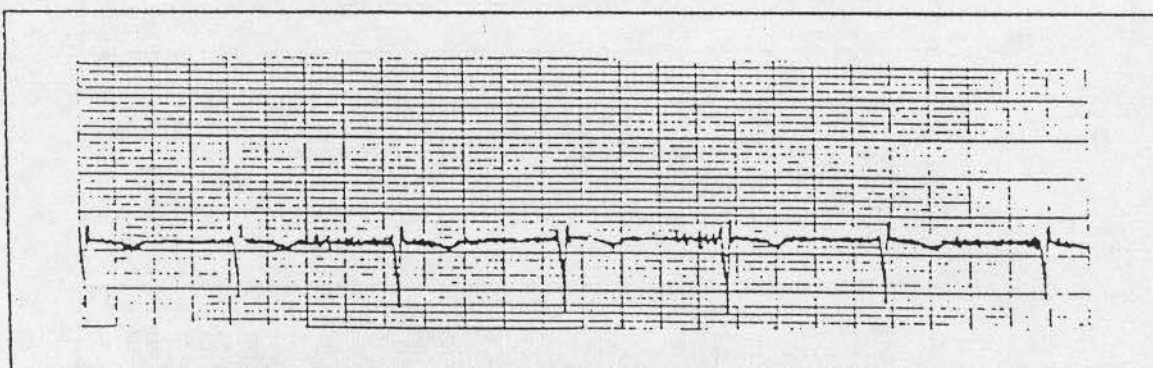




Figure 9. Artifact Caused by Muscle Tremor

1(c). Transmitting ECGs by Telephone

Note: Only a MAC PC equipped with a modem can transmit ECG reports by telephone.

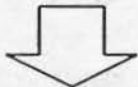
1. Prepare the MAC PC as described in section 1.
2. Connect a telephone cord from a telephone wall jack to the backpanel jack on the MAC PC.
3. If the Main Menu is not already displayed, press  :

↑Task	V1 + II + V5			
PatInfo	Rhythm	25mm/s	10mm/mv	100Hz

4. Press  and F1↑ to display the System Functions menu. Then press one of the two keys listed under each of the following displays:

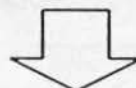
System Functions				
Storage	Setup	Diag	RevXmit	Monitor

F1	F1↑
1	2



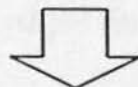
Storage Functions				
Plot	Directory	Summary	Delete	More

F5	F5↑
9	0



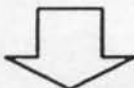
Storage Functions			
Transmit	Edit	Format	More

F1	F1↑
1	2



Transmission Type	
Phone	Local RS232


F1	F1↑
1	2



** No Data in Storage **

OR

Phone Number:
0-9 # * = ,

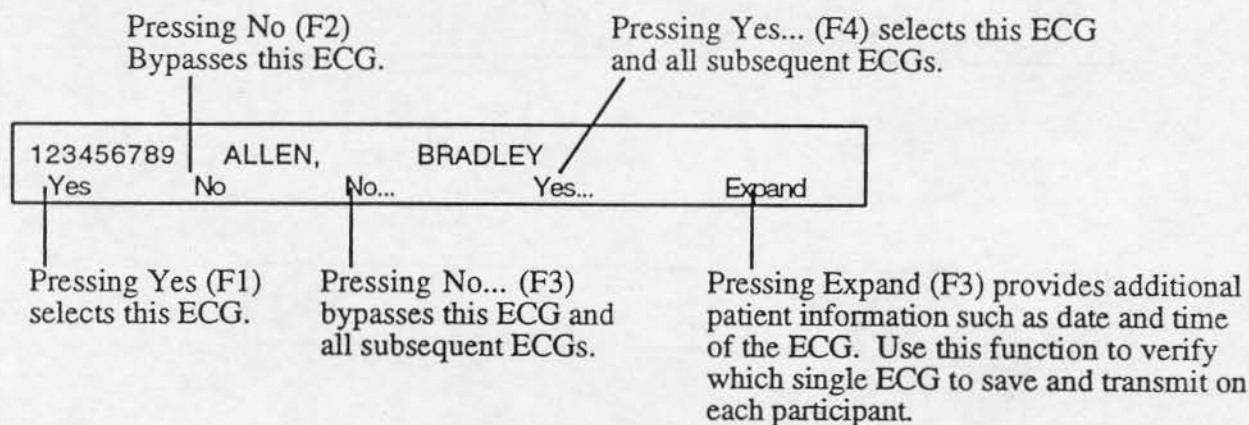
5. If the second display appears, type in the phone number of the location where you will be transmitting and press .

The # and * are touch-tone symbols.

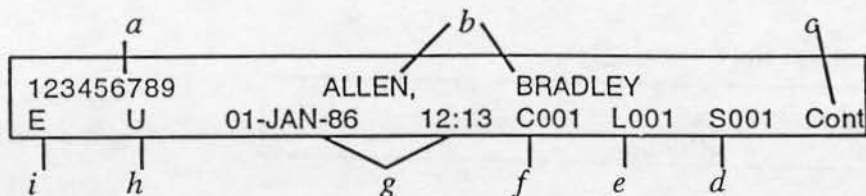
The , sign provides a 2-second pause and may be used repeatedly for longer parses. (For example, in the phone number 1,,8081112345 there will be a 6-second pause between the numbers "1" and "8" when dialing.)

The = sign is used to wait for a dial tone. (For example, in order to dial an outside number, your phone system may require you to dial "9" first. A sample number would look like this: 9=1234567.)

6. Next, patient data on each stored ECG will be displayed similar to the following:



7. To display additional patient information, press Expand (F5) and a message similar to the one below will be displayed:



- | | |
|---|---|
| a. Patient identification number. | f. Cart number of the unit where ECG was recorded. |
| b. Last name, first name of patient or the date and time when ECG was recorded. | g. Date and time of ECG acquisition. This is a unique identifier if more than one ECG was saved on a particular subject. |
| c. Select to return to former display. | h. A U means that the ECG is unconfirmed. An C means that the ECG is confirmed. Use the Edit function described in section 6 to change an unconfirmed ECG to a confirmed ECG. |
| d. MUSE site number where ECG was recorded. | i. Type of Data. E stands for ECG. |
| e. Location number where ECG was recorded. | |

8. Depending on which ECGs you want to transmit or bypass, press the appropriate function (F) key.

9. After selecting the ECGs you want to transmit, displays similar to the following will appear:

```

** Batch Transmission **
Waiting for Dial Tone

```

THEN

```

** Batch Transmission **
Dialing 1112345

```

THEN

```

** Batch Transmission **
Waiting for an Answer Tone

```

THEN

```

** Batch Transmission **
123456789      JONES,      JACK

```

10. After the last ECG has been transmitted, a message indicating the number of ECGs that were transmitted vs the number you selected to transmit will be displayed similar to the following:


```

5 of 5 Transmitted
Type Any Key to Continue

```

11. Pressing any key displays the following:

Transmission Type	
Phone	Local RS232

Press  to return to the Main Menu.

12. If, despite previously mentioned safeguards, you have still erroneously transmitted a tracing with improper ID #, time, or a non-SHS ECG, please FAX this data to Dr. Okin immediately at (212) 746-8451.
13. All transmitted ECGs should be logged at the study field clinic.

A copy of this log page should be faxed to Dr. Okin weekly on Monday to verify ECG authenticity before ECGs are sent to Minneapolis.

Erroneous ECGs consumed much time during Phase I.


SHS ECG TRANSMIT LOG

[illegible]


1(d). Receiving ECGs by Telephone Receiving By Telephone

Note: Only a MAC PC equipped with a modem can receive ECG reports by telephone.

Note: If 75% or more of the MAC PC's memory is used, then the message "Plotter Output Only" will appear. This means that incoming data will be printed but NOT stored. In this case, if you want to store incoming data, then delete some ECGs from the MAC PC *before* you begin receiving data (refer to section 9).

1. Prepare the MAC PC as described in section 1.
2. Connect a telephone cord from a telephone wall jack to the backpanel jack on the MAC PC.
3. If the Main Menu is not already displayed, press  :

↑Task	V1 + II + V5
PatInfo	Rhythm 25mm/s 10mm/mv 100Hz

4. Press  and F1↑ to display the System Functions Menu:

System Functions				
Storage	Setup	Diag	RevXmit	Monitor

F4
7

F4↑
8

5. Select RevXmit (Reverse Transmission) to display:

Transmission Type	
Phone	Local RS232

F1
1

F1↑
2

6. Select Phone (F1) and one of the following two message will appear:

No Data Storage - Plotter Output Only Type Any Key to Continue

OR

Select Option:	
Store	Plot

F1
1

F1↑
2

F2
3

F2↑
4

7. If the second display appears, select Store (F1) to store and print out the ECG(s) you receive, or select Plot (F2) to just print out the ECG(s) without storing them. Then a display similar to the following will appear:

**** Reverse Transmission ****
Check the Phone Line

d

8. If the following message appears, then the telephone line is not attached:

**** Reverse Transmission ****
Phone Line Not Attached

9. Otherwise, the following series of message will be displayed for each ECG that is received:

**** Reverse Transmission ****
Ready to Receive

THEN

**** Reverse Transmission ****
Answer the Phone

THEN

**** Reverse Transmission ****
Receiving Data

THEN

**** Reverse Transmission ****
End of Data Packet

THEN


**** Reverse Transmission ****
Page xx of xx

10. After all ECGs have been received, following will appear:

**** Reverse Transmission ****
End of Transmission

THEN

**** Reverse Transmission ****
Ready to Receive


11. If no other ECGs will be received, then press  to return to the Main Menu. NOTE: Use the Directory function (section 8) to check that all ECGs have been received.

1(e). Deleting an ECG


Since most ECG storage is only temporary, there will probably be times when you want to delete recordings from the MAC PC's memory. Also, there may be times when the memory is almost full, and the MAC PC itself suggests that you delete ECGs. (Refer to the Section on "Forced Deletion".) ECGs taken in the Strong Heart Study should be kept in memory until confirmed copy is returned. The machine will not automatically delete ECGs except that procedures are carried out as described in "Forced Deletion".

Routine Deletion

ECGs are usually deleted after you print a paper copy of the ECG, when more than one ECG per patient has been stored or when the ECG is transmitted to another location. To delete one or more ECGs, follow these steps:

1. Prepare the MAC PC as previously described.
2. If the Main Menu is not already displayed, press  :

↑Task	V1 + II + V5
PatInfo	Rhythm 25mm/s 10mm/mv 100Hz

3. Press  and F1↑ at the same time to display the System Functions menu. Then press one of the two keys listed under each of the following displays:

System Functions				
Storage	Setup	Diag	RevXmit	Monitor

F1 1	F1↑ 2
---------	----------



Storage Functions			
Plot	Directory	Summary	Delete More

F4 7	F4↑ 8
---------	----------

4. After selecting Delete (F4) a message similar to the following one will be displayed:

5%	123456789	ALLEN,	BRADLEY
Delete	Save	Save...	Quit Expand

Pressing Save (F2) saves this ECG.

Pressing Expand (F5) provides additional patient information such as date and time of the ECG.

Pressing Delete (F1) Deletes this ECG.

Pressing Save... (F3) saves this ECG and all Subsequent ECGs.

Pressing Quit (F4) leaves the Delete function.



5. To display additional patient information, press Expand (F5) and a message similar to the one below will be displayed:

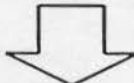
<i>a</i>	<i>b</i>	<i>c</i>		<i>d</i>
5%	123456789	ALLEN,	BRADLEY	
<i>j</i>	<i>i</i>	<i>h</i>	<i>g</i>	<i>f</i>
E	U	23-MAR-88	09:53	G001
				L001
				S001
				Cont

- | | |
|--|--|
| <i>a.</i> Percentage of memory used by this ECG. | <i>g.</i> Cart number of the unit where ECG was recorded. |
| <i>b.</i> Patient identification number. | <i>h.</i> Date and time of ECG acquisition. This is a unique identifier if more than one ECG was saved on a particular subject. |
| <i>c.</i> Last name, first name of patient or the date and time when ECG was recorded. | <i>i.</i> A U means that the ECG is unconfirmed. An C means that the ECG is confirmed. Use the Edit function described in section 6 to change an unconfirmed ECG to a confirmed ECG. |
| <i>d.</i> Select to return to former display. | <i>j.</i> Type of Data. E stands for ECG. |
| <i>e.</i> MUSE site number where ECG was recorded. | |
| <i>f.</i> Location number where ECG was recorded. | |
6. Depending on what you want to delete, save, or bypass, press the appropriate function (F) key.
7. After you have decided which ECGs you want to delete, you have another chance to change your mind. For instance, if you have decided to delete two ECGs, this message would be displayed:

Delete		2 ECG(s) ? :	
Yes		No	

F1 1	F1↑ 2	F2 3	F2↑ 4
---------	----------	---------	----------


Cancels the Delete.

Deletes the selected ECGs.

If the ECG you are recording requires more memory than the MAC PC is able to spare, a prompt will appear after the Processing ECG for Storage display:

ECG storage: Insufficient Space Available
Type Any Key to Continue

- Pressing any key to continue causes this message to be displayed:

Select Option:
Delete Quit Xmit

F1 1	F1↑ 2	F2 3	F2↑ 4	F3 5	F3↑ 6
---------	----------	---------	----------	---------	----------

- Select Delete (F1) to display one of the ECGs stored in the MAC PC's memory. A small explanation of how each function key affects ECGs stored in the MAC PC follows.
- Select Quit (F2) to return to the "ECG Storage: Insufficient Space Available" display.
- Select Xmit (F3) if you want the MAC PC to transmit the ECG you just acquired instead of storing it. (Xmit will only appear if your MAC PC is equipped with a modem.)

- If you select Delete, a display similar to the following will appear:

Pressing Expand (F5) provides additional patient information such as date and time of the ECG.

(5%) Delete	24% Save	123456789 Quit	ALLEN, Expand	BRADLEY
----------------	-------------	-------------------	------------------	---------

Pressing Delete (F1) deletes this ECG.

Pressing Save (F2) saves this ECG.

Pressing Quit (F4) return to the "Insufficient Storage" display.

- To display additional patient information, press Expand (F5) and a message similar to the one below will be displayed:

a (5%) k	b 24% j	c 123456789 i	d ALLEN, h	e BRADLEY g	S001 f	Cont
E	U	23-MAR-88	09:53 C001	L001		

a. Percentage of storage that must be deleted to provide room for the ECG just acquired. This number decreases as ECGs are selected for deletion.

g. Location number where ECG was recorded.

h. Cart number of the unit where ECG was recorded

- b. Percentage of memory used by this ECG.
- c. Patient identification number.
- d. Last name, first name of patient or the date and time when ECG was recorded.
- e. Select to return to former display.
- f. MUSE site number where ECG was recorded.
- i. Date and time of ECG acquisition. This is a unique identifier if more than one ECG was saved on a particular subject.
- j. A U means that the ECG is unconfirmed. An C means that the ECG is confirmed. Use the Edit function described in section 6 to change an unconfirmed ECG to a confirmed ECG.
- k. Type of Data. E stands for ECG.

4. After you have either Saved or Deleted all stored ECGs, one of the following two displays will appear:

Not enough ECG(s) selected for deletion
Type Any Key to Continue

OR

Delete 2 ECG(s) ? :
Yes No

F1
1

F1↑
2

F2
3

F2↑
4

If the first display appears, then you will return to the "ECG Storage: Insufficient Space Available" display. In this case, you will have to start the deletion process all over.

If the second display appears, or one like it, then select Yes (F1) to delete the selected ECGs or No (F2) to return to the "ECG Storage: Insufficient Space Available" display.

5. If you selected Yes (F1), the ECG you just recorded will be stored. The this message will be displayed:

** ECG Storage Complete **
Type Any Key to Continue

Pressing any key to return you to the *Main Menu*.

2. STANDARD ECG INSTRUCTIONS

1. BASELINE ECGs

1.1 Introduction

During the baseline examination, a standard supine 12-lead resting ECG is recorded at least one half hour after ingestion of glucose.

1.2 Procedure for Recording Baseline ECG

The standard electrocardiograph for the Strong Heart Study is the MAC PC Personal Cardiology by Marquette Electronics, Inc. The standard configuration for the MAC PC is shown in Appendix A. 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.

Procedures for charging the battery of the MAC PC: The MAC PC runs only from its battery. The battery can be charged by plugging the unit into a wall outlet. The MAC PC will record and print about 50 ECGs on one charge. The amount of charge left is displayed for one-half second when the machine is turned on. It takes about 10 hours to charge the battery.

Plug in the unit each evening after transmitting data to Cornell. Unplug the unit in the morning. It is not good for the machine to spend several days in either the fully charged or completely drained state. For weekends and holidays the machine may be left plugged in, or, if the brief charge display shows at least 25 ECGs remaining, it may be left unplugged.

1.3 Electrode Position Measuring and Marking

Because it is essential for the study to be able to compare baseline ECG data with subsequent records, a uniform procedure for electrode placement and skin preparation is required. The method and procedure for standardizing electrode 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 on the MAC PC during this time. This waiting time is not so critical with the suction electrodes, if it is anticipated that data entry will take > 3 minutes, you may want to enter data first when using these electrodes. It is recommended that the stick-on electrodes be applied 2-3 minutes prior to acquiring the ECG.

A good felt tip pen is used to mark the six chest electrode positions. Wipe the general area of the following 10 electrode sites with a sterile alcohol prep to remove skin oil and perspiration. 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 (Figure 1)

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.

2. Electrode V₁

Locate 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.

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 better anatomic position.

5. Electrode V_4

Electrode V_4 is located using the E- V_6 Halfpoint Method. Using the medical tape measure employed 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 anthropometry, 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 employed in anthropometry, mark the location of electrode V_5 midway between the locations of V_4 and V_6 .

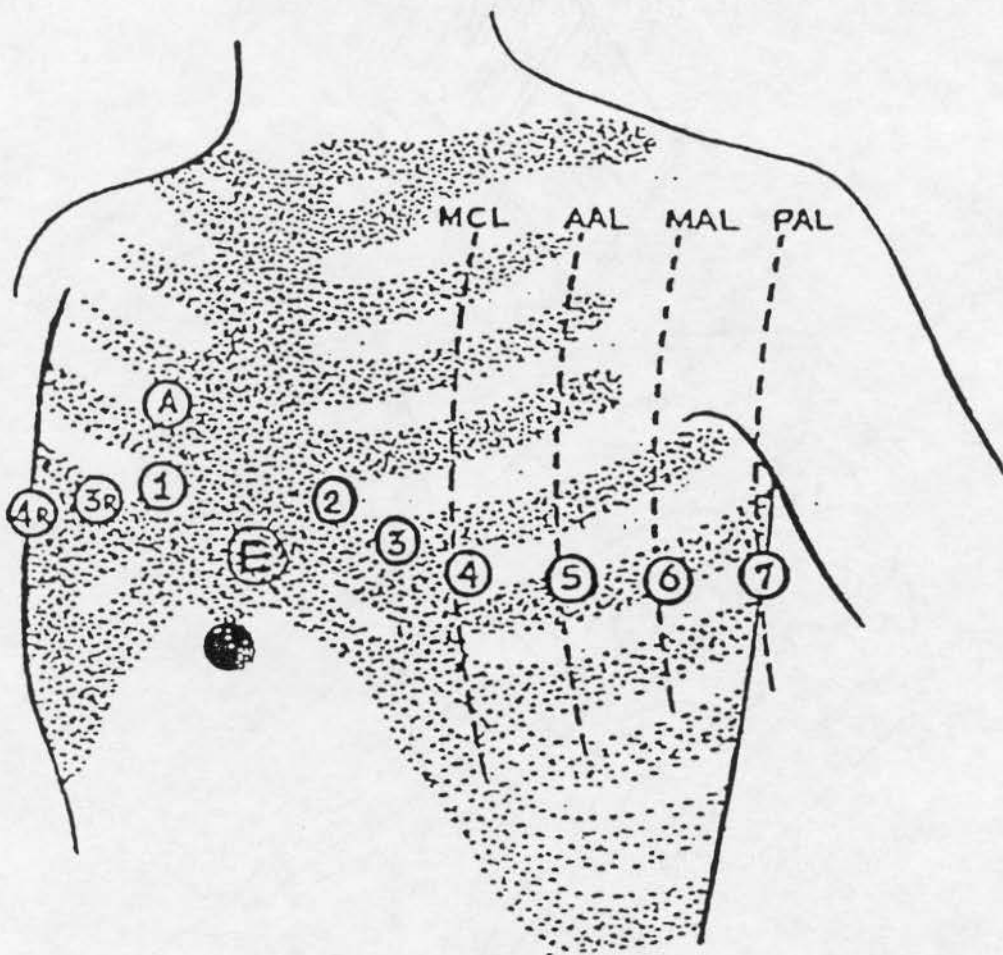


Figure 7. Precordial points from which chest leads are derived

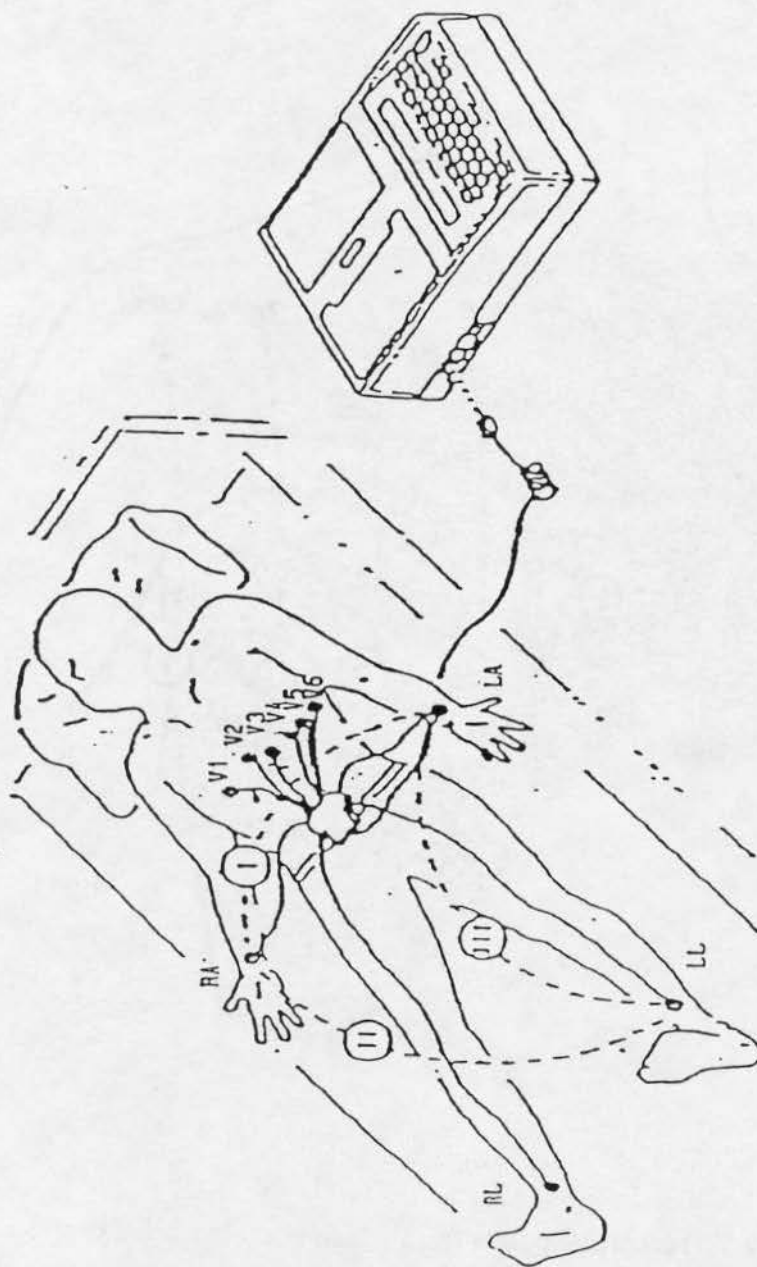


Figure 8. Electrode and leadwire placement

1.3.2 Limb Leads (Figure 2)

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).

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 a tongue depressor or 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 in Electrode Position Measuring and Marking. It is important that the electrode sites be marked using the exact technique described.

1.5 Application of Electrodes

Either disposable or suction electrodes are used in the Strong Heart Study. Adaptors are used with the leadwires to connect the "banana" plug from the MAC PC leadwire to the disposable electrode via a clip.

When placing each electrode, massage it in a small circular motion to maximize the pre-gel contact with the skin but avoid overlap of gel from one electrode to the next.

Center the four limb electrodes on the inside of the wrist or ankle with the tab for the clip 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 leadwire to each electrode (Figure 1). Do not pull or jerk tangled wires. To untangle wires, disconnect lead wires from electrodes.

1.6 Recording the 12-lead ECG

Change the roll of paper as needed. Each roll is 75 feet long; each patient takes approximately one foot of paper.

Each ECG is automatically stored in memory until it is deleted. After placing the electrodes on the skin, enter the participant information into the MAC PC (Figure 3) according to Appendix B. Disposable electrodes particularly must be on the skin for at least 2-3 minutes before taking the ECG. Make a final check of the electrodes and lead wires. Ask the participant to relax and keep still, then press the RECORD key.

The machine will display "Acquiring Data" and the left side of the display will show a count. If there are technical problems the display will show which lead is involved and will keep counting until it gets 10 seconds of good data. Check electrode contacts and leadwires, then check the display again. If the display counts past 75, push the STOP key and remove the electrodes. Prepare the electrode sites as discussed in Skin Preparation and follow the above protocol for exact relocation of electrodes. Press RECORD ECG. The machine will tell you to "enter a new patient or press RECORD." Press RECORD ECG a second time to start the ECG. The machine will automatically print the ECG after it has acquired 10 seconds of good data (Appendix C).

Tear the ECG off the machine and file it in your records.

Press RECORD ECG. The machine will tell you to "enter a new patient or press RECORD." Press RECORD ECG a second time to start the ECG. The machine will automatically print the ECG after it has acquired 10 seconds of good data (Appendix C).

Tear the ECG off the machine and file it in your records.

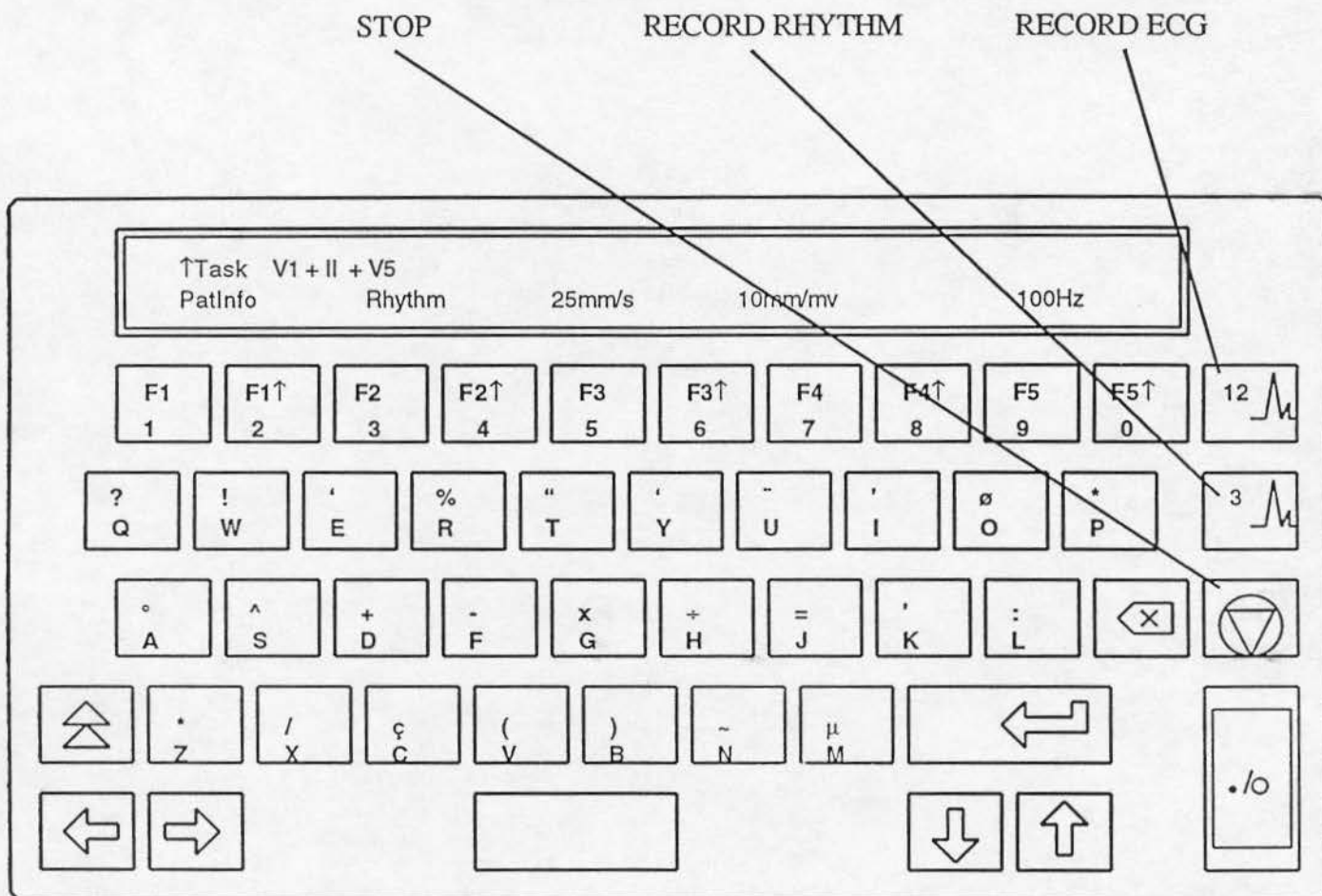
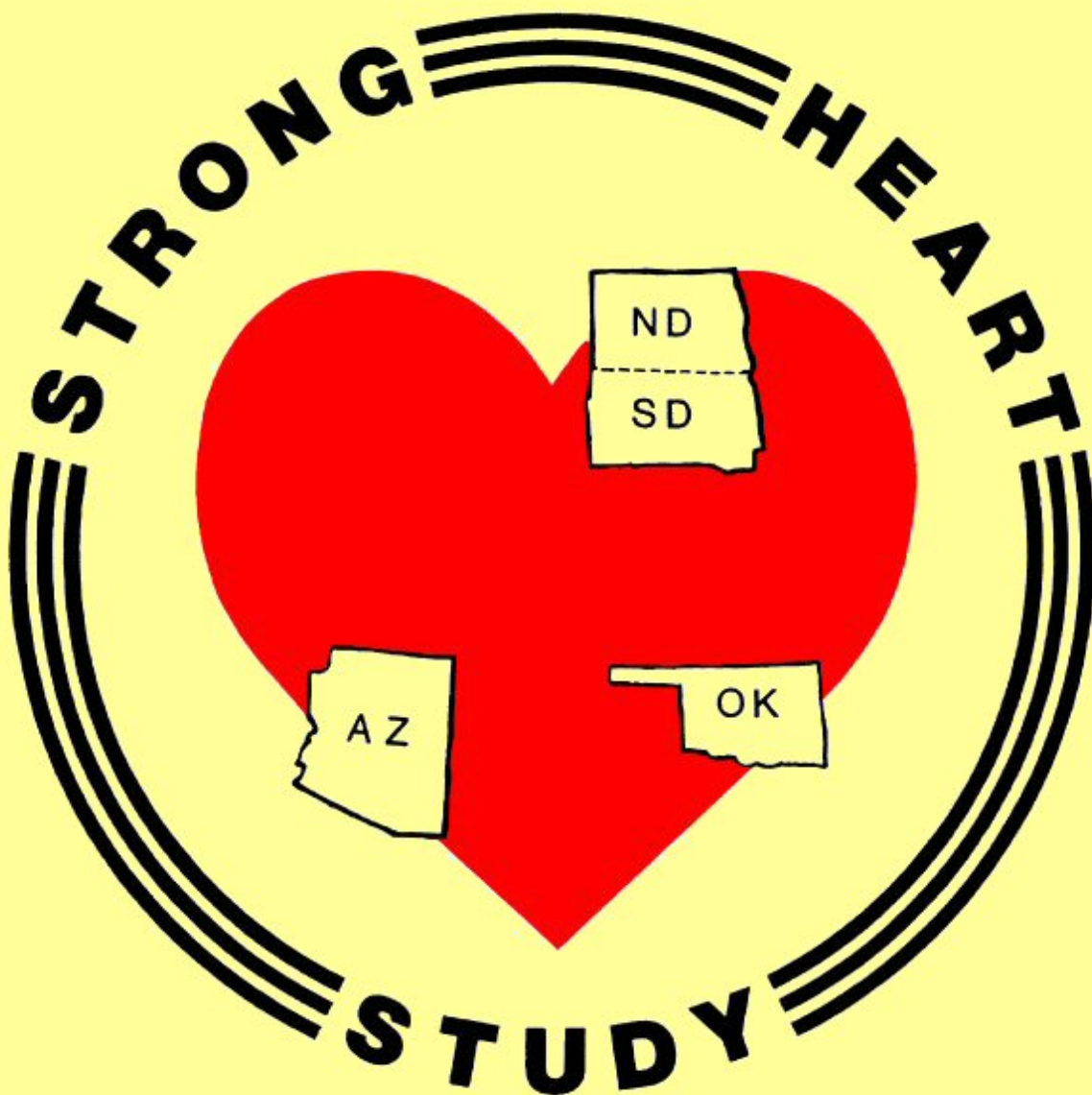


Figure 3. The MAC PC Keyboard and LCD Display by Marquette Electronics Inc.



