General Description

Manual of Operations Volume I

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

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Tracking of Revisions to Manual of Operations Volume III: Personal Interview and General Examination

Date of Revision	Revised Section	Revision	Approved by, Date
1/17/2025	Section 9: Referral Guidelines Section 10: Quality Control (QC) Program	Fixed formatting issue with section title in the footer	SHS CC, 1/16/2025
7/15/2024	Appendix A-2: Ancillary Study consent Forms	Updated affiliation for Astrid Suchy-Dicey and listed her as a PI for Psychological Risk Factors Study	SHS CC, 7/15/2024
5/22/2023	Section 8: Ancillary Studies	Update specific aims for Resilience study	SHS Ancillary Study Committee, 5/22/2023
5/4/2023	Appendix 6: SHS Phase VII Exam Forms	Add ECG question Minor wording fixes	SHS SC, 4/24/2023
5/4/2023	Section 9: Referral Guidelines	Add ECG Referral Guidelines Change local IHS lab to local lab for CBC results	SHS SC, 4/24/2023
5/4/2023	Section 4: Personal Interview	Update COVID 19 Guidelines	SHS SC, 4/24/2023
5/4/2023	Section 2: Components of the Exam Section 8: Ancillary Studies	Add Bilingual study description	SHS SC, 4/24/2023
5/4/2023	Section 1: Introduction	Add information about training	SHS CC, 4/24/2023
4/27/2023	Entire document	Fixed formatting issues and broken web page links	SHS CC, 11/1/2022

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I. General Description and Study Management

1. Background

1.1 General

Prior to establishment of the Strong Heart Study (SHS) in 1989, 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 determined that there was little if any information available on the prevalence of cardiovascular disease (CVD), nor an understanding of the major risk factors for CVD, among U.S. American Indians. To address this, an historic partnership was formed between NHLBI, the SHS participating tribes, and the SHS Field Centers and Coordinating Center, all continuing in existence through today (Lee 1990). In Phase I (1988-1991), the SHS Field Centers in North/South Dakota (under the Aberdeen Area Indian Health Service and Aberdeen Area Tribal Chairman's Health Board for the 1rst and 2nd exams, later under Missouri Breaks Industries Research, Inc.), Arizona (under MedStar, which also serves as the clinical assay lab and blood sample repository), and Oklahoma (under the University of Oklahoma Health Sciences Center (OUHSC), which also serves as the SHS Coordinating Center) recruited 4,549 participants (the original cohort) ages 45-74 years for the 1rst SHS exam. A Cardiovascular Center at Cornell was added in 1992 to enable preclinical cardiac imaging during the Phase II SHS exam (1993-95). Finally, a pilot genetics family study was added during the Phase III exam (1997-1998) to determine the feasibility of studying genetic risk factors; due to its success the Genetics Center (at Texas Biomed) was established as a 5th SHS center. In Phase IV, the family cohort (the Strong Heart Family Study) had a final recruitment of 3,776 members of 94 multi-generational families. Phase V included a follow-up exam of the family cohort and continuation of ongoing morbidity and mortality (M&M) surveillance of the original cohort. While no follow-up exam occurred in Phase VI, M&M surveillance for both the original and family cohort continued (2013-2018).

The SHS Steering Committee includes original and current SHS investigators, ancillary study investigators, Native Investigators, and community representatives and members. The SHS Steering Committee implements SHS policies and procedures which include obtaining Tribal approval, an absolute requirement for all SHS publications, presentations, and ancillary and sub studies. A trust has developed between the partnering tribes and the SHS investigators from the five centers who have had an active presence in their communities since 1989 or before. The SHS organizational structure and long-standing relationships between the SHS Centers and the participating communities has resulted in a strong and effective collaboration that has and continues to significantly and positively impact American Indian health.

The SHS was the first to document the very high rates of cardiovascular disease (CVD) in American Indians, and identified type 2 diabetes (T2D) as a major risk factor (Welty 1995; Howard 1999; Zhang 2008). This contributed to T2D being recognized as a major risk factor for CVD across other population groups in the U.S. (Go 2014). Findings from the SHS have contributed to reports from the Surgeon General, the AHA, ADA and the CDC (Go 2014; The 2004 United States Surgeon General's Report). We have been very active in disseminating information for translation into health care. The SHS has developed coronary heart disease, hypertension and T2D risk calculators specific for American Indians that have been used

extensively by health care providers (available on the SHS website), and the Indian Health Service (IHS) developed procedures for risk factor control in diabetic American Indians based on SHS data. SHS data form the basis for current IHS recommendations on dyslipidemia management, and the IHS strategic plan for CVD prevention and therapy. We have summarized publications of clinically significant SHS findings for dissemination in *The IHS Primary Care Provider: A journal for health professionals working with American Indians and Alaska Natives.* The most recent was a summary (Han, S, 2009) of stroke data (Zhang 2008).

The SHS remains an active resource for leveraging additional studies impacting American Indian health. A number of ancillary studies have increased our understanding of stroke and its risk factors in American Indians (Suchy-Dicey 2016), the impact of low-moderate environmental metal and metalloid exposures on CVD (Moon 2017; Moon 2013; Newman 2016), diabetes (Grau-Perez 2017; Kuo 2015), and chronic kidney disease (Zheng 2015; Zheng 2013), and are characterizing fatty liver disease and its risk factors; (R01DK110096; PI Cole), to name a few. Interventions have included successful CVD prevention trials (Howard 2008; Lee 2012) and ongoing environmental as well as culturally-based behavioral interventions (R01AG049084, PI Verney; R01HL122148, PI Nelson; and R01ES025135, PI George).

From another perspective, SHS has had major public health impact and has been a pioneer in community participatory research. SHS data serve as the reference for major tribal organizations in planning programs for health care delivery, education and prevention strategies. SHS summaries and a Data Book along with a series of newsletters, brochures and educational materials focused on translating SHS findings and on CVD risk and prevention have been disseminated to multiple tribes and health care providers. The SHS is committed to capacity building in SHS communities, as, to date, >250 staff are or were members of the communities, and the SHS has contributed to training of 49 Native investigators, including investigators at each of the three current SHS field centers, who have used SHS data for their research manuscripts, graduate dissertations, and other publications.

The SHS has extensive experience translating and disseminating its findings to communities. This has ranged from health education provided to our participants during exams and in regular newsletters, to informal meetings and continuing education of local providers, to comprehensive presentations to regional groups, Tribal Health Boards, and the Association of American Indian Physicians. For local communities, our work has been discussed at tribal council meetings, on radio talk shows, in science classrooms, at elder nutrition programs, and at community honoring ceremonies. We believe this 'translational' effort is unparalleled as a conduit between the NHLBI and underserved communities, and our community relations and training and career development activities serve as a model for other studies.

1.2 Rationale for SHS Phase VII Exam

The long-standing relationships of the SHS and its Field Centers with participating communities have resulted in a strong and effective collaboration that continues to positively impact American Indian health. The SHS has published important information about the epidemiology of cardiovascular disease and a wide range of risk factors among American Indians. A firmly established collaboration exists among the three incumbent Field Centers and biomedical research and data groups at MedStar, Cornell, Texas Biomed and OUHSC, as well as with the Wake Forest Phase 7 ECG Reading Center and with their longstanding collaborators at other institutions, nationally and internationally. This will ensure that the proposed SHS study, sub-studies and ancillary studies have access to scientists and experts with needed expertise to implement cutting-edge methods and effectively foster and implement studies that will further positively impact on our understanding of the unique constellation of disease risk factors in American Indians, and lead to effective, targeted and culturally appropriate interventions and approaches to treatment.

Because of the tribal and institutional partnerships, we are uniquely poised to accomplish the goals for Phase VII. One mark of unique SHS success is the continuing relationship with its participants and tribal officials. This is reflected in very high rates of participant retention (e.g. 92% for the Phase V exam). This relationship has been maintained by distribution of many reports compiled specifically for community use, participating in local health fairs and events, collaborating with community members to assess health needs, and by regularly meeting with tribal officials and health boards. This success was largely the result of insistence by the SHS investigators that they operate in partnership with both communities and participants.

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2. Research Objectives

2.1 Scientific Objectives

Through the relationships that we have established over the past 33 years and with the support of the tribes participating in the SHS, we are well poised to continue making important scientific contributions towards improving cardiovascular health among American Indians over Phase VII of the SHS.

The scientific objectives are to:

1. Utilize the data from the five previous SHS exams and 32 years of continuous surveillance of the two SHS cohorts (original and family) to investigate the high risk of cardiovascular disease and related conditions in this special population;
2. Enable investigations of new risk factors or interactions among factors that inform disease pathophysiology through use of the existing and newly collected data and samples; and
3. Enhance statistical power, through extended follow-up and the application of cutting-edge statistical analysis approaches, to perform analyses of predictors of clinical events.

2.2 Operational Objectives

Building on existing infrastructure of the three Field Centers and the Coordinating Center, Central Laboratory and Cardiovascular and Genetics Centers, the operational objectives are to:

1. Continue to foster scientific collaborations with outside investigators and institutions
2. Maintain existing data and biospecimen repositories for use in testing of new research hypotheses;
3. Continue mortality and morbidity surveillance of study participants;
4. Conduct a limited clinical examination of study participants as a platform for independently-funded ancillary study examination components;
5. Maintain and enhance tribal relations by increasing tribal community engagement activities;
    a. Formally establish Community Advisory Boards to provide additional community perspective and engagement pertaining to SHS activities; and
    b. Establish a mechanism to award community pilot grants to community serving entities.
6. Support training of junior investigators, especially American Indian (AI) investigators.

3. Study Design

3.1 Ancillary Studies and Collaborations

In SHS VII, we will continue our active ancillary collaborations with a variety of partners. The SHS has successfully disseminated important results impacting American Indian health through publications and presentations; continued morbidity and mortality surveillance of surviving participants; and fostering the design, supporting funding and implementation of ancillary and sub-studies. A few of our accomplishments are as follows:

To date, the SHS Publications and Presentations Committee has approved **697 paper proposals** that have resulted in **468 published papers**.

To date, the SHS has approved **169 ancillary and sub-study proposals**.

3.1.1 SHS Phase VII Exam as a Platform for Ancillary Studies

The SHS Phase VII Exam will be a limited clinical examination that will also serve as a platform for independently-funded ancillary studies. An ancillary study is an investigation which, although not part of the core exam protocol, will yield additional information related to study objectives. They may include all or a subgroup of the cohort at a given center, and may involve additional interviews or examinations of study participants as well as analysis of blood or tissue samples, tapes, or images collected previously.

Ancillary studies were solicited through announcements on the SHS website, communications with NHLBI consortia (e.g. the Cross-Cohort Collaborative), and a Notice in the NIH Guide informing the research community that the NHLBI will fund the Phase VII exam in the SHS to begin on or about February 2022. At least 16 ancillary study proposals were submitted, including responses to funding opportunities, interventions (of particular interest to our communities), renewals of existing programs, and non-NIH Federal agency RFPs.

The SHS Steering Committee, including representation from the NHLBI Project/Contract Office, reviewed ancillary studies for scientific soundness and compatibility with SHS goals. Those with Steering Committee approval were reviewed by the SHS Observational Study Monitoring Board (OSMB). Evaluations gave highest priority to studies which: 1) did not interfere with the main SHS objectives, 2) had the highest scientific merit, 3) limited burden on SHS participants and demand on SHS resources, such as blood samples, and 4) required the unique characteristics of the SHS cohort. Participation in ancillary studies also requires approvals by applicable tribal partners, Tribal IRBs, Tribal Health Boards, and Institutional IRBs.Ultimately, eight ancillary studies were funded (see **Table I**, below). The Project Summary/Abstracts for each funded study are included in **Appendix 8**. These ancillary studies are operationally integrated into the main study (see Section 1.3.4). Ancillary studies are subject to the same policies, reviews and approvals as the core protocol. Investigators conducting ancillary studies are viewed as collaborating investigators of the primary study, with access to necessary data from the full data set. Ancillary study data, collected under a grant mechanism or other funding mechanism, will become part of the SHS data set; these data will be incorporated into the study data set after an

appropriate period (generally 12 months after completion of data collection). All data will be provided to qualified investigators through a defined process that encourages maximum data utilization but that protects participant confidentiality and tribal community sovereignty. (See **Appendix 9**, SHS Data Sharing).

Table I. Ancillary Studies to the SHS Phase VII Exam

Award #; URL to NIH RePORTER (if applicable)	Principal Investigator	P.I. Institution	Title	Award Dates
NIH R01AG068865; https://reporter.nih.gov/projectdetails/10048385	Zhao, Jinying	University of Florida	Gut microbiome, aging and cardiometabolic diseases in American Indians	09/10/20-05/31/25
NIH R01AG070822; https://reporter.nih.gov/projectdetails/10264169	Suchy-Dicey, Astrid	Washington State University	Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study	09/30/20-05/31/25
NIH R01ES032638; https://reporter.nih.gov/projectdetails/10140691	Navas-Acien, Ana; Baccarelli, Andrea; Mason, Christopher	Columbia University	The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes	01/01/21-10/31/25
NIH RF1AG071677; https://reporter.nih.gov/projectdetails/10182205	Barbosa-Leiker, Celestina; SuchyDicey, Astrid	Washington State University	Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study	07/01/21-06/30/24
OUHSC College of Medicine Research Fund	Wu, Huimin	University of Oklahoma Health Science Center	Chronic respiratory diseases among Native Americans	07/01/21-06/30/22
P01AG066584; https://reporter.nih.gov/projectdetails/10172086	Buchwald, Dedra; Sinclair, Ka'imi	Washington State University	Cognition After (OSA)Treatment in Native American People (CATNAP)	08/01/21-04/30/26
NIH P42ES033719 https://reporter.nih.gov/project-details/10354268	Navas-Acien, Ana	Columbia University	Columbia University and Northern Plains Partnership for the Superfund Research Program	09/21/2022-06/30/2027
R01AG080398 https://reporter.nih.gov/project-details/10582307	Barbosa-Leiker, Celestina; SuchyDicey, Astrid	Washington State University	Bilingualism as a protective factor of ADRD in American Indian adults: the Strong Heart Study	04/01/2023-01-31-2028

3.2 SHS Infrastructure

Phase VII funding provides for continued maintenance of existing SHS data and samples from the previous exam phases and ancillary studies of the SHS, and for maintenance of new data and samples generated during the Phase VII exam and ancillary studies conducted during the contract-funded period.

3.2.1 SHS Data

SHS exam data (the majority of SHS data) are maintained at the OUHSC Coordinating Center. Pedigree and genetic data are maintained at the Texas Biomed Genetics Center. Individual identifiers are retained only at the respective field centers. The Genetics Center, Cardiovascular Center and Central Laboratory and Biorepository retain the primary technical data documenting individual assays/analyses and quality control.

3.2.1.1 Coordinating Center

In previous SHS phases the Coordinating Center has utilized an Access database for data entry and management. The database is stored on a HIPAA-compliant and secure server that is hosted in the OUSHC Data Center, and is housed in a locked and guarded data center staffed at all hours (24 X 7). Entrance to the Data Center requires use of a card key to unlock the center door and a second card key lock secures the cage that the servers reside within. The security of the Data Center is further protected by an Operations desk that is staffed 24x7 and by a security camera system. CAIHR servers are guarded by multiple firewall and intrusion detection systems. All electronic connections to the server environment are encrypted. Permission to access the folder is limited to authorized personnel of the SHS. Standardized procedures have been developed for double-data entry, editing data, correcting data entry errors, data entry codes, and data clean up that are described in the Psychosocial Questionnaire Manual of Operations (Volume V) and the Data Entry and Quality Control Manual of Operations (Volume VII).

To allow for greater functionality and efficiency in data capture, data monitoring and data reporting, data capture, quality assurance, management, and processing of the data captured during Phase VII will be consolidated through the Research Electronic Data Capture (REDCap) system. REDCap is a secure, web-based application designed to support data capture for research studies, it provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. The REDCap system will also allow for automated and real time reporting of double-data entry errors. Online forms for capture of data identified by SHS ID number will be created using REDCap, exported as pdf files, and printed for off-line use so that a hard copy will be available for data checks. REDCap will allow for multi-personnel access of project files and will be used by each of the Field Center offices to capture data. The data will be coordinated centrally at the Coordinating Center at OUHSC. The Coordinating Center will continue to support collaboration with SHS and outside investigators according to the established data request, review and distribution policies of the SHS and partnering tribes. A well-established protocol is followed to ensure that de-identified data are distributed only with approvals from the

SHS Publications and Presentations Committee (for manuscripts) or Steering Committee (for ancillary or sub-studies).

3.2.1.2 Genetics Center

The Genetics Center has grown to include a data repository of all genetic marker data on the study which is maintained in the Texas Biomed High-Performance Computing Center (HPCC). SHS genetic data includes ~2M genetic marker genotypes in the SHS cohort for use in GWAS, approximately 216,400 polymorphic markers on up to 3,800 SHFS participants, exome sequence data on 96 participants, GWAS exome genotype data on 72 Dakota participants, gene/locus specific deep sequence data on 1500 SHFS participants, genome-wide (EPIC chip) methylation data on >2,600 SHS participants from the original cohort, a microsatellite map used for linkage analyses, SHS pedigree information (identity-by-descent matrices and kinship coefficients with 75,117 total relative pairs), and phenotypic datasets supplied by the SHS Coordinating Center in order to enable secure genetic analyses on Texas Biomed servers. Currently, >15 tribally approved collaborators have external access to the GCC server to perform SHS analyses.

Genetics Center data will be maintained at the HPCC, and we will continue to provide access to a SHS-specific server for tribally-approved collaborators in order to perform SHS analyses, which complies with the wishes of the SHS participating tribes that SHS pedigree information and genetic marker data remain to the greatest extent possible on (not be copied from) Texas BioMed's secure servers. We have implemented extensive security measures to protect our computers and data files against unauthorized access. Our security measures are compliant with IRB requirements for human data. Access to central files containing research, clinical, support, or administrative data is restricted to a list of approved users. Backup of all data sets is incorporated in the overall department computer backup system.

3.2.2 SHS Biorepositories

There are two biorepositories that maintain existing and future SHS biological specimens. The MedStar Central Laboratory and Bio-repository, and the Texas Biomed Genetics Center.

3.2.2.1 Biorepository at MedStar Health Research Institute

MedStar Health Research Institute's B3 Core (previously known as Penn Medical Laboratory) has served as the central laboratory and biorepository for the SHS since its inception. It has defined procedures related to biorepository management, quality control, sample handling, tracking, and disposition as well as for the return of residual samples from collaborating laboratories (consistent with the International Society for Biological and Environmental Repositories [ISBER] and the NCI Best Practices for Biospecimen Resources). The B3 Core has a plan for lifecycle replacement of SHS freezers, for installation of redundant computerized and web-enabled monitoring and alarm systems, and for distribution of SHS samples across two distinct biorepository sites (in the Hyman Research Building at MedStar Washington Hospital Center in Washington, DC and at MedStar Health Research Institute's main facility in Hyattsville, MD) to further mitigate risk, beyond backup AC, power and backup freezers on site. The biorepository provides the identification, retrieval, distribution, tracking and return of SHS biospecimens to collaborating investigators for ancillary and sub-studies approved by the

steering committee. The biorepository currently holds almost 800,000 SHS aliquots (serum, EDTA plasma, heparin plasma, NaFl EDTA plasma, Na-Citrate plasma, urine, whole blood, DNA or buffy coats) in 35 dedicated -80C freezers (including 5 dedicated backup freezers) collected during all exams of the SHS plus specimens from other (ancillary) studies of SHS participants, and ~400,000 split and residual aliquots from distribution of these samples for completed ancillary or sub-studies.

In Phase VII, the biorepository will work with the coordinating center to harmonize, combine, and migrate its multiple legacy sample tracking software solutions (including spreadsheets, flat files, and proprietary databases) to a single, stable, user-friendly and easily maintained database that will better facilitate specimen inventory and tracking, including freeze-thaw cycles and specific sub-study uses. Due to the explosion of sensitive analytic techniques that require never thawed samples, we plan to markedly increase the number of aliquots from the planned basic exam blood draw and "spot" morning urine sample. This strategy, should make it more efficient and less costly to access and distribute specimens for ancillary and sub-studies in the future.

3.2.2.2 Genetics Center

The Genetics Center houses more than 20,000 buffy coat samples in four -80°C freezers, and more than 8,000 DNA sample aliquots and additional dilutions of SHS DNA samples in two 20°C freezers and one 4°C refrigerator. Sample and freezer inventories are maintained on personal computers and GCC servers, and backed-up regularly. Sample storage procedures are consistent with guidelines from ISBER and the NCI Best Practices for Biospecimen Resources. Sample storage is governed by the SHS Sample Storage Policy which was approved by the SHS participating tribes. The freezers are located in two separate lab spaces (the Cole laboratory and the cryopreservation facility) and participant samples are distributed between the two locations, they are connected to emergency power outlets, are monitored by automated dial-out systems and by 24-hour guard personnel, and the ultra-low freezers have a CO2 back-up system in case of freezer failure. Personnel monitor and record freezer temperatures daily, perform freezer defrost and arrange scheduled maintenance, and all lab personnel work cooperatively (through group text and email) if/when there are issues with any of the freezers.

Space is available in the current SHS freezers to accommodate buffy coat samples that will be obtained during the Phase VII basic exam. All current and future samples are maintained securely, without identifiers, accurately-inventoried, and easily retrievable. Inventories are updated with new samples from the basic as well as ancillary studies. Reports are provided to the Coordinating Center and NHLBI.

3.3 Surveillance

Our methods for morbidity and mortality surveillance are described in the Morbidity and Mortality Surveillance Manual of Operations (Volume II). Surveillance methods for Phase VII of the SHS are the same as those used successfully in Phases II-VI. Surveillance of the SHS cohort for CVD morbidity and mortality has been ongoing since 1989, and for the SHFS since 2001. Mortality surveillance includes annual ascertainment of deaths in survivors of the original cohort and in participants in the SHFS of all ages. Inclusion in the mortality surveillance of SHFS members permits continued examination of CVD risk factors in relation to "early" events and

comparisons of these factors to those associated with CVD at older ages. Morbidity surveillance will be done in the SHS and SHFS cohorts using the same methodology as in previous phases. Individuals are designated at each center, who are specifically responsible for mortality and morbidity surveillance activities. Surveillance contacts are 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.

New to Phase VII is the opportunity to link SHS data with Medicare claims data from the Centers for Medicare and Medicaid Services (CMS). To implement the process, the Coordinating Center is collaborating with Duke University School of Medicine for both acquisition of Medicare claims data, as well as to provide best practices for the use of the CMS data. In addition, as preparation for several possible ancillary and sub-studies, the SHS is working to connect to multiple, population-based cancer registries in the U.S. through the Virtual Pooled Registry Cancer Linkage System (VPR).

3.4 Clinical Examinations

The SHS Phase VII will include a re-exam of all consenting participants who are still living (~2,700) which will occur November 1, 2022 to October 31, 2024. The exam is intended in part to serve as a platform for additional, independently funded exam components via investigator-initiated grants or other independently funded projects to enrich the exam data collection with additional hypothesis-driven content. The research aims of such exam-related ancillary projects need not be limited to those within the mission of the NHLBI but must be consistent with and/or complement the SHS's objectives.

3.4.1 SHS Phase VII Basic Exam

The components of the basic core examination will include the following: recruitment, informed consent, blood pressure and anthropometry measurements, ECG, phlebotomy and spot urine for key lab analytes (serum lipid profile, plasma glucose, whole blood HbA1c; and urinary creatinine and albumin) and sample storage for future research use, and questionnaires to update personal and medical history, diet, and current medications use. (see **Table II**).

The clinical examination will last approximately 3 hours. Procedures are described in brief below, with details presented in SHS Phase VII Manual of Operations Volume III – Volume VIII.

The following questionnaires will be administered:

1. Demographic information: income, residence, marital status, and education will be determined.
2. Health habits: Smoking, alcohol intake, food frequency questionnaire (FFQ), medical and reproductive history, medication history.

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

1. Weight, height, waist circumference, arm circumference.

2. Blood pressure measurements, including ankle-brachial index
3. ECG
4. Fasting blood samples will be obtained for measurements of total triglyceride (TG) and cholesterol, HDL cholesterol, glucose, creatinine, HbA1c.
5. Urine will be collected for measurement of albumin and creatinine.
6. Medical records from the Indian Health Service and/or other medical providers will be abstracted to ascertain hospitalizations, outpatient evaluations, or other manifestations of CVD that are SHS endpoints.

Table II. SHS Phase VII Exam Components and Participant Time Burden

Study	Component	Measure	Center(s)	no. participants	Time (in minutes)	measures used in multiple studies
Basic exam	Reception, Consent		all	2,700	30	X
	Questionnaires					
		Demographics information	all	2,700	20	X
		Smoking history	all	2,700	5	X
		Medical history, medications	all	2,700	25	X
		FFQ	all	2,700	30	X
	anthropometry		all	2,700	10	X
	Blood pressure		all	2,700	15	X
	Blood draw (fasting)		all	2,700	15	X
		tot chol, HDL-chol, TG				
		glucose, HbA1c, creatinine				
	Urine collection	creatinine, albumin	all	2,700	10	X
	ECG		all	2,700	10	
Gut microbiome, Aging and Cardiometabolic Diseases in American Indians	informed consent		all	1,500	5	
	stool sample (home collection0)	microbiome analysis	all	1,500	10	
	Stool sample delivery				30+	
	Questionnaires				45	
		Bristol stool chart			-	
	DNA				0	

Table II. SHS Phase VII Exam Components and Participant Time Burden Cont.						
Study	**Component**	**Measure**	**Center(s)**	**no. participants**	**Time (in minutes)**	**measures used in multiple studies**
Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study	informed consent		all	2,700	10	
	Questionnaires		all	2,700	90	
		14-item Resilience Scale (RS-14)				X
		22-item Multidimensional &Interpersonal Resilience measure				X
		7-item Multigroup Ethnic Identity Scale				X
		6-item Orthogonal Cultural Identity Scale (OCIS)				X
		25-item Native Identity Scale				X
		13-item Participation Scale – short				X
		30-item Montreal Cognitive Assessment (MOCA)				X
	blood aliquot	Serum neurodegeneration markers	all	2,700	-	
The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes	blood draw	PAXgene tube	all	1,100	2 minutes	
	urine aliquot	metals	all	1,100		
	blood aliquot	CBC, insulin	all	1,100		X
Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study	informed consent		all	2,700	10	
	Questionnaires		all	2,700	15	
		Perceived Stress Scale (PSS)				X
		Center for Epidemiological Survey-Depression (CES-D)				X
		Substance use				X
		SF-36				X
		Inclusion of Community in the Self (ICS) Scale				X
	NIH Toolbox		all	2,700	45	

Table II. SHS Phase VII Exam Components and Participant Time Burden Cont.						
Study	**Component**	**Measure**	**Center(s)**	**no. participants**	**Time (in minutes)**	**measures used in multiple studies**
Chronic respiratory diseases among Native Americans	informed consent		OK	120	5	
	COVID-19 test				2	
	Questionnaires	chronic respiratory disease & healthcare			10	
	spirometry				15	
Cognition After (OSA)Treatment in Native American People (CATNAP)	informed consent		DK	450	10	
	at-home sleep apnea screening		DK	450		
	cognitive screening		DK	450		
	PAP intervention		DK	300		
Health effects of metals in American Indian communities: a longitudinal multi-omics study	Informed Consent					
	Urine aliquot	Metals	OK	350		
			DK			
			AZ			
Bilingualism as a protective factor of ADRD in American Indian adults: the Strong Heart Study	Informed Consent					
	qualitative interviews		all	3 per tribe		
	quantitative questionnaire	Indigenous, tribal, or Native language use	all	1,000-1,500	5	

3.4.2 SHS Phase VII Ancillary Study Exam Components

The SHS Phase VII exam includes eight additional ancillary studies. Six studies are conducted across all centers, one in the Oklahoma Field Center only, and one in the Dakota Field Center only. The ancillary studies and their additional exam components are listed in **Table II.**

As can be seen in **Table II**, the majority of additional participant burden from ancillary studies is from the administration of additional questionnaires. For the microbiome study, a stool collection using a commercial kit would occur. The study of chronic respiratory disease conducted in Oklahoma includes administering a questionnaire. The CATNAP study conducted in the Dakota Field Center includes an at-home test for sleep apnea and a PAP intervention in a subset of participants.

During the consenting process, the participant will also be provided with information on each of the ancillary studies for which they are eligible, including the informed consent document for

each study. A staff member will explain the study and procedures to the participant, answer questions, if any, and administer the consent form for each ancillary study that the participant wishes to join. Field Centers will administer any additional measures required for those studies. Procedures are described in detail in the SHS Phase VII Manual of Operations Volume III through Volume VIII.

3.5 Community Engagement

The SHS has been a leader in Community Engagement amongst NHLBI-funded cohort studies, with a long history of conducting community engagement, and active programs at all three Field Centers. These include semi-annual SHS newsletters, numerous brochures, educational materials, community events, health screenings, educational programs, seminars, social media pages, to name but a few. The SHS Phase VII funding provides for the generation of a SHS Data Book at the end of the SHS Phase VII exam. The data book will summarize the research results through Phase VII of the study for tribal governments and health advocacy groups. This publication will serve as a follow-up to the Data Book published in 2001.

The SHS Phase VII contract provides for 3 new opportunities to expand engagement with community leaders and entities that serve community health interests, described below.

3.5.1 SHS Community Advisory Group

During Phase VII, a SHS Community Advisory Group (CAG) has been formed. The purpose of this group of advisors will be to provide feedback and cultural input into questions arising from SHS Steering Committee discussions. The CAG is comprised of community representatives nominated by the Field Centers from the three geographic regions of the study (3 from Oklahoma, 3 from North and South Dakota, and 2 from Arizona). The CAG will meet through teleconferences or webinars, where a SHS investigator will help facilitate the call and provide information on SHS Steering Committee questions for CAG consideration. The emphasis will be on a format that encourages soliciting and listening to ideas from the community. One in person meeting every ~1.5 years, will occur as a satellite meeting to an in-person Steering Committee meeting. These meeting will allow more focused interactions amongst community members on topics of interest to all three geographical regions.

3.5.2 STAR Community Pilot Studies

The SHS Phase VII includes funding and support for the Strong heart Tribal Approach to Research (STAR) Projects. Th STAR program provides pilot funding in support of projects that address community health priorities related to the prevention and treatment of heart, lung, blood, and sleep disorders and eliminate or reduce health disparities for these conditions in the SHS communities. STAR projects are available to any applicant/organization whose research serves the Strong Heart Study partnering tribes including community members, college students, and Tribal and other organizations.

Two separate cycles of STAR projects will be funded, each with a duration of one year (cycle one is anticipated to be funded from May 2022 to April 2023, and cycle 2 from May 2023 to April 2024). Applicants may request grant funds starting at $5,000 up to a maximum of $30,000. The program includes an optional re-application, which is reviewed by SHS and NHLBI personnel and is intended to help applicants develop public health knowledge and skills and refine their applications before submission.

STAR pilot applications are limited to 5 pages, and are reviewed by a review committee comprised of Strong Heart Study Steering Committee members. Proposals will be evaluated

based on scientific merit similar to the NIH review criteria, including significance, approach, investigators, environment, and overall impact. The Strong Heart Study in collaboration with NHLBI will make the final decision for funding.

3.5.3 Community and Tribal Leadership Meetings

In addition to the CAG, three SHS Community Meetings will be held for tribal leaders and/or representatives from each Field Center, with each Field Center hosting one of the meetings. The host Field Center will plan the agenda to include topics for engagement, with an emphasis on a format that encourages soliciting and listening to ideas from the community attendees, and may include presentations on current research approaches and results from the Strong Heart Study. The benefit of these meetings is that it allows community members from all three geographical regions to meet together, something that has only happened once before in the SHS.

Finally, three, in-person, SHS leadership Meetings will be held during the contract for tribal leaders and/or representatives to meet with NHLBI leadership. NHLBI leadership did not meet with tribal leaders in the previous phases of the SHS, so this presents a unique opportunity for NHLBI to dialogue with the SHS tribes about timely and important topics related to the SHS and use of its resource.

3.6 Trainings for Native Investigators

Training of Native (and non-native) staff, students, and new and early-stage investigators is an ongoing focus of the SHS. Staff who are members of local tribes, as well as high school, college, and graduate students have all had opportunities in the SHS, where investigators work on many levels to train investigators through collaboration, development of manuscripts and grant proposals, and training seminars.

The SHS will continue to provide formal and/or informal training opportunities for staff, junior and early career investigators, fellows, and students during Phase VII. This may include but is not limited to engaging early stage investigators with experience and responsibilities for specific scientific and study management areas. A focus will be on mentoring early career investigators from underrepresented racial and ethnic groups, especially American Indians. SHS investigators will pursue “NHLBI Research Supplements to Promote Diversity in Health-Related Research for Individuals in Postdoctoral Training” as well as continuing to incorporate SHS experiences into existing training programs.

4. Study Management

4.1 Funding and Timeline

The Strong Heart Study Phase VII is funded by the National Heart, Lung, and Blood Institute (NHLBI) federal contracts to the SHS Coordinating Center and the three SHS Field Centers (contract numbers 75N92019D00027, 75N92019D00028, 75N92019D00029, & 75N92019D00030). The study was previously supported by research grants: R01HL109315, R01HL109301, R01HL109284, R01HL109282, and R01HL109319 and by cooperative agreements: U01HL41642, U01HL41652, U01HL41654, U01HL65520, and U01HL65521. Subcontracts through the Coordinating Center fund the Biorepository and Central Laboratory, the Cardiovascular Reading Center, and the Genetics Center. The Principal Investigators and contact information for the Centers and for NHLBI can be found in **Appendix 1.** Staff members and consultants at each center are listed in **Appendix 4.**

Pending the timely award of contracts to all responses submitted to the funding solicitations, the SHS Phase VII components will occur over the following timeline shown in **Table III**:

Table III: SHS Phase VII Timeline

	2019	2020	2021	2022	2023	2024	2025	2026
Core Study Operations Feb 2019 – Feb2025								
Phase VII Exam Planning Apr 2021 – Feb 2022								
Phase VII Exams Apr 2022 – Apr 2024								
Community Pilot Planning & Projects Apr 2021 – Apr 2024								
Phase VII Data Book & Study Closeout Apr 2025 – Feb 2026								
Diversity Supplement Feb 2019 – Nov 2025								

4.2 Oversight

Administrative oversight is shown in **Appendix 2.** Four entities oversee and approve SHS activities: the NHLBI Contracting/Project Offices, the SHS leadership, the SHS participating tribal partners, and a NHLBI-appointed SHS Observational Study Monitoring Board (OSMB) approve all studies and publications and presentations arising from the SHS. The operations of the study are directed by the SHS Steering Committee (SC) (see below), and the SHS OSMB provide guidance to SHS investigators and assessment of progress or the NHLBI during the annual OSMB meetings when SHS progress and plans are presented; they also review and approve ancillary studies focusing on participant burden and compatibility with SHS goals.

The SHS has an established management structure consisting of the SHS Steering Committee (SC) and its advisory subcommittees that have helped to develop and successfully implement and achieve study objectives. All processes are transparent and defined in SHS manuals of

operations, and all existing policies have been approved by the SHS tribal partners. The current membership of each committee in Phase VII is listed in **Appendix 3.** Their charges and membership requirements are described below

1. **SHS Steering Committee (SC) --** Charge; the main SHS administrative body, will develop and approve all study aspects including its policies and protocols. A particular focus will be to ensure that the SHS adheres to agreements and understandings with each of its distinct and sovereign tribal partners, and to review ancillary and sub-studies for compatibility with SHS goals, and participants' consents. The SC will meet monthly by videoconference, and in-person twice per year. Membership: SC Chair, the PIs of the Coordinating Center, Field Centers, key subcontracted centers, the NHLBI Contracting Officer's Representative (COR), PIs of SHS ancillary studies, community advisors and co-investigators, consultants and staff on this proposal, as nominated and approved by the SC
2. **SHS Sub-Committees** make recommendations to the SHS SC, which finalizes decisions. These committees usually meet monthly by teleconference unless otherwise noted.
3. **Administrative Committee –** Charge: act in an advisory capacity to the SC Chair, undertaking expedited review and consideration of time-sensitive matters, and votes on approval of ancillary studies and other items of business when consensus cannot be reached by the SC. It meets on an as-needed basis. Membership: SC Chair, PIs from CC, the Field Centers, key subcontracted centers, the NHLBI COR, and three SHS SC members who can act as community advisors (one named by each of the three Field Centers).
4. **Ancillary Study Committee –** Charge: address issues involving participant burden and concerns, especially the impact of multiple ancillary studies on recruitment and exams, exam training and procedures and issues surrounding the return of research results. Membership: committee chair, study field coordinators and key staff, with input from laboratory staff and the Morbidity and Mortality Committee, and consideration by tribal leadership and governing IRBs.
5. **Publications and Presentations (P&P) Committee –** Charge**:** efficiently review manuscripts and presentations using and establishing policies that incorporate the required SHS tribal approval for each manuscript. Membership: members' expertise should parallel the major disciplines and approaches used in the SHS (cardiology, diabetes, biostatistics, genetics, nutrition, and epidemiology). The NHLBI COR also participates in the review and approval of paper proposals.
6. **SHS Coordinators Committee –** Charge: review protocols, track recruitment goals, develop dissemination materials and recommend revisions to exam protocols. Membership: field coordinators and staff.

7. **Morbidity and Mortality (M&M) Review Committee –** Charge: maintains necessary protocols for, and classifies and adjudicates cardiovascular (CV) events and other study clinical endpoints as approved by the participating Tribes and contained in the informed consents. It meets quarterly, or as needed. Membership: CC PI and staff, along with specifically-trained and certified SHS clinical investigators, and consultants who will be paid honoraria for their reviews.
8. **Quality Control (QC) Committee –** Charge: meet regularly during the exam phase of the contract to develop methods to assess accuracy and reliability, control variability, collect and evaluate data quality and recommend corrective action, when appropriate. Membership: CC and laboratory personnel.
9. **SHS Ethics Committee –** Charge: provide counsel regarding ethical considerations arising during study conduct. Our experience shows that this is especially valuable in assessing the impact of cultural issues, which tend to change over time, on the operation and focus of the SHS. Membership: SHS investigators, staff, and community members who have extensive and active experience in tribal community engagement.

4.3 Communication

Management of the SHS could become unwieldy given the distributed locations of the Field Centers and research centers of the SHS Coordinating Center. Despite this challenge, the SHS centers have functioned collaboratively for years through participation in their multiple, established committees. The committees' effectiveness is the result of active communication and longstanding relationships among members using regular meetings with prior notification of the meeting agenda, recorded minutes, and interim email or phone discussions as needed.

Investigator communication primarily uses email and videoconference. To reach non-SHS investigators, there is a Google Scholar page, a Wikipedia page and a Contact Us page on the SHS website. Each Field Center maintains social media accounts (e.g. Facebook and/or Twitter). Several SHS investigators have their own Twitter accounts where SHS findings and progress are posted.

The SHS website is the main repository of SHS policies and procedures. It includes lists of SHS scientific papers, both published and in press, available and linked to abstracts posted on the National Library of Medicine PubMed website.

The Manual of Operations for each of the phases of SHS is also available, along with a wealth of other information including annotated data collection forms, data dictionaries, a data matrix, virtually all of the SHS newsletters in Adobe Acrobat format, announcements on various aspects of SHS, research opportunities/scholarships for undergraduate and graduate American Indian students, and information for researchers, community members, and medical providers.

5. Data Management

Data Entry and Quality Control are described in detail in the SHS Phase VII Operations Manual Vol. 7. Below is a summary of Phase VII exam data-related activities.

5.1 Development of Study Manual and Data Collection Forms

The Field Center Coordinators and Ancillary Study Committee worked closely with the Steering Committee in the development and production of the study manual and data collection forms. All forms were reviewed and recommendations were made for revisions, deletions, and additions of forms. For the questionnaires, ancillary study PIs were also asked for additions, revisions, changes, and in particular elimination of redundancy and unnecessary questions. The Community Advisory Group provided input on the instructions for administering questionnaires to the study population. The Manual was revised by Steering Committee members, Field Coordinators and CC personnel. Further input and improvements will be provided during the training sessions scheduled in early 2022. After initiation of the Phase VII exams in May 2022, the entire manual will be reviewed and modifications will be incorporated.

5.2 Sources of Data

Online forms for capture of exam and questionnaire data identified by SHS ID number will be created using REDCap, exported as pdf files, and printed for off-line use so that a hard copy will be available for data checks. REDCap will allow for multi-personnel access of project files and will be used by each of the Field Center offices to capture data. The data will be coordinated centrally at the Coordinating Center at OUHSC. Coordinating Center (CC) staff will generate data summaries and related queries every two weeks. The CC data analyst will communicate with the staff at each Field Center site to address implausible or extreme values, as well as missing data values or delinquent data. Data entry and quality reports will be programmed in REDCap for automated and real-time data monitoring by Field Center and Coordinating Center personnel. Revisions to the REDCap forms or screens, as well as personnel training and retraining, will be performed as needed to address data quality concerns. Data quality and completeness will be reported to the SHS Steering and Quality Control committees and to the OSMB. The Coordinating Center includes information technology support personnel who are experienced in training users in the use of REDCap and in supporting Field Center staff in remote locations. The Coordinating Center will continue to support collaboration with SHS and outside investigators according to the established data request, review and distribution policies of the SHS and partnering tribes. A well-established protocol is followed to ensure that deidentified data are distributed according to SHS data distribution policy.

Morbidity and Mortality data for surveillance will be obtained as described in the Manual of Operations (Volume II). Sources from the Field Centers include the Death Certificate Form, Morbidity Survey Medical Chart Review Form, and from the Mortality and Morbidity Review Committee members the Mortality or Morbidity Study Chart Review Form, Mortality or Morbidity Final Decision Form, and Mortality Informant Interview Form.

The laboratory data and data from ancillary studies are transmitted to the Coordinating Center using secure electronic means. SHS Data are stored on the OUHSC secure server; M&M charts are uploaded to a secure REDCap site managed by the OUHSC IT. Routine backup procedures are used to ensure the safety of the SHS data files at Field centers and the Coordinating Center, including regular backups to external media that are maintained in locked storage in different buildings.

5.3 Confidentiality of Data

All personnel with access to data collected for the study at each field 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 5**.

Completed data forms will be placed in locked file cabinets in offices assigned to the study at each study field center. Only authorized staff members have the key to the office and access to the data forms. Data with identifiers are collected at each study center, but only data with identifiers removed are shared with the coordinating center. SHS data received by the CC are stored at the OUHSC Data Center. Only authorized CC team members have access to those data.

5.4 Quality Control (QC) Program

The quality control (QC) program includes close monitoring of the quality of all measurements and interview data. A Quality Control Subcommittee oversees the QC program of the Study. Its charge is described in **Section 4.2**, above, and the members of this Subcommittee are listed in **Appendix 3.** The Quality Control Committee meets periodically via conference calls during the examination period to assess the results of quality control activities. The QC Committee reviews the QC data and summary statistics provided by the Coordinating Center and reports to the Steering Committee with recommendations. Recommendations are made to the appropriate centers when problems are identified. Follow-up procedures are established and monitored for all the QC activities. If indicated, field staff are retrained, re-certified, and re-monitored by the QC personnel. For lab data, aberrant pairs are investigated and corrective actions are taken both in the core lab and in the field sites. The quality control program includes: a) data collection, b) recruitment progress, c) routine maintenance and monitoring of instrument performance, d) duplicate measures for physical examinations, laboratory tests, observations of personal interviews, and e) QC for surveillance. Details on SHS Phase VII Quality Control procedures are described in the SHS Phase VII Manual of Operations (Volume VII.

6. Publication Policy

We encourage investigators to submit paper proposals that utilize Strong Heart Study data to address research questions supported by the SHS consents, which encompass risk factors and outcomes related to cardiovascular and metabolic health. SHS P&P guidelines and forms can be found on the SHS website and are described below.

The Publications and Presentations Committee (P&P) reviews paper/thesis/dissertation proposals at the beginning of each month. The submission deadline is the first day of a month. All submitted proposals are then sent to reviewers for review. It usually takes about two weeks for SHS P&P to receive reviewers' comments, to summarize reviewers' comments in a memo, and then to send the memo to authors.

6.1 Abstract approval policy

1. It is assumed that all SHS abstracts will have at least one SHS PI as a co-author. The PI co-author is responsible for ensuring that the abstract abides by SHS standards and guidelines. If none of the PIs is a co-author, the abstract must be approved by the PI who works most closely with the authors. The title of the abstract should include the phrase "Strong Heart Study" whenever possible.
2. If the abstract has an NIH co-author, it must be submitted for NHLBI review. Comments will be returned to the email address provided by the author in the submission process. Please submit the abstract to the following email address for NHLBI Review: ebpdocs@nhlbi.nih.gov
3. Abstracts must be sent to Dakota Center, Oklahoma Center, and Arizona Center for approval by their IRBs which include area IHS IRBs. Please include a brief LAY SUMMARY of the work to be presented. Please specify that the abstract is being forwarded for Dakota/Oklahoma/Arizona Center IRBs approval, include information about the meeting or other venue intended for the presentation, and send the abstract to:

    a. Wendy Lawrence, R.N.
    Strong Heart Study
    Missouri Breaks Industries Research, Inc.
    118 S. Willow Street
    PO Box 1824
    Eagle Butte, SD 57625
    Phone: (605) 964-1260
    Fax: (605) 964-1263
    Email: wendy.lawrence@mbiri.com

b. Jessica Reese, PhD
Univ. of Oklahoma Health Sciences Center
801 N.E. 13th Street, Room 372
Oklahoma City, OK 73104
Phone: (405) 271-2229 Ext. 46733
Email: jessica-reese@ouhsc.edu

c. Cynthia West
Clinical Research Coordinator
MedStar Health Research Institute
1616 E. Indian School Road, Ste 480
Phoenix, AZ 85016
Phone: (602) 526-1110
Email: cynthia.l.west@medstar.net

4. Prior to presenting the paper, the presenting author should verify (if notice has not been received) that the Dakota Center IRB (Great Plains Area IRB) and Oklahoma City Area IHS IRB approval has been obtained. The information can be found on the SHS website.

6.2 Paper Proposal Guidelines

Investigators submit a paper proposal that is then reviewed by the Strong Heart Study Publications and Presentations Committee (SHS P&P). The SHS paper proposal guidelines and submission portal can be found on the SHS website and is shown in **Appendix 6**. The proposal itself must also be uploaded along with the completed submission form. The form and paper proposal will be automatically forwarded to the Chair and Coordinator of the SHS P&P Committee. SHS P&P members review all proposals and consults with investigators regarding the availability of data that are needed for each proposed project, which should be feasible in terms of availability of data. The committee makes a recommendation to approve the proposal, deny the proposal, or to defer a decision pending additional information or clarification from the investigators. After receiving approval from the Publications and Presentations Committee, the project may commence. After the paper is drafted, the draft must be submitted to the IHS IRBs and tribal health boards from each community for approval. Papers may be submitted for publication **only after** the drafts have been reviewed and approved by the tribal health agencies and IHS IRBs.

The following are additional requirements:

1. The title of the paper must include the phrase “Strong Heart Study” or “Strong Heart”.
2. If you have SHS data from previous work, please delete data collected from a community that withdrew consent for further research. Their data may not be included in any analyses. An exclusion list will be provided upon request for an approved paper proposal.
3. If no SHS PI is a co-author and if the analyses are not performed by the Strong Heart Study Coordinating Center, the authors must agree to submit the penultimate (next to final) draft to the Coordinating Center for statistical review.

4. Authors must comply and respond regularly to the status survey on their approved paper proposals conducted by the SHS Publications and Presentations Committee twice a year.
5. For papers lacking a PI as a co-author, Publications and Presentations Committee will advise the primary author whether a near final draft will need to be sent to the Publications and Presentations committee for review by at least two reviewers (selected by the Chairperson). This review is the first step that must be completed prior to review of the penultimate draft by NHLBI/Tribes/IHS.
6. A Lay Summary is required when completing the requirement for submitting the completed draft for IHS IRB and tribal approvals. To obtain approvals, please submit the completed draft and lay summary to each center using the contacts shown in Section 1.6.1.C above. If one or more co-authors are IHS employees, the manuscripts must contain the following disclaimer (verbatim): "The opinions expressed in this paper are those of the author(s) and do not necessarily reflect the views of the Indian Health Service."
7. An acknowledgement of the grant support for the Strong Heart Study is required for publications and presentations.
    a. Suggested acknowledgement of the grant support for the SHS: The Strong Heart Study has been funded in whole or in part with federal funds from the National Heart, Lung, and Blood Institute, National Institute of Health, Department of Health and Human Services, under contract numbers 75N92019D00027, 75N92019D00028, 75N92019D00029, & 75N92019D00030. The study was previously supported by research grants: R01HL109315, R01HL109301, R01HL109284, R01HL109282, and R01HL109319 and by cooperative agreements: U01HL41642, U01HL41652, U01HL41654, U01HL65520, and U01HL65521. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
    b. Do not mention any tribal/community names in a manuscript, including the acknowledgement section.
    c. If the abstract/manuscript has a NIH co-author, it must be submitted for NHLBI review. Comments will be returned to the email address provided by the author in the submission process. Please submit the abstract/manuscript to the following email address for NHLBI Review: ebpdocs@nhlbi.nih.gov

6.3 Thesis Proposal Guidelines

We encourage degree candidates to submit proposals that utilize Strong Heart Study data to address research questions related to cardiovascular health.

Degree candidates submit a thesis or dissertation proposal that is then reviewed by the Strong Heart Study Publications and Presentations Committee (SHS P&P). The SHS thesis/dissertation proposal guidelines and submission link can be found on the SHS website and is shown in **Appendix 6**. The proposal itself must also be uploaded along with the completed submission form. The form and thesis/dissertation proposal will be automatically forwarded to the Chair and Coordinator of the SHS P&P Committee. SHS P&P members review all proposals and consults with degree candidates regarding the availability of data that are needed for each proposed project, which should be feasible in terms of availability of data. The committee makes a

recommendation to approve the proposal, deny the proposal, or to defer a decision pending additional information or clarification from the investigators. After receiving approval from the Publications and Presentations Committee, the project may commence.