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME FIVE

DIETARY AND QUALITY OF LIFE STUDIES

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

THE STRONG HEART STUDY
Cardiovascular Disease in American Indians
(Phase III)

Operations Manual

Volume Five

Dietary and Quality of Life Studies

July 1, 1997

For copies, please contact

Strong Heart Study Coordinating Center

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MANUAL V

DIETARY AND QUALITY OF LIFE STUDIES

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1. DIETARY INTERVIEW

1.1 Purpose of the Dietary Interview

To obtain mean intakes of nutrients for males and females of different ages in the population.

1.2 Overview of the 24-hour Recall

Introductions

- Introduce yourself.
- Communicate the importance of the subject's role in the Strong Heart Dietary study and the importance of receiving complete and accurate dietary information.
- Explain that the 24-hour recall will be part of the report on the average intake of all persons participating in the study, that it will be completely confidential and private.

Create an itemized list of foods consumed in a 24 hour period

- List all foods and beverages consumed during the **previous day**--a complete 24 hour period from midnight (12AM) to midnight (11:59)
- Specify eating times or meal names associated with these foods and beverages
- Ask if the way they ate was changed because of the fasting requirement

Fill in the list of foods and beverages with more detail

- Explain how to use the models to show the amount consumed
- Probe about each food and record as complete a description as possible
- Record the amount consumed
- Ask if something was added to the food and record the new food on a separate line.

Review the form with the participant again, giving time for any additions or alterations.

Ask about commonly forgotten foods

Complete the top section of the form.

Thank the participant for her/his time and repeat the value of all the information.

We strongly discourage interviewing the client in their home because all interviews should be carried out as similarly as possible. So, in the unlikely event you have to go to a client's home to do the dietary recall interview, **do not allow the client to get up and show you the food from the refrigerator or the cupboard.** Do not do anything differently than the interview done in the clinic.

General Probing Guidelines

- Ask questions in an open-ended way.

For example, "What was the first thing you ate or drank yesterday?"

Not "What did you have for breakfast?"

- Obtain additional information by probing.

Relate eating to other activities, e.g. "Did you stop any place after work? Did you have anything to eat or drink there?"

- Ask non-leading questions, which do not expect a particular answer, to obtain specific detail.

"Was that the same margarine as at breakfast?"

- Allow adequate time for the client to think about the answers.
- Be neutral in your responses to the information. Do not indicate approval or disapproval.
- Rephrase questions if the participant does not seem to understand the questions.

"Did you have anything in your coffee?" explain as follows:

"Did you put anything in your coffee before drinking it or was it plain coffee?"

- Stop probing when the client begins to be irritated or annoyed. We do not want the client to stop cooperating or to refuse the rest of the interview procedures.

1.3 General Interviewing Techniques

Before Beginning the Interview

Before beginning the interview, take some time to make sure you are thoroughly prepared. Review your manual and other materials given to you during training until you fully understand all aspects of your job. Practice doing the interview until you are comfortable with the procedure. This practice will help in building your confidence so that you can deal with any situation you may encounter when you begin interviewing. Your ability to work comfortably will help keep your respondents interested in the interview and will help your interviews go smoothly. Respondents quickly lose interest when the interviewer is constantly stopping, losing track of his/her place and stumbling in his/her efforts to ask questions or probe.

Check to make sure you have sufficient quantities of all necessary materials, and that your materials are organized in an orderly way. Materials that are to be handed to respondents should be easily accessible to avoid any awkward fumbling or searching.

The first thing a respondent notices about an interviewer is appearance. In general, an interviewer should aim at an appearance that is neat, suitable, and inconspicuous. Avoid extremes of any kind. Keep in mind that it is better to be a little underdressed than overdressed, and that, regardless of what clothes you wear, cleanliness and neatness are always very important.

1.3.1 Beginning the Interview

When you first make contact with a respondent, your initial task is to establish a friendly but professional relationship. Your own confident and professional manner will reassure the respondent and set a tone that will enable you to complete the interview in an efficient manner. Experience with past surveys has indicated that there are three main factors that determine whether a respondent will consent to be interviewed.

The Rapport Established Between the Interviewer and the Respondent

"Rapport" is the term used to describe the personal relationship between the interviewer and the respondent. Rapport provides the foundation for good interviewing. Your appearance, your introductory remarks, and the way you answer any questions the respondent may ask will strongly influence the rapport that develops between you and the respondent. What you say and how you say it should set the tone for the friendly, cooperative, but businesslike relationship that will continue to develop throughout the interview.

Whether the Respondent Sees the Survey as Being Important and Worthwhile

An interviewer must try to interest the respondent in the survey. Encourage the respondent to see the interview as an opportunity to express his/her views and to have those views taken seriously.

From the start, the respondent must be given certain basic information about the interview: what to expect during the interview, and what the purpose of the interview is. If asked, you may also explain how the information will be used, and the length of the interview.

Whether the Interviewer Can Respond Convincingly to the Respondent's Objections and Questions

Even respondents who are convinced of the importance of the study may, for a variety of reasons, be reluctant to grant a certain part of the interview. Your friendly manner, your introductory statements, and your success in answering the respondents' questions will help you sell both yourself and the survey to the respondents. Your effectiveness will be increased by your knowledge that your job is legitimate and important, and by your thorough understanding of what you are doing and how to do it.

Your own state of mind -- your conviction that the interview is important -- will strongly influence the respondent's cooperation. Your belief that the information you obtain will be significant and useful will help motivate the respondent to answer fully and accurately. Most people want to be heard and are happy that you have asked their opinions. Those who are reluctant to give specific information will often do so willingly, if they are convinced that good use will be made of it and that their privacy will be protected.

1.3.2 Administering the Interview

The interviewer's task is to collect accurate information. You must have a thorough understanding of the general principles for administering the interview and comprehend fully its confidential nature. The material in the following sections of this manual will acquaint you with the general principles and procedures to follow when collecting survey data.

Asking the Questions

The 24-hour recall is essentially an open-ended interview. Collecting accurate and reliable data requires that every respondent hears exactly the same questions read in exactly the same way. Even small changes in the way a question is asked can affect the way a respondent answers and, in the long run, affect the results when researchers combine the answers given by large numbers of respondents. The basic rules for asking survey questions, discussed below, are all designed to ensure uniformity in the way questions are asked of respondents.

Always Remain Neutral.

During the entire interview you must always maintain a completely neutral attitude. As an interviewer, you must never allow anything in your words or manner to express criticism, surprise, approval, or disapproval of the questions you ask or of the answers respondents give.

An important part of your role as an interviewer is to get the respondent actively involved in the interview, to lead him/her to talk comfortably and freely in response to your questions. While encouraging the respondents to talk freely, however, you must carefully avoid saying or doing anything to influence the content of the respondent's answers. No matter what topics you ask about, no matter how strongly you agree or disagree with the respondent's answers, and no matter how interesting, unusual or discouraging you might find those answers to be, you must always maintain the same neutral and professional stance during the interview. You are there to ask for and record the respondent's answers, not to influence or advise in any way.

At times, particularly if your respondent is talking freely, you may feel that he/she has already answered a question before you get to it. **DO NOT SKIP OVER ANY SCHEDULED QUESTIONS, EVEN THOUGH YOU THINK THERE MAY BE SOME REPETITION.** If a respondent becomes annoyed or says something like "I just told you that," you can acknowledge the repetition, but explain that you are required to ask all questions. You might say something like:

"I need to make sure that I have your full answer on that."

"I thought perhaps you might have more to say about that."

Sometimes it may be helpful to anticipate the respondent's reaction to the repetition by saying something like:

"You may already have mentioned this, but I need to make sure I have your answer recorded here."

or

"You may have told me about this before, but let me ask this questions to make sure I have the right answer."

To be a good interviewer, you must be comfortable with the questions you ask. If you feel uncomfortable with certain questions, it is likely that you will transmit something of that feeling to the respondent and influence the answers you receive. If you are uneasy with some questions, you should practice them repeatedly until you can ask them in a simple, straightforward, matter-of-fact way. Occasionally you will find a respondent who refuses to answer some questions, but usually you will find that as long as you can deal with all of your questions in the same relaxed and professional manner, your respondents will answer without hesitation.

MAINTAINING RAPPORT

You began your rapport-building process with your introduction, and it must be continued throughout the interview. Through accepting and understanding behavior and your interest in the respondent, you can create a friendly atmosphere in which the respondent can talk freely and fully.

Occasionally rapport may be broken during the interview for some reason such as the respondent feeling that a particular question is "too personal." If this happens, take time to reassure the respondent that he/she may speak freely without fear. This may be done by restating the confidential nature of the interview and the impersonal nature of the survey. If a respondent refuses to answer a question after you have reassured him or her of confidentiality, do not press the respondent -- enter a refusal response and the system will automatically skip to the next appropriate question. It is mandatory to attach a note to a refusal response.

Occasionally a question may lead a respondent to begin reminiscing or to relate a lengthy story that has little or no relevance to the survey. As an interviewer, your task is to discourage such irrelevant conversation and keep the discussion focused on the interview. In some ways, this requires that you subtly teach the respondent how to be a good respondent. If you maintain a businesslike attitude, acknowledge answers with neutral comments such as "I see," "OK," or a simple nod of your head, and tactfully interrupt rambling and irrelevant answers to bring the conversation back to the question you have asked, the respondent will soon learn how to be a good respondent and provide the kinds of answers you need. If you must interrupt a respondent, do it politely, taking care not to antagonize him/her. You might say something like:

"That sounds very interesting, but what I need to ask is..."

"I see what you mean, but let me repeat that last question..."

1.3.3 PROBING: WHAT IS PROBING AND WHY IS IT NECESSARY

Probing is the technique used by the interviewer to stimulate discussion and obtain more information. The quality of the interview depends a great deal on the interviewer's ability to probe meaningfully and successfully. We probe when a respondent's answer is not meaningful or is incomplete, i.e., when it does not adequately answer the question. There are a number of reasons respondents sometimes do not answer the question to our satisfaction.

In every day social conversation, people normally speak in vague and loose terms. It is understood that respondents will at first respond to our questions in a way which is not clear or specific. It is important to encourage the respondent to express himself/herself more concretely, in very specific terms.

Sometimes respondents will think that they are answering a question when all they are doing is simply repeating an answer which was already given, or simply repeating parts of a question. A respondent can talk a great deal and still be just repeating the question in different words.

Respondents will sometimes miss the point of the question. Many times they will give responses which seem to answer the question, but when you look further, are not to the point of the question and are therefore irrelevant. It is easy to be "taken in" by a respondent who is talkative and gives a lengthy and detailed response which, however, is quite beside the point. It is not the answer to the question asked. In most cases, a respondent gives an irrelevant response because he/she has missed an important word or phrase in the question.

Probing, therefore, has two major functions. First, probing motivates respondents to enlarge, clarify, or explain the reasons for their answers. Secondly, probing focuses the respondent's answer so that irrelevant and unnecessary information can be eliminated. All this must be done, however, without introducing bias or antagonizing the respondent.

Some examples of answers that for different reasons fail to answer the questions properly are given next. Because of the answers given, each requires probing.

EXAMPLES OF ANSWERS THAT REQUIRE PROBING

Question: How much plain water do you usually drink in a 24-hour period of time?

Answer: My doctors says I should drink more water.

Probing Methods Should be Neutral

It is very important to always use neutral probes. By this we mean you should not imply to the respondent that you expect a specific answer or that you are dissatisfied with an answer.

Remember the reason for probing is to motivate the respondent to respond more fully or to focus the answer, without introducing bias. The potential for bias is great in the use of probes. Under the pressure of the interviewing situation, the interviewer may quite unintentionally imply that some answers are more acceptable than others or may hint that a respondent might want to consider this or include that in giving responses. You must be careful not to do this.

The following example consists of a response from the client, and two possible problems. The first of these probes is neutral, the other is not.

Example:

Client: I had a cup of coffee at 9:00 a.m.

Neutral Probe: Did you add anything to your coffee?

Non-neutral Probe: So you probably added cream and sugar?

The non-neutral probe suggests a specific answer to the respondent and thus leads the respondent toward that answer, rather than leaving the range of possible responses completely open for the respondent to specify.

1.3.4 Kinds of Probes

There are several different neutral probes which appear as part of a normal conversation that can be used to stimulate a fuller, clearer response.

1. **AN EXPRESSION OF INTEREST AND UNDERSTANDING.** By saying such things as "un-huh" or "I see" or "yes," the interviewer indicates that the response has been heard, that it is interesting and that more is expected.
2. **AN EXPECTANT PAUSE.** The simplest way to convey to a respondent that you know he/she has begun to answer the question, but has more to say, is to be silent. The pause -- often accompanied by an expectant look or a nod of the head -- allows the respondent time to gather his or her thoughts. Eye contact is important here.
3. **REPEAT THE QUESTION.** When the respondent does not seem to understand the question, or misinterprets it, or seems unable to decide, or strays from the subject, it is often useful to repeat the question. Many respondents, when hearing the question for the second time, realize what kind of answer is needed.
4. **REPEATING THE RESPONDENT'S REPLY.** Simply repeating what the respondent has said is often an excellent probe. Hearing the response just given often stimulates the respondent to further thought.

5. **A NEUTRAL QUESTION OR COMMENT.** Neutral questions or comments are often used to obtain clearer and fuller responses. The following are some suggestions for probing questions that may help explore many types of insufficient answers.

PROBES TO CLARIFY:

"What do you mean exactly?"

"What do you mean by...?"

"Could you please explain that a little? I don't think I quite understand."

PROBES FOR SPECIFICITY:

"Could you be more specific about that?"

"Tell me more about that."

PROBES FOR RELEVANCE:

"I see. Well, let me ask you again...(REPEAT EXACT QUESTION)."

PROBES FOR COMPLETENESS:

"What else?"

"What else can you think of?"

I Don't Know (DK) Response

The "I don't know" answer can mean a number of things. For instance,

- The respondent doesn't understand the question and says DK to avoid saying he/she doesn't understand;
- The respondent is thinking the question over, and says DK to fill the silence and give himself/herself time to think;

Try to decide which of the above may be the case. Don't be in too big a rush to settle for a "don't know" reply. If you sit quietly -- but expectantly -- your respondent will usually think of something. Silence and waiting are frequently your best probes for a "don't know" reply.

Always try at least once to obtain a reply to a "don't know" response, before

accepting it as the final answer. But be careful not to antagonize respondents or force an answer. If they say again that they "don't know," proceed to the next appropriate question after coding the DK reply.

Additional Guidelines for Probing

The following rules and examples provide further guidance to help you select problems that will not bias respondent's answers.

1. Don't ask "Do you mean ____ or ____?" Such a probe suggests only one or two possible answers, when the respondent may actually be thinking about other possibilities. Do not use probes for clarity and specificity when a respondent's answers are unclear.

Example

Question: Did you put anything on your grapefruit?

Answer: Yes, Sweetener

Neutral Probe: Could you be more specific? What type of sweetener?

Non-neutral Probe: You mean it was Equal or Sweet 'n Low?

Example

Question: What did you eat at that time?

Answer: I had eggs and juice

Neutral Probe: Did you eat or drink anything else at that time?

Non-neutral Probe: So you had breakfast -- you probably had coffee, too then?

When to Stop Probing

When you have obtained all necessary information about the respondent and when you have encouraged the respondent to clarify the meaning of his/her own words so that you (and we) know exactly what he/she had in mind -- only then do you have a complete answer and only then should you stop probing. However, if at any time the respondent becomes irritated or annoyed, discontinue probing. We do not want the respondent to refuse the rest of the interview.

1.3.5 Ending the Interview

All people who give their time for an interview are entitled to courteous and tactful treatment. Try to leave respondents with the impression that they have taken part in an interesting and worthwhile experience -- one they would be willing to repeat.

After all questions have been asked, indicate your appreciation to respondents by thanking them; also mention that their contribution has been most helpful in providing important information to the study. Remember that the respondent is familiar with your task from the discussion at the beginning of the interview, so don't spend too much time going over the same information. Spend a few minutes answering any additional questions your respondent may have; then close the interview.

1.3.6 Editing

After you have completed the interview with a respondent, you are to edit or check your work. You should try to complete the edit before the client leaves. Once the client leaves, data that were not collected or data that needed to be corrected are lost forever.

Although editing is not difficult, it is an important part of an interviewer's job. The main purposes of editing are:

1. **TO REVIEW ALL SECTIONS OF INTERVIEW** -- Review each section to assure all information is complete and accurate.
2. **TO LEARN FROM MISTAKES SO THEY ARE NOT REPEATED** -- There is an educational value in editing. Many interviewers feel that the interviewing procedures become more meaningful after they have conducted the first few interviews. Editing will improve the quality of your interviews for the remainder of the study, as well as catch errors. Editing, therefore, is part of the learning process for a survey.
3. **TO WRITE OUT ABBREVIATIONS** -- The clerical aspect of editing is an obvious one. This includes checking to make sure any abbreviations that are not commonly understood are clarified, and to assure that notes and any other comments are presented for easy comprehension.
4. **TO ADD YOUR COMMENTS WHICH MIGHT HELP TO UNDERSTAND A RESPONSE OR AN INTERVIEW AS A WHOLE** -- Add notes concerning the respondent, the interviewing situation, or anything else that you feel might help in the correct interpretation of the interview.

1.4 Detailed Format for the 24-hour Recall

Before beginning the dietary recall, record:

1. The subject's name and ID number (social security or strong heart) in participant ID section.
2. Your ID number and initials in interviewer ID section.
3. The date of the visit, the visit number, and the intake day (i.e. the day being recalled). subject's date of birth, sex - M / F.

1.4.1 Introductions

Introduce yourself and communicate the importance of the subject's role in the Strong Heart Dietary study and the importance of receiving complete and accurate dietary

information. Explain that the data you will be collecting will be part of a report on the average intake of all persons participating in the study and that it will be completely confidential and private.

For example:

"Hello, my name is (). I work with The Strong Heart Dietary Study and we are collecting information on what people in your age group eat and drink. We are going to look at this information to find out if some of the foods you eat or the way they are cooked lead to heart disease." Everything you say here will be kept confidential."

1.4.2. Create an itemized list of foods and beverages consumed

The client must understand that you are interested in recording everything eaten or drunk during the 24 hours of the previous day, from midnight to midnight. It is important to define the day and time exactly, such as, "We'll be talking about the period from 12 midnight Tuesday to 12 midnight last night. If the client were to report eating an item at midnight the day before and the night before the exact time frame is 12:00 am to 11:59 pm.

Explain to the client that during the first step of simply listing the foods and beverages consumed, the client must tell you the approximate time the foods and beverages were eaten. Have the respondent categorize the foods and beverages by using a time frame, e.g., "At 8:00 am, I had coffee and eggs. At 10:00 am, I had a doughnut."

Inform the client that you will be asking for more detail about these foods later.

Emphasize that the client is to tell you everything eaten or drunk, including snacks, coffee breaks and alcoholic beverages, at home or away from home. Include tap and bottled water, Perrier, mineral water, herbal tea, alcoholic beverages and pop or soda. Do not include chewing gum, or chewing tobacco (snuff or chew), or any fiber supplements.

For example,

"What we want to do first is to make a list of all the foods and beverages that you have had in a 24 hour period of time, a complete day. This includes alcoholic beverages, pop or soda, tap water, mineral water like Perrier, herbal teas, Indian teas and tap or spring water. Remember to include all snacks."

"Today is (day of the week)... I'd like you to tell me everything you ate or drank all day (yesterday)... from midnight (previous night) until midnight (yesterday). This means if you went to bed (previous night) after midnight, and you ate or drank something, you would start there. If you were asleep at that time, start with the first thing you ate or drank after you woke up

yesterday."

"I would also like you to tell me what time you ate. For example, at 8:00 am I had this, at 10:00 I had that." We'll make a very general list at first, then we'll go back and fill it in with more detail."

You can start with the first food whenever you're ready."

As the participant tells you what he/she ate, record each food or beverage on a separate line. Record enough detail so that you can remember what they ate and ask for more detail later. If they give you more detail than you need, record this but remember to check it during the second part of the interview. Don't worry about the order of the foods.

For example, if the client says coffee, eggs, and toast, enter coffee on the first line, eggs on the second line and toast on the third line. When you go back through the 24 hour recall form for the second part of the interview, you will ask what he/she added to their coffee. If sugar and cream are mentioned, record sugar and cream on separate lines. Put the line number of the coffee in parentheses next to the sugar and cream so that the data entry person know that these items were in the coffee.

Try not to interrupt the respondent--the only exception is if they forget to give you the time consumed (or a meal name). If the respondent is unable to recall what they ate, use non-leading probes, such as:

- 1) "What was the next thing you had?"
- 2) "What else did you have at that time?"
- 3) "Perhaps it will help you to think about what you did yesterday."

Don't mention a meal name or ask about foods they usually eat: i.e. "What did you have for breakfast?" or "Do you usually have a cup of coffee first?"

Print clearly in ink. Use additional lines freely. If you or the subject makes an error, draw a line through the entry, and rewrite it either on another line, with the appropriate time and place, or at the bottom of the form, with reference to the original line number. Mark continuation pages as required.

1.4.3. Ask about fasting

After the foods are listed, you need to assess if the participant changed their usual eating habits because of the fasting requirement. For example, "Did you change the way you ate last night between the hours of ... and ... because of the fasting requirement?" If they did, ask: "How did you change the way you ate?"

If the amount of food or the time eaten had changed, continue with the interview.

If food or beverages were not eaten because of the requirement, ask what the participant had eaten during that time period the previous evening (two evenings before the interview). Record these foods but **note** with an asterisk (*) that they were from the previous evening.

Fill in the list with more detail

For every food, you need to complete the following information: time eaten, and the place food was prepared (1=home, 2=restaurant). In addition, you will be asking the amount consumed and for a complete description of the food (including if salt was added in preparation or at the table, fat was added in preparation, and type of fat used in preparation).

You can introduce this next step by saying:

"We are now going to fill in this list with more information about the foods you ate."

1.4.4. Amount of food consumed

Introduce the use of food models and measures. For example:

"I need to know the amount of the foods and beverages that you ate. As we go through the list of foods, you can use any of these models (point to them) to show me how much of each food you ate. If you use the spoons, please tell me the amount in terms of level spoonfuls."

It is good practice for the participant to show you using one of the models even if they explicitly state the amount, i.e. the participant responds verbally with the number of cups or ounces. For example, if a respondent says: "It was an 8 oz glass", your response should be: "Please show me with one of the models."

After they've shown you, **always** ask: "How many did you eat?" Also ask if they ate or drank the whole portion. For example, "How full was the glass? How much did you drink?"

We don't record foods in amounts less than one tablespoon unless it is a fat, salty food, sugar, artificial sugar or other food that is a nutrient or calories dense source. **No matter what quantity is reported, artificial sweeteners must always be recorded.**

1. Fats include: margarine, oil, butter, nuts, coconut, salad dressing, avocado, cream cheese and other cheeses, non-dairy creamer and cream
2. Salty items include: soy sauce, teriyaki sauce, tamari, mustard, catsup, pickles, bacon bits, olives, anchovies and caviar.

3. Sugars include: sugar, honey, jelly, jam, corn syrup, fructose, pancake syrup and chocolate syrup.
4. Others: protein supplement, oat or wheat bran, wheat germ, vegetables high in Vitamin A/C.

If the respondent is having trouble with a particular model or the model seems inappropriate, suggest that they use a different model. For example, they pick up a teaspoon but say it was heaping and can't say how many level teaspoons it was.

Have the participant point to lines on the models (i.e. 4 oz, 6 oz, 8 oz.). Record both sizes if subject states his serving was between 2 sizes, e.g. 1/2 to 3/4 cup.

Food-specific guidelines

- 1) Try to get beverages without ice. If this is impossible, note that the amount was with ice.
- 2) Try to get the amount of meat without the bone. If you cannot, have the participant estimate the size of the bone.
- 3) If you record the brand for packaged foods (eg. candy bars, soda/pop, cookies, crackers, pre-sliced cheeses or luncheon meats), the participant does not need to use a food model but try to be aware of different serving size options that are commonly available and record this (eg. mini- versus regular-size candy bars).
- 4) The form is important for some foods, i.e. chopped, diced, melted, solid, ground, or shredded (eg. cheeses or meats). Some of these are noted in the probing guidelines in Appendix I.
- 5) Thickness is also important for some foods (eg. fry breads, pieces of cake/pie, homemade tortillas)

1.4.5. Completing the food description

After filling in the amount of a food consumed, you need to get as complete a description of that food as possible. Use open-ended questions that are non-leading but specific to the kind of food. Appendix I contains questions you should ask about each kind of food. Follow these probing guidelines for each food or food group. If you have to mention specific options, try to give more than 2 options and always say "or some other type". For example, "At 6am you drank coffee, was the coffee brewed from ground, instant, from a vending machine, or some other type of coffee?"

Fill in the columns about salt added in preparation or at the table and fat added in preparation. Note the type of fat and/or the brand name used in preparation in the description; **the type of fat used in preparation or added to foods is very important to the goals of this study**. If the client ate in a restaurant or at someone else's home, ask if they thought that salt was added and as a last resort "if the food tasted like salt was added". If

they say "Yes" then mark on the form that salt was added in preparation.

Obtain brand names of commercially-prepared foods, however, be careful because some respondents may use a brand name instead of a generic name to refer to a food. For example, Coke instead of cola or koolaid versus some powdered mix. Probe: "Was is actually Coke or was it another brand of soda or pop?"

Record the names of restaurants and fast food establishments where the food was prepared.

If a subject is unsure of how the food was prepared or the ingredients, record what he called the food, in "quotation marks" and note as much as possible even if it seems too vague. For example, general categories of foods (eg. a vegetable), color, and shape.

Appendix II lists certain foods for which you should ask the participant to tell you the ingredients. These are foods that have highly variable ingredients and for which a participant should be able to list the component parts. Sometimes obvious foods are forgotten, eg. they said they ate a sandwich and you've asked them for more detail but they forget the bread. It's OK to ask: "Was that eaten plain, on bread, a roll or with something else?"

Always ask: "Did you add anything to your (food)?" even if it seems unlikely. Indicate foods eaten together by putting brackets around them.

Examples of food-specific probes:

- 1) "How was the gravy made?"
- 2) "Did you eat any of the vegetables that you cooked with the meat?"
- 3) "How much fat was left after you trimmed the meat?"
- 4) "Can you describe how your eggs were prepared?"

1.4.6. Review the foods

After you have filled in the description and amount of each food, read the list of foods and amounts to the participant quickly to ensure accuracy and completeness. Tell the participant what you are going to do before you start and ask them to stop you at any time if they remember something else or if something needs to be corrected.

Once you have finished, read through the list of "commonly forgotten foods". Add any foods that they have omitted using the same instructions as for other foods.

RECALL REVIEW

Since the information that you have given me will make an important contribution to this

health and nutrition study, I would like to make sure that it is as complete as possible. On this card are some foods and beverages which are often forgotten.

Fruits, Chips, Candy, Nuts, Cheese

Coffee, Tea, Soft Drinks, Juice, Water

Beer, Wine, Cocktails, or Any Other Alcoholic Beverage

Crackers, Breads

Can you think of anything else that you ate or drank yesterday that you haven't mentioned?

Complete the remaining questions on the form

Record your opinion of the reliability of the information. An explanation must be given for any recall not coded reliable. This code only refers to the quality of the 24 hour recall.

1.4.7. Reliability

Reliable: You feel that the respondent made a sincere effort to answer the questions, and that the information given is probably correct. Include recalls in which the respondent does not know certain ingredients in a recipe, such as in a casserole, or whether fat was used in preparation. Classify the recall as reliable even if the majority of food amounts are unknown.

If you perceive the foods reported by the client as accurate, yet he/she says he/she cannot remember his midnight snack, still code this as a reliable recall. In the latter situation, the client has made a sincere effort to report all foods, but just cannot remember his/her snack; the information is reliable.

Unreliable: You feel the respondent was not able to give information that you think is correct. Include, for example, an elderly client who cannot seem to understand the instructions or remember what was eaten, or a client who was drunk. Before coding an interview as unreliable, make sure you have exhausted all sources of possible proxies for the client. An elderly client may have been accompanied to the center by a daughter or son who cares for and feeds the client. Do not code unreliable in cases where you do not believe the client, such as an obese person who reports very little intake.

Refusal: The client refuses to do the interview before you are able to obtain any information.

Not Interviewed: Due to time constraints, there will be occasions when the dietary interviewers are unable to complete interviews on those scheduled for a specific session. A mandatory note is required to explain the situation. Since clients with medical problems may

return in the future once their problems have been treated, attach a note "sent home due to medical problems; may be rescheduled".

In general, if a client recalled food items for the previous day and you were able to record them even though the client had some difficulty with detailed descriptions or amounts, this would still be a RELIABLE interview. An example of an UNRELIABLE interview is a situation where an elderly client reported an entire day's recall and during the Recall Review said those were not the foods he actually had. In this case the client was confused and unlikely able to accurately give a day's recall, especially in the time you would have. In a case like this, record the interview as UNRELIABLE; do not take the additional time to try to start over. If this type of situation happens and after 15-20 minutes you can tell that the client cannot provide a reliable interview, end the interview, thank the client, and attach a note explaining the situation. Check to see if a proxy is available to give the recall for the client.

Ask the participant if "the amount of food they consumed yesterday was typical, considerably less than usual, or considerably more than usual".

Read the question about vitamin or mineral supplement use and if they took one the previous day, list these as a food item. Remember to ask for brand names of vitamins, eg. One A Day Vitamins, and how many they took and dose if possible.

Thank the participant!

Thank the participant for her/his time and repeat the value of the information they have given you.

APPENDIX 1 : RECALL REVIEW

Since the information that you have given me will make an important contribution to this health and nutrition study, I would like to make sure that it is as complete as possible. On this card are some foods and beverages which are often forgotten.

Fruits, Chips, Candy, Nuts, Cheese

Coffee, Tea, Soft Drinks, Juice, Water

Beer, Wine, Cocktails, or Any Other Alcoholic Beverage

Crackers, Breads

Can you think of anything else that you ate or drank yesterday that you haven't mentioned?

APPENDIX 2

ASK PARTICIPANTS TO LIST INGREDIENTS FOR THESE FOODS

SANDWICHES: Most clients can give some information about a sandwich. The client should be able to describe a sandwich purchased in restaurant. He/she should be able to tell you if the bread was brown or white, hot dog, hamburgers, chopped or shredded meat or poultry mixed with barbecue sauce on a bun. He/she should be able to tell you if there was lettuce and tomato on it. Certain sandwiches are fairly standard, and if not prepared by the client, are difficult to specify. You do not need to break down sandwiches purchased at national fast food chains into their component parts.

TOSSED SALADS: It is preferable to have a client list and quantify the items in a tossed salad. Remember to apply the small amount recording rule to avoid entering and specifying items which are not necessary due to the small quantity consumed. Should the client know the components of the salad, you can determine the amount based upon whether the client can provide you with information as to the proportion of the ingredients in the salad, for example, "2/3 lettuce and 1/3 other vegetables".

If the client reports a salad but cannot break it down into its individual components, get as much of a description as possible (eg. iceberg versus leaf lettuce, with or without tomatoes).

MIXED DISHES AND SOUPS: This usually refers to recipes that are mixed together and served together as a dish rather than assembled at the table. Include in this category such items as pizza, spaghetti with sauce, meat loaf, beef stroganoff with noodles, beef and broccoli stir fry, quiche, pot pies and casseroles. In general, it is best not to attempt to have the client break down recipes that may have many ingredients into their component parts.

Macaroni and cheese: ask if it was a box mix or if it was made from scratch. If it was made from scratch ask the kind of milk (whole, low fat or skim) and if butter or margarine was added. Remember to ask for brand names of butter and margarine.

TACOS: Tacos can be highly variable. Ask about the kind of tortilla (corn or flour), whether the tortilla was fried or warmed without fat (on a griddle), and what was contained in the topping.

VEGETABLES: Use the color of the vegetable as the main indicator of its nutritional importance. If the vegetable is green, orange or red, the vegetable is worth noting. Do not count small amounts of onions, mushrooms or celery. Do count broccoli, green peppers, orange squash, carrots and tomatoes. Remember that the small amounts recording rule still applies for those vegetables low in Vitamin A and/or C.

APPENDIX 3

PROBES ABOUT TRADITIONAL FOODS

Berry pudding, may be called "wojapi" in the Northern Plains:

- wild berries or canned berries used
- the type of berry eg. blueberries, blackberries
- corn starch or flour was used to thicken it
- sugar or an artificial sweetener was added to it.

Burrito

- type of filling
- sauce added?

Cheese crisp

- type of cheese
- with chili peppers?

Chili

- stew or sauce?
- if stew, with meat and/or beans? red or green chili?

Chili peppers

- the variety or at least the color, size, and shape.

Cholla bud stew

- type of fat used

Chorizo sausage and egg

- enter egg separately and record type of fat used

Corn, squash, and cheese

- type of fat used
- type of cheese

Enchilada

- type of filling
- type of sauce

Fry bread

- type of fat used in frying
- diameter and height

Guyvsa

- type of fat added if any

Lazy bread

- type of fat

Menudo

- get recipe or at least ingredients (eg. white corn, beef feet)

Posole

- get recipe or at least ingredients (eg. wheat and beans)

Pinole

- milk added instead of water?

Red chili stew

- type of fat used

Salsa or chili (sauce not a stew):

- red or green salsa
- commercially-prepared or homemade
- if homemade, was fat used in the preparation and the type of fat used

Skillet bread

- type of fat used
- size (diameter)

Soup with turnips:

- wild (timsila) or store bought turnips

Taco

- fry bread or tortilla (corn or flour)
- if tortilla, fried or warmed without fat?
- ingredients in topping or filling

Tamale

- type of filling
- type of sauce
- dimensions including height

Tepary beans

- type of fat used if any

Tortillas:

- corn or flour tortillas
- fried or warmed without using fat

Tortilla soup

- get recipe or at least ingredients

Wild spinach

- type of fat used if any
- additions (eg. chili peppers, tomatoes)

1. **BEEF**

- Was it a steak, roast or ground? If ground, was it regular, lean or extra lean?
- What cut?
- Was fat trimmed or not trimmed?
- How was it prepared?
- Was anything added before, during or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coated, was coating eaten?
- Fat and salt added in preparation?

2. **BEVERAGES**

A. Beer

- What type (i.e., regular, light, low alcohol, malt or nonalcoholic)?

B. Cocktails, liquor, and liqueurs

- Name of drink or type of liquor or liqueur and what was added to it?
- Accompaniments (i.e., fruit, olive, cherry)?
- With or without ice, or frozen where applicable (i.e., daiquiri).

C. Coffee

- Type (i.e., regular, espresso, specialty coffees, coffee substitutes)? Get brand name for coffee substitutes, and regular or low calorie for flavored coffees.
- Regular or decaffeinated?
- Ground, instant, liquid, or vending machine?
- Accompaniments (i.e., milk, cream, sugar, artificial sweetener)?
- Liquid or dry amount?
- Plain or flavored?

D. Juices

- What kind?
- Real juice or a juice-flavored drink? Get brand name, and type of sweetener for juice-flavored drinks. If brand name unknown, get flavor, regular or low calorie; or whether fortified with vitamin C.
- Fresh, frozen, or ready-to-drink?
- Sweetened or unsweetened?
- Regular or no salt (where applicable, such as tomato or V-8 juice)?
- With or without ice?

E. Soda

- Brand name (if known)?
- Flavor?
- Regular or diet? If diet, was it sweetened with aspartame or saccharin?
- With or without caffeine?
- With or without ice?

F. Tea

- Brewed, herbal (flavor), instant, or ready-to-drink? If sugar-free instant, get brand name.
- Regular or decaffeinated?
- Unsweetened or presweetened with sugar or artificial sweetener? If artificial sweetener, was it aspartame, or saccharin?
- Accompaniment (i.e., lemon, sugar, or cream added)?
- With or without ice?

G. Water

- Quinine, tonic, or mineral? If quinine or tonic, was it regular or diet?

H. Wine

- Name?
- If name is unknown, red, white, rose, or sparkling; table or dessert; regular or homemade?
- Plain or mixed (i.e., spritzer, cooler)?

I. Cocoa

- Brand name? Regular, sugar-free, or low calorie?
- Recipe or dry mix? If recipe, what percent milk was used? If dry mix, regular or sugar-free? Was water or milk added? If milk added, what percent fat?
- Any additions (i.e., marshmallows, whipped topping)?

3. BREAD

A. Bread

- Kind (i.e., white, wheat, rye, etc.)?
- Homemade or commercial?

- Regular or diet? Low sodium? If diet, with or without added fiber?
- Toasted or untoasted?
- Accompaniments?

B. Rolls or buns, bagels, English muffin and biscuits

- Kind?
- Baked commercially, or from refrigerated dough, mix, or recipe? If recipe, ask type of fat for biscuits.
- Accompaniments?

C. Coffee cake

- Yeast or quick bread?
- Type of fat in preparation of cake (and topping)?
- Fruits, nuts, fillings, frosting, glaze, and/or streusel topping?

D. Cornbread

- Regular or stuffing?
- Type of fat in preparation?
- Accompaniments?

E. Danish and sweet rolls

- Fruit, nuts, filling, frosted? If frosted, type of fat in frosting.
- Type of fat used in preparation?
- Accompaniments?

F. Donuts

- Yeast, cake, or filled? If filled, with cream/custard or fruit/jelly?
- Plain, frosted, glazed, or powdered sugar? If frosted, what flavor?

- With or without coconut?

G. French Toast

- Fat used in preparation?
- Accompaniments?

H. Fruit Breads

- Type of fat used in preparation?
- Nuts?
- Accompaniments?

I. Muffins

- Kind?
- Prepared from mix, commercial, or scratch?
- Type of fat used in preparation?
- Fruit or nuts?
- Accompaniments?

J. Pancakes and Waffles

- Kind?
- Type of fat used in preparation?
- Fruits, nuts?
- Accompaniments?

K. Tortillas

- Flour (white or whole wheat) or corn?
- Plain or fried?

- Accompaniments?

4. **CAKES**

- Kind (e.g., yellow, devil's food, white, pound, etc.)?
- Mix, ready-to-eat, or recipe? If recipe, type of fat used in preparation. If mix, oil added in preparation?
- Kind of frosting, glaze, or topping? If made from recipe or mix, type of fat used?

5. **CANDY**

- Brand name?
- If brand if unknown, get complete description (kind, coating, filling, nuts). If contains chocolate, what kind? Is it a candy bar or individual pieces?
- Size of candy bar (i.e., regular, miniature, etc.)

6. **CEREAL**

A. Cold (ready-to-eat)

- Brand name (or kind if brand unknown)?
- Plain or presweetened?
- If granola, brand name or was it a recipe? If recipe, type of fat used in preparation. Coconuts or nuts added?
- Accompaniments (i.e., milk, sweetened, fruit)?

B. Hot

- Kind (includes some brand names like Wheatena or Maypo)?
- Flavored?
- Regular, quick cooking, or instant?
- Cooked with water or milk? If milk, what percent fat?

- Cooked with or without salt?
- Accompaniments (i.e., milk, sweetener, fats)?

7. **CHEESE**

A. **Cheese**

- Brand name?
- Type (i.e., processed, imitation, natural, cheese food, cheese spread; low sodium, low fat, low cholesterol)?
- Name (i.e., cheddar, Swiss, mozzarella, etc.)?
- Form (i.e., sliced, shredded, brick)?

B. **Cottage Cheese**

- Percent of fat (creamed or uncreamed)?
- Low Sodium? Low Fat?
- Additions (i.e., fruit, vegetables, sweetener)?

8. **COMMERCIAL FOOD ENTREES**

- Brand names?
- Description of product

9. **CONDIMENTS**

- Kind (i.e., catsup, mustard, pickles, etc.)? If mustard, regular, Chinese, or horseradish?
- Low calorie or low sodium?
- If homemade BBQ sauce, specify fat.

10. **COOKIES AND BARS**

- Kind and brand name?

- If brand unknown, commercial, mix/dough, bakery, or recipe? If recipe, type of fat used in preparation?
- Nuts, chips, fillings, raisins, frosting or icing?
- Dietetic?

11. **CRACKERS**

- Brand name (or kind, if brand name unknown)?
- Regular, low sodium, or unsalted, where applicable.
- Accompaniments (i.e., spread, cheese, deli meat)?

12. **CREAM/CREAMER**

- Kind (i.e., real, imitation)?
- For real cream, ask type (i.e., heavy, light, half and half).
- For non-dairy creamers, get brand name. If unknown, was it liquid/frozen or powdered?
- For whipped cream, get brand name or type (i.e., aerosol, frozen, powder, or recipe). If recipe, get type of cream used. Sweetened or unsweetened? If aerosol or frozen, dairy or non-dairy. If powder, regular or low calorie?
- For sour cream, get type (i.e., regular, half and half, or non-dairy substitute).

13. **DESSERTS**

A. Pudding/Custard

- Kind (flavor)?
- From dry mix, ready-to-eat, frozen on stick, or recipe? If dry mix or recipe, was it regular or sugar-free? What type of milk was used in preparation?
- Any additions (i.e., bananas in banana pudding, whipped cream)?

B. Gelatin

- Regular or sugar-free?

- Clear or whipped?
- Prepared with cream cheese? Fruit? If fruit, what kind (e.g., canned peaches, fresh banana)?
- Any additions (i.e., whipped cream)?

14. **EGGS**

- How were they prepared (i.e., fried, boiled, scrambled)?
- Fat and salt in preparation?
- Whole egg? White only? Yolk only?
- Brand name of egg substitutes? If brand name unknown, was it liquid or powder?
- Accompaniments?

15. **FAST FOODS**

- Name of fast food chain?
- Food item(s) eaten?
- Additions to food item (i.e., catsup on fries, lettuce or tomato on hamburgers, extra mustard or catsup, etc.)?
- Deletions of "extras" on a food item (i.e., a hamburger without the special sauce.)
- For hamburger and fries, what size (e.g., regular or junior, or regular or large)?
- For soda, what kind (i.e., Coke, Pepsi)? Regular or diet? Small, medium, or large? With or without ice?

16. **FATS**

A. Butter

- Type (i.e., regular, whipped or butter/margarine blend)?
- Salted or unsalted?

B. Margarine

- Brand name, if known.
- Type (i.e., whipped, diet, spread, or butter/margarine blend)?
- Form (i.e., stick, tub, or liquid)?
- Salted, unsalted or low sodium?
- Type of oil (e.g., corn, safflower)?

C. Oils

- Brand name or type of oil.

D. Shortening

- Brand name or type of base (i.e., animal, vegetable, or a combination)?

E. Animal Fat

- Kind?

17. FISH AND SEAFOOD

- Kind?
- How was it prepared?
- Fat and salt in preparation?
- Form for some types (i.e., fresh, frozen, canned, smoked, dried)?
- Was anything added before, during or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coated, was coating eaten?
- For canned fish, in what was it canned (i.e., oil, water, tomato sauce)? Was the fish drained and/or rinsed? Regular or low sodium?

18. FRUITS

- Kinds?
- Form (fresh, cooked, canned, frozen, dried, juice)?

- For some fruits, with or without skin?
- Sweetened or unsweetened?
- For canned fruit, what type of syrup (i.e., water pack, juice pack, light or heavy syrup)?
- For juice, was it real? If real, what form (i.e., fresh, frozen, or ready-to drink) and sweetened or unsweetened?
- For cooked fruits, was anything added before, during, or after preparation, e.g., fried apple rings?

19. **GAME**

- Kind (i.e., antelope, rabbit, squirrel)?
- Was fat trimmed or not trimmed?
- How was it prepared?
- Was anything added before, during, or after cooking?
- If venison/deer, what cut?
- If bird (i.e., pheasant, quail, dove), skin eaten or removed?

20. **GRAINS**

- Kind of grain (i.e., rice, barley, bulgur)?
- Type of preparation (i.e., instant, quick, regular)?
- Fat and salt used in preparation?
- Anything added (i.e., gravy, fat)?

21. **GRAVY**

- Kind of gravy (i.e., beef, chicken, mushroom, onion)?
- Prepared from recipe, canned or dehydrated? Prepared with canned soup, skimmed broth, meat juices, or bouillon? If bouillon, regular or low sodium?

- Plain, milk base, or water base? If milk, what percent fat?

22. ICE CREAM

- Brand name?
- Type (i.e., regular, ice milk, dietetic, imitation)?
- Form (i.e., regular, soft serve or a stick)?
- Flavor?
- Any additions (i.e., cone, topping, whipped cream, nuts)?
- For milkshakes, flavor and ingredients (e.g., hard ice cream, soft serve ice cream, nondairy fast food "thick shake")?

23. LAMB

- What cut?
- Was fat trimmed or not trimmed?
- How was it prepared?
- Was anything added before, during, or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coated, was coating eaten?
- Fat and salt added in preparation?

24. LUNCHMEATS

- Brand name?
- Kind (e.g., bologna, ham, salami, frankfurter)?
- Meat base (e.g., chicken, beef, pork)?
- Form (e.g., canned, loaf, thin sliced, spread, minced, chopped)?
- Regular or low sodium?

25. MILK

- Kind (i.e., white, chocolate, buttermilk, substitute)?
- Type (i.e., whole, 2%, 1%, skim)?
- Form, (i.e., regular, evaporated, dry, condensed)? If evaporated, was it diluted or undiluted?
- Flavorings or additions (i.e., egg, malt, sugar, chocolate)?
- Brand name for milk-based breakfast or diet mixtures.
- For milk substitutes, ask base (i.e., soy-based, filled saturated fat).

26. **MIXED DISHES**

A. **Mixed Dishes**

- Name of mixture (e.g., chili, beef stew, macaroni and cheese).
- Recipe or commercial (i.e., dry mix like tuna helper or frozen entrees)?
- Main ingredient (e.g., beef, chicken, noodles, tuna). Obtain information on main ingredient in the manner outlined under appropriate food group.
- Additional ingredients (i.e., vegetables, cheese, sauce, or gravy)? Obtain information as directed above.
- Fat and salt in preparation?
- Any additions?

B. **Pizza**

- Thin, thick, French bread, or double (priazzo) crust?
- Toppings (e.g., pepperoni, cheese, sausage, olives, mushrooms)?

27. **NOODLES**

- Name (i.e., macaroni, spaghetti, noodles)?
- Type of pasta (i.e., white, wheat, spinach, egg)?
- Fat and salt in preparation?

- Any additions after cooking?

28. **NUTS AND SEEDS**

a. Nuts

- Kind
- Type (i.e., raw or blanched; dry, oil, honey roasted; sugar or chocolate coated, or a nut butter)?
- Salt or unsalted?
- Nut mixture (e.g., mixed with dried fruit)?

b. Seeds

- Kind?
- Salted or unsalted?
- Whole (unshelled) or kernels (shelled)?
- Type (i.e., raw, dry or oil roasted)?

29. **ORGAN MEATS**

- Name and from what animal (e.g., beef liver or pork brains)?
- Was fat trimmed or not trimmed?
- How was it prepared?
- Was anything added before, during, or after cooking?
- Fat and salt added in preparation?

30. **PIES**

A. Pies/tarts

- Kind (e.g., apple, lemon, chocolate)?
- Single or double crust?

- Regular or individual size?
- Prepared at home or commercially prepared?
- Type of fat used in crust?
- Type of fat used in filling (if appropriate)?
- Additions (i.e., meringue, whipped cream, ice cream, cheese)?

B. Turnovers

- Baked, fast food, or fried? If fast food, get name of establishment. If baked, get flavor. If fried, get type of fat used in frying? Prepared commercially or at home. If commercial, get brand name (e.g., Hostess).

Cobblers/crisps

- Flavor?
- Type of topping (i.e., streusel, pastry, biscuit)?
- For cobbler, type of fat used in topping? For crisps, type of fat used in recipe?
- Additions, (e.g., ice cream, cheese, whipped cream)?

31. PORK

- Was it a steak, roast, chop, or ground?
- What cut?
- Was fat trimmed or not trimmed?
- Fresh or cured?
- How was it prepared?
- Was anything added before, during, or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coated, was coating eaten?
- Fat and salt added in preparation?

32. **POULTRY**

- What part of it light or dark meat?
- How was it prepared?
- Was anything added before, during or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coated, was coating eaten?
- Fat and salt added in preparation?
- Cooked with skin or without? If with skin, skin eaten or not eaten?

33. **SALAD DRESSING**

- Brand name or kind if brand if unknown?
- Commercial or homemade? If homemade, type of fat used in preparation?
- Low calorie? Low sodium?
- Clear, creamy, or tomato base?

34. **SALADS**

A. Tossed

- Major ingredients (i.e., lettuce, spinach)?
- Raw, cooked, canned, or marinated? If cooked, from fresh or frozen? If canned, regular or low sodium?
- For cooked, marinated, and canned, get fat and/or salt used in preparation.
- Additional ingredients (i.e., dressing, cheese, croutons, bacon bits)?

B. Fruit Salad

- Kind of fruit?
- Fresh, frozen, or canned?

- With dressing? What kind (mayo-type, whipped cream, etc.)
- Additional items (i.e., nuts, cream cheese)?

C. Other Salads

- Type, (i.e., tuna, macaroni, egg, potato, coleslaw)?
- With or without eggs?
- Major ingredients (i.e., meat, cheese, etc.)? Obtain information on main ingredient in manner outlined under appropriate food group.
- Type of fat used in preparation?

35. SAUCE

- Name (i.e., Bearnaise, cheese, hollandaise, steak, soy, spaghetti)?
- Homemade or commercial, where applicable?
- Ingredients, where applicable (i.e., meat or meatless spaghetti sauce, green or red enchilada sauce, or salsa)?
- Type of fat used in recipe?
- Regular or low sodium, where applicable (i.e., soy or tomato sauce)?

36. SAUSAGE

- Brand name?
- Pork, beef, or other?
- Fresh, smoked, or brown and serve?

37. SNACKS

- Brand name for cheese puffs, corn chips, microwave-type popcorn, granola bars, potato chips, party-type mixes and tortilla chips. Otherwise, ask name of item (e.g., cornuts, pretzels, etc.)?
- Salted or unsalted?

- For popcorn, method of preparation and whether plain, cheese flavored, or coated? If popped in oil, get type of oil. If commercially popped, was it "buttered" (butter-flavor) or not "buttered"?
- Any additions such as dip or salsa to chips or butter and salt to popcorn?

38. **SOUP**

- Kind (e.g., onion, mushroom, asparagus, chicken noodle)?
- Form (i.e., canned, dry mix, homemade)? If canned, regular, chunky, or low sodium? If condensed, diluted or undiluted? If diluted, what liquid was used? If milk, specify percent fat.
- For cream soups, type of fat in preparation?
- Any additions (e.g., crackers, croutons, etc.)?

39. **SPECIAL FORMULATED PRODUCTS**

A. Bar/Wafer

- Brand name?
- Kind (breakfast bar, diet meal, high protein)?

B. Drink

- Brand name?
- Kind (i.e., fluid/electrolyte replacement solution, low calorie gelatin beverage, low or high calorie milk beverages, meal replacement drink)?
- For low calorie milk beverages, was it canned or prepared from a powder? What flavor?
- For meal replacement drink, was it gelatin, milk, or soy based? High protein? Predigested protein?

C. Protein Supplement Tablet

- No further probing necessary.

D. Dry Unprepared Powder

- Brand name?
- Kind (e.g., instant breakfast, high calorie, meal replacement, nutrient supplement, protein supplement)?
- For instant breakfast, was it regular or sugar free? What flavor?
- For meal replacements, was it diet (and fortified)? If so, what flavor? If not was it a gelatin base, soy based with herbs, or was it high protein (milk based)?
- For nutrient supplements, was it regular or low calorie?
- For protein supplements, was it a beverage? If so, was it regular or sugar free? If not, was it low calorie, low lactose, milk or soy based or sodium controlled?
- Reconstituted with what type of liquid? If milk, specify percent fat.

40. SWEETENERS

- Kind of sweetener?
- For jams, jellies, and preserves: regular, low sugar, or dietetic?
- Types of sugar (i.e., white, brown, powdered)? If brown, was it crystal or liquid?
- Type of syrup (i.e., pancake, pure or mixture)? If pancake syrup, was it regular, low calorie, diet, maple flavor, buttered blend, or fruit flavor? If pure mixture, specify base(s).
- Brand name of artificial sweetener? If unknown, specify whether saccharin or aspartame; liquid or dry?

41. VEAL

- Was it steak, roast, chop, or ground?
- What cut?
- Was fat trimmed or not trimmed?
- How was it prepared?

- Was anything added before, during, or after cooking, e.g., marinade or coating? If marinated, was it a soy sauce or non-soy sauce mixture? If coating, was coating eaten?
- Fat and salt added in preparation?

42. **VEGETABLES**

- Kind?
- Form (i.e., raw, cooked, canned, or dehydrated)? If raw, was the vegetable plain or marinated? If cooked, from fresh or frozen? If canned, regular or low sodium?
- Method of preparation?
- Fat and salt in preparation?
- Anything added before, during or after preparation (e.g., fat, cream sauce, sour cream)?
- For potatoes, eaten with or without peel?
- For juices, kind? Was the juice regular or low sodium (as in tomato juice)?

43. **YOGURT**

- Brand name?
- Type (i.e., plain, fruited, flavored, with fruits and nuts, or frozen? If frozen, get form (i.e., sandwich, on a stick, coated bar) or flavor?
- Made from whole, low fat or nonfat milk?
- Any additions (e.g., toppings, sweeteners, or fruit).

APPENDIX 4 - THE STRONG HEART STUDY III **DIETARY INTAKE - 24-HOUR RECALL**

Strong Heart Study III - 01/24/97

V - 44

Dietary Intake - 24-hour Recall

Participant's ID Number (SHS) _____	Date of Visit ____/____/____ month day year	Social Security Number <div> <div> <div></div> <div></div> <div></div> </div> <div> <div></div> <div></div> <div></div> </div> <div> <div></div> <div></div> <div></div> </div> </div>		Date of Birth ____/____/____ month day year	Sex: 1=Male <input type="checkbox"/> 2=Female <input type="checkbox"/>
Participant's Name _____ _____	Initials _____ _____	Intake Day 1=Sun 2=Mon 3=Tue 4=Wed 5=Thu 6=Fri 7=Sat <input type="checkbox"/>	Interviewer's opinion of information 1=Reliable 2=Unable to recall one or more meals *3=Unreliable for other reasons <input type="checkbox"/>	Was amount eaten 1=Typical? 2=Considerably less than usual? *3=Considerably more than usual? <input type="checkbox"/>	Did you take any supplements (vitamins, minerals, etc)? 1=No 2=Yes (If "Yes," describe under <i>Food and Beverage</i> , below) <input type="checkbox"/>
Interviewer's ID _____ _____		Place of interview: 1=Clinic, 2=Home <input type="checkbox"/>			

Explain starred () items in the COMMENTS space provided below*

Line No.	Prepared: 1=At home 2=Restaurant 3=Other				Salt added in preparation? 1=No, 2=Yes, 9=Unknown	Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>	amt.	Complete Description
	Time eaten a=a.m., p=p.m.		Food and Beverage	amt.				
	Hour	Minute						
01								
02								
03								
04								
05								

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant, 3=Other						Participant's ID Number (SHS)					
	Time eaten a=a.m., p=p.m.						Salt added in preparation? 1=No, 2=Yes, 9=Unknown			Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>		
	Hour	Minute					Food and Beverage	amt.				Complete Description
06												
07												
08												
09												
10												
11												
12												
13												
14												
15												
16												
17												

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant 3=Other						Participant's ID Number (SHS)			
	Time eaten a=a.m., p=p.m.				Salt added in preparation? 1=No, 2=Yes, 9=Unknown		Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>			
	Hour	Minute			Food and Beverage	amt.		Complete Description		
06										
07										
08										
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10										
11										
12										
13										
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15										
16										
17										

COMMENTS (Give line no. when appropriate):

Line No.	Prepared: 1=At home 2=Restaurant, 3=Other						Participant's ID Number (SHS)					
	Time eaten a=a.m., p=p.m.						Salt added in preparation? 1=No, 2=Yes, 9=Unknown			Was fat added in preparation? 1=No, 2=Yes, 9=Unknown <i>Please note type of fat used, in description</i>		
	Hour	Minute					Food and Beverage	amt.			Complete Description	
06												
07												
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COMMENTS (Give line no. when appropriate):

2. QUALITY OF LIFE INTERVIEW

The objective of this study is to evaluate the Strong Heart Study participant's day-to-day functioning and well-being. The significance of this study can be summarized as following:

1. That there are needs and interests of obtaining data in regard to the quality of life in a population with a great burden of chronic conditions^{1,2,3,4,5}, and there is virtually no information about the quality of life in the Indian population.
2. With the amount of data that Strong Heart Study has collected, such as information about heart disease, hypertension and its treatment, diabetes and its control, use of medications, echocardiogram, pulmonary function, gallbladder, dietary intake, and various lab measurements, the potential use of the quality of life data is tremendous.
3. Through data linkage, the information collected from this study can be linked to the IHS database, thus providing the opportunity to study the quality of medical care outcomes.
4. The Strong Heart Study may be the first large-scale epidemiologic study, not only in the American Indian population, but also in the general population, which includes about 40% of healthy subjects to assess the quality of life and provides invaluable baseline data for other or future studies to compare with¹⁴.

The potential contribution of the study of the quality of life may become one of the most interesting and important findings to the Indian community, its health providers, and health policy makers.

The Medical Outcome Study (MOS) 36-ITEM SHORT-FORM HEALTH SURVEY (MOS SF-36, appendix 5) questionnaire will be used in this study to collect the data. Originally the questionnaire was developed by the RAND Corporation for the Medical Outcome Study (MOS), and later being condensed and standardized by Ware and Sherbourne (1992). The MOS SF-36 contains 36 questions which covers eight areas, physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitation due to emotional problems, vitality, and general health perception. It was designed as self-administer questionnaire, and should not take more than five minutes to complete. If scoring slightly differently, the results can be compared with data collected by the RAND 36-ITEM HEALTH SURVEY 1.0.

The reasons the Rand 36-item Health Survey 1.0 was chosen as the tool to collect the data are based on the following reasons.

1. It is a generic (nondisease-specific), multi-item scale measuring each of eight health concepts: 1) physical functioning; 2) role limitations because of physical health problems; 3) bodily pains; 4) social functioning; 5) general mental health (psychological distress and psychological well-being); 6) role limitation because of emotional problems; 7) vitality

(energy/fatigue); and 8) general health perceptions. Most of these items have been adapted from instruments that have been used for 20 to 40 years or longer⁶, and all the items have been validated by various groups^{3,7,8,9}.

2. The form is designed for self-administration, telephone administration, or administration by personal interview. It has been applied to general public³; participants who attended primary care facilities^{7,9}; elderly low-income veterans¹⁰; patients with diabetes¹¹; and patients who received hip replacement¹². The age of participants ranged from 16 to over 80 years old. The response rates were about 85% in two of the studies administered by mailing the questionnaire to the participants^{9,11}, and over 95% of the respondents completed the questionnaire in one of the studies⁹. The average time to administer the questionnaire was 15 minutes for elderly veterans¹⁰, while it took about 5 to 10 minutes for younger participants⁶. The questionnaire also has the precision to detect the difference of health status due to the different levels of severity of chronic medical conditions⁷, due to the control of disease¹¹, or due to the treatment of medical conditions¹².
3. The scoring system of the questionnaire is straightforward. All measures were scored on a scale of 0 to 100, with a higher score indicating a more favorable health status. First, assign this numeric score to each of the questions according to the answer chosen by the participant¹³. This score, between 0 and 100, represents the percentage of the total possible score achieved. Second, items in the same scale (i.e., each of the eight health concepts) are averaged together to create the scale scores; thus, eight scale scores will be created. Since the scores are treated as continuous variables, most of the parametric statistical methods can be used for data analysis. The eight scales can be analyzed individually or combined into different categories, depending on the purpose of the studies.

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**Please see Operations Manual
Volume II Appendix D-12 or Appendix E-10
for Quality of Life Questionnaire**

3. CENTER FOR EPIDEMIOLOGICAL STUDIES DEPRESSION SCALE (CES-D) (Oklahoma Center SHS-I Cohort Only)

Reference Radloff, L. The CES-D Scale: A self-report depression scale for research in the general population. Applied Psychosocial Measurement, 1: 385-401, 1977.

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 CES-D was designed to measure current level of depressive symptomology, and especially depressive affect. The CES-D has been established as the "standard" for brief assessment of depression, i.e., in large scale epidemiological studies.