The following are additional requirements:

1. If you have SHS data from previous work, please delete data collected from one participating community. This community withdrew consent. Their data may not be included in any analyses. An exclusion list will be provided upon request for an approved paper proposal.
2. Degree candidates must comply and respond regularly to the status survey on their approved thesis or dissertation proposals conducted by the SHS Publications and Presentations Committee twice a year.
3. If any papers are to be generated from a thesis or dissertation, authors should submit separate paper proposals to SHS P&P by following the SHS Paper Proposal Guideline.
4. An acknowledgement of the grant support for the Strong Heart Study is required for publications and presentations.
5. Suggested acknowledgement of the grant support for the Strong Heart Study: The Strong Heart Study has been funded in whole or in part with federal funds from the National Heart, Lung, and Blood Institute, National Institute of Health, Department of Health and Human Services, under contract numbers 75N92019D00027, 75N92019D00028, 75N92019D00029, & 75N92019D00030. The study was previously supported by research grants: R01HL109315, R01HL109301, R01HL109284, R01HL109282, and R01HL109319 and by cooperative agreements: U01HL41642, U01HL41652, U01HL41654, U01HL65520, and U01HL65521. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
6. Do not mention any tribal/community name in a thesis or dissertation, including the acknowledgement section.

7. Ancillary Studies and Sub-Studies Policy

7.1 General Policy

To enhance the value of the Strong Heart Study (SHS) and to ensure the continued interest of the investigators, the Steering Committee (SC) welcomes proposals from individual investigators to carry out ancillary and sub-studies that are related to cardiovascular disease and its risk factors using resources that can be provided by the SHS. to promote the advancement of science. Nevertheless, to protect the integrity of SHS and the privacy of its participants, such ancillary studies, before their inception, must be reviewed and approved by the SC and by the NHLBI through its SHS Observational Study Monitoring Board (OSMB). In general, ancillary studies require outside (non-SHS) funding.

7.2 Definitions of Ancillary Study or Sub-Study

An ancillary study is one based on information from SHS participants in an investigation that is not described in the SHS protocol and involves data collection or participant contact that are not included as part of the routine SHS dataset or data analyses. The core Strong Heart Study includes the use of data, blood, DNA, and urine stored for additional studies not described within the original protocol, but within the scope of the participant consents and approved by the SC; these are considered as sub-studies, not as ancillary studies. In general, ancillary studies require external (non-SHS) funding. Funding for both ancillary and sub-studies must cover any costs incurred by the SHS biorepositories (Biological Core and/or Genetics Center), (e.g., cost reimbursement for sample handling & shipping), the Cardiovascular Reading Center (RC) (e.g., any customized selection or reading of clinical material), and by the Coordinating Center (CC) (e.g., for tasks such as sample selection, preparing and documenting analysis files, participating in statistical analysis, and integrating the new ancillary data back into the combined SHS database). No funds for this purpose are available within the Strong Heart Study.

7.3 Requirements for Approval of an Ancillary Study

Ancillary studies require SHS Steering Committee approval and approval from the SHS OSMB before a grant application to support it is submitted. Approval is also required from the participating tribes, institutional IRBs and the Indian Health Service IRBs.

Approval from the Steering Committee and OSMB will be based on finding that the ancillary study will have scientific merit but will not do any of the following:

1. Violate existing consents or Tribal agreements.
2. Interfere with the completion of the main objective of SHS.
3. Adversely affect participant cooperation, or cause undue participant burden.
4. Create a serious diversion of study resources (personnel, equipment or study samples), either locally or centrally.
5. Jeopardize the public image of SHS and/or the Study relationship with the tribes.
6. Use SHS grant resources without reimbursement

7.4 Preparation of a Request for Approval of an Ancillary Study

For approval of an ancillary study, a SHS Ancillary Proposal Form (see **Appendix 7** must be submitted to the Steering Committee using the SHS web portal. The proposal itself and an ancillary study agreement form (**Appendix 7)** must also be uploaded along with the completed proposal form. The forms and proposal will be automatically forwarded to the Chair of the SHS Steering Committee.

Submission Deadlines: Investigator-initiated Ancillary Study proposals must be submitted to the SHS no later than three months prior to the due date of the funding agency. Ancillary proposals in response to an RFA must be submitted to the SHS as soon as possible or no later than six (6) weeks prior to the due date of the funding agency.

7.5 Review of Ancillary Study Proposal

The Steering Committee will review and will approve, reject or request modification of ancillary study proposals in a timely manner (generally 4 weeks for initial review, longer for those proposals requiring modifications). Once Steering Committee Approval is obtained, the investigator fills out the SHS OSMB Ancillary Study Participant Burden Form (**Appendix 7**) and submits it to the SHS Steering Committee Chair and/or Associate Chair for submission to the SHS OSMB. The OSMB requires a minimum of 2 weeks for review.

Investigators who are not affiliated with SHS need to work with a SHS investigator (PI or coinvestigator). A directory of current SHS investigators is located on the SHS website. This investigator, collaborating with the ancillary study PI, will facilitate preparation of the ancillary study proposal, its submission to the SHS SC, and subsequent communications between the collaborating studies. Other SHS investigators may request to become collaborators on a proposal. The key criteria for approval of proposals are scientific merit and impact on SHS. In addition, the plan for reimbursing SHS components for all ancillary study-related costs must be adequate.

Formal IRB approval will be required, if such studies require further interaction with SHS participants (e.g., interviews or additional procedures). The principal investigator (PI) of the ancillary study, working with the three SHS field centers, is responsible for obtaining approval from the American Indian communities, the grantee institution IRBs, and the three area IHS IRBs.

Proposals related to cardiovascular and pulmonary diseases and their risk factors, which include measurements (even of stored samples) that are not specifically described in the original SHS protocol must obtain approval from some SHS IRBs. If the SHS Steering Committee feels that the ancillary study will result in a major change in the protocol, the PI will be required to seek IRB approval prior to conducting the study. Any ancillary study that is not related to cardiovascular or pulmonary diseases or their risk factors will require IRB and tribal approval

7.6 Amendments of Ancillary Study Proposals

Amendments to ancillary study proposals (e.g., adding analytes to be measured) require approval via submission of a revised proposal with a note describing the changes. It should be noted that such amendments may require further review and approval by the SHS IRBs.

Any previously-approved Strong Heart Study (SHS) ancillary study proposal that is subsequently modified must obtain NHLBI SHS OSMB re-approval if the modification(s):

1. Increase the number of ancillary participants by more than 10%
2. Increase ancillary sample volume needed by more than 10%
3. Increase the scope of the project through additional hypotheses/specific aims
4. Increase the amount of participant burden by adding one or more additional participant visits
5. Increase the amount of participant burden by adding additional measures that would result in more than an estimated 30 minutes of additional participant burden

7.7 Requirements for Approval of a Sub-Study

Sub-study proposals of the SHS parent study follow similar requirements as ancillary studies. The main difference is that in general, they do not require SHS OSMB review. A sub-study does not require participant contact. It uses the SHS repository data and/or specimens to study cardiovascular disease and its related risk factors. Separate funding may be required, for example, if the sub-study requires additional lab tests. Sub-study proposals must be approved by the SHS Steering Committee. Investigators who are not affiliated with SHS need to work with a SHS investigator (PI or co-investigator). A directory of current SHS investigators is located on the SHS website. A proposal is required to be submitted via the SHS website and then it will automatically be forwarded to the Chair of the SHS Steering Committee for SHS Steering Committee review. A sub- study proposal form must be completed and the required narratives attached (**Appendix 7)**.

Submission Deadlines: Investigator-initiated Sub-Study proposals must be submitted to the SHS no later than two (2) months prior to the due date of the funding agency. Sub-Study proposals in response to an RFA must be submitted to the SHS as soon as possible or no later than six (6) weeks prior to the due date of the funding agency. If summary statistics or other data are needed from the SHS Coordinating Center (CC), at least four (4) weeks will be allowed for the CC to provide the information. Agreement with the SHS CC about the costs needed to perform such tasks is negotiable.

7.8 Analysis and Publication of Results of Ancillary and Sub-Studies

SHS Ancillary and Sub-Studies must follow all procedures and protocols of the Strong Heart Study. The goals of this policy are to provide participant protection (ensure use of data does not exceed informed consent), Tribal agreements and understandings, coordination of efforts to avoid duplication of work, and to minimize barriers to publication of Ancillary Studies.

The PI or other representative of the ancillary/sub study, and if necessary the SHS SC, will consult with the CC during data analysis to ensure that all study data used in analysis of ancillary results are consistent with data in the main SHS database. Manuscript proposals must be approved in advance by the SHS Publications and Presentations Committee (P&P). This procedure is necessary to establish authorship and prevent overlap in the publication effort. Approval of manuscript proposals is sought by submitting the proposal using standard SHS format (see SHS Paper Proposal form in **Appendix 6,** below) to the P&P. The ancillary study PI will be required to sign an Ancillary Study Proposal Agreement Form (see form in **Appendix 7,** below). This agreement stipulates that the ancillary study investigators agree to submit paper proposals for approval by the SHS P&P and to submit draft manuscripts for review by the NHLBI (if there is a NIH co-author) and approval by the IHS IRBs and the Tribes (see **Section 6.2,** above). Abstracts for presentations at meetings require similar review by the NHLBI (if there is a NIH co-author) and approval by the IHS IRB (see **Section 6.1** above). The investigator who assumes lead responsibility for the ancillary study shall generally be listed as an author. Whenever possible, the phrase "Strong Heart Study" should be included in the manuscript title and listed as a key word. Manuscripts will also contain an acknowledgment section listing individual SHS investigators and staff as deemed appropriate.

7.9 Feedback of Results of Ancillary Studies to Participants

Results of ancillary studies shall be reported to participants and/or their physicians if such reporting is medically useful and approved by the relevant IRBs and SHS. Once approved, such reporting should follow standard SHS protocol for notification of participants. Overall results of ancillary studies shall be reported to participating tribes via lay language articles in the SHS Newsletter and/or by oral presentations of results at tribal community meetings.

7.10 Handling of SHS Data and Specimens

At the time of distributing SHS specimens and/or data, the SHS Collaborating Investigator, with help from SHS CC and SHS Labs (Central Lab and/or Genetics Center), makes explicit arrangements with the ancillary study PI for:

1. security of these study materials
2. completion of the SHS Ancillary Study Proposal Form and the SHS Data and/or Materials Distribution Agreement Form (See **Appendix 7** below)
3. documentation of IRB approval
4. final disposition of study materials at the conclusion of the ancillary study

The safety and confidentiality of the SHS data at the collaborating institution are the responsibility of the ancillary study PI, as is the appropriate disposition of data and remainders of SHS samples after the ancillary study has been completed. Leftover DNA and any other types of

laboratory specimens must be returned to the Central Laboratory or Texas Biomed. Files of SHS data must be returned or deleted, as established and agreed upon at the outset of the collaboration. An archival copy of the newly collected data and/or laboratory results must be sent in a secure manner to the SHS CC one year after the conclusion of the data cleaning and closure or one year after acceptance of the primary publication, whichever comes first. This should allow sufficient time for publication of the main (ancillary) study hypothesis. This transfer is the responsibility of the SHS representative(s) collaborating with the ancillary study. The data from the ancillary study will be included in the SHS dataset for distribution according to procedures agreed upon with the participating Tribes and the NHLBI.

The SHS Steering Committee (SC) monitors the development of the ancillary studies, receipt of funding, initiation dates, and progress. The progress of ongoing ancillary studies is included in the monthly Coordinators' report and presented monthly SC videoconference meetings. Each Field Center (FC) also reports on the progress of ongoing ancillary studies for the SHS CC who includes the summary in the annual report to the SHS OSMB. This annual report should include a list of data collected and/or analytes measured.

The ancillary study PI will send the completed SHS Data and/or Materials Distribution Agreement Form to the SHS Coordinating Center PI (see contact info in **Appendix 1)**. The CC will review the agreement, obtain appropriate signatures (from CC for data, Biorepository and Central Lab for samples, and/or the Genetics Center for genetic data or DNA samples from Phases 4, 5, and 7), and forward the agreement to the SHS NHLBI Program Officer. A file copy with all required signatures will be retained by CC, and a copy will be returned to the Ancillary Study Principal Investigator.

7.11 Ancillary Studies Using DNA or Other Stored Samples

SHS represents a unique public resource to be used by the American Indian communities in conjunction with clinical, public health, and scientific entities to better understand the etiology and epidemiology of cardiovascular and pulmonary diseases and their risk factors, and clinical sequelae. The SHS investigators are committed to managing the stored biologic material for the good of this endeavor in the manner agreed to and expected by the participating Tribes and study participants. This resource includes blood, DNA, and other biological samples obtained from the SHS participants and stored at the SHS Biorepository and Central Lab at Medstar, or the SHS Genetics Center at Texas Biomed, for future studies of scientific merit related to cardiovascular and pulmonary diseases and their risk factors that are proposed by SHS or collaborating investigators.

Appendices

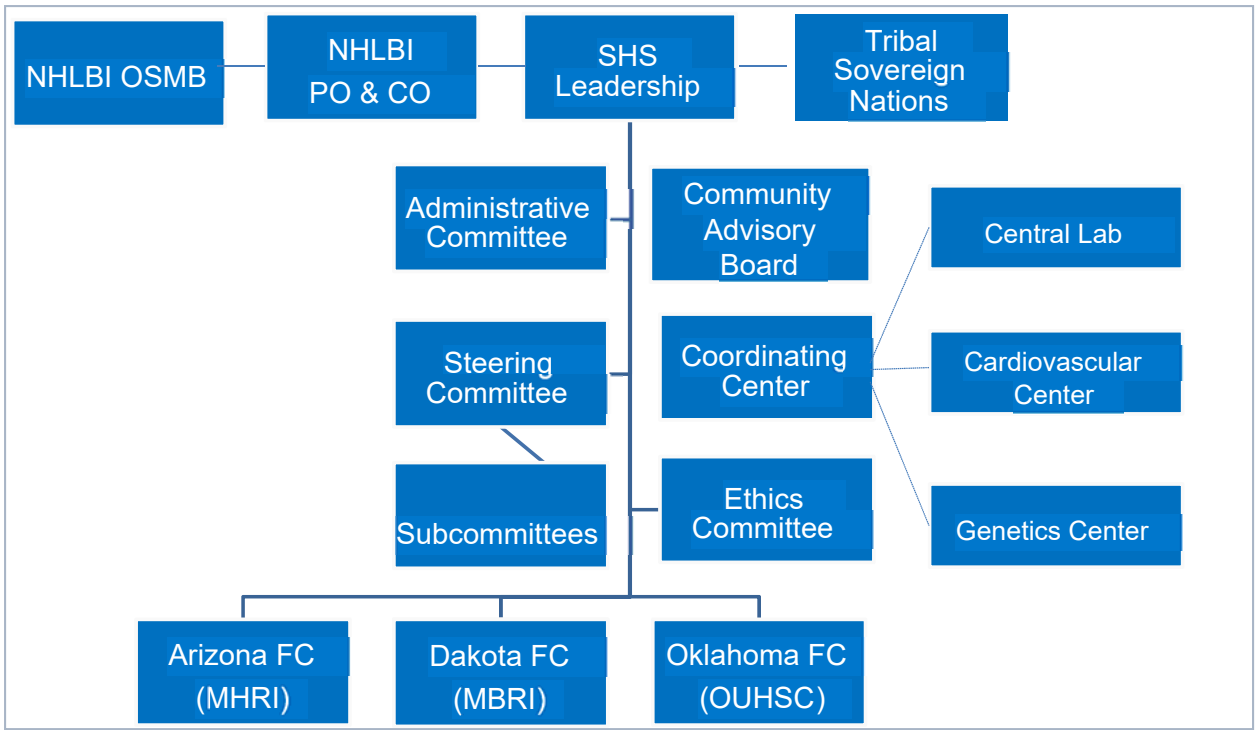
Appendix 1 Strong Heart Study Centers and Principal Investigators

Institution	Role	Point of Contact
University of Oklahoma Health Sciences Center,	Project and Data Coordinating Center	P.I.: Ying Zhang M.D., M.S., Ph.D. Center for American Indian Health Research Department of Biostatistics and Epidemiology Hudson College of Public Health 801 NE 13th Street, Room 303 Oklahoma City, OK 73104 Tel: (405) 271-2229 Ext 48073 Email: Ying-Zhang4@ouhsc.edu
University of Oklahoma Health Sciences Center,	Oklahoma Field Center	P.I.: Tauqeer Ali, M.D., Ph.D. Center for American Indian Health Research Department of Biostatistics and Epidemiology Hudson College of Public Health 801 NE 13th Street, Room 105 Oklahoma City, OK 73104 Tel: (405)-271-3090 Ext. 2 Email: Tauqeer-Ali@ouhsc.edu
Missouri Breaks Industries Research, Inc.	Dakota Field Center	P.I.: Amanda Fretts, Ph.D. 118 Willow Street P.O. Box 1824 Eagle Butte, SD 57625 Tel (MBIRI): (866) 865-3418 Tel (PI): (206) 221-7775 Email: amfretts@uw.edu
Medstar Health Research Institute	Arizona Field Center	P.I.: Jason G. Umans, M.D., Ph.D. 1616 E. Indian School Road, Ste 470 Phoenix, AZ 85015 Tel (PHX): (602) 244-8700 Office: (301) 560-2959 Email: jgu@georgetown.edu
Medstar Health Research Institute	Central Laboratory	P.I.: Jason G. Umans, M.D., Ph.D. Director, Biomarker, Biochemistry & Biorepository Core (B3 Core) MedStar Health Research Institute 6525 Belcrest Rd. Ste. 700 Hyattsville, MD. 20782 Office: (301) 560-2959 E-mail: jgu@georgetown.edu

Institution	Role	Point of Contact
Texas Biomedical Research Institute	Genetics Center	PI.: Shelley A. Cole, Ph.D. Texas Biomedical Research Institute P.O. Box 760549 San Antonio, TX 78245-0549 Office: (210) 258-9688 E-mail: scole@txbiomed.org
Weill Medical College of Cornell University	Cardiovascular Center	P.I.: Richard B. Devereux, M.D. Director, Laboratory of Echocardiography Weill Cornell Medical College 520 East 70th Street New York, NY 10021 Office: (646) 962-4733 E-mail: rbdevere@med.cornell.edu
Wake Forest School of Medicine	ECG Reading Center	P.I.: Elsayed Soliman, M.D. Director, Epidemiological Cardiology Research Center (EPICARE) Professor, Department of Internal Medicine, Cardiology Section Professor, Department of Epidemiology and Prevention Wake Forest School of Medicine Medical Center Blvd, Winston Salem, NC 27157 Office: (336) 716-5530 Email: esoliman@wakehealth.edu
National Heart, Lung, and Blood Institute	Project Office	Project Officer & Contracting Officer Representative: Mona Puggal, M.P.H, M.B.A., P.M.P. National Heart, Lung, and Blood Institute/National Institutes of Health Division of Cardiovascular Sciences 6705 Rockledge Drive Room 305-G, MSC 7936 Bethesda, MD 20892 Office: (301)-435-0704 E-mail: mona.puggal@nih.gov

Appendix 2 Administrative and Study Organization

Figure 1: Strong Heart Study Governance Structure



Appendix 3 Steering Committee and Subcommittee Members

SHS Steering Committee	
Member	**Affiliation**
Cole, Shelley; Chair	Texas Biomedical Research Institute
Ali, Tauqeer; co-Chair	University of Oklahoma Health Sciences Center
Best, Lyle	Missouri Breaks Research Industries, Inc.
Buchwald, Dedra	Washington State University
Deen, Jason	University of Washington
Devereux, Richard	Weill Cornell Medical College
Fabsitz, Richard	Missouri Breaks Research Industries, Inc.
Fretts, Amanda	University of Washington, Seattle
Haack, Karin	Texas Biomedical Research Institute
Howard, Barbara	Medstar Health Research Institute
Lee, Elisa	University of Oklahoma Health Sciences Center
MacCluer, Jean	Texas Biomedical Research Institute
Malloy, Kimberly	University of Oklahoma Health Sciences Center
Navas-Acien, Ana	Columbia University
O'Leary, Marcia	Missouri Breaks Research Industries, Inc.
Puggal, Mona	NHLBI
Reese, Jessica	University of Oklahoma Health Sciences Center
Rhoades, Dorothy	University of Oklahoma Health Sciences Center
Roman, Mary	Weill Cornell Medical College
Umans, Jason	Medstar Health Research Institute
West, Cynthia	Medstar Health Research Institute
Yeh, Jeunliang	University of Oklahoma Health Sciences Center
Zhang, Ying	University of Oklahoma Health Sciences Center
Zhao, Jinying	University of Florida, Gainesville

Administrative Committee	
Member	**Affiliation**
Cole, Shelley; Chair	Texas Biomedical Research Institute
Ali, Tauqeer	University of Oklahoma Health Sciences Center
Deen, Jason	University of Washington, Seattle
Fretts, Amanda	University of Washington, Seattle
Zhang, Ying	University of Oklahoma Health Sciences Center
Devereux, Richard	Weill Cornell Medical College
Puggal, Mona	NHLBI
West, Cynthia	Medstar Health Research Institute
O'Leary, Marcia	Missouri Breaks Research Industries, Inc.
Rhodes, Dorothy	University of Oklahoma Health Sciences Center
SHS Ancillary Studies Committee	
Member	**Affiliation**
Ali, Tauqeer; Chair	University of Oklahoma Health Sciences Center
Fretts, Amanda	University of Washington
Haack, Karin	Texas Biomedical Research Institute
O'Leary, Marcia	Missouri Breaks Research Industries, Inc.
West, Cynthia	Medstar Health Research Institute
Zhu, Jianhui	Medstar Health Research Institute
Publications & Presentations Committee	
Member	**Affiliation**
Zhang, Ying; Chair	University of Oklahoma Health Sciences Center
Reese, Jessica	University of Oklahoma Health Sciences Center
Best, Lyle	Missouri Breaks Research Industries, Inc.
Cole, Shelley	Texas Biomedical Research Institute
Fretts, Amanda	University of Washington, Seattle
Howard, Barbara (through 2022)	Medstar Health Research Institute
Lee, Elisa	University of Oklahoma Health Sciences Center
MacCluer, Jean (through 2021)	Texas Biomedical Research Institute
Puggal, Mona	NHLBI
Singh, Parmanand	Weill Cornell Medical College

Coordinators Committee	
Member	**Affiliation**
Ali, Tauqeer	University of Oklahoma Health Sciences Center
O'Leary, Marcia	Missouri Breaks Research Industries, Inc.
West, Cynthia	MedStar Health Research Institute
Morbidity and Mortality Committee	
Member	**Affiliation**
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Ali, Tauqeer	University of Oklahoma Health Sciences Center
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Deen, Jason	University of Washington
Devereux, Richard	Weill Cornell Medical College
Fallis, Bernardita	MedStar Research Institute
Footracer, Michaela	MedStar Research Institute
Halfred, Florence	Missouri Breaks Research Industries, Inc.
Jhamnani, Sunny	MedStar Research Institute
Lawrence, Wendy	Missouri Breaks Research Industries, Inc.
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Murthy, Santosh Bhaskar	Weill Cornell Medical College
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West, Cynthia	MedStar Research Institute
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Ethics Committee	
Member	**Affiliation**
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Haas, John	Dakota Center Community Member
Ramos, Joni	Arizona Center Community Member
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Appendix 4 Personnel and Consultants

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	TBD	Research Tech	
	TBD	Research Tech II	
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Strong Heart Study Consultants			
Institute/Center	**Consultant**	**Role**	**Affiliation** **(if applicable)**
Project and Data Coordinating Center, University of Oklahoma Health Science Center	Howard, Wm James	Mortality reviewer and adjudicator; Chair of the M&M Committee	
	Lee, Elisa T	Co-investigator	OUHSC
Genetics Center, Texas Biomedical Research Institute	Jean MacCluer, Ph.D. Jack Kent, Jr., Ph.D.	Investigator (through 2021) Genetic analysis	Southwest Iconics
Dakota Field Center, Missouri Breaks Industries Research, Inc.	Stacey Jolly	Investigator	Cleveland Clinic
Oklahoma Field Center, University of Oklahoma Health Science Center	Lee, Elisa T	Co-investigator	Elisa-Lee@ouhsc.edu

Appendix 5 Sample Confidentiality Pledge

THE STRONG HEART STUDY VII

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

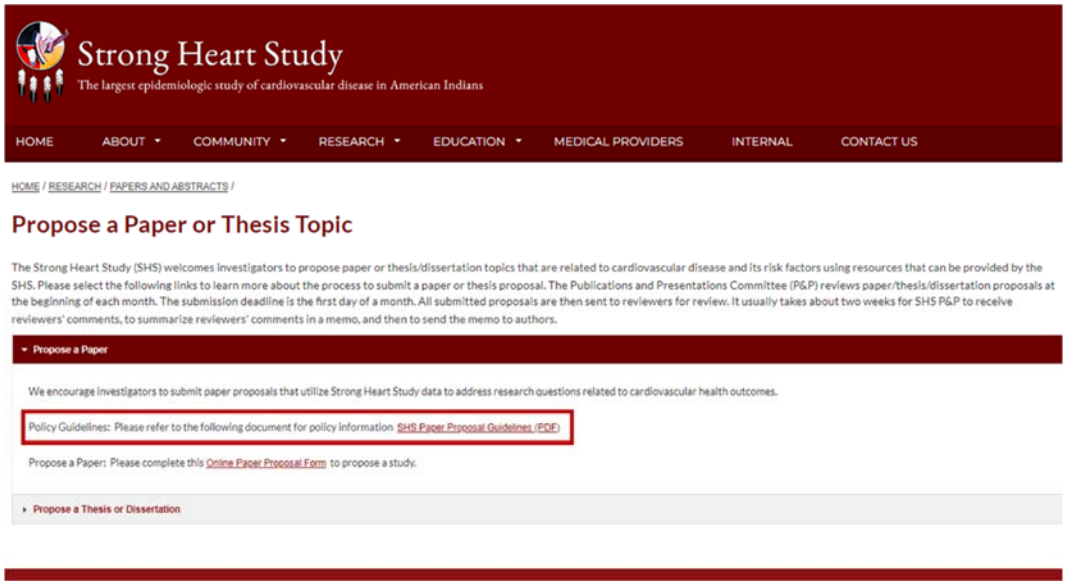
_____
Date

Appendix 6 Publication and Presentation Forms

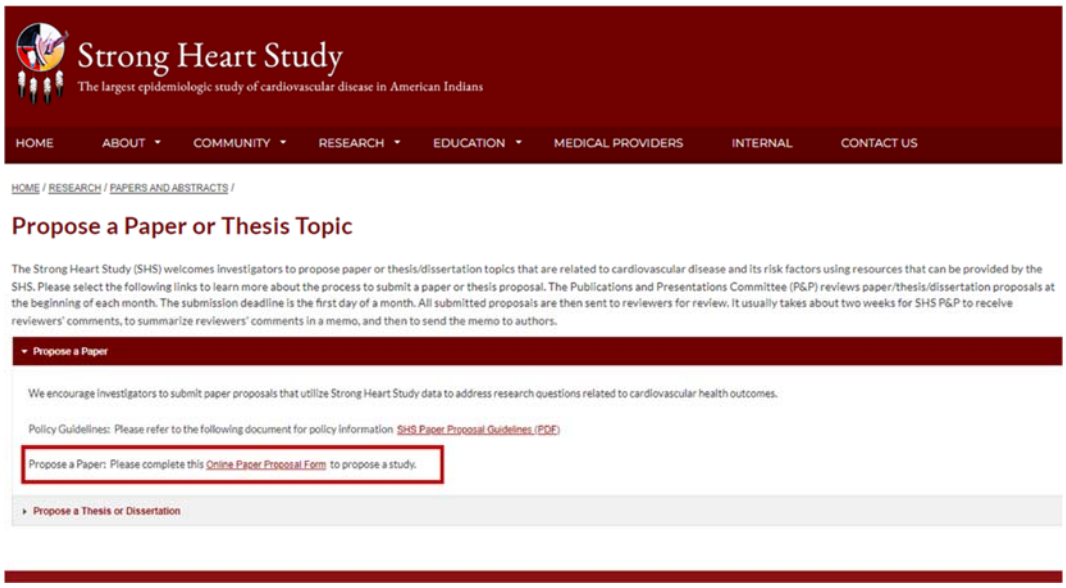
The SHS paper proposal guidelines and submission portal can be found on the SHS website.

A6.1 Propose a Paper

Select the SHS Paper Proposal Guidelines (PDF) link to access the PDF document with guidelines:



Select the Online Paper Proposal Form link to access the submission portal:



STRONG HEART STUDY

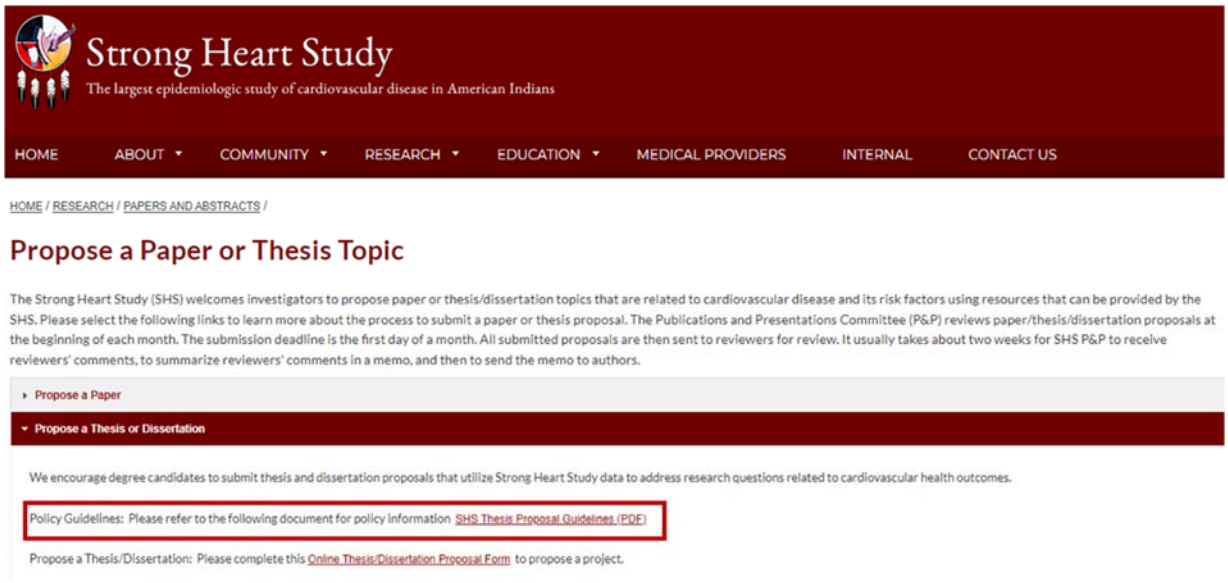
PAPER PROPOSAL TEMPLATE

Please provide a description of the proposed paper by completing the following sections.

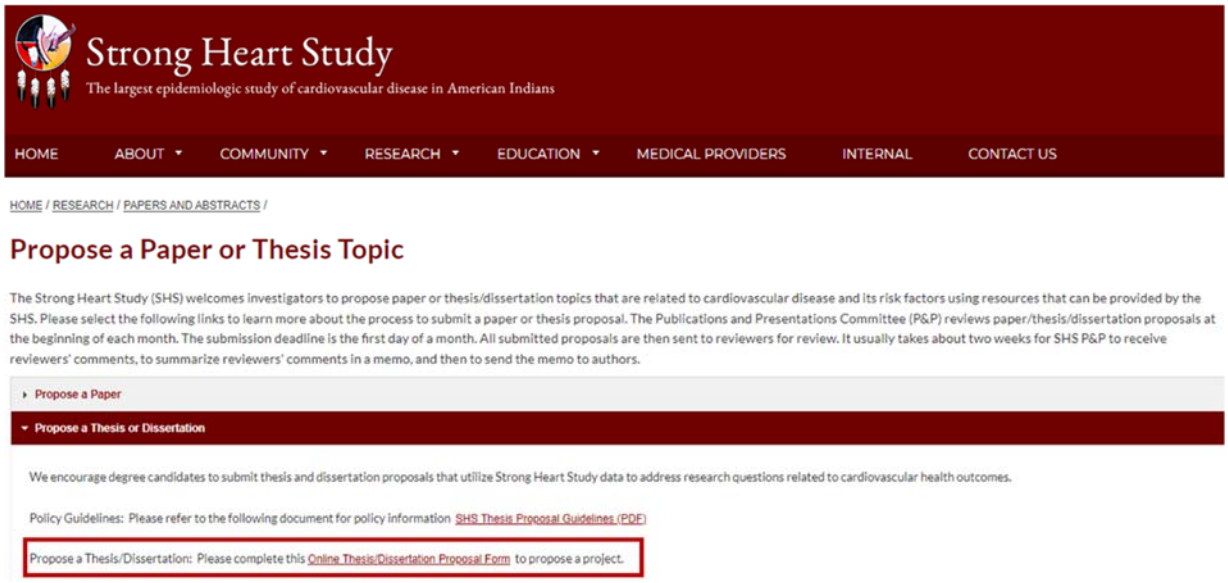
- **Paper Title:**
- **Name of Primary Author:**
- **Name(s) of Strong Heart Study Principal Investigator(s):**
- **Names of Other Authors:**
- **Outline of Paper:**
    a) **Introduction (Rationale):**
    b) **Methods:**
    c) **General analysis plan:**
    d) **A tentative list of SHS variables** which you plan to request from the Coordinating Center for the approved paper, and a simple justification of the request. Include the cohort (original cohort and/or Family Study cohort) and the study Phase.

A6.2 Propose a Thesis or Dissertation

Select the SHS Thesis Proposal Guidelines (PDF) link to access the PDF document with guidelines:



Select the Online Thesis/Dissertation Proposal Form link to access the submission portal:



STRONG HEART STUDY

THESIS PROPOSAL TEMPLATE

Please provide a description of the proposed thesis or dissertation by completing the following sections.

- **Thesis/Dissertation Title:**

- **Name of Degree Candidate:**

- **Outline of Thesis/Dissertation:** (you may include the sections from your doctoral dissertation or thesis prospectus if a prospectus is required by your degree program)
    a) **Introduction (Rationale):**

    b) **Methods:**

    c) **General analysis plan:**

    d) **Timeline:**

    e) **A tentative list of SHS variables** which you plan to request from the Coordinating Center for the approved paper, and a simple justification of the request. Include the cohort (original cohort and/or Family Study cohort) and the study Phase.

Agreement for Strong Heart Study (SHS) Data Distribution

To: Kimberly Malloy, SHS Coordinating Center

From: _____**(Requestor)**

Title/Institution/Address: _____

Title of project: _____

I agree to read and follow the SHS protocol with regard to proper use of SHS data that I receive for my project. I have attached a copy of the protocol/proposal describing how I will use these data to better understand cardiovascular disease and related diseases in American Indians.

I agree to protect the confidentiality and privacy of the SHS participants and the security of the data. I will not seek, transfer, or disclose any individually identifiable information about any SHS participant at any time. Violation of this confidentiality agreement is considered a serious breach of ethical conduct and may leave me, my colleagues, and my institution liable to legal action on the part of the affected SHS participants and their families. I agree that the SHS data provided to me by the SHS Coordinating Center are to be used **only** for the research as described in the attached research protocol. **I promise not to share or distribute the SHS data to anyone else. I further agree not to use the data for commercial purposes, profit, or patents.**

For each paper I wish to write from this research study using the SHS data, I agree to comply with the SHS Publication Policy (http://strongheartstudy.org) and to submit a paper proposal for review and approval of the SHS Publications and Presentations (P&P) Committee. As described in the policy, further approvals from the National Heart, Lung, and Blood Institute (NHLBI), the Indian Health Service (IHS), and the participating tribes will be needed prior to publication in any journal. **If approval from the SHS P&P Committee, the NHLBI, the IHS, or the participating tribes is not granted, I agree not to publish these results.** I understand that the SHS P&P Committee or Steering Committee will assist me in revising my paper in such a way that will make it acceptable to the above-mentioned entities. I will send a reprint of my published article to the NHLBI Program office, and all others as detailed in the **SHS P&P Publication Policy.**

Signed: _____
Date: _____

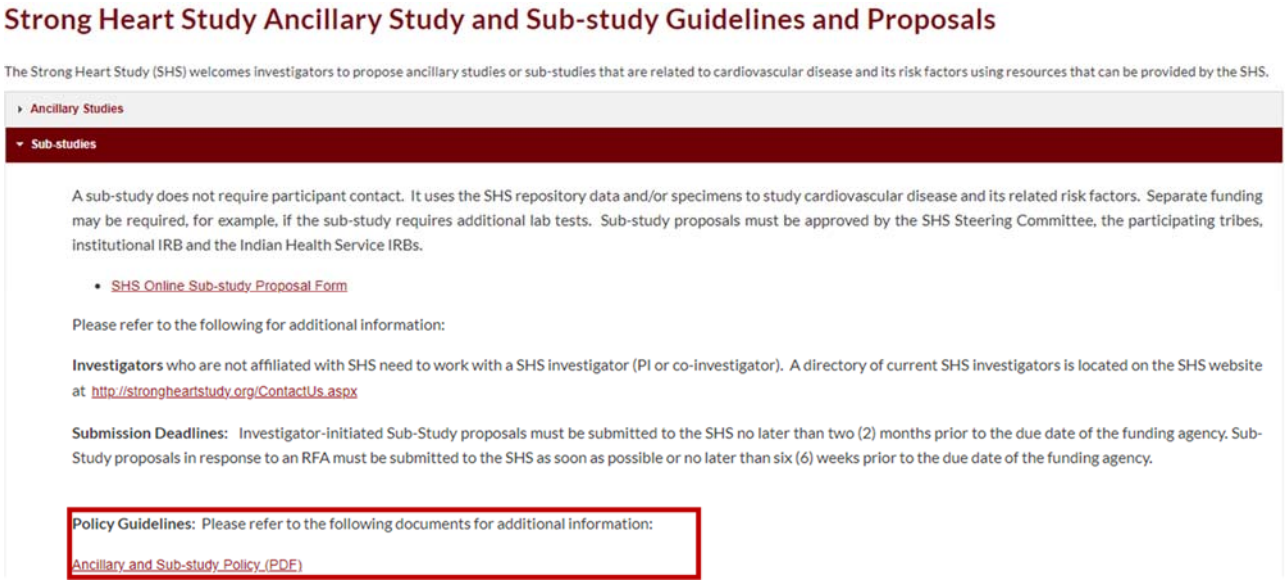
Data request number (to be assigned by the SHS Coordinating Center): _____

Appendix 7 Ancillary and Sub-Study Forms

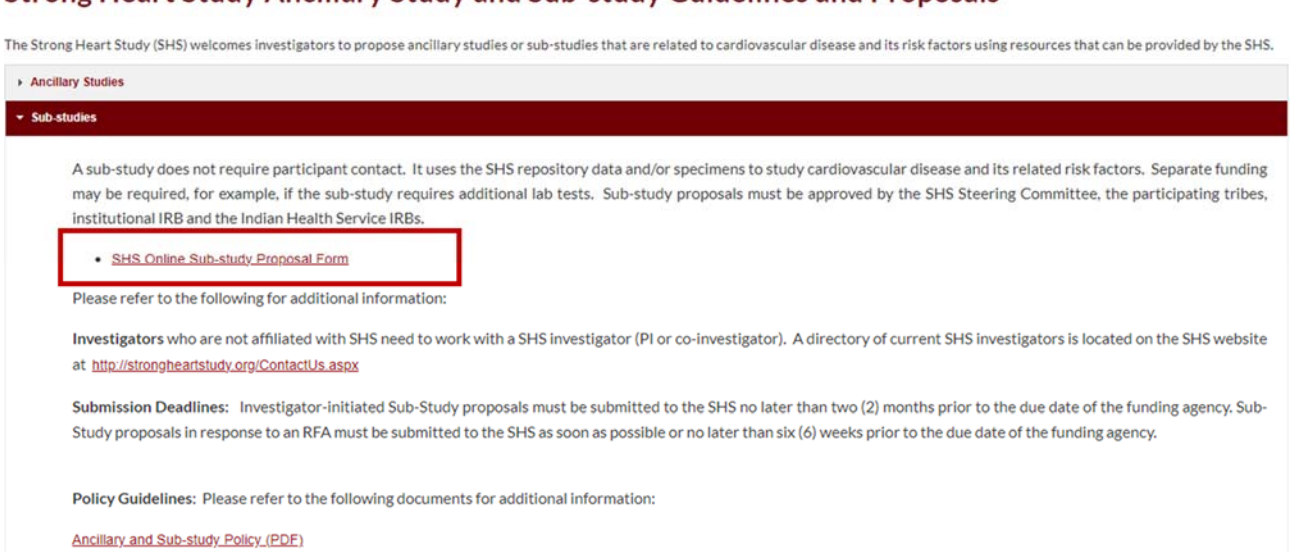
The SHS ancillary and sub-study policy guidelines and submission portals can be found on the SHS website.

A7.1 Ancillary and Sub-Study policy

Select the Ancillary and Sub-study Policy (PDF) link to access the PDF document with guidelines.



Select the SHS Online Ancillary Proposal Form for Ancillary studies and the SHS Online Sub-study Proposal Form Link for Sub-studies to submit the form to the SHS Steering Committee.



A7.2 Strong Heat Study Ancillary Study and Sub-Study Proposal Template

Please provide a description of the proposed study. The completed narrative should not exceed twelve (12) pages, per PHS 398 format (excluding literature citations and appended questionnaires and forms). The narrative should include the following: project summary, relevance, specific aims, research strategy (significance, innovation, and approach), references and resource sharing.

a) In the **summary,** state the application's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving the stated aims.
b) In addressing **relevance,** describe the relevance of this research to the aims of the SHS.
c) Under **specific aims**, state concisely the goals of the proposed study and summarize the expected outcome(s), including the impact that the results of the proposed study will exert on the research field.
d) In addressing **research strategy**, address significance, innovation and approach separately. If you have multiple aims, you may address significance, innovation and approach for each aim individually, or you may opt to do so collectively for all of the specific aims. The approach should include a formal sample size justification and statistical analysis plan.
e) When addressing **significance;**
    - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
    - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
    - Describe how the concepts, methods, technologies, treatments, services or preventive interventions that drive this field will be changed if the proposed aims are achieved.
f) When addressing i**nnovation**;
    - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
    - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).

g) When addressing **approach**;

A7.3 Agreement Form

Agreement for Strong Heart Study (SHS) Ancillary and Sub-study

To: Dr. Shelley Cole, SHS Steering Committee Chair

From: _____(Requestor)

Title/Institution/Address: _____

Title of project: _____

Please provide the following assurances (check each)

_____ The Study PI will report progress of the study as requested.

_____I agree to protect the confidentiality and privacy of the SHS participants and the security of the data. I will not seek, transfer, or disclose any individually identifiable information about any SHS participant at any time. Violation of this confidentiality agreement is considered a serious breach of ethical conduct and may leave me, my colleagues, and my institution liable to legal action on the part of the affected SHS participants and their families. I agree that the SHS data provided to me by the SHS Coordinating Center are to be used **only** for the research as described in the attached research protocol. **I promise not to share or distribute the SHS data to anyone else. I further agree not to use the data for commercial purposes, profit, or patents.**

_____Data collected by the Ancillary Study or Sub-study, with documentation, will be provided to the SHS Coordinating Center for integration into the main database, one year after data collection has been completed. The ancillary study PI is given the first and exclusive opportunity to analyze, present and publish data collected by the ancillary study, with certain conditions, when appropriate. Collaboration with the study investigators who collected the data is required. A study PI who wishes to extend the period of protected use must send a written request with justification to the Steering Committee for review. SHS manuscript proposal policies will be followed in all cases.

_____For each paper I wish to write from this research study using the SHS data, I agree to comply with the SHS Publication Policy (http://strongheartstudy.org) and to submit a paper proposal for review and approval of the SHS Publications and Presentations (P&P) Committee. As described in the policy, further approvals from the National Heart, Lung, and Blood Institute (NHLBI), the Indian Health Service (IHS), and the participating tribes will be needed prior to publication in any journal. **If approval from the SHS P&P Committee, the NHLBI, the IHS, or the participating tribes is not granted, I agree not to publish these results.** I understand that the SHS P&P Committee or Steering Committee will assist me in revising my paper in such a way that will make it acceptable to the above-mentioned entities. I will send a reprint of my published article to the NHLBI Program office, and all others as detailed in the **SHS P&P Publication Policy.**

Signed: _____

Date: _____

Proposal request number (to be assigned by the SHS Coordinating Center): _____

A7.4 SHS OSMB Ancillary Study Participant Burden Form

Strong Heart Study (SHS) Ancillary Study

Summary & Participant Burden

Study Title:	
Principal Investigator (PI):	
PI email address:	
PI Institute, address, phone contact:	
SHS investigator(s):	
Funding agency:	
Due date to funding agency:	
Funding Solicitation, if applicable:	
Project Period:	
Number of participants from SHS Cohort/SH Family Study:	
Feasibility of conducting measures/study in the participating American Indian communities	
Contribution to American Indian health:	
Contribution to SHS study:	
Participating SHS Centers: (Please specify center and summary of involvement)	
Plans for tribal review & approvals:	

Abstract, Specific Aims, and Study Design (2 pages maximum length):

Participant Burden: Intervention, Procedure, Questionnaire Data

	Description of type of data to be collected	# of participants	Estimated time in minutes to administer	Additional time (e.g. transportation, pr or follow-up contact)
a.	Informed consent			
b.				
c.				
d.				

Use of Existing SHS Data

Type of Data	# of participants	Timepoint (e.g., baseline, SHS2)	Specific measure or variable (be specific e.g., list each separately)

Repository Burden: Sample Volume and Analytes

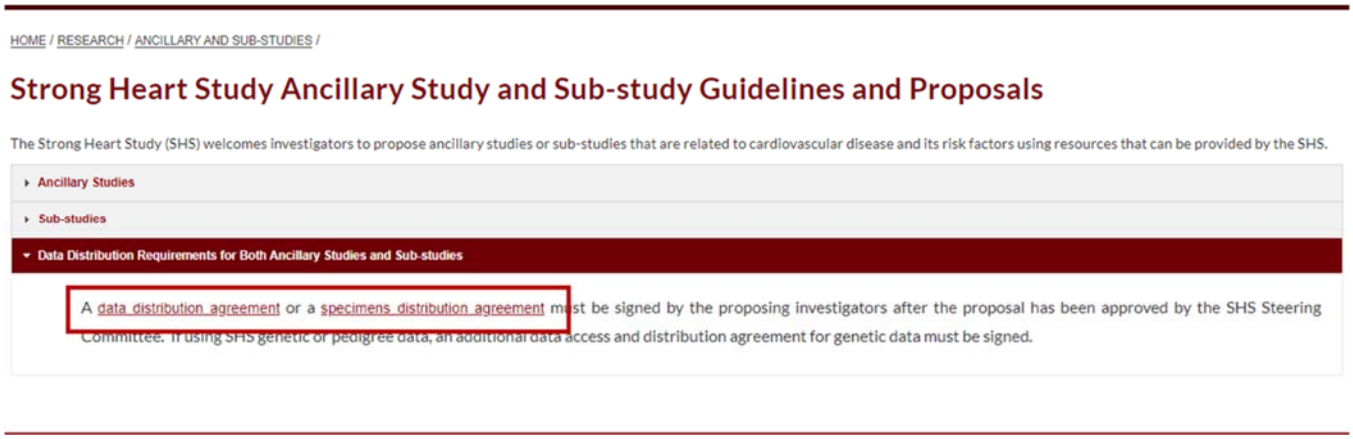
Type of Specimen	# of samples	Volume Requested	Timepoint (e.g., baseline, SHS2)	Specific proposed lab and analytes at each lab (be specific e.g., list each separately)

Approvals

Original submission date to SHS:	
SHS Steering Committee approval date:	
OSMB approval date:	
Resubmission date, if applicable:	
Modification request & approval dates, if applicable (note modifications in tables, above):	

A7.5 Data Distribution Requirements

Select the Data distribution agreement link to request clinical data and sign the data distribution agreement form. Select the specimens distribution agreement link to request specimen data and sign the specimen distribution agreement.



Agreement for Strong Heart Study (SHS) Data Distribution

To: Kimberly Malloy, SHS Coordinating Center

From: _____
(Requestor)

Title/Institution/Address: _____

Title of project: _____

I agree to read and follow the SHS protocol with regard to proper use of SHS data that I receive for my project. I have attached a copy of the protocol/proposal describing how I will use these data to better understand cardiovascular disease and related diseases in American Indians.

I agree to protect the confidentiality and privacy of the SHS participants and the security of the data. I will not seek, transfer, or disclose any individually identifiable information about any SHS participant at any time. Violation of this confidentiality agreement is considered a serious breach of ethical conduct and may leave me, my colleagues, and my institution liable to legal action on the part of the affected SHS participants and their families. I agree that the SHS data provided to me by the SHS Coordinating Center are to be used **only** for the research as described in the attached research protocol. **I promise not to share or distribute the SHS data to anyone else. I further agree not to use the data for commercial purposes, profit, or patents.**

For each paper I wish to write from this research study using the SHS data, I agree to comply with the SHS Publication Policy (http://strongheartstudy.org) and to submit a paper proposal for review and approval of the SHS Publications and Presentations (P&P) Committee. As described in the policy, further approvals from the National Heart, Lung, and Blood Institute (NHLBI), the Indian Health Service (IHS), and the participating tribes will be needed prior to publication in any journal.