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.

THE STRONG HEART STUDY III

CES-D SCALE (Oklahoma Center SHS-I Cohort Only)

SHS ID Number:

1. How is this questionnaire administered?

☐ 1=By interviewer ☐ 2=By self ☐ 3=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
2.	I was bothered by things that don't usually bother me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	I did not feel like eating; my appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	I felt that I could not shake the blues even with help from my family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	I felt that I was just as good as other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	I felt that everything I did was an effort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	I felt hopeful about the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	I thought my life had been a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	I felt fearful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	I was happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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** . . .

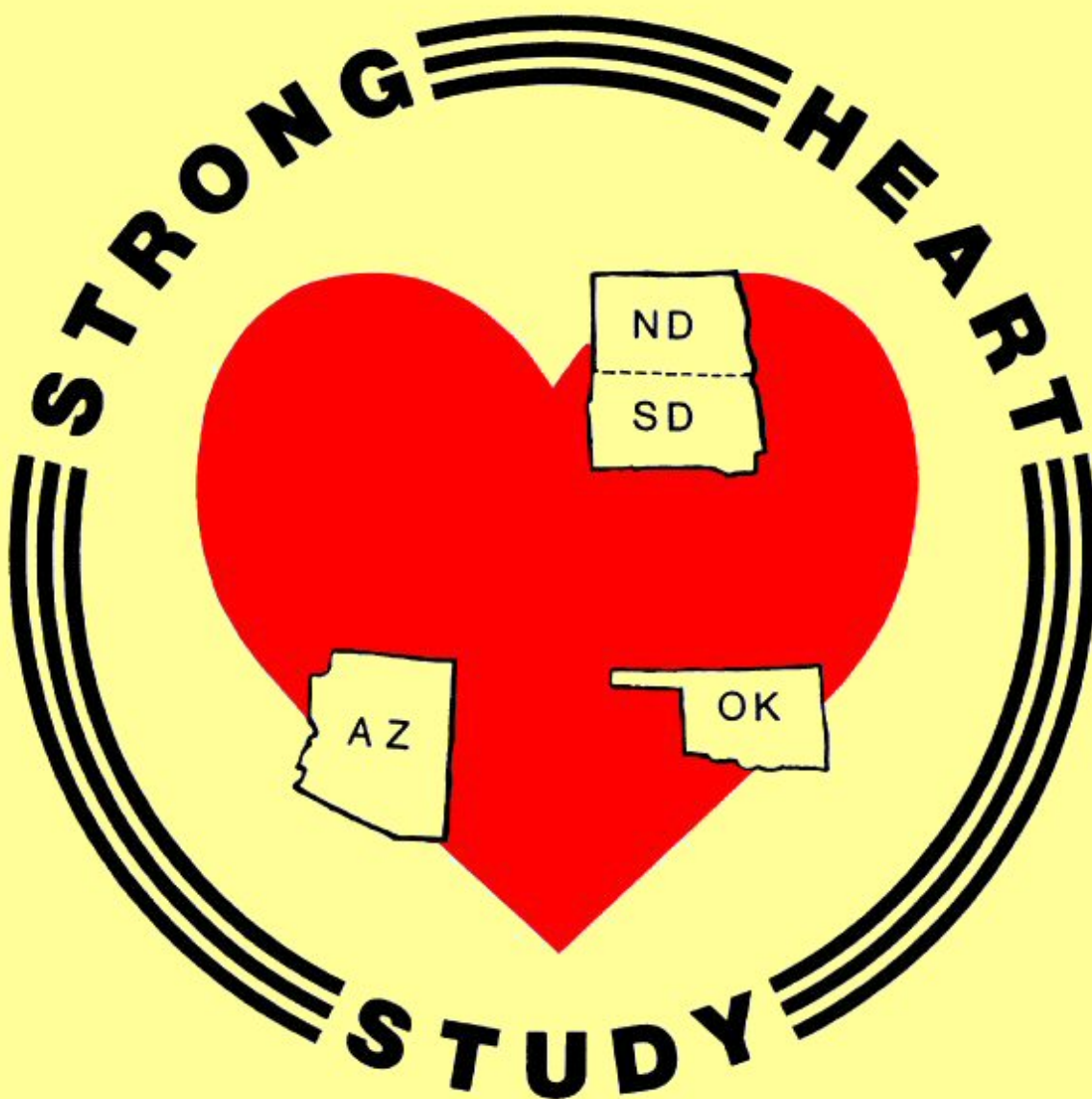
Rarely or Not at ALL < 1 day 1	Some 1-2 days 2	Often 3-4 days 3	Most of the Time 5-7 days 4	Not Applicable 9
---	-----------------------	------------------------	--------------------------------------	------------------------

- | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 14. I talked less than usual. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. I felt lonely. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. People were unfriendly. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. I enjoyed life. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. I had crying spells. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. I felt sad. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. I felt that people disliked me. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. I felt like I couldn't do what I needed to do. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

For Question 22, please use the following scale:

Rarely or Not at ALL 1	Some 2	Often 3	Most of the Time 4	Not Applicable 9
------------------------------	-----------	------------	--------------------------	------------------------

- | | | | | | |
|---|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 22. I have felt depressed or sad in this past year . | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. Interviewer's code | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | | | |
| 24. Date completed (mo/day/yr) | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | | | |



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME SIX

**SPECIAL STUDIES
CAROTID ULTRASOUND AND TONOMETRY**

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

THE STRONG HEART STUDY
Cardiovascular Disease in American Indians
(Phase III)

Operations Manual

Volume Six

Special Studies
Carotid Ultrasound and Tonometry

September 8, 1997

For copies, please contact

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CAROTID ULTRASOUND AND TONOMETRY

MANUAL OF OPERATIONS

STRONG HEART STUDY, PHASE III 1997

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VOLUME VI

SPECIAL STUDIES CAROTID ULTRASOUND AND TONOMETRY

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STRONG HEART STUDY ULTRASOUND READING CENTER MANUAL OF OPERATIONS

A. 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 III of the Strong Heart Study to accomplish the following specific aims:

1. Determine the distributions of carotid arterial wall thickness and atherosclerosis in American Indians and compare them to findings in other ethnic groups.
2. Assess the distribution of arterial stiffness in American Indians and the relations of arterial stiffness to: a) concurrently measured arterial hypertrophy, atherosclerosis and risk factors and b) echocardiographic measures of left ventricular structure assessed previously during SHS phase II.
3. Determine the impact of diabetes, impaired glucose tolerance and insulin resistance on arterial structure and function in American Indians.
4. Examine the relation of elevated blood pressure and treated hypertension to arterial hypertrophy, atherosclerosis and arterial stiffness in American Indians.
5. Determine the relations of adipose and fat-free body mass and their distribution (waist-hip ratio) to arterial hypertrophy, atherosclerosis and stiffness in American Indians.
6. Determine the phenotypic heritability of arterial wall thickness, atherosclerosis and arterial stiffness in American Indian sibships and extended families.

B. Background of the Study:

Findings in Phases I and II of the Strong Heart Study identify its participants as a population of unusual interest with regard to studying the biology of cardiovascular disease. The overall prevalence of diabetes is high, with age-adjusted prevalence rates ranging from 33% among male SHS participants in North/South Dakota to 73% in female Arizona participants. Similarly, the degree of obesity (mean body mass index = 31.5 ± 6.5 kg/m² in SHS women and 29.8 ± 5.9 kg/m² in SHS men) is much greater than in the overall U.S. population (1). Strong Heart Study participants in Arizona and Oklahoma have prevalences of hypertension (by application of JNC-V criteria to standardized single-visit blood pressures) comparable to NHANES III data for the general U.S. population, whereas hypertension prevalences in the Sioux (28% in women and 27% in men) were lower. Notably, 55% and 53% of hypertensive SHS men and women were both treated and had controlled blood pressure, exceeding the respective 46% and 51% general U.S. rates of successful management of hypertension. Of particular biologic interest, dyslipidemia was relatively uncommon, with mean total cholesterol concentrations about 20 mg/dl lower in SHS men and 40 mg/dl lower in SHS women than national mean values for the same age group despite the higher relative body weight in our subjects (1-2).

Despite the relatively low prevalence of uncontrolled hypertension and lack of extremely elderly subjects (>80 years), high prevalences of increased left ventricular mass (19% had values above the prognostically-validated partition value of 51 g/m^{2.7}) and ejection fractions <40% (nearly 3%) were revealed by the echocardiographic data from the first 3,121 Phase II

participants to have their studies processed. The high total mortality in Strong Heart Study communities -- ranging up to twice the rates in U.S. whites among 45 to 64 year-old Indians (2a) -- and substantial contribution thereto of cardiovascular death indicates that the different mix of risk factors and evidence of target organ damage than in other populations is not associated with a benign cardiovascular prognosis. This makes the Strong Heart Study population an ideal one in which to evaluate whether standard risk factors retain the same relative strength for prediction of subsequent cardiovascular events and for the presence of concurrent preclinical target organ disease as in models derived from predominately Caucasian or urban populations with very different risk factor distributions. In addition, the large family size of Strong Heart Study participants facilitates sib-pair analysis of phenotypic inheritance, permitting identification of heritability of arterial abnormalities in the SHS Family Study, as has already been found for echocardiographic variables measured during Phase II.

C. Arterial Evaluation:

Carotid Ultrasound: Recent progress has made available non-invasive methods to evaluate arterial structure and function. Ultrasound measurement of carotid wall thickness (combined intimal-medial thickness) has been validated using gross and histopathologic reference standards (3-5) and has been found to be highly reproducible (5-9). Ultrasound scanning of the carotid arteries gives precise measures of structure (3-4), detects atheromatous plaque (3,10-12) and, in population-based studies, has proven to be a powerful noninvasive tool for the prediction of subsequent morbid events (10,13,14). Two large U.S. epidemiologic studies involving over 10,000 subjects, the Atherosclerosis Risk in Communities (ARIC) study (15) and the Cardiovascular Health Study (16), have provided carotid artery measurements in black and white men and women over a broad age range and will permit comparison of distribution of wall thickness and prevalence of atherosclerosis in American Indians with these populations.

The presence of carotid arterial abnormalities is strongly correlated with coronary atherosclerosis (17-20). In fact, both carotid atherosclerosis and carotid wall thickness were predictors, independent of standard risk factors, for the development of subsequent myocardial infarction in the Kuopio Heart Disease Risk Factor Study (11,13,21). For each 0.1mm increase in common carotid artery intimal-medial thickness, the risk of myocardial infarction increased by 11% (13). In the Cardiovascular Health Study common carotid artery wall thickness was found to be an independent correlate of both prevalent coronary heart disease and stroke (16). In keeping with these observations, carotid wall thickness and/or prevalence and severity of atherosclerosis have been found to correlate with cardiovascular risk factors such as smoking (22-25), serum lipids (25-27) and diabetes mellitus (28). Furthermore, data from our laboratory have identified ultrasound evidence of carotid hypertrophy as at least as sensitive a marker of end-organ damage as is echocardiographic left ventricular (LV) hypertrophy in hypertension (6,29).

Another strong advantage of this technique is the high prevalence of abnormalities which are likely to be detected, increasing the ability of the study to detect the influence on the circulation of diabetes, obesity and other risk factors that are prevalent in American Indians. In the Cardiovascular Health Study (all subjects ≥ 65 years), 75% of men and 62% of women were

found to have some degree of carotid atherosclerosis, although significant stenosis was uncommon (16). In the Kuopio Heart Disease Risk Factor Study involving 412 men aged 42 to 60 years, 49% had some abnormality of carotid anatomy (30). Among a subset of 100 men followed for two years, some progression of disease was noted in 83 and was correlated with smoking habits but not serum lipids at baseline (31). Among 517 French women aged 45-54 years, Bonithon-Kopp et al. detected intimal-medial thickening in 30% and plaque in 8.7% (25). Ultrasound measurement of the common carotid artery intimal-medial thickness has also been used as the primary endpoint in assessing efficacy of lipid-lowering therapy (32,33), with computer image processing permitting the detection of wall thinning over a two-year period in as few as 50 subjects (20).

Several approaches to the measurement of carotid wall thickness and quantification of atherosclerosis have been employed in previous studies, using either discrete measurements of specific segments (6,15,16,20,34) or scoring systems derived from measurements at multiple sites (12,19). Protocols have included measurement of both near and far wall thicknesses (16,19) or have been limited to far wall thickness (6,15,20,28,34). As experience and analyses have accumulated, several observations have emerged. It is apparent that measurement of the far wall intima-media complex is more accurate than that of the near wall. There is systematic encroachment of the adventitial acoustic signal into the media and of the intimal acoustic signal into the lumen of the near wall, whereas encroachment of the intimal acoustic signal into the medial of the far wall is irrelevant since the combined intima-media complex is being measured. Thus it has been suggested that investigators measuring and incorporating near wall thickness also provide separate measurements of the far wall for comparability with other studies (35). Secondly, the optimal imaging plane is one wherein the transducer beam is perpendicular rather than oblique to the structure of interest. Thus the parallel walls of the tubular common carotid artery are more crisply imaged than those of the carotid bulb (28) resulting in much higher measurement yield and reproducibility of common carotid artery intimal-medial thickness than of the bulb or internal carotid artery (9,15,36). In fact Crouse has recently reported a yield of only 78% for measurement of internal carotid artery wall thickness (36).

Because of flow dynamics the common carotid artery is much less susceptible to discrete atherosclerosis than are the bulb and proximal portion of the internal carotid artery (37) indicating that intimal-medial thickening of various segments may have different pathophysiologic implications and mechanisms (27). Although it has been proposed that diffuse intimal-medial thickening may represent "early" atherosclerosis (15,27), there remains considerable controversy in this regard (35), and the interpretation of findings may also be influenced by the study population, i.e., the predominance of one or another cardiovascular risk factor. Although common carotid artery wall thickening may or may not represent early atherosclerosis, common carotid wall thickness itself clearly relates to the risk of associated coronary atherosclerosis (11,13,16,20,21). These latter considerations support an approach which separates measurement of wall thickness and discrete plaque rather than deriving a score from combined maximal and/or average measurements.

Intimal-medial thickness has traditionally been measured from B-mode, or two-dimensional, images. Although we have made plaque measurements from B-mode images, we have utilized M-mode ultrasound images for measurement of lumen diameter and wall

thicknesses for several reasons. Two-dimensionally-guided M-mode images provide the same spatial resolution as B-mode images but add substantially higher temporal resolution thereby providing two major advantages to measurement from B-mode images. First, there is a significant decrease in intimal-medial thickness during systole concomitant with the increase in lumen diameter (38). Thus lack of ECG-gating and/or the limited temporal resolution of B-mode images will result in systematic underestimation of intimal-medial thickness. Secondly, a higher temporal resolution is mandatory if one additionally wishes to estimate vascular stiffness (as described below).

In consideration of the foregoing, the proposed study will measure far wall thickness of both common carotid arteries in addition to minimum and maximum lumen diameters from M-mode images. Discrete carotid atherosclerosis will be measured both qualitatively and quantitatively from the two-dimensional and Doppler studies (as described in detail in the Methodology section).

Arterial Function: In contrast to the anatomic view of arteries as static conduits, in vivo ultrasonography reveals pulsatile expansion of arteries during systole that transiently accommodates much of the blood ejected from the heart. The degree of arterial expansion (vascular strain) is, in turn, affected by age and disease states. The addition of sophisticated, non-invasive measures of arterial compliance which we have already applied in other, predominately white or African-American normotensive and hypertensive populations will permit a careful examination of the influences of diabetes, hypertension and other cardiovascular risk factors on vascular functional properties.

A high-fidelity solid-state non-invasive transducer, manufactured by the Millar Corporation, has recently been FDA-approved and made commercially available. The transducer functions as an applanation tonometer (39) and produces arterial pressure waveforms which are virtually indistinguishable from those obtained using invasive solid-state transducers. Accuracy of the transducer has been widely validated (40-43). The application of catheterization-validated transfer functions (44) to a radial artery pressure waveform obtained using applanation tonometry allows accurate determination of central aortic pressure and reconstruction of the central aortic pressure waveform as demonstrated by simultaneous intra-arterial catheters (45). Whereas previous estimates of arterial stiffness (or its inverse, compliance) were limited to selected subjects undergoing invasive evaluation or, when derived non-invasively, were subject to the confounding influence of distending pressure, applanation tonometry combined with ultrasound measurement of vascular pulsatility provides a powerful noninvasive tool to assess vascular function on an epidemiologic scale. Furthermore, the ability to measure wall thickness and the development and validation of a pressure-independent measure of arterial stiffness (to be described in detail in the Methodology section) represent substantial methodologic advances.

Arterial imaging and Doppler ultrasound evaluation in combination with noninvasive arterial pressure waveform recording provide three distinct bioassays: (1) carotid wall thickness in an area (common carotid) relatively spared by atherosclerosis as a measure of arterial hypertrophy and/or generalized atherosclerosis, with high yield and reproducibility; (2) detection of discrete atheromas (usually within the carotid bulb or proximal branch vessels) and grading of atheroma size or lumen stenosis as unambiguous measures of atherosclerosis; and (3) measures

of arterial stiffness in the carotid artery and in the entire arterial circulation. This makes it possible to identify the relations of the separate components of arterial disease (atherosclerosis, hypertrophy, stiffness) to cardiovascular risk factors, cardiac structure and function, and to prevalent and incident cardiovascular morbidity and mortality.

D. Progress Report/Preliminary Studies:

Carotid Ultrasound Studies at the Cornell laboratory: Carotid ultrasound studies to determine vascular structure and to detect atherosclerosis have been performed by the Cornell laboratory in combination with simultaneous echocardiography in over 800 subjects participating in ongoing studies (6,29,34,46-48). In half these subjects the arterial pressure waveform from one carotid artery has been recorded using a Millar solid-state high-fidelity external pressure transducer as an applanation tonometer (41) simultaneously with imaging of the contralateral carotid artery. Calibration of the applanation tonometry recordings for the mean brachial artery pressure yields calibrated instantaneous carotid pressures which, when combined with simultaneous carotid dimensions, provide estimates of arterial compliance. Experience to date demonstrates that this approach provides reproducible results (6).

Use of this methodology has permitted initial descriptions of several aspects of vascular structure and function in both hypertensive and normotensive populations studied in our laboratory. We have detected substantially higher intimal-medial arterial thickness in healthy asymptomatic hypertensive subjects compared to age- and gender-matched controls (6,29) and provided the first description of parallel increases in cardiac and vascular structure in hypertension (6). This finding has been subsequently validated in numerous other populations (5,49-52). The presence of visible atherosclerotic plaques was associated with left ventricular hypertrophy (LVH), independent of blood pressure, lipids, or other standard risk factors (34), providing a potential mechanism for the observed increase in vascular events, including stroke, in the setting of LVH (53). We have found vascular, in addition to cardiac, structure to be similar in 'white coat' hypertensives to that in normotensives in contrast to evidence of hypertrophy in sustained hypertensives (54), suggesting that 'white coat' hypertension is not associated with target organ damage and may have a benign prognosis. In contrast, individuals with 'white coat normotension' (normal clinic blood pressure with elevated ambulatory blood pressure) have vascular hypertrophy and atherosclerosis comparable to that seen in sustained hypertensives (55), an observation which may provide insight into cardiovascular morbidity in ostensibly normal individuals.

Our approaches to the estimation of arterial compliance have indicated that compliance is reduced in hypertensives at their operating level of pressure, but that these differences are substantially related to the level of distending pressure and structural adaptation by vascular hypertrophy (46). Furthermore, the shape of the arterial pressure waveform as manifested by a higher augmentation index is related to higher left ventricular mass, independently of age, gender, body size or the level of mean arterial pressure (47).

We are currently in the process of applying these same methodologies in two intervention trials to determine the impact of pharmacologic therapy (with an ACE inhibitor, a calcium channel blockers and a thiazide diuretic) on arterial structure and function, in addition to left

ventricular structure and geometry, and, ultimately, clinical outcome. In addition, we have recorded the radial artery pressure waveform using the Millar applanation tonometer with analysis provided by the Sphygmocor System which will be used in SHS Phase III to derive central arterial pressure waveforms that closely resemble those obtained by the more skill-dependent procedure of applanation of the carotid artery. Subjects studied in the Cornell laboratory include white and African-American normotensive and hypertensive subjects for comparison with SHS findings.

E. Research Design and Methods

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 and previously-described methods (6,46). 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 (3,10,30). Carotid atherosclerosis identified in this way has been shown to correlate strongly with coronary artery disease (17-20) and risk of subsequent myocardial infarction (11,13,16). 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. Whenever lumen stenosis is significant ($>50\%$) on the imaging study, the severity of stenosis is quantified using standard Doppler techniques (56). 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 (16). 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 thickness at end-diastole and lumen diameter at end-diastole (minimum diameter) 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 (Imaging Technology, Inc., Woburn, MA) interfaced with a high-resolution (480 x 640 pixel field) video monitor and stored on diskettes (Table 2). Following calibration for depth, 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. The ultrasound characterization and measurements of carotid wall layers has been validated by Pignoli et al (3) using gross and histopathologic reference standards. Measurement of carotid wall thickness is never made at the level of a plaque (infrequent in the common carotid artery).

Carotid Artery Function: Carotid artery function will be assessed using information derived from pressure waveforms acquired using applanation tonometry of the radial artery. Following completion of the carotid ultrasound study, brachial blood pressure will be measured in triplicate and averaged. The necessary information required for the SphygmoCor system will

be entered: SHS number (under patient ID), family name, first name, date of birth, social security number (under patient code), brachial blood pressure, and operator ID. The radial artery pressure waveform will be acquired with computer-generated derivation of the central pressure waveform using a transfer function. The information generated by the program is depicted on the attached sample report (see last page of manual). The relevant information for the principle measures of arterial function includes central blood pressure (to be used in regional compliance estimates [see Table 4]) and augmentation index. The additional parameters (excluding the pressure waveform) will be electronically transferred to the main database. The waveform raw data may be extracted separately for future analyses.

F. Ultrasonographer Training and Quality Control:

Arterial ultrasonography training, reading procedures and quality-control will be similar to those successfully employed for echocardiography in Phase II 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 with over 15 years of experience in research echocardiography and 7 years of experience with the carotid research protocol. 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. In addition, a specialist from PWV Medical, the supplier of the applanation tonometry system and software (SphygmoCor) will visit each site to install and demonstrate the system and further instruct the sonographer in its use. 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; sonographers should verify that this is performed by Acuson as part of routine maintenance. The 7.0 Mhz vascular probe will be set to default with processing curves and a persistence setting optimal for imaging of the carotid artery (1/C/7). The usual depth is 30 to 40 mm.

Patient Preparation: Imaging is 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) and lateral rotation, as necessary. Electrodes are placed for a modified three-lead electrocardiogram. The last name of the subject, first initial and SHS number should be entered before beginning the imaging study. In addition, the arterial system being imaged (left vs. right) should be entered on the screen.

Two-Dimensional Imaging and Doppler Study: Two-dimensional (B-mode) long-axis imaging from multiple planes (posterior, lateral, anterolateral) should be done to maximize detection of discrete plaque. Following identification of the carotid bulb, the transducer should be moved caudally to examine the common carotid artery until its origin from the aortic arch (left) or innominate artery (right). Both branch vessels should be scanned in a cephalad direction until their disappearance. Identifying features of the internal carotid artery on the imaging study include its larger size and motion away from the transducer as it proceeds intra-cranially, whereas the external carotid artery is usually smaller and has extracranial branches. Pulsed Doppler analysis should also be performed to identify distinguishing characteristics of the internal and external carotid arteries: the low resistance internal carotid artery is characterized by spectral broadening and persistence of flow during diastole whereas the high resistance external carotid artery has a rapid deceleration to the baseline with minimal diastolic flow. Extensive imaging of the bulb and proximal bifurcation should be performed given the high predilection for plaque in these regions. If plaque is present, the cine function should be activated to allow frame-by-frame scrolling to obtain the maximum plaque diameter. Electronic calipers should be used to measure maximum plaque diameter (mm) and, if possible, vessel diameter (mm) at the level of the plaque and diameter reduction (%). The transducer should then be rotated to obtain a cross-sectional image identifying the maximum incursion of the plaque into the lumen and plaque diameter, vessel diameter at the level of the plaque and diameter reduction of the lumen should again be measured using the cine function. Maximum plaque diameter from either of these views should be recorded on the Sonographer Worksheet based on plaque location. Addition of color flow to the cross-sectional image may aid in distinguishing plaque from lumen and in wall detection. If the plaque occupies a substantial percentage of the lumen area (>50%), pulsed Doppler analysis (with angle correction, if appropriate) should be performed to quantify the degree of stenosis by obtaining the peak velocity distal to the obstruction (1.5 to 2.5 m/sec = 50-74% obstruction, >2.5 m/sec = ≥75% obstruction).

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. Using the cine or freeze-frame function, preliminary measurements of the intimal-medial thickness of the far wall at end-diastole should be made on several cycles (time permitting) and entered onto the Sonographer Worksheet.

The complete protocol is videotaped and the procedure is repeated on the contralateral artery.

Clinical Alerts and Referral Criteria The presence of significant obstruction ($>50\%$) constitutes a clinical alert. Such studies will be identified at the Reading Center and processed within 48 hours of receipt. Results of such studies will be reported by telephone to the Field Center. The presence of $\geq 75\%$ obstruction should result in immediate referral whereas obstruction of 50-74% should result in routine referral. The detection of non-obstructive plaque ($<50\%$) should provoke assessment of risk factors for atherosclerosis and discussion between the physician and the SHS subject regarding their reduction at the next routine visit.

TABLE 2: CAROTID IMAGE ANALYSIS PROTOCOL

Logsheet: The sonographer will keep two log sheets, one with the subjects' full name, age, gender, height and weight and the other with the last name and first initial. Other information will include study date, tape number, SHS number and social security number.

Sonographer Worksheet: The sonographer will complete a limited worksheet (see page 11) following performance of the study which will include study center, study date, SHS number and social security number. The worksheet will provide information regarding the technical aspects of the study (image quality); plaque presence, location and diameter; and intimal-medial thickness of the far wall.

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 an electronic worksheet (see page 12). Plaque will be graded as present/absent, according to side and location, and quantified by maximum diameter (mm), diameter reduction (%; if available, given the plaque location and geometry of the vessel), peak velocity (if diameter reduction is $\geq 50\%$) and percent lumen stenosis ($< 50\%$, $50-74\%$, $\geq 75\%$). Following calibration for depth, measurement of the intimal-medial thickness of the far wall at end-diastole (minimum diameter) will be made on as many cycles as are available on the acquired frame and averaged. 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.

SONOGRAPHER WORKSHEET

Sonographer _____
 Study center _____
 Study date _____
 Tape number _____
 Frame numbers _____

Last name, first initial _____
 SHS number _____
 Social security number _____

Technical quality: Left: excellent _____ good _____ poor _____
 Right: excellent _____ good _____ poor _____

Brachial Blood Pressure: _____ + _____ + _____ /3 = _____

Plaque Location	Plaque +/- Diam (mm)	Vessel Diam (mm)	Diameter Reduction (%)	Peak Velocity (m/sec)*
L CCA, near	_____	_____	_____	_____
L CCA, far	_____	_____	_____	_____
L bulb, near	_____	_____	_____	_____
L bulb, far	_____	_____	_____	_____
L ICA, near	_____	_____	_____	_____
L ICA, far	_____	_____	_____	_____
L ECA, near	_____	_____	_____	_____
L ECA, far	_____	_____	_____	_____
R CCA, near	_____	_____	_____	_____
R CCA, far	_____	_____	_____	_____
R bulb, near	_____	_____	_____	_____
R bulb, far	_____	_____	_____	_____
R ICA, near	_____	_____	_____	_____
R ICA, far	_____	_____	_____	_____
R ECA, near	_____	_____	_____	_____
R ECA, far	_____	_____	_____	_____

*Obtain only if diameter reduction $\geq 50\%$

M-mode common carotid dimensions

				Average
L CCA far wall, end-diastole	_____	_____	_____	_____
R CCA far wall, end-diastole	_____	_____	_____	_____

Clinical Alert Yes _____

READER WORKSHEET

Study date _____
 Study center _____
 SHS number _____
 Social security number _____

Common carotid dimensions

Average

L CCA far wall, end-diastole	_____	_____	_____	_____
R CCA far wall, end-diastole	_____	_____	_____	_____
L CCA diameter, minimum	_____	_____	_____	_____
L CCA diameter, maximum	_____	_____	_____	_____
R CCA diameter, minimum	_____	_____	_____	_____
R CCA diameter, maximum	_____	_____	_____	_____

Plaque Location	+/-	Plaque Diam (mm)	Vessel Diam (mm)	Diameter Reduction (%)	Peak Velocity (m/sec)
L CCA, near	_____	_____	_____	_____	_____
L CCA, far	_____	_____	_____	_____	_____
L bulb, near	_____	_____	_____	_____	_____
L bulb, far	_____	_____	_____	_____	_____
L ICA, near	_____	_____	_____	_____	_____
L ICA, far	_____	_____	_____	_____	_____
L ECA, near	_____	_____	_____	_____	_____
L ECA, far	_____	_____	_____	_____	_____
R CCA, near	_____	_____	_____	_____	_____
R CCA, far	_____	_____	_____	_____	_____
R bulb, near	_____	_____	_____	_____	_____
R bulb, far	_____	_____	_____	_____	_____
R ICA, near	_____	_____	_____	_____	_____
R ICA, far	_____	_____	_____	_____	_____
R ECA, near	_____	_____	_____	_____	_____
R ECA, far	_____	_____	_____	_____	_____

TABLE 3: PROCEDURE FOR ARTERIAL APPLANATION TONOMETRY

1. Subject will remain in the supine position following completion of the carotid ultrasound study. Brachial blood pressure will be determined by the sonographer at this time using a cuff and mercury sphygmomanometer. The first and fifth Korotkoff sounds will be used as systolic and diastolic pressures, based on the average of three sequential determinations.
2. The following information will be typed into the SphygmoCor system: first screen (Appendix, page 1): Patient ID=SHS number, family name, first name, sex, date of birth, patient code=social security number; second screen (Appendix, page 2): radial artery, systolic blood pressure, diastolic blood pressure, operator ID=employee ID #; other data needn't be included.
3. The applanation tonometer is positioned over the left or right radial artery (whichever is most accessible) and manipulated to obtain an arterial pressure waveform of an appropriate contour with the highest pulse pressure (Appendix, page 3). 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. A report is generated automatically and displayed on two computer screens which can be viewed with the space bar (Appendix, page 4).
4. The data acquired will be stored on diskette and sent to the Cornell Reading Center. In addition, a one page print-out (Appendix, page 5) of the data will be generated as back-up and forwarded to Cornell. Following verification of fidelity of the pressure waveform, data will be transferred by diskette for incorporation in the main computer database.
5. Monthly back-up of the SphygmoCor database should be performed as indicated in the SphygmoCor manual (Section 5.2, version 4.0). The diskettes should be forwarded to the Reading Center.

TABLE 4: ARTERIAL WAVEFORM ANALYSIS PROTOCOL

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 (44,46). These estimates of arterial compliance will be derived from primary measurements stored in the main database:

Arterial stiffness (beta), the inverse of compliance, is estimated using the approach of Hayashi et al (57), according to the formula:

$$\text{beta} = \ln(P_s/P_d)/([D_s-D_d]/D_d)$$

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. This method has been shown to be independent of changes in distending pressure (58) and to correlate with severity of autopsy-proven severity of atherosclerosis (59).

Peterson's elastic modulus (E_p), an estimate of vascular stiffness which does not account for differences in distending pressure (60), 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 (61), 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).

Augmentation index, a quantitative measure of the rapidity of wave reflection, will be measured from the arterial pressure waveform (48) and is automatically generated by the Sphygmocor system.

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59. Wada T, Kodaira K, Fujishiro K, Maie K, Tsukiyama E, Fukumoto T, Uchida T, Yamazaki S. Correlation of ultrasound-measured common carotid artery stiffness with pathological findings. *Arterioscler Thromb* 1994; 14:479-482.
60. Peterson LN, Jensen RE, Parnell R. Mechanical properties of arteries in vivo. *Circ Res* 1968;

8:78-86.

61. O'Rourke M. Arterial stiffness, systolic blood pressure, and logical treatment of arterial hypertension. *Hypertension* 1990; 15:339-347.

Appendix 1

First screen: Patient Identification Data

SPHYGMOCOR

PATIENT IDENTIFICATION DATA

SHS # = Patient ID : 4527 SID : 00050

✓ Family Name : Smith

✓ First Name : John

Other Names : Michael

✓ Date Of Birth : 01/01/54 DD/MM/YY

✓ Sex : MALE

Patient Height : 175 cm

Social Security # = Patient Code : ns

Address : 31 Hope Street

Ernington NSW 2115

PHYSIO MEDICAL

Figure 4.4.1: A sample of the Patient Identification Screen (Patient Screen).

Appendix 2

Second screen: Tonometry Data

SPHYCMOCOR

TONOMETRY DATA
(New Study)

Patient Name : SMITH, John Michael

✓ Peripheral Artery : (Radial, Carotid)

✓ Systolic Pressure : mmHg

✓ Diastolic Pressure : mmHg

Medication :

Notes :

Employee ID # = Operator ID :

Press <Enter> to proceed or <Esc> to return to the previous screen.

ENTV MEDICAL

Figure 4.5.1: A copy of the Tonometry Screen containing typical data.

Appendix 3

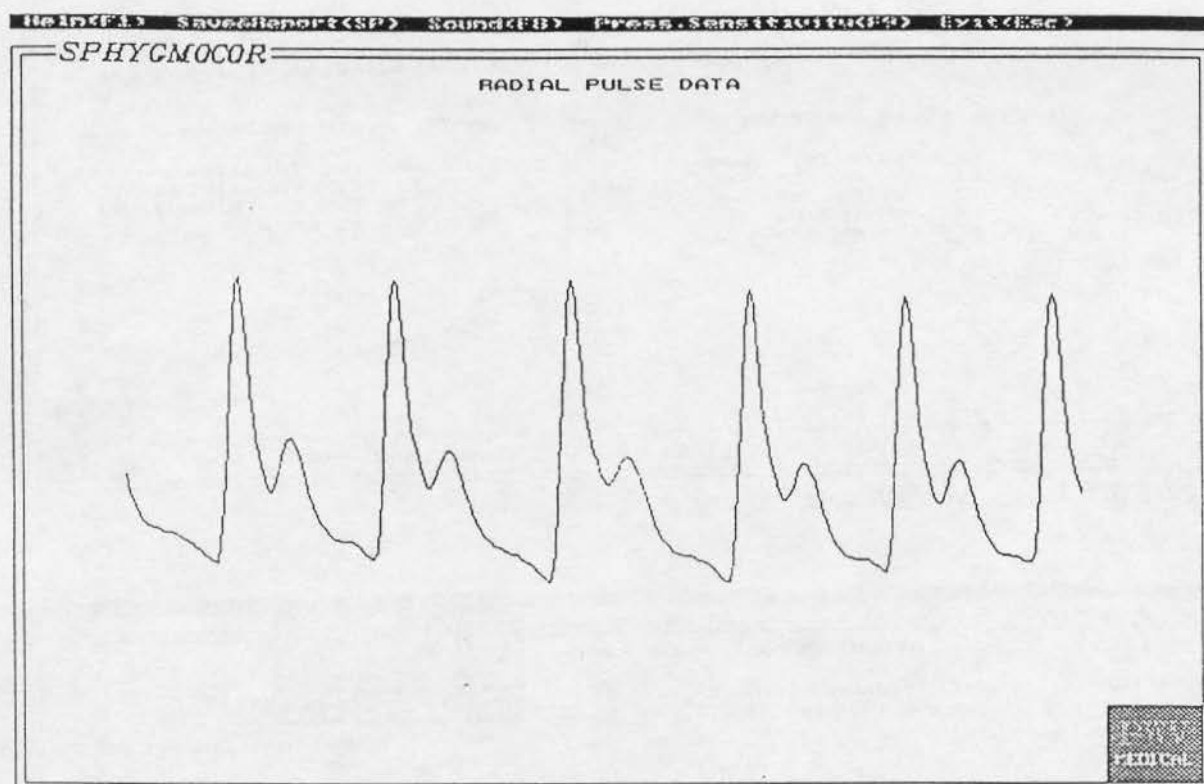


Figure 4.6.1: A sample of the Pulse Data Screen

Two Page Report (on computer)

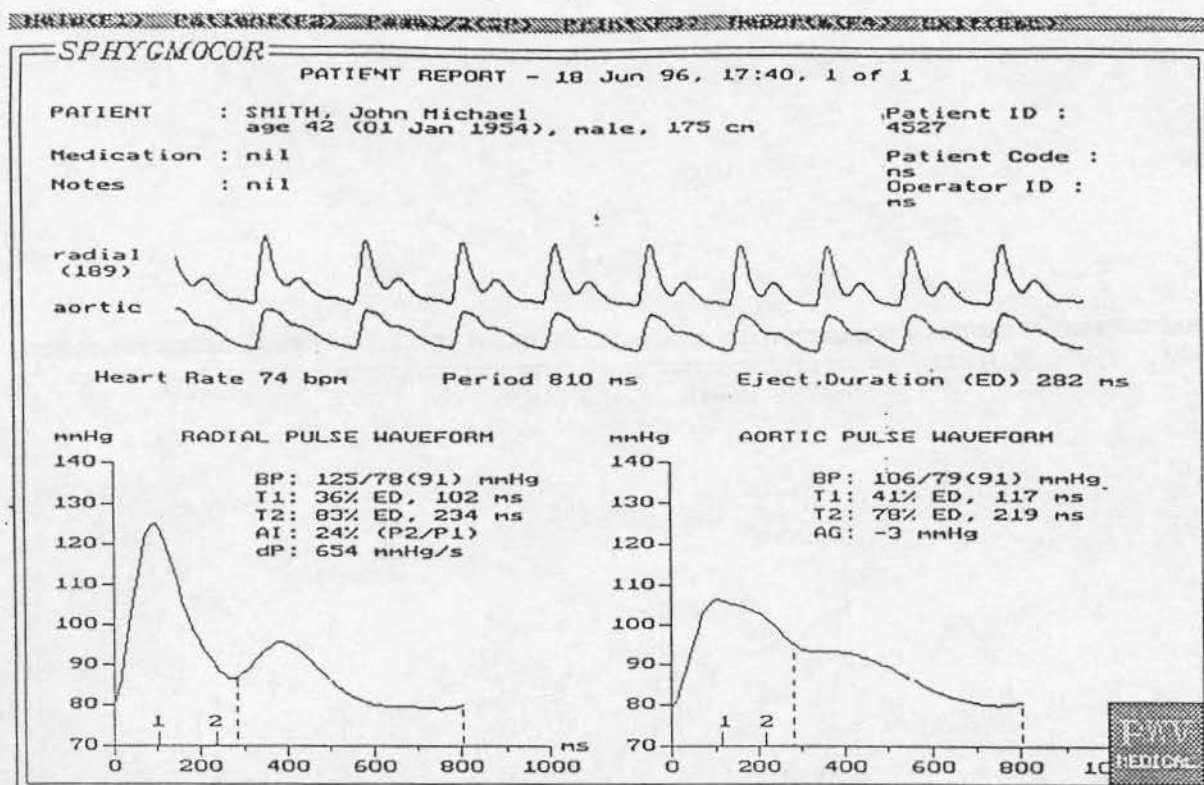


Figure 4.7.1: A sample report, page 1 of 2.

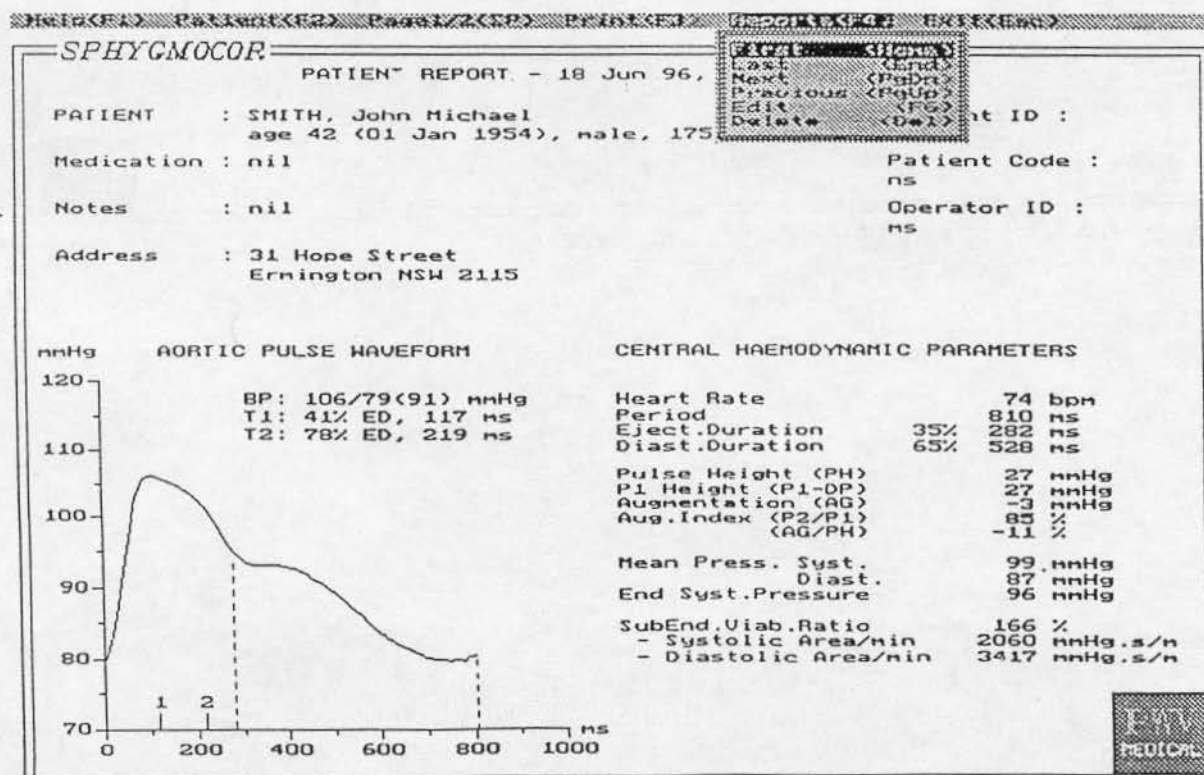


Figure 4.7.2: A sample report, page 2 of 2.

One Page Report (hard-copy)

S P H Y G M O C A R D I O G R A P H
HAEMODYNAMIC EVALUATION

PATIENT DATA

SMITH, John Michael

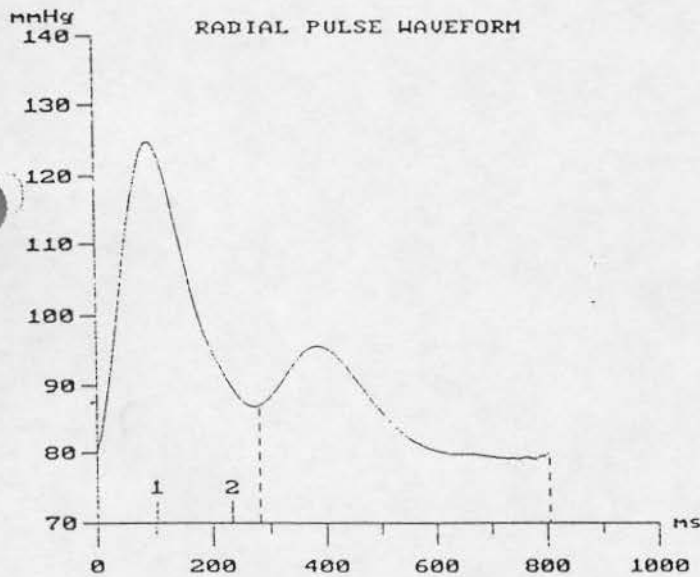
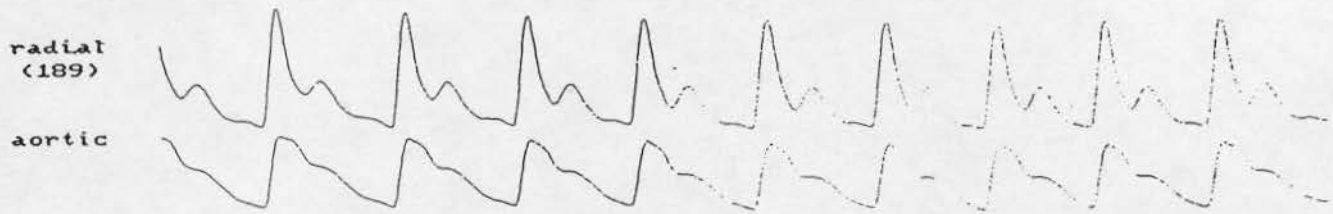
Patient ID : 4527
Patient Code : ns
age 42 (01 Jan 1954), male, 175 cm

Address : 31 Hope Street
Ermington NSW 2115

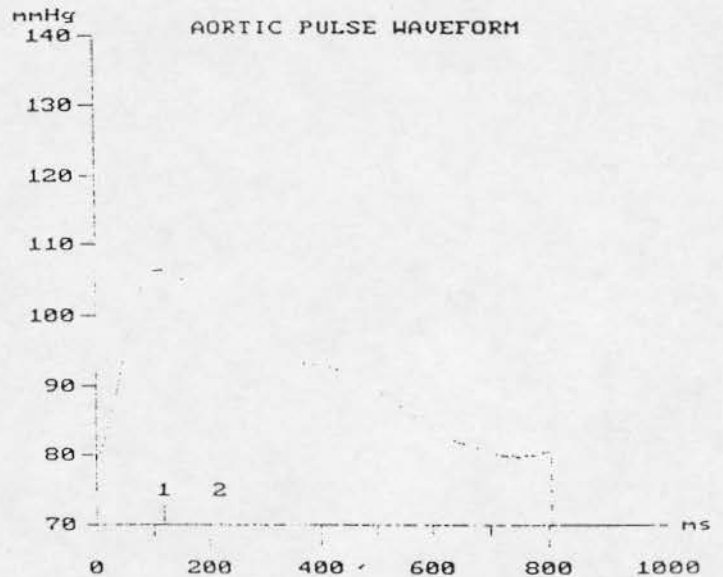
STUDY DATA

18 Jun 96, 17:40
Operator ID : ns

Medication : nil



Blood Pressure 125/78(91) mmHg
1st, 2nd Peak 36 %ED, 83 %ED
Aug.Index 24% (P2/P1)
Maximum dP/dt 654 mmHg/s



Blood Pressure 106/79(91) mmHg
1st Peak 41 %ED, 117 ms
2nd Peak 78 %ED, 219 ms
Augmentation -3 mmHg

CENTRAL HAEMODYNAMIC PARAMETERS

TIMING DATA

Heart Rate, Period 74 bpm, 810 ms
Eject. Duration (ED) 35%, 282 ms
Diast. Duration 65%, 528 ms
SubEnd. Viab. Ratio 166% (2060/3417)

PRESSURE DATA

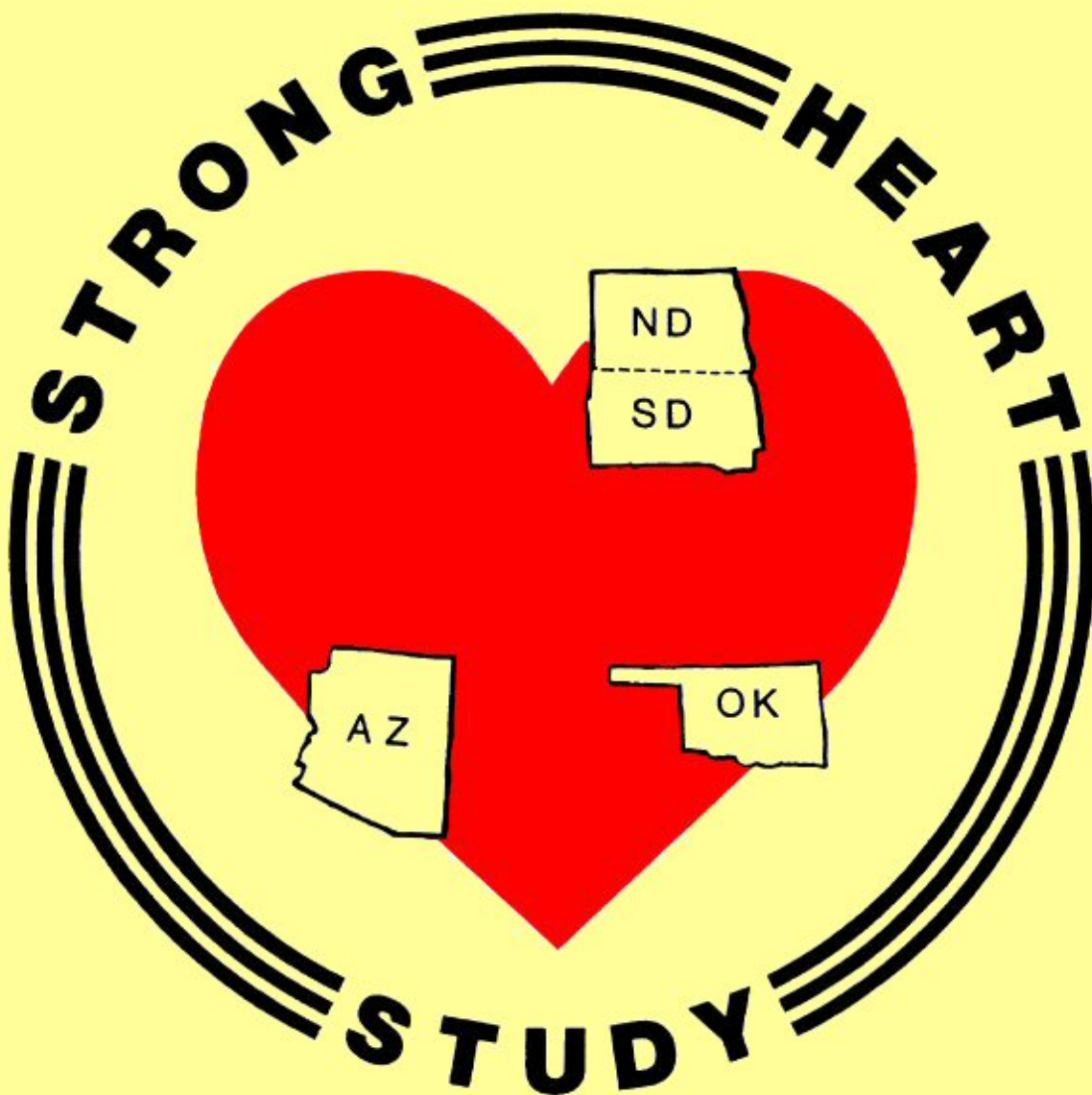
Pulse Height (PH) 27 mmHg
P1 Height (P1-DP) 27 mmHg
Augmentation (AG) -3 mmHg
Aug.Index (P2/P1, AG/PH) 85%, -11%
Mean Press. (Syst/Diast) 99 / 87 mmHg
End Systolic Pressure 96 mmHg

PHU Medical

4.00, 00000

Figure 4.7.5:

A sample of the Sphygmocor printed report.



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

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 III)

Operations Manual

Volume Seven

Data Entry

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Systems Specialist: Leon Kalbfleisch, M.S.

For copies, please contact

Strong Heart Study Coordinating Center

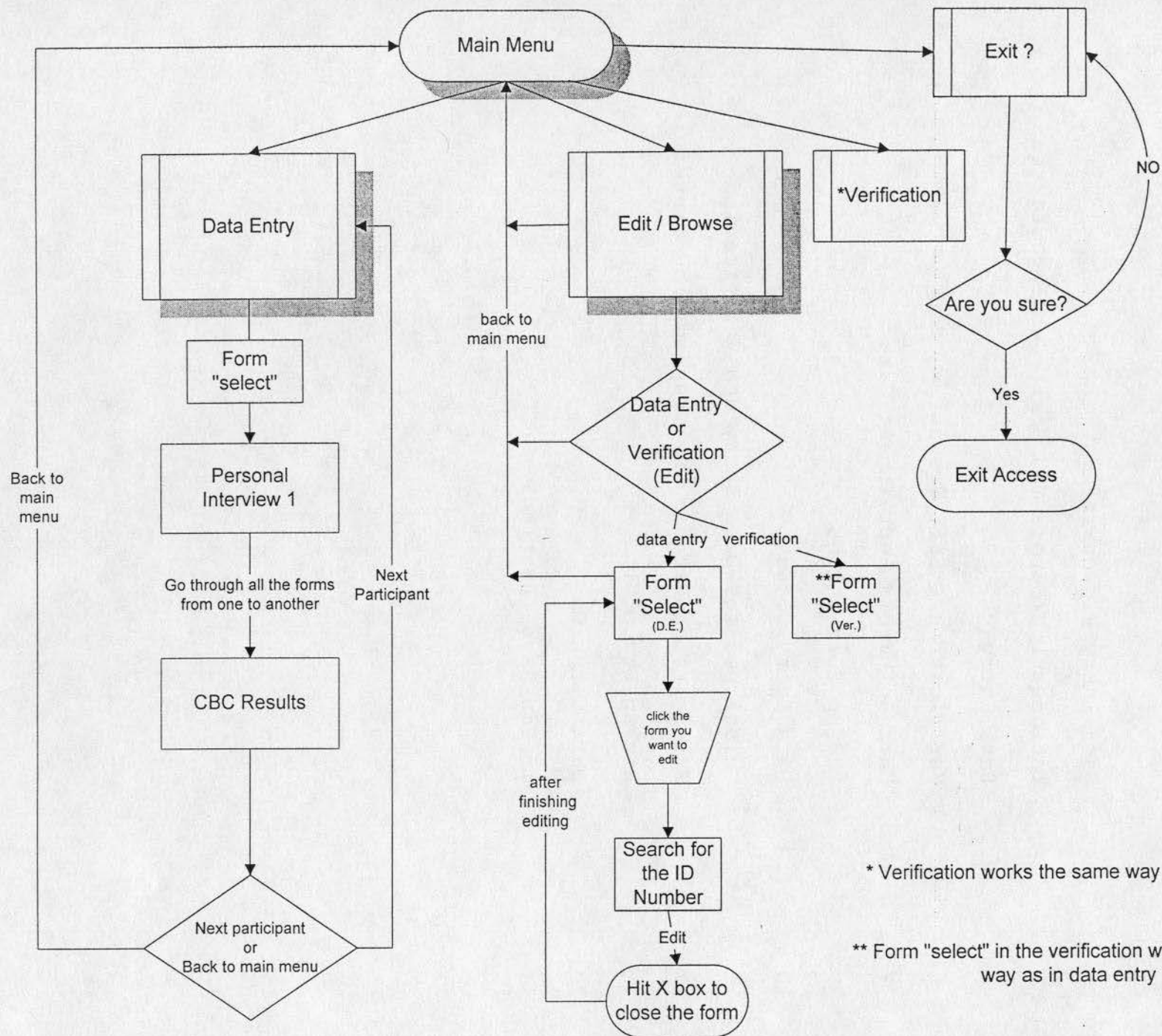
Center for American Indian Health Research

University of Oklahoma Health Sciences Center
College of Public Health

P.O. Box 26901
Oklahoma City, OK 73190

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12	Transmitting Data to the Coordinating Center
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14	If You Have Questions



* Verification works the same way as Data Entry

** Form "select" in the verification works the same way as in data entry

DATA ENTRY FLOWCHART

Introduction

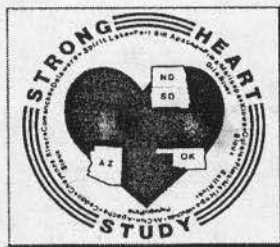
This manual was developed to assist data entry personnel understand and use the programs developed for Phase III of the Strong Heart Study. Since the Cohort and Family data entry programs are similar, an understanding of one will enable the data entry operator to use the other. Therefore, only screens from the Family data entry program will be used in this manual. The following topics will be discussed: data entry/verification, editing data, entering field recruitment data, correcting data entry errors, data entry codes, transmitting data to the Coordinating Center, 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. Do not attempt to correct the program yourself.

Getting Started

To get started, double click the Cohort or Family icon in Windows '95. The following menu will appear (Main Menu):



THE STRONG HEART STUDY III

The Family Study

Please select one of the following options:

Data Entry

Verification

Backup Data

Edit / Browse

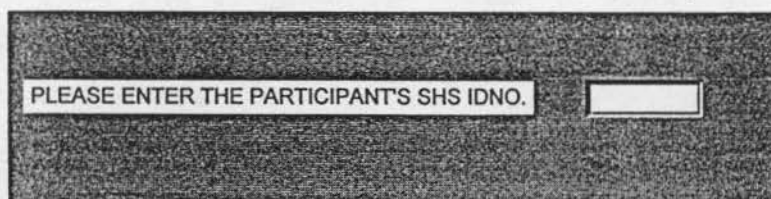
Recruitment

Transmit Data

Exit Access

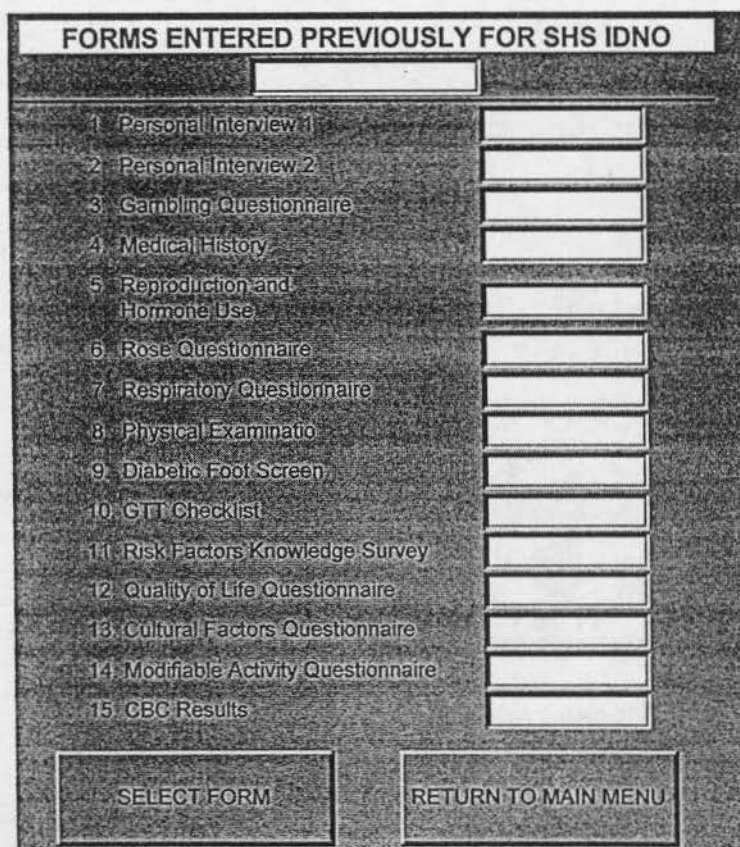
Data Entry

When one selects 'Data Entry', the following input box will appear:



PLEASE ENTER THE PARTICIPANT'S SHS IDNO.

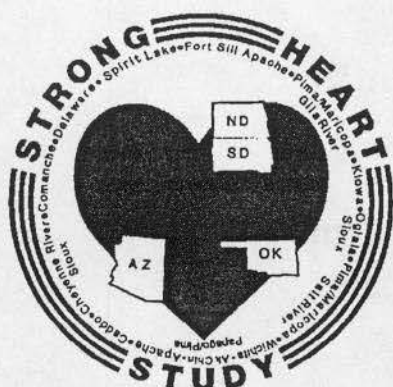
After entering an ID number and pressing the 'Enter' key, another screen will appear:



FORMS ENTERED PREVIOUSLY FOR SHS IDNO	
	<input type="text"/>
1 Personal Interview 1	<input type="text"/>
2 Personal Interview 2	<input type="text"/>
3 Gambling Questionnaire	<input type="text"/>
4 Medical History	<input type="text"/>
5 Reproduction and Hormone Use	<input type="text"/>
6 Rose Questionnaire	<input type="text"/>
7 Respiratory Questionnaire	<input type="text"/>
8 Physical Examination	<input type="text"/>
9 Diabetic Foot Screen	<input type="text"/>
10 GTT Checklist	<input type="text"/>
11 Risk Factors Knowledge Survey	<input type="text"/>
12 Quality of Life Questionnaire	<input type="text"/>
13 Cultural Factors Questionnaire	<input type="text"/>
14 Modifiable Activity Questionnaire	<input type="text"/>
15 CBC Results	<input type="text"/>
<div><input type="button" value="SELECT FORM"/> <input type="button" value="RETURN TO MAIN MENU"/></div>	

If an ID number 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 has already been entered for a participant. In order to avoid incomplete records, we suggest that you complete all of the data entry for a participant before taking a break or leaving for the day.

To proceed, left click the button labeled 'SELECT FORM'. You will see a screen like the one below. This is called the Select Form:



THE STRONG HEART STUDY III Family Study

You are now in

To continue in this mode, select form below.

To change mode or IDNO, click "Back To Main Menu" below.

<p>Back to Main Menu</p> <p>Exit Access</p>	Personal Interview 1	Rose Questionnaire	Risk Factor
	Personal Interview 2	Respiratory	Quality of Life
	Gambling Questions	Physical Exam Exam	Cultural Factors
	Medical History	Diabetic Foot Screen	Modifiable Activity
	Reproduction	GTT Checklist	CBC Results

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.

Open next form?

Yes No Cancel

If you select 'Yes', the next form, Personal Interview Two, will be opened and Personal Interview Form 1 will be closed. If you select 'No', the cursor will go back to the 'Main Menu'. If you select 'Cancel', you will remain in Personal Interview Form One. For all subsequent forms, except the last one (CBC Results), a message box prompting you for the next form will appear after exiting the last field. We suggest that once you exit a form you do not attempt to open it up again until you have completed entering the data for that participant.

After exiting from the last field of the last form (CBC Results), a message box like the following will appear:

You just finished this participant!!!
Do you want to...

1	Go back to the Main Menu
2	Enter the next participant

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 (next page):

<u>Please select one of the following:</u>	
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 5) 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 **first** participant will be displayed. In order to find a **specific** participant do the following:

- 1) Make sure that the cursor is in the field 'IDNO'.
- 2) Use the mouse and **left** click 'Edit' on the menu bar at the top of the computer screen (not shown).
- 3) Select 'Find' by moving your mouse down to that option. You will know that the option is selected when it is highlighted. Now **left** click. Note that you can skip steps 2 & 3 by depressing the 'F' key while holding down the control key.
- 4) An input box will appear prompting you for an ID number. Type the ID number you want to locate in the box labeled 'Find What:'. Then, select 'Find First' which is to the right of the 'Find What:' input box.