If approval from the SHS P&P Committee, the NHLBI, the IHS, or the participating tribes is not granted, I agree not to publish these results. I understand that the SHS P&P Committee or Steering Committee will assist me in revising my paper in such a way that will make it acceptable to the above-mentioned entities. I will send a reprint of my published article to the NHLBI Program office, and all others as detailed in the **SHS P&P Publication Policy.**

Signed: _____
Date: _____

Data request number (to be assigned by the SHS Coordinating Center): _____

Specimen Storage Policy
Sample Use Agreement

The Strong Heart Study release tracking number _____

The release of the Strong Heart Study samples is subject to the following policies and procedures. No samples will be released until the investigator agrees to the following policies and procedures approved by the Steering Committee:

1. Samples can be released to foster specific meritorious and ethical research as outlined in the consent forms. The specific use is subject to prior approved scientific review of the Steering Committee and the NHLBI. The laboratory releases samples only after written instructions are received from the Steering Committee.
2. Released samples can only be used for the approved measurements in the specified laboratory and unused samples are to be returned in good condition to MedStar and/or TBRI with documented history of the uses of each sample including a log of freeze thaw cycles. The investigator must supply MedStar and/or TBRI with the name, phone number, E-mail address and shipping address of the person responsible for receiving the samples.
3. The samples will be released for a period of __ days ending on (dd/mm/yyyy). At the termination of this period, the investigator must either return the samples to MedStar and/or TBRI, or request and receive permission from the Steering Committee for a specified extension to complete the analyses.
4. Samples must be returned to the MedStar and/or TBRI with any remaining material at the completion of the approved use period as described above. Samples should be returned in their original containers with the original label. Samples are to be shipped under conditions specified by the Medical or Technical Director of the MedStar Central Core Laboratory and Biorepository and/or Director of the Genetics Center Lab at TBRI. Unused samples must not be discarded.
5. Data derived from the use of these samples are the joint property of the Steering Committee and the investigator. Publication of the results of these investigations is subject to the policies and prior approval of the Publications Committee, the NHLBI and the appropriate tribal councils.
6. The investigator acknowledges and abides by the informed consent document limiting use of these specimens for the study of cardiovascular disease and its risk factors and specimens will only be used for those purposes. The samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

I have read the sample storage policies and understand that the samples must be used only for uses approved in writing by the Steering Committee. I agree to abide by the limitations set forth in these policies.

Printed name: _____ Date: _____

Signature: _____

_____
Address, city, state, zip, phone number, e-mail address

Appendix 8 Project Summaries of Funded Phase VII Ancillary Studies

A8.1 Gut microbiome, aging and cardiometabolic diseases in American Indians

Project Number 1R01AG068865-01

Contact PI/Project Leader ZHAO, JINYING

Awardee Organization UNIVERSITY OF FLORIDA

PROJECT SUMMARY
Aging and age-related cardiometabolic diseases (CMDs) such as obesity, type 2 diabetes, hypertension, cardiovascular disease, and chronic kidney disease, along with their risk factors (e.g., insulin resistance, inflammation, dyslipidemia, etc.), result from the complex interplay between genetic, lifestyle, and environmental factors. American Indians (AIs) suffer disproportionately from these chronic cardiometabolic conditions. Gut microbiota (bacteria, viruses, fungi, multicellular parasites, and archaea in our intestine) has emerged as a novel, metabolically active "organ" that regulates many key biological processes and physiological functions. Gut dysbiosis (imbalance in gut microbial community, e.g., loss of microbial diversity or beneficial microbes, expansion of pathogenic microbes) has been associated with chronic metabolic disorders. However, several fundamental knowledge gaps exist, e.g., what are the key microbial signatures associated with aging and CMDs? What host factors shape the gut flora and how? What are the specific microbes or microbial species in human gut, and how does their composition and function differ across different populations/ethnic groups? Is the variation in human gut microbiota influenced by host genome, and if so, to what extent? Despite these unknowns, it is well accepted that the gut microbiome varies significantly among individuals and its composition heavily depends on an individual's age, gender, geography, dietary preference, lifestyle, health status, etc. Since AIs suffer from high rates of obesity and diabetes, live on reservations or other tribal lands, eat traditional food and medicine, and practice other unique lifestyles, it is possible that they harbor different sets of disease- and health-associated gut microbiomes compared to other populations/ethnic groups. The objectives of this study are to address these fundamental questions by generating the first complete map of the human gut microbiome and identifying key microbial features associated with aging and CMDs in American Indians. To achieve this, we will leverage the parent SHS Phase VII (funded by NHLBI as a contract, 2019-2026) that will re-exam all living participants (N~=3,000) in 2020-2024 to collect stool samples from 1,500 well-phenotyped AI participants. We will conduct whole-genome shotgun metagenomic sequencing and perform innovative statistical analyses to: (1) identify key age-related gut microbiome features associated with biological aging (assessed by leukocyte telomere length) and CMDs (Aim 1); (2) identify host factors that shape the human gut microbiota in AIs (Aim 2); (3) explore the mechanistic links between gut dysbiosis, aging, and CMDs (Aim 3). Our long-term goal is to understand the mechanisms through which gut microbes interact with host factors in leading to accelerated aging and CMDs, with an ultimate goal to develop novel, precision therapeutic interventions (e.g., diet, drugs, live organisms, fecal microbiota transplantation) to promote healthy aging and improve cardiometabolic health.

A8.2 Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study

Project Number 5R01AG070822-02

Contact PI/Project Leader SUCHY-DICEY, ASTRID M

Awardee Organization WASHINGTON STATE UNIVERSITY

PROJECT SUMMARY When life stresses are especially intense, chronic, or overwhelming, deleterious health effects can occur, including inflammation, cardiovascular disease, disability, depression, low quality of life, and dementia. In this context, resilience can be defined as the ability to maintain a healthy aging trajectory despite adverse conditions of stress. American Indians (AI) have a unique history and ongoing experience of trauma and disparities in environmental and socioeconomic conditions, which amplify daily stresses and contribute to health risks. Despite these adverse circumstances, remarkable resilience has been described in AI populations. Recent work by our group suggests that social support and alignment with Native culture correlate with lower levels of stress, negativity, anger, hostility, depression, mortality, and cardiovascular disease. However, our findings on cultural alignment are limited, and none has yet explored associations of resilience and social support. It remains an open question whether neurodegenerative conditions such as Alzheimer's disease and related dementias (ADRD) can result from chronic stress, or whether individual psychosocial characteristics such as resilience can mediate such risk. We propose to address these knowledge gaps by efficiently leveraging an existing effort funded by the NHLBI in the Strong Heart Study, a longitudinal cohort of AI adults from 13 tribal communities across the US. The existing contract covers recruitment, consenting, and basic clinical examination of 3,000 eligible participants in 20222024; we propose to augment the limited protocol by administering additional psychosocial and neuropsychological instruments on resilience, social support, cultural identity and alignment, and cognition. Our Specific Aims are to: describe associations of individual resilience among AI adults with identity and self-regard, social support, and cultural alignment, by age and sex; evaluate resilience, social support, and cultural features in relation to ADRD; and use machine learning to develop explanatory models of resilience and dementia. Our study has the potential to advance epidemiologic knowledge of modifiable psychosocial conditions in a vulnerable, underserved population, and consequently to offer a clearer picture of the relative contributions of psychosocial, behavioral, interpersonal, and socioeconomic factors related to ADRD.

A8.3 The Epitranscriptomic as a Novel Mechanism of Arsenic-Induced Diabetes

Project Number1R01ES032638-01

Contact PI/Project Leader NAVAS-ACIEN, ANA Other PIs

Awardee Organization COLUMBIA UNIVERSITY HEALTH SCIENCES

PROJECT SUMMARY in the United States, the prevalence of type 2 diabetes mellitus (T2DM) is particularly high among American Indian (AI) communities. Arsenic (As), a pervasive environmental contaminant disproportionately affecting AI communities, may explain this increased risk. Arsenic induces oxidative stress and systemic low-grade inflammation leading to β-cell dysfunction and insulin resistance in target tissues. However, the impact of As on T2DM has been disputed due to a lack of coherent mechanism for these findings. Previous studies have focused on epigenomic mechanisms (e.g., DNA methylation, histone modifications), overlooking downstream regulatory mechanisms that can more directly shape phenotypes. We propose to investigate the RNA modification N6- methyladenosine (m6A), the most prevalent epitranscriptomic modification on messenger RNA, which is directly involved in the cellular stress response. In experimental systems, arsenic induces a m6A response. m6A also modulates key processes underlying T2DM pathogenesis, including immune response and systemic inflammation. m6A is controlled by a group of proteins called reader, writer, and erasers (RWEs), responsible for adding, interpreting, and removing m6A marks. Fat mass and obesityassociated protein (FTO) is one example of an arsenic-sensitive m6A eraser with strong ties to T2DM and glucose homeostasis. Our pilot study in elderly men exposed to low-level arsenic supported these findings. We propose to test the hypothesis that altered m6A and RWEs are plausible mechanisms for As-related T2DM in the Strong Heart Study (SHS). The SHS is an ongoing longitudinal study in AI communities in Arizona, Oklahoma, and North/South Dakota with detailed clinical data for T2DM and metabolic syndrome (MetS). The SHS has measured speciated As exposure data covering childhood and adult exposure windows, both independently associated with T2DM in previous research. Leveraging the cohort design, exposure and phenotypic data, infrastructure, and study team, we propose to conduct epitranscriptomic analysis of mRNA m6A profiles via m6A sequencing and measure mRNA expression of 20 RWEs using whole blood from 1100 participants at the upcoming SHS follow up visit (scheduled for 2022- 23).

Our specific aims are to: 1) determine the association of past and current As exposure with epitranscriptomic profiles of m6A and RWEs mRNA expression levels in blood; 2) determine the association of blood m6A epitranscriptomic profiles with metabolic markers and MetS, clinical T2DM prevalence, and T2DM control (glycated hemoglobin, albuminuria); 3) develop a predictive m6A fingerprint that quantifies the risk of T2DM due to As exposure using machine learning approaches. For aims 1 and 2 we will further use Mendelian randomization to assess causal relationships. Characterization of m6A profiles in a population of AI adults highly impacted by T2DM will reveal biological features linking a pervasive toxicant such as As to diabetes. In addition to leading to interventions to reduce As exposure in the US and globally, defining the roles of m6A and RWEs in T2DM may contribute to new targets for future diabetes therapies.

A8.4 Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study

Project Number1RF1AG071677-01
Former Number1R01AG071677-01

Contact PI/Project Leader BARBOSA-LEIKER, CELESTINA

Awardee Organization WASHINGTON STATE UNIVERSITY

PROJECT SUMMARY Every 65 seconds someone in the US is diagnosed with Alzheimer's Disease and Related Dementias (ADRD). American Indian (AI) adults have greater burden of cerebrovascular and ADRD-related comorbidities than their non-Hispanic white counterparts. AI adults also suffer disproportionate stress and trauma, and concomitant high rates of depression. Relatedly, AI adults also have high rates of substance misuse compared to other racial/ethnic groups. These public health problems become exacerbated as a population ages, since stress, depression and substance use have been linked to cognitive impairment later in life. Fortunately, improvements to health-related quality of life (HRQoL) and community connectedness may ameliorate these negative impacts, although none of these associations have been fully evaluated in AI adults. As impaired cognitive performance precedes development of ADRD, we will determine risk and protective factors of cognitive performance in AI adults to inform prevention strategies to potentially circumvent later development of ADRD. Longitudinal relationships between psychological risk factors and cognitive impairment need to be directly evaluated to examine the temporal sequence of clinical changes that occur with aging. Additionally, research testing the longitudinal relationship with cognitive performance and dementia in AI adults is missing. Established, longitudinal cohort studies offer opportunity to assess modifiable risk and protective factors in aging adults, with multiple data collections. Given these gaps in knowledge, our objectives are to test the longitudinal relationship among stress, depression, and substance use (alcohol, tobacco, prescription opioids) with cognitive performance in AI adults, and whether HRQoL and community connectedness moderate these relationships. Our central hypothesis is that higher stress results in higher depression, more substance use and especially misuse, and that all three are associated with lower cognitive scores, whereas better HRQoL and better community connectedness moderate these deleterious effects. Using the psychometrically-robust NIH Toolbox, we will also test and develop normative standards for the AI community, making it possible for the first time to directly compare AI cognitive data with non-Hispanic white, Asian, African-American, and Hispanic adults.

Our proposed study is in partnership with the Strong Heart Study, a 30-year cohort of aging AI adults. We propose to collect these psychological and cognitive data in a follow-up examination (N=3,000). Defining associations among stress, depression, substance misuse, HRQoL, and community; and defining cognitive standards in a commonly used, established platform will inform future public health prevention and treatment strategies for this underserved, overburdened population.

A8.5 Chronic respiratory diseases among Native Americans: The Strong Heart Study

Funding: OUHSC College of Medicine Research Fund

Principal Investigator: Huimin Wu, MD MPH, Pulmonary section, Department of Medicine, University of Oklahoma Health Sciences Center (OUHSC)

PROJECT SUMMARY With an aging of the world's population, chronic respiratory diseases, such as chronic obstructive pulmonary disease (COPD) and asthma are becoming a more prominent cause of death and disability. Patients with chronic respiratory diseases are most at risk of severe illness from Coronavirus disease 2019 (COVID-19). Chronic respiratory diseases have higher prevalence in Native Americans than in other races and significant impact to Native American communities. However, the respiratory health needs of Native Americans have rarely been systematically assessed. We propose a pilot study with the goal to evaluate chronic respiratory disease status and assess barriers to respiratory healthcare among Native Americans. In this cross-sectional pilot study with SHS cohort, survey and spirometry will be conducted. The study aims to assess the chronic respiratory symptoms, treatment, respiratory knowledge, attitude, behavior, potential barriers to respiratory healthcare and lung function.

A8.6 Cognition After (OSA)Treatment in Native American People (CATNAP)

Project Number P01AG066584

Contact PI/Project Leader BUCHWALD, DEDRA

Awardee Organization WASHINGTON STATE UNIVERSITY

PROJECT SUMMARY Obstructive sleep apnea (OSA) is a complex disorder characterized by episodes of complete (apnea) or partial (hypopnea) obstruction of the upper airway during sleep. Prevalence among older adults in the US is as high as 56%. Short-term neurological consequences of OSA include excessive daytime sleepiness and cognitive changes such as poor attention and impaired executive function,3 although the mechanisms for these associations are unclear. OSA increases risk of Alzheimer's disease and related dementias (ADRD)6 and mild cognitive impairment (MCI), and alters ADRD biomarkers such as cerebrospinal fluid amyloid beta protein, deposition of amyloid beta protein measured by PET scan, and brain morphology measured by MRI. A metanalysis estimated 15% of Alzheimer's disease risk may be attributed to sleep problems. Another study found prevalent OSA in 89% of patients with mild ADRD. Behavioral changes (e.g., weight loss, sleeping position) can improve OSA in some individuals. Positive airway pressure (PAP) therapy is considered the gold standard treatment for OSA and improves cognition in clinical trials,16-21 including in patients with ADRD. However, PAP therapy requires wearing a cumbersome apparatus while sleeping and adherence may be low, especially among minorities and people with low socioeconomic status. Research by our group and others suggests that ADRD and MCI are common and often undetected among older American Indians (AIs). OSA is linked to vascular disease through a complex pathophysiology, and AIs experience disparities in vascular disease risk factors (e.g., obesity, hypertension, diabetes) that contribute to development of cognitive impairment and dementia. Notably, compared to other minority groups, AIs have the highest prevalence of obesity (40% to 44%), a major risk factor for both OSA and ADRD. Yet, no reliable population-based estimates of OSA prevalence exist for AIs, although a multicenter cohort study found that AIs had 1.7 times higher odds of OSA and more often reported breathing pauses during sleep than Whites. These scant data suggest a disparity in this modifiable ADRD risk factor but OSA is likely underdiagnosed in AIs, given population-specific barriers to diagnosis. Evidence-based behavioral interventions that facilitate PAP adherence are available on which to base ADRD prevention programs for AIs with OSA

In this study, we will generate population-based estimates of OSA prevalence and its association with cognitive function in AIs. Next, we will develop a novel intervention, "Cognition After OSA Treatment Among Native American People" (CATNAP) to promote adherence to PAP therapy for OSA, then in a pragmatic randomized controlled trial (RCT), test whether CATNAP enhances adherence and improves cognitive function. Participants will be recruited from 2 study cohorts affiliated with the Strong Heart Study: the Strong Heart Family Study (SHFS) and the Cerebrovascular Disease and its Consequences in American Indians (CDCAI) study. The Strong Heart Study was conducted in Arizona, Oklahoma, and South Dakota and is the only population-based study of cardiovascular diseases in AIs.47-49 For the observational epidemiology component, we will screen all cohort members ages 55+ (n ≈ 450) living on 2 Northern Plains

reservations (South Dakota site) for OSA and cognitive function. Participants with suspected OSA will undergo testing with Watch PAT, an FDA-approved home sleep apnea diagnostic device. Participants whose results confirm OSA will be referred for PAP therapy and be eligible for the RCT, while those with indeterminate results will be referred for polysomnography to confirm OSA. Analyses will leverage existing data to identify fixed and time-varying risk factors for OSA. We will develop the CATNAP intervention to increase PAP adherence by using qualitative methods to revise motivational interviewing (MI) and electronic messaging protocols we have used with AIs. For the RCT, we will recruit 300 AIs ages 55+ who are receiving PAP therapy from the same 2 Northern Plains communities. In keeping with pragmatic trial principles, community members who are not SHFS or CDCAI members will be eligible for the RCT. Participants will be randomized to receive usual care of PAP therapy only (control), or usual care plus CATNAP (intervention). Data collected at baseline, 3 months (short-term effects) and 12 months (long-term effects) will include PAP adherence, sleep quality, cognitive function, and vascular risk factors for ADRD. Primary outcomes are PAP adherence and cognitive function, with the former evaluated as a mechanism for change in the latter. This unique study explores the relationship between OSA and cognitive function in an understudied, at-risk, frontier population of AIs with limited access to specialized healthcare. It also takes an important step toward evaluating OSA as a mechanism for the strong association between sleep disorders and ADRD.

A8.7 Health effects of metals in American Indian communities: a longitudinal multi-omics study

Project Number: 1P42ES033719

Contact PI/Project Leader NAVAS-ACIEN, ANA Other PIs

Awardee Organization COLUMBIA UNIVERSITY HEALTH SCIENCES

PROJECT SUMMARY Native American populations have higher rates of cardiometabolic disease, including cardiovascular disease (CVD) and diabetes, than any other racial/ethnic group in the US. In the Strong Heart Study (SHS), the most important study of CVD and its risk factors in Native American communities, we showed that long-term arsenic (As) exposure can explain part of the excess burden of cardiometabolic disease. Uranium (U) exposure is associated with CVD in occupational cohorts, but data from general populations are limited. Importantly, As and U are common contaminants in Superfund sites and tribal lands, so exposure to these contaminants could be partially responsible for increased rates of cardiometabolic disease in Native American populations. Advancing effective interventions for metal-related cardiometabolic diseases requires robust data on the lasting effects of past exposures, the joint effects of As and U, and the relevant mechanisms, including downstream molecular effects. To address these needs, we will establish the Strong Heart As/U Lifelong (SHAUL) study (n=1,300) by linking data from participants at SHS visit 1 (1989–91) with their offspring recruited during the SHS family expansion in 2001–03 (visit 4). We will leverage 30 years of data and a new visit planned for 2022–23 to address the following aims. (1) Determine the cardiometabolic effects (diabetes and CVD) of childhood and adult As and U exposures overall and by sex, region, and nutritional status. Urinary metal biomarkers are available at visits 1 (reflecting childhood exposure) and 4 (reflecting adult exposure), and will be measured at visits 5 (2006–09) and 7 (2022–23) to reconstruct lifelong exposures. Water metal data, including spatial patterns, temporal trends, and stable isotope data tracing potential sources, will be available from Projects 1 and 2. (2) Determine the longitudinal epigenetic and metabolomic effects of childhood and adult As and U exposures overall and by sex, region, and nutritional status. We will measure genome-wide DNA methylation (DNAm) at visits 4 and 5, leverage extant targeted and untargeted metabolomics from the same visits, and use a joint DNAm/metabolomic multi-omics strategy. (3) Develop a predictive multi-omics fingerprint that quantifies latent and concurrent cardiometabolic risk due to As and U exposures. We will use machine learning approaches to characterize DNAm and metabolomic profiles that identify individuals at risk of diabetes or CVD due to past or current metal exposures. We will also conduct a cross-species multi-omics comparison with Project 4's mouse data. Cardiovascular disease, diabetes, and metal exposures are major concerns for our partnering communities in the Northern Plains. By investigating the latent and concurrent effects of As and U exposures, the SHAUL study can reveal epigenetic and metabolomic mechanisms for metal-induced health effects, identify susceptible populations, and inform risk assessment. The findings will have direct implications for the prevention and control of water contaminants and cardiometabolic diseases in affected communities, including in the Northern Plains, near Superfund sites, and near other contaminated areas in the US and globally.

A8.8 Bilingualism as a protective factor of ADRD in American Indian adults: the Strong Heart Study

Project Number R01AG080398

Contact PI/Project Leader BARBOSA-LEIKER, CELESTINA

Awardee Organization WASHINGTON STATE UNIVERSITY

PROJECT SUMMARY American Indian populations have greater burden of cerebrovascular and Alzheimer's disease and Related Dementias (ADRD) comorbidities compared with non-Hispanic White U.S. populations and may also have greater burden of cognitive decline and dementia. Bilingualism—common in American Indian communities— may enhance working memory capacity, attentional control, and cognitive reserve, thus reducing cognitive risk. However, bilingualism is a highly individual experience, and the context of use can modify its cognitive effects. Factors that may influence this association include age, sex, vocabulary, physical and mental status, socioeconomic status, culture, and social activity. Comprehensively assessing the relationship between bilingualism and cognitive performance may be critical to fully understanding ADRD in American Indian adults. Although the link between bilingualism and cognitive reserve has been studied in many populations, bilingualism research in American Indian populations has been limited, due in part to critical cofactors related to their experiences, perspectives, and standardized assessments. Unjust United States (U.S.) federal policies affecting American Indian people included forced attendance at English-speaking boarding schools where use of Native languages was punished, and cultural assimilation was prioritized over quality of education. As a result, bilingualism in American Indian adults who attended such schools may present differently than for other populations. Indeed, NIA (RFA-AG-23-001) defines bilingualism as "proficiency in two or more languages", however no validated, detailed assessment of proficiency exists for U.S. Native languages, or for American Indian speakers of those languages. Our proposed study will be the first to culturally adapt a language use and history instrument in a large, heterogeneous American Indian population. In response to RFA-AG-23-001, we will leverage the Strong Heart Study, a large, longitudinal, heterogeneous, population-based study of aging in American Indian adults over 3 geographic regions (N=2,500). In this proposed work, we will build on this study, as well as our prior work, to assess the continuum of bilingualism in American Indian peoples by culturally adapting the Language History Questionnaire, evaluate bilingualism in American Indians of multiple generations in association with a detailed cognitive performance battery, and construct conceptual models to assess intervariable relationships including effect modification and moderation by crystallized cognition. This project will illuminate questions of public health significance in a vulnerable population that remains underrepresented in ADRD research, with potential implications for future prevention and treatment strategies.

Appendix 9 SHS Resource and Data Sharing Plan

Approved Strong Heart Study (SHS) ancillary and sub-studies use existing data available through the SHS databases. Any additional data generated through these studies are integrated into these databases at the end of the study following SHS policies and procedures. Those data will then be shared with the scientific community in accordance with the data sharing plan of the parent SHS.

Details of the process are described below.

A9.1 Resource and Data Sharing

Strong Heart Study data will be available for approved requests (by the SHS Steering Committee) and through the SHS Coordinating Center at the University of Oklahoma and the SHS Genetics Center at Texas Biomedical Research Institute. Summary data is shared with the scientific community in accordance with the data sharing plan of the parent SHS (which includes Data Use Agreements and anonymizing data to protect subject confidentiality). Results of research are returned to the Tribal entities through periodic dissemination.

The SHS and Strong Heart Family Study (SHFS) investigators actively partner with the SHS participating Tribes, each of them a sovereign nation, in order to conduct and administer the studies. As a result, SHS investigators are not at liberty to make unilateral decisions regarding any aspect of the various studies without prior approval of the respective Tribes. However, the Tribes participating in the SHS and SHFS have established protocols for Resource and Data Sharing which includes efficient review of all data requests by the Tribal entities representing the American Indian participants. These requests include those of ancillary and sub-studies, as well as approval of manuscripts and results contained therein prior to their publication. For SHS investigators, our goal is a process that respects the uniqueness of the inherent sovereignty of American Indian communities and that is agreeable to NIH leadership.

The ultimate goal of the SHS and similar studies is to conduct research within American Indian communities that will promote knowledge to address issues of health and at the same time provide assurance to the communities that research data are being used appropriately and in ways that do not harm the community or its members.

The American Indian participants of the SHS and SHFS have established limitations to broad data sharing. Broad, upfront, agreements to data sharing have not been given by SHS and SHFS participants or their Tribal representatives. The Tribes, while granting authority to share data, have presently placed restrictions upon distribution of certain data, particularly personalized and/or genetic data, even when the data are anonymized. Individual genotype and phenotype data are available to investigators through SHS and SHFS established protocols. Outside investigators may apply to use the data to be generated by this project through the established protocols for SHS Resource and Data Sharing, which include Tribal considerations, as described above.

A9.2 Genomic Data Sharing Plan

In response to the NIH Genomic Data Sharing Policy, in 2008 and 2009, Tribes partnering with the SHS passed Tribal resolutions reasserting and emphasizing their ownership of SHS data and samples, their continued partnership with SHS investigators to include their approval of any publication and/or dissemination of SHS data, and requested that a waiver of the NIH data sharing policy be granted by authority of the Executive Order 13175 entitled "Consultation and Coordination with Indian Tribal Governments". Based upon these Tribal resolutions, *the SHS cannot deposit individual-level data into public genomic databases, as the study could not meet the criteria for Institutional Certification*.

Efforts have been ongoing between the SHS and SHFS participants and the NIH, at both operational and policy levels, to develop a mutually beneficial approach to the use of genomic data. For instance, the SHS and SHFS have ongoing collaborations with iDASH, a NHLBI funded project which is developing tools for data sharing through secure data enclaves. This process is currently being assessed both by investigators and Tribes in order to develop a process that would respect and accommodate Tribal review of all such data analysis requests. At the policy level, the NIH has recently adopted a Tribal Consultation Implementation Policy as required by DHHS. This provides an opportunity for nation-to-nation negotiations to develop a genomic data sharing policy that addresses the interests of both NIH and the Tribes. A recent NIH Tribal Consultation Report on the NIH Draft Policy for Data Management and Sharing, dated September 24, 2020, emphasizes the role of Tribal sovereignty in a future data management and sharing policy. To supplement the policy, NIH intends to develop and disseminate guidance that promotes research partnerships between researchers, Tribal Nations, and urban AI/AN communities and that helps researchers respectfully manage and share data. The current NHLBI funding for the SHS specifies several meetings between NHLBI leadership and SHS Tribal leadership, where data sharing can be discussed. This study would then follow the mutually agreed upon policy created from these NIH Tribal Consultations.

1. Data Type: Genomic data (genotypic data) are available on ~7,000 American Indian participants of the SHS and SHFS. These include data generated using the Illumina Metabochip in the SHFS, and the Illumina MEGA chip in the SHS. Epigenetic data is available from the Illumina EPIC methylation array on SHS participants. Telomere length data are available on SHFS and a subset of SHS participants.

2. Data Repository: As described above, individual level SHS and SHFS genetic data are not available through public data repositories. Genomic and epigenetic data are available for Tribally approved studies through the SHS Genetics Center at Texas Biomedical Research Institute.

3. Data Submission and Release Timeline: Data from this study will be made available to investigators for SHS Tribally-approved requests at the time of first publication.

4. IRB Assurance of the Genomic Data Sharing Plan: The SHS data and resource sharing policies described above have been approved by the participating SHS Tribe's Tribal IRBs and Indian Health Service IRBs. The SHS cannot deposit individual-level data into public genomic databases, as the Tribal agreements and resolutions do not allow the SHS to meet the criteria for Institutional Certification.

5. Appropriate Uses of the Data: The SHS and SHFS were designed to address risk factors for cardiovascular disease. Consents allow for the study of cardiometabolic disease and its risk factors, and more recently for cancer, inflammatory, and autoimmune disease.

6. Request for an Exception to Submission: Submission of genetic data generated in a study would not be appropriate because the Institutional Certification criteria cannot be met. An alternative mechanism for data sharing has been described, above. The SHS and SHFS are registered in dbGaP.

Morbidity & Mortality Surveillance

Manual of Operations Volume II

Strong Heart Study Phase VII

September 28, 2023

Version 2.1

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

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Tracking of Revisions to Manual of Operations Volume II: Morbidity & Mortality Surveillance

Date of Revision	Revised Section	Revision	Approved by, Date
9/28/2023	Table of Contents	Remove track changes	SHS CC, 9/28/2023
5/18/2023	Section 3.7: List or Morbidity and Mortality Reviews	Remove Dr. Adrian Ruiz and Dr. Sunny Jhamnani as a mortality reviewer	SHS CC, 5/8/2023
4/27/2023	Section 3.5 Post-Scanning Procedures	Add instructions about uploading charts and assigning reviewers for non-fatal stroke events	SHS CC, 12/15/2022
4/27/2023	Entire document	Fixed formatting issues and broken web page links	SHS CC, 11/1/2022

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II. Morbidity and Mortality Surveillance

1. Mortality Surveillance

1.1 Eligible Population

The participants of the Strong Heart Study and Strong Heart Family Study are monitored in an on-going fashion to identify deaths and to determine causes of those deaths. Deaths are documented and abstracted whenever recognized by the Center staff. Of the original members of the Phase I cohort and the Family Study participants, it is estimated that as of February 15, 2019 (beginning of Phase VII), 3,174 surviving individuals are eligible for mortality surveillance for Phase VII.

1.2 Sources of Data

The following sources will be monitored on a regular basis to identify deaths in the cohort and family participants as they occur: local newspapers and community notices, community and tribal members, and Indian Health Service (IHS), tribal and Bureau of Indian Affairs (BIA) records. The respective State Health Departments will be contacted to obtain death certificates in the study communities for the deceased participants. Additionally, information will be obtained from the following sources:

1. A combined list from all three centers of deceased and lost to follow-up participants will be sent to the National Death Index for ascertainment of vital status (for lost to follow-up) and to obtain lists of ICD–9 and ICD–10 codes for cause of death.
2. A combined list of participants from all three centers will be sent to the Centers for Medicare and Medicaid Services to obtain information of the terminal hospital admission and all other admissions within one year of death.
3. A list of participants will be sent to the North American Association of Central Cancer Registries or specific state cancer registries to request cancer type, information about diagnosis (date, stage, grade, age at diagnosis, location and spread of tumor), treatment information, and outcomes.

1.2.1 Data for Cardiovascular (CVD) Events

All deaths will be investigated, regardless of the cause indicated on the death certificate. In order to conduct an independent, standardized review of participant deaths, the following types of information will be collected.

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 when medical records data are not sufficient or for deaths listed as "unknown" in death certificate.
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).

CVD deaths are documented and reviewed by the SHS Mortality Review Committee. Underlying and contributing causes of death will be coded. Each death will be coded by two members of the review committee, and discrepancies in CVD diagnosis will be adjudicated by Dr. James Howard and the Mortality Committee.

1.2.2 Data for Non-Cardiovascular Events

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, then abstract:
   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 DISEASES 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:
   a. Obtain all consultant reports when the cause is not clear-cut (e.g., cancer, septic shock, gunshot wound).

5. INTENTIONAL OR UNINTENTIONAL INJURY:
   a. Police and EMS reports, if available.
   b. Alcohol use information, including blood alcohol.

In addition, the SHS Mortality Review Committee will review the material obtained for each non-CVD death among SHS participants. Underlying and contributing causes of death will be coded. Each death will be coded by two members of the review committee.

1.3 Summary of Procedures for Mortality Surveillance

Eligible deaths outside of the study area are also included in the review and confirmation procedure.

The identification and confirmation of CVD deaths will involve the following steps: (1) identification of all deaths, (2) obtaining all death certificates, (3) obtaining Coroner's/Medical Examiner's report, (4) review medical records, and (5) independent confirmation of cause of death by the Mortality Review Committee.

1. Identification of all deaths
   All deaths will be identified by each center from tribal records, IHS hospitals, BIA, State Department of Health and/or the National Death Index. Persons who die out-of-state will be included.

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.

3. 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.

4. Review of Medical Chart
   Review medical chart to see if the decedent was hospitalized within one year prior to death and fill out Morbidity Survey Medical Records Abstract Checklist.

5. Confirmation of Cause of Death
   a. If the decedent was hospitalized within one year prior to death, the Morbidity Survey Medical Records Abstract Checklist will be completed for each morbid event. Mortality Survey Packet Checklist, the death certificate, the autopsy report, the Coroner's/Medical Examiner's report, and police report, if available. Checklist for Medical Records Review Mortality Surveillance with relevant medical records information, and Morbidity Survey Medical Records Abstract Checklist with relevant medical records are scanned into PDF files with redacted PHI. The PDF file will be uploaded to Reviewer Assignment & CC tracking form on REDCap.

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, the attending physician or nursing home staff, and an informant will be identified from the death certificate or other sources and contacted for an interview. The Informant Interview Form, and the Mortality Survey Packet 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 scanned into PDF files with redacted PHI. The PDF file will be uploaded to Reviewer Assignment & CC tracking form on REDCap.

c. The Informant Interview is done for: 1) deaths that were not medically attended, and 2) those that are requested by a member of the Mortality Review Committee. If there is any question as to whether or not an interview is needed in a particular circumstance, field staff should consult with their local Mortality Review Committee physician.

d. The two mortality reviewers will return the completed Final Decision Form to the Coordinating Center for data entry. Discrepancies in CVD diagnosis will be adjudicated by Dr. James Howard.

2. Morbidity Surveillance

2.1 Eligible Population

Non-fatal events, cardiovascular events and other events of interest will be identified among surviving SHS cohort members and the SHS Family Study participants in the three study areas through annual contacts or review of medical records, and through interviews of the participants at their Phase VII examination. Events of interest are those occurring since the last follow-up. Some prior events that were inadvertently missed may also be picked up during Phase VII surveillance.

2.2 Identification of New and Recurrent Events of Interest

Identification of non-fatal CVD events in the SHS cohort will continue in Phase VII. Participants will first be recruited and consent to the SHS-VII. Once consent is obtained, the participant will be contacted annually or their IHS records will be reviewed. These events include non-fatal myocardial infarction (MI), coronary heart disease, stroke, new diagnoses of congestive heart failure (CHF) and atrial fibrillation (AFIB), kidney failure, liver diseases, cancer, and inflammatory conditions. 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.

Criteria used to define acute MI, stroke, and congestive heart failure in Phase VII are the same as those previously used by the SHS. These criteria were derived primarily from the International Diagnostic Criteria, the Atherosclerosis Risk In Communities study (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.

In addition to the CVD events, cancer, liver diseases, and certain inflammatory conditions are added to the Phase VII surveillance.

2.3 Procedures for Morbidity Surveillance

The morbidity survey will involve the following steps:

2.3.1 Identification of Potentially Eligible Case

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 in the Phase VII examinations will 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 or ICD-10 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-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Hypertensive heart disease	I11.X	402
Acute myocardial infarction	I21.X	410.X
Other acute and subacute forms of ischemic heart disease	No Equivalent Code	411
Post-myocardial infarction syndrome	I24.1 (Dressler's syndrome)	411.0
Intermediate coronary syndrome	I20.0 (Unstable angina)	411.1
Other acute and subacute forms of ischemic heart disease	124.0, 124.8	411.8X
Old myocardial infarction	I25.2	412
Angina pectoris	I20.X	413.X
Other forms of chronic ischemic heart disease	I25.X	414.X
Cardiac dysrhythmias	I46.9, I47.X, I48.X, I49.X, R00.1	427.X

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

Disease	**ICD – 10**	**ICD – 9**
Heart failure	No Equivalent Code	428.
Congestive heart failure, unspecified	I50.9 (Heart failure, unspecified)	428.0
Left heart failure	I50.1 (Left ventricular failure)	428.1
Systolic heart failure	I50.20 - I50.23	428.2X

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

Disease	**ICD – 10**	**ICD – 9**
Acute edema of lung, unspecified	J81.0 Acute pulmonary edema	518.4

2. Cerebrovascular Disease (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Subarachnoid hemorrhage	I60.9 Nontraumatic subarachnoid hemorrhage, unspecified	430
Intracerebral hemorrhage	I61.9 Nontraumatic intracerebral hemorrhage, unspecified	431
Other and unspecified intracranial hemorrhage	No equivalent ICD-10-CM Code	432
Nontraumatic extradural hemorrhage	I62.1	432.0
Subdural hemorrhage	I62.00 Nontraumatic subdural hemorrhage, unspecified	432.1
Unspecified intracranial hemorrhage	I62.9 Nontraumatic intracranial hemorrhage, unspecified	432.9
Occlusion and stenosis of precerebral arteries - includes embolism, narrowing, obstruction or thrombosis of basilar, carotid, and vertebral arteries	I63.X, I65.X	433, 433.0X, 433.1X, 433.2X, 433.3X, 433.8X, 433.9X
Occlusion of cererbral arteries	I63.X, I66.X	434, 434.0X, 434.1X, 434.9X
Transient cerebral ischemia	G45.X, I67.848	435, 435.0 – 435.3, 435.8, 435.9
Acute, but ill-defined, cerebrovascular disease, - includes CVA, NOS, Stroke	I67.89 Other cerebrovascular disease	436
Other and ill-defined cerebrovascular disease - includes cerebral atherosclerosis, chronic cerebral ischemia, hypertensive encephalopathy, cerebrovascular disease or lesion not otherwise specified	G45.4, I67.X	437, 437.0 – 437.9
Late effects of cerebrovascular disease	I69.9X	438, 438.0X – 438.9X

3. End Stage Renal Disease (ICD-10 and ICD-9 Codes)

Disease/Procedure	**ICD – 10**	**ICD – 9**
Hemodialysis	5A1.D00Z, 5A1.D60Z	39.95
Peritoneal dialysis	3E1.M39Z	54.98
Kidney transplant	0TS.00ZZ, 0TS.10ZZ 0TY.00Z0, 0TY.00Z1, 0TY.00Z2, 0TY.10Z0, 0TY.10Z1, 0TY.10Z2,	55.6, 55.61, 55.69
Chronic kidney disease (CKD) that includes CKD stage I-V, end stage renal disease, and other CKD	N18.1 – N18.6, N18.9	585, 585.1 – 585.6, 585.9
Renal failure, unspecified	N19	586

It is only necessary to identify and collect chart information for the FIRST time one of these diagnoses was made.

4. Chronic Valvular Heart Disease (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Diseases of mitral valve	I05.0 – I05.2, I05.8	394, 394.0 – 394.2, 394.9
Diseases of aortic valve	I06.0 – I06.2, I06.8, I06.9	395. 395.0 – 395.2, 395.9
Diseases of mitral and aortic valves	I08.0, I08.8, I08.9	396
Mitral valve disorders	I34.0, 134.8	424.0
Aortic valve disorders	I35.0 - I35.2, I35.8, I35.9	424.1

5. Aortic Aneurysm (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Dissection of aorta	I71.00 – I71.03	441.0, 441.00 - 441.03
Thoracic aneurysm, ruptured	I71.1	441.1
Thoracic aneurysm without mention of rupture	I71.2	441.2
Abdominal aneurysm, ruptured	I71.3	441.3
Abdominal aneurysm without mention of rupture	I71.4	441.4
Aortic aneurysm of unspecified site, ruptured	I71.5	441.5
Thoracoabdominal aneurysm, ruptured	I71.6	441.6
Thoracoabdominal aneurysm, without mention of rupture	I71.7	441.7
Aortic aneurysm of unspecified site without mention of rupture	I71.9	441.9

6. Procedures for Treatment of Peripheral Vascular Disease (ICD-10 and ICD-9 Codes)

Procedures	**ICD – 10**	**ICD – 9**
Aorta-iliac-femoral bypass	041X	39.25
Other (peripheral) vascular shunt or bypass	031X, 041X, 051X, 061X	39.29
Angioplasty of other non-coronary vessel(s)	027X, 037X, 047X, 057X, 067X	39.50
Lower limb amputation, not otherwise specified	0Y6.CX, 0Y6.DX, 0Y6.HX, 0Y6.JX	84.10
Arteriography of femoral and other lower extremity arteries	B40.FX, B40.GX, B40.JX, B41.FX, B41.GX, B41.JX	88.48

7. Cancer
   a. Only abstract records that mention diagnoses for these conditions. Do not abstract further records of treatment for these conditions.

   b. If pathology report is available indicating the type of cancer, include this report in the PDF file for the reviewers; and check the "Pathology" checkbox in the Mortality Surveillance Checklist (for mortality event) or put a check mark in the "Yes" column in the "Other, specify:" item in the Morbidity Surveillance checklist for morbidity event.

8. Liver Disease
   Only abstract records that mention diagnoses for these conditions. Do not abstract further records of treatment for these conditions.

9. Inflammatory Conditions
   For inflammatory conditions, field centers should abstract the following diagnoses:
   Osteoarthritis
   Rheumatoid arthritis
   Systemic lupus erythematosus (SLE)
   Psoriatic arthritis
   Ulcerative colitis
   Crohn's disease
   Regional ileitis
   Sjogren's syndrome
   Scleroderma
   Juvenile rheumatoid arthritis
   Ankylosing spondylitis
   Iritis, uveitis
   Thyroiditis
   Anti-phospholipid syndrome
   Dermatomyositis
   Polymyalgia rheumatic
   Any form of "nephritis" and IgA nephropathy
   Kawasaki disease
   Mixed connective tissue disease
   Polyarteritis nodosa
   Primary sclerosing cholangitis (should have been captured by screen for hepatic disease as well)
   Raynaud's phenomenon
   Temporal arteritis

2.3.2 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 by the abstractor. 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.

2.3.3 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 Morbidity Survey Medical Records Abstract Checklist for that admission should be completed. If evidence is present suggesting that one or more myocardial infarctions or strokes occurred, a separate medical record 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 should be arranged in chronological order from earliest to latest.

2.3.4 Confirmation and Diagnosis

The collected medical records of the interested events will be redacted for PHI and scanned into PDF file. The scanned file will then be uploaded to the SHS Morbidity & Mortality Surveillance 2022-2026 REDCap database.

2.3.5 CMS Data Acquisition

We will obtain Centers for Medicare and Medicaid Services (CMS) data for those who give us the permission to use them. CMS data will capture events missed during regular surveillance. If any is found, we will follow the procedure described above to prepare the packet for review.

2.3.6 Linkage to Cancer Registries

A list of participants will be sent to the North American Association of Central Cancer Registries or specific state cancer registries to request cancer type, information about diagnosis (date, stage, grade, age at diagnosis, location and spread of tumor), treatment information, and outcomes

3. Morbidity and Mortality Surveillance Procedures

3.1 Guidelines for Outpatient Tests

These guidelines should be used in the PDF files for the reviewers:

1. Echocardiogram
   a. Do not include reports showing only mild valvular abnormalities; include reports with moderate and severe valvular abnormalities
   b. Do not include reports only showing left atrial enlargement.
   c. Do not include reports only showing small pericardial effusion.
   d. Do not include reports only showing left ventricular hypertrophy.
   e. If multiple outpatient echocardiograms were done during the time frame of 2009 to present, include only the latest report – unless earlier reports show important findings that are not present in the latest report.

2. Carotid Ultrasound
   a. Do not include reports showing less than 70% obstruction. However, in the presence of stroke or TIA, carotid ultrasound reports showing any degree of obstruction or no obstruction should be included.

3. Stress Test
   a. Do not include normal reports

4. Holter Monitor
   a. Upload only the cover page that contains summary of findings\

5. Computed Tomographic Calcium Scoring
   a. In the event when this test is done as a stand-alone test, reviewers will only complete Cardiovascular Test and Procedures Abstract form.

3.2 Guidelines for Abstracting Recurrent CHF and AFIB Events

For recurrent CHF and AFIB events, abstract no more than three hospitalizations or outpatient visits for these events.

3.3 Guidelines for Abstracting Non-CVD Events

Only abstract records that mention diagnoses of inflammatory conditions, cancer, or liver diseases. Do not abstract further records of treatment for these conditions.

1. For inflammatory conditions, field centers should abstract the following diagnoses:

   Osteoarthritis
   Rheumatoid arthritis
   Systemic lupus erythematosus (SLE)
   Psoriatic arthritis
   Ulcerative colitis
   Crohn's disease
   Regional ileitis
   Sjogren's syndrome
   Scleroderma
   Juvenile rheumatoid arthritis
   Ankylosing spondylitis
   Iritis, uveitis
   Thyroiditis
   Anti-phospholipid syndrome
   Dermatomyositis
   Polymyalgia rheumatic
   Any form of "nephritis" and IgA nephropathy
   Kawasaki disease
   Mixed connective tissue disease
   Polyarteritis nodosa
   Primary sclerosing cholangitis (should have been captured by screen for hepatic disease as well)
   Raynaud's phenomenon
   Temporal arteritis

2. For cancer diagnoses:

   If pathology report is available indicating the type of cancer, include this report in the PDF file for the reviewers; and check the “Pathology” checkbox in the Mortality Surveillance Checklist (for mortality event) or put a check mark in the “Yes” column in the “Other, specify:” item in the Morbidity Surveillance checklist for morbidity event.

3.4 Pre-Scanning Procedures

1. Stamp SHS ID number: on each page of participants' medical records.

2. Redact Participant Personal Information: Participants' personal information must be redacted (either with a secure redacting marker or by using the redaction tool in Adobe Acrobat) before uploading their files to the SHS REDCap site.

3. Scanning Order for Multiple Events:
   a. For participants with multiple events, organize events in reverse chronological date order, i.e., put latest event at the beginning and earliest event at the end.
   b. All events should be separated by Morbidity and/or Mortality Checklists.
   c. Using Morbidity Checklist for outpatient tests, procedures, and consultations will be left up to the discretion of the field sites.

4. Scanning Documentation Order for Each Event: Organize medical records for each event in the Scanning Documentation Order provided in **Appendix 1**.

5. For Mortality Files organize medical records in the following order:
   a. Put the Mortality Survey Packet Checklist and include death certificate, autopsy report (if done) and informant interview (if done).
   b. Then the Mortality Checklist and include the most recent discharge summary or other clinical information immediately preceding the death.
   c. Then previous CVD related discharges for past year in reverse chronological date order. Non-CVD discharges not needed in most cases.

6. For Morbidity Files: A single PDF File should be created even if a participant had multiple events.

3.5 Post-Scanning Procedures

1. Naming of PDF File: Name the PDF file using the format shown in the examples below:
   a. Name Morbidity file as follows: 203557MB2019-03-26-P7-RI (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2019 denotes the year of event, 03 denotes the month of event, and 26 denotes the date of event, P7 denotes Phase VII, RI denotes the first round of abstraction in Phase VII. For subsequent rounds of abstractions, add R2 to denote second round of abstraction or R3 to denote third round of abstraction, and so on.

   b. Name Mortality file as follows: 203231MT2013-10-02 (wherein 203231 denotes the SHS ID number; MT denotes Mortality; 2013 denotes the year of death, 10 denotes the month of death, and 02 denotes the date of death). Date of death should be based on the date shown on the death certificate.

   c. Make sure to add a "0" in front of a single digit day and month in the PDF file name.

d. For hospitalization/outpatient visit involving stroke, the PDF file for the stroke reviewer should be named according to the following example: 203557MB2019-03-17-STK-P7-R1 (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2019 denotes the year of event, 03 denotes the month of event, 26 denotes the date of event; STK denotes stroke event, P7 denotes Phase VII, and R1 denotes the first round of abstraction in Phase VII. For subsequent rounds of abstractions, add R2 to denote second round of abstraction or R3 to denote third round of abstraction, and so on.

e. For participants belonging to the Gila River Indian Community (GRIC), add GI at the end of the file name as follows: 203557MB2011-05-17GI (for morbidity file); 203231MT2013-10-02GI (for mortality file); 203557MB2011-05-17-STKGI (for stroke file); 203557MB2016-06-15R2GI (for round 2 of morbidity file).

2. Create Bookmarks in PDF File: Create separate book marks for each event and for sections under each event.

3. Activate Text Recognition Feature in PDF File

4. Redact Participant Personal Information: Participants' personal information must be redacted (by using the redaction tool in Adobe Acrobat) before uploading their files to the SHS REDCap database.

5. Upload PDF Files into the M&M Reviewers' Folders on the SHS REDCap Website: All PDF files should be uploaded to the Reviewer Assignments & CC Tracking data collection instrument under *Attach review PDF packet*. The type of review (Morbidity (including Stroke), Mortality (including Stoke, and Adjudication) and the reviewer will be assigned on REDCap.

6. Uploading Charts / Assigning Reviewers for Non-fatal Stroke Events:
   a. First, non-fatal stroke case should be sent to regular morbidity reviewers.

   b. If it comes back as stroke (definite, possible and TIA), then the case will be sent to stroke reviewer for confirmation (like we have done so in SHS-1 through 5).

   c. In such case, CC will ask field to upload just that event (if it was among many events of that cycle of surveillance then cut off all the other events) to the REDCap.

3.6 Notify M&M Reviewer and Coordinating Center (CC)

1. When a PDF file is uploaded on REDCap and a reviewer is assigned, an automatic email will be generated and sent to the selected reviewer(s). The Coordinating Center's email (shs@ouhsc.edu) will also automatically be copied in the email.

2. The reviewer will receive an email that there is a chart ready for review. Reminder emails will be sent every 30 days for 3 months.

3. Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

3.7 List of Morbidity and Mortality Reviewers

Following is a list of SHS M&M reviewers along with their email addresses:

Morbidity Reviewers:

1. Dr. Lyle Best: lbest@restel.com
2. Dr. Jason Deen: jason.deen@seattlechildrens.org
3. Dr. Richard Devereux: rbdevere@med.cornell.edu
4. Dr. Huimin Wu huimin-wu@ouhsc.edu
5. Dr. Nupoor Narula nun9005@med.cornell.edu

Mortality Reviewers:

1. Dr. Dorothy Rhoades: Dorothy-Rhoades@ouhsc.edu
2. Dr. Gernot Pichler: gernotpichler@gmx.at
3. Dr. Lyle Best: lbest@restel.com
4. Dr. Richard Devereux: rbdevere@med.cornell.edu
5. Dr. Stacey Jolly: jollys@ccf.org

Stroke Reviewers:

1. Dr. Alexander Merkler: alm9097@med.cornell.edu
2. Dr. Santosh Murthy: sam9200@med.cornell.edu

Mortality Adjudicator

1. Dr. William Howard: wjh1@comcast.net

3.8 Instructions to Access SHS M&M REDCap Website

1. Go to the SHS REDCap website
2. Enter your Username and Password
3. Click on Log in
4. If there are issues with logging into REDCap, please email the Strong Heart Study Coordinating Center at shs@ouhsc.edu with the subject line "Issues with REDCap log in"

3.9 Procedures for Reviewers to Access PDF Files

1. Click on SHS Morbidity & Mortality Surveillance 2022-2026 project in REDCap.
2. Select the respective Reviewer Assignment Report under the Reports section on the left hand of the screen. These reports provide the pending charts for review for each reviewer.
3. To access the participants chart, click on the Record ID number. REDCap will be redirected to the Reviewer Assignment & CC Tracking page.
4. Click the PDF file that was uploaded under Attach review PDF packet. The reviewer will be directed to download the PDF file.

Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

3.10 Responsibility or M&M Reviewer After Completing Chart Reviews

Reviewers have two choices in completing chart reviews:

1. The reviewer can use the provided fillable PDF forms to complete their decision process and email the completed PDF forms to the CC at shs@ouhsc.edu. The CC will be responsible for entering the decision forms into the REDCap database.
2. The review can log in to REDCap and enter their decisions directly into the decision form data collection instruments.

Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual

3.11 Tracking Uploaded Events

The CC will track uploaded events on a monthly basis. These tracking reports will be sent to the Steering Committee prior to their monthly meeting. Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

Appendices

Appendix 1 Scanning Documentation for Each Event

1 – Hospital Admin Documents
- – Hospital Face Sheet – ICD9-CM Codes
- – Physician Attestation; Coding Abstract

2- Discharge Summary
- – Discharge Summary
- – Outpatient/Short Stay Record

3 – Physician Documents
- – History and Physical/Physical Exam
- – Emergency Room/Emergency Department report

4 – Consultations
- – Consult

5 – ECGs
- – 12-Lead ECG tracings, all days

6 – Labs
- – Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMG, CK or CPK), all days
- – Lab: Brain B-type natriuretic peptide (BNP), pro-BNP
- – Lab: Blood urea nitrogen (BUN), creatinine
- – Complete blood count (CBC)
- – Lab: Electrolyte Reports

7 – Imaging
- – Chest X-ray Report all days
- – Stress Test by treadmill ECG echo or nuclear perfusion scintigraphy report
- – Carotid Artery Angiography, Doppler flow study
- – Doppler flow study report
- – Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)
- – Ventilation/Perfusion Lung Scan Report
- – Pulmonary Angiogram
- – CT Scan Report
- – MRI Report
- – Radiology and/or bone scan reports/isotope or nuclear med bone scan
- – Nuclear Scans, e.g., thallium, Myoview®, sestamibi, RVG/MUGA
- – Reports of cardiac MRI/MR angiography
- – Reports of Cardiac CT scan /CT angiography
- – Reports of angiograms of head, neck or brain (MRA, CT, or catheter based)
- – Reports of angiograms of the lower extremities (MRA, CT, or catheter-based angiography)

7 – Imaging (continued)
- – Reports of Segmental Doppler assessment of the lower extremities
- – Reports of Abdominal Ultrasound of aorta or other arteries
- – Reports of Head/Brain CT scans
- – Reports of head/brain MRIs

8 – Op and Procedures
- – Coronary Artery Bypass Graft (CABG)
- – Percutaneous Coronary Intervention (PCI): PTCA; Coronary Stent/Atherectomy
- – Operative or Procedure Report
- – Cardiac catheterization including coronary angiograms and arteriograms and contract ventriculogram
- – Venogram report
- – Operative/Procedure reports (including Aortic Stent Graft)
- – Operative/Procedure reports (including angioplasty and /or stent of lower extremities)

9 – Pathology
- – All pathology reports
- – Cytology reports, all

10 – Fatal Events
- – Death certificate
- – Autopsy or Medical Examiner/Coroner's report
- – Emergency Medical Services (EMS) or ambulance report

11 – Miscellaneous
- 99 – Miscellaneous document, specify

Appendix 2 Morbidity and Mortality Data Collection Forms

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Medical Records Abstract Checklist for Non-Fatal CVD Events or Procedures

ID number:

|___|___|___|___|___|___|

1. a. Hospital name:_____

   b. Hospital location _____

2. Date of ADMISSION to this hospital or date of this OUTPATIENT visit:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Date of discharge:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

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. Record the hospital discharge diagnoses and procedure recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. You can include any ICD-10 codes if they are available.

1. _____	9. _____
2. _____	10. _____
3. _____	11. _____
4. _____	12. _____
5. _____	13. _____
6. _____	14. _____
7. _____	15. _____
8. _____	16. _____

RENAL DIALYSIS AND KIDNEY TRANSPLANT

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

   If yes, was the transplant done this admission? Yes |___| 1 No|___|2

   If no, date of first transplant: |___|___|/|___|___|/|___|___|___|___|
   month day year

7. Was the participant receiving kidney dialysis during this hospital or outpatient visit?

   Yes |___| 1 No|___|2

   If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and assemble them for each admission). Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets), including Diagnoses	_____	_____	_____
Discharge Summary	_____	_____	_____
Admitting History and Physical Exam	_____	_____	_____
ECGs (see instruction)	_____	_____	_____
Cardiac enzyme report (days 1 to 4)	_____	_____	_____
Neurology Consult Report	_____	_____	_____
Reports of Procedures:			
1. Echocardiogram	_____	_____	_____
2. Coronary angiogram	_____	_____	_____
3. Exercise tolerance test (Treadmill)	_____	_____	_____
4. Cardiac catheterization	_____	_____	_____
5. Coronary bypass	_____	_____	_____
6. Coronary angioplasty	_____	_____	_____
7. Swan-Ganz catheterization	_____	_____	_____
8. Intracoronary or I.V. streptokinase, or TPA reperfusion	_____	_____	_____
9. Aortic balloon pump	_____	_____	_____
10. Radionuclide scan	_____	_____	_____
11. CAT or CT of the head	_____	_____	_____
12. Magnetic Resonance Image (MRI) of the head	_____	_____	_____
13. Carotid ultrasound/Doppler	_____	_____	_____
14. Lumbar puncture	_____	_____	_____

15. Angiography (including vessels in the lower extremities) _____ _____ _____
16. Peripheral Angioplasty (lower extremity vessel(s)) _____ _____ _____
17. Surgical revascularization of peripheral vessel(s)) _____ _____ _____
18. Amputation _____ _____ _____
19. Chest X-ray _____ _____ _____
20. Carotid endarterectomy _____ _____ _____
21. CAT or CT of abdomen or other part of the body _____ _____ _____
22. MRI of abdomen or other part of the body _____ _____ _____
23. Other, specify: _____ _____ _____ _____
24. Other, specify: _____ _____ _____ _____
25. Other, specify: _____ _____ _____ _____
26. Other, specify: _____ _____ _____ _____
27. Other, specify: _____ _____ _____ _____
28. Other, specify: _____ _____ _____ _____
29. Other, specify: _____ _____ _____ _____
30. Other, specify: _____ _____ _____ _____
31. Other, specify: _____ _____ _____ _____
32. Other, specify: _____ _____ _____ _____

Be sure to include Tracking Sheet in the packet

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Morbidity Survey – DECISION

ID number: |___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. DIAGNOSIS (enter appropriate code number):

01. Definite non-fatal myocardial infarction |___|___|

1b. Probable non-fatal myocardial infarction |___|___|

02. Possible non-fatal myocardial infarction |___|___|

03. Definite non-fatal stroke |___|___|

04. Possible non-fatal stroke |___|___|

06. Definite CHD |___|___|

07. Possible CHD (those with some, but not all, criteria or with equivocal criteria for definite CHD) |___|___|

08. TIA |___|___|

09. Other CVD, specify: _____ |___|___|

10. Non–CVD, specify: _____ |___|___|

11. ESRD (dialysis or transplant): _____ |___|___|

12. Heart Failure (**Please fill out the HF PROCEDURE FORM**) |___|___|

B. Criteria used:

1. MYOCARDIAL INFARCTION (Please check all applicable criteria)

A. Definite MI |___|
1. Evolving diagnostic ECG*, or |___|
2. Diagnostic biomarkers (2 x ULN)* |___|

B. Probable MI |___|
1. Positive ECG findings plus cardiac symptoms or signs without available biomarkers, or |___|
2. Positive ECG findings plus equivocal biomarkers |___|

C. Possible MI |___|

1. Equivocal biomarkers plus nonspecific ECG findings, or |___|
2. Equivocal biomarkers plus cardiac symptoms or signs, or |___|
3. Missing biomarkers plus positive ECG |___|

**** For ECG and cardiac biomarker definition, please refer to: SHS VI Manual, Section 2.3.***

COMMENTS: _____

_____

_____

2. STROKE

A. Definite non-fatal stroke |___|

1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage. |___|
2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI, (or lumbar puncture if done). A nonvascular etiology must be absent. |___|
3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke. |___|
4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI - not caused by trauma. |___|
5. Non-fatal stroke after cardiovascular invasive interventions: Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions. |___|
6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery. |___|

B. Possible non-fatal stroke |___|

a. History or 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 |___|

2a. Discharge diagnosis with consistent primary or secondary codes (ICD-9-CM codes: 431, 432, 434, 436, 437; ICD-10-CM: I61.9, I62.1, I62.00, I62.9, I66.09, I66.19, I66.29, I63.30, I63.40, I66.9, I63.50, I67.89, I67.2, I67.81, I67.82, I67.89, I67.4, I67.1, I67.7, I67.5, I67.6, G45.4, I67.89, I67.9), and |___|

2b. 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. |___|

C. Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data,

and results of diagnostic studies are consistent with one subtype and other etiologies have been excluded. A **possible** diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but other studies are not done.

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

COMMENTS: _____

_____

_____

3. DEFINITE CORONARY HEART DISEASE (CHD)

a. Cardiac cath proven coronary artery disease (1 or more vessels ≥ 50% stenosis), ***or*** |___|

b. PTCA, ***or*** |___|

c. Coronary artery bypass grafting, ***or*** |___|

d1. Abnormal stress ECG, **and** |___|

d.2. Abnormal imaging, ***or*** |___|

e. Positive functional test of ischemia (such as treadmill) |___|

COMMENTS: _____

_____

_____

4. HEART FAILURE (***if yes, fill out Heart Failure form)***

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 >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

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

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

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

COMMENTS: _____

_____

_____

5. OTHER NON-FATAL CARDIOVASCULAR DISEASE

a. Purposely left blank – CHF moved to #4 above

b. Purposely left blank – CHF secondary to ESRD has been included in Diagnosis code 10 (Question A of this form).

- [ ] c. Cardiomyopathy
- [ ] d. Valvular Heart Disease
- [ ] e. Left Ventricular Hypertrophy
- [ ] f. Atrial Fibrillation
- [ ] g. Non-coronary heart surgery or carotid or other vascular surgery (does not include procedures for PVD)
- [ ] h. Pacemaker implantation
- [ ] i. Positive non-coronary angiography (does not include procedures for PVD)
- [ ] j. Arrhythmia

[ ] k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; diagnosis = 07)
[ ] l. PVD (either peripheral arterial surgical procedures, angiogram or amputation)
[ ] m. Aortic aneurysm

If there was coronary or peripheral vascular procedure done, fill out CVD Test Procedures form or Peripheral Vascular Procedure form.

COMMENTS: _____

_____

_____

_____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Cardiovascular Test Procedures Abstract

ID number: |___|___|___|___|___|___|

1. **WAS CATHETERIZATION/ANGIOGRAM DONE?**
   Yes |___|1 No (***Go to Q18***) |___|2 Yes, but no report |___|3

2. If YES, When? |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Where: _____
   Hospital/Clinic City/State

Was Any Vessel ≥ 50% Stenotic in ...

		Yes	No	Uncertain	Unknown
4.	Left Main:	|___|1	|___|2	|___|8	|___|9
5.	Left anterior descending:	|___|1	|___|2	|___|8	|___|9
6.	Right coronary:	|___|1	|___|2	|___|8	|___|9
7.	Circumflex artery:	|___|1	|___|2	|___|8	|___|9

8. ***Ejection Fraction (%):*** |___|___|___|

777= normal, % not specified 888=abnormal, % not specified
999=unknown/no response

9. ***Left Ventricular Function:*** Normal |___|1 Assessed, results not specified |___|3
Depressed |___|2 Not assessed (***Go to Q17***) |___|9

10. ***Was Akinetic Wall Observed?***

Yes |___|1 No (***Go to Q15***) |___|2 Uncertain |___|8 Unknown|___|9

		Yes	No	Uncertain	Unknown
11.	Anterior:	|___|1	|___|2	|___|8	|___|9
12.	Inferior:	|___|1	|___|2	|___|8	|___|9
13.	Apex:	|___|1	|___|2	|___|8	|___|9
14.	Diffuse:	|___|1	|___|2	|___|8	|___|9

Finding of Valvular Function:

		Yes	No	Uncertain	Unknown
15.	Mitral regurgitation:	|___|1	|___|2	|___|8	|___|9
16.	Aortic regurgitation:	|___|1	|___|2	|___|8	|___|9
17.	***Was Angioplasty performed?***	|___|1	|___|2	|___|8	|___|9

18. WAS COMPUTED TOMOGRAPHIC CALCIUM SCORING DONE?

Yes |___|1 No **(*Go to Q22*)** |___|2 Yes, but no report |___|3

19. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

20. Where: _____
Hospital/Clinic City/State

21. **Agatston score:** |___|___|___|___|

22. WAS TREADMILL EXERCISE TEST DONE?

Yes |___|1 No **(*Go to Q29*)** |___|2 Yes, but no report |___|3

23. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

24. Where: _____
Hospital/Clinic City/State

25. Treadmill ECG:

Normal |___|1 Borderline |___|2 Abnormal |___|3 Inconclusive |___|8 No report |___|9

26. Maximum heart rate (beats/minute): 999=no report |___|___|___|

27. Maximum systolic blood pressure (mmHg): 999=no report |___|___|___|

28. Treadmill time (round to nearest whole number minute): 99=no report |___|___|

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

Yes |___|1 No **(*Go to Q34*)** |___|2 Yes, but no report |___|3

30. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

31. Where: _____
Hospital/Clinic City/State

32. What Stress: Exercise |___|1 Adenosine |___|2 Dobutamine |___|3 Other Drug |___|4

If Other drug, please specify: _____

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

ADMINISTRATIVE INFORMATION:

34. Reviewer code |___|___|___|

35. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Peripheral Vascular Procedures/Revascularization Abstract

ID number: |___|___|___|___|___|___|

1. **Was peripheral angiogram (ICD-9 procedure code 88.48, ICD-10: B40.X, B41.X) done?**

Yes |___|1 No |___|2 **(Go to Q2)** Yes, but no report |___|9

a. If yes: Contrast angiogram |___| MR angiogram |___| CT angiogram |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

d. Was any vessel ≥ 50% stenotic?

i. Aorta: Yes |___|1 No |___|2 Uncertain|___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

ii. Iliac: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iii. Femoral: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iv. Popliteal or lower: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

v. Carotid stenosis Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

e. Was there evidence of previous revascularization? Yes |___|1 No |___|2

2. **Was peripheral angioplasty or surgical revascularization done?**

Yes, angioplasty |___|1
(ICD-9 procedure code 39.50)
(ICD-10: 027X, 037X, 047X, 057X, 067X)

Yes, revascularization |___|3
(ICD-9 procedure code 39.25 and 39.29)
(ICD-10: 031X, 041X, 051X, 061X)

No |___|2 **(Go to Q3)** Yes, but no report |___|9

a. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

b. Where: _____

3. **Was amputation (ICD-9 procedure codes 84.10 – 84.19, ICD-10: OY6.X) performed?**

Yes |___|1 No |___|2 **(Go to Q4.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. Which part?

Upper body, Arm=1, Hand=2, Finger=3, |___|

Lower body, Above knee=1, Below knee=2 |___|
Foot=3, Toe(s)=4

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

4. **Was carotid angioplasty/stenting done?**

Yes |___|1 No |___|2 **(Go to Q5.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

5. **Was carotid endarterectomy done?**

Yes |___|1 No |___|2 **(Go to end.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

ADMINISTRATIVE INFORMATION:

5. Reviewer code: |___|___|___|

6. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Instructions: The same procedures used for the ongoing surveillance in each center should be used, including evaluation of clinic charts and/or use of the IHS computerized records as well as direct contact with participants when necessary.

The purpose of this study is to derive an estimate of the proportion of participants who have undergone diagnostic or therapeutic procedures documenting definite lower extremity peripheral arterial disease since the Phase III SHS examination, and the proportion thereof for whom the necessary records are still available. Therefore, medical records for hospitalizations or outpatient encounters dealing with the diagnostic or procedural codes listed below and occurring since 1 January 1998 should be requested and reports of the procedures of interest should be obtained. Earlier events that correspond to the same procedures should be noted but charts need not be abstracted.

The following diagnostic codes should be identified:
For Peripheral Angiograms: ICD-9 procedure code **88.48**
ICD-10: **B40.X, B41.X**
For Peripheral Angioplasty: ICD-9 procedure code **39.50**
ICD-10: **027X, 037X, 047X, 057X, 067X**
For Peripheral Surgical Revascularization: ICD-9 procedure codes **39.25 and 39.29**
ICD-10: **031X, 041X, 051X, 061X**
For Amputation: ICD-9 procedure codes **84.10-84.19**
ICD-10: **OY6.X**
For Carotid Endarterectomy: ICD-9 procedure code **38.12**
ICD-10: **03CX**
For Angioplasty: ICD-9 procedure code **00.61**
ICD-10: **037X, 03CX, 057X**
For Stenting: ICD-9 procedure code **00.45**
ICD-10: **027X**

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

HEART FAILURE PROCEDURES

SHS ID: |___|___|___|___|___|___| Date of Event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. ATRIAL FIBRILLATION AT TIME OF HF? Yes |___| 1 No |___| 2 Unknown |___| 9

B. WHICH IMAGING STUDY WAS PERFORMED DURING THIS ADMISSION? Please check ALL that were done. If more than one imaging study was done in the same admission, please use one of these forms for EACH IMAGING STUDY to record the results of that study.

|___|1 Echocardiogram

|___|2 Nuclear Imaging

|___|3 Invasive Angiogram

|___|4 CT Angiogram

|___|5 MRI Angiogram

|___|6 Other, Specify: _____

|___|7 Not sure, no results found in chart

|___|8 None

If not sure or none, skip to Q8.

1. Name of test: _____

2. Date of test: |___|___|/|___|___|/|___|___|___|___|
month day year

3. Facility name: _____

   City/State: _____

4. Ejection fraction: Measured: |_____|% Estimated: |_____|%

   If % not stated, 777 = normal, or range ≥ 50% 888 = abnormal, or range < 50% 999 = unknown/no response

5. Ejection fraction interpretation: Normal |___| 1 Depressed |___| 2 NR |___| 9

6. Segmental wall motion abnormalities? Yes |___| 1 No |___| 2 NR |___| 9

   If yes, degree of abnormality: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

7. Transmitral time: E Velocity: ____cm/sec A Velocity: _____ cm/sec Peak E/A Ratio: _____

   Decel. Time: _____msec IVRT: ____ Septal E':_____ Peak S':_____ Septal A':____

8. **Valvular disease?** Yes |___| 1 No |___| 2 Unknown |___| 9

If No or Unknown, go to Q9.

If Yes,

a. Mitral regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

b. Mitral stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

c. Aortic regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

d. Aortic stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

e. Tricuspid regurgitation:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

9. **Right ventricular systolic pressure/PA systolic pressure (mmHg):** **|___|___|___|**

If not stated, 777 = normal 888 = abnormal 999 = unknown/no response

C. B-TYPE NATRIURETIC PEPTIDE (BT-BNP):_____pg/ml. Upper Limit of Normal:_____pg/ml

N-TYPE NATRIURETIC PEPTIDE (NT-BNP): _____ pg/ml. Upper Limit of Normal:_____pg/ml

D. CARDIOMYOPATHY DIAGNOSIS: Ischemic: ____ Non-Ischemic: _____ Hypertrophic:

Valvular disease: ____ Acute MI:_____ NR |___| 9

No cardiomyopathy _____

ADMINISTRATIVE INFORMATION:

Reviewer Code: |___|___|___|

Review Date: |___|___|/|___|___|/|___|___|___|___|

Month day year

STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

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

Admission date: |___|___|/|___|___|/|___|___|___|___| ID Number: |___|___|___|___|___|___|
mo day year

For each hospital admission WITHIN the YEAR prior to death, obtain electronic records or 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.

1. a. Hospital name: _____

b. Hospital location _____

2. Date of discharge: |___|___|/|___|___|/|___|___|___|___|
month day year

3. Record the hospital discharge diagnoses and procedures recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. You can include any ICD-10 codes if they are available.

1. _____ 8. _____
2. _____ 9. _____
3. _____ 10. _____
4. _____ 11. _____
5. _____ 12. _____
6. _____ 13. _____
7. _____ 14. _____

RENAL DIALYSIS AND TRANSPLANT

Provide answers to Question 4 only for the last admission within 12 months prior to death.

4. Was the participant receiving kidney dialysis during this hospital visit? Yes |___| 1 No|___|2

If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

Did participant request stopping dialysis during this hospitalization? Yes |___| 1 No|___|2

5. Has this participant ever had a kidney transplant? Yes |___|1 No |___|2

6. **<u>FOR MORTALITY REVIEW:</u> Obtain the following medical records (when available) for this final admission. In addition, obtain these medical records for each hospitalization WITHIN the YEAR prior to death (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>).**
<u>FOR MORBIDITY REVIEW:</u> Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>). Be sure that photocopies are legible.

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

Other Laboratory results, SPECIFY:

_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9
Operative reports:			
Coronary bypass	|___|1	|___|2	|___|9
Angioplasty	|___|1	|___|2	|___|9
Swan-Ganz catheterization	|___|1	|___|2	|___|9
Non-CVD operation	|___|1	|___|2	|___|9
For terminal Event Only:			
Ambulance report	|___|1	|___|2	|___|9
ER Admission and Discharge Summary	|___|1	|___|2	|___|9
Any clinical notes regarding DOA	|___|1	|___|2	|___|9
Autopsy Report/ Coroner's Report	|___|1	|___|2	|___|9
From IHS clinic chart (if available), photocopy notes and test results from the most recent visit prior to death	|___|1	|___|2	|___|9

ADMINISTRATIVE INFORMATION:

Abstractor Number |___|___|___|

Date abstract completed: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Mortality Survey Packet Checklist

ID number: |___|___|___|___|___|___|___|

1.	Death Certificate	Yes |___|1	No |___|2
2.	Autopsy performed	Yes |___|1	No |___|2
3.	Autopsy report	Yes |___|1	No |___|2
4.	Medical Records Checklist	Yes |___|1	No |___|2
5.	Copy reports as specified	Yes |___|1	No |___|2
6.	Check if the decedent is eligible for the morbidity survey and proceed as required by the morbidity survey protocol.	Yes |___|1	No |___|2
7.	Check if tracking form was sent	Yes |___|1	No |___|2
8.	Informant Interview Form	Yes |___|1	No |___|2

9. Was he/she in a nursing home at the time of death?

   Yes |___|1 No |___|2 Unknown |___|9

10. Was he/she receiving care from a home hospice care program at the time of death?

    Yes |___|1 No |___|2 Unknown |___|9

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Mortality Survey – Final Decision

ID number: |___|___|___|___|___|___|___|

Date of death: |___|___|/|___|___|/|___|___|___|___| (month / day / year) Age at death: |___|___|

A. Cause of death, choose from the list below:

Cause of death: |___|___|

Contributory cause of death 1: |___|___|

Contributory cause of death 2: |___|___|

01 = Definite myocardial infarction
1a = Probable myocardial infarction
02 = Definite sudden death due to coronary heart disease
03 = Definite coronary heart disease
04 = Possible coronary heart disease
05 = Definite stroke
06 = Possible stroke
07 = Definite congestive heart failure
08 = Possible congestive heart failure
09 = Other cardiovascular diseases, specify: _____

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
88 = Other, specify: _____
99 = Can not be determined.

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: _____

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

B. Criteria used for the cause of death: (Please check the appropriate boxes.)

01. Definite fatal myocardial infarction

[ ] 1(a) Definite MI within 4 weeks of death by criteria: Yes No

1.	Evolving diagnostic ECG*, or	|___|1	|___|2
2.	Diagnostic biomarkers (2 x ULN)*	|___|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.

1a. Probable fatal MI

[ ] 1. Death within 28 days of hospital admission, cases defined as:

		Yes	No
1a.	Positive ECG findings plus cardiac symptoms or signs Without biomarkers, or	|___|1	|___|2
1b.	Positive ECG findings plus equivocal biomarkers	|___|1	|___|2

OR

[ ] 2. Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or non-diagnostic. \|___\|1 \|___\|2

**** For ECG and cardiac biomarker definitions, please refer to: SHS VI Manual, Section 2.3.***

02. Definite sudden death due to CHD

[ ] 1. Death witnessed as occurring within 1 hour after the onset of 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.

03. 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
[ ] 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 (without meeting criteria for Probable MI),
OR
[ ] 5(d) Angiogram reporting severe (≥ 50% narrowing) atherosclerotic coronary artery disease,
OR
[ ] 5(e) Other positive physical signs or lab findings.

04. 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.

05. Definite fatal stroke (**also complete 6.1, 6.2 and Supplemental Form**)

[ ] 1a. Cerebral infarction or hemorrhage diagnosed at autopsy,
AND
[ ] 1b. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,
OR

[ ] 2a. History of rapid onset (approximately 48 hours from onset to time to admission or maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness,

AND

[ ] 2b. Focal neurologic deficit within 6 weeks of death documented by unequivocal physician or laboratory findings with 24 hours duration of objective physician findings,

AND

[ ] 2c. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,

06. Possible (Undocumented) fatal stroke

[ ] 1. Death certificate consistent with underlying or immediate cause (ICD-9, code 431 – 437, ICD10: I61.X – I63.X, I65.X-I67.X, G45.X), but neither autopsy evidence nor adequate pre-terminal documentation of the event,

AND

[ ] 2. No evidence at autopsy examination of the brain, if performed, of any disease process that could cause focal neurologic signs that would not be connected with cerebral infarction or hemorrhage.

OR

[ ] 3. Focal neurological deficit and death within 24 hours, without MRI or other diagnostic image.

<u>Stroke subtype classification (complete for cases of definite fatal stroke).</u>

[ ] 1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage.

[ ] 2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI. A nonvascular etiology must be absent.

[ ] 3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke.

[ ] 4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI, not caused by trauma.

[ ] 5. Non-fatal stroke after cardiovascular invasive interventions: Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

[ ] 6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery.

Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data, and results of diagnostic studies are consistent with one subtype and other

etiologies have been excluded. A **possible** diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non-atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

07. Definite fatal congestive heart failure (**Please fill out the HF PROCEDURE FORM**)

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 >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

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

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

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

08. 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.

09. Other fatal cardiovascular diseases

[ ] i. Death certificate or medical records with consistent underlying or immediate Cause. Check that applies.

[ ] ii When death certificates are the only source of information: ICD9: 390 to 398, 402, 404 to 429; ICD 10: I00 to I09, I11, I13, I20 to I25, I27, I30 to I52. Check that applies.

ICD – 9	**ICD – 10**	**Disease**	
390-392	I00, I01.X, I02.X	Rheumatic fever/chorea with/without heart involvement	[ ]
393-398	I05.X - I09.X	Chronic rheumatic heart disease	[ ]
402	I11.X	Hypertensive heart disease	[ ]
404-405	I13.X, I15.X	Hypertensive disease	[ ]
410-414	I20.X, I21.X, I24.X, I25.X	Ischemic heart disease	[ ]
415-417	I26 – I28.X, T80-T82.X	Pulmonary Heart Disease, or other diseases of pulmonary circulation	[ ]
420-429	I23.X, I25.X, I30.X, I31.X, I32, I33.X, I34.X - I40.X, I41, I42.X-I45.X, I46.9, I47.X – I51.X, I97.X, R00.1,	Other forms of heart disease	[ ]
429.2	I25.10	Cardiovascular disease, unspecified	[ ]
431-437	I61.X – I63.X, I65.X-I67.X, G45.X	Cerebrovascular disease	[ ]
799	R09.X, R41.X, R45.X, R53.81, R64, R68.X, R69, R99	Ill-defined or unknown	[ ]
443.9	I73.9	Peripheral vascular disease, unspecified	[ ]

Comment: _____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Coordinating Center Use Only

Reviewer:
First review |___|1 Second review |___|2 Stroke review |___|3 Adjudication |___|9

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SUPPLEMENTAL STROKE FORM - Mortality and Morbidity Surveys

(Complete for mortality codes 5 or 6 and morbidity codes 3, 4 or 8)

ID number: |___|___|___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
Month day year

A. ISCHEMIC STROKE LOCATION

		YES	NO
1.	Right hemisphere	|___|1	|___|2
2.	Left hemisphere	|___|1	|___|2
3.	Basilar	|___|1	|___|2
4.	Hemispheric and Basilar	|___|1	|___|2
5.	Unknown	|___|1	|___|2

B. BRAIN IMAGING

6. *HEAD CT*

	Yes	|___|1
	No (go to Q 7)	|___|2
	Yes, but no report	|___|3
6.1 If yes, timing of Head CT	<48 h since symptom onset	|___|1
	≥48 h since symptom onset	|___|2
	Unknown	|___|3

7. *BRAIN MRI*

Yes	|___|1
No (go to Q 8)	|___|2
Yes, but no report	|___|3

C. NEUROVASCULAR IMAGING

8. *CAROTID DUPLEX*

Yes	|___|1
No (go to Q 9)	|___|2
Yes, but no report	|___|3

9.	*TRANSCRANIAL DOPPLER (TCD)*	Yes	|___|1
		No, (go to Q 10)	|___|2
		Yes, but no report	|___|3
10.	*MAGNETIC RESONANCE ANGIOGRAPHY* (*MRA)*	Yes	|___|1
		No (go to Q 11)	|___|2
		Yes, but no report	|___|3
11.	*CT ANGIOGRAPHY*	Yes	|___|1
		No (go to Q 12)	|___|2
		Yes, but no report	|___|3
12.	*ANGIOGRAPHY*	Yes	|___|1
		No, (go to Q 13)	|___|2
		Yes, but no report	|___|3

D. STROKE DEFICIT

13. MODIFIED RANKIN SCALE (0-6) |___|
(Code Maximal Severity Within 7 Days of Stroke)

0 = no symptoms at all
1 = no significant disability despite symptoms: able to carry out all usual duties and activities
2 = slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
3 = moderate disability: requiring some help, but able to walk without assistance
4 = moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance
5 = severe disability: bedridden, incontinent, and requiring constant nursing care and attention
6 = death
9 = information insufficient for coding

E. STROKE TREATMENT

14.	Intravenous thrombolysis	Yes	|___|1
		No	|___|2
15.	Presentation within 3 hours from symptom onset	Yes	|___|1
		No	|___|2
F.	**BRAIN EXAMINATION AT AUTOPSY**	Yes	|___|1
		No	|___|2
		Yes, but no report	|___|3

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

If you have any comments on this case, please use the space below:

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORTALITY SURVEY
INFORMANT INTERVIEW

ID number: |___|___|___|___|___|___|

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

1. Name: _____
Last First Middle

2. Date of death: |___|___|/|___|___|/|___|___|___|___|
month day year

B. 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)	_____	_____	_____	_____	_____

C. Person Providing Information (*Completed by study center staff prior to interview.)*

3. a. Name: _____
Last First Middle

b. Address: _____

c. Telephone: ( ) _____

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

You are the _____ of the deceased.

5. What did the patient die from?

_____
_

6. Were you present when he/she died?

Yes |___|1 (Go to Q8) No |___|2 Unknown |___|9

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

1 hour or less	|___|1	More than 24 hours	|___|3
24 hours or less	|___|2	Unknown	|___|9

8. Do you know of anyone else who may have been present at about the time of his/her death?

Yes |___|1 No |___|2 Unknown |___|9

If yes can you give me that person's name and contact information:
Contact information_____
_____
_____

9. Please describe the events that occurred at the time of death, specifically, did he/she manifest any of the following conditions: chest pain, shortness of breath, agitation, sudden collapse or loss of consciousness, sudden weakness, slurred speech, etc. Please tell me what you know of his/her general health, health on the day he/she died, and of the death itself. This information will be reviewed by a physician and will help to better understand the cause of your loved one's death. ***(Record summary verbatim and ask pertinent questions when appropriate attach additional sheet if needed)*** Probing Questions: Are you aware of any illnesses the individual had prior to death? If yes – how long did the person have the illness? Was the individual involved in any accidents or trauma prior to death? If yes – what type and how long prior to death.

The next set of questions deal specifically with the last episode of pain or discomfort that occurred before his/her death. This is defined as starting at the time you noticed discomfort that caused him/her to stop or change what he/she was doing. ***NOTE TO INTERVIEWERS: If the informant has already answered these questions in the description of circumstances, just fill out the correct answer(s) as noted below.*** **Respect the informant's wishes about continuing the interview and record answers to as many of the following questions as possible.**

10. Did his/her last episode of pain or discomfort specifically involve the chest?
Yes |___|1 No |___|2 Unknown |___|9

11. 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 go to Q15)

12. Did he/she take nitroglycerine because of this last episode of pain or discomfort?
Yes |___|1 No |___|2 Unknown |___|9

13. Did he/she take any other medicine for chest discomfort prior to death? Yes_____ No____
If yes what?_____

14. 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	|___|1	24 hours or less	|___|4
10 minutes or less	|___|2	More than 24 hours	|___|5
1 hour or less	|___|3	Unknown	|___|9

15. Did he/she ever have dialysis for kidney failure? Yes No Unknown
|___|1 |___|2 |___|9

a. If yes, what year did he/she start dialysis? |___||___||___||___|

b. How many times per week did he/she receive dialysis? |___||___|

c. Did he/she stop dialysis before death? Yes No Unknown
|___|1 |___|2 |___|9

If yes, how long before death? |___||___|/ |___||___|/ |___||___|
days months years

16. Within 3 days of death, or just before he/she died, did any of the following symptoms begin for the first time or did the patient complain of any of these symptoms:

		Yes	No	Unknown
a.	Shortness of breath?	|___|1	|___|2	|___|9
b.	Dizziness?	|___|1	|___|2	|___|9
c.	Palpitations (pounding in the chest)?	|___|1	|___|2	|___|9

d.	Marked or increased fatigue, tiredness, or weakness?	|___|1	|___|2	|___|9
e.	Headache?	|___|1	|___|2	|___|9
f.	Sweating?	|___|1	|___|2	|___|9
g.	Paralysis?	|___|1	|___|2	|___|9
h.	Loss of speech?	|___|1	|___|2	|___|9
i.	Attack of heartburn or indigestion or abdominal discomfort?	|___|1	|___|2	|___|9
j.	nausea or vomiting?	|___|1	|___|2	|___|9
k.	Other? specify: _____	|___|1	|___|2	|___|9

<u>These next questions are about his/her medical history</u>
<u>Please provide as much information as possible</u>

17. 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 Q20?)*** Unknown |___|9

18. Did he/she ever take nitroglycerin for this pain?
Yes |___|1 No |___|2 Unknown |___|9

19. Any other medications such as aspirin, tums or other antacids?
Yes |___|1 No |___|2 Unknown |___|9

20. 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.	any other heart disease or heart condition If yes, specify:_____	|___|1	|___|2	|___|9
e.	coronary bypass surgery (CABBAGE)	|___|1	|___|2	|___|9
f.	coronary angioplasty (balloon angioplasty)	|___|1	|___|2	|___|9
g.	insertion of pace maker (defibrillator)	|___|1	|___|2	|___|9
h.	any other heart surgery?	|___|1	|___|2	|___|9

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

21. Was he/she hospitalized or taken to a clinic

	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

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

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

24. What was the date of the ***<u>last</u>*** hospital admission? |___|___|/|___|___|/|___|___|___|___|
(If unknown, draw two lines across the boxes) month day year

If the information in questions 25- 28 is already known to you, skip to Q29.

25. Can you tell me the name and location of the hospital? ***(If unknown, check the box.)*** |___|
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

26. Was he/she seen by a physician anytime in the year prior to death?
    Yes |___|1 No |___|2 Unknown|___|9

27. Can you tell me the name and address of this physician or healthcare facility? |___|
    IHS only
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

28. Can you tell me the name and address of his/her usual physician?
    If same as Q27, check here. |___|
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

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

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

30. Was he/she being cared for at a nursing home or at another place at the time of death?
    Yes, nursing home, specify |___|1_____
    Yes, at home |___|2
    Yes, other, specify |___|3 _____
    No |___|4
    Unknown |___|9

The next few questions are concerned specifically with emergency medical care he/she may have received just prior to or at the time of death.

31. Was he/she taken to a hospital/clinic in the week before his/her death? Yes |___|1 No |___|2

32. If Yes, could you tell me the name and location of this facility:

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

33. 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)

34. Did informant provide consent to gather further information?

Yes |___|1 No |___|2 Not applicable |___|3

(If Yes, ask the informant to sign the consent form for us to review the decedent's medical records)

35. How reliable was the participant in completing the questionnaire?

Very reliable |___|1 Reliable |___|2 Unreliable |___|3 Very unreliable |___|4 Uncertain |___|5

ADMINISTRATIVE INFORMATION:

36. Interviewer code: |___|___|___|

37. Interview date: |___|___|/|___|___|/|___|___|___|___|

month day year

Personal Interview and General Examination

Manual of Operations Volume III

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
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The University of Oklahoma Health Sciences Center

P.O. Box 26901
Oklahoma City, OK 73190

Tracking of Revisions to Manual of Operations Volume III: Personal Interview and General Examination

Date of Revision	Revised Section	Revision	Approved by, Date
1/17/2025	Section 9: Referral Guidelines Section 10: Quality Control (QC) Program	Fixed formatting issue with section title in the footer	SHS CC, 1/16/2025
7/15/2024	Appendix A-2: Ancillary Study consent Forms	Updated affiliation for Astrid Suchy-Dicey and listed her as a PI for Psychological Risk Factors Study	SHS CC, 7/15/2024
5/22/2023	Section 8: Ancillary Studies	Update specific aims for Resilience study	SHS Ancillary Study Committee, 5/22/2023
5/4/2023	Appendix 6: SHS Phase VII Exam Forms	Add ECG question Minor wording fixes	SHS SC, 4/24/2023
5/4/2023	Section 9: Referral Guidelines	Add ECG Referral Guidelines Change local IHS lab to local lab for CBC results	SHS SC, 4/24/2023
5/4/2023	Section 4: Personal Interview	Update COVID 19 Guidelines	SHS SC, 4/24/2023
5/4/2023	Section 2: Components of the Exam Section 8: Ancillary Studies	Add Bilingual study description	SHS SC, 4/24/2023
5/4/2023	Section 1: Introduction	Add information about training	SHS CC, 4/24/2023
4/27/2023	Entire document	Fixed formatting issues and broken web page links	SHS CC, 11/1/2022

Table of Contents

III. Personal Interview and General Examination

1. Introduction

All participants of the original Strong Heart Study (SHS) cohort and/or the SHS family study are invited to enroll in the Phase VII re-exam. This component of the study consists of a personal interview, a limited physical examination, and laboratory tests. The Phase VII Strong Heart Family Study provides opportunities to maximize use of data and samples amassed in the SHS over a 30-year period to address new questions about the development of clinical CVD and related conditions of particular relevance to the AI population. The scientific objectives are to (1) enhance statistical power to perform analyses of predictors of clinical events; (2) investigate the high risk of cardiovascular disease and related conditions in this special population; and (3) enable investigations of new risk factors or interactions among factors that inform disease pathophysiology. The operational objectives are to (1) conduct continued follow-up in the SHS original and family cohorts to increase the number of clinical endpoints, thus increasing statistical power for morbidity and mortality-related analyses; (2) continue to foster scientific collaborations; (3) conduct a limited clinical examination of the study participants as a platform for independently-funded ancillary study examination components; (4) support tribal community engagement activities by fostering partnerships with community representatives and stakeholders, including tribal leaders; and (5) support training of junior investigators, especially AI investigators.

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

The objectives of the Strong Heart Study and the examination procedures will be explained to the participants, and informed consent will be obtained from each participant. (See **Appendix 1**) Persons who are institutionalized will be excluded. Pregnant women will not be examined until at least six weeks post-partum, and lactating women must be at least six weeks post-partum.

All examinations are performed by trained personnel, nurse practitioners, registered nurses, medical assistants, health profession students, health aides, medical assistants, 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.

The virtual training of the field staff, registered nurses, nurse practitioners, health profession students, physician assistants and physicians on the Phase VII protocol occurred on January 12-13. 2023 at the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma based on the written protocol. Each Study Center location 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. The review of positive findings is part of the medical data review. After the initial training, continuing education includes regular review of the protocol.
Physical exams are intended for research purposes and public health analysis and as such it is critically important to ensure uniformity of the data collection processes at all field centers. In addition, the anthropometric measurements are collected during one visit and it is important to return the most correct information possible to the participant.

2. Components of the Clinical Examination, Endpoints, and Risk Factors

2.1 Interview Questionnaires

The following questionnaires will be administered as part of the Phase VII SHS examination:

Core SHS Phase VII questionnaires:

1. Personal interview I includes demographic and medical facility information.
2. Personal Interview II includes questions on gender, marital status, education, weight satisfaction, used of artificial sweeteners, family income, tobacco and alcohol use, and perceived stress.
3. Medical History includes medical conditions, heart problems,
4. Medication Reception Form
5. Reproduction and Hormone Use (Women Only)
6. Rose questionnaire for angina pectoris and intermittent claudication.
7. CES-D Scale
8. Quality of Life (SF-12)
9. Multidimensional Health Locus of Control Scale (MHLC)
10. Other questions about your Life (includes the Inclusion in community question)
11. Food Assistance and Food Security
12. Food Frequency Questionnaire

Resilience, Cultural Alignment, and Social Support in Brain Aging Questionnaires:

1. 14- Item Resilience Scale (RS-14)
2. Multidimensional and Interpersonal Resilience Measure (MIRM)
3. Multigroup Ethnic Identify Scale (MEIM-R)
4. Orthogonal Cultural Identity Scale (OCIS)
5. Rosenberg self-Esteem Scale (R-SES)
6. Social Support and Social undermining Items (SS/U)
7. Social Network Index (SNI)
8. Functional Activities Questionnaire (FAQ)
9. Montreal Cognitive Assessment (MOCA)

Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians Questionnaires:

1. Perceived Stress Scale
2. NIH Tool Box
3. The following questions are asked as part of the SHS Core questionnaires and are shared with this study and available to all study investigators:
    a. Center for Epidemiological Survey Depression (CES-D)
    b. Substance use
    c. SF-12 scale
    d. Inclusion of Community in the Self (ICS) Scale

Gut Microbiome, Aging and Cardiometabolic Disease in American Indians Questionnaires:

1. Bristol Stool Chart
2. Food Frequency Questionnaire which is also asked as part of the SHS Core questionnaires and are shared with this study and available to all study investigators

Health Effects on Metals in Native American Communities: A Longitudinal Multi-omics Questions:

1. Additional questions about previous residence and water usage are asked as part of the Personal Interview I questionnaire in the SHS Core questionnaire.

Chronic respiratory diseases among Native Americans:

1. Additional questions to evaluate participant's chronic respiratory symptoms and history of respiratory diseases.

Bilingualism, cognitive reserve, Alzheimer's disease and related disorders in American Indians: the Strong Heart Study:

1. Two sub-projects: (A) qualitative interviews in N=33 (3 per participating tribe) and (B) quantitative questionnaire, 1 scale < 20 questions in estimated half of SHS7 during second half of recruitment period (N=1000-1500).

2.2 Physical Examination

The Physical Examination form will be completed along with the Physical Examination QC Duplicate measurement form when appropriate as part of the SHS Core questionnaires.

The Physical Examination form includes the following procedures that were collected in previous SHS examinations:

1. Examination of extremities for amputation.
2. Anthropometric measurements which will be made with participants in loose clothing without shoes, and with heavy objects removed from pockets.
    a. Weight
        i. 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.
        ii. Results will be rounded to the nearest kilogram.
    b. Height
        i. 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
        ii. Results will be rounded to the nearest centimeter.
    c. Waist circumference
        i. For the waist, anthropometric tape will be applied at the level of the navel with the patient supine and breathing quietly.
        ii. Results will be rounded to the nearest
    d. Hip circumference

i. 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.
ii. These measurements are rounded to the nearest centimeter.

e. Arm circumference
i. The participant will sit with his right arm hanging freely, with the right hand resting on the right knee. The tape measure will be placed horizontally at the midpoint between the acromion and olecranon.
ii. Results will be rounded to the nearest centimeter.
iii. The measure will be used to select the proper size blood pressure cuff.

3. Examination of the following
   a. Pedal pulses
      i. With the participant supine, the presence of posterior tibial (palpating inferior to the medial malleolus of each foot) and dorsalis pedis (palpating superior) pulses will be determined.
   b. Ankle edema
      i. 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 (absent, mild, marked – 1 - 3) will be recorded
4. Blood Pressure Measurements
   a. With the participant sitting with right arm on table, the brachial artery will be palpated (just medial to and above the ante-cubital fossa), and this location will be marked for stethoscope placement.
   b. The correct cuff size will be chosen and the cuff will be wrapped around the arm with the center of the bladder over the artery. After a 5-minute wait, the cuff will be connected to a standard manometer, and the pulse obliteration pressure will be established and recorded.
   c. The participant will be asked to raise the measurement arm for five seconds and then wait another 25 seconds with the arm on the table. The cuff will then be 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.
   d. Blood pressure will be measured two more times. 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 2 more times.
   e. The average of these first two measurements will be used for analysis
   f. Using a Doppler, with the participant supine, right brachial and both ankle systolic pressures will be measured two times

2.3 Phlebotomy and Laboratory Collection

1. Sample Collection Checklist
   a. Provides information on the amount of blood and the type of collection tubes to be used.
2. CBC Results

Checklists to be used for the examination and as a reminder of post examination activities are given in **Appendix 4**.

The SHS Core clinical examination is estimated to last two 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 (see **Appendix 1** below for consent forms used in the 3 SHS Field centers and **Appendix 2** for the ancillary consent documents). The participant will then be instructed to go to the laboratory for the collection of blood and urine specimens after which the participant will be offered a light snack. The nurse clinician and other staff will conduct the personal interview, obtain

anthropometric measurements and blood pressure. Participants will have the option to self-answer some questionnaires at home and bring to their appointment once consent has been completed. Study staff will administer cognitive test (MoCA then Toolbox). After all the procedures are completed, the participant will receive payment or sign the payment form and be thanked for his/her participation.

If possible, all of the components should be completed in one visit. The consent must be completed before any data is collected. With the exception of the medical history, medications and MOCA, all questionnaires can be self-administered prior to the physical exam. If self-administered questionnaires are not complete, every effort should be made to have the participant complete them while in the clinic for the physical exam.

3. Recruiting

3.1 Recruitment Techniques

Always remember that the participant is a volunteer.

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, there is no Strong Heart Study.

Eligible participants for the Phase VII exam are all living eligible previous participants of the original and family Strong Heart Study cohorts; only these previous participants are eligible for enrollment in Phase VII, which is a re-exam of all surviving and willing study participants.

Recruitment Suggestions:

1. Greet people wherever you see them. Call them by name and make the effort to acknowledge them and show appreciation for their taking time to participate.

2. Take time to be in places like the Tribal Office, Post Office, Hospital and any location where there is a large gathering of people. Be a positive presence. Recognize that this should be your approach regardless of the venue as the methods of communication have changed significantly since the pandemic. Talk with them about other subjects in addition to speaking with them about Strong Heart participation. Do not rush or hurry your discussion.

3. When making home visits, do not sit in your car and honk the horn **(unless you have safety concerns).** Walk to the door and tell them why you are there. Take the initiative to visit with them first and see how they are.

4. 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.

5. 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.

6. Dress casually and never act like you can't be touched with a ten-foot pole.

7. Enjoy your home visits as most people like someone coming in with a smile. It really helps to enjoy what you do.

8. Depending on the participants risk factors, vaccination status and your institutions/Tribal safety protocols, wearing a mask and observing social distancing will be standard policy but may also include talking with them outside in order to reduce risks for COVID-19 for everyone's safety. Inquire with participants to confirm that they feel safe as well as any additional measures that they would like to see in order to ensure to reduce risk for transmission of COVID-10

9. Be patient and explain things in a variety of ways so that people will understand what they are being asked to do.

10. **PLEASE** always remember that the SHS participants are volunteers. Treat them with courtesy and recognize that they have often gone to a great deal of effort in both time and energy in volunteering to participate in the SHS.

11. Recruiting is not a 9 to 5 job. It is important to recognize the staff and recruiters who do it very well and to support them.

12. 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.

13. Recognize the daily rhythms of your community. Some participants are affected more by the community events, seasons and check days than others are. Try to be sensitive to the participant's needs when scheduling.