Once you have finished making corrections, **you must close the form manually**. You can either go to the menu bar, **left** click on 'File', and select the option 'Close' or you can **left** click the 'X' which is located in the upper right hand corner of the screen and on the menu bar. Most of the time you will see two 'X's in the upper right hand corner. Make sure you select the 'X' that is in line with the menu bar (**the bottom one**) or you will exit Access. After you close the form you will return to the Select Form.

Entry of Field Recruitment Data (Family Study Only)

To enter recruitment forms select the button labeled 'Recruitment' from the Main Menu. The following screen will appear:

Genetics of Cardiovascular Disease
Field Recruitment

Please select one of the following options:

Data Entry	Edit/Browse	Back to Main Menu
------------	-------------	-------------------

If you select Data Entry or Edit/Browse, the following screen will appear (Recruitment Select Form):

Genetics of Cardiovascular Disease
Field Recruitment

Participant Interview (Pages 1 - 4)	Your Children	Additional Siblings	Deceased
	Additional Children	Parents	Go Back
Participant Interview (Pages 5 - 7)	Siblings	Grandparents	

In Data Entry mode the forms are not linked. This means that once you finish a form you will be prompted by a message box to go back to the Recruitment Select Form or stay in the current form. Therefore, after completing a form you must return to the Recruitment Select Form and choose another section of the form you wish to enter.

Edit/Browse works the same way as in Family and Cohort data entry programs. You must manually close the form once you have edited or browsed your selection.

Making Corrections

In order to produce a data entry program which is user friendly and selective about the data entered, skip patterns and message boxes have been added. Unfortunately, the same features which 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 Access 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 (next page):

NOT ALLOWED!

You cannot leave this field blank.

Solution

If the question was not answered: 7=Missing,
8=Refused, and 9=Unknown



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: 01/01/year
if only month and year are known use: month/01/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.

We prefer that you follow #1. Which ever suggestion you follow, make sure that it doesn't conflict with transmitting complete sets of data. In other words, make sure that you have completed both data entry and verification for each participant before transmitting.

Transmitting Data to the Coordinating Center

In order to minimize potential problems (e.g. missing data), we feel that the following suggestions should be followed when possible.

1. Transmit complete sets of data. This means all forms ('Data Entry' and 'Verification') for each participant should be sent to the Coordinating Center (CC) in the same transmission.
2. For each transmission, e-mail (to Joss at jlangevi@etowah.uokhsc.edu) a separate list of the SHS ID numbers that you are transmitting to the CC.
3. After the data for a particular participant has been transmitted, do not edit his/her file. **All post-transmission changes of a participant's file will be done at the CC.**

Backup Protocol

Each data entry system has been supplied with a Zip disk labeled "SHS3 Data Backup". This disk should be used for routine backups after each data entry session. For further data security, we recommend that at least three additional disks for each system be acquired and set up as backup disks (simply copy the files from the main backup disk onto a blank Zip disk), to be used as follows:

Disk #2: Secondary backup at intervals of 1-2 weeks, to be stored "offsite"; i.e., in a different room (and preferably in a different building) from the one where the data entry system resides.

Disk #3: Tertiary backup, performed monthly (may be stored with system).

Disk #4: "Spare" - not routinely used, but kept on hand for quick substitution in case one of the other backup disks fails.

Note: For the backup routines (from the Main Menu in the data entry applications) to complete successfully, the Zip disk being used at that time must contain a copy of the backup files which were supplied with the *current version* of the data entry software. In other words, if the files on the main backup disk are replaced as part of a data entry software upgrade, then the files on the secondary, tertiary, and spare backup disks must also be upgraded.

Data Clean-Up

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 is transmitted to the CC. Incomplete items and discrepancies between 'Enter' and 'Verify' are listed and sent to the field via e-mail. The field will e-mail back corrections 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. Verification of the suspect data will be performed by field personnel. A response (e-mail) is expected within five working days.

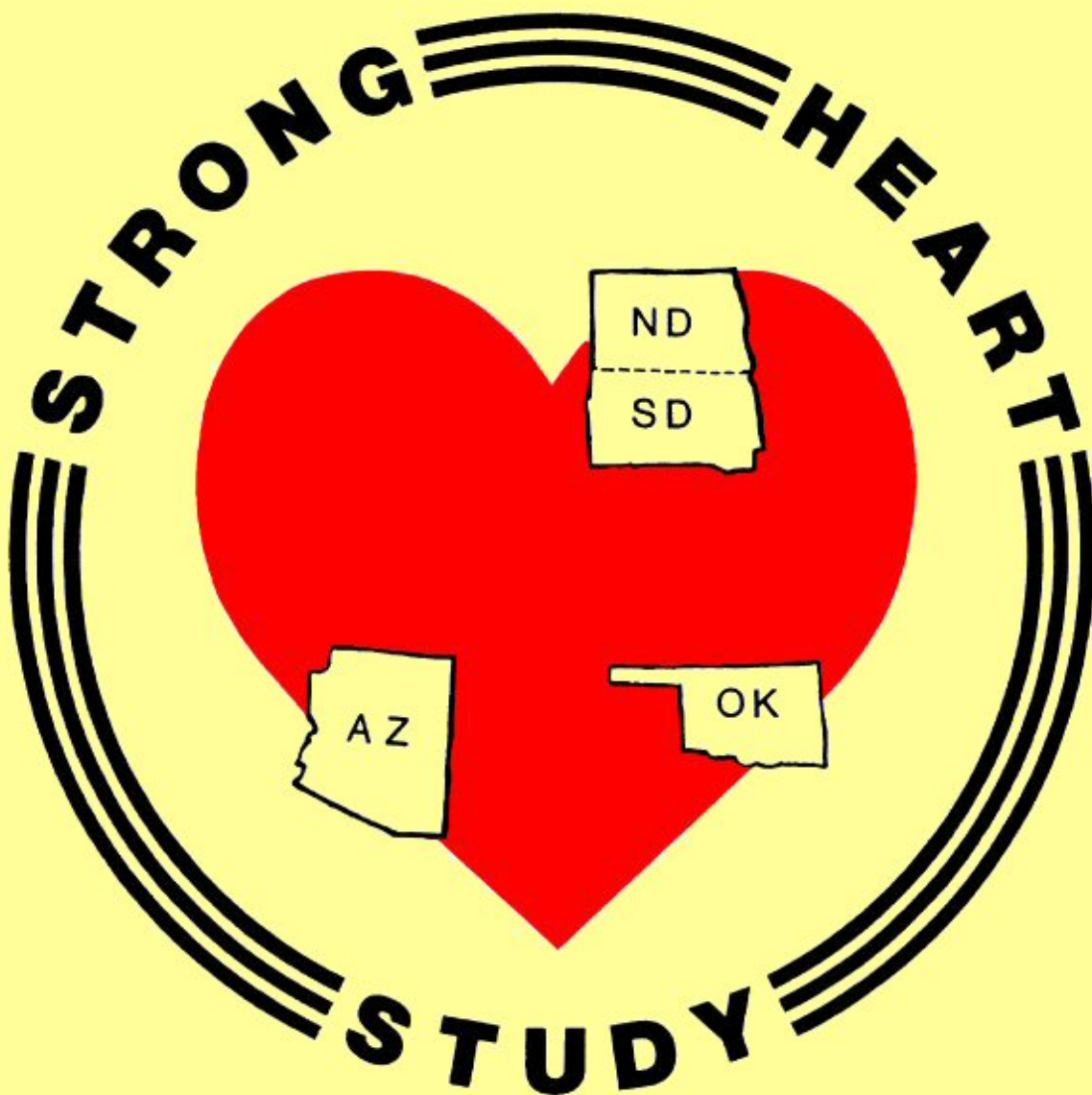
Upon completion of both stages, cleaned records will be appended to the Main Database. Please note that the Main Database will be used to perform analyses for reports and publications. Therefore, if a field site were to identify any data entry errors after data clean-up has been completed, they must 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 retransmitted.

If You Have Questions

So that your questions may be answered efficiently, please address your queries to the following personnel:

Data Transmission/Data Backup	- Leon Kalbfleisch
Data Entry Programs	- Ya-Jiun Brower
Data Clean-Up	- Joss Langevin
Forms	- Dr. Jeunliang Yeh



**CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(PHASE III)**

OPERATIONS MANUAL - VOLUME EIGHT

CARBON MONOXIDE DETERMINATION AND ASTHMA SUB-STUDY

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

THE STRONG HEART STUDY

Cardiovascular Disease in American Indians (Phase III)

Operations Manual

Volume Eight

Carbon Monoxide Determination and Asthma Sub-study

June 1, 1997

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research

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EXPIRED AIR CARBON MONOXIDE (CO) DETERMINATION
MANUAL OF OPERATIONS
STRONG HEART STUDY, PHASE III 1997

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Vitalograph CO Monitor

Vitalograph Medical Instruments,
8347 Quivira Road,
Lenexa, Kansas,
phone 1-800-255-6626

- Manual Version 1.0
- April 7, 1997
- Filename: co2shs.wpd

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MANUAL OF OPERATIONS
EXPIRED AIR CARBON MONOXIDE (CO) DETERMINATION
STRONG HEART STUDY

Filename: co2shs.wpd

Date: April 7, 1997

BACKGROUND

Cigarette smoking is one of the strongest risk factors for cardiovascular disease and all cause mortality. Self-report of smoking status (via questionnaire) results in a certain degree of mis-classification due to misrepresentation by some study participants. There are several methods of biochemical validation of self-reported non-smoking. The most commonly used by epidemiological studies are analysis of blood, urine, or saliva samples for nicotine (or one of its metabolites, usually cotinine), thiocyanate, or the measurement of carbon monoxide (CO) in blood samples or in exhaled breath. The Strong Heart Study has chosen breath CO measurement since it is non-invasive, sample collection is quick, it provides immediate results, and it is relatively inexpensive. A false negative result will occur if the participant has not smoked cigarettes during the previous 24 hours. A false positive result will occur if the participant was recently exposed to excessively high levels of CO in their environment. Sources of high levels of environmental CO include poorly vented gas appliances (kerosene room heaters, water heaters, central heaters, or gas ranges), indoor wood-burning, or gasoline engines with leaking exhaust systems. Detection of these sources in non-smoking participants with high CO levels may be accomplished using commercially available home CO monitors (\$30-60 each). Recent exposure to second-hand smoke from other smokers (cigarette, pipe, or cigar) results only in small elevations of breath CO.

The carboxyhemoglobin concentration (COHgb) is elevated in the blood of smokers because the inhaled smoke contains carbon monoxide (CO). The hemoglobin within red blood cells binds CO much more avidly than it does oxygen. The average half-life of CO in the blood is about 4 hours, so that when a person smokes a cigarette, their CO level will remain higher than that of a non-smoker (more than 10 ppm, parts per million) for at least 8 hours following their last cigarette. A measurement of the concentration of CO in the exhaled breath provides a quick non-invasive estimate of COHgb. A direct measurement of COHgb would require a blood sample and a large expensive analyzer (called a co-oximeter). Hand-held battery operated CO analyzers (like the unit chosen for this study, made by Vitalograph) measure ambient or exhaled CO in the range of 0-500 ppm, although the highest levels normally seen in smokers, immediately after smoking, are about 50 ppm.

Principle of Operation of the CO Analyzer

The Vitalograph EC50 CO Monitor is a compact, portable instrument powered by either alkaline or rechargeable batteries. A simple sampling system traps the last portion of an exhaled breath (an "alveolar" sample) in a T-piece which is adjacent to the surface of the instrument's sensor. Diffusion of the sample into the sensor results in an electrical signal directly proportional to the CO concentration. The sensor is an electrochemical polarographic type cell. The cell electro-oxidizes carbon monoxide to carbon dioxide in direct proportion to the partial pressure of CO in the sample area. The resulting signal is amplified, temperature compensated, and then is displayed in parts per million on the liquid crystal display.

Performance Specifications of the Vitalograph CO Analyzer

Gas Detected	Carbon Monoxide
Concentration Range	0-500 ppm
Detection Principle	Sealed electrochemical sensor
Meter	Liquid crystal display
Sampling System	Two flutter valve T-piece
Mouthpieces	Cardboard, disposable
Warm-up Time	Less than 10 seconds
Response Time	Less than 30 seconds to 97% of final reading
Drift	Less than 1% of signal per month at constant temperature
Operating Temp Range	0-40 degrees centigrade
Operating Pressure	Atmospheric
Humidity Range	0-100% relative humidity (a hydrophobic filter protects sensor from condensed water vapor)
Life of the Sensor	2-3 years (guaranteed 6 months)
Sensor Selectivity	Negligible interference from alcohol and other organic species under normal situations. A high capacity carbon filter is available to remove unusually high concentrations of alcohol. 20 ppm hydrogen gives less than a 4 ppm reading.
Power Supply	9 volt Alkaline battery

Steps to Measure the Breath CO Level of a Study Participant

- 1) Push the black on/off switch, located above the display on the top of unit, to "On" position. The display will start at a high number, then rapidly fall to around "000" (± 2).
- 2) When the unit has reached "000" (± 2), attach the blue T-valve. **Record** the ambient reading; record the + or - sign in the first field, and the reading in the second field (see figure 1). The open end of the T-valve should face away from the display, towards the "Breath CO" logo.
- 3) Attach a new disposable cardboard mouthpiece to the open end of the T-valve.
- 4) Instruct the participant to exhale completely, then to inhale deeply and hold the breath for 20 seconds.
- 5) Instruct the participant to go on the cardboard mouthpiece, and seal their lips tightly around the mouthpiece.
- 6) Instruct them to exhale as completely as possible through the sampling system (approximately 15 seconds).
- 7) At the end of the participant's expiratory breath, **record** the reading after it reaches its peak (after about 30 seconds). The reading obtained is the concentration of carbon monoxide in the participant's breath (an "alveolar" sample).
- 8) Allow your participant to "catch their breath" between trials (approximately 30 seconds to 1 minute).
- 9) Two trials are completed for each participant; repeat steps 4 through 7.
- 10) If the first 2 trials are within 4 ppm (± 4), record both results on the study form (see figure 1a, "1st" and "2nd"), and record "X" in trials 3 and 4. If they are not within 4 ppm, both trials should be repeated with careful coaching and recorded. No more than two sets of 2 trials should be done even if the second set also differs by more than 4 ppm.

Note: It is not necessary to wait for the instrument to return to zero before another test is performed.

11) When doing sampling:

- Turn off the display (using the black on/off display switch)
- Disassemble the sampling equipment, and discard the mouthpiece.

Breath CO:	
Ambient:	CO [ppm]:
<div><div></div><div>+</div><div></div></div> <div><div></div><div></div></div> <div>circle</div>	<div><div></div><div></div></div> <div>1st</div> <div><div></div><div></div></div> <div>2nd</div> <div><div></div><div></div></div> <div>3rd</div> <div><div></div><div></div></div> <div>4th</div>

figure 1a

CO Analyzer Maintenance and Troubleshooting

- Turn the unit OFF after each participant, unless you plan to use it again within ONE HOUR.
- Typically, the 9 volt Alkaline battery has a life of 250 - 500 hours of use. The unit will display "low battery" when it needs to be replaced. To replace the battery:

On the back of the unit, press down on the compartment panel marked "OPEN" and slide cover in the direction of the arrow. Then, lift cover from the unit. Remove and discard the old battery. Replace with a new 9 volt battery. Tuck the wires neatly away before replacing the compartment cover.
- Storage and Transporting. The unit should always be turned off when stored. The battery should be removed if you don't intend to use it for several weeks. If the machine is used for field work, the padded carrying case is highly recommended. Avoid leaving the machine in freezing temperatures or temperatures above 80 degrees. Always carry 2 sets of spare batteries.
- Sensor Cell Replacement. The sensor cell should last 2-3 years, and is guaranteed for 6 months. A loss in sensitivity will generate erratic readings and an inability to be calibrated correctly. These signals indicate that replacement of the sensor cell is necessary. Ship the instrument to Vitalograph for maintenance.
- T-valve Sterilization. The T-valves should be sterilized each week.
 - 1) Using a test tube brush and a solution of mild detergent and warm water, scrub each T-valve inside and out.
 - 2) Rinse and then immerse them in a sterilizing solution (i.e. Lysol I.C., glutaraldehyde) for 20 minutes.
 - 3) Thoroughly rinse each T-valve again, and air dry and wrap in paper towels for storage. To avoid skin irritation or allergic sensitization, always wear rubber gloves when removing T-valves from the sterilizing solution.
- Erratic Readings. If an instrument does not display a background reading between +2 and -2 ppm, let the instrument sit with the unit on, for up to 30 minutes. Usually the background reading will fall to within the range of acceptable drift. If not, follow the calibration procedure.

The Calibration Procedure

Equipment needed:

Tank of 50 ppm CO Test Gas with regulator, hose
Calibration Check Chart and Log
Small screwdriver
2 minute count up/down timer
T-valve

The CO analyzer must be calibrated at least monthly, and more often if excessive drift is noted.

- 1) If the Vitalograph has been used recently to measure CO, allow it to sit for at least 30 minutes with the unit off. This provides sufficient time for any CO remaining within the sensor to be consumed.
- 2) Turn the unit ON and take a reading. Record the reading in the "zero valve" spot on the calibration check chart and log sheet.
 - If the zero reading is not between -2 and +2 ppm, (the acceptable drift range) adjust the zero potentiometer located on the front panel (black slide above the "Vitalograph" logo) to give a reading of "000". DO NOT ADJUST the zero if within +/-2 ppm, simply record the reading. Once it reads "000" (± 2), tape down the black slide bar so it can not be adjusted between calibration checks.
- 3) Attach the T-valve. Fit the calibration cap into the end of the T-valve which accepts the mouthpiece. Open the regulator valve, releasing gas, until the needle rests at 10 psi. The calibration gas will enter the T-valve.
- 4) Start timer, and leave the gas on for the 1 minute. This will allow the unit to achieve a stable reading.
- 5) When timer goes off, note the reading, then turn off the gas tank.
- 6) Allow 30 seconds to pass before noting the reading (allows the unit to achieve its peak reading). Record the result on the calibration check chart and log sheet.
 - If the reading is between 48 to 52 ppm, DO NOT ADJUST THE SPAN, just record the reading. If the CO reading is NOT between 48 to 55 ppm, use a miniature screwdriver to adjust the span potentiometer located on the back of the unit to give a reading of 50 ppm.
- 7) Detach the hose from T-valve, and switch the unit off.

8) Record your tech ID code and data on the calibration check chart and log sheet.

If you have difficulty in obtaining zero or 50 ppm readings, replace the battery and repeat the entire calibration procedure. If you still have difficulty, the sensor may need replacement. Call Vitalograph for advice.

Background CO

Background (ambient) CO is that CO which is present in the room air at the time a CO sample is collected. Normal background CO levels are 0-4 ppm. We define the background CO level as the reading immediately prior to testing the first participant of the day. The background reading is made before attaching the T-valve.

Environmental factors such as car exhaust and faulty heating systems will influence background CO levels. If the background CO level is greater than 4 ppm, take the machine outside a building and rezero the meter. (See step 2 of the cal check procedure.)

Standard Equipment, Service, and Maintenance

Vitalograph CO Monitor \$1000

T-valve, miniature common screwdriver

Additional T-valves can be bought from the company \$4

Mouthpieces #20.202 (box of 210) \$30

Calibration gas cylinder 50 ppm CO \$85

(15-20 calibrations per tank)

Count up/down timer (Radio Shack Cat# 63-878 or similar unit) \$12

All apparatus and replacements are available from Vitalograph Medical Instruments, 8347 Quivira Road, Lenexa, Kansas, phone 1-800-255-6626

APPENDIX

WHAT IS CARBON MONOXIDE?

Carbon monoxide (CO) is a colorless, odorless, poisonous gas produced by burning organic material. It is one of the three main constituents of tobacco smoke along with tar and nicotine. All three represent some risk to health. Carbon monoxide mainly effects the heart, blood vessels, and lungs.

Carbon monoxide is found in atmospheric pollution. It is produced by burning petrol and gas so that all modern cities will have at least some CO in the air. Compared to the concentrations found in tobacco smoke, however, the levels found in the body from pollution are low.

Some carbon monoxide is produced naturally by the body. So even non-smokers in country areas will not have a level of zero. However, the levels produced naturally are so small that they could not be confused with those resulting from smoking.

What this means in practice is that the level of carbon monoxide in the body shows the amount of tobacco smoke inhaled. Even moderate CO levels are rare in non-smokers except in unusual circumstances.

When tobacco smoke is inhaled into the lungs, carbon monoxide passes through the lining of the lung into the bloodstream, where it becomes attached to hemoglobin (Hb) - the red blood cells. The function of the red cells is to carry oxygen around the body. However, they have a much more powerful chemical attraction to CO than to oxygen (200 times greater) so if there is any CO in the blood at all, it becomes attached to hemoglobin in the place of the oxygen forming carboxyhemoglobin or COHb.

The percentage of COHb is the proportion of red blood cells carrying CO rather than oxygen. Thus, if you have five percent COHb this means that your body is five percent short of oxygen: five percent of your red cells are carrying CO and not oxygen.

This places extra strain on the system. The heart has to work harder to make up for the oxygen loss, and it has to do this extra work when its own blood supply is short of oxygen. There is a double effect.

SOME EXAMPLES OF CARBON MONOXIDE LEVELS

1. In The Country Air

Natural free CO can be measured where there is no major industry or motor vehicles and air is fairly pollution-free - mountain regions, remote rural areas or offshore islands without cars. Such places show less than one part per million (ppm) CO. These on non-smoking inhabitants show an average Carboxyhemoglobin (COHb) level of 0.68 percent (5 ppm CO), produced naturally by the body, mainly from breakdown of hemoglobin.

2. In a Small, Badly Ventilated "Smoking" Office

In a controlled test, 12 non-smokers and eight smokers were confined in an unventilated room for nearly 80 minutes, during which 80 cigarettes and two cigars were burned or smoked. The average COHb level of non-smokers rose from 1.6 percent (10 ppm) to 2.6 percent (17 ppm) in that time.

This one percent increase is approximately the amount of CO a smoker obtains from one cigarette. It is also similar to the CO intake by a driver working for a whole day in a major city, or by policeman after three hours of traffic duty.

3. In Heavy Smokers

Tests showed that smokers attending a London stop smoking clinic had an average COHb level of eight percent (45 ppm).

Summary - Distinguishing Smokers from Non-smokers

CO levels will vary a little in non-smokers because of pollution, including passive smoking. The best cut-off point for dividing smokers and non-smokers is around 1.6 percent COHb or 8 ppm of CO. Levels above this normally indicate an unusual level or source of pollution, or smoking.

MEASURING CARBON MONOXIDE

Holding your breath for a short while allows the CO concentration in the lungs and the blood vessels to equalize. You then blow into the instrument which registers your CO level almost immediately.

As you stop smoking, you will see your CO level drop dramatically.

WHAT THIS READING MEANS

The average level for smokers is about 5.5 percent (33 ppm), but this does not translate exactly into the number of cigarettes smoked per day. How heavy a smoker you really are depends on the amount of smoke inhaled and not on the number of cigarettes smoked.

The cut off point will not always be exactly 1.6 percent or 8 ppm, but this is the level which separates smokers and non-smokers best. Normally, non-smokers will only have higher levels due to unusual factors.

Levels above 15 percent are uncommon except in cigar and pipe smokers (because cigar and pipe smoke have a high CO concentration). This is why switching from cigarettes to cigars or pipe is useless, or be even more dangerous. Measuring CO will show if those who have switched are still inhaling. Most do.

Symptoms of intoxication start at around 20 percent and levels above 30 percent are approaching danger (from asphyxiation).

ASTHMA SUBSTUDY - SPIROMETRY

MANUAL OF OPERATIONS

STRONG HEART STUDY, PHASE III 1998

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Spirometer

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Renaissance Spirometry System
11150 Thompson Avenue
Lenexa, KS 66219-2301
(800) 225-6773
Software Version F Serial Number: RU707012

- Manual Version 2.0
- February 6, 1998
- Filename: SHS_spiroMOP98 .wpd

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FORWARD:

This manual serves three purposes:

- a study guide for training of physicians, nurses and technicians to perform spirometry (pre & post bronchodilator, BD).
- a practical "how-to" reference guide to be used during the study
- documentation of the procedures for analyses and manuscript preparation.

BACKGROUND:

Spirometry is the simplest, most effective test for assessment of lung function. That is why it has been included in many cardiovascular epidemiology studies, including SHS.

Spirometry (without bronchodilator) was measured during SHS Phase II for the original cohort. Spirometry reference values are being developed from the healthy subset of American Indian participants.

Spirometry records the relationship between airflow (FEV1) and the exhaled volume of air during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). The most common lung diseases reduce forced expiratory flows. Such "obstructive" lung diseases include **asthma**, bronchitis, and emphysema. The ratio of FEV1/FVC is very sensitive for detecting mild airways obstruction.

SUB-STUDY SPIROMETRY CHANGES

When compared to spirometry testing done during SHS Phase II,

1. A maximum of 5 maneuvers will be done (not 8). Maneuvers will last only 6 seconds (not 10).

2. The spirometer is very small. Disposable flow sensors will be used (no hoses or cleaning).

NEW PROCEDURES

1. Baseline Spirometry will be done on all substudy participants including controls. For those with abnormal results on baseline spirometry, 2 puffs (from an asthma inhaler) will be given to the participant, with spirometry repeated 10 minutes later (post BD).

DEFINITIONS (GLOSSARY)

ALBUTEROL (official generic name in the U.S.) is an asthma medication for the relief of bronchospasm in patients with reversible obstructive airway disease (asthma). After administering albuterol, an improvement of 15% or greater in FEV1 values indicates precedence of asthma.

ALLERGEN: a substance that causes an allergy.

ANTIGEN: a liquid made from an allergen that when introduced onto the skin stimulates the production of an antibody.

ATS is short for American Thoracic Society, the scientific branch of the American Lung Association (ALA). The ATS promotes accurate spirometers by recommending spirometry standards. The ATS and ALA divorced in 1997.

BD: is short for bronchodilator.

BIOLOGIC CONTROL CALIBRATION CHECK is a baseline spirometry done by a non smoker and non asthmatic tech. The same tech should be used every Monday morning before the 1st participant.

CALIBRATION SYRINGE is a large plastic cylinder with a rubber sealed piston used to check the volume accuracy of spirometers.

COPD stands for Chronic Obstructive Pulmonary Disease, a general term for lung disease caused by cigarette smoking - a mixture of emphysema, bronchitis, and hyper reactive airways (asthma).

FEV1: Forced Expiratory Volume in 1 Second (liters). The volume of air exhaled in the first second of an FVC maneuver.

FEV1/FVC RATIO is the most sensitive and specific index of airways obstruction measured by a spirometer. It is normally above 70% in adults.

FLOW SENSOR see pneumotach

FVC is the Forced Vital Capacity, the volume of air exhaled during the maneuver named after it. The subject takes as deep a breath as possible and then quickly exhales (BLAST) as much air as possible. The FVC is reduced with restrictive disorders.

MDI is a meter dose inhaler, a small pressurized cannister commonly used to deliver asthma medications directly to the airways. Also called "asthma puffers".

OBSTRUCTION is a decrease in maximal airflow rates caused by airway narrowing. The FEV1/FVC ratio and the FEV1 are both decreased.

PEF stands for Peak Expiratory Flow, the highest flow measured during the FVC maneuver. It is a good index of blast effort.

PF is short for Pulmonary Function (lung tests).

PNEUMOTACH is the white plastic "trumpet" mouthpiece that is used with the Renaissance Spirometer.

PRED is short for the predicted value of a PF parameter. It is determined from the regression equation from a large population study of supposedly normal people.

RESTRICTION is a decrease in lung volumes. Scarring of lung tissue (fibrosis), heart failure (CHF), pneumonia, and simple obesity are some of many causes. The FVC is reduced while the FEV1/FVC ratio is normal or increased.

SPACER is a device attached to a MDI asthma inhaler, designed to improve deposition of the drug deeper into the patient's lungs.

DESCRIPTION OF THE SPIROMETER

The PB100 Spirometer weighs about one pound and complies with ATS standards for spirometer accuracy: Volume: $\pm 3\%$ of reading or ± 50 ml, whichever is greater. FEV1 measured by back extrapolation. It has an internal rechargeable NiCad battery pack, and an AC adaptor/charger.

The PB110 Base Station weighs 19 oz, and provides docking for the spirometer to charge the NiCad battery pack and also sends reports to a printer.

The PB130 Patient Data memory card stores participant test information for future printing; interfaces with the PB100 spirometer or the PB110 base station. It stores approximately 65-75 participant tests. All results will be stored on the memory cards, and mailed at the end of each month to the Reading Center in Tucson, Arizona. Data will be downloaded from the memory card and returned to the site within 2 weeks.

Disposable pneumotach (FS200). The Renaissance system uses pre-calibrated, white plastic disposable pneumotachs. These single-participant use pneumotachs eliminate the need to clean or sterilize any part of the spirometry system.

The Printer - Canon model is a color capable ink jet printer. We will use BJ02 Black Ink printer cartridges.

PARTICIPANT INFORMATION at the MAIN MENU

After the calibration check, a MAIN MENU is automatically displayed.

You usually move forward within a program by pressing either the Enter key or the test key. Directions are given for each step in the spirometry's screen. If you make a mistake, you can usually get back to the MAIN MENU by pressing the TEST key. Calibration, configuration, and previous participants' data

are stored after each use.

The MAIN MENU displays

ID:■
UP TO 10 DIGITS

1. Type the participant's ID number, press ENTER.

AGE:■ (yr)
(4-99)

2. Type in the age, then ENTER.

HEIGHT:■ (in)
(40-84)

3. Type in the height (in inches), then ENTER. Confirm the participant's height in feet and inches.

SEX:■
1=MALE 2=FEMALE

4. Select the participant's gender, press ENTER.

WEIGHT:■ (lb)
(33-440)

5. Type the participant's approximate weight, press ENTER.

RACE ADJUST:■
1=YES 2=NO

6. Select 2 for no correction, press ENTER. (race correction is used ONLY for African Americans).

ROOM TEMP: 70 F
(32-113)

7. Press ENTER (no need to change this).

PARTICIPANT PREPARATION

You, the technician, are **the** critical part of the pulmonary function testing system, since you must guide the participant through breathing maneuvers which are highly dependent on their effort. You **must** coach the participant to inhale maximally and then to **BLAST** out their air. To obtain accurate results, the testing must be done in a standardized fashion.

Note: This manual refers to the participant as "he" or "him" for easy reading. Of course SHS participants are both women and men.

Wash your Hands Participants will appreciate your consideration if you make a point of washing your hands before testing them. Do this as you enter the room if it has a sink.

Explain the Procedure Explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out candles on a birthday cake." Explain that, he should take in as deep a breath as possible, and when his lungs are completely full, quickly position the pneumotach, and exhale his air as hard and fast as possible.

Suggest to women that they may wish to go to the bathroom first, especially if their bladder is full (to avoid stress incontinence).

Position the Participant Testing will be done in the sitting position without nose clips.

Any tight clothing (a tie, bra, vest, belt) which might restrict maximal breathing efforts should be loosened. **Dentures**, if they are loose, should be removed and placed in a clean denture cup, since they will prevent a tight seal from being formed around the pneumotach. If dentures are not loose, leave them in place.

Always Demonstrate the Maneuver First ask the participant to watch you perform the FVC maneuver with your own pneumotach. Stand up straight. Take a deep breath, throw

back your shoulders, widen your eyes, and stand on your toes to emphasize the maximal depth of inhalation. Then, stick out your tongue, place the pneumotach on it. Seal your lips around it, and dramatically **BLAST** out as hard and as fast as you can for a couple of seconds.

Your vigorous demonstration will prevent their time and effort from being wasted on unacceptable forced maneuvers.

BASELINE SPIROMETRY

1. Ask the participant to remove the plastic bag covering the white pneumotach. Attach it to the grey rubber adaptor at the end of the clear tubing.

2. Press TEST.

PRE MED TEST
SELECT TYPE 1-4

3. Press the **FVC (1)** key.

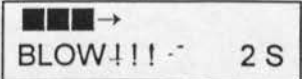
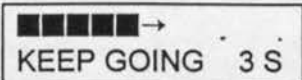

KEEP PNEUMOTACH
STEADY! ZEROING

The participant should not move the white flow sensor at this time.

→
BLOW!!!

When the screen shows "BLOW!!!", its ready to test.

4. Instruct the participant to take in as deep a breath as possible. Watch them put the pneumotach in their mouth, seal their lips around and make a tight seal. Ensure that their fingers are not touching the white filter paper of the sensor.
5. Then yell **BLAST** out!

6.  2 sec into test
-  3 sec into test
-  6 sec into test

Keep your eyes on the participant throughout EVERY maneuver.

7. Allow them to stop after six seconds.

PREFORMING
CALCULATIONS

GOOD TEST!!!
#2 QC: A B DATA

8. After a second or two, the screen displays a maneuver quality message, the maneuver sequence number (#), and the test quality QC grades. Only the first letter (the flow grade) is important for this study.
9. Press the FVC key to perform another test. Repeat the above tests until you obtain three good tests with a flow QC grade of A or B.

PRINTING RESULTS:

Be sure that the base station is turned on and that the printer is connected, with paper in the hopper and the ON-LINE glowing green.

1. Press PRINT SEND.

PRINT: ■ 1 = LAST
2 = BEST 3 = DISB

2. Select 2 ('BEST TEST SUMMARY'), then press ENTER.

SENDING DATA

Wait for the report to be printed.

Review the flow-volume curves for evidence of poor efforts. To perform additional maneuvers, press FVC (1) and follow the instructions (steps 1-8 above). If the interpretation is **NORMAL**, they are done with spirometry testing. Discard their pneumotach.

If baseline spirometry interpretation was **NOT NORMAL**, explain to the participant that you would like them to inhale a breathing medication and see if it improves their results in 10 minutes. If they agree, administer albuterol.

GIVING A BRONCHODILATOR

Show the patient how to correctly use a metered dose inhaler (MDI). Attach a clean spacer to the Albuterol MDI canister.

1. Instruct the participant to exhale completely, then put the canister with the spacer in front of their lips.
2. Instruct the participant to seal their lips around the spacer.
3. Instruct them to SLOWLY take a big breath. As soon as they begin inhaling, press the canister to release the albuterol.
4. Have the participant hold their breath for 5 seconds, as you count to 5 slowly.
5. Allow them to breathe normally for about a minute.
6. Repeat steps 1 through 4 (for a second "puff" of the medication).
7. Using the timer, wait 10 minutes before performing the post-bronchodilator spirometry.

POST-BRONCHODILATOR SPIROMETRY

1. Press POST (6) key.

DO POST MED: ■
1 = YES 2 = NO

2. Select 1,
then press ENTER.
3. Select **FVC (1)** key.
4. Repeat all steps in **BASELINE SPIROMETRY** starting on page 4 (using the same flow sensor).
5. Print a final report and discard the baseline printed report. Discard their pneumotach. Offer to send a copy of the report to their physician.

MANEUVER QC GRADES

Coach every participant to obtain at least three maneuvers that are "acceptable" including two that are "reproducible". The best test summary report includes 2 test grades (A to F). The FEV1 grade, the first letter, indicates the reliability of the reported FEV1.

Errors in maneuver performance are identified by the system and displayed after each test (QC grades).

<u>QC Message</u>	<u>Criterion</u>
Start faster	Extrapolated volume is > 5% of FVC and > 100ml. Participant is hesitating or lips are not sealed around pneumotach before blasting
BLAST out harder	The time from the beginning of test to peak flow is > 90 msec. Participant must BLAST out the air more quickly at the beginning of test.
Avoid coughing	Substantial drop and recovery in flow within first second. Ask the participant to clear their throat and offer a drink of water.

Blow out longer	Exhalation time is too short. Coach the participant to blow out for at least 6 seconds.
Abrupt ending	The participant quit before lungs were completely empty. Ignore this message for this study.
FEV1 Variable	FEV1 value is at least 5% less than their best FEV1. Coach participant to take a deeper breath before the next maneuver.
FVC Variable	FVC value is at least 5% less than their best FVC.
PEF Variable	Peak expiratory flow is at least 10% less than their best PEF. Loudly coach the participant to BLAST air out.
GOOD TEST!!!	No problems detected. Good job!

Maximum Number of Maneuvers. Don't exhaust the participant by asking them to perform more than **FIVE** maneuvers (5 baseline plus 5 post BD). Make a note on the printed report why the participant couldn't perform the maneuvers.

SPIROMETRY INTERPRETATION

Making a diagnosis of asthma. Symptoms which suggest asthma include intermittent episodes of shortness of breath with wheezing, chest tightness, and/or cough. In patients with these symptoms, spirometry is recommended to help confirm a diagnosis of asthma. If baseline spirometry shows airways obstruction in such a patient, and administration of an inhaled bronchodilator is followed by a 12% or greater increase in the FEV1 (post BD), the patient is likely to have asthma. The bronchodilator acts to quickly relieve the constriction of airway smooth muscle. However, the lack of a "significant" response to the bronchodilator is not helpful in excluding the possibility of asthma, since chronic inflammation of the airways due to asthma may not respond quickly to inhaled bronchodilator. The patient may then be asked to take inhaled or oral corticosteroids every day for a few weeks, and then return for repeat spirometry to see if the FEV1

improved due to the anti-inflammatory therapy.

Many persons with asthma have only mild intermittent episodes (only a few times each year). Spirometry in such patients may be entirely within normal limits (a normal FEV1/FVC) during periods (or seasons) when they have no symptoms. In order to obtain objective test data to confirm asthma in such patients, a 45 minute methacholine challenge test may be performed in a hospital-based pulmonary function laboratory. Alternatively, the patient may be given a peak flow meter to use at home for a few weeks. The results may show excessive variability in lung function, confirming asthma. SHS participants in the asthma substudy will be given an electronic peak flow meter for this purpose.

Categorizing asthma severity. In patients who are known to have chronic asthma, and are taking asthma medication, spirometry is used to provide an objective measurement which helps to determine the severity of their asthma (or the degree of disease control). Mild obstruction suggests mild asthma (or reasonable control); moderate obstruction suggests moderate asthma; and severe obstruction suggests severe asthma (or poor control). Moderate or severe chronic asthma suggests the need for better control, which usually means the daily use of inhaled anti-inflammatory medications (controller meds).

The printed interpretation. The spirometer interprets the numeric results automatically and prints an interpretation message after the numeric results. These interpretations are based on widely recognized clinical practice guidelines (ATS 1991) but assume that the instrument was calibrated and the test sessions were performed with good quality (QC grades of A or B). Falsely positive interpretations may be printed if these conditions were not met. (The participant is disease free but the report says that they have obstruction or restriction.) Likewise, the degree of BD response may be misinterpreted if either the baseline or post

BD maneuvers were of poor quality. For these reasons, technicians and nurses should not be fully confident in the computer interpretations during discussions with study participants. Always suggest that the participant take a copy of the spirometry results to their primary care physician for interpretation. Doctor Enright at the Reading Center will then be happy to discuss the spirometry results with the participant's physician.

Here then are the criteria used by the computer in the spirometer to interpret the spirometry results:

<u>Interpretation:</u>	<u>Criteria</u>
Normal spirometry	FEV1/FVC ratio $\geq 70\%$ and FEV1 $\geq 80\%$ pred and FVC $\geq 80\%$ pred
Borderline obstruction	FEV1/FVC ratio $< 70\%$ but FEV1 $\geq 80\%$ pred.
Mild obstruction	FEV1/FVC ratio $< 70\%$ and FEV1 60% to 79% pred.
Moderate obstruction	FEV1/FVC ratio $< 70\%$ & FEV1 of 41% to 59% pred.
Severe obstruction	FEV1/FVC ratio $< 70\%$ and FEV1 $< 40\%$ pred.
Reduced vital capacity	FVC $< 80\%$ pred (in addition to obstruction).
Mild restriction	FVC 60% to 79% pred, with FEV1/FVC ratio $\geq 70\%$
Moderate restriction	FVC 51% to 59% pred, with FEV1/FVC ratio $\geq 70\%$
Severe restriction	FVC 50% or less than pred with FEV1/FVC ratio $\geq 70\%$.
Bronchodilator response	Post-BD shows a 12% increase in FEV1

MONDAY CALIBRATION CHECKS

To perform a calibration (cal) checks you need the calibration syringe and a FS200 calibration pneumotach: marked "for calibration use only".

1. Connect the pneumotach to the calibration syringe using the adaptor.

2. Press **TEST**.

3. Press **CAL** (4).
Carefully follow the messages.

CAL TYPE: ■
1=CHECK 2=DISB

4. Press 1 (1=CHECK), then ENTER.

ROOM TEMP: ■ 0 F
(32 - 113)

5. Enter the room temperature, then ENTER.

KEEP PNEUMOTACH
STEADY! ZEROING

6. Don't move the syringe and pneumotach until the "STEADY" message disappears.
7. Pull out the syringe plunger completely (until it "clicks"), then press any key to start the cal check.

DO EXP CAL ■■→

8. Push the syringe plunger in evenly and completely while counting "one Mississippi".
9. The screen will display a message regarding calibration.

Message here
10. Place the calibration pneumotach back into a protective plastic baggie.

If the Volume Check Fails

Possible reasons for the volume check to fail (in order of decreasing likelihood) include:

- Failure to completely fill and/or discharge the syringe into the spirometer. Make sure the syringe clicks against the stops with each stroke, but don't "bang" it too forcefully.
- Differences in the air temperature between the spirometer and the syringe. Reflush and repeat the check.
- Try a new flow sensor (pneumotach).
- An air leak in the calibration syringe (see "Cleaning and care of the equipment").

WEEKLY BIOLOGIC CONTROL

The Bio-Control tech must not be a smoker and must not have asthma. The same Bio-Control tech should do a spirometry test each week.

1. On Monday mornings following the CAL Check, use the following assigned ID number (enter on main menu as "ID") for your location:

999001 = Arizona

999010 = S. Dakota at Eagle Butte
999020 = S. Dakota at Pine River

999100 = Oklahoma at Anadarko
999200 = Oklahoma at Lawton

2. Do 3 good FVC maneuvers (QC grade A or B).
3. Ensure that your current FEV1 is within 0.2L of the mean of your previous 5 values. If not, repeat using a new pneumotach. If still not, do a 3

flow calibration check, and repeat the test.

4. Print 1 copy of the report. The test automatically saved to the memory card. Place the report in the Biologic Control Log 3-Ring Binder.

CLEANING AND CARE OF THE EQUIPMENT

Cleaning the Spirometer. Use a damp cloth and wipe down the external face of the system. Use water or a mild detergent solution.

Calibration Syringe Care

The 3.00 liter calibration syringe should be stored near the spirometer so that it remains at the same temperature as the spirometer. Store the syringe with the plunger pushed all the way in. Take care not to drop it.

DO NOT attempt to make any adjustments to the syringe. Do not loosen the metal rings on the shafts, since this will spoil the factory calibration.

Periodically check each syringe for leaks. Fill it with air, hold your palm against the outlet snout, and try to empty it. If you can expel any air with the outlet plugged, the syringe has a leak and must be repaired. Notify the Reading Center.

TECHNICIAN CERTIFICATION

The certification examination includes 50 multiple choice questions based on this Manual of Procedures, and a practical demonstration of skills including calibration checks, cleaning, biological control and testing of a naive subject (50 points). A passing score of at least 75 points is necessary for certification. Only certified technicians will perform pulmonary function testing.

Certification of new technicians after the initial central training session may be performed by a centrally trained, certified PF technician. The written exam will be administered locally, and the first 20 PF tests performed will be observed by a certified PF technician and then examined by the Reading Center and found to be satisfactory before the new technician is certified. The results of the first 20 spirometry test sessions performed by each technician will be closely examined at the Reading Center. Copies of suboptimal quality test sessions (where QC grades are less than B) with comments for improvements will be mailed to the technician as they are evaluated.

A site visit to the clinical/site centers will be made early during phase, and mid-way through Phase III. **Complete calibration, biological control QC check, and complete PF testing of at least three participants by each PF certified technician will be observed and reviewed.** More efficient methods as well as protocol violations will be discussed during the site visits and later in a written report.

QUALITY CONTROL

Need for Spirometry QC. Examination of spiograms from the Framingham study revealed that more than 18% were of clearly unacceptable quality. Two more recent studies, with over 12,000 adults each, found that 40 - 50% of the spirometry maneuvers were of unacceptable quality. Deviations in test performance and lack of regular leak checking and calibration checks can result in loss of study data.

Feasibility of QC Procedures. The Renaissance spirometry system assists the pulmonary technician with quality control of maneuvers when spirometry testing is being performed, calculates the PF variables, suggests interpretations, formats and prints reports, and compresses graphics data for archival storage. The computerization of spirometry QC procedures dramatically

decreases the overhead time associated with spirometry testing.

Implementation of QC Procedures. There are five separate levels of quality control implemented for spirometry testing which address the four factors known to influence the results:

1. Daily volume calibration checks using a 3.00 liter syringe as the "gold standard".
2. QC grading of maneuver acceptability and reproducibility **immediately after every maneuver.**
3. The PF technician is trained to recognize the patterns of unacceptable maneuvers, **watching the participant** during the performance, and reviewing the QC grades and resulting printed flow-volume curves.
4. The results of the calibration checks, biologic control and the best 3 FVC maneuvers are stored and sent to the Reading Center for review by the QC Supervisor. Results are reported to the Data Coordinating Center.
5. Each week **biologic control.** The results will be compared with their prior mean values for FVC and FEV1.

DOWNLOADING OF MEMORY CARDS

On the first Monday of each month, mail the previous month's memory card to the Reading Center. The Reading Center will download all PF data for participants tested during the previous month into a database (Renaissance DB). The data is deleted from the memory card, and the memory card is mailed back to the site.

REFERENCES: Please call the PF Reading Center for a copy of any of these references.

1. American Thoracic Society official statement: Lung function testing: Selection of reference values and interpretative strategies. *Am Rev Respir Dis* 1991; 144:1202-1218.
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5. Gardner RM, Hankinson JL, Clausen JL, Crapo RO, Johnson RL, Epler GR. Standardization of spirometry -- 1987 update. Official statement of the American Thoracic Society. *Am Rev Respir Dis* 1987; 136:1285-1298.
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APPENDIX

Spirometer Configuration: The spirometry system comes to you set with the standard configuration. You should, however, go through the configuration routine to set the correct date and time. This shows the correct settings for the SHS Asthma Sub-Study settings:

1. Press **TEST**.
2. Press the forward arrow key **▶**.

To retain the current configuration, press **ENTER**.

To change the configuration press the number of the desired option, then press **ENTER**.
3. TECH CODE: **2** (2=NO)
4. UNITS: **1** (1=English)
5. INTERP: **1** (1=YES)
6. DATE FORMAT: **1** (1=Amer)
7. TIME FORMAT: **2** (2=12HR)
8. TIME: **XXXX** (HHMM)
9. AM/PM: **1=AM, 2=PM**
10. DATE: **XX XX XX** (mm dd yy)
11. ADULT NORMS: **2** (2=Knudson)
12. KNUDSON REF: **2** (2=1983)
13. PED NORMS: **2** (2=Polgar)
14. PEF UNITS: **2** (2=LPM)
15. REPORT: **2** (2=INDS)
16. BESTVAL: **1** (1=VAL)
17. GRAPH FORM: **1** (1=Flow-Vol)

18. GRAPH SIZE: **2** (2=Validation)
19. SCALE GRAPH: **2** (2=NO)
20. NUM CURVES: **3**
21. OVERLAY CRV: **1** (1=YES)
22. PRED POINTS: **1** (1=YES)
23. PRINTER: **4** (4=HP)
24. GRID: **2** (2=NO)
25. LUNG AGE: **2** (2=NO)
26. SYR VOL: **3**
27. QC GRADES: **1** (1=YES)
28. INS INCNT: **2** (2=NO)
29. AUDIO INCENT: **1** (1=YES)
30. RACE ADJUST: **85**
31. ALL DATA: **1** (1=YES)
32. ALL CURVES: **2** (2=No)
33. PRES: **730** Arizona
 730 Oklahoma
 675 S. Dakota
34. CUST HEADER: **1** (1=YES)
using the 7 (advances 1 letter), 9
(back 1 letter) and both arrows
(forward/back in sentence), enter the
header as "Strong Heart Study")

SUPPLIES

Attach the spirometer cable to the computer with the two screws on the connector, otherwise it will fall off easily. Attach the printer cable to the rear of the PC. Attach all power plugs to the switched outlet strip.

Spirometry Major Components

1. PB100 Renaissance spirometer
2. PB110 Renaissance base station
3. PB130 Memory card (qty 2)
4. AC Adapter
5. Pressure tube and spare
6. Canon BJ240 inkjet printer, printer cable and 1 extra BJ-02 Black Ink cartridges
7. Hans Rudolph 3.00 L calibration syringe
8. MDI spacers, box of 100 (6 inch lengths of ventilator tubing)
9. PB Spirometry video
10. A pneumotach marked "FOR CALIBRATION ONLY"
11. SASE padded mailing envelopes (qty 15) for sending memory cards to the Reading Center

Spirometry Supplies

FS200 disposable pneumotachs, box of 250
Power strip with 4 outlets
Denture cups (qty 50)
8½ " x 11" paper; a ream of standard copier paper
Electronic timer; Radio Shack catalog # 63-896

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SPIROMETRY REPORT

Uofa Med College Resp Sci
SCOR Specialized Center of Research

TEST DATE: 02/27/98
TIME: 02:46 PM

Patient Name:

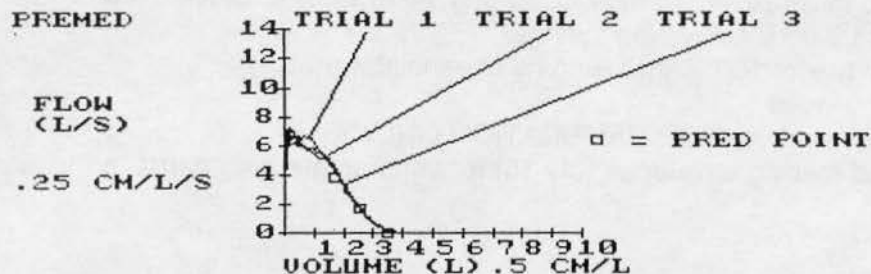
Patient ID: 6653 Age: 41 Height (in): 65 Weight (lbs): 135 Sex: Female Race Correction: No
Barometric Pressure (mmHg): 698 Temp (deg F): 70 BTPS Correction: 1.115 Sensor: FS200 Insp Code: None

FVC TEST DATA - Industrial Format

Measurement	PreMed QC	TRIAL 1	TRIAL 2	TRIAL 3	Pred	%Pred	PostMed QC	Knudson Adult Predicted Normals
FVC (L)	A	3.86*	3.80	3.76	3.44	112%		%Pred %Change
FEV1 (L)	A	3.03*	2.98	2.96	2.88	105%		
%FEV1 (%)	78.49	78.49*	78.42	78.72	83.19	94%		

Variability: PreMed: FVC = 1.6% FEV1 = 1.7% PEF = 3.0%

PREMED



Interpretations:

PREMED: Testing indicates normal spirometry.

Comments:

ASTHMA SUBSTUDY - AMBULATORY PF MONITORING
USING THE AIRWATCH (TM)
MANUAL OF OPERATIONS
STRONG HEART STUDY, PHASE III 1998

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- Manual Version 2.0
- February 6, 1998
- Filename: SHS_airwatchMOP98 .wpd

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FORWARD:

This manual serves three purposes:

- a study guide for training of physicians, nurses and technicians to perform ambulatory PF monitoring.
- a practical "how-to" reference guide to be used during the study
- documentation of the procedures for analyses and manuscript preparation.

BACKGROUND:

Participant selection. The Data Coordinating Center (the DCC at UOK) has preselected a subset of SHS participants for the Asthma Substudy. These participants include all of those who reported asthma or a history of episodes of wheezing with shortness of breath during the Phase II exam (n=600). Participants who report asthma or wheezing at the time of the Phase III exam (recent onset) will also be added to the asthma substudy. All asthma substudy participants will be asked to perform ambulatory PF monitoring at home for two weeks following their clinic visit.

There is no risk to the test. It is merely inconvenient.

Rationale for Ambulatory PF Monitoring. Asthma is a disease of variable airways obstruction. Many patients with asthma have only mild intermittent asthma. Such patients have long intervals without symptoms, during which lung function is often normal. Baseline spirometry is then normal and there is no bronchodilator (BD) response. The only objective evidence of asthma may then be excessive lability of pulmonary function (PF, which includes both PEF and FEV1). This lability (hyperreactivity) may be measured within 30 minutes by administering a methacholine challenge test in a hospital PF laboratory. An easier method of detecting PF lability is to measure diurnal variation in lung function over a couple of weeks in the

patient's own environment (at home). Most patients with asthma have larger than normal "morning dips" in lung function, which may be measured by ambulatory PF monitoring. A morning dip in PEF of more than 20% in adults usually indicates excessive airway lability.

In patients with mild to severe persistent asthma, baseline spirometry usually shows airways obstruction, with a large acute (10 minute) response to an inhaled bronchodilator (albuterol). However, this response may be blunted by the recent use of an asthma inhaler or by chronic airway inflammation. The severity of asthma may then be measured by the severity of the morning dip in lung function during ambulatory monitoring. A morning PEF dip of more than 30% is associated with moderate to severe asthma.

Ambulatory PF monitoring has two primary purposes: #1) to assist asthma management, or #2) to help establish the diagnosis of asthma or determine the severity of asthma. Peak flow meters and the new electronic PF monitors (like AirWatch) were designed for asthma management; however, we will be using the AirWatch in this study only for purpose #2.

During the two weeks we ask a participant to use the AirWatch unit, we do not want those who have asthma to use the results to adjust their asthma medications (as they would for asthma management purposes). However, if following the study they and their physician decide that they would like to use a peak-flow meter for asthma management, we will provide one without charge.

Airway lability is calculated for each day as the highest minus the lowest PEF, divided by the average PEF. The lowest PEF during the day is almost always the early morning value, because blood adrenaline and cortisol levels are lowest in the early morning, and because indoor allergens such as house dust mites and molds are inhaled from bedding during the night. This means that

for a valid measure of PF lability, PF must be measured at least twice a day, including once in the early morning. Since compliance is better if the AirWatch is kept in the bathroom, and not taken to the workplace, we will ask only for early morning and evening or bedtime measurements (when most people brush their teeth).

In order to obtain reasonable sensitivity, PF must also be measured for several days, because high levels of allergens may be inhaled only during a couple of days or nights during any given week. Studies have also found a "learning effect" of low PF values and high PF lability during the first 3 days of a study, and rather poor compliance after 2-3 weeks of daily PF measurements, so two weeks seems an optimal duration of testing.

When compared to diagnostic spirometry testing, ambulatory PF testing requires only one second maneuvers (not 6 seconds), since only the PEF and FEV1 are measured, and not the vital capacity. Also, the participant is asked to perform only 3 blows during each test session (not up to 8). The deep inhalation and BLAST efforts remain important, so teaching the participant to use the AirWatch will be done immediately after spirometry testing during their clinic visit.

Most previous epidemiologic studies of ambulatory PF monitoring have used inexpensive mechanical peak flow meters along with a written asthma diary. However, the recent introduction of relatively inexpensive electronic spirometers allows automatic storage of the results, improving compliance and accuracy. They also allow measurement of the FEV1 which is more accurate, more reproducible, and more sensitive to bronchoconstriction when compared to the PEF. Spirometry is the simplest, most effective test for assessment of lung function. That is why it has been included in many cardiovascular epidemiology studies, including SHS.

Spirometry (without bronchodilator) was measured during SHS Phase II for the

original cohort. Spirometry reference values are being developed from the healthy subset of American Indian participants.

Spirometry records the relationship between airflow (FEV1) and the exhaled volume of air during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). The most common lung diseases reduce forced expiratory flows. Such "obstructive" lung diseases include **asthma**, bronchitis, and emphysema. The ratio of FEV1/FVC is very sensitive for detecting mild airways obstruction.

NEW PROCEDURES

1. Ambulatory PF monitoring of the participant for 2 weeks.
2. The AirWatch is very small.
3. The AirWatch will be returned to the clinic for downloading of the data, cleaning and reissue. The participant will be paid \$0.25 per GOOD test (\$0.50 per day for a total of \$7.00).

DEFINITIONS (GLOSSARY)

ALBUTEROL (official generic name in the U.S.) is an asthma medication for the relief of bronchospasm in patients with reversible obstructive airway disease (asthma). After administering albuterol, an improvement of 15% or greater in FEV1 values indicates precedence of asthma.

BD: is short for bronchodilator.

COPD stands for Chronic Obstructive Pulmonary Disease, a general term for lung disease caused by cigarette smoking - a mixture of emphysema, bronchitis, and hyper reactive airways (asthma).

FEV1: Forced Expiratory Volume in 1 Second (liters). The volume of air exhaled in the first second of an FVC maneuver.

FEV1/FVC RATIO is the most sensitive and specific index of airways obstruction measured by a spirometer. It is normally above 70% in adults.

FVC is the Forced Vital Capacity, the volume of air exhaled during the maneuver named after it. The subject takes as deep a breath as possible and then quickly exhales (BLAST) as much air as possible. The FVC is reduced with restrictive disorders.

MDI is a meter dose inhaler, a small pressurized cannister commonly used to deliver asthma medications directly to the airways. Also called "asthma puffers".

OBSTRUCTION is a decrease in maximal airflow rates caused by airway narrowing. The FEV1/FVC ratio and the FEV1 are both decreased.

PEF stands for Peak Expiratory Flow, the highest flow measured during the FVC maneuver. It is a good index of blast effort.

PF is short for Pulmonary Function (lung tests).

MOUTHPIECE is the blue plastic part off the end of the AirWatch. This is where the participant blows. When the mouthpiece is fully open or closed, it will click into place when you rotate it.

NUMBER LINE shows either (1) the date and time, or (2) the peak flow, or (3) FEV1 measurement.

PRED is short for the predicted value of a PF parameter. It is determined from the regression equation from a large population study of supposedly normal people.

RESTRICTION is a decrease in lung volumes. Scarring of lung tissue (fibrosis), heart failure (CHF), pneumonia, and simple obesity are some of many causes. The FVC is reduced while the FEV1/FVC ratio is normal or increased.

SPACER is a device attached to a MDI asthma inhaler, designed to improve deposition of the drug deeper into the patient's lungs.

WILBY is the coach. He looks like a mutated Pac-Man or an eraser head.

DESCRIPTION OF THE AIRWATCH

The AirWatch™ is a hand-held electronic spirometer the size of a stopwatch. It costs about \$120. When a person blows into the attached blue plastic flow sensor, lung function (PEF and FEV1) is measured, displayed, and stored, along with the date and time of day. The unit is usually configured to store the highest FEV1 and the highest PEF from multiple maneuvers performed during a 10 minute period of time (during a single test session). During each test session, the patient may indicate if the maneuvers were performed before or after inhaling a bronchodilator (pre or post-BD).

The AirWatch was designed to assist the patient with asthma to monitor the severity of airways obstruction at home, as a guide to the need for asthma medications, and to periodically send the results to the primary care physician, via telephone and FAX. However, during this study we will not ask the participants to connect the AirWatch unit to a telephone, and we will not send the results to their physician.

The AirWatch was designed to be just as accurate as an office spirometer (FEV1s are measured with 3% accuracy or better). However, spirometry requires acceptable FVC maneuvers, as judged by the apparent degree of effort during inhalation and subsequent forced exhalation (Blast), and by the pattern of the resulting flow-volume curves. There is no coach to help the participant perform acceptable FVC maneuvers at home, and flow-volume curves are not stored or printed by AirWatch, so the results are usually not of optimal diagnostic quality when compared to office spirometry. The AirWatch developers are planning to include maneuver quality checks, similar to those incorporated in many spirometers. We will switch to those improved units when they become available later in 1998.

The two quarter-size AirWatch batteries last about one year with daily use and are easily replaced. It automatically goes into standby

mode to conserve battery power after about 30 seconds of inactivity. Press any of the 3 blue buttons to turn it on again.

Recent studies in Denver found that about 10% of the units become inoperative during one year of use in the field, half due to the electronics and half due to the blue sensor, which is easily replaced. A 3 liter calibration syringe cannot be used to check the AirWatch accuracy. However, correct and accurate operation is conveniently verified by comparing the PEF and FEV1 values obtained by the participant during spirometry testing with those obtained using the AirWatch.

AIRWATCH PROTOCOL

AirWatch Setup. Please view the 20 minute AirWatch videotape and review the "Getting Started with AirWatch" manual to learn how to install the batteries, attach or replace the mouthpiece, and set the date and local time. During the setup, set the personal best PEF to 100 LPM, leave the first zone boundary at 80%, the second zone boundary at 50%, set the session length to 10 (minutes), and set the phone dialing method to tone (not pulse). The final number is the unit's serial number (verify but don't change).

Look for a battery symbol in the upper right corner of the display. If there is the display is blank or if the battery symbol is displayed, replace the batteries with two new 3 volt batteries, type CR2032, both with + sides up. Then recheck for correct setup. To enter the setup mode, press and hold the two outside buttons for 5 seconds.

A demonstration unit was given to each site during training. Keep the "demo" unit in the "DEMO" ziplock. Each staff member should have his/her own blue mouthpiece stored in a ziplock labeled with their name.

Teaching the Participant. Teach the participant how to use the AirWatch immediately following spirometry testing, after

administering the bronchodilator, while waiting the 10-15 minutes for it to take effect, or following post-BD spirometry.

Tell the participant, "We have a new little gadget to test your lungs at home." Show them the AirWatch. "You push one of these blue buttons and then blow into it just like you did into this spirometer." Point to the Renaissance spirometer. "Asthma causes variations in lung function throughout the day, and we would like to measure those variations. You would keep this gadget in the bathroom and use it when you brush your teeth in the morning and in the evening."

Say, "we'd like you to use it twice a day for two weeks and then mail it back to us in this envelope." Show them a self-addressed stamped padded envelope. "Do you think that you could do this?"

If they agree, open the package of a clean AirWatch, take its log sheet and confirm the correct serial number (printed on the back of each AirWatch unit). Write down the date, the participant's name, and their ID number.

Install a clean blue mouthpiece on the AirWatch. Be certain to align the two small (nearly invisible) triangles, pointing the mouthpiece downwards, before *gently* snapping the mouthpiece onto the spirometer.