14. Let the participant know you may not have answers to all questions, but that you will try to find answers **and follow-up.**

15. Let people know you will provide transportation to and from clinic when necessary.

16. Give people encouragement, even when they are doing well.

17. Research is not a "priority" to some people. Take your time - don't reschedule them continuously. Find a time that works for the participant and let them know that you will check back with them at a later time.

18. 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.

19. Regular team meetings are important in setting goals, communicating with team members in a meaningful way, in helping to focus efforts and in supporting the efforts of the personnel. Sometimes personnel can become discouraged when events do not go as they were planned. This does not have to mean that things are going badly. Be aware of staff burn-out and the need to stop and to promote other team members or to give them a helping hand.

20. There may be times a "potential" participant is going through a personal crisis. Allow them time to deal with it and go back in a couple of weeks, if possible.

3.2 Recruitment Instructions

For the Phase VII clinical examination, eligible participants are the previous participants of the Strong Heart original and family study; only these previous participants are eligible for enrollment in Phase VII, which is a re-exam of all surviving family study participants. Some local publicity and mailed information will alert the eligible participants before their enrollment in Phase VII is requested.

When contacting an eligible participant, the interviewer re-introduces the Strong Heart Study and once again explains its purpose and importance. A brochure and a letter explaining the purpose of the study and exam can be used for recruitment. The voluntary nature of the study and the confidentiality of the collected data are stressed. If the participant is not at home at the time of the phone call or visit, call backs are made as necessary to meet the individual and schedule the clinic appointment. 100% participation is the goal.

In all areas, the recruiter should wear an identification badge. When scheduling appointments, the recruiter should emphasize the following:

1. That the volunteer should not eat breakfast the morning of the exam and should not eat or drink anything but water after 9:00 p.m. the previous evening. Stress that drinking water is a good idea to keep people hydrated unless they have a medical reason to limit their water intake;

2. That the volunteer should bring with him/her all medications, which he/she has been prescribed and is currently taking (including any they purchased on their own) <u>in their original bottle</u>;

3. That the volunteer should not take any of his/her morning medications; he/she will take them later at the clinic after blood drawing is completed. Let the participant know that they will be given a snack to take with their medications if they choose;

4. That the volunteer should not use tobacco or engage in vigorous activity before the clinic visit;

5. That the volunteer should wear loose clothing (ladies should wear a skirt and blouse or pants and shirt, rather than a dress).

If the participant is *mentally handicapped* or otherwise mentally incapacitated, a surrogate must accompany him/her to the examination, preferably someone who is very familiar with the medical and family history.

The recruiter schedules the appointment with the clinic for each subject. Whenever possible, eligible members of a single household are scheduled on the same day. The recruiter should also verify name, address, date of birth and phone numbers at the time of the recruiting visit. When possible, participants should be reminded by phone or in person the day prior to the visit.

After the visit appointment is made, the clinic staff should assemble all forms and labels necessary for the exam and arrange, *when possible,* to have medical records for that participant available the morning of the clinic visit.

4. Personal Interview

4.1 Components of the Interview Instruments

The questionnaires as list above in **Section 2.1** (see **Appendix 6** for copies of final questionnaire forms) will be administered during the clinical examination or when appropriate, after consent is obtained given to the participant to complete and bring to their examination visit.

4.2 Guidelines for Interviews

4.2.1 Introductions

The personal interview is probably one of the most important procedures for data collection in epidemiologic research. The staff administered interview usually increases response over self-administered questionnaires. Although some of the SHS questionnaires are self-administered there are those that should be interviewer administered or assisted and SHS staff should enquire to ensure that the participant understands the questions and has an opportunity to seek clarification.

When rapport is established between the interviewer and the interviewee, the interview has been shown to be an excellent source of high-quality information for epidemiologic research purposes. However, the interviewer must be able to show tact, care, and sensitivity to be effective. Not everyone can become a successful interviewer.

Also, the personal interview can lead to a lack of standardization in the data collected, particularly in a multicenter study such as the Strong Heart Study. Since the interviewer is known to have a large effect on the quality of the data obtained, interviewer training is very important. Please read this interviewer's manual frequently, and refer to it as needed during the study. It is 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. If there are ever questions about the proper procedures for collecting study data, please look to the manual as the authority. If problems are identified, changes will be made to the manual. Therefore, it is important to keep the manual updated and readily available to maintain consistency across centers. Consistency is extremely important if data across the centers in the Strong Heart Study are to be used in combined data analyses.

4.2.2 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. This sometime requires that the person administering the questionnaire probe for a clear answer. Probing technique is discussed further in section 3e. 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. Ask the questions in the order they are given in the interview form. By following these procedures, staff can achieve a high degree of consistency in the way the interviews are conducted.

4.2.3 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 critical since we will be asking sensitive questions to volunteers, in a situation where they may be uncomfortable. Sensitivity on the part of the interviewer is 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:

1. Non-judgemental, non-evaluative style. A large portion of the impression, which the respondent has of the interviewer is based solely on the interviewer's voice and the manner with which the interviewer responds to the respondent's comments. A judgmental or evaluative response would indicate that the interviewer has made a judgment of the relative goodness, appropriateness, effectiveness, or rightness of the respondent's statement. The interviewer should not, in response to the respondent's statements, state what the respondent should or should not do in a given situation. The interviewer's task is simply to ask the question, listen and record the participant's answer.

2. 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 listen and capture the participant's intent. We are interested in the respondent's impression of what was happening, not in the interviewer's impression.

3. 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 or repeating the question.

4. 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. Other supportive remarks may be to confirm that you are listening by repeating what the participant has stated. However, these should be in keeping with local terms and expressions, and should be short so as not to detract from the interview itself.

5. Probing. This is an important response style. A probe is an inquiry, which indicates that the interviewer's intent is to seek further information, to provoke further discussion along a certain line, or to get more detail. Direct probes will be specific questions about what the respondent said and are intended to add meaning and clarification to the participant's response.

6. Non-directive, or understanding. A typical non-directive response might be "I see". This is the general idea of understanding murmuring. The interviewer might also repeat what the respondent just said. This may prompt the respondent to elaborate.

4.2.4 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.

4.2.5 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 to disease variables relevant to the objectives of the study, and (2) to maximize completeness and minimize error in these measurements. The presence of an interviewer may both reduce error and increase error. It may reduce error by increasing the response rate, motivating the subject to respond well and probing to obtain complete data when the responses volunteered fall short of what is desired. The presence of an interviewer may increase error if, by his or her appearance, manner, method of administration of the questionnaire or method of recording of the responses, he or she exerts a qualitative influence on the subject's responses. Possible sources of error in the interview for data collection include (1) conditions of administration (privacy, heat, light, ventilation, freedom from distraction, lack of time, etc.); (2) interaction of the personality, sex or race of the interviewer with that of the subject; and, (3) performance by the interviewer (questioning, prompting and recording of responses).

The following are the common interviewer errors:

1. Asking errors. Omitting questions or changing the wording of questions. This may be particularly important if the interview is performed in Native language.

2. 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.

3. Recording errors. Recording something not said, not recording something said, incorrectly recording response.

4. 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 by writing "refused/8" in the response space.

4.2.6 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:

1. 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.

2. Place. The place for the interview should be chosen where there are as few distractions as possible. The location of the interview will depend on your institutions policies and procedures during the pandemic and spread of Covid virus. Try to select a place where the participant feels safe, the location is quiet, comfortable and private. If it is possible, it is ideal to sit at a table, with the interviewer facing the interviewee at an appropriate distance. Privacy and ventilation is very important. If the respondent will need to refer to records during the interview, be sure that the records are available before the interview begins.

4.2.7 Asking Procedures

In general, the rules for asking questions in structured interviews can be summarized as follows:

1. Questions must be asked according to the instructions for each form and question. Be sure to read and re-read the instructions for each questionnaire you are using, and to ask all the questions in the same way to each person interviewed.

2. 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.

3. Read each question slowly.

4. Use correct intonation and emphasis.

5. Ask the questions in the order that they are presented in the questionnaire.

6. Ask every question that applies to the respondent (all inapplicable questions will be identified as such by skip instructions in the questionnaire).

7. Repeat questions IN FULL that are misheard or misunderstood.

8. Read all linking or transitional statements exactly as they are printed.

9. 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:

1. 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."

2. The expectant pause. Waiting expectantly will tell the respondent that the interviewer is expecting more information than has been provided.

3. Repeat the reply. Repeating the reply aloud while recording it may stimulate the respondent to provide more details.

4. 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?"

5. 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.

4.2.8 Specific Instructions for Telephone Interviewing

The principles outlined above have been derived solely from research into and experience of face-to-face interviewing. While it is generally believed that these apply to telephone interviewing, the evidence that this is true is very limited. Telephone interviewing is probably not simply the transfer of face-to-face techniques to the telephone. Use of visual cues, such as "show cards", is impossible on the telephone and must be compensated for in questionnaire design. There is evidence that this compensation may lead to response differences. In addition, other non-verbal communication, both from the interviewer to respondent and respondent to interviewer, is absent. The "expectant pause", for example, may be much more difficult to use as a probe for additional information on the telephone. It is also more difficult for the interviewer to establish the legitimacy of the interview on the telephone, and the pace of the interview may be faster (because of the need to keep talking) leading to hurried and, perhaps, less thoughtful responses. On the positive side, the telephone should eliminate non-verbal biasing activity by the interviewer, and may encourage more honest reporting of threatening behaviors. Empirical data, however, have not shown consistent evidence of these effects.

Approval to conduct telephone consents and interviews are Field center specific and must receive approval from each center institutional review board. Telephone interviews conducted with verbal consents will be audio recorded per the request of the Oklahoma IRB

4.2.9 Instructions for Recording Responses

Each interview form (See Appendix C), contain a set of instructions covering each question in the interview form to clearly describe the information that is being solicited. These instructions should be read carefully and understood before attempting to fill out an interview form.

In addition, see the attached instructions for filling out forms. The following are some additional guidelines for recording responses:

1. Make sure that you understand each response.
2. Make sure that the response is adequate.
3. Do not answer for the respondent (i.e., do not infer a response from an incomplete or inadequate reply).
4. 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).
5. Use the respondent's own words and record the answers verbatim.
6. Include everything that pertains to the question's objectives.
7. Note in the questionnaire the nature and place of each probe used.
8. Do not erase anything. If a response is wrong, strike it out and enter the correct response above the previous response.
9. Write or enter "refused/8" beside any question that the respondent refused to answer

4.3 Training & Quality Control of Interviewers

4.3.1 Training

Central training for interviewers was conducted Via Zoom in January 2022 in preparation to the start of exams. Interviewers were trained in the use of a standardized procedure for administering each questionnaire. Training included instructions in research interviewing techniques and in completing each form.

Interviewer skill training includes:

1. Adherence to the standardized protocol
2. Use of non-judgmental attitudes
3. Degree and nature of prompting permitted
4. Dealing with problem interviewing situations
5. Handling participants' comments and recording relevant information on the note logs
6. Post-interview responsibility for the data

4.3.2 Quality Control of Interviewers

To ensure consistency and accuracy and to minimize interviewer variances, the study coordinator will monitor and tape one interview during the first exam month on interviews conducted by each interviewer. For "new staff", this should be repeated each month until the coordinator determines that the interviewer has met the standards of the study. Then, new staff members will be observed on a quarterly basis along with the experienced interviewers. Should any interviewer fall short of the required standards, retraining will be required with special attention given to problem areas. If the problem persists, the interviewer will be removed from the task of conducting interviews.

4.4 COVID-19 Prevention Guidelines for In-person Contact with Participants

Please note that these recommendations are current as of March 21, 2023. Staff are recommended to review current recommendations at the CDC website frequently to remain well-informed and up to date on COVID precautionary recommendations.

<u>If you were exposed</u> to COVID-19, you should start taking precautions.

1. When to Isolate
   a. Regardless of vaccination status, you should isolate from others when you have COVID-19.
   b. You should also isolate if you are sick and suspect that you have COVID-19 but do not yet have <u>test</u> results. If your results are positive, follow the full isolation recommendations below. If your results are negative, you can end your isolation.

2. Isolation Guidelines
    a. If you test positive for COVID-19, stay home for at least 5 days and isolate from others in your home.
    b. End isolation based on how serious your COVID-19 symptoms were. Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation.
    c. If you had no symptoms you may end isolation after day 5.
    d. If you had symptoms and:
        i. Your symptoms are improving you may end isolation after day 5 if you are fever-free for 24 hours (without the use of fever-reducing medication).
        ii. Your symptoms are not improving continue to isolate until you are fever-free for 24 hours (without the use of fever-reducing medication) and your symptoms are improving.
    e. If you had symptoms and had moderate illness (you experienced shortness of breath or had difficulty breathing) you need to isolate through day 10.
    f. Severe illness (you were hospitalized) or have a weakened immune system you need to isolate through day 10.
    g. Consult your doctor before ending isolation.
    h. Ending isolation without a viral test may not be an option for you.
    i. If you are unsure if your symptoms are moderate or severe or if you have a weakened immune system, talk to a healthcare provider for further guidance.
3. Removing Your Mask
    a. After you have ended isolation, when you are feeling better (no fever without the use of fever-reducing medications and symptoms improving), wear your mask through day 10.
    b. If you have access to antigen tests, you should consider using them. With two sequential negative tests 48 hours apart, you may remove your mask sooner than day 10.

        Note: If your antigen test results are positive, you may still be infectious. You should continue wearing a mask and wait at least 48 hours before taking another test. Continue taking antigen tests at least 48 hours apart until you have two sequential negative results. This may mean you need to continue wearing a mask and testing beyond day 10.

5. Physical Examination

Exam visit procedures will be performed in the following order: consent, collection of biospecimens, snack (without caffeine) provided to participant, anthropometry, BP - more than 15 minutes after phlebotomy, ankle edema, pedal pulses, ABIs, SHS questionnaires, and cognitive testing (if applicable).

During the examination, participants wear an exam cape, or loose-fitting clothes that do not impair accurate body measurements and the examination. Shoes and socks are removed for the supine examination and weight and height measurements. The form to be used is given in **Appendix 6**.

5.1 Anthropometric Measurements

According to Hassan et al obesity is an independent risk factor for cardiovascular disease—it is associated with higher rates of known cardiovascular risk factors (diabetes, hypertension, hyperlipidemia, and metabolic syndrome) and it leads to accelerated atherosclerosis and ventricular remodeling. The prevalence of obesity has nearly tripled worldwide since the 1970s. Using anthropometric measures that accurately define obesity is critical to identifying high risk groups for interventions. In the ECHORN Cohort Study the use of waist to hip ratios proved to be a better indicator of obesity than BMI, waist circumference only or waist to height ratios.

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 waist circumference or 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.

Anthropometry is performed with the participant's bladder empty. The subject may wear a scrub suit or light 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.

Values taken are rounded to the nearest unit indicated for each measure. Fractions less than 0.5 will be omitted and rounded down to the closest units while fractions greater than or equal to 0.5 will be rounded up to the next higher unit.

5.1.1 Standing Body Height

The participant stands erect on the floor or the horizontal platform with his/her back against the vertical mounted ruler, shoes removed, 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, the bony socket containing the eye, and 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 footstool 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 stadiometer is mounted perpendicular to the floor).

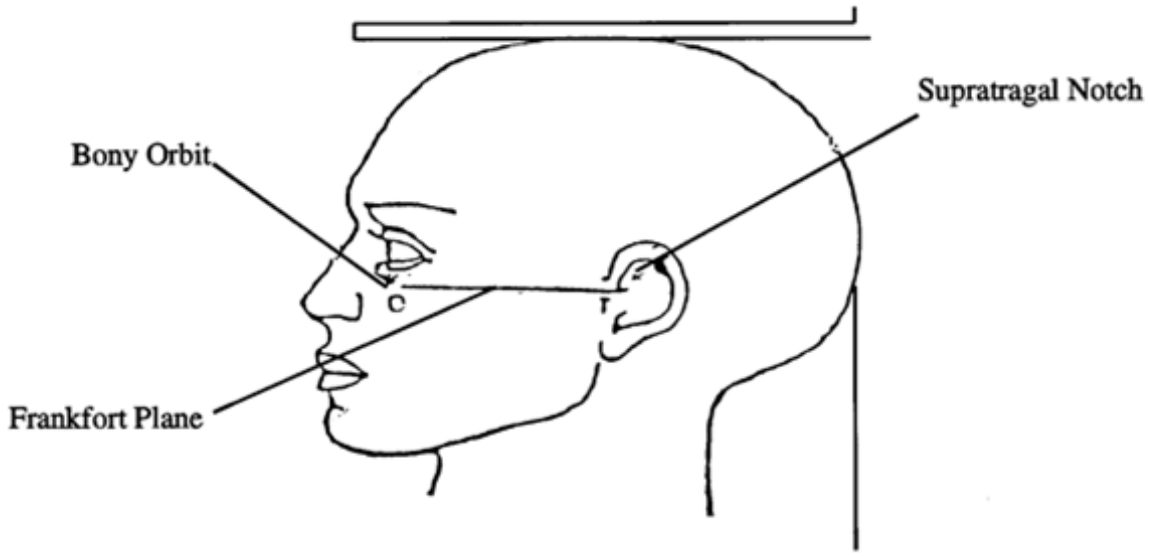


Figure 1 (b). the Frankfort Plane: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external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

5.1.2 Body Weight

Before a participant is weighed, they are asked to empty their pockets, remove any heavy items such as belts with buckles, coats and shoes. The scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Tanita BWB-8005 Adult Digital Scale) with head erect and eyes looking straight ahead. Record the results to the nearest kilogram using the rounding method described above. To maintain accuracy, the scale is zeroed daily and must be calibrated with a known weight (50-lb) every month or whenever the scale is moved. To calibrate the scale, check that the 50-lb weight weighs 50 lbs. after zeroing the scale. Furthermore, the operator should make sure that an adult must weigh 50 lbs. more when standing on the scale holding the weight.

5.1.3 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.

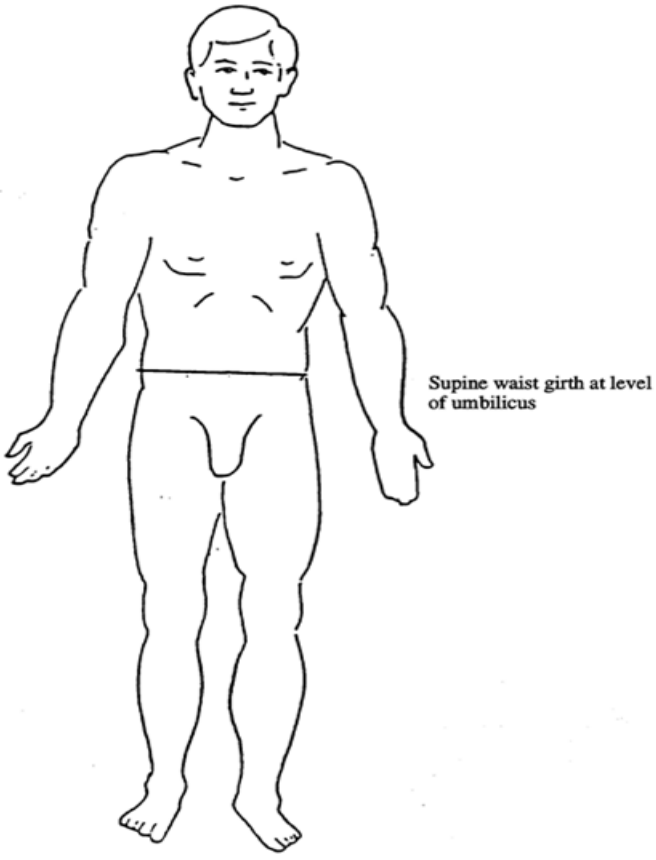


Figure 2. Location of Waist Girth Measurement

5.1.4 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.

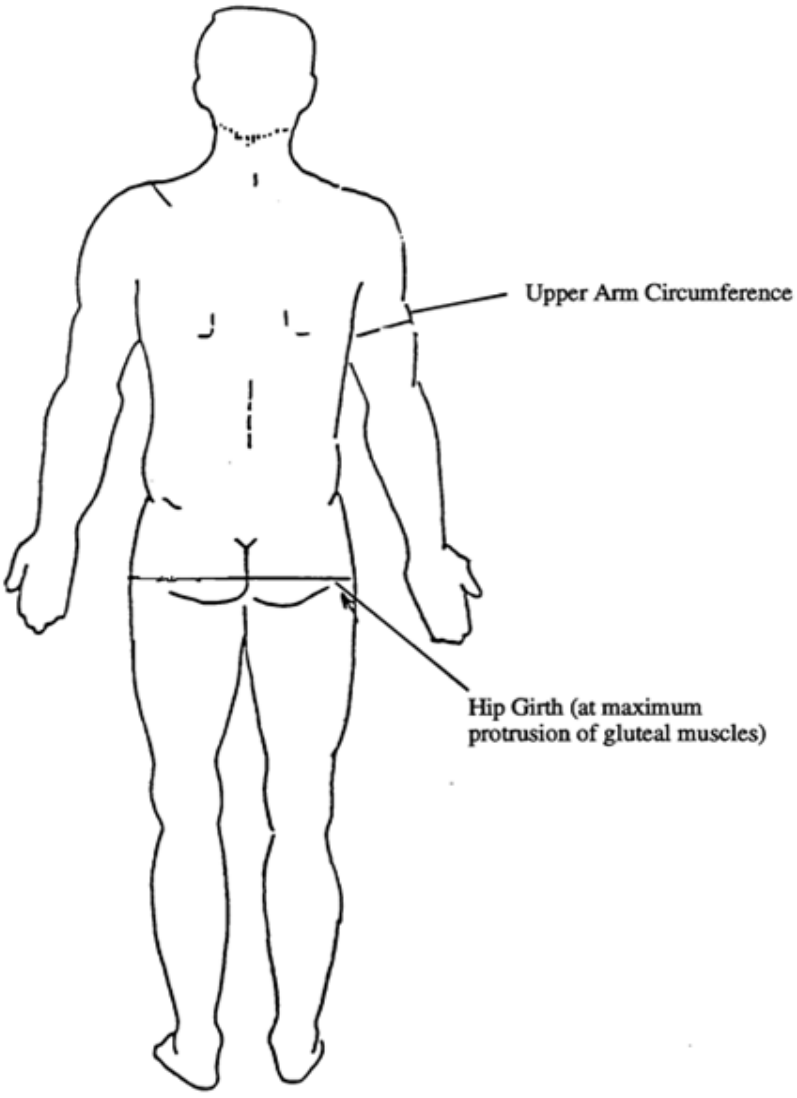


Figure 3. Location of Upper Arm, Hip, and Calf Circumference

5.1.5 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 body measurement tension tape measure is used to measure both abdominal and hip girth and the upper arm circumference.

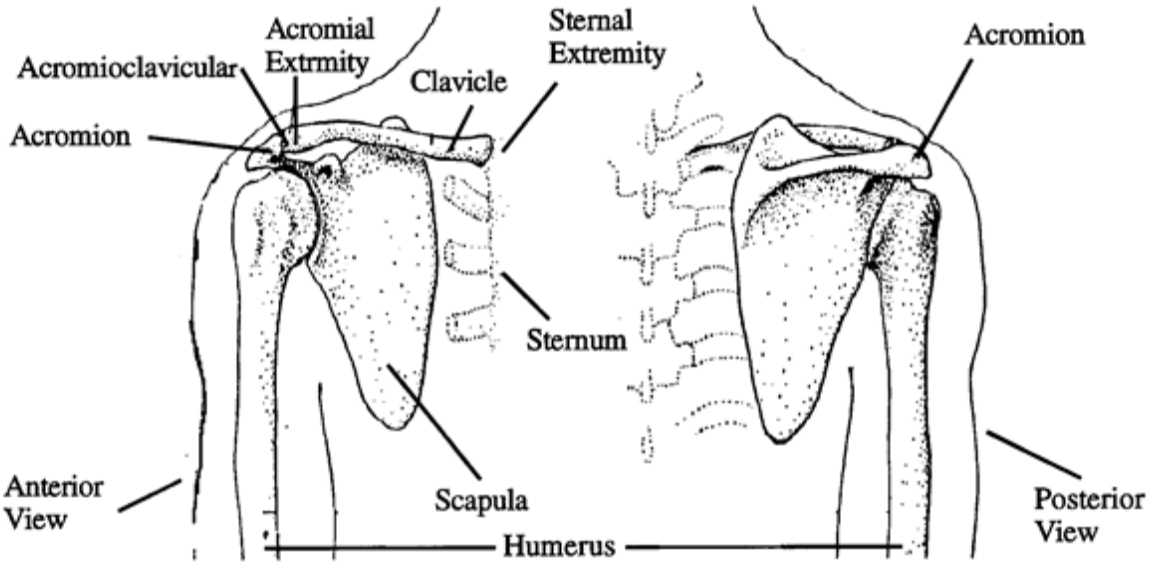


Figure 1 (a). General Description: The **scapulae**, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body.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

5.2 Measurements of Peripheral Vascular Disease

The atherosclerotic process affects vessels in many parts of the body. While the most conspicuous morbidity and mortality arise from coronary atherosclerosis, large vessel peripheral arterial disease (PAD) often results in significant incapacitation of the lower extremities and has also been strongly associated with the incidence of coronary heart disease. Criqui and co-workers have shown that large vessel PAD is strongly and significantly predictive of all-cause mortality in both sexes with a relative risk of 4 to 5, and this was independent of other cardiovascular risk factors in a multivariate analysis. Moreover, data from the Framingham study indicate that diabetes was associated with an even greater magnitude of increase of peripheral vascular disease than was coronary heart disease.

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 following indices of peripheral vascular disease will be made in this study.

1. Palpation of posterior tibial and dorsalis pedis pulses.
2. Rose Questionnaire for intermittent claudication.
3. Measurement of the ratio between blood pressures taken at the antecubital fossa (brachial) and ankle (posterior tibial) using a Doppler listening device.

5.3 Ankle Systolic Blood Pressure

1. Move the participant to the supine position.
2. Assist the participant in moving to the supine position on the examination table.
3. Apply the blood pressure cuff.

The appropriate ankle blood pressure cuff is applied on the right calf. The same size cuff should be used on the lower leg (calf) as the one used on the arm. In special instances, different cuff size may be used.

At this point, a blood pressure cuff is applied above the ankle of the right leg, as shown in Figure 4 (see below). Place the cuff flat on the table (the surface marked "side to the patient" face up) with the appropriate ankle centered on the cuff. At this time disregard the "over the artery" marker. The lower edge of the cuff (from which the hoses extend) should be approximately 2 to 2.5 inches above the medial malleolus. Following the contour of the lower leg, wrap the end of the cuff with the velcro "fabric" over the ankle, as shown in Figure 5. Note that depending on the degree of tapering in this area, the cuff corner will be offset from parallel toward the knee. Holding the cuff from sliding, wrap the other end over the ankle (step 3 in Figure 5 below), again following the contour of the ankle, and secure the Velcro. Check to be sure that the corners of the cuff extending above the upper edge of the cuff are about equal: if one end extends more than the other, loosen the Velcro and adjust the wrap. Next, locate the "over the artery" marker of the cuff, and rotate the cuff so that this line is directly over the posterior tibial artery. The cuff may be rotated more easily by sliding it toward the malleolus, and after alignment, the cuff can be made snug by pulling it up toward the calf. The cuff should conform closely to the shape of the ankle, with the lower edge 2 to 2.5 inches above the malleolus.

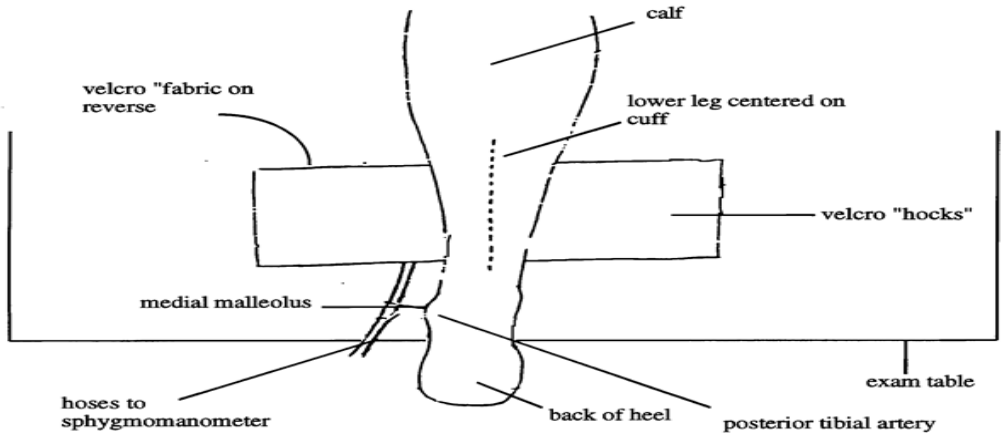


Figure 4. Placement of the blood pressure cuff on the ankle. Step 1 - Positioning the lower leg on the cuff.

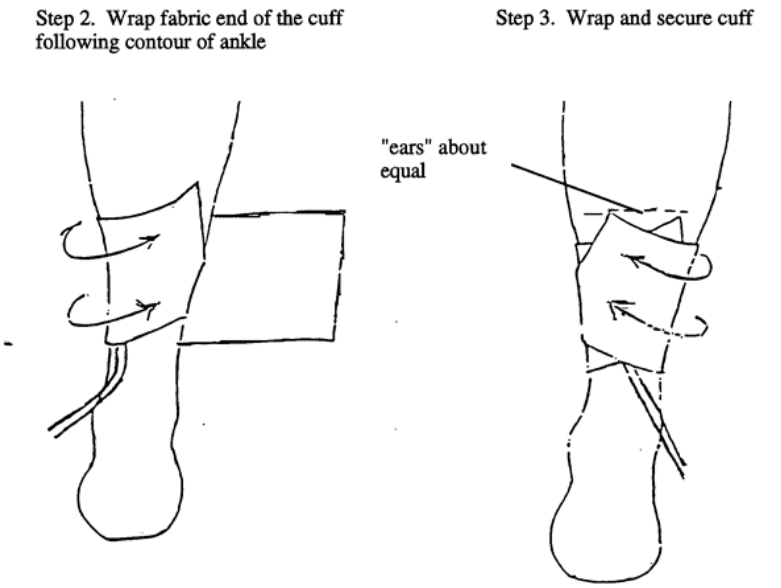


Figure 5. Placement of the blood cuff on the ankle. Step 2 and Step 3: Wrapping and securing the cuff

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.

5.4 Procedure for Measuring Ankle Blood Pressure

1. Palpate both posterior tibial pulses and mark these locations. Apply ultrasound gel to the posterior tibial areas over the pulse or in the area shown in Figure 4.

2. Listen for the right posterior tibial pulse using the Nicolet Imex Elite 100 Doppler. If no pulse is audible or palpable, then try to use the dorsalis pedis pulse for the determination of blood pressure. If no pulse is audible, record zero for ankle blood pressure after the absence of pulses is verified by a second observer.

3. Inflate cuff to a pressure reading 20 mm higher than the "Peak Pressure" used for the sitting arm pressure (i.e., obliteration plus 50 mm) and utilize identical deflation techniques while listening with the Doppler. Record the first sound heard as systolic blood pressure on the physical exam form.

4. Take a second blood pressure using the same techniques, and record the second blood pressure on the Physical Examination Form.

5. Repeat this procedure to record the left ankle blood pressure.

6. Repeat this procedure to record the right brachial blood pressure using the Doppler. The blood pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual. By consulting the participant's Data Form, the observer verifies that the same arm and the same cuff size are used as for the sitting blood pressure readings.

7. If the participant prefers to have his/her sitting blood pressure taken on the right arm 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.

8. To determine the right ankle arm index, add the 2 right ankle measurements and divide by 2 to obtain the average right ankle reading. Then add the 2 right arm measurements and divide by 2. Now divide the average of the right ankle by the average of the right arm to obtain the right ankle arm index. For the left ankle index, obtain the left ankle arm average by dividing the 2 left ankle readings by 2. Then divide this left ankle average by the right arm average to obtain the left ankle arm index. If the ratio of the ankle/arm pressure is less than 0.8 in either leg, the participant should be referred to his/her health care provider.

9. If it is impossible to obliterate the sounds after increasing the pressure to above 250 mm, record 999 on the physical examination form.

10. The observer now removes all conduction jelly. Socks and a robe or other garments are now replaced, and the participant is escorted to the next workstation.

5.5 Examination of the Pulses

5.5.1 Ankle Edema

The socks or other foot covering are removed. The participant is examined in the supine position. Gentle but firm pressure is applied along the mid tibia, anteriorly down to the ankle in each leg. Pitting or indentation remaining after pressure is removed constitutes definite edema. The examiner identifies the mid-point between the prominence of the medial malleolus and the inferior border of the patella. Pitting at or above that mid-point is recorded as "marked" edema. Pitting only below that point is recorded as "mild" edema. The degree of edema is based on the extent.

5.5.2 Posterior Tibial Pulse

The examiner palpates posterior and 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.

5.5.3 Dorsalis Pedis Pulse

The superior aspect of each foot is palpated for the presence or absence of this pulse.

6. Blood Pressure

As blood pressure rises, so does risk of ischemic heart disease and stroke. 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 nondiabetic adults and 130/80 for those with diabetes. Hypertension is an especially strong risk factor for stroke, renal disease, and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure.

6.1 Sitting Blood Pressure

In the Strong Heart Study, sitting blood pressure is measured in a resting state, using 3 measurements with a Baum aneroid sphygmomanometer. With 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.

6.1.1 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.

6.1.2 Description of the Equipment

6.1.2.1 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.

1. The earpiece should be directed downwards and forwards into the external ear canal.

2. The earpieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.

3. The valve between the bell and the diaphragm should be turned in the correct direction.

4. 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.

6.1.2.2 Sphygmomanometers

Standardized Baum mercury instruments have historically been used for all clinic visits for the SHS. In Phase VII of the SHS, the mercury sphygmomanometers will only be used to QC the aneroid sphygmomanometers. The aneroid sphygmomanometers will be utilized for the measure of all blood pressures.

Follow the steps below in order to get the best results from use of the aneroid sphygmomanometer when measuring a patient's blood pressure, taking care to avoid some common errors.

1. Properly expose the patient.
   The blood pressure cuff should never be placed over clothing, as doing so will increase pressure on the cuff and produce an inaccurate reading.

2. Properly position the patient.
   The patient should be seated comfortably, with the legs uncrossed. The artery used to measure the blood pressure should be close to the level of the heart, with the arm supported.

3. Select the appropriate cuff.
   A cuff should be selected that's able to completely encircle the patient's upper arm with 80% of the cuff. If it takes more than 80% of the cuff to encircle the upper arm, the cuff is too small for the patient, and will produce a reading that's higher than accurate. If it takes less than 80% of the cuff to encircle the upper arm, the cuff is too large, and will produce a reading that's lower than accurate. Measure the cuff according to the instructions below to choose the correct cuff size (**Table 1** below).

4. Palpate the artery.
   With the arm fully extended, feel for the pulsation of the brachial artery. Failure to fully extend the arm will result in difficulty both in locating the artery and in auscultating Korotkoff sounds. In most people, the pulse can be felt at the medial aspect of the antecubital fossa, where the artery comes closest to the skin.

5. Properly position the cuff.
   The lower margin of the cuff should be positioned 1 inch above the point where the pulse was located, and should be snug to the arm. In actual practice, it's difficult to make the cuff too tight to the arm; it's quite easy to make it too loose. Locate where the bladder is sewn into the cuff, and ensure that the bladder is positioned over the artery in order to properly occlude blood flow when the cuff is inflated.

6. Use palpation to estimate the systolic blood pressure.
   While palpating the radial pulse, inflate the cuff until the pulse disappears. Release the pressure until the pulse returns, and note the reading on the sphygmomanometer at this point. This is your palpated systolic blood pressure.

Explain to participants that although many EMS professionals and clinicians skip this step-in favor of obtaining an immediate auscultated pressure that for the purpose of research examinations blood pressures are collected differently than in medical care settings. This step is important in order to avoid an underestimation of the systolic blood pressure in the presence of an auscultatory gap–a condition in which Korotkoff sounds disappear for a range of up to 30 mmHg before reappearing.1 Typically noted during Phase 2, the auscultatory gap has been associated with serious vascular disease and chronic hypertension.2

7. Inflate the cuff to 30 mmHg above the palpated systolic pressure.
   You should strive to inflate the cuff to 30 mmHg above the palpated systolic pressure–no more and no less. This avoids both under- and over-inflating the cuff.

8. Slowly release the pressure while looking straight-on at the sphygmomanometer.
   Looking at the face of the manometer at an angle can result in parallax error–an inaccurate measurement due to optics.

6.1.2.3 Cuffs and Bulbs

Proper size of the cuff is essential for accurate blood pressure measurement. Study Centers have four standardized Baum cuffs available – pediatric, adult, large adult, and thigh cuff. The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the Strong Heart Study, arm size is measured, and the cuff size is selected as follows:

Table 1: Determination of cuff size based on arm circumference (Mid humeral)

Cuff	Arm circumference (cm)
Small adult	< 24 CM
Adult	24-32cm
Large adult	33-41cm
Adult thigh	>41 cm

The ideal cuff bladder length is ≥ 80 percent of the patient's arm circumference. The ideal cuff bladder width is ≥ 40 percent of the patient's arm circumference.

6.1.3 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 staff are recorded, so that they can be taken into account during analysis.

The SHS 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 nonprescription drugs, is recorded on the day of the examination. A detailed history of smoking and alcohol intake are also recorded.

6.1.4 Staff Preparation for Measuring Blood Pressure

In relating to the Strong Heart participants, remember that participation in the study is voluntary. Participants are given a 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.

6.1.5 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.

1. 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.

2. Seat the participant with the right arm on the table. The bend at the elbow (ante-cubital fossa) should be at heart level. Legs should be uncrossed and head support comfortable. The participant should be able to relax the neck and shoulder muscles as much as possible.

3. 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 (**Table 1**) and wrap the cuff on the arm with the center of the bladder over the artery. The lower margin of the cuff should be positioned 1 inch above the point where the pulse was located, and should be snug to the arm. In actual practice, it's difficult to make the cuff too tight to the arm; it's quite easy to make it too loose. Locate the artery marker and align it with the brachial artery mark. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five minute wait.

4. 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.

5. Connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no longer felt. Deflate and record the pulse obliteration pressure. Have the participant raise measurement arm for 5 seconds and the wait another 25 seconds with the participant's arm on the table.

6. 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 mm 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 needle falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the higher number should be used.

7. Between measurements 2 and 3: Have the participant raise his/her measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement in step 6 above.

Average blood pressure readings are calculated using the first and second blood pressure readings. Because of the importance of the blood pressure averages, to inform the participant and for the purposes of referral, all arithmetic is done with a calculator.

If for any reason the observer is unable to complete, or has forgotten to complete any portion of the examination (and the participant is gone), draw two horizontal lines through the space(s) on the form. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure workstation, completely deflate the cuff and start over with a replacement reading.

6.1.6 Reporting the Blood Pressure Results to the Participant

Using a calculator, average the second and third readings and mention the results to the participant. State clearly the systolic and diastolic pressures.

6.1.7 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 mm above the previous level.

6.2 Training and Certification

Each technician must undergo training and certification by staff experienced in SHS protocols. Please consult the SHS Training Manual of Operations (Volume VIII) for detailed instructions on the training and certification of staff member. The training program consists of the following components:

1. Consent
2. Personal Interview
3. Anthropometry
4. Blood Pressures
5. Doppler pressures/ Edema/Pedal pulses
6. Diet – FFQ
7. Lab
8. Morbidity and Mortality Surveillance

Training is conducted centrally by an experienced staff member. Each field center trains one or two individuals before the start of the examinations. One individual from each center is designated the center's supervisor. If additional personnel are needed by a center to perform measurements or collection of data points, training is provided by the center's training supervisor.

Training includes:

1. Introduction, rationale for data collection point or body measurement, overview of technique, expected limits of reproducibility, and pitfalls related to measurement.

2. Demonstration of technique. The trainer demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as recording of data.

3. Practice. Technicians perform measurements on each other or on a volunteer under the observation of an experienced trainer. Differences in technique and clarification of problems are discussed.

4. Testing several subjects are assessed independently and blindly by each technician. Each technician's measurements are compared with the trainer's measurements and the results discussed with the technician.

5. Certification. Technicians must measure one or more test subjects and be within the standards of error:
6. The waist and hip measurements must agree within 2 cm on each subject, and the arm and height measurements must agree within 1 cm.

7. The weight must agree within 1 kg.

If these are met, the staff member receives certification for field work. Trainees who have problems are identified, and they are allowed to practice and try again to be certified.

6.2.1 Sitting Blood Pressure Training and Certification

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". At each field center a minimum of two clinic staff persons are trained for measuring sitting blood pressure. They need not be health professionals, but they must be trained and certified in the blood pressure measurement technique. Observers should also have experience in relating to people.

The first training session begins with a description and demonstration of the correct blood pressure measurement procedure. Trainees watch the American Heart Association blood pressure instruction videotape. A checklist is used for certifying all persons taking BPs (**Appendix 4**). Simultaneous BPs will be recorded using a Y stethoscope as described in **Appendix 4**.

It is the responsibility of each field center to conduct these procedures and report to the Coordinating Center when the procedures are completed. Initial site QC should be conducted once a month after initial training has been completed and then quarterly during the first year unless issues arise which require closer monitoring. QC logs are reported to the coordinating center and kept on file at each field centers QC file. 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 mm on any one reading (systolic or diastolic) and averages should agree within 3 mm.

The Coordinating Center directs a blood pressure quality assurance program to review monthly data. This includes quality analysis and review of blood pressure data every 3 months, comparing means for each technician with the values for all technicians, by center. These statistics are adjusted for weight, age and sex of the participants by the use of Z scores. Arbitrary levels of Z-scores, (which can be modified according to performance) are used to detect possible systematic deviations in blood pressure measurement by individual technicians. Digit preference is also monitored for each technician. The Form for Recording Simultaneous Blood Pressure Observations in Appendix A-6 will be used.

6.3 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:

1. Recruitment of the most qualified personnel
2. Standardized training and certification
3. Retraining as necessary
4. Observation of data collection by supervisors, using the checklist given in **Appendix 4**. One checklist is used for each technician and sent to the Coordinating Center and kept on file in the Field centers QC file.
5. Frequent staff meetings to provide feedback
6. Editing of data, both manual and by computer
7. A quality assurance program administered by the Coordinating Center
8. Simultaneous Y Tube observation of each technician by the blood pressure supervisor
9. Equipment maintenance program

6.4 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 enters this data into a Red Cap form to ensure that the coordinating center can monitor in real time. A copy of this log is given in **Appendix 4**.

The standard mercury and aneroid sphygmomanometer is inspected once a month. These inspections include a check of:

1. The zero level
2. Air leakages
3. Manometer column for dirt or mercury oxide deposit for the mercury device
4. Confirmation of zero for the aneroid
5. 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 4**. A mercury sphygmomanometer that is dirty or broken needs to be disposed using a biomedical waste disposal service.

7. Laboratory Collection

Biomarker, Biochemistry and Biorepository Core (B3) aka (MHIR B3 Core Lab), also previously called Penn Medical Laboratory (PML) at Medstar Health Institute Research is the core lab for SHS that performs assays for SHS Phase VII. Blood analytes to be measured are total cholesterol, low-density cholesterol (LDL), high-density cholesterol (HDL), triglycerides, fasting glucose, and HbA1c. Spot Urine analytes to be measured are microalbumin and creatinine.

7.1 Lab Assays

The following are assays conducted at the SHS phase I to V examination and will be repeated on samples from the SHS Phase VII re-examination.

7.1.1 Lipid panel

The lipid panel includes total cholesterol, low-density cholesterol (LDL), high-density cholesterol (HDL) and triglycerides. The relationship between cholesterol and coronary heart disease is well established. Total cholesterol measures the overall cholesterol level. LDL, known as "bad cholesterol," can collect in blood vessels and increase the risk of cardiovascular disease. HDL, known as "good cholesterol" helps reduce the buildup of LDL. Triglycerides are associated with cardiovascular disease and pancreatic inflammation. Lipid panel measurements, especially LDL and HDL are important predictors of atherosclerosis. While somewhat more controversial, triglyceride concentrations, especially in relation to HDL, are an important factor in assessing the risk of coronary heart disease in either populations or individuals.

Measurement of Lipid panel . Lipid panel is analyzed on serum samples on the Siemems Atellica CH930 Chem Analyzer. Testing value for total cholesterol is from 25-618 mg/dL and the assay has <10% CV. Testing value for HDL is from 20-258 mg/dL and the assay has <10% CV. Testing value for triglycerides is from 10-550 mg/dL and the assay has <10% CV. If the level of triglycerides >400 mg/dL, calculated LDL result will be replaced by direct LDL assay. Testing value for direct LDL is from 5.0-1000.0 mg/dL and the assay has <10% CV.

7.1.2 Fasting Glucose

Diabetes is a well-established risk factor for CVD and this condition occurs with a great frequency in the SHS population. This measures glucose in blood after an overnight fast (not eating). A fasting glucose level of 99 mg/dL or lower is normal, 100 to 125 mg/dL indicates having prediabetes, and 126 mg/dL or higher indicates having diabetes.

Measurement of Glucose. Siemems Atellica CH930 Chem Analyzer is used to measure fasting glucose concentration in plasma. Testing value for glucose is from 4-700 mg/dL and the assay has <10% CV.

7.1.3 Hemoglobin A1c

HbA1c provides an integrated measure of glycemia, allows a better estimate of glucose control, and may be a better marker of the entire symptom complex of diabetes than glucose values derived from the oral glucose tolerance test. Changes in HbA1c may be correlated with other genetic analyses focused on progression of diabetes and the relations among diabetes severity and cardiovascular abnormalities.

Measurement of Hemoglobin A1c. The assay will be performed on frozen whole blood samples using the Siemems Atellica CH930 Chem Analyzer. Testing value for HbA1C is from 3.8%-14.0% and the assay has <5% CV.

7.1.4 Urinary MicroAlbumin/Creatinine

Microalbumin is a small amount of a protein that is normally found in the blood and called as albumin, and Creatinine is a normal waste product found in urine. A microalbumin creatinine ratio compares the amount of albumin to the amount of creatinine in urine. If there is any microalbumin in urine, the amount can vary greatly throughout the day. But creatinine is released as a steady rate. Because of this, the health care provider can more accurately measure the amount of microalbumin by comparing it to the amount of creatinine in urine. If elevated microalbumin is found in urine, it may mean there is a problem with kidneys. Thus, a microalbumin creatinine ratio is most often used to screen people who are at higher risk for kidney disease. These include people with diabetes or high blood pressure. Increased level of microalbumin in the urine of diabetic individuals predicts all-cause and CVD mortality in the SHS and in other studies. For the SHS, continue to monitor changes in albuminuria in the family members and relate these to changes in ECHO, carotid and popliteal parameters will add additional power to the genetic analyses.

Measurement of UrinaryMicroAlbumin and Creatinine. Urine microalbumin and Creatinine are measured on the Siemems Atellica CH930 Chem Analyzer. Testing value for microalbumin is from 1.0-6.0 g/dL and 1.0-245.0 mg/dL for creatinine in urine. The assay has <10% CV.

7.1.5 Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes Study:

The following assays are to be collected:

Table 2: Epitranscriptome Study Assays

Data	Study Procedures	Expected Burden to Participants
Whole blood epitranscriptomics (m^6A RWE proteins, global m^6A levels, and transcript specific m^6A modification levels)	Frozen whole blood sample in PAXgene Blood RNA Tube (2 x 2.5mL)	None beyond the already planned blood sample collection
Urine Metals	ICPMS (1.5 mL)	Urine metals are currently planned as part of the Superfund Application to be reviewed in July. By Oct we will know the chances of funding. If funded in that grant, we can leverage those data.
Complete Blood Count	500 uL fresh whole blood in EDTA tube	None beyond the already planned blood sample collection
Fasting plasma to measure fasting insulin	Radioimmuno assay at the MHIR B3 Core Lab	None beyond the already planned blood sample collection

7.1.6 Gut microbiome, Aging and Cardiometabolic Disease in American Indians

A fecal microbiome sample (stool sample) is collected for this study.

In the past few years, it has become clear that the bacteria in your gut (i.e., your "gut microbiome") plays a critical role in health. In particular, bacteria in the gut have been shown to impact weight, heart health, brain health, and immune function. A stool sample will be collected as part of the SHS Phase VII. This will allow researchers to quantify the types of bacteria in participants guts, and to better understand the relationship of the gut microbiome with diet and cardio-metabolic health.

7.2 Sample Storage

The following describes receipt, storage, and quality control of samples received by the lab.

An SOP for DNA and sample storage has been approved by the SHS Indian Communities. It is contained in the SHS Laboratory Manual of Operations (Volume IV).

The SHS field centers notify the lab at least one day in advance of shipments via the laboratory's e-mail account Angelia.Clark-Green@medstar.net> and cc to Jianhui.zhu@medstar.net. Upon receipt of the specimens, the specimen processors at lab open the package and inventory specimens. The specimens are logged into the logbook and, based on the turn-around-time, the processing and assaying schedule is set. The sample inventory information, including date received, sample type, vial number, location of freezer, shelf, and box number) is computerized using the FreezerWork that provides the study updated inventory information when needed.

7.2.1 Storage Conditions

SHS samples are stored in–80°C in Freezers at the lab of MHIR B3 Core Lab. The freezers are continually monitored for variations in temperature using the TempTrak 24/7 remote monitoring system, and technical personnel if needed.

7.2.2 Inventory System

SHS VII samples are inventoried using the FreezerWork that is operated at the OK data center. The FreezerWork currently underway, enables researchers to learn about the specimens available for future research needs.

Each specimen logged into the database is assigned a unique, bar-coded, ID number with the following information recorded: SHS participant ID, type of specimen, volume, vial number, description of storage vial, condition of specimen, storage box number, grid location within the storage box, column and row assignment within a particular freezer, and physical location of the freezer. The sample storage inventory maintained by the lab can query the database by participant ID, volume, and type of specimen. Such versatility makes the retrieval of specimens easier and more accessible to researchers. Additionally, freeze/thaw cycles and disposition of specimens are electronically tracked when specimens are removed from the freezer for assaying.

7.2.3 Off-Site Storage of Subset of Specimens

In accordance with the NIH recommended sample storage policies, the lab, under the direction of the Sample Storage Committee, during the first year of Phase VII, will send a subset of the storage samples to an off-site storage location. The location of the facility will be outside of the Washington, DC, metro area, but close enough for access to the specimens if necessary. Storing a portion of the study specimens off site in a geographically diverse location provides an additional layer of security and helps ensure the preservation of the samples in the event of a natural disaster, terrorist attack, or other catastrophic event occurring in the vicinity.

7.2.4 Sample Retrieval, Processing, and Release

Upon receiving written authorization from the Sample Storage Committee to release specimens and the sample list from the study PI, the lab generates a pull list from the inventory database based on the request. A pull list will contain, but is not limited to, the following information: participant ID, specimen type, volume, box number, freezer number, and freezer location. Upon completion of the pulling specimen aliquots, the lab will ship the samples out as requested and email the sample release form to the PI for the signature. The specimens are checked back into their designated permanent location in the inventory after completing the release. During the inventory process, the database is updated with the new volume and a revised freeze/thaw count. Additionally, a batch database function enables the lab staff to quickly import a brief description of why the specimens were removed from inventory.

The Coordinating Center at OK managers and shares the FreezerWork with the lab. They will provide the FreezerWork service to the lab if needed.

Samples are released from the lab to investigators only by written authority of the SHS Steering committee according to guidelines approved by tribal councils and IRBs of participating institutions. Regulations concerning confidentiality, such as HIPAA, are strictly followed. In addition, because the samples in this study are ultimately the property of the participating Indian Communities, unused material is returned to the lab at the MHIR B3 Core Lab so that community oversight can be maintained. The lab maintains a computerized database of stored samples. The policies governing release of specimens are contained in SHS General Description and Study Management Manual of Operations (Volume I).

7.3 Quality Control

The Biomarker, Biochemistry and Biorepository Core (B3) aka the MHIR B3 Core Lab, previously called Penn Medical laboratory (PML) is a College of American Pathologists (CAP) certified laboratory. The laboratory and the SHS participate in extensive internal and external control programs to ensure stable, accurate, and precise measurements. Quantitative measurements are performed according to strict written guidelines conforming to those of the CAP. Good Laboratory Practice rules are used throughout the laboratory. Instrumentation is maintained according to manufacturer's standards, and performance is monitored according to CAP guidelines. Reagents are purchased from stable sources and purity is monitored according to CAP regulations. Assays are checked for linearity, sensitivity, parallelism, effects of sample freeze/thaw, recovery, and within-batch and between-batch coefficients of variation. All sample storage, short-term or long-term, is at -80°C to minimize degradation. Calibration performs following the CAP guidelines. Controls at several levels are used to monitor assay performance and run with every batch and plotted on Levy-Jennings plots. Whenever possible, lyophilized and frozen controls are used for long-term drift assessment. Quality control samples are also be assayed when performing a calibration.

The lab technicians receive ongoing continuing education and rigorous periodic performance evaluations. Standard Westgard rules are applied to quantitative assays using at least two, and no more than three, quality control samples per run. Standard rules used for assay acceptance include Quality 2_{2s} $10_{x,}$ 1_{3s}. Quality control rules are programmed into on-line software (BioRad

DADE), and technicians are required to visually review Levy-Jennings plots to look for drift. All assay results are reported only after all quality control results are acceptable and reviewed by a technical supervisor before final release into the data system.

The lab participates in all available CAP proficiency tests. SOPs of assays are available for the lab staff. The laboratory staff participates in monthly quality control meetings, in which each analyte is reviewed and actions taken to address problems are critiqued. Laboratory errors and deviations from standard operating procedures (SOPs) are documented in quality assurance incident reports that undergo multiple levels of supervisory review. These are used to implement training or revise procedures to continually minimize variance and maximize adherence to standard procedures.

The lab is used the RedCap for the SHS7 result report. All lab staff will be training by the OK Coordinator Center for using the RedCap. The SHS samples are only identifiable by their study ID at the lab. The RedCap data system is fully documented and maintained by the SHS Coordinator Center at OK.

The lab receives the QC reports of the variance from the OK Coordinating Center summarizing the data by site for the blinded duplicates for each analyte. These are reviewed by the lab director. If the data has >10% Tech Error, the lab will repeat the assay. If the data suggested a sample mix-up, the coordinator at that site is contacted and the local procedures are reviewed and corrected as necessary.

7.4 Field Training

The lab provides a detailed lab manual for the field centers. Central training (group and individual) for the laboratory staffs and phlebotomists of the 3 field centers is conducted at the training session in Oklahoma City prior to the start of exams. The lab can provide visits by the Laboratory supervisor, if necessary. The training sessions emphasized uniform and optimal sample handling, as well as shipping procedures designed to ensure accountability and safe transfer of samples. Site technicians are trained or re-trained in the safe handling of biologic specimens, and considerable emphasis is placed on maintaining communication between the sites and the lab. To maximize uniform and optimal collection of samples across sites, the lab provides the flowcharts and the participant sample form to the field centers. Both are designed to be used at the sample collection stations as quick reminders of SHS sample processing procedures. This methodology has been well used by SHS colleagues in SHS Phase I to V.

8. Ancillary Studies

The Ancillary consent forms are provided in **Appendix 2**.

8.1 Resilience, Cultural Alignment, and Social Support in Brain Aging

The study will efficiently collect psychosocial, biological stress markers, and cognitive aging data as part of ongoing National Heart Lung and Blood Institute contracted examination with the Strong Heart Study cohort, a 30-year population-based longitudinal cohort in American Indian adults from 13 communities across 3 geographic regions of the United States.
This study will conduct novel assessment on psychosocial resilience, cultural alignment and engagement, wellness and personal beliefs; sleep habits and quality; biological data on allostatic load [defined as the wear and tear on the body of the individual as they are exposed to repeated or chronic stressors] and inflammation; serum markers for neurodegeneration [defined as the progressive loss of structure or function of neurons, including neuron death, and associated with diseases such as Parkinson's or Alzheimer's] ; and cognitive and functional data using standard Alzheimer's screening instruments.

8.1.1 Specific Aims

1. Describe associations of individual resilience and features which promote resilience, including social support, cultural identity, and cultural alignment, among AI adults, by age and by sex.

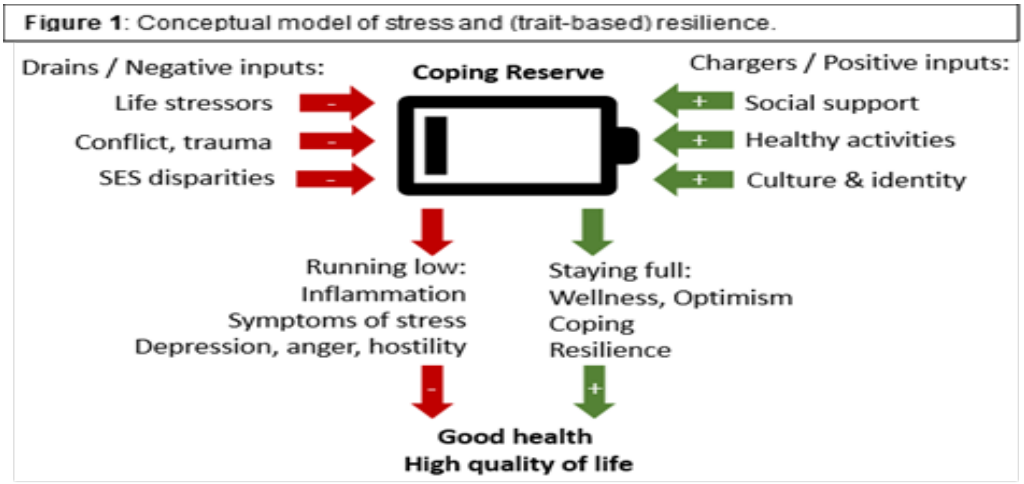
2. Evaluate resilience, social support, and cultural identity and alignment in relation to cognition and ADRD.

3. Use classification-based machine learning to develop explanatory models of resilience and dementia.

8.1.2 Research Strategy

Effects of Trauma and Stress on Health and Aging: There are known experiences within the American Indian communities for both and historical and ongoing traumas. These may contribute to ongoing generational cycles that increase stress and trauma. There are Gaps in Knowledge on the Measurement of stress, and this study will measure cortisol and other biomarkers of stress in a saliva sample. Epigenetic [genetic changes passed down from previous generations] changes may be contributing to ongoing transmission of intergeneration stress and trauma. The contribution of sleep disorders, disrupted sleep following trauma will also be considered.

8.2 Psychological Risk Factors, Quality of life, Community, and Brain Aging in American Indians



The overall objective of the "Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study" is to test the relationships among stress, depression, and substance use (defined as alcohol, tobacco, prescription opioids) with cognitive performance in American Indians (AI) adults and examine whether Health-Related Quality of Life (HRQoL) and community connectedness moderate these relationships. Our central hypothesis is that higher stress results in more depression and substance use, and all three are associated with lower cognition, whereas better HRQoL and community connectedness statistically moderate these deleterious effects.

Results from this study will provide important information for the participating tribes. American Indians are especially burdened by health conditions that may result from chronic stress, depression, and substance use and may include cerebrovascular and neurodegenerative injury, which themselves cause cognitive impairment, dementia, and loss of functional independence. Data from this project may clarify these disease associations and the relative contributions of beneficial personal characteristics, preventing or alleviating the burden of these devastating conditions. Characteristics and related features such as quality of life and community connectedness and participation may be modifiable conditions that can improve a person's health trajectory.

The parent Strong Heart Study will use an umbrella consent form for all ancillary studies participating in the Phase 7 examination. Ancillary consent form for this proposal is found in **Appendix 2**.

8.2.1 Introduction to the NIH Toolbox

The National Institutes of Health (NIH) Toolbox initiative sought to assemble a set of briefs, comprehensive assessment tools that would be useful to clinicians and researchers in a variety of settings, with a particular emphasis on measuring outcomes in longitudinal epidemiologic studies and prevention or intervention trials across the lifespan.

The Cognition Domain Battery includes measures of:

1. Executive Function: is defined as the capacity to plan, organize and monitor the execution of behaviors that are strategically directed in a goal-oriented manner. The NIH Toolbox focuses on the following components of Executive Function:
   a. set shifting, or the capacity for switching among multiple aspects of a strategy or task which is measured by the Dimensional Change Card Sort Test (DCCS).

   b. inhibition of automatic response tendencies that may interfere with achieving a goal which is measured by the Flanker Inhibitory Control & Attention Test (Flanker).

2. Episodic Memory: refers to cognitive processes involved in the acquisition, storage, and retrieval of new information. It involves conscious recollection of information learned within a context. The term "learning" refers to the acquisition of skills and knowledge, while the term "memory" refers to the persistence of this learning over time and/or the facility with which one is able to spontaneously recall the information following a delay. Episodic Memory can be verbal, as in remembering a conversation or a list of grocery items, or nonverbal, as in imagining a place one visited or a picture one saw a week before. In the NIH Toolbox, the Picture Sequence Memory Test (PSM) is a measure tapping Episodic Memory.

3. Working Memory: refers to the ability to store information until the amount of information to be stored exceeds one's capacity to hold that information. Usually, working memory refers to the capacity of an individual to:
   a. process information across a series of tasks and modalities

   b. to hold the information in a short-term buffer

   c. to manipulate the information

   d. to hold the products in the same short-term buffer

   This concept updates the traditional construct of "short-term memory", which refers to a passive storage buffer, to include the notion of an active computational workspace. Working Memory overlaps with constructs of attention and Executive Function. In the NIH Toolbox, the List Sorting Working Memory Test is a measure tapping Working Memory.

4. Processing Speed: is defined as either the amount of time it takes to process a set amount of information, or, conversely, the amount of information that can be processed within a certain unit of time. It is a measure that reflects mental efficiency. Processing Speed is central for many cognitive functions and domains and is sensitive to change and/or disease. In the NIH Toolbox, the Pattern Comparison Processing Speed Test and aspects of the Flanker test are measures tapping Processing Speed.

5. Language: refers to a set of mental processes that serve to translate thought into symbols (words, gestures) that can be shared among individuals for purposes of communication. The NIH Toolbox focuses on two aspects of language.
   a. The first measure is the NIH Toolbox Picture Vocabulary Test, tapping receptive word knowledge that is fundamental to learning and that also has a very high association with overall intelligence.

   b. The second measure is the NIH Toolbox Oral Reading Recognition Test, tapping oral reading skill that reflects level and quality of prior educational experiences. This measure provides a fairly robust indication of verbal intelligence that is relatively undisturbed by many medical conditions that affect the brain.

6. Attention: refers to the allocation of one's limited capacities to deal with an abundance of environmental stimulation. It is measured by the NIH Toolbox Flanker Inhibitory Control and Attention Test.

The fully computerized battery (tablet version) takes approximately 30 minutes to administer. The Picture Vocabulary test uses an audio recording of words and photographic images on the computer screen. On the Oral Reading Recognition test, participants are asked to read and pronounce letters and words. Dimensional Change Card Sorting requires participants to set-shift by selecting a target picture between two pictures that vary along two dimensions. The Flanker Inhibitory Control and Attention Test requires participants to focus on a target middle stimulus in a series and respond quickly while inhibiting attention to similar stimuli flanking it. The Picture Sequence Memory Test involves recalling the order of increasingly longer series of pictured objects after delay periods. On the List Sorting Test, pictures of different foods and animals are presented that must be mentally sequenced in a given order. Lastly, on the Pattern Comparison Test, participants must decide whether pairs of pictures and designs are the same or not. The Administrator's Manual will be followed for this assessment.

Interviewers will be trained using a standardized procedure for administering the NIH Toolbox Cognition Battery. Training will be coordinated an NIH Toolbox consultant, with training sessions as needed. The NIH Toolbox instruction manual will be used to train each field center on how to administer the cognition battery on an I-Pad.

8.2.2 Material Needed

1. iPad
2. NIH Toolbox List Sorting Working Memory Test Examiner Answer Sheet

8.3 The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes.

Diabetes is the second leading cause of death worldwide, with particularly high prevalence among American Indian communities. Experimental and epidemiologic research, including from within the SHS, demonstrates that Arsenic (As), a prevalent environmental contaminant, can impact the development of diabetes and diabetes control. However, the mechanisms underlying these effects remain unknown, hampering key prevention and early detection efforts. Post-transcriptional modifications of RNA play a fundamental role in gene expression. Emerging evidence demonstrates that this "epitranscriptome" plays a key role in the pathogenesis of diabetes and obesity. Furthermore, the epitranscriptome is regulated by oxidative stress, suggesting modulation by metals and metalloids like As. One modification in particular, N6-methyladenosine (m6A) is the most prevalent mRNA modification in mammals and a key regulator of mRNA stability and translation1–3. However, health effects from environmental exposure-induced changes in m6A remain unknown and current evidence is mostly based on model organism research.

SHS has detailed arsenic exposure data from multiple generations, covering several exposure windows, as well as obesity and diabetic outcomes collected over 30+ years. Through this exceptional exposure and outcome data, the SHS has been integral to uncovering the impact of arsenic on diabetes and metabolic health, providing compelling data on mechanistic pathways and avenues of intervention. Combining the unique history of the cohort, availability of the data, and the resources available at visit 7 (planned for 2021-23), we have an exceptional opportunity to examine the epitranscriptomic impact of chronic arsenic exposure and the role of epitranscriptomics in obesity and diabetic risk, progression, and control. We hypothesize that exposures to As and other metals induce changes to m6A levels on specific transcripts and expression levels of m6A modification reader, writer, and eraser proteins (RWE), leading to diabetes and obesity. To investigate this hypothesis, we propose an ancillary study within the SHS to examine m6A profiles in 1300 participants at the Phase VII visit with a mixture of diabetes and metabolic syndrome.

8.3.1 Specific Aims

1. Examine the associations of As and other metals with epitranscriptomic marks in whole blood.
    a. Examine the cross-sectional and prospective associations of exposures to As and other metals with m6A RWE mRNA expression in whole blood.

    b. Examine the cross-sectional and prospective associations of exposures to As and other metals with global and transcript specific levels of m6A modification in whole blood.

    c. Identify an epitranscriptomic "fingerprint" using transcript specific levels of m6A modification that reflects past and/or long-term exposure to As and other metals.

2. Examine the associations of epitranscriptomic marks in whole blood with obesity and diabetes.
    a. Examine the associations of m6A RWEs mRNA expression in whole blood with obesity, subclinical indicators of diabetic risk (plasma glucose, plasma insulin, serum lipids), risk of clinical diabetes, and diabetic control/severity (whole blood HbA1c and albuminuria).

    b. Examine the associations of global and transcript specific m6A levels in whole blood with obesity, subclinical indicators of diabetic risk (plasma glucose, plasma insulin, serum lipids), risk of clinical diabetes, and diabetic control/severity (whole blood HbA1c and albuminuria).

3. Evaluate whether the associations between long-term arsenic exposure and diabetic risk is mediated by specific changes in m6A RWE mRNA expression or m6A levels in specific transcripts.

4. Identify specific m6A RWEs and/or m6A-bearing transcripts that may mediate the relationship between arsenic and incident diabetes. We will additionally study subclinical indicators of diabetic risk (plasma glucose, plasma insulin, serum lipids) and diabetic control/severity (whole blood HbA1c and albuminuria) as secondary outcomes.

8.3.2 Significance

Environmental Risk Factors for Diabetes: Increasing evidence supports that environmental chemicals, including endocrine disrupters and metals/metalloids, play a role in the diabetes epidemic. Diabetes burden is markedly greater in American Indian (AI) populations than other races/ethnicities in the US[4–9]. In 1989-91, diabetes prevalence in the Strong Heart Study population 45-74 years of age ranged from 34% in North/South Dakota to 68% in Arizona. Diabetes incidence has increased at a high rate even though obesity rates have remained stable. Environmental chemicals such as arsenic may be contributing to this excess risk. Little is known, however, about the molecular mechanisms that link exposure to environmental chemicals and diabetes outcomes. We propose to examine RNA modifications- collectively called the "epitranscriptome"- as a novel epigenetic regulator and predictor of As-induced diabetes.

The Epitranscriptome as a Novel Mechanism of Diabetes: There are over 100 post-transcriptional modifications across all types of RNA. These marks play a critical role in RNA folding, stability, localization, and translation with significant alterations in function based on the location and quantity of the modifications on the RNA. N^6-methyladenosine (m^6A) is the most prevalent mRNA modification in mammals and a key regulator of mRNA stability and translation. m^6A is regulated by a group of proteins called reader, writer, and erasers (RWEs), which are responsible for adding, interpreting, and removing m^6A modifications on RNA. m^6A and RWEs are responsive to chemical stimuli and have been implicated in diabetes and obesity, however, more work in human population studies is necessary to untangle these mechanisms and establish m^6A as a mediator between As exposure and diabetes.

Environmental Exposures and the Epitranscriptome: Research in experimental models clearly shows that the epitranscriptome is responsive to external stressors, particularly pro-oxidants like As and other metals. For instance, a distinct pattern of RNA modifications predicted exposure by individual stressors, arsenite. Furthermore, *in vitro* oxidative stress exposures induce hundreds of m^6A on mRNA, while *in vivo* arsenite treated mice had increased global m^6A content in neurons. These effects may be driven by changes in RWE expression and activity, as demonstrated by reduced expression of m^6A demethylase FTO in mice following arsenite exposure. Recent advances also demonstrate that the epitranscriptome plays a functional role in stress response regulation following environmental exposure, leading to mRNA triage to stress granules and promoting selective translation. The studies outlined above demonstrate that external stimuli, and particularly pro-oxidants like As, alter the epitranscriptome to play a functional role in the stress response. To date, research on As and the epitranscriptome have focused on the effects of arsenite on neurodevelopment. However, no study has examined the effects of As and other metals on the epitranscriptome in human populations, nor in relation to diabetes.

The Epitranscriptome in Diabetes and Adiposity: With such a crucial role in basic biological processes, it stands to reason that m^6A would play a key part in disease. Mounting evidence suggests that m^6A and its RWEs are critical in development of diabetes and obesity, a key risk factor for diabetes. Fat mass and obesity-associated protein (FTO) is an m^6A demethylase with strong ties to adiposity and diabetes in both experimental and human population studies. Genetic variants of FTO have been linked to diabetes and obesity in large population studies. In diabetic patients, FTO mRNA expression was correlated with diabetic status, patient glucose levels, and lower global m^6A content, while higher FTO mRNA expression was observed in patients with hyperglycemic emergency than those with hypoglycemic emergency. These effects were confirmed in diabetic rats and following glucose stimulation *in vitro*. Similarly, prenatal low fat diet, which induces insulin resistance in the model organism *P. obeseus*, increased FTO and methyltransferase, METTL3, expression accompanied by decreased global m^6A. Additional evidence indicates that m^6A plays a critical role in fat cell development, called adipogenesis. FTO regulates mRNA splicing of targets required for adipocyte differentiation. Furthermore, FTO-dependent demethylation of a specific mRNA transcripts is a key regulator of excess skeletal muscle lipid accumulation associated with diabetes.Thus, experimental and human population research suggests that the epitranscriptome plays a critical role in the pathogenesis of diabetes and obesity, however, no study has examined these relationships in a large observation study nor in relation to metals exposure. Furthermore, genetic variants of FTO have not be linked to FTO expression or m^6A content, leaving a critical gap in our understanding of the role of these variants in health and disease.

8.3.3 Methods

Population: Blood will be collected from a subpopulation of 1300 participants at the Phase VII visit with complete data on metals exposure, anthropometric measures, and metabolic health outcomes. We expect this population to have ≥500 cases of diabetes at visit 7. This population will be selected based on the subset of participants from the Strong Heart Family Study (SHFS) who also have their mother in the Strong Heart Study (SHS). These inclusion criteria will allow us to characterize current (at the time of visit 7 in 2021-2023), past (at the SHFS baseline visit in 2000-2003), and early life (maternal data available in the SHS baseline visit in 1989-1991) arsenic exposure.

Blood Collection: The ancillary study will provide two 2.5mL PAXgene tubes specialized for RNA stability for the phlebotomy, which can be handled similar to other tubes in the study, and frozen at -80°C for future analysis. A third standard blood draw tube (with EDTA) will be collected for complete blood count (CBC) on site. This will provide essential information on the cell composition of each sample for comparison with epitranscriptomic results, as each cell type may have different transcriptional regulation. PAXgene tubes will then be sent on dry ice to the Baccarelli Laboratory for epitranscriptomic analyses, where RNA will be isolated via standard protocol. It is estimated that only one 2.5mL PAXgene tube will be necessary for this analysis and the second tube can be stored for future RNA studies.

Epitranscriptomics Analysis: We propose three separate analyses of the m^6A epitranscriptome to provide a comprehensive assessment of the mechanistic role of m^6A in As-induced diabetes. First, we will quantify total m^6A to obtain an overview the response of total m^6A to As/metals and diabetes/obesity, as previous studies have demonstrated reduced m^6A content in diabetic patients. We will use commercially available Enzyme-Linked ImmunoSorbent Assays (ELISAs) to quantify whole blood m^6A. Next we will examine gene expression levels of m^6A RWEs (e.g. FTO) to assess m^6A regulation following exposure to As and other metals and in relation to diabetes. FTO, m^6A writer METTL3, and m^6A readers YTHDF2, have been shown to be altered during diabetes and adipogenesis and in response to arsenite exposure. We will use a quantitative real time PCR (qRT-PCR) assay designed in the Baccarelli Laboratory to examine the gene expression of 15 m^6A reader, writer, and eraser genes. Finally, research has demonstrated that the quantity and location of m^6A on specific mRNA transcripts determines the cellular response[1,2], so we will perform m^6A RNA Immuno-Precipitation Sequencing (m^6A RIP-Seq) to investigate metals-induced alterations in m^6A modified transcripts and their role in diabetes and obesity. This method uses an anti-m^6A antibody to specifically target m^6A modified mRNA transcripts that can then be quantifyed using next-generation sequencing methods. To date, no study has investigated the location and number of m^6A on mRNA transcripts in diabetics or following As exposure. By sequencing m^6A modified transcripts, we will be able to identify specific mRNA targets that may reflect As exposure and/or predict diabetes development or control.

8.3.4 Data to be Collected

Data	Study Procedures	Expected Burden to Participants
Whole blood epitranscriptomics (m^6A RWE proteins, global m^6A levels, and transcript specific m^6A modification levels)	Frozen whole blood sample in PAXgene Blood RNA Tube (2 x 2.5mL)	None beyond the already planned blood sample collection
Urine Metals	ICPMS (1.5 mL)	Urine metals are currently planned as part of the Superfund Application to be reviewed in July. By Oct we will know the chances of funding. If funded in that grant, we can leverage those data.
Complete Blood Count	500 uL fresh whole blood in EDTA tube	None beyond the already planned blood sample collection
Fasting plasma to measure fasting insulin	Radioimmuno assay at the MHIR B3 Core Lab	None beyond the already planned blood sample collection

8.3.5 Benefit to American Indian Health and the SHS Communities

American Indian communities are suffering a high burden of disease from diabetes and diabetes complications. This study will provide necessary information on relevant mechanisms for the relationship between environmental chemicals and diabetes in the Strong Heart Study. Several SHS communities have been (and some community subsets continue to be) exposed to relatively high levels of arsenic and other metals/metalloids. Other rural populations, including many other tribal communities beyond the SHS, continue to be exposed to arsenic. This study can contribute to early detection of disease risk and to a better management of diabetes control and disease severity. Beyond arsenic and environmental exposures, this study can contribute to identify critical mechanisms for diabetes development, which could result in the development of novel interventions for the prevention and treatment of diabetes.

8.4 Gut microbiome, aging and cardiometabolic disease in American Indians

Gut microbiota (bacteria, viruses, fungi, multicellular parasites, and archaea in our intestine) has recently emerged as a novel, metabolically active "organ" that participates in numerous key biological processes such as energy production, aging, immune system, glucose metabolism, low-grade inflammation, etc. Gut dysbiosis (imbalance in gut microbial community, e.g., loss of microbial diversity and/or beneficial microbes, expansion of pathogenic microbes) has been closely linked to aging and age-related cardiometabolic diseases (CMDs) such as obesity, diabetes, hypertension, cardiovascular disease, chronic kidney disease, insulin resistance, and dyslipidemia. However, several fundamental gaps exist in this field. First, current research has mainly focused on animal models, results from which are not directly transferable to humans. Of the limited epidemiological studies in humans, most investigations included individuals with European ancestry and results are mixed.

Moreover, most human studies focused on the composition of gut microbiota at the phyla- or the genus-level (e.g., Firmicutes, Bacteroidetes, Actinobacteria, Proteobacteria, etc.), but knowledge of individual microbial species is required to decipher their biological roles in human pathophysiology. To date, a complete mapping of the human gut microbiome (both composition and function) in a well-characterized population of aging and age-related chronic metabolic conditions is still lacking. Second, the human gut microbiota is a function of the host's age, gender, geography, genetic makeup, and environmental factors (e.g., diet, use of antibiotics, etc.), all of which could be population-specific, but our understanding of their roles in shaping gut microbiome composition and function in different populations/ethnic groups remains very limited. The lack of such knowledge hampers our ability to develop personalized gut microbiome-targeting therapeutic interventions for aging and age-related disorders. Third, although experimental studies support a causal role of gut microbiota in aging and CMDs, studies in humans are largely correlative in nature and our understanding on host-microbe interactions is limited. Additional research is needed to delineate how and why gut dysbiosis affects aging and age-related disorders. Leveraging a well-characterized longitudinal cohort of American Indians (AIs), who will be re-examined in 2020-2024 through the Strong Heart Study (SHS) Phase VII (funded by NHLBI as a contract, 2019-2026), the objectives of this ancillary study are to close these fundamental gaps by profiling the first complete map of the human gut microbiome and to examine how age-related gut dysbiosis contributes to accelerated biological aging and CMDs in AIs who live on reservations or other tribal lands, are exposed to a unique set of environmental and cultural exposures and often practice quite unconventional lifestyles.

8.4.1 Specific Aims

1. Identify age-related gut microbial features associated with biological aging and CMDs in AIs. Leveraging the parent SHS Phase 7 that will re-examine all living participants in 2020-2024, this ancillary study will collect fecal samples from 1,500 American Indian participants and conduct whole-genome deep shotgun metagenomic sequencing to generate the first complete blueprint of the human gut microbiome (both composition and function) in this high-risk but historically understudied population. Statistical analyses will be conducted to identify age-related gut microbial features and assess their associations with biological aging (assessed by leukocyte telomere length) and cardiometabolic diseases.

2. Identify clinical correlates of gut microbiome in relation to biological aging and CMDs in AIs. An individual's gut microbiota is highly variable and depends on his/her diet, geography, genetic makeup, lifestyle, health status, etc. Leveraging the comprehensive cardiometabolic phenotypes collected in the SHS, we will identify clinical and epidemiological factors influencing gut microbiome variation in relation to aging and CMDs. As many SHS participants live on reservations or other tribal lands, consume traditional AI food and medicine, and practice other AI-specific lifestyles, the work proposed here is anticipated to identify individual- and community-specific risk and protective factors that could be modulated for healthy aging and cardiometabolic health in this high-risk population.

3. Explore the mechanistic links between gut dysbiosis, biological aging, and CMDs. Leveraging the existing genetic data in the SHS, we will conduct innovative statistical analyses to evaluate the impact of host genome on key microbial features associated with biological aging and CMDs, examine host-microbiome interactions, and explore the potential causal role of gut dysbiosis in CMDs using a systems biology approach.

Results of this pioneering project will: (1) fill in critical knowledge gaps and obtain mechanistic insights into the relationship between gut microbiome, biological aging, and CMDs; (2) lead to personalized, evidence based therapeutic interventions (e.g., diet, drugs, live organisms) for healthy aging and cardiometabolic health

8.4.2 Data collection

1. Bristol stool chart: a self-administrated questionnaire at the time of stool sample collection. A total score will be derived to assess stool frequency and stool type.

2. Diet: will be collected dietary using the Food Frequency Questionnaire (FFQ), a widely used dietary assessment tool validated in large-scale epidemiological studies including the SHS. Dietary pattern will be derived based on FFQ and dietary quality will be measured using the Alternative Health Eating Index-2010 [AHEI-2010]), a popular tool that is based on evidence-based recommendations and has been consistently shown to strongly predict risk of major CMDs (e.g., T2D, CVD) and mortality.

8.5 Health effects of metals in American Indian communities: a longitudinal multi-omics study

Native American populations have higher rates of cardiometabolic disease, including cardiovascular disease (CVD) and diabetes, than any other racial/ethnic group in the US. Previous investigations in the Strong Heart Study (SHS), it was observed showed that long-term arsenic (As) exposure can explain part of the excess burden of cardiometabolic disease. Uranium (U) exposure is associated with CVD in occupational cohorts, but data from general populations are limited. Importantly, As and U are common contaminants in Superfund sites and tribal lands, so exposure to these contaminants could be partially responsible for increased rates of cardiometabolic disease in Native American populations. Advancing effective interventions for metal-related cardiometabolic diseases requires robust data on the lasting effects of past exposures, the joint effects of As and U, and the relevant mechanisms, including downstream molecular effects. To address these needs, we will establish the Strong Heart As/U Lifelong (SHAUL) study (n=1,300) by linking data from participants at SHS visit 1 (1989–91) with their offspring recruited during the SHS family expansion in 2001–03 (visit 4). We will leverage 30 years of data and a new visit planned for 2022–23 to address the following aims. (1) Determine the cardiometabolic effects (diabetes and CVD) of childhood and adult As and U exposures overall and by sex, region, and nutritional status. Urinary metal biomarkers are available at visits 1 (reflecting childhood exposure) and 4 (reflecting adult exposure), and will be measured at visits 5 (2006–09) and 7 (2022–23) to reconstruct lifelong exposures. Water metal data, including spatial patterns, temporal trends, and stable isotope data tracing potential sources, will be available from Projects 1 and 2. (2) Determine the longitudinal epigenetic and metabolomic effects of childhood and adult As and U exposures overall and by sex, region, and nutritional status. We will measure genome-wide DNA methylation (DNAm) at visits 4 and 5, leverage extant targeted and untargeted metabolomics from the same visits, and use a joint DNAm/metabolomic multi-omics strategy. (3) Develop a predictive multi-omics fingerprint that quantifies latent and concurrent cardiometabolic risk due to As and U exposures. We will use machine learning approaches to characterize DNAm and metabolomic profiles that identify individuals at risk of diabetes or CVD due to past or current metal exposures. We will also conduct a cross-species multi-omics comparison with Project 4's mouse data. Cardiovascular disease, diabetes, and metal exposures are major concerns for our partnering communities in the Northern Plains. By investigating the latent and concurrent effects of As and U exposures, the SHAUL study can reveal epigenetic and metabolomic mechanisms for metal-induced health effects, identify susceptible populations, and inform risk assessment. The findings will have direct implications for the prevention and control of water contaminants and cardiometabolic diseases in affected communities, including in the Northern Plains, near Superfund sites, and near other contaminated areas in the US and globally.

8.5.1.1 What Is Involved in The Study?

This study will use a portion of the urine and the blood samples already collected by the Strong Heart Study in previous phases. We will measure urinary arsenic, uranium and other metals in samples from phase 5. We will measure DNA methylation in samples from phases 4 and 5. These measures of DNA will help us assess the function of the genes. In addition, we will collect a sample of water from study participants' kitchen faucet, and conduct a brief water and residential history questionnaire. These questions have been added to the Strong Heart Study Phase VII Exam questionnaire.

8.6 Chronic respiratory diseases among Native Americans

With an aging of the world's population, chronic respiratory diseases, such as chronic obstructive pulmonary disease (COPD) and asthma are becoming a more prominent cause of death and disability. Patients with chronic respiratory diseases are most at risk of severe illness from Coronavirus disease 2019 (COVID-19). Chronic respiratory diseases have higher prevalence in Native Americans than in other races and significant impact to Native American communities. However, the respiratory health needs of Native Americans have rarely been systematically assessed. We propose a pilot study with the goal to evaluate chronic respiratory disease status and assess barriers to respiratory healthcare among Native Americans. In this cross-sectional pilot study with SHS cohort, survey will be conducted. The study aims to assess the chronic respiratory symptoms, treatment, respiratory knowledge, attitude, behavior, potential barriers to respiratory healthcare and lung function. The preliminary data will inform a larger, population-based study to generate critical information to develop effective interventions to improve respiratory health in Native American communities.

Despite new and improved treatments for many chronic respiratory diseases, racial disparities in risk factors, access to care, and outcomes are common. Much attention of policy makers, program planners, clinicians, and researchers in physical health disparities focuses on cardiometabolic diseases and cancer. Chronic respiratory diseases, such as chronic obstructive pulmonary disease (COPD) and asthma, receive less attention despite documented racial disparities in outcomes for these conditions.

The respiratory health needs of Native Americans (NAs) have rarely been systematically assessed, despite respiratory diseases being highly prevalent in this population. We will conduct a pilot cross-sectional study with the following goal: To evaluate chronic respiratory disease status and assess barriers to respiratory healthcare among NAs. Our hypothesis is that NA participants have unique needs to improve chronic respiratory diseases healthcare.

Specific Aim: Assess the basic characteristics, chronic respiratory symptoms, and collect self-reported history of respiratory diseases.

8.6.1.1 What Is Involved in The Study?

A questionnaire will evaluate participant's chronic respiratory symptoms and collect self-reported history of respiratory diseases. Sociodemographic information (age, sex), smoking history, height, weight, and waist-hip ratio will be collected during the regular SHS (phase VII) physical examination visit.

8.7 Bilingualism, cognitive reserve, Alzheimer's disease and related disorders in American Indians: the Strong Heart Study

American Indian populations have greater burden of cerebrovascular and Alzheimer's disease (AD) comorbidities compared with non-Hispanic White U.S. populations. These comorbidities are leading causes of cognitive decline and dementia. However, bilingualism can enhance working memory capacity, attentional control, and cognitive reserve. Bilingualism is a highly individual experience and the context of use strongly modifies cognitive effects. Factors that may influence this association include age, sex, vocabulary knowledge, physical and mental status, socioeconomic status, culture, and social activity. Thus, it is critical to assess the relationship between bilingualism and cognitive performance in American Indian adults.
Although the link between bilingualism and cognitive reserve and resilience has been studied in many populations, bilingualism research in American Indian populations has been limited, due in part to critical cofactors related to their experiences, perspectives, and assessments of bilingualism compared to other racial, ethnic, and cultural groups. Due to unjust U.S. federal policies affecting American Indian people, such as forced attendance at English-speaking boarding schools where use of Native languages was punished and cultural assimilation was prioritized over quality of education, bilingualism in American Indian adults may present differently than in other populations. For example, although NIA (RFA-AG-23-001) defines bilingualism as "proficiency in two or more languages", no validated, detailed assessment of speaker proficiency exists for Native U.S. languages. Our proposed study will comprise the first to culturally adapt a language history instrument using a large, heterogeneous American Indian population.

In response to RFA-AG-23-001, we will leverage the Strong Heart Study, a large, longitudinal, heterogeneous, population-based study of aging in American Indian adults over 3 major regions. Our research team has validated related and demonstrated and functional features, the assessment of population strata differences in cognitive test scores, specifically, 1) a 40% lower association between education and crystallized cognition in American Indian adults (rho=0.3) compared to the general population (rho=0.7) and 2) bilingualism inversely related to cognitive performance. However, this work has been limited in the detail available on language assessment; on the number and age of individuals assessed; on the cognitive domains simultaneously measured; and on the relationship with crystallized cognition, or educational achievement. This project aims to overcome those limitations by efficiently leveraging ongoing recruitment efforts within the Strong Heart Study, which is already funded to measure acculturation (R01AG070822, PI: Suchy-Dicey) and cognition using NIH Toolbox in 3000 American Indians age>45 (R01AG071677, MPI: Barbosa-Leiker, Suchy-Dicey). In the proposed work, we will build on our prior work and on planned recruitment in order to assess the continuum of bilingualism in American Indian peoples by culturally adapting the Language History Questionnaire; evaluating bilingualism in American Indians of multiple generations in association with a detailed cognitive performance battery; and by constructing conceptual models to assess intervariable relationships including effect modification and moderation by crystallized cognition.

8.7.1 Specific Aims

1. Culturally adapt and measure the Language History Questionnaire for American Indian adults. We will work directly with the Strong Heart Study Community Advisory Board to adapt the questionnaire and then use qualitative interviews to identify older American Indian adult experiences related to bilingualism to gain a thorough understanding of salient aspects of a culturally appropriate assessment of bilingualism in these populations and use these features to adapt the existing instrument for new data collections.

2. Examine associations of the continuum of bilingualism, using both newly adapted and existing measures, with the NIH Toolbox Cognition Battery. We expect that American Indian adults with greater bilingual skills will have higher scores on NIH Toolbox Fluid Component, but lower scores on NIH Toolbox Crystalized Component, independent of age, sex, education, physical and mental status, socioeconomic status, and cultural factors.

3. Examine the moderating roles of crystalized cognition and educational achievement with respect to relationships between bilingualism and fluid cognition in American Indian adults. We expect that years of education and higher scores on the NIH Toolbox Cognition Battery Crystallized Component will modify the relationship between bilingualism and NIH Toolbox Cognition Battery Fluid Component scores. We expect that years of formal education will not be strongly informative in the relationship between bilingualism cognition.

   Nearly 7 million Americans identify as American Indian, approximately 10% aged over 65 years. Given comparable prevalence of AD and neurodegeneration as in non-Hispanic Whites, an estimated 70,000 American Indians may have AD or related dementias. Use of multiple languages, common in American Indian communities, but also heterogeneous in permutation, may protect against cognitive loss but may also inhibit cognitive test performance, inhibiting accurate measurement and diagnosis. This project will illuminate questions of public health significance in a vulnerable population that remains underrepresented in ADRD research, with potential implications for future prevention and treatment strategies.

8.7.1.1 What Is Involved in The Study?

Two sub-projects: (A) qualitative interviews in N=33 (3 per participating tribe) and (B) quantitative questionnaire, 1 scale < 20 questions in estimated half of SHS7 during second half of recruitment period (N=1000-1500).

9. Referral Guidelines

It is the intention of the Strong Heart Study that individuals who participate in the physical examination will be provided both with education and encouragement concerning a healthy life style aimed at preventing cardiovascular disease. If significant medical conditions are uncovered during the course of the study, participants will receive assistance in arranging appointments for medical care. They will also receive assistance arranging transportation for emergent, immediate and urgent referrals.

9.1 Referral procedure

1. All participants reporting for the medical exam will receive appropriate educational materials concerning a heart healthy lifestyle. In addition, the examining personnel, when possible, will endeavor to educate the participants during the exam concerning the importance of risk factor reduction and modifications that the individual might make to improve his/her risk for cardiovascular disease. At the end of the exam, the participant will receive a copy (see **Appendix 4**) of their BP and their BMI calculation, as well as any significant physical findings that may have been noted. The importance of any abnormal findings from the exam and recommendations for referral will be communicated to the participant at this time. For referrals in the emergent, immediate or urgent categories, the participant will be assisted in arranging transportation and appointments. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant's provider or clinic of choice (see **Appendix 4** for a sample letter to be sent when an emergent, immediate, or urgent referral is needed but repeated efforts to contact the participant have failed). For routine referrals, the reason for the referral and information necessitating referral will be given to the participant and a referral letter will be sent to the provider of their choice.

2. When the clinically useful laboratory results have returned, a follow-up letter will be mailed to each participant thanking him or her for participating and supplying him/her with basic medical information obtained during the exam. Any results requiring referral will be pointed out in this letter and a referral letter will also be sent to the provider designated by the participant at the time of their exam. (See example of letter and suggested interpretation in Appendix 4).

3. In order to ensure that the patient receives appropriate referral and treatment for significant medical conditions uncovered during the course of the study, consistent referral levels have been established as described below in **Table 3**, **Table 4**, and **Table 5** which will be applied at each center. Communication with the participant will be initiated at the time results indicating Emergent, Urgent and Immediate referrals are made available to the field centers. Communications regarding results indicating routine referrals may be held for short periods of up to two weeks to allow batching of results and somewhat fewer letters.

4. Before exams begin, the local SHS director will discuss the referral process with the clinical director for the primary IHS clinic for the community. The proposed method of notifying patients regarding referral will be reviewed, and the clinical director's input will be sought as to which individual or office will be receiving referral information. There needs to be a designated provider to accept referrals for participants who do not specify a particular provider at that facility; the provider handling emergency duty for that day would be the most reasonable for Emergent and Immediate referrals. The clinical director should also designate which provider(s) will be responsible for handling Routine and Urgent referrals, and who would assume that responsibility if a particular provider were on leave or otherwise unavailable. The basic plan should be documented in writing and signed by the clinical director and SHS representative.

It is understood that the SHS staff will provide referral information to the participants and to the provider or clinic of their choice if the participant so choses. Assistance will often be given in arranging an appointment or providing transportation, but further follow-up of missed appointments and secondary referrals to specialty care by the participant's provider will not be the responsibility of SHS. It is important to stress to participants that the screening results of the participants SHS visit must be confirmed by their medical provider and that the SHS screening is not equivalent to a medical appointment.

9.2 Referral Levels

The Strong Heart Study refers participants using established guidelines for referral. Uniform criteria for referral of participants are implemented at all centers. Emergency, immediate, urgent, and routine referrals are made. Methods for referring participants who have no physician are established with the participant. All referrals are documented on a separate log, and copies of the referrals are kept in the Strong Heart Study folders.

No Referral: At the conclusion of the exam, if there are no findings requiring referral, the participant will be given their results, advised that they are within acceptable limits and given verbal and written encouragement for continued best health practices. They will also be advised that further results from laboratory tests will be sent to them in the mail, and that results of carotid and popliteal ultrasound and echocardiograms will be sent to their provider (if so designated in the consent form).

Guidelines for blood pressure referral are provided in **Table 3**. The SHS nursing staff determines the acuteness of the findings, as well as whether or not the condition is being followed by a physician.

If the participant is aware of and being followed medically for a condition, judgment is exercised about whether to refer. The standard IHS referral form or other written summary is used to provide appropriate clinical information to the health care professional who will evaluate the patient. A copy of this referral will be retained with the research forms to document the referral that was made.

Table 3: Referral Levels for Blood Pressure

Blood Pressure Measurements	Referral Guidelines
SBP ≥ 200 mm or DBP ≥ 120 mm	**Emergency Referral**: "Your BP is extremely high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) immediately, or accompany participant to acute care setting for MD evaluation before continuing examination.
SBP 180-199 mm or DBP 110-119 mm	Ask Additional Questions*:* 1) Do you have a severe headache? 2) Do you have chest pain or pressure? 3) Are you short of breath? 4) Do you have a new problem with your vision? If "Yes" to ANY of the Additional Questions - **Emergency Referral** "Your BP is extremely high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) immediately, or accompany participant to acute care setting for MD evaluation before continuing examination. If "No" to ALL of the Additional Questions - Ask if participant has had any previous treatment for hypertension. If "No" to previous treatment for hypertension - **Immediate Referral**: "Your BP is very high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) on the same day, to obtain treatment for hypertension. If "Yes" to previous treatment for hypertension - **Immediate Referral**: "Your BP is very high. This means it is not in control. If you have used hypertension medications, you should restart them now to avoid serious complications." Have participant restart their medication the same day, and consult with physician (M.D.) within 2-3 days to see whether medication is working.
SBP 160-179 mm or DBP 100-109 mm	Ask if participant has had previous treatment or medication for hypertension. If "No" to previous treatment for hypertension - **Urgent Referral**: "Your BP is very high. This means it not in control and may require treatment to avoid serious complications." Have participant consult with physician (M.D.) within 1 week to confirm hypertension and decide need for treatment. If "Yes" to previous treatment for hypertension - **Urgent Referral**: "Your BP is very high. This means it not in control. If you have used hypertension medications, you should restart them now to avoid serious complications." Have participant restart their medication the same day, and consult with physician (M.D.) within 1 week to see whether medication is working.
SBP 140-159 mm or DBP 90-100 mm	**Routine Referral**: "Your BP is not well controlled and may need additional treatment if it remains abnormal." Suggest participant consult with physician (M.D.) within next 1-4 weeks.
SBP 130-139 mm or DBP 80-89 mm	Ask if participant has been diagnosed with diabetes, increased CVD risk or chronic kidney disease. If "Yes" to diagnosed diabetes or chronic kidney disease - **Routine Referral**: "Your BP is not well controlled for someone with [diabetes / kidney disease] and may need additional treatment if it remains abnormal." Suggest participant consult with physician (M.D.) within next 1-4 weeks. If "No" to diagnosed diabetes or chronic kidney disease - **Routine Referral**: "Your BP is in a range that puts you at risk for hypertension. There may be things you can do to bring it into a better range." Suggest participant consult with physician (M.D.) within next month.

Table 4: Additional standing orders for nursing or staff referral:

Emergency Referral	**Statement to Participant ("Consult M.D. immediately")**
Any finding or symptom suggestive of a life-threatening illness, including evidence of acute MI, unstable angina, or pulmonary edema	Describe rationale for referral to participant
Immediate Referral	**Statement to Participant ("Consult M.D. today")**
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
Urgent Referral	**Statement to Participant ("Consult M.D. within a week")**
Angina over 24 hours ago	Your chest pains may be important
Neurologic symptoms, untreated, one week to six months ago	Your symptoms may be important
Suspected congestive heart failure	Your symptoms may be important
Other acute, but less severe symptoms	Your symptoms may be important
Inappropriate medication usage	Taking medication incorrectly may be dangerous
Chronic cough, fever, weight loss, and other symptoms suggestive of active TB or valley fever	You may have a serious problem in your lungs
Routine Referral	**Statement to Participant ("Consult M.D. within one month or at first convenient appointment")**
Old MI (Rose Questionnaire), previously unrecognized	Your chest pain may be important
Neurologic problem (stroke, TIA symptoms) > 6 months ago, unrecognized	Your symptoms may be important
Claudication, previously unrecognized	Your leg pain may be important
Both pedal pulses are missing in one extremity and not previously referred ***or*** the ratio of Doppler pressure of ankle/arm < 0.9	You may have a problem in your feet and you should check with your doctor.
If participant answers yes to smoking and expresses interest in quitting	Smoking is a major cause of heart disease and death. Work with your medical provider or your State tobacco quit line to find a quit plan that works for you

9.3 Referral After Lab and Other Test Results Are Available

9.3.1 Critical values

Laboratory will call field center; or use an alternative system involving a verified receipt (e.g., certified Email, FAX with return message confirming). Follow-up will be considered either immediate or urgent as indicated in the list of critical values. For immediate referral, SHS staff should notify participants by phone, or home visit, and (if they cannot be reached personally within 4-6 hours) by certified letter. Efforts should continue to contact the participant and discuss results in person. SHS staff should help arrange transportation if needed. If the participant choses to have a referral an IHS referral form or another written summary is provided.

9.3.2 Routine report

Copies of routine results are sent to each participant with an interpretation of results by the Field centers. If the participants have new findings that they have not previously been advised of, such as newly diagnosed diabetes, or cholesterol > 300, an IHS referral form or other written summary should be provided, and SHS staff should assist the participant in making an appointment and arranging transportation for follow-up (see sample letters in and interpretations in **Appendix 4**).

Table 5: Strong Heart Study Critical Values for Laboratory Results

Referral*	Test	Critical Value
Urgent	Total Cholesterol	≥ 300 mg/dl
	UACR**	>=300
Immediate	Fasting Glucose	≤ 50 or ≥ 400 mg/dl
	Total Triglyceride	≥ 1000 mg/dl
	HbA1c	6.4% or greater
Local Laboratory critical values for CBC results will be followed	CBC	

* Note: Since the shipment of the samples from the field center to the MHIR B3 Core Lab involve lab values (Glucose, Cholesterol and Triglyceride) determined at the lab by a batch of the samples received, immediate or urgent referral (within 24 hours after the lab testing and confirming the result) seems appropriate, even though some extreme values represent very serious conditions.

** Note: When the field center is aware of End-Stage Renal Disease, or dialysis treatments for the participant, these values can be simply noted as abnormal on the summary sheet to the participant, with the explanation that we expect these to be abnormal when an individual has ESRD or is on dialysis.

9.4 ECG Referral

The following ECG referral shall be made based on the machine-read findings:

1. Initiate emergency referral for the following findings:
   a. ST segment elevation or depression consistent with acute myocardial infarction or subendocardial ischemia
   b. 3rd degree AV-block
   c. Ventricular tachycardia
   d. Sustained supraventricular tachycardia with heart rate >135
   e. Any heart rate < 30

2. Initiate immediate referral for the following ECG findings:
   a. Any heart rate <35 or >135
   b. Atrial fibrillation or atrial flutter with ventricular rate <50 or >110
   c. QT prolongation

3. Initiate urgent referral for the following ECG findings:
   a. VPC couplets
   b. 2nd degree AV block
   c. New left bundle branch block
   d. New right bundle branch block
   e. Wolff-Parkinson-White
   f. Left ventricular hypertrophy
   g. T-wave inversion consistent with myocardial ischemia
   h. myocardial infarction of indeterminate age or age undetermined

4. Examples of isolated abnormal ECG findings that do not require referral but can be sent to participant's physician as part of routine report:
   a. Single ectopic beats of any frequency
   b. Left axis deviation/left anterior hemiblock
   c. Unusual p-wave axis (non-sinus atrial rhythm), wandering atrial pacemaker, av junctional rhythm
   d. Old left or right bundle branch block
   e. Incomplete right bundle branch block (right ventricular conduction delay)
   f. ST elevation consistent with early repolarization
   g. 1st degree AV block

10. Quality Control (QC) Program

A quality control committee oversees the conduct and evaluation of QC procedures. Field center coordinators will be responsible for reviewing all QC data as they become available and following up on any problems that are detected. The QC committee will monitor efficacy of retraining and problem solving.

10.1 Data QC

Every data form will be checked for completeness at the field center. Ambiguous or erroneous items will be clarified and corrected. The data entry programs generated by the Coordinating Center will provide an additional quality control check by building in range and logic checks. The program refuses to accept such data until the errors are corrected. Computer printouts of inconsistent data items will be sent to each field center for clarification or correction. Summary statistics such as mean, median, range, maximum and minimum for continuous variables and frequency distributions for categorical variables will be calculated monthly for each center, and data not meeting consistency checks will be flagged. Summary statistics will be generated quarterly to identify any peculiar or unreasonable values. Further verifications will be made and errors corrected.

10.2 Site Visit QC

One quality control site visit will be made to each of the three centers in the first year of the physical exam unless quality control data suggests that a follow up is required. 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.

10.3 Equipment QC

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

10.4 Examination QC

Collection of duplicate physical examinations and laboratories will be done on every 10th participant at each center until 500 participants have been enrolled in Phase 7 (done approximately on 10% of the participants). After 500 participants have been enrolled, collection of duplicate laboratory samples will be done on every 20th participant at each center (done approximately on 5% of the participants)..

10.4.1 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 quarterly. Duplicate measures of anthropometry (height, weight, waist, and electrical impedance measurements) will be performed by a second observer on a quarterly basis. These data will be sent to the Coordinating Center for analysis. Results of the analysis will be provided to the field centers and the Steering Committee. Differences between duplicate measures exceeding the following values will be considered unacceptable:

1. Systolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.
2. Diastolic Blood Pressure: 4 mmHg, using Y-shaped stethoscope for two simultaneous observations.
3. Height: 1 cm
4. Weight: 1 Kg
5. Waist circumference: 2 cm
6. Hip circumference: 2 cm
7. Arm circumference: 1 cm

In addition, distributions of measurements and digit preference for each staff member will be compiled and repeated quarterly.

10.4.2 Laboratory tests

Duplicate blood and urine specimens will be collected on approximately 5% of the participants and sent to the Core Laboratory at Medstar in a blind fashion. Results obtained for each test will be analyzed quarterly by the Coordinating Center for accuracy and consistency. The percent of pairs with differences within 5% and 10% will be computed. Correlation coefficients and technical error rates will be calculated, and be sent to the lab from the Coordinating after analysis. Poor correlation or unreasonably high technical error will be reported to the Laboratory and the Steering Committee.

10.4.3 Personal interview

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

10.4.4 Certification of technicians

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

10.4.5 Monitoring of Study progress

The Coordinating Center will work closely with the field centers to monitor recruitment and progress of the examinations. At the beginning of the study, a projected monthly number of participants to be recruited will be generated, and the Coordinating Center will monitor the progress of each field center according to these projected numbers and provide monthly progress reports to the Steering Committee. If the percentage of projected recruitment in a certain field center falls below 80%, the PI and the field coordinator will be informed, so that the efforts can be focused on recruitment. This program proved to be an efficient tool for monitoring the progress of SHS- in previous phases and will be continued in Phase VII of SHS. The Coordinating Center will also monitor QC physical exams, and QC blinded blood samples and report to the Steering Committee quarterly.

10.5 Confidentiality and security of data

All personnel with access to the collected data are required to sign a confidentiality pledge. Completed data forms are placed in locked file cabinets at every center and are accessible by authorized staff members only. The data are stored on secure OU Center network drives which is backed up daily

Appendices

Appendix 1 Strong Heart Study Phase VII Consent Forms

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Form to Participate in a Research Study

Dakota Strong Heart Study Phase VII
Researchers:

Amanda M Fretts, PhD, Principal Investigator
Department of Epidemiology, University of Washington
Cardiovascular Health Research Unit
Phone number: 206-287-2777

Lyle Best, MD, Co-investigator
Missouri Breaks Ind Research Inc
Watford City, ND
Phone Number: 701-842-6770

Marcia O'Leary, RN, Field Site Principal Investigator
Missouri Breaks Industries Research, Inc
Eagle Butte, SD
Phone Number: 605-964-1260
Toll Free: 1-800-865-3418

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to take part in this study because you participated previously in the Strong Heart Study (SHS) and/or in the Strong Heart Family Study (SHFS). Research studies are voluntary and include only people who choose to take part.

- The purpose of this consent form is to give you the information you will need to help you decide whether to continue to be in the study or not. Please read the form carefully. If you have trouble reading this form, one of the staff will read it to you. You are encouraged to ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research study or this form that is not clear.
- Please take your time to review this consent form, discuss with family and friends, and ask the study team any questions you may have.
- When we have answered all your questions, you can decide if you want to continue to participate in the Strong Heart Study. This process is called "informed consent." You will receive a copy of this form for your records.

WHY IS THIS STUDY BEING DONE?

The Strong Heart Study began in 1988 to try to help find out why some American Indian people get diseases of the heart, blood vessels, and lungs, and others do not. The Strong Heart Study was also designed to better understand risk factors for these diseases, like diabetes, high blood pressure, and smoking in the American Indian population. Over the past 30 years, researchers have learned a lot about how to prevent and manage heart disease and related conditions from the Strong Heart Study. However, these diseases are still common among American Indian people. Researchers now know that diseases of the heart, blood vessels, and lungs shouldn't be studied all by themselves since they may also be related

to other medical problems like liver disease, cancer, and inflammation in the body (which can cause things like arthritis, kidney damage, and heart conditions). We now wish to expand the Strong Heart Study to learn more about liver disease, cancer and inflammation in the body—and how these conditions impact risk for heart disease and related conditions. Examples of other conditions that involve inflammation include:

- all forms of arthritis
- inflammatory bowel disease, like ulcerative colitis
- inflammatory conditions of the eye (uveitis), the skin (scleroderma), and arteries (temporal arteritis)

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to take part in the Strong Heart Study (Phase 7) because you participated previously in the Strong Heart Study or Strong Heart Family Study (Phases 1-6).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 5000 American Indians will take part in this study nationwide. About 1250 of individuals from North Dakota and South Dakota will participate.

HOW LONG WILL THE STUDY LAST?

We will include you in the study as long as it continues. We think the study will last until at least 2026. If additional funding is available, additional exams and testing may be possible. Participation in this study is voluntary. You may choose not to participate, or you may drop out at any time.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?

This research study will be conducted by the Missouri Breaks Industries Research, Inc (MBIRI). If you choose to participate, you will come into one of the MBIRI offices or other specified location to have a physical examination, fill our surveys about your health, and have your blood drawn. The examination and questions may take about 3 to 4 hours to complete. As part of the study, we would also like to review your medical records on a regular basis in the future for all of the diseases and conditions in this study.
In addition, we also have exam data, blood, DNA (a genetic material) and urine samples that you have given us in past exams; and we would like to continue using these for the study of heart, lung, liver and blood vessel diseases, risk factors (like diabetes, inflammation and others), and cancer.

At the in-person study exam:

- You will be asked to fast for 12 hours prior to your scheduled study visit.
- You will be asked to answer questions about your age, sex, education, and medical history.
- You will be asked to complete questionnaires about many things that can change your general health, including tobacco use, alcohol use, where you get healthcare, what you eat, and stress.
- Your vital signs will be taken. This will include your heart rate (pulse) and blood pressure in both your arms and your legs.
- Your height, body weight, hip and waist circumference, pedal pulses and ankle brachial blood pressures will be measured.
- About 4 ounces (approximately 8 Tablespoons) will be drawn to measure blood sugar levels and cholesterol.
- You will be asked to provide a urine sample to find out how your kidneys are working.
- You will not routinely receive results of the tests done for this study. However, you will be contacted if clinically important test results are abnormal.
- Some of your blood will be saved at MedStar Health Research Institute's B3/Penn Medical Research Laboratories in Hyattsville, MD and at the Texas Biomedical Research Institute in San Antonio, TX for future tests, including gene testing (more information is given below).

Medical Record Review:

• On a regular schedule, we will review your medical records at the Indian Health Service (IHS) and non-IHS healthcare facilities for diseases of the heart, blood vessels, and lungs; diabetes, liver disease, cancer, and inflammation in the body (which can cause things like arthritis, kidney damage, and heart conditions). We will also utilize state and national disease registries (for example, state cancer registries) and Medicare data to help ascertain outcomes and maximize data quality. This is a very important part of this research and will continue as long into the future as funding allows, unless you let us know you would like to stop taking part in the study.

Follow-up:
• You will occasionally be sent Strong Heart Study newsletters to tell you about results of the study. We will contact you annually (until the Study ends) to ask you about the current state of your health. This contact will likely be by phone, letter, or home visit and will be brief (about 20 minutes or less) in order to find out any new health-related events, for example, if you have had a heart attack, stroke, or have been told by a doctor that you have cancer or other health problems. We also ask your permission to contact you from time to time if there are other studies that you might be willing to take part in. They might be about these Strong Heart Study conditions or some other medical problems.

OTHER INFORMATION ABOUT THE STUDY

BENEFITS OF THE STUDY: WHY I MIGHT WANT TO PARTICIPATE?
If you agree to take part in this study, there will be little direct medical benefit to you. The goal of public health research is to learn something that will contribute to the advancement of science and understanding the effects of heart disease and related conditions on health and wellness.
STUDY-RELATED RISKS, STRESSES, AND DISCOMFORT
The risks associated with this study are slight discomfort or bruising from the blood draws, possible dizziness, headache, stomach discomfort, or fainting from fasting for 12 hours, and the possible loss of privacy if your data or information is accidently disclosed outside of the study. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team uses very strong methods to protect your privacy. Their plans for keeping your information private are described in the Confidentiality section below.

The following risks apply only if you choose to have any of your leftover blood samples stored and used for genetic testing:
A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making decision to hire, promote, or fire you or when setting the terms of your employment.
• Your samples are stored with only a number that is not associated with individual names.

Be aware that this Federal law does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test will only be given to a few authorized Strong Heart Study staff and to you if you request those results. This means that the results will NOT be made available to your family members, your private physician, your employer, your insurance company, or any other party as allowed by law without your permission

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There is no cost to you if you participate in this study. You will be given $100 for your time.

CAN I WITHDRAW FROM THE STUDY?
You can stop participating in this study at any time. Deciding not to participate in this study will not affect your relationship with the researchers or your healthcare provider. If you decide to withdraw from the study or do not want your data used for the study, please contact Dr. Amanda Fretts at 206-287-2777 or Marcia O'Leary at 605-964-1260. We will destroy your data and it will not be used in any further reports about this research after you withdraw. You will be asked to send this request to the SHS Field site in writing. Attention Marcia O'Leary Coordinator, PO Box 1824, Eagle Butte, SD 57625.

CONFIDENTIALITY OF RESEARCH INFORMATION
Efforts will be made to keep your personal information confidential. We will label your samples and the information about you with a number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from your samples and surveys. Only a few authorized study personnel will have access to your name, address, and other information that may identify you. If your data or sample is shared with another investigator for research purposes, they will not have access to your name or other identifying information. Your name or any other identifying information will not be used in any report about this research. All publications will be reviewed and approved by the Tribal partners, representatives of the Strong Heart Steering Committee and study centers.
Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be 100% secure.

- Government or university staff sometimes review studies like this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the Federal National Institutes of Health. This helps us protect your privacy, even if we are asked to release information by a court of law. We will use the Certificate to resist any demands for identifying information that you do not approve. To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, a member of the Federal government or individuals at the funding agency or other regulatory agencies involved in the research who needs it in order to audit or evaluate the research.
There are some limits to this protection. We will voluntarily provide the information to:

- Individuals at the funding agency or other groups involved in the research if they need the information to make sure that the research is being done correctly or a member of the Federal government who needs it in order to audit or evaluate the research.
- the federal Food and Drug Administration (FDA), if required by the FDA;
- The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state or Tribal law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

HOW WILL THE DATA BE STORED?

The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?
If you have questions, complaints or concerns about this study, contact the research team at: 1-866-865-3418. If you think you have a medical problem or illness related to this research, see your medical provider or call 911. Then follow-up with MBIRI at 1-866-865-3418 after you have seen your medical provider. MBIRI and/or their employees are not responsible for payment of any medical tests or treatments.
If you have questions about your rights as a research participant, please call Dewey Ertz, EdD, Chairman of the Great Plains IRB, at 605-341-8647 or toll free at 1-866-331-5794. If you are a member of the Ogalala Lakota Nation you may also contact the OSTRRB Coordinator at 605-867-1704.

SOURCE OF FUNDING
The study team is receiving financial support to conduct this study from the National Heart Lung and Blood Institute which is a division of the National Institutes of Health.

Consent for Future Use of Blood Samples and/or Genetic Testing:

After we complete the blood tests for this study, we would like to save any leftover blood for future research on heart disease and related risk factors. This may include genetic testing. We will save blood samples for up to 5 years after the study is complete (with the possibility of extending for an additional 3-5 years with permission from Great Plains IRB, and your respective Tribal research review board, including the Oglala Lakota Nation Research Review Board, the Cheyenne River Sioux Tribe Health Board, and the Spirit Lake Nation Health Board. Your blood sample and data may be used for future studies not expressly described in this consent form, but which fall under the aims of the study. We will follow appropriate submission processes for all future studies, including review and approval by the Great Plains IRB, the Oglala Lakota Nation Research Review Board, the Cheyenne River Sioux Tribe Health Board, and the Spirit Lake Nation Tribal Leadership. Your blood sample will be stored with a number assigned to it instead of your name. The number will be linked to your name, which means you can withdraw at any time. Once the researchers are through with your blood, it will be disposed of like any other laboratory or clinic that tests your blood if you are a member of the Cheyenne River Sioux Tribe or Spirit Lake Nation. For members of the Oglala Lakota Nation, we will adhere to Oglala Lakota Nation Research Review Board policies to return samples to the tribe; you have the option of electing to have the SHS staff dispose of samples once the research is complete or to have the samples returned to the Oglala Lakota Nation.

☐ I want to participate in the Strong Heart Study Phase 7,
☐ I want my samples to be stored and used for future research.
☐ I do not want my samples to be stored and used for future research

If you would like your samples to be stored and used for future research, when the research is completed:

☐ I would like the SHS staff to dispose of leftover samples.

☐ I would like my samples to be returned to the Oglala Lakota Nation.

It is possible that researchers (other than Strong Heart Study researchers) may request access to the blood samples or data collected as part of this study. Strong Heart Study investigators will review these requests carefully to assure the scientific merit of the proposed research and the qualifications of the researchers. Your blood samples and data will only be used for studies approved by the Great Plains IRB, the Oglala Lakota Nation Research Review Board, the Cheyenne River Sioux Tribe Health Board, and the Spirit Lake Nation Tribal Leadership --and no identifying information about you will be shared.

You may withdraw permission to share blood samples and data or have them destroyed at any time by contacting study investigators listed above in writing.

RESEARCH-RELATED INJURY

If you have questions, complaints or concerns about this study, contact the research team at: 605-964-1260. If you think you have a medical problem or illness related to this research, see your medical provider or call 911. Then follow-up with study staff at 1-866-865-3418 after you have seen your medical provider. Missouri Breaks Industries Research, Inc. and/or their employees are not responsible for payment of any medical tests or treatments.

Printed name of study staff obtaining consent

_____

Signature _____Date _____

Audio recordings are used for the purpose of quality control and training of staff members. On occasion you may be asked to participate in order to ensure that staff members are appropriately trained.

Consent for Audio Recording:

☐ Yes, I consent to audio recording of my phone or in-person interview by the study staff. I understand that this audio recording will be erased at the end of the study.

☐ No, I do not consent to audio recording of my phone interview.

Consent to be contacted for future research:

☐ Yes, I consent to be contacted for future research projects.

☐ No, I do not consent to be contacted for future research projects.

Participant's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research participant, I can call contact Dewey Ertz, EdD, Chairman of the Great Plains IRB, at 605-341-8647 or toll free at 1-866- 331-5794. If you are a member of the Ogalala Lakota Nation you may also contact the OSTRRB Coordinator at 605-867-1704. I will receive a copy of this consent form.

Printed name of participant

_____

Signature of participant _____ Date _____

Copies to: Researcher

Title of research study: THE STRONG HEART STUDY, PHASE VII: CVD in American Indians

Investigator: Jason G. Umans, MD, PhD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being asked to take part in this study because you participated previously in the Strong Heart Study (SHS) and/or in the Strong Heart Family Study (SHFS).

What should I know about a research study?

Someone will explain this research study to you.
Whether or not you take part is up to you.
You can choose not to take part.
You can agree to take part and later change your mind.
Your decision will not be held against you.
You can ask all the questions you want before you decide.

Why is this research being done?

We invite you to continue your participation in the Strong Heart Study (SHS). The Strong Heart Study that began in 1988 is trying to find the causes of and how to prevent diseases of the heart, blood vessels, lungs, and the risk factors for these conditions, like diabetes, high blood pressure and smoking. You have attended at least one exam in which we made a variety of physical and blood measures that could be related to long term health. Now we wish to continue to follow your health in order to learn more about what causes the above diseases. Research has shown that diseases of the heart, blood vessels and lungs shouldn't be studied all by themselves, since they may also be related to other medical conditions. This was one of the reasons that we expanded our study to include liver disease, cancer and inflammation in the body (which can cause things like arthritis and kidney damage, but also heart conditions).

This research is to learn more about heart, lung, and blood vessel diseases, the risk factors for these conditions and how they change over time, and how they may be related to liver disease, cancer, and conditions that involve inflammation. Conditions that involve inflammation include the following:

Osteoarthritis	Thyroiditis
Rheumatoid arthritis	Anti-phospholipid syndrome
Systemic lupus erythematosus (SLE)	Dermatomyositis
Psoriatic arthritis	Polymyalgia rheumatic
Ulcerative colitis	Any form of "nephritis" and IgA
Crohn's disease	nephropathy Kawasaki disease
Regional ileitis	Mixed connective tissue disease
Sjogren's syndrome	Polyarteritis nodosa
Scleroderma	Primary sclerosing cholangitis

Juvenile rheumatoid arthritis Ankylosing spondylitis Iritis, uveitis	Raynaud's phenomenon Temporal arteritis

How long will the research last and what will I need to do?

By joining this study, you consent to have a physical examination (physical examination procedures are described below). The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. After your exam, SHS researchers will contact you as soon as your medically useful results become available; subsequently, they will contact you annually to ask you about the current state of your health.

In addition, we also have exam data, blood, DNA (a genetic material) and urine samples that you have given us in past exams; and we would like to continue using these for the study of heart, lung, liver and blood vessel diseases, risk factors (like diabetes, inflammation and others), and cancer.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?"***

Is there any way being in this study could be bad for me?

Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm can be a little painful, may give you a bruise, cause you to feel faint, and has a slight risk of infection. You may have some discomfort in your arms and/or legs, when blood pressure is taken.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Confidentiality section below.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are not expected to be any immediate benefits to you for taking part in this study. We expect the findings to be helpful to people in the future. If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study

should not take the place of regular medical checkups. You should go to your regular clinic for physical exams and treatment of any health problems.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at MedStar's Arizona Field Center (602) 277-0488.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

Your questions, concerns, or complaints are not being answered by the research team.
You cannot reach the research team.
You want to talk to someone besides the research team.
You have questions about your rights as a research participant.
You want to get information or provide input about this research.

How many people will be studied?

We expect about 360 people here will be in this research study out of 3,600 people in the entire study nationally.

What happens if I say yes, I want to be in this research?

If you take part in this study, you will have the following tests and procedures:

Physical Examination Procedures

- Blood Tests. Twelve or more hours after you last ate anything, we will take four ounces (8 tablespoons) from your arm by a needle to find the level of sugar, Hemoglobin A1C, cholesterol and other fatty substances. Some of your blood will be saved at MedStar Health Research Institute (MHRI) in Hyattsville, MD and at Texas Biomedical Research Institute in San Antonio, TX for future tests, including gene testing (more information is given below). Your blood and other specimens will be stored, and the genetic information and these specimens may be used indefinitely until it has no more scientific value for studying these problems. Once the researchers are through with your blood, it will be disposed of like any other laboratory or clinic that tests your blood. The specimens will be stored in –70-degree Celsius freezers with a number code in place of any personal information. Only SHS personnel have access to the specimens. Your blood cells will not be cloned or kept growing, and your blood will not be used to develop products that will be sold. You will retain the right to have the sample material destroyed at any time by contacting the Principal Investigator.
- Urine Test. We will ask you for some urine to find out how your kidneys are working.

- Physical Examination. Blood pressures in your arms and legs, pulses in your ankles and feet, your height, weight, waist, hip, and arm size will be measured.
- Health Questions. Questions will be asked about many things that can change your general health, including exercise, diet, alcohol and tobacco use, where you get health care, what you eat, and stress.

Follow-up

You will be told immediately, if any life-threatening health problems are found. After your exam, SHS researchers will contact you as soon as medically useful results become available (e.g., results of your blood tests) to tell you about these results and any implications for your health care needs. You may obtain a copy of any of your other results by asking the Study staff or phoning the Principal Investigator at (602) 277-0488. You will also be sent Strong Heart Study newsletters now and then to tell you about results of the study. We will contact you annually (until the Study ends) to ask you about the current state of your health. This contact will likely be by phone, letter, or home visit and will be brief (about 20 minutes or less) in order to find out if you have had any sort of cardiovascular test (e.g., a treadmill test) or a cardiovascular episode (e.g., a heart attack or stroke), hospitalizations, and new health issue diagnosis and treatment for diseases such as diabetes or cancer.

Medical Records Review

We will review and collect information from your medical records at the Indian Health Service (IHS) and non-IHS healthcare facilities for conditions related to heart, lung, liver and blood vessel diseases, risk factors (like diabetes, inflammation and others), and cancer.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. However, if you decide to stop participating in the study, we encourage you to talk to the study researchers first. Deciding not to participate in this study will not affect your relationship with the researchers or your health care provider.

Is there any way being in this study could be bad for me? (Detailed Risks)

Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm can be a little painful, may give you a bruise, cause you to feel faint, and has a slight risk of infection. You may have some discomfort in your arms and/or legs when blood pressure is taken.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Confidentiality section below.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) it is intended to make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law is intended to protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- Your samples are stored with only a number that is not associated with individual names.

Be aware that this Federal law does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test will only be given to a few authorized Strong Heart Study staff and to you if you request those results. This means that the results will NOT be made available to your family members, your private physician, your employer, your insurance company, or any other party as allowed by law without your permission.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

There are organizations outside the MedStar Health Research Institute (MHRI) that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies, the National Heart, Lung, and Blood Institute of the National Institutes of Health. The MHRI Human Research office, the MHRI Institutional Review Board, MHRI Office of Compliance, and other MHRI administrative offices may also inspect and/or copy your research records for these purposes.

<u>Identifiable Private Information and Biospecimens:</u>

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies which fall under the aims of the study without your additional informed consent.

All future research must be related in some way to the basic scientific questions that the Strong Heart Study is trying to answer. We will remove direct identifiers from your information and specimen and assign a code. The key to this code will be kept separately and only a few authorized Arizona Strong Heart Study personnel will have access to the code. If your data or sample is shared with another investigator for research purposes, they will not have access to the

key code and will not be able to re-identify you. You will not be identified by name or described in any reports or publications about Strong Heart Study. All publications are reviewed and approved by representatives of the Strong Heart Steering Committee, tribal authorities and study centers.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- All information related to CVD, Covid, diabetes, cancers, inflammatory disorders and other related diseases in a medical record
- Results of physical examinations
- Medical history
- Lab tests and certain health information indicating or relating to a CVD as well as diaries and questionnaires
- Genetic health information: This longstanding data falls withing the data sharing agreement between the Strong Heart Study and your tribal community.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of MedStar Health and its clinical partners (or affiliates): the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or MedStar Health policy.

The following entities may receive your health information:

1. Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.

2. Laboratories and other individuals and organizations that may need to see your health information in connection with this study.

3. Other MedStar Health research centers and MedStar Health contractors who are also working on the study.

4. Study monitors and auditors who make sure that the study is being done properly,

5. National Heart, Lung and Blood Institute**,** who is sponsoring the study, and that company's contractors and partners.

6. Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it has no expiration date.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Jason Umans, MD, PhD
Institution: MedStar Health Research Institute
Department: Arizona Field Center
Address: 1616 E. Indian School Road, Suite 470, Phoenix, AZ 85015

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

What else do I need to know?

This research is being funded by the National Heart, Lung and Blood Institute of the National Institutes of Health.

If you agree to take part in this research study, you will be given a $100 gift card for your time and effort. The payment is to help you with your travel expenses and to compensate you for your time in helping this study**.**

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do

have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Strong Heart Study Phase VII Research Study Participation:

☐ I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntary agree to be in this study **and I re-affirm previous consent I have signed in other Strong Heart Study phases.** I am free to stop being in the study at any time without the need to justify my decision and if I stop being in the study, I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Dr. Jason Umans, MD, PhD and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms. .

☐ No, I do not consent to participate the Strong Heart Study Phase VII.

Consent for Audio Recording:

☐ Yes, I consent to audio recording of my phone interview by the study staff. I understand that this audio recording will be erased at the end of the study.

☐ No, I do not consent to audio recording of my phone interview.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: THE STRONG HEART STUDY, PHASE VII:
CVD in American Indians Study and
Data Management Center and Oklahoma Field Center –
Physical Examination and Ancillary Studies
Sponsor: National Heart, Lung and Blood Institute
Tauqeer Ali, PhD, MPH, MBBS, Principal Investigator Oklahoma Field Center
Ying Zhang, MD, PhD, Principal Investigator Coordinating Center
Phone Number: (405) 271-3090

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to take part in this study because you participated previously in the Strong Heart Study (SHS) and/or in the Strong Heart Family Study (SHFS).

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

We invite you to continue your participation in the Strong Heart Study (SHS). The Strong Heart Study that began in 1988 is trying to find the causes of and how to prevent diseases of the heart, blood vessels, lungs, and the risk factors for these conditions, like diabetes, high blood pressure and smoking. You have attended at least one exam in which we made a variety of physical and blood measures that could be related to long term health. Now we wish to continue to follow your health in order to learn more about what causes the above diseases. Research has shown that diseases of the heart, blood vessels and lungs shouldn't be studied all by themselves, since they may also be related to other medical conditions. This was one of the reasons that we expanded our study to include liver disease, cancer and inflammation in the body (which can cause things like arthritis and kidney damage, but also heart conditions).

This research is to learn more about heart, lung, and blood vessel diseases, the risk factors for these conditions and how they change over time, and how they may be related to liver disease, cancer, and conditions that involve inflammation. Examples of other conditions that involve inflammation include the following:

- all forms of arthritis
- inflammatory bowel disease, like ulcerative colitis

- inflammatory conditions of the eye (uveitis), the skin (scleroderma), and arteries (temporal arteritis)

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
By joining this study, you consent to have a physical examination (physical examination procedures are described below). The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. After your exam, SHS researchers will contact you as soon as your medically useful results become available; subsequently, they will contact you annually to ask you about the current state of your health.

In addition, we also have exam data, blood, DNA (a genetic material) and urine samples that you have given us in past exams; and we would like to continue using these for the study of heart, lung, liver and blood vessel diseases, risk factors (like diabetes, inflammation and others), and cancer.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?
There are not likely to be any immediate benefits to you for taking part in this study. We expect the findings to be helpful to people in the future. If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical checkups. You should go to your regular clinic for physical exams and treatment of any health problems.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
Participation in this study is voluntary. You may choose either to take part or not take part in the study.

WHAT OTHER OPTIONS ARE THERE?
This is a research study. Research studies involve only individuals who choose to participate, and you are free to choose not to participate.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There is no cost to you if you participate in this study.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 3,600 people will take part in this study nationwide. About 1,150 of these individuals will participate from Oklahoma.

WHAT IS INVOLVED IN THE STUDY?
If you take part in this study, you will have the following tests and procedures:

Physical Examination Procedures

- Blood Tests. Twelve or more hours after you last ate anything, we will take four ounces (8 tablespoons) from your arm by a needle to find the level of sugar, Hemoglobin A1C, cholesterol and other fatty substances. Some of your blood will be saved at MedStar Health Research Institute's B3/Penn Medical Research Laboratories in Hyattsville, MD and at the Texas Biomedical Research Institute in San Antonio, TX for future tests, including gene testing (more information is given below). Your blood and other specimens will be stored, and the genetic information and these specimens may be used indefinitely until it has no more scientific value for studying these problems. Once the researchers are through with your blood, it will be disposed of like any other laboratory or clinic that tests your blood. The specimens will be stored in –70-degree Celsius freezers with a number code in place of any personal information. Only SHS personnel have access to the specimens. The Complete Blood Count (CBC) test will be performed by a local lab. Your blood cells will not be cloned or kept growing, and your blood will not be used to develop products that will be sold. You will retain the right to have the sample material destroyed at any time by contacting the Principal Investigator.
- Urine Test. We will ask you for some urine to find out how your kidneys are working.
- Physical Examination. Blood pressures in your arms and legs, pulses in your ankles and feet, your height, weight, waist, hip, and arm size will be measured.
- Health Questions. Questions will be asked about many things that can change your general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, and stress.

Follow-up

You will be told immediately, if any life-threatening health problems are found. After your exam, SHS researchers will contact you as soon as medically useful results become available (e.g., results of your blood tests) in order to tell you about these results and any implications for your health care needs. You may obtain a copy of any of your other results by asking the Study staff or phoning the Principal Investigator at 405-271-3090. You will also be sent Strong Heart Study newsletters now and then to tell you about results of the study. We will contact you annually (until the Study ends) to ask you about the current state of your health. This contact will likely be by phone, letter, or home visit and will be brief (about 20 minutes or less) in order to find out if you have had any sort of cardiovascular test (e.g., a treadmill test) or a cardiovascular episode (e.g., a heart attack or stroke).

Medical Records Review

We will review and collect information from your medical records at the Indian Health Service (IHS) and non-IHS healthcare facilities for conditions related to heart, lung, liver and blood vessel diseases, risk factors (like diabetes, inflammation and others), and cancer. In addition,

we would like to request death information about you from state health departments if we are not able to contact you for annual follow up.

CAN I WITHDRAW FROM THE STUDY?
You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study researchers first. Deciding not to participate in this study will not affect your relationship with the researchers or your health care provider.

WHAT ARE THE RISKS OF THE STUDY?
Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm can be a little painful, may give you a bruise, cause you to feel faint, and has a slight risk of infection. You may have some discomfort in your arms and/or legs, when blood pressure is taken.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Confidentiality section below.

RISKS OF GENETIC TESTING:
A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

1. Health insurance companies and group health plans may not request your genetic information that we get from this research.
2. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
3. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test will be given to a few authorized Oklahoma Strong Heart Study staff and to you only if you request for those results. This means that it will NOT be made available to your family members, your private physician, your employer, your insurance company, or any other party as allowed by law.

Certain tribes may have concerns regarding genetic testing in their tribal membership. Please feel free to contact your tribal authorities to see if they have questions about genetic testing.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee

absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies, the National Heart, Lung, and Blood Institute of the National Institutes of Health. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

Certificate of Confidentiality:
To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally-funded projects or for information that must be disclosed in order to meet the requirements of the US Food and Drug Administration.

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

Storing and Sharing Your Information
Your blood sample and data may be used for future studies not expressly described in this consent form, but which fall under the aims of the study. All future research must be related in some way to the basic scientific questions that the Strong Heart Study is trying to answer. We will remove direct identifiers from your information and specimen and assign a code. The key to this code will be kept separately and only a few authorized Oklahoma Strong Heart Study personnel will have access to the code. If your data or sample is shared with another investigator for research purposes, they will not have access to the key code and will not be able to re-identify you. You will not be identified by name or described in any reports or publications about Strong Heart Study. All publications are reviewed and approved by representatives of the Strong Heart Steering Committee and study centers.

WHAT ARE THE COSTS?
There are no costs aside from travel costs in order to participate. You will be given a $100 payment for completing the physical examination procedures. The payment is to help with your travel expenses and to give you something for your time helping this study.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?
In the case of injury or illness resulting from this study, you will be expected to seek care through your regular health care provider. No funds have been set aside by the OUHSC, the Indian Health Service, or the National Institutes of Health to compensate you in the event of an injury. If you have questions about the availability of care, you may contact the Lawton Indian Health Service Hospital at (580) 354-5000 or the Anadarko Indian Health Center at (405) 247-7900.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. If you choose not to participate, you will not be penalized or lose benefits to which you are entitled. You can also stop participating at any time and for any reason without penalty or loss of benefits to which you are entitled. If you decide to stop participating, and/or would like to opt-out of further study participation, or if you decide that you do not want your data or biospecimens used, please send a request in writing to Dr. Tauqeer Ali at the Center for American Indian Health Research, P.O. Box 26901, Oklahoma City, OK 73126 or email him at tauqeer-ali@ouhsc.edu. Once we receive this request, we will destroy your data and biospecimens. Your results will not be used after you withdraw.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

DO I HAVE ANY OTHER RIGHTS OVER MY DATA?
Depending on where the sponsor for your study is located and other factors, you may have additional rights over your personal data collected in this study. For example, the European Union General Data Protection Regulation (GDPR) and some state privacy laws might apply. If the GDPR applies, generally you may have the following rights:

1. The right to request the information collected to be corrected.
2. The right to withdraw your consent for the use of your personal information at any time.
3. The right, in some circumstances, to receive your personal information in a structured, commonly used and machine-readable format and the right to provide your information to a third party.
4. The right to strict confidentiality of your personal data when it is used/shared.
5. The right to limit the use/sharing of your personal information in certain circumstances.
6. The right under some circumstances to request the erasure of your personal data.
7. The right to file a complaint with a privacy protection regulator if you believe any of the rights above have been violated.

You can receive more information regarding these rights in the Privacy Notice for Research Participants, located on the OUHSC Office of Human Research Participant Protection (HRPP) website at *https://compliance.ouhsc.edu/HRPP/Participant/Privacy-Notice*.

If you have any questions and requests, please contact the HRPP Office at 405-271-2045.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?
If you have questions, concerns, or complaints about the study or have a study-related injury, contact the Dr. Tauqeer Ali at (405) 271-3090. If you cannot reach Dr. Ali, or wish to speak to someone other than the Investigators at the top of this page, you may contact the Director of the OUHSC Office of Human Research Participant Protection at (405) 271-2045.

For questions about your rights as a research participant, contact the Director of the OUHSC Office of Human Research Participant Protection at (405) 271-2045 or Captain Ryan Schupbach, U.S. Public Health Service, IHS IRB Co-Chairman, Oklahoma City Area Indian Health Service, 701 Market Drive, Oklahoma City, OK 73114; telephone number (405) 951-3928.

SIGNATURE:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

Strong Heart Study Phase VII Research Study Participation:

☐ **Yes, I consent** to participate, and I also consent that my samples and data may be stored and used for future testing
☐ Including genetic testing or ☐ Excluding genetic testing

OR

☐ **Yes, I consent** to participate, but my samples and data may not be stored and used for future research after Phase VII ends. However, my samples and data can be used in Phase VII for testing,
☐ Including genetic testing or ☐ Excluding genetic testing

OR

☐ **No, I do not consent** to participate in the Strong Heart Study any longer. All samples and data collected in the previous phases will be discarded. No data or samples will be used for future testing. (THANK YOU, THIS BRINGS TO AN END YOUR PARTICIPATION IN THE STRONG HEART STUDY).

Consent to Share Specimens and Data with Non-SHS Researchers, Including Those in Other Countries:

☐ **Yes, I consent** that my samples and data from this phase and from the previous phases may be shared with researchers other than the Strong Heart Study researchers, including researchers in other countries. All requests by other researchers who wish to share my data, samples or genetic information will be reviewed carefully in regard to the scientific merit of the proposal and the qualifications of the researchers. Only those who are approved by the Strong Heart Study Steering Committee will be provided with the specimens.

OR

☐ **No, I do not consent** to share my samples and data with researchers other than the Strong Heart Study researchers.

Consent for Audio Recording:

☐ **Yes, I consent** to audio recording of my phone interview by the study staff. I understand that this audio recording will be erased at the end of the study.

OR

☐ **No, I do not consent** to audio recording of my phone interview.

Consent to be contacted for future research:

☐ **Yes, I consent** to be contacted for future research projects.

OR

☐ **No, I do not consent** to be contacted for future research projects.

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

Appendix 2 Strong Heart Study Phase VII Ancillary Study Consent Forms

A2.1 Resilience, Cultural Alignment, and Social Support in Brain Aging: Data from the Strong Heart Study (PI: Astrid Suchy-Dicey)

Consent Addendum to the Strong Heart Study
Phase VII to Participate in an Ancillary Research Study
Study Title: Resilience, Cultural Alignment, and Social Support in Brain Aging: Data from the Strong Heart Study
Sponsor: National Institute on Aging

Researchers:

Amanda M Fretts, PhD, MPH **Principal Investigator** **Department of Epidemiology** **University of Washington** **Cardiovascular Health Research Unit** **Phone Number: 206-287-2777**	**Astrid Suchy-Dicey PhD, MPH** **Principal Investigator** **Epidemiologist, Biostatistician** **Huntington Medical Research Institutes** **Phone Number: 626-397-5818**
Lyle Best, MD, Co-investigator **Missouri Breaks Industries Research, Inc** **Watford City, ND** **Phone Number: 701-842-6770**	**Marcia O'Leary, RN** **Field Site Principal Investigator** **Missouri Breaks Industries Research, Inc** **Eagle Butte, SD** **Phone Number: 605-964-1260** **Toll Free: 1-800-865-3418**

Why Is This Study Being Done?
This study is being done to better understand if how you respond to negative experiences and challenges (called "resilience") or your relationships with friends and family, influence brain aging.

What Is Involved in The Study?
If you choose to be in this study, you will be asked to answer questions about self-reliance, perseverance, humor, resourcefulness, composure, optimism, communication, social support, and helping behaviors. You will also be asked to complete a questionnaire about your cultural beliefs and practices and your ability to complete day-to-day activities. You will be asked to answer a brief 1-page page questionnaire to measure memory, attention, language, and perception. We expect that it will take approximately 30-35 minutes to complete the study questionnaires and assessments.

What Are the Risks of The Study?
The risks associated with this study are minimal. The primary risks include loss of confidentiality. We will take measured steps to minimize these risks through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
You will not benefit directly from this study. However, findings from this study may improve our understanding of how individual and community features influence brain aging. This may help researchers better understand how to prevent conditions, such asdementia or Alzheimer's disease.

How Will the Data Be Stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study database that is stored securely in the Strong Heart Study Coordinating Center along with data collected from previous Strong Heart Study exams and ancillary studies.

Will I Be Paid for Participating in This Study?
You will receive $50 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

MedStar Health
Research Institute

Permission to Take Part in a Human Research Study

Title of research study: "Resilience, cultural alignment, and social support in brain aging: The Strong Heart Study"

Investigator: Dr. Jason Umans [Arizona field center] Medstar Health Research Institute 301-560-2959 **Jgu@georgetown.edu**

Why am I being invited to take part in a research study?

We invite you to participate in a research study called **Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study** which is an ancillary study of the **Strong Heart Study**. You were selected as a possible participant in this study because you previously participated in the original **Strong Heart Stroke Study**. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends, and your doctor(s).

What should I know about a research study?

If you choose to be in the study, you will complete a questionnaire on measures related to psychological resilience and self-regard, including questions on self-reliance, perseverance, humor, resourcefulness, composure, optimism, access to resources, spirituality, emotional regulation, expression, communication, social support, nurturance, and helping behaviors; and measures related to cultural alignment and identity including ethnic commitment and expression, family activities and traditions, and Indigenous or Native racial identity.

Why is this research being done?

We are asking you to take part in a research study being done within the **Strong Heart Study**. This study is being done to expand the knowledge of psychosocial factors such as resilience, social support, cultural identity and alignment, and cognitive function in American Indians. We are interested in learning more about different psychosocial factors among American Indians.

How long will the research last and what will I need to do?

We expect the study procedures to take **approximately 30-40 minutes** all together.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?"***

Is there any way being in this study could be bad for me?

The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

The **benefits to participation are indirect**. There are no direct benefits to participation, but there may be larger benefits to your community and to scientific knowledge in general, as this study has the potential to improve our understanding of how individual, cultural, and community features can help benefit or protect an individual in their risk of developing cognitive impairment and dementia, such as from Alzheimer's disease. We hope that strength-based research like this will help us to identify ways to improve public health programs and impact the lives of American Indian elders, their families, and their communities.

What happens if I do not want to be part of this research?

Participation in this study **is voluntary**. You may choose to stop participation at any time without loss to the benefits to which you are otherwise entitled.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Medstar Health Research Institute, 301-560-2959 Jgu@georgetown.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about **(819) people** here will be in this research study out of (**3000) people** in the entire study nationally.

What happens if I say yes, I want to be in this research?

You will be asked to complete a questionnaire on measures related to psychological resilience and self-regard, including questions on self-reliance, perseverance, humor, resourcefulness, composure, optimism, access to resources, spirituality, emotional regulation, expression, communication, social support, nurturance, and helping behaviors; and measures related to cultural alignment and identity including ethnic commitment and expression, family activities and traditions, and Indigenous or Native racial identity. Field staff will also conduct a brief interview with written tasks designed to measure your cognitive function using standard instruments. The cognitive test is not designed to test your intelligence; it is designed to be used in clinic to screen for cognitive conditions like Alzheimer's disease and vascular dementia.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you choose to stop participation, you may either tell the field center staff with whom you are working, or you may call or email the field center Investigator for the Strong Heart Study to alert them that you do not wish to continue. Even if you choose not to complete the study, you will still be entitled to receive your participation incentive.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks. Protection against loss of privacy and confidentiality will be maintained through strict, established data protections. Data collected at our field center offices are deidentified on site, with links to your identity and all materials with identity marks (including signed consent forms) stored in separate, locked file cabinets inside of locked, restricted-access offices. All materials with your research data are kept separate from these identifying materials, with study coded IDs. These coded data will either be scanned by field center staff, and then uploaded, and hand-entered into Redcap from the paper based forms by Washington State University staff; or they will be entered directly into Redcap datasets from tablet-based forms, depending on the availability of internet-ready tablets at the time of the study. The coded, deidentified data will be stored in databases and maintained on secure servers that are backed up daily at Washington State University. No personnel may access datasets without explicit permission. No personnel, except for field center staff, have access to both identity links and data. Password-protected datafiles will be accessible only to approved investigators who are current with human subject's research certification.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization:

- **Washington State University IRB**
- **Great Plains Indian Health Service IRB**
- **Cheyenne River Sioux Tribe Tribal Council,**
- **Oglala Sioux Tribe Research Review Board**
- **University of Oklahoma Health Sciences Center IRB**
- **Oklahoma City Area Indian Health Service IRB**
- **Southwest Oklahoma Intertribal Health Board**
- **MedStar Health Research Institute IRB**
- **AK-CHIN Tribal Council**

- **Salt River Indian Community Tribal Council**.

We will keep your answers **confidential** and will not share your information with anyone outside of the research team. You can skip questions that you do not want to answer or stop at any time. This research is not likely to provide direct benefits to subjects.

What else do I need to know?

This research is being funded by the National Institutes of Health. If you agree to take part in this research study. You will be offered an **incentive** of $50 gift card for your participation.

If you choose to participate in this study, please fill in your name, sign, and date on the next page.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: Resilience, Cultural Alignment, and Social Support in Brain Aging: Data from the Strong Heart Study – An Ancillary Study of IRB# 10188
Sponsor: National Institute on Aging
Tauqeer Ali, MD, PhD, Principal Investigator Oklahoma Field Center
Astrid Suchy-Dicey PhD, Principal Investigator
Phone Number: (405) 271-3090

Why Is This Study Being Done?
This study is being done to improve understanding of how individual, strength-based characteristics like resilience might be associated with better brain aging and cognitive function in elders, and also how culture and community features like social support or cultural participation might enhance affect these associations. We hope to gain insights that will help us to develop programs to strengthen resilience and improve brain aging in all American Indians.

What Is Involved In The Study?
If you choose to be in the study, you will complete a questionnaire with standard questions measuring topics on and related to resilience, self-reliance, perseverance, humor, resourcefulness, composure, optimism, communication, social support, and helping behaviors; additional questions will measure cultural identity and participation, and ability to complete activities of daily living. A brief, 1-page cognitive assessment will measure visual, memory, attention, language, abstraction, and orientation. We expect procedures to take approximately 30-35 minutes.

What Are The Risks of The Study?
The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks, through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
The benefits to participation are mostly indirect. There may be benefits to your community, and to scientific knowledge in general, as this study has the potential to improve our understanding of how individual and community features might help to maintain better brain aging, and potentially to prevent conditions such as dementia or Alzheimer's disease. If our research is successful, then we hope in future studies to work towards developing strength-based interventions that might protect against these conditions.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies. A copy of the dataset will also be maintained at Washington State University for analysis purposes through the end of the project period

Will I Be Paid for Participating in This Study?
You will be given a $50 payment for completing participant interviews for this study. The payment is to help with your travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

A2.2 Psychological Risk Factors, Quality of Life, Community, and Brain Aging in Americans (PI: Astrid Suchy-Dicey)

Consent Addendum to Strong Heart Study Phase VII
to Participate in an Ancillary Research Study
Study Title: Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians

Researchers:

Amanda M Fretts, PhD, MPH **Principal Investigator** **Department of Epidemiology** **University of Washington** **Cardiovascular Health Research Unit** **Phone Number: 206-287-2777**	**Astrid Suchy-Dicey, Ph.D.** **Principal Investigator** **Huntington Medical Research Institutes** **Phone Number: 626-397-5818**
Lyle Best, MD, Co-investigator **Missouri Breaks Industries Research, Inc** **Watford City, ND** **Phone Number: 701-842-6770**	**Marcia O'Leary, RN** **Field Site Principal Investigator** **Missouri Breaks Industries Research, Inc** **Eagle Butte, SD** **Phone Number: 605-964-1260** **Toll Free: 1-800-865-3418**

Why Is This Study Being Done?
This study is being done to better understand if stress, depression, alcohol use, tobacco use, and prescription opioid use are associated with measures of brain health, including memory, thinking, reasoning, problem solving, decision making, and attention. We also hope to better understand if quality of life and whether you feel connected to your community impacts these relationships.

What Is Involved in This Study?
If you choose to be in this study, you will be asked to complete a questionnaire about stress, depression, use of alcohol, tobacco, and prescription opioids, health-related quality of life, and connectedness to your community. You will also be asked to complete a series of activities on a tablet designed to measure different functions of memory, including thinking, reasoning, problem solving, decision making, and attention. We expect the study procedures to take approximately 30-40 minutes to complete.

What Are the Risks of The Study?
The risks to participation are minimal. The primary risks include loss of confidentiality. We will take measured steps to minimize these risks through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
There are no direct benefits to you for participation in this study. However, this study has the potential to improve our understanding of how individual, cultural, and community features impact brain aging, including the development of dementia and Alzheimer's disease.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous Strong Heart Study exams and ancillary studies.

Will I Be Paid for Participating in This Study?
You will receive $50 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

MedStar Health
Research Institute

Permission to Take Part in a Human Research Study

Title of research study: **"Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians"**

Investigator: *Dr. Jason Umans [Arizona field center] Medstar Health Research Institute 301-560-2959 Jgu@georgetown.edu*

Why am I being invited to take part in a research study?

We invite you to participate in a research study called **Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians** which is an ancillary study of the **Strong Heart Study**. You were selected as a possible participant in this study because you previously participated in the original or Phase 6 of the **Strong Heart Study**. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends, and your doctor(s).

What should I know about a research study?

If you choose to be in the study, you will complete a questionnaire with standard questions measuring topics on and related to stress, depression, use of alcohol, tobacco, and prescription opioids, health-related quality of life, and connectedness to your community. You will also complete a brief, fully computerized cognitive function battery (tablet version) called the National Institutes of Health (NIH) Toolbox. We expect these study procedures to take approximately 30-40 minutes.

Why is this research being done?

This study is being done to assess the relationships among stress, depression, alcohol, tobacco, and prescription opioids with cognitive performance in American Indians adults; and also to examine whether health-related quality of life and community connectedness moderate these relationships. We hope our findings will provide insights into improving brain aging for all American Indians.

How long will the research last and what will I need to do?

We expect the study procedures to take **approximately 30-40 minutes** all together.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?"***

Is there any way being in this study could be bad for me?

The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

The **benefits to participation are indirect**. There are no direct benefits to participation, but there may be larger benefits to your community and to scientific knowledge in general, as this study has the potential to improve our understanding of how individual, cultural, and community features can help benefit or protect an individual in their risk of developing cognitive impairment and dementia, such as from Alzheimer's disease. We hope that strength-based research like this will help us to identify ways to improve public health programs and impact the lives of American Indian elders, their families, and their communities.

What happens if I do not want to be part of this research?

Participation in this study **is voluntary**. You may choose to stop participation at any time without loss to the benefits to which you are otherwise entitled.

Detailed Information: *The following is more detailed information about this study in addition to the information listed above.*

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Medstar Health Research Institute, 301-560-2959 Jgu@georgetown.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about **(819) people** in Arizona will be in this research study out of **(3000) people** in the entire study nationally.

What happens if I say yes, I want to be in this research?

You will be asked to complete a questionnaire with standard questions measuring topics on and related to stress, depression, use of alcohol, tobacco, and prescription opioids, health-related quality of life, and connectedness to your community. You will also complete a brief, fully computerized cognitive function battery (tablet version) called the National Institutes of Health (NIH) Toolbox. We expect these study procedures to take approximately 30-40 minutes.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you choose to stop participation, you may either tell the field center staff with whom you are working, or you may call or email the field center Investigator for the Strong Heart Study to alert them that you do not wish to continue. Even if you choose not to complete the study, you will still be entitled to receive your participation incentive.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks. Protection against loss of privacy and confidentiality will be maintained through strict, established data protections. Data collected at our field center offices are deidentified on site, with links to your identity and all materials with identity marks (including signed consent forms) stored in separate, locked file cabinets inside of locked, restricted-access offices. All materials with your research data are kept separate from these identifying materials, with study coded IDs. These coded data will either be scanned by field center staff, and then uploaded, and hand-entered into Redcap from the paper-based forms by Washington State University staff; or they will be entered directly into Redcap datasets from tablet-based forms, depending on the availability of internet-ready tablets at the time of the study. The coded, deidentified data will be stored in databases and maintained on secure servers that are backed up daily at Washington State University. No personnel may access datasets without explicit permission. No personnel, except for field center staff, have access to both identity links and data. Password-protected datafiles will be accessible only to approved investigators who are current with human subject's research certification.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization:

- **Washington State University IRB**
- **Great Plains Indian Health Service IRB**
- **Cheyenne River Sioux Tribe Tribal Council,**
- **Oglala Sioux Tribe Research Review Board**
- **University of Oklahoma Health Sciences Center IRB**
- **Oklahoma City Area Indian Health Service IRB**
- **Southwest Oklahoma Intertribal Health Board**
- **MedStar Health Research Institute IRB**
- **AK-CHIN Tribal Council**
- **Salt River Indian Community Tribal Council**.

We will keep your answers **confidential** and will not share your information with anyone outside of the research team. You can skip questions that you do not want to answer or stop at any time. This research is not likely to provide direct benefits to subjects.

What else do I need to know?

This research is being funded by the National Institutes of Health. If you agree to take part in this research study. You will be offered an **incentive** of $50 gift card for your participation.

If you choose to participate in this study, please fill in your name, sign, and date below.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians – An Ancillary Study of IRB# 10188
Sponsor: National Institute on Aging
Tauqeer Ali, MD, PhD, Principal Investigator Oklahoma Field Center
Astrid Suchy-Dicey, PhD, Principal Investigator
Phone Number: (405) 271-3090

Why Is This Study Being Done?
This study is being done to assess the relationships among stress, depression, alcohol, tobacco, and prescription opioids with cognitive performance in American Indians adults; and also to examine whether health-related quality of life and community connectedness moderate these relationships. We hope our findings will provide insights into improving brain aging for all American Indians.

What Is Involved In The Study?
If you choose to be in the study, you will complete a questionnaire with standard questions measuring topics on and related to stress, depression, use of alcohol, tobacco, and prescription opioids, health-related quality of life, and connectedness to your community. You will also complete a brief, fully computerized cognitive function battery (tablet version) called the National Institutes of Health (NIH) Toolbox. We expect these study procedures to take approximately 30-40 minutes.

What Are The Risks of The Study?
The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks, through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
The benefits to participation are mostly indirect. There are no direct benefits to participation, but there may be larger benefits to your community and to scientific knowledge in general, as this study has the potential to improve our understanding of how individual, cultural, and community features can help benefit or protect an individual in their risk of developing cognitive impairment and dementia, such as from Alzheimer's disease. We hope that research like this will help us to identify ways to improve public health programs that directly impact the lives of American Indian elders, their families, and their communities.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies. A copy of the dataset will also be maintained at Washington State University for analysis purposes through the end of the project period.

Will I Be Paid For Participating in This Study?
You will be given a $50 payment for completing participant interviews for this study. The payment is to help with your travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

A2.3 The Epitranscriptome as a Novel Mechanism of Arsenic- Induced Diabetes (PI: Ana Navas-Acien)

Consent Addendum to Strong Heart Study Phase VII
to Participate in an Ancillary Research Study
Study Title: The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes – An Ancillary Study of IRB# 10188
Sponsor: National Institute of Environmental Health Sciences

Researchers:

Amanda M Fretts, PhD, MPH **Principal Investigator** **Department of Epidemiology** **University of Washington** **Cardiovascular Health Research Unit** **Phone Number: 206-287-2777**	**Ana Navas-Acien, MD PhD** **Principal Investigator** **Professor of Environmental Health Sciences** **Columbia University** **Mailman School of Public Health**
Lyle Best, MD **Co-investigator** **Missouri Breaks Industries Research, Inc** **Watford City, ND** **Phone Number: 701-842-6770**	**Marcia O'Leary, RN,** **Field Site Principal Investigator** **Missouri Breaks Industries Research, Inc** **Eagle Butte, SD** **Phone Number: 605-964-1260** **Toll Free: 1-800-865-3418**

Why Is This Study Being Done?
The goal of this study is to better understand how environmental exposures influence the development of diabetes, heart disease, and other health outcomes. We are interested in understanding how genes work (called gene function) and how they influence heart, lung, and blood vessel diseases, cancer, and conditions that involve inflammation. We also want to study how lifestyle factors (for example, smoking and diet) and environmental factors (for example, air pollution and water pollution) can influence the way genes work. Gene function can be studied looking at how genes are expressed through measures of the RNA in blood. The RNA carries the instructions from the DNA to synthesize proteins. In this study, we are asking for your permission to collect blood samples with a special tube that allow us to measure gene function. The collection of this tube does not add any additional burden to the blood collection. When we study how genes function, it is also important to have information about the genetic code of a person. For that reason, we are also asking you for permission to do genetic testing.

What Is Involved In This Study?
If you choose to be in this study, we will ask for a blood sample (in addition to what is already being collected as part of the Strong Heart Study). We will also use a portion of the urine sample that is already being collected as part of the main Strong Heart Study (no additional urine will be collected as part of this study). The blood sample will be used to measure how genes function and genetic testing will be done at the Baccarelli Laboratory at Columbia University. The blood sample will also be used to perform the complete blood test (CBC), which is a group of tests that evaluate the cells that circulate in blood, including red blood cells (RBCs), white blood cells (WBCs), and platelets (PLTs). The urine sample will be used to measure heavy metals.

What Are the Risks of This Study?
The risks associated with this study are slight discomfort or bruising from the blood draw, and the possible loss of confidentiality if your data or information is inadvertently disclosed outside of the study. We will take measured steps to minimize risk of loss of confidentiality through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part In This Study?
There are no direct benefits for your participation in this study. However, we may learn more about arsenic exposure levels in your community. This may have public health implications if arsenic exposure levels are above the current US EPA safety standard (10 µg/L). These results are important for the general population at large due to the potential role of arsenic on diabetes risk, and the importance of arsenic safety standards in drinking water.

How Will the Data Be Stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study database that is stored securely in the Strong Heart Study Coordinating Center along with data collected from previous Strong Heart exams and ancillary studies.

Will I Be Paid for Participating in This Study?
You will receive $10 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

MedStar Health
Research Institute

Permission to Take Part in a Human Research Study
Title of research study: *Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes*
Investigator: *Jason G. Umans, MD, PhD*

Key Information: *The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.*

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are participating in Strong Heart Study Phase VII.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are looking at how environmental exposures influence the development of diabetes, heart disease, and other health outcomes. I understand that some of the testing for this study will be related to how genes function and that genetic testing will be conducted.

Is there any way being in this study could be bad for me?

The study coordinator, nurses and technicians will be trained in the proper techniques for administering the questionnaire, collecting urine and blood samples, and conducting the physical examination. They will be instructed to take every precaution to minimize potential discomfort and risks. There is the potential for possible pain or bruising at the site of the blood draw.

Will being in this study help me in any way?

There are no direct benefits for your participation in this study, however, there are indirect anticipated benefits for the participant communities with arsenic exposure levels above the current US EPA safety standard (10 µg/L), and for similar communities in the US and worldwide. The results are important for the general population at large, mainly derived from the potential role of arsenic on diabetes risk and regarding arsenic safety standards in drinking water and food.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information: *The following is more detailed information about this study in addition to the information listed above.*

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***(602) 277-0488.***
This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

1. Your questions, concerns, or complaints are not being answered by the research team.

2. You cannot reach the research team
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

What happens if I say yes, I want to be in this research?

During the Strong Heart Study Phase VII examination, we will obtain an additional blood sample and use a portion of the urine sample that is already being collected from you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Will I be paid for participating in this study?

You will receive $10 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes – An Ancillary Study of IRB# 10188
Sponsor: National Institute of Environmental Health Sciences
Tauqeer Ali, MD, PhD, Principal Investigator Oklahoma Field Center
Ana Navas-Acien PhD, Principal Investigator
Phone Number: (405) 271-3090

Why Is This Study Being Done?
We are looking at how environmental exposures influence the development of diabetes, heart disease, and other health outcomes.

What Is Involved In The Study?
We will obtain an additional blood sample and use a portion of the urine sample that is already being collected from you. The blood sample will be used to measure how genes function and genetic testing will be done at the Baccarelli Laboratory at Columbia University. The blood sample will also be used to perform the complete blood test (CBC), which is a group of tests that evaluate the cells that circulate in blood, including red blood cells (RBCs), white blood cells (WBCs), and platelets (PLTs). The urine sample will be used to measure heavy metals.

What Are The Risks of The Study?
The risks to participation are minimal. The study coordinator, nurses and technicians will be trained in the proper techniques for administering the questionnaire, collecting urine and blood samples, and conducting the physical examination. They will be instructed to take every precaution to minimize potential discomfort and risks. There is the potential for possible pain or bruising at the site of the blood draw.

Are There Benefits to Taking Part in The Study?
There are no direct benefits for your participation in this study, however, there are indirect anticipated benefits for the participant communities with arsenic exposure levels above the current US EPA safety standard (10 µg/L), and for similar communities in the US and worldwide. The results are important for the general population at large, mainly derived from the potential role of arsenic on diabetes risk and regarding arsenic safety standards in drinking water and food.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies.

Will I Be Paid For Participating in This Study?
You will be given a $10 payment for completing participant interviews for this study. The payment is to help with your travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

A2.4 Gut Microbiome, Aging and Cardiometabolic Diseases in American Indians (PI: Jinying Zhao)

Consent Addendum to Strong Heart Study Phase VII
to Participate in an Ancillary Research Study
Study Title: Gut Microbiome, Aging and Cardiometabolic Diseases in American Indians – An Ancillary Study of IRB# 10188
Sponsor: National Institute on Aging

Amanda M Fretts, PhD, MPH **Principal Investigator** **Department of Epidemiology** **University of Washington** **Cardiovascular Health Research Unit** **Phone Number: 206-287-2777**	**Jinying Zhao MD, PhD** **Principal Investigator** **Deans Endowed Chair and Professor** **Director, Center For Genetic Epidemiology and Bioinformatics (GeneBio)** **University of Florida**
Lyle Best, MD, Co-investigator **Missouri Breaks Industries Research, Inc** **Watford City, ND** **Phone Number: 701-842-6770**	**Marcia O'Leary, RN** **Field Site Principal Investigator** **Missouri Breaks Industries Research, Inc** **Eagle Butte, SD** **Phone Number: 605-964-1260** **Toll Free: 1-800-865-3418**

Why Is This Study Being Done?
The goal of this study is to better understand what bacteria exist in your gut, and how bacteria interact to affect aging, diabetes and heart problems. Findings from this study may provide guidance for lifestyle interventions, and are likely to lead to new strategies that can promote healthy aging and prevent or treat diabetes, heart disease and related health problems.

What Is Involved In This Study?
If you choose to be in this study, we will ask for a stool sample. This will allow us to determine the amount and types of bacteria in your intestines. We will ask you to fill out questionnaires about the types of food you typically eat and your bowel habits. We will also measure telomere length (a marker of aging) using DNA blood samples already being collected by the Strong Heart Study (no additional blood will be drawn as part of this study).

What Are the Risks of This Study?
The risks associated with this study are minimal. The primary risks include loss of confidentiality. We will take measured steps to minimize these risks through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in This Study?
There is no direct benefit to participating in this study. However, results of this study are expected to provide valuable information that will help us understand the role of gut microbiome in diabetes and heart diseases. Since the bacteria in your gut can be manipulated by diet change, and with treatments such as antibiotic use and probiotic use, findings of this study will provide valuable information to improve the health of American Indians.

How Will the Data Be Stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study database that is stored securely in the Strong Heart Study Coordinating Center along with data collected from previous Strong Heart Study exams and ancillary studies.

Will I Be Paid for Participating in This Study?
You will receive $50 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

MedStar Health
Research Institute

Human Research Study

Title of research study: Gut microbiome, aging and cardiometabolic traits in American Indians
Investigator: Jason G. Umans, MD, PhD

Key Information: *The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.*

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are participating in Strong Heart Study Phase VII.

What should I know about a research study?

- Someone will explain this research study to you.
  - Whether or not you take part is up to you.
  - You can choose not to take part.
  - You can agree to take part and later change your mind.
  - Your decision will not be held against you.
  - You can ask all the questions you want before you decide.

Why is this research being done?

The human gut is made up of trillions of bacteria, viruses, fungi and other microbes (collectively called gut microbiota). Some of these are useful, and some are harmful. These microbes live in our body from birth and throughout life. As we age, the beneficial bacteria in the intestines tend to decrease, whereas the harmful bacteria tend to increase. An imbalance of good and bad microbes in our gut may cause many diseases such as high cholesterol, obesity, diabetes, heart disease, early aging and other disorders. The gut microbiome includes all genes that control the metabolism of the microbes in our gut. Gut microbiome plays an important role in our health by controlling food digestion, energy production, immune system, central nervous system and many other biological processes. The goal of this study is to find what bacteria exist in your gut and how they interact to affect aging, diabetes and heart problems. Findings of this study may provide guidance for lifestyle change and are likely to lead to new strategies that can promote healthy aging and prevent or treat diabetes, heart disease and other health problems.

Is there any way being in this study could be bad for me?

There is no risk to participate in this study. Written consent will be obtained from all participants. The study investigators and research personnel will ensure that participants understand the voluntary nature of the study. Participants are free to discontinue participation in this study at any time. Similarly, participants will be told that they are free not to answer any questions in the packet of questionnaires and can withdraw from this study at any time. All information will be collected by the SHS and is identified only through study ID numbers, which do not link to any of the personal identifiers. The SHS ID numbers are stored separately from the main database and access to these identifiers is restricted according to the policies and procedures of the SHS as well as the human subject's office at each participating site. In order to reduce the risk of breach of confidentiality and maximize the privacy of study participants, data for this study are collected by the SHS staff and study investigators have no contact with the

participants. All data collected in this study will be stored in secure, locked areas with access limited to the SHS and study personnel.

Will being in this study help me in any way?

There is no direct benefit to participating in this study. However, results of this study are expected to provide valuable information that will help us understand why some people suffer from diabetes and heart diseases earlier and more easily than others. Since gut microbiome can be manipulated with treatments such as antibiotics and probiotics as well as lifestyle choices such as diet, findings of this study will provide valuable information to delay aging and improve cardiometabolic health to American Indians.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information: *The following is more detailed information about this study in addition to the information listed above.*

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***(602) 277-0488.***

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

What happens if I say yes, I want to be in this research?

If you choose to be in this study, we will ask you to self-collect a Stool Sample using a kit that is provided. Study staff will instruct participants on how to use the Stool Sample kit and 3-5 days prior to their scheduled clinical visit. use a portion of the urine and the blood samples collected by the Strong Heart Study at previous study exams. A set of questionnaires will also be provided to participants in advance of the clinic visit exploring diet patterns in addition to a Bristol stool chart that measures stool frequency and type.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Will I be paid for participating in this study?

Participants will be provided a gift card (worth $50) to compensate their time and contribution to this sub-study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: Gut Microbiome, Aging and Cardiometabolic Diseases in American Indians – An Ancillary Study of IRB# 10188
Sponsor: National Institute on Aging
Tauqeer Ali, MD, PhD, Principal Investigator Oklahoma Field Center
Jinying Zhao PhD, Principal Investigator
Phone Number: (405) 271-3090

Why Is This Study Being Done?
The goal of this study is to find what bacteria exist in your gut and how they interact to affect aging, diabetes and heart problems. Findings of this study may provide guidance for lifestyle change, and are likely to lead to new strategies that can promote healthy aging and prevent or treat diabetes, heart disease and other health

What Is Involved In The Study?
If you choose to be in the study, we will collect stool samples from you. We will then perform test to determine the amount and types of bacteria in the intestines to evaluate their association to obesity, diabetes, heart disease and other health problems. We will also collect information from you regarding your dietary and bowel habits. We will also measure telomere length (a marker of aging) using DNA samples collected by the parent Strong Heart Study.

What Are The Risks of The Study?
The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks, through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
There is no direct benefit to participating in this study. However, results of this study are expected to provide valuable information that will help us understand the role of gut microbiome in diabetes and heart diseases. Since gut microbiome can be manipulated with treatments such as antibiotics and probiotics as well as lifestyle choices such as diet, findings of this study will provide valuable information to improve cardiometabolic health of American Indians.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies.

Will I Be Paid For Participating in This Study?
You will be given a $50 Wal-Mart gift card for completing participant interviews for this study. The payment is to help with your travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

A2.5 Health Effects of Metals in Native American Communities: A Longitudinal Multi-Omics Study (PI: Ana Navas-Acien)

Consent Addendum to Strong Heart Study Phase VII
to Participate in an Ancillary Research Study
Study Title: Health Effects of Metals in Native American Communities: A Longitudinal Multi-omics Study
Sponsor: National Institute of Environmental Health Sciences

Researchers:

Amanda M Fretts, PhD, MPH **Principal Investigator** **Department of Epidemiology** **University of Washington** **Cardiovascular Health Research Unit** **Phone Number: 206-287-2777**	**Ana Navas-Acien, MD PhD** **Principal Investigator** **Professor of Environmental Health Sciences** **Columbia University Mailman School of Public Health**
Lyle Best, MD **Co-investigator** **Missouri Breaks Industries Research, Inc** **Watford City, ND** **Phone Number: 701-842-6770**	**Marcia O'Leary, RN,** **Field Site Principal Investigator** **Missouri Breaks Industries Research, Inc** **Eagle Butte, SD** **Phone Number: 605-964-1260** **Toll Free: 1-800-865-3418**

Why is this study being done?
Arsenic and uranium are metal contaminants found in polluted areas throughout the USA, including at abandoned mines and Superfund sites. Arsenic and uranium are also found naturally in groundwater. It is possible that exposure to these contaminants increase risk of diabetes and heart disease. The goal of this study is to better understand if exposure to arsenic and uranium influence development of diabetes, heart disease and other health outcomes. We will also evaluate how these metals affect the way genes work by measuring DNA methylation.

What is involved in this study?
If you choose to be in this study, we will use a portion of the urine and the blood samples collected by the Strong Heart Study at previous study exams. We will measure urinary arsenic, uranium and other metals in samples collected at the study exam that occurred in 2007-2009. We will evaluate how these metals affect the way genes work by measuring DNA methylation in the blood from samples collected at the study exams that occurred in 2001-2003 and 2007-2009. In addition, we will collect a sample of water from your kitchen faucet, and ask you to complete a short questionnaire about your water and where you live (and have lived in the past).

What are the risks of this study?
The risks to participation are minimal. No blood or urine are collected for this project. Only samples collected at previous Strong Heart Study exams will be used. We will take measured steps to minimize risk of loss of confidentiality through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
There are no direct benefits for your participation in this study. However, we may learn more about arsenic and uranium levels in your community. This may have public health implications if arsenic levels are above the current US EPA safety standard of 10 µg/L or uranium is above the safety standard of 30 µg/L. These results are important for the community due to the potential role of arsenic and uranium on disease risk, and the importance of meeting safety standards in drinking water.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study database that is stored securely in the Strong Heart Study Coordinating Center along with data collected from previous Strong Heart exams and ancillary studies.

Will I be paid for participating in this study?
You will receive $10 as a “thank you” for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) **OBTAINING CONSENT**	**Printed Name**	**Date**

MedStar Health
Research Institute

Permission to Take Part in a Human Research Study

Title of research study: Health Effects of Metals in Native American Communities: A Longitudinal Multi-Omics Study
Investigator: *Jason G. Umans, MD, PhD*

Key Information: *The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.*

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are participating in Strong Heart Study Phase VII.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
Arsenic and uranium are metal contaminants found in polluted areas throughout the USA, including at abandoned mines and Superfund sites. Arsenic and uranium are also found naturally in groundwater. It is possible that exposure to these contaminants increase risk of diabetes and heart disease. The goal of this study is to better understand if exposure to arsenic and uranium influence development of diabetes, heart disease and other health outcomes. We will also evaluate how these metals affect the way genes work by measuring DNA methylation.

Is there any way being in this study could be bad for me?
The risks to participation are minimal. No blood or urine are collected for this project. Only samples collected at previous Strong Heart Study exams will be used. We will take measured steps to minimize risk of loss of confidentiality through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Will being in this study help me in any way?
There are no direct benefits for your participation in this study. However, we may learn more about arsenic and uranium levels in your community. This may have public health implications if arsenic levels are above the current US EPA safety standard of 10 µg/L or uranium is above the safety standard of 30 µg/L. These results are important for the community due to the potential role of arsenic and uranium on disease risk, and the importance of meeting safety standards in drinking water.

What happens if I do not want to be part of this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information:

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***(602) 277-0488.***
This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

What happens if I say yes, I want to be in this research?

If you choose to be in this study, we will use a portion of the urine and the blood samples collected by the Strong Heart Study at previous study exams. We will measure urinary arsenic, uranium and other metals in samples collected at the study exam that occurred in 2007-2009. We will evaluate how these metals affect the way genes work by measuring DNA methylation in the blood from samples collected at the study exams that occurred in 2001-2003 and 2007-2009. In addition, we will collect a sample of water from your kitchen faucet and ask you to complete a short questionnaire about your water and where you live (and have lived in the past).

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Will I be paid for participating in this study?

You will receive $10 as a "thank you" for the time taken to participate in this study.

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: Health Effects of Metals in Native American communities: A Longitudinal Multi-Omics Study – An Ancillary Study of IRB# 10188
Sponsor: National Institute of Environmental Health Sciences
Tauqeer Ali, MD, PhD, Principal Investigador Oklahoma Field Center
Ana Navas-Acien PhD, Principal Investigador
Phone Number: (405) 271-3090

Why Is This Study Being Done?
We are looking at the effects of arsenic and uranium exposure on the development of diabetes, heart disease and other health outcomes. We will also evaluate how these metals affect the way genes work (called gene function), by measuring DNA methylation in blood. Arsenic and uranium are contaminants at Superfund sites, near abandoned mines, and near other hazardous sites. These contaminants are also naturally occurring in groundwater. Exposure to these contaminants could explain some of the excess burden of diabetes and heart disease affecting Native American communities in the US.

What Is Involved in The Study?
If you choose to be in this study, we will use a portion of the urine and the blood samples already collected by the Strong Heart Study in previous phases. We will measure urinary arsenic, uranium and other metals in samples from phase 5. We will measure DNA methylation in samples from phases 4 and 5. These measures of DNA will help us assess the function of the genes. In addition, we will collect a sample of water from your kitchen faucet, and conduct a brief water and residential history questionnaire.

What Are The Risks of The Study?
The risks to participation are minimal. No blood or urine are collected for this study as only samples from previous visits will be used for the analysis of metals and DNA, so there are no risks derived from sample collection. We will take measured steps to minimize risk of loss of confidentiality through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
There are no direct benefits for your participation in these studies. However, we may learn more about arsenic and uranium levels in your community. This may have public health implications if arsenic levels are above the current US EPA safety standard of 10 µg/L and uranium is above the corresponding standard of 30 µg/L. These results are important for the population at large due to the potential role of arsenic and uranium on disease risk, and the importance of meeting safety standards in drinking water.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Coordinating Center with data collected in previous SHS phases and ancillary studies.

Will I Be Paid For Participating in This Study?
You will be given a $10 payment for completing interviews and providing a water sample for this study. The payment is to help with travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**

A2.6 Chronic Respiratory Diseases in American Indians (PI: Huimin Wu and Administered at the Oklahoma site only)

STRONG HEART STUDY ID NUMBER |___||___||___||___||___||___||___|

Consent Addendum Form to Participate in an Ancillary Research Study
University of Oklahoma Health Sciences Center (OUHSC)
Study Title: Chronic Respiratory Diseases in American Indians – An Ancillary Study of IRB# 10188
Sponsor: University of Oklahoma Health Sciences Center, College of Medicine
Tauqeer Ali, MD, PhD, Principal Investigator Oklahoma Field Center
Huimin Wu, MD, MPH, Principal Investigator
Phone Number: (405) 271-6173

Why Is This Study Being Done?
This study is being done to assess respiratory symptoms and associated chronic respiratory diseases in American Indians adults. We hope our findings will provide insights into improving lung health for all American Indians.

What Is Involved In The Study?
If you choose to be in the study, you will complete a questionnaire with standard questions measuring the topics on and related to respiratory symptoms and chronic respiratory diseases. We expect the study procedure to take approximately 5 minutes.

What Are The Risks of The Study?
The risks to participation are minimal. The primary risks include breach of confidentiality. We will take measured steps to minimize these risks, through protection of your data by standard privacy and confidentiality procedures that the Strong Heart Study always uses.

Are There Benefits to Taking Part in The Study?
The benefits to participation are mostly indirect. There are no direct benefits to participation, but there may be larger benefits to your community and to scientific knowledge in general, as this study has the potential to improve our understanding of how healthcare agencies and professionals can help protect an individual in their risk of developing chronic respiratory diseases, such as chronic obstructive pulmonary disease (COPD). We hope that research like this will help us to identify ways to improve public health programs that directly impact the lives of American Indians.

How will the data be stored?
The data for this study will be kept private to the extent allowed by federal and state law. Data generated from this ancillary study will become part of the Strong Heart Study (SHS) database that is stored securely in the Strong Heart Study Coordinating Center along with data collected in previous SHS phases and ancillary studies.

Will I Be Paid For Participating in This Study?
You will be given a $10 payment for completing participant interviews for this study. The payment is to help with your travel expenses and to give you something for your time helping this study

☐ **Yes, I consent** to participate in this study.

☐ **No, I do not consent** to participate in this study.

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	**Printed Name**	**Date**
_____	_____	_____
SIGNATURE OF PERSON Date OBTAINING CONSENT	**Printed Name**	

Appendix 3 Question by Question and Instructions

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.

Personal Interview Form I

SHS I.D. (previously assigned) and SHS Family ID (previously assigned) should be completely filled in after the consent form is completed.

1st digit represents the center number (1=SD, 2=OK, 3=AZ).
2nd digit represents the cohort enrollment (0 for original cohort, 6 for family cohort)
Remaining digits are consecutive numbers of the subject when previously interviewed.

When using paper packets be sure to have ID's filled in on all questionnaires before distributing to the participant. And all written answers should be left justified on the paper. When using the REDCap data entry system, the ID's will auto populate.

Enter Date of Birth using numerical month (01 through 12)/day/ four digits for year.

DEMOGRAPHIC INFORMATION

1. Your (Participants) Name
   a. Enter last name
   b. Enter first name
   c. Enter middle name. If no middle name, leave blank.
   d. Enter nickname or other name being used by friends. If no nickname, leave blank.

2. If a female participant has ever married, write down her maiden name.

3. Write down the name of a married participant's spouse.

4. Write down the name of Indian Health Service hospital (IHS) and the non-IHS hospital usually used by the participant. Enter the participants chart number if known and indicate if the facility is an IHS facility.

5. Current mailing address.
   a. Separate unit number and street name with a space. If post office box, enter after street address.
   b. City/town or reservation of residence.
   c. County of residence. If it is unknown, leave blank.
   d. Enter state of residence as two-digit postal abbreviation and 5-digit postal zip code.
      i. AZ= Arizona
      ii. OK= Oklahoma
      iii. SD= South Dakota
      iv. ND= North Dakota

6. Indicate if residential address is different from the mailing address by checking (1) yes or (2) no,
   a. – d. If no write in the residential address following the rules given in item 5a-d.
   e. Using google satellite maps, locate the participants home, click right on that location to identify the global position system (GPS) code. Write the geocodes indicated beginning with the latitude on the first line and the longitude on the second line. Be sure to include all decimals and positive or negative symbols as indicated on the map.

7. Indicate how long the participant has lived at their current residence. Enter the number of months and years. If these are unknown, leave blank.

8. Indicate if this is the residential address where the participant has lived the longest by marking yes or no. If No complete sections 8 a-e including the geo code data following the instructions for completing questions 5 and 6 as appropriate.

Questions 9 – 15 are only answered if the participant consented "Yes" to "The Health Effects of Metals in Native American Communities" Ancillary Study.

9. Indicate whether the participant's current residence or the residence they have lived the longest is in the same city or town as the participant lived when they were born, during their childhood (1 to 11 years old) and during their adolescence (12 to 17 years old).

10. Provide the address that the participant lived in during their first year of life (< 1 years old) following the rules given in item 5a-d. If unknown, leave blank.

11. Provide the address that the participant lived in during childhood (1 to 11 years old) following the rules given in item 5a-d. If unknown, leave blank.

12. Provide the address that the participant lived in during adolescence (12 to 17 years old) following the rules given in item 5a-d. If unknown, leave blank.

13. Indicate the source of drinking water that is used in the residential home. Check all options that may apply.

14. Indicate if the drinking water that is used in the residential home is treated or filtered. If (1) yes, continue to answer how the water is treated or filtered.

15. Provide the approximate percentage of the water that the participant drinks is tap water or bottled water. The two percentages entered should add up to 100%. Enter 0 if one isn't used.

Resume Personal Interview I questions.

16. Enter complete telephone number of home phone or phone at which participant can be reached or at which a message can be left.

17. Enter work phone number at which participant can be reached. Enter 0 if the number is the same as the home phone number or 9 if not applicable.

18. Enter contact information including name, mailing and residential address, city/town, state, zip code, phone numbers and email addresses of two individuals who would be able the Field center personnel to locate the participant in the future. Probe the participant to identify parents, siblings, aunts, uncles, hunka relatives or friends who the participant feels would know how to contact the participant.

ADMINISTRATIVE INFORMATION

19. Enter interviewer code

20. Enter date that interview was completed.

Personal Interview Form II

Complete the SHS ID and SHS Family ID same as entered for Personal Interview I if using paper forms.

BASIC INFORMATION

1. Check the sex of the participant assigned at birth

2. Check the gender which best describes the participants gender identity.

3. Enter the number of the participant's current marital status.

4. Enter number of years of education the participant has completed to the closest estimate. High school or GED equivalency = 12. Do not count preschool or kindergarten separate.

5. Indicate if the participant attended preschool, kindergarten or participated in the Head Start Program.

SLEEP HEALTH

5. a. Enter the average hours of sleep the participant gets every night. If unknown, then leave blank.

FAMILY INCOME

Questions 6-9 assess the family income so that the subject's socioeconomic status can be determined. Ask the questions as stated in the questionnaire

6. Ask participant whether their household income meets her/his family's needs?

7. Ask whether the participant is attending a school.

8. Ask participant, on the average, how many hours per week they work in a paid job(s).

9. Ask participant to choose the correct annual household income level from all sources for her/his household. Prepare a sheet of income levels to show the participant so that they can respond by number associated with the income levels to this question.

TOBACCO

These questions are very important to assess accurately because smoking is a major risk factor for cardiovascular disease.

10. Ask the participant if they have smoked 100 cigarettes or more total in their lifetime. This question will determine whether the participant is a smoker or not. A person who has smoked less than 100 cigarettes in their lifetime is not considered a smoker since the damage caused by smoking is negligible. If the answer is “No” Skip to question 18. If the answer is “Yes”, continue to question 11.

11. Determine when participant started smoking regularly. Record age in years. If never smoke regularly - write 0 if unknown write 999.

12. Ask participant whether they quit smoking. If No skip to question 12.
    a. If yes enter the year that they quit smoking in the space
    b. Read the list of reasons they have for quitting marking either yeas or no for each reason and if they indicate yeas for other write in specific reason for quitting

13. Determine average cigarettes smoked per day, which may have a significant effect on heart diseases and other health problems. Write in the average number of cigarettes per day.
    a. If the participant averages less than one cigarette per day, write in their average number of cigarettes per month.

14. Ask the participant about the occasions when they are most likely to smoke or increase smoking. Check ALL the appropriate boxes.

15. Ask the participant, regarding occasions they increased smoking, how many cigarettes she/he smoked per day.

16. Ask the participant whether they are smoking currently. If "No", skip to question 18.

17. Ask the participant, if currently smoking, whether they want to change her/his smoking habit and how.
    a. If "Yes" select all the participants preferences i) through v)

18. Ask the participant whether she/he uses chewing tobacco or snuff now. If "No", skip to question 20.

19. If yes, how often per day does the participant use chewing tobacco or snuff.

PASSIVE SMOKING

This section asks about second-hand smoke exposure.

20. Ask participant, regardless of her/his smoking status, on the average, how many hours is she/he 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.

E-CIGARETTES OR OTHER ELECTRONIC VAPING PRODUCT

21. Ask participants if they have ever used an e-cigarette or other electronic vaping product, even if just one time in their life. If "No" skip to next section.

22. If yes, enter number of days the participant used e-cigarettes/vaping products in the past 30 days.

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. Give the participant a copy of the drink chart and review the chart with them. Many people are not familiar with the size or number of ounces which equal a drink.

23. Ask the participants when and if the individual last had an alcoholic beverage. If the person has never consumed alcohol. skip to question 30.
    a. If yes, indicate when the participant last had a drink, if within the last year write in the number of months. If more than a year ago is marked, skip to question 30.

24. Assess 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. Use the drinks chart to estimate the number of drinks in a typical week.

25. Indicate 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. Estimate the number of days in a month that the individual drinks using a 30-day calendar.

26. Assess the quantity of alcohol consumed in a day when participant drinks. Ask the participant to estimate how many drinks they consume on an average on the days when they drink alcohol. (Provide the participant with a copy of the drink chart)

27. Ask the participant when they drink more than the usual consumption, how many drinks do they have.

28. How many times in the past month did the participant have more than 5 drinks on an occasion.

29. How many times in the past year did the participant drink 5 or more drinks on an occasion?

LANGUAGE QUESTIONS

30. Ask the participant if they speak their native language. The interviewer should specify the native language when asking the question. If they answer “No”, skip to Question 32.

31. Indicate how often the participant speaks their native language.

US MILITARY OR ARMED FORCES SERVICE

32. Ask if the participant has served in the US military or Armed Forces. If "No", skip to the next section)

33. Which branch of the military did the participant serve

34. Enter how many years and months that the participant served in the military?

ADMINISTRATIVE INFORMATION

35. Enter interviewer code

36. Enter date that interview was completed.

Medical History Interview

Before beginning, make certain that the correct study identification number of the participant is entered at the top of the form. Explain to the participant that some questions need to be asked about her/his medical history so that we can better evaluate whether or not she/he has heart disease or a tendency for heart disease. Stress that the information will be confidential and that his/her name will never be used in any publication.

MEDICAL CONDITIONS:

Ask the participant if a <u>medical person</u> has ever told them that they have the following conditions?

1. a. 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. Participants can respond yes/no/only during pregnancy or unknown.
   b. If yes, how old was the individual when they were first told that they had high blood pressure? If unknown or don't know indicate with 999. This question pertains to the age that the individual first had high blood pressure that occurred when the participant was not pregnant.
   c. If "Yes" ask the individual if they are currently taking medication to control high blood pressure?

2. The interviewer should also inquire about arthritis (of any kind) mark yes/no or unknown

3. Any fractures associated with brittle bone disease or osteoporosis? Fractures associated with osteoporosis should be explained as fractures caused by bones getting weak. Such fractures often occur in 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. Indicate if yes/no or unknown. If yes - record the location of each fracture that is related to osteoporosis.

4. Rheumatic heart disease is a sequela of rheumatic fever and typically stenosis or insufficiency (tightness or leakiness) of the valves of the heart.

5. The interviewer should inquire if the participant has had gallstones. If participants say they have had their gall bladder removed, check "yes" because almost all cholecystectomies are done for gallstones. Respond yes/no or unknown.

6. The interviewer, when inquiring about cancer, should ask about cancer and diseases such as leukemia or lymphoma.
   a. If yes, record the type of cancer.

7. Diabetes indicate yes/no/ only during pregnancy or unknown. If no or unknown, skip to question 8. The interviewer should be alert to individuals who reply no, who are in fact taking oral hypoglycemic agents or insulin.
   a. If yes enter the actual age when they were first told they had diabetes.
   b. Record the type of treatment they are taking. Check "yes" or "no" for each question i –through vi. Check "do nothing" if they are not taking any medication nor exercising, nor controlling their diet for their diabetes. If other is checked "yes" – write in what the participant is doing for their diabetes.

8. Ask if the participant has ever been told by a medical person that they have kidney failure. The interviewer should describe this as kidney failure if she/he has been told that their kidneys are not working. If "No" or unknown go to question 11.
   a. If "yes" indicate if one or both kidneys are working well now?
   b. Enter the age when the participant was first told that they had kidney failure, write 999 if unknown.

9. Ask if the participant is on renal dialysis. When inquiring about renal dialysis, the interviewer can explain this by asking if the patient must go two or three times a week to have a machine cleanse his/her blood.

10. Ask if the participant has had a kidney transplant?
    a. if "yes" is the kidney working well?
    b. if "no" ask if the participant is waiting for a kidney transplant?

11. Ask if the participant has been told by a medical provider that they have cirrhosis of the liver. The interviewer should stress that this can occur both because of alcohol and for other reasons as well such as hepatitis or other conditions.

HEART PROBLEMS:

12. Ask if patient had any kind of heart catheterization.
    a. If "yes", determine whether they had an angioplasty or other procedure for Question 13. Enter the date of the heart catheterization procedure and the hospital where the procedure was done.

13. Ask if the participant ever had an angioplasty procedure. Explain that this is a procedure that opens up a blocked or narrowed artery around the heart.
    a. If yes, record when and where.

14. Ask if the participant has had an exercise or chemical stress test to examine the heart. Explain to the participant that this is a test which cause the heart rate to increase or the coronary arteries to dilate either through exercise on a treadmill or with the use of a medication. During this test, the patient's heart is monitored with an ECG and blood pressure as well as other equipment.
    a. If "yes", determine the date of the procedure and the hospital where it was done.

15. Heart failure. "That is, did the doctor or health care provider ever tell you that your heart was not working properly?" The necessity to sleep with several pillows (orthopnea) suggests heart failure.
    a. If "yes" enter the date of the most recent event and place that they were hospitalized
    b. b. If "yes" ask if they still have 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 they had a heart attack, ask if there were more than one.
    a. Obtain the date of the most recent heart attack and the hospital where the participant was hospitalized or diagnosed.

17. Ask if the participant has had other heart trouble,
    a. if yes, the interviewer should ask about the symptoms or type of heart trouble
    b. if "yes" indicate the most recent date and location of hospital or clinic.

18. Stroke. If the participant indicates that she/he has not had a stroke, ask also whether she/he has had any episode where she/he suddenly could not move a part of her/his body for a prolonged period of time.
    a. If "yes" enter when and location of hospital or clinic participant received care.

19. Surgery on chest. This question is designed to ensure that we get accurate information on cardiac surgery so that medical records can be obtained. Use anatomical diagrams or have the participant describe the type of surgery they had.
    a. if "yes" was the surgery on the heart?
       Ask the participant to confirm if the surgery was
       i) bypass surgery
       ii) valvular repair/replacement
       iii) pacemaker
       iv) other

    in each of these responses indicate "yes" or "no" and if "yes" the date and the hospital or clinic where treatment took place. If the participant indicates that other surgery was done on the check ask them to please be specific about the kind of surgery and when and where the procedure occurred.

20. Ask if participant is taking aspirin daily to prevent a heart attack or stroke.

21. Ask the participant if he/she has ever been told that they had COVID-19? Participant can respond yes, yes, probably/suspected or No

ORAL HEALTH QUESTION

22. Ask the participant how many natural teeth they have? They can respond all, most, some or none. Humans have 32 teeth which including the wisdom teeth.

23. Ask them how they chew their food (choose only one answer from the options)

24. Ask the participant to rate their ability to chew food (choose only one answer)

25. Ask the participant to rate the overall health of their teeth and gums.

26. Ask the participation if they have ever had treatment for gum disease such as scaling or root planning. Scaling or root planning periodontal therapy is a non-surgical therapy or deep cleaning treatment which involves removal of dental plaque and calculus (scaling or debridement) and then smoothing, or planning, of the (exposed) surfaces of the roots to reduce the microorganisms that cause inflammation.

27. Ask if a dental professional has ever told the participant that they have lost bone around their teeth?

ADMINISTRATIVE INFORMATION

28. Enter interviewer code

29. Enter date that interview was completed.

If the participant is Female go to the Reproduction and hormone use form
If the participant is male, go to the Rose questionnaire

Medication Reception

Confirm that the correct SHS ID and SHS Family ID number is entered at the top.

MEDICATION RECEPTION – participants should be requested in advance to bring all of their medications in their original container. Enter each medication on each consecutive line. Enter the strength of each medication and the frequency that the instructions on the bottle give for administration of the medication. If the medication is a PRN or an as needed medication that their medical provider instructed the participant to take only when needed- circle yes.

Compliance is important and should be written down as the participant actually takes the medication. After writing down the frequency per the prescription bottle and if the medication is PRN – ask the participant for each medication how many times they actually use or take the medication.

Indicate the number of medications that are not able to be transcribed.

Traditional remedies, therapies and practices should be transcribed similar to the previous medications. Write down the name and if known the strength, how the medication is recommended to be used, if taken routinely or only on a as needed basis and then how the medication is actually taken by the participant. All medications either prescribed, over the counter or traditional should be collected. Once the participant has listed all medications that they take or use, be sure to review the list and ask them if there is anything that they use for the purpose of curing or treating a medical condition, relieve symptoms of an illness or for the prevention of an illness or disease, List any additional items.

Reproduction and Hormone Use: Women Only

1. How many times have you been pregnant? This refers to gravidity or the state of being pregnant regardless of the outcome of the pregnancy. 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). If never pregnant, skip to question 25.

2. Indicate how many of the participants pregnancies resulted in a live birth (parity)

3. Ask how many living children the participant has?

4. Ask and write down the number of pregnancies that the participant lost to stillbirth/miscarriage or abortion).

Questions 5 through Question 14 pertain to the first pregnancy or pregnancy loss.

5. Indicate if the participants first birth resulted in a live birth?

6. Indicate the date of the delivery of first pregnancy (this includes both live and lost pregnancies).

7. Indicate how many weeks pregnant individual was at the time of their first delivery. Full term pregnancy is about 40 weeks. Use 999 for unknown.

8. Enter the hospital and city for their first delivery.

9. Ask if participant was diagnosed with hypertension or high blood pressure for the first time during their first pregnancy? Answer no if they were told prior to their first pregnancy that they had high blood pressure. If "no", skip to question 11.

10. If "yes", how many weeks pregnant was the participant when they were first diagnosed with high blood pressure? Use 999 if unknown.

Preeclampsia (pree-i-CLAMP-see-ah0, also called toxemia, is a condition that typically starts after the 20th week of pregnancy and is related to increased blood pressure and protein in in the mother's urine.

11. Ask if the participant was told that that they had preeclampsia, toxemia or protein in their urine during their first pregnancy. If "no", skip to question 13.

12. If yes, ask how many weeks pregnant the participant was when they were first diagnosed with preeclampsia, toxemia or protein in their urine. Use 999 if unknown.

13. Ask participant if they were diagnosed with diabetes during their first pregnancy. If "no", go to question 15.

14. If yes, ask how many weeks pregnant the participant was during their first pregnancy when they were diagnosed with diabetes. If unknown use 999.

Questions 15 and 16 pertain to any other pregnancies.

15. Indicate if the participant was told that they had preeclampsia, toxemia or both hypertension and protein in their urine in one or more later pregnancies. If "no", go to question 16.

16. If yes, indicate by pregnancy if they were diagnosed with pre-eclampsia or toxemia, the date of each delivery or loss of pregnancy and number of weeks pregnant when they were given the diagnosis.

17. Indicate if the participant ever had eclampsia (a seizure or convulsion) along with hypertension during a pregnancy or around the time of delivery.

18. Indicate if a mother or sister ever had preeclampsia.

19. Indicate if the participant had diabetes in any later pregnancies. If "no", go to question 21.

20. If yes, indicate by each pregnancy if they were diagnosed with diabetes, the date of that delivery or loss of pregnancy and the number of weeks pregnant when they received the diagnosis of diabetes.

21. Indicate how many cigarettes/day the participant smoked during their first pregnancy Enter "0" if participant did not smoke or use 999 for unknown.

22. Indicate how many e-cigarettes/day the participant smoked during their first pregnancy. And e-cigarette is a battery powered devices that provide inhaled doses of nicotine. Enter "0" if participant did not smoke or use 999 for unknown.

23. Indicate if the participant used chewing tobacco or snuff during their first pregnancy. If "No", skip to question 25.

24. If yes, ask how many times in a day they used chewing tobacco or snuff. Enter "0" if less than once a day or sporadically.

25. Ask participant if they have ever used birth control pills. If "no" or "not sure", skip to question 26. If "yes"
    a. ask if the participant is still using birth control pills.
    b. indicate in years how old the participate was when they first started to use birth control pills. Enter 999 if unknown.
    c. Enter the total number of years that the individual used birth control pills. Enter 0 if less than 6 months, enter 1 if 6-12 months, enter 999 if unknown.

26. Indicate if participant has ever had a birth control implant (such as Norplant). If "no" or "Not sure" skip to question 27. If "yes"
    a. are you still using a birth control implant?

b. indicate age in years when the participant started to use a birth control implant. Eenter 999 if unknown or can't remember.
c. Enter how many years altogether that participant used an implant. Specify the duration in year. 0 = less than 6 months, 1= 6-12 months, 999 = unknown.

27. Indicate if the participant has every used birth control shot? (such as Depo Provera). If "no" or unsure skip to question 28. If "yes"
    a. Is the participant still using birth control shots?
    b. Indicate in years how old participant was when they started to use birth control shots? If unknown or can't remember enter 999.
    c. Indicate how many years altogether the participant used birth control shots. Specify the duration in year. 0 = less than 6 months, 1= 6-12 months, 999 = unknown.

28. Indicate in years the age at which the participant started to have regular menstrual cycles (periods). Enter 999 if unknown.

29. Indicate if the participants menstrual cycles (periods) have stopped. If "no" skip to question 30. If "yes"
    a. Indicate if they have they have stopped for 12 months or more? If "no" skip to question 30. If "yes"
        i. Ask the participant in years how old they were when their menstrual cycles (periods) stopped completely. Enter 999 if unknown or can't remember.
        ii. Indicate if the participants menstrual cycles (periods) stopped naturally, because of surgery, hormone use or for some other reason. If natural, hormonal or other skip to question 30. If other is indicted in the specify the reason field.
        iii. If the participant indicated that their menstrual cycles stopped because of surgery ask if they had both ovaries removed.

"**ESTROGEN and PROGESTERONE are types of female hormones that may be taken for many reasons, including after a hysterectomy or menopause, to regulate your periods or for other reasons"**

30. Indicate if the participant has taken estrogen -either in pills, as a patch or by shot – for any reason. Other than in a birth control pill. If 'no" or "not sure" skip to question 38.

31. Indicate age in years that the participant started using estrogen.

32. Specify the duration in years, how many years altogether the participant took estrogen. If less than 3 months enter 0, If more than 3 months but less than 1 year, record 1.

33. Answer by marking yes/no or not sure all applicable reasons that the participant has taken estrogen. If entering yes for other, specify the reason.

34. Indicate if the participation takes progesterone in addition to or in combination with estrogen treatment.

35. Indicate the form of estrogen that the participant is taking.

36. Indicate if the participant is still taking estrogen. If "yes" skip to question 38.

37. Mark all that apply for the reason why the participant stopped taking estrogen.

38. Indicate if other than in combination with estrogens if the participant has taken progesterone by itself for any reason. If "no" or "not sure", skip to question 42.

39. Indicate in age how old participant was when they started using progesterone.

40. Indicate in years how many years altogether the participant took progesterone. If less than 3 months enter 0, If more than 3 months but less than 1 year, record 1. Indicate if the participant is still taking progesterone.

41. Indicate if the participant is still taking progesterone.

ADMINISTRATIVE INFORMATION