Next say "Let me show you how easy it is to use this gadget. I will also give you this instruction sheet in case you forget. First, push any of these 3 blue buttons to turn on the unit. You will then see this little man displayed. Our asthma doctor calls him eraser head, but his real name is Wilby. Rotate the blue mouthpiece like this, until it snaps open. Take as deep a breath as possible. Quickly put your teeth around the blue mouthpiece and seal your lips around it. Blast out your air as fast as you can for one or two seconds."

Take the demonstration unit, attach your blue mouthpiece with your name on it and

show them how it is done. Then hand their unit to them and coach them to do a test. Stop their exhalation after two seconds. Look for numbers on the display and a smiling Wilby. Wait for a minute and blow into the gadget again. Wait for another minute and repeat the test for a third time. State, "the goal is to get Wilby to smile three times, then you are done with that test session."

Store your blue mouthpiece in your labeled ziplock, and place it and the demonstration unit into "DEMO" ziplock.

Validating AirWatch Accuracy. On their baseline spirometry printed report, write down the best PEF (in LPM) displayed on the AirWatch. Then press down on the center blue button for 3 seconds to view and record the best FEV1 from the test session. Compare the two PEF results (Renaissance and AirWatch values) to ensure that they match within 50 LPM (about 10%). Compare the two FEV1 results to ensure that they match within 0.3 liters.

If the results from the two spirometers do not compare favorably, the problem could be either differences in participant effort (submaximal inhalations or blasts), bronchodilator response, or instrument inaccuracy. Following the post bronchodilator spirometry, replace both the white Renaissance flow sensor and the blue AirWatch sensor and coach the participant to repeat 3 maneuvers using the AirWatch. Press the right-hand blue button to indicate a post-BD test session, note that an MDI symbol appears above Wilby. Then compare the post-BD PEF and FEV1 values and write the AirWatch values on the post-BD spirometry report. Note on the report that you replaced the flow sensor. Hopefully the results will match this time.

Ask the participant, "any questions? Please call me later if you have any problems or questions using the gadget during the next two weeks." Place the AirWatch and instruction sheet inside the padded envelope and hand it to them to take home.

Follow-up. If possible, call the participant three days later and ask if they have had any problems using the gadget. Discuss how important it is to blow into it at least twice a day. If you have not received the unit three weeks later, call them to remind them to place it in the mail.

Receipt and Data Transmission. Upon receipt of an AirWatch from a participant, gently detach the blue mouthpiece and place it into the Tupperware container which is full of disinfectant cleaning solution. There is no need to keep the mouthpieces and AirWatch units paired together. Any mouthpiece should be accurate when attached to any other AirWatch unit.

Find the AirWatch Log Sheet for that unit, verify the serial number, and write down the Return Date. Remove the blue rubber connector cover and attach the unit to an analog telephone line (like the one attached to your FAX machine or computer modem). Press any blue button. Confirm that the phone is connected by noting the phone symbol displayed next to Wilby's ear. Press any blue button to begin transmission. The phone symbol will blink during the transmission, which should last less than one minute. If the transmission was successful, Wilby smiles and a star is displayed above his head. On the log sheet, write down the time of the phone call.

If Wilby frowns, the call to the central computer was not successful. Press any button to try again. If transmission is still unsuccessful, call the AirWatch toll-free help line at (800) 267-9452. Don't worry, the unit stores the last 500 test sessions until the batteries are dead.

Thoroughly wipe the AirWatch with a damp cloth to clean it. Press a button and verify that the batteries are still good (the low battery symbol is not displayed). Wash your hands. Obtain a clean dry blue mouthpiece, gently attach it to the unit and place them in a new sandwich bag. Place a new instruction sheet, the Log Sheet, and the AirWatch into

a new padded envelope, ready for the next participant.

REFERENCES: Please call the PF Reading Center for a copy of any of these references.

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APPENDIX

AIRWATCH LOG SHEET

Unit _____ Serial # _____

[illegible]

AIRWATCH INSTRUCTION SHEET

Please use twice a day for two weeks.
Early in the morning and in the evening.

1. Press any button to turn it on.
2. Take a very deep breath.
3. Seal your lips around the blue mouthpiece.
4. BLAST out your air, for 1-2 seconds. Wait for a minute and blow into it again.
5. Wait again and blow into it a third time. The goal is to make Wilby smile 3 times.

The unit will turn off by itself.

You don't need to clean the unit. We will.

Return the unit after using it for 2 weeks.

If problems or questions, please call:

[clinic phone number and staff name here]

SUPPLIES

AirWatch Major Components

1. AirWatch[™] Airway Monitoring System
2. Mouthpiece

AirWatch Supplies

Tubberware or plastic container

Disinfectant cleaning solution

Demo Ziplock (large ziplock) containing:

1 demonstration unit (1/site)

3 blue mouthpieces in 3 small ziplocks (to be labeled with tech's name)

ASTHMA SUBSTUDY - ALLERGY SKIN TESTING

MANUAL OF OPERATIONS

STRONG HEART STUDY, PHASE III 1998

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Allergy Skin Testing

GREER Laboratories, Inc.
DermaPIK System
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(800) 438-0088

Bayer Corporation
Pharmaceutical Division
Allergy Products
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FORWARD:

This manual serves three purposes:

- a study guide for training of physicians, nurses and technicians to perform allergy skin testing.
- a practical "how-to" reference guide to be used during the study

BACKGROUND:

Many patients with asthma and hayfever are allergic to aeroallergens -- plant or animal derived "antigens" which are small enough to be inhaled. A person with multiple allergies is often referred to as being "atopic." These allergies often develop during the first few years of life, but the onset of allergic symptoms may begin at any age. It is worthwhile to determine exactly which antigens a given patient is allergic to, because they may then be able to avoid exposure to the sources of these antigens -- thereby reducing the frequency and severity of symptoms and perhaps, the need for medication. Of course, many patients have already identified some animals, plants, or seasons which trigger their symptoms, but the test results remain useful to confirm what experience (by trial and error) has taught them.

Two tests are available and standardized to determine which antigens a patient is allergic to: 1) allergen skin testing and 2) serum (blood) levels of specific IgEs (immunoglobulin E). Results in a half hour and low cost (for a large number of antigens) are the primary advantages of allergen skin testing. The cost of analyzing 20 specific IgE levels is about \$200 for a single patient and the results are usually not available for a couple of weeks. Disadvantages of allergen skin testing are that it takes more technician time than drawing a sample of blood, and the subject often has an itchy arm or back for about a half hour (where the allergic skin reactions occurred).

The second National Health and Nutrition Survey (NHANES II) performed allergen skin testing of 8 common aeroallergens for 4300 young participants. Asthma was most strongly associated with positive skin tests to *Alternaria* (a mold) and to house dust mite, but asthmatic subjects were also more likely than other subjects to be skin test positive to dog, cat, oak, bermuda grass, rye grass, and ragweed. The followup NHANES III study performed skin testing for many other antigens. We have chosen to use allergen skin testing for the 19 allergens which have been reported by local allergists to be positive most frequently at each SHS site.

The concentration of each antigen is standardized and was selected to produce a rather small skin reaction (about ½ inch in diameter) if a patient is allergic to that antigen. The "immediate hypersensitivity reaction" is produced by the release of histamine from mast cells present in the skin. The resulting inflammation causes swelling (called a wheal) centered on the point of antigen entry (the skin prick site) with a larger area of redness (erythema or flare) surrounding the bump. A large wheal and flare are produced when the patient is very sensitive to that antigen, so the diameter of the wheal is measured as the degree of skin test response.

About 5% of persons will have a small reaction to the skinprick by itself (without any antigen) and so this wheal to the "negative control" must be subtracted from any antigen response. A few persons are "anergic" and have no skin test response of any kind, probably because they don't have any mast cells in their skin, or their histamine response has been blocked by medications. For this reason, a dilute concentration of histamine is also applied as a "positive control."

Several methods of applying the antigens just below the surface of the skin, without drawing blood, have been developed. We have chosen a method (the DermaPIK) which has the following advantages when compared to other methods: speed of

application, small chance of accidentally switching antigens, lack of cross-contamination (single-use DermaPIKs), high sensitivity, and good repeatability.

NEW PROCEDURES

1. Allergy skin test will be done using 21 antigens and controls.

DEFINITIONS (GLOSSARY)

ALLERGEN: a substance that causes an allergy.

ANTIGEN: a liquid made from an allergen that when introduced onto the skin stimulates the production of an antibody.

CONTROL (made from glycerine): used to identify participants who have sensitive skin which might give the false impression of positive skin test results.

CONTROL PARTICIPANT: to verify asthma in an asthmatic participant (those who indicate they have asthma or have been told that they have asthma) by conducting the same procedures on a participant without asthma.

HISTAMINE (the end product of the allergic reaction): checks to be certain that the skin's ability to react positively to an antigen has not been blocked by the participant's use of other medications. Taking an antihistamine 1 or 2 days before skin testing may block the test results, as well as taking certain medications.

WEEKLY PROCEDURES

Daily:

- After each participant, replace with new DermaPIKs
- Wash your hands

Friday: After last participant:

- Refill supplies (70% alcohol, cotton balls, sterile pads, tissue, hydrocortisone, antihistamine lotion)

REPLACEMENT OF DERMAWELLS FEBRUARY (STARTUP) & AUGUST 1998 FEBRUARY 1999

- New DermaWells will be placed in the DermaRAK in February 1998 at startup.
- Replace the DermaWells every 6 months for this study. **DO NOT REFILL DERMAWELLS.** When wells are emptied they should be discarded and replaced with new ones.
- Each DermaWell should be filled with approximately 0.05 cc of the appropriate extract. At least 1.0 cc of each extract has been provided. Filled DermaWells (0.5cc) provide sufficient antigen for approximately 100 skin tests.
- Always wash your hands after handling the antigens.

THE DERMAPIK SYSTEM

The Greer DermaPIK is a plastic, single use "toothpick" with six tiny tines arranged at the tip in a 2 mm circle for epicutaneous allergy skin testing. There is 1 DermaPIK per antigen; 21 DermaPIKs per participant.

The Greer DermaWell is a plastic container that seats into the DermaRAK. Each DermaWell is assigned an antigen and holds approximately 0.5cc of the antigen. A DermaPIK seals each DermaWell. Each DermaWell is marked with its antigen (G1-3, W1-4, T1-4, F1-4, C1-7, C⁻ and C⁺). *The Greer DermaRAK* is a plastic rack containing 21 DermaWells.

The Antigens we are using were carefully picked using high percentage of positive reactions seen in the Phoenix and Tucson areas, and adjusting for localized pollens within the same family.

G = grass pollens

G1	Bermuda
G2	Timothy
G3	Bluegrass, Kentucky

W= weed pollens

W1	Russian Thistle (tumbleweed)
W2	Ragweed Mix (short variety)
W3	Sagebrush Mix
W4	Careless Weed

T= tree pollens

T1	Mulberry
T2	Cottonwood
T3	Elm
T4	Ash

F= fungi

F1	Alternaria
F2	Aspergillus
F3	Helminthosporium
F4	H. Cladosporium

C= common contactants

C1	Cat
C2	Dog
C3	House Dust mite (D. farinae)
C4	Cockroach

C -	control (glycerine)
C +	histamine

Additional Contactants

C5	House Dust mite (pteronysinus)
C6	Horse Hair and Dander
C7	Cattle Hair and Dander

ANTIGEN STORAGE

The antigens and DermaRAK must be stored in the refrigerator. After applying the antigens to the participant's arm, please return the DermaRAK to the frig as soon as possible.

ANTIGEN EXPIRATION DATES

The Bayer Corp. marks each antigen with an expiration date. Outdated antigens may be poured down the sink and the bottles are placed in a SHARPS container.

PARTICIPANT PREPARATION

In order to obtain valid and useful skin testing results, the participant must discontinue the use of certain medications for 72 hours before skin testing. OTC (over the counter) and prescription medications such as:

Antihistamines - includes Benadryl, Chlor-trimeton, Allerest, ARM, Contact, Extendryl, Sedane, Claritin, Bromfed, and other OTC and prescription antihistamine/decongestant medications.

Cough preparations - any type, OTC or prescription.

But they shouldn't stop these:

Stomach medications - such as Zantac, Tagamet.

Antidepressants and Tranquilizers

If participant has taken any of the above, note them on the Skin Test (ST) worksheet.

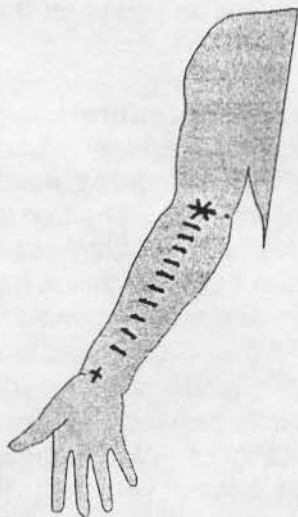
TEST PREPARATION

Wash your Hands Participants will appreciate your consideration if you make a point of washing your hands before testing them. Do this as you enter the room if it has a sink.

Explain the Procedure Explain that the purpose of the next test is to determine if they are allergic to trees, molds, grasses, animal or insects. The test using 21 "toothpicks" will be lightly pushed on their skin. Each of the toothpick has a drop of antigen made of a tree, mold, grass, or animal. If they are allergic to one of the antigens, after 15 minutes, you will circle any raised bump (will look and feel like a "mosquito" bite). We will measure the bump, then we will wash your arm. If you are still itchy, we have lotion that will take away the itchiness.

PREPARING THE ARM

1. Ask the participant to bare their non-dominant forearm.
2. Using the 70% alcohol and cotton balls, clean the inside of the forearm gently. Stop cleaning the area when the cotton ball(s) come up clean.
3. Using 4x4s or 2x2s gauze pads, gently dry the area.
4. Using the template on the "Skin Test Worksheet" (left side), line up the 1st mark (darker line under "template") with the antecubital fosse (the crease between the forearm and upper arm). Then, place template down the middle of the forearm.
5. Using an ink pen, mark the template on the arm. Make the marks 1" wide.
6. Mark the antecubital mark with an "X".
7. 1" from the line above the wrist (stay clear of creases & veins), mark an "+". If there is not enough room, you may place the "+" above the elbow, or on the other arm, or if the arm is wide, enough, place the "+" on the side (at least 1 1/2" away from the other marks).



APPLYING THE ANTIGENS

Allergy testing with the DermaPIK, as with any skin test device, requires that the proper technique be used. Proper contact between the DermaPIK and the skin is required to ensure that the antigen bearing tines of the DermaPIK penetrate the first layer of the epidermis to deliver the antigen to the underlying reactive dermis layer of the skin, but proper test technique will not cause bleeding.

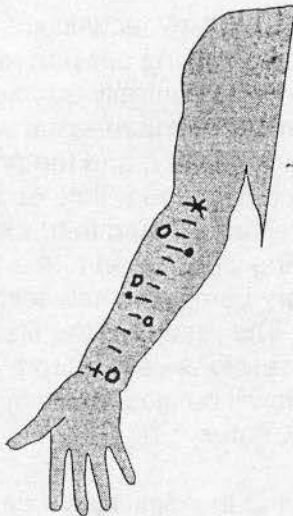
1. Match up the DermaRAK with the arm (left side marked on the DermaRAK is **your left side** [participant's right side of their forearm]).
2. Hold the participant's arm steady at the palm with your non-dominate hand.
3. Starting with the left side; Using your dominate hand and starting at the 1st line past the antecubital line, remove the DermaPIK from the DermaWell, and briefly inspect to assure that a small amount of the liquid antigen is present between the tines.
4. Place the antigen to the appropriate spot 1" at the left of the line. **Make a SLIGHT DIMPLE (IMPRESSION) into the skin with the DermaPIK ensuring that all six tines are in contact and gently twist, rotating the DermaPIK approximately one-quarter turn.**
5. Discard used DermaPIK in the paper cup.
6. Proceed down the left side using the above technique. Then, proceed down the right side.
7. Following the application of all the antigens and controls, set the timer for 15 minutes.
8. Remind the participant not to scratch

or move their arm.

9. Administer the 2-4 page Asthma Questionnaire.
10. Discard the contents of the paper cup into a SHARPS container.

RECORDING THE RESULTS

1. At the end of the 15 minutes, set the scotch tape dispenser next to the arm.
2. Using the ink pen, carefully circle each reaction (the raised part that looks like a mosquito bite).



3. Cut a piece of scotch tape approximately 8½" to 9" long.
4. Running down the left side (your left-side; their right-side) from a little above the antecubital line to the wrist, press the scotch tape on the skin.
5. Press down on the scotch tape so it adheres to the skin (picking up the ink circles/marks).
6. Repeat steps 3-6 for the right side.
7. Cut a third piece of scotch tape

approximately 1½" long.

8. At the '+' mark near the participant's wrist, place the scotch tape on the skin over their marked reaction.
9. Press down on the scotch tape so it adheres to the skin.
10. Pull the left-side up just a little, making sure the ink marks are coming up with it. If ink marks are not coming up with the tape, press the scotch tape back down and press harder across the tape.
11. Pull the left-side up and off the arm (see the actual "reaction" template left on the tape).
12. Under the '**left-side**' column on the participant's ST worksheet, match the line. Press the scotch tape onto the ST worksheet.
13. Do steps 9 and 12 for the right-side.
14. Under the '**right-side**' column on the participant's ST worksheet, match the line. Press the scotch tape onto the ST worksheet.
15. Pull the '+' strip up just a little, making sure the ink marks are coming up with it. If ink marks are not coming up with the tape, press the scotch tape back down and press harder across the tape.
16. Pull the '+' strip up and off the arm .
17. Under the '+' column on the participant's ST worksheet, press the scotch tape onto the ST worksheet.

HISTAMINE CONTROL

All participants should have a reaction to the Histamine Control (C+).

1. If there is no histamine reaction, redo the Histamine (C+) at another location on the arm using the same method as described in **PREPARING THE ARM AND APPLYING THE ANTIGENS**.
2. Wait at least 5 minutes.
3. Record the reaction using the method described in **RECORDING THE RESULTS**.
4. If Histamine Control is still negative, carefully go over the medications listed in **PARTICIPANT PREPARATION** section with the participant and record any changes.

STOP THE ITCHING

1. Cleanse the forearm with 70% alcohol and cotton balls, wiping gently. The participant will appreciate this procedure since their arm will be itchy where they had reactions.
2. Apply 1% hydrocortisone cream or the anti-itching lotion to the area. You can also apply ice to the area.
3. Severe reactions are rare. If a severe reaction has occurred (flushing, low blood pressure, shortness of breath, chest tightness) administer Benadryl liquid (adult dosage is 2 teaspoons). The Benadryl often causes drowsiness (see PDR). Watch the participant for at least 30 minutes before releasing them. Don't let them drive.

CLEANING EQUIPMENT

Cleaning the DermaRAK. Using an alcohol prep or the 70% alcohol on a cotton ball,

wipe down the external face of the DermaRAK.

Quarterly replacement of the DermaWells.

The DermaWells will be replaced every 6 months (February , August 1998) during this substudy.

TECHNICIAN CERTIFICATION

The certification examination includes 10 multiple choice questions based on this Manual of Procedures, and a practical demonstration of skills including cleaning and testing of a naive subject (50 points). Only certified technicians will perform allergy skin testing.

Certification of new technicians after the initial central training session may be performed by a centrally trained, certified technician. The written exam will be administered locally, and the first 5 allergy skin tests performed will be observed by a certified technician and then examined by the Reading Center and found to be satisfactory before the new technician is certified. The results of the first 5 allergy skin test sessions performed by each technician will be closely examined at the Reading Center.

A site visit to the clinical/site centers will be made early during phase, and mid-way through Phase III. **Complete allergy skin testing of a participant by each allergy certified technician will be observed and reviewed.** More efficient methods as well as protocol violations will be discussed during the site visits and later in a written report.

REFERENCES: Please call the Allergy Reading Center for a copy of any of these references.

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SUPPLIES

Skin Testing Major Components

1. DermaPIK
2. DermaRAK
3. DermaWells
4. Antigens (scratch testing formula):

SHSid#	Common Name	Bayer Item#	Concentration	Qty
G1	Bermuda	1142	1:20	5ml
G2	Timothy	2597	1:20	5ml
G3	Bluegrass, Kentucky	1190	1:20	5ml
W1	Russian Thistle	2363	1:20	5ml
W2	Mixed Ragweed	2297	1:20	5ml
W3	Sagebrush mix	2428	1:20	5ml
W4	Careless Weed (Amaranth palmeri)	1298	1:20	5ml
T1	Mulberry	1895	1:20	5ml
T2	Cottonwood	1436	1:20	5ml
T3	Elm	1541	1:20	5ml
T4	Ash	1061	1:20	5ml
F1	Alternaria tenuis	5009	1:10	5ml
F2	Aspergillus fumigatus	5021	1:10	5ml
F3	Helminthosporium interseminatum	5125	1:10	5ml
F4	Hormodendrum cladosporioides	5129	1:10	5ml
C1	Cat (Fel d 1)	4810TR	10,000 BAU	5ml
C2	Dog hair and dander	4825	1:50 AP	5ml
C3	HouseDust mite; D. farinae	6720UP	30,000AU/ml	5ml
C4	Cockroach mix (Amer&German)	6585	1:10	5ml

5. Controls

C -	glycerine	6806ED	50% gly.	5ml
C +	histamine	7099ED		5ml

6. Additional antigens

C5	House Dust mite; pteronyssinus	6692UP	30,000 AU/ml	5ml
C6	Horse Hair and Dander	4856AP	1:50 AP	5ml
C7	Cattle Hair and Dander	4812AP	1:50 AP	5ml

Skin Testing Supplies

70% Alcohol
 Cotton balls
 Antihistamine lotion
 Hydrocortisone cream (1%)
 Benadryl (12.5mg/5ml)
 Black Ink pen
 3/4" Scotch tape
 Paper cups
 4x4 or 2x2 sterile gauze pads
 15 minute Timer

Skin Test Worksheet

Date: ___/___/___

Tech: _____

SHS ID#:

IHS Chart#: _____

TEMPLATE

LEFT SIDE

RIGHT SIDE

CONTROL +

☐ C -
DILUENT

☐ T3
ELM TREE

☐ C +
HISTAMINE

☐ G1
BERMUDA GRASS

☐ T4
ASH TREE

☐ G2
TIMOTHY GRASS

☐ F1
ALTERNARIA - MOLD

EXTRA

☐ G3
KENTUCKY BLUEGRASS

☐ F2
ASPERGILLUS - MOLD

☐ C5
HO MITE -D. PTER

☐ W1
TUMBLERWEED

☐ F3
HELMINTHOSPORIUM - MOLD

☐ C6
HORSE

☐ W2
RAGWEED

☐ F4
H. CLADOSPORIUM - MOLD

☐ C7
CATTLE

☐ W3
SAGEBRUSH MIX

☐ C1
CAT

☐ W4
CARLESS WEED

☐ C2
DOG

☐ T1
MULBERRY TREE

☐ C3
HOUSE DUST MITE

☐ T2
COTTONWOOD TREE

☐ C4
COCKROACH

SHS-III Asthma Sub-Study Screening Questions

SHS ID:

1. Have you been diagnosed as having asthma since the Phase II exam? ☐
1=Yes 2=No
2. Are you aware of shortness of breath with wheezing at night? ☐
1=Yes 2=No
3. Have you had an attack of wheezing with shortness of breath ☐
during the last 12 months? 1=Yes 2=No
4. Have you used any asthma inhalers during the last 12 months? ☐
1=Yes 2=No

*If the answer to any of these four questions is "YES",
participant is eligible for the asthma sub-study.*

Date: //
mo day year

STRONG HEART STUDY PHASE III

Asthma Sub-Study Questionnaire

SHS ID:

1. Was this questionnaire administered in a language other than English? Yes ☐₁ No ☐₂
2. Do you *ever* have trouble with your breathing? Yes ☐₁ No ☐₂
If "YES", how often do you have this trouble?

☐₁ = continuously so that your breathing is never quite right

☐₂ = repeatedly, but it gets completely better

☐₃ = only rarely

3. Does your chest ever sound wheezy or whistling apart from colds? Yes ☐₁ No ☐₂
4. Have you *ever* had an attack of wheezing that made you feel short of breath? Yes ☐₁ No ☐₂
5. *At any time during the last 12 months*, have you had wheezing or whistling in your chest? Yes ☐₁ No ☐₂

If so, was this wheezing brought on or made worse by exposure to *any* of the following (*check all that apply*):

☐ colds or sore throats

☐ exercise or exertion

☐ house dust

☐ fumes

☐ smoke

☐ contact with animals

☐ contact with plants or pollens

☐ other, specify: _____

6. Was this wheezing worse during a particular season of the year? Yes ☐₁ No ☐₂
- If so, which season: winter ☐₁ spring ☐₂ summer ☐₃ fall ☐₄

7. Does shortness of breath or chest tightness ever wake you up? Yes ☐₁ No ☐₂
8. Have you had an attack of shortness of breath that came on *soon after you finished* a strenuous physical activity (especially in cold weather)? Yes ☐₁ No ☐₂
9. Have you had hay fever or any other allergy that makes your nose runny or stuffy apart from colds? Yes ☐₁ No ☐₂
1. If yes, how much were you bothered by hay fever or allergy?
 very little ☐₁ somewhat ☐₂ very much ☐₃
2. Did you take any of the following medications for your hay fever or allergy ?
1. antihistamine pills by prescription? Yes ☐₁ No ☐₂
- ii nose sprays by prescription? Yes ☐₁ No ☐₂
- iii decongestant pills (like Sudafed)? Yes ☐₁ No ☐₂
10. Have you had problems with your sinuses during the last 12 months? Yes ☐₁ No ☐₂
11. Do you have heartburn (gastroesophageal reflux)? Yes ☐₁ No ☐₂
12. Which best describes the building in which you live? (**check one**)
- ☐₁ = a home in which more than one family lives
- ☐₂ = a mobile home or trailer
- ☐₃ = a one family home
- ☐₄ = an apartment
- ☐₅ = a nursing home
- ☐₆ = other, specify: _____
13. What do you use for heating in your home? (**check all that apply**)
- ☐ a. a fireplace or a woodstove
- ☐ b. a gas, oil, or coal burning furnace
- ☐ c. a gas or kerosene space heater
- ☐ d. electric heat
- ☐ e. nothing

14. What do you use for cooling in your home? (*check all that apply*)
- ☐ a. an evaporative (swamp) cooler
- ☐ b. room air conditioners
- ☐ c. a central air conditioner
- ☐ d. fans or nothing
15. Is there an exhaust fan in **both** your **kitchen and bathroom**? Yes ☐₁ No ☐₂
16. Does your bedroom (or where you sleep) have wall-to-wall carpeting? Yes ☐₁ No ☐₂
17. Has there been any water damage to your home, for example, from broken pipes, roof leaks, or floods? Yes ☐₁ No ☐₂ don't know ☐₉
if yes, which year did this occur? 19☐☐☐
18. Is there mold or mildew on any walls inside your home? Yes ☐₁ No ☐₂
19. Do you ever see any of the following pests in your home? (*check all that apply*)
- ☐ a. mice
- ☐ b. rats
- ☐ c. cockroaches
- ☐ d. none
20. What types of animals or pets stay *inside* your home? (*check all that apply*)
- ☐ a. one or more cats
- ☐ b. birds
- ☐ c. one or more dogs
- ☐ d. other furry animals
- ☐ e. none
21. Have you *ever* had asthma? Yes ☐₁ No ☐₂
1. If "**NO**", you are done with this questionnaire. **GO TO Q42.**
2. If "**YES**", do you still have asthma? Yes ☐₁ No ☐₂
- If "YES", please complete the rest of the questions.**
If "NO", go to Q42.

Skip The Rest of These Questions If You Don't CURRENTLY HAVE ASTHMA.

22. How old were you when you had your *first* episode of asthma?
age in years

23. How old were you when you had your *most recent* episode of asthma?
age in years

24. Are *any* of your relatives (living or deceased) known to have asthma?

Yes ₁ No ₂ Don't know ₉

If "YES",

	Yes	No	Don't know
a. Did your natural father ever have asthma?	<input type="text"/> ₁	<input type="text"/> ₂	<input type="text"/> ₉
b. Did your natural mother ever have asthma?	<input type="text"/> ₁	<input type="text"/> ₂	<input type="text"/> ₉
c. Do you have any children with asthma?	<input type="text"/> ₁	<input type="text"/> ₂	<input type="text"/> ₉

25. When you are near animals (such as cats, dogs, or horses), near feather pillows, quilts, or comforters, or in a dusty part of the house, do you ever:
(check all that apply)

- ☐ a. start to cough
- ☐ b. start to wheeze
- ☐ c. feel chest tightness
- ☐ e. start to feel short of breath
- ☐ f. get a itchy or stuffy nose
- ☐ g. start to sneeze
- ☐ h. get itchy or watery eyes
- ☐ i. none

26. During the last 4 weeks, how often have asthma attacks awakened you at night or in the early morning? **(Check one only)**

₁ = never

₂ = less than once a week

₃ = one to four nights a week

₄ = almost every night

27. During the last 4 weeks, about how many days did you miss from work, or were your usual activities limited, because of your asthma? |_|_|
days
28. Have you ever worked at a job which exposed you to vapors, gas, dust, or fumes?
- Yes |_|₁ No |_|₂ Don't know |_|₉
- If yes, what was the job? _____
29. Have you ever had to leave a job because it affected your breathing? Yes |_|₁ No |_|₂
30. Please list **ALL** the medicines or other remedies (including hand-held sprayers, inhalers, aerosols, or tablets) you have taken for asthma during the last 12 months.

Asthma Medications in the past 12 months	When wheezing	Every day
_____	_	_
_____	_	_
_____	_	_
_____	_	_
_____	_	_
_____	_	_

Which of these asthma medications do you take when you have an asthma episode (with wheezing and shortness of breath)? Check the “**When wheezing**” box after the medication.

31. Do you use an asthma inhaler *every day* even if you don't feel short of breath? Check the “**Every day**” box after the medication in Q30. Yes |_|₁ No |_|₂
32. Do you use a spacer tube with any of your asthma inhalers? Yes |_|₁ No |_|₂
33. Do you ever use a nebulizer with an air compressor (electric pump) for your asthma? Yes |_|₁ No |_|₂
34. Have you *ever* taken steroid pills (prednisone) for your asthma?
- Yes |_|₁ No |_|₂ Don't know |_|₉
35. Have you ever been given a peak flow meter to help manage your asthma? Yes |_|₁ No |_|₂
- If yes, did you use it 5 days or more during the last month? Yes |_|₁ No |_|₂

36. Have you *ever* visited an Emergency Room (ER), or been hospitalized because of asthma or other breathing problems? Yes ☐|☐_1 No ☐|☐_2
- If yes, how many times during the last 12 months? |||_ times
37. How many times during the last 12 months have you seen a health care provider for breathing problems or asthma? |||_ times
38. Do you seek care for your asthma from any other source (medicine man or alternative medicine)? Yes ☐|☐_1 No ☐|☐_2
39. Do you feel that you have been given enough information about what to do when your asthma gets worse? Yes ☐|☐_1 No ☐|☐_2
40. Have you been given written instructions for what to do when your asthma worsens? (an asthma action plan)? Yes ☐|☐_1 No ☐|☐_2
41. Please rate the quality of care that you receive for your asthma:
- poor ☐|☐_1 fair ☐|☐_2 good ☐|☐_3 very good ☐|☐_4 excellent ☐|☐_5
42. Interviewer code ||||
43. Interview date |||/||||/|||||
mo day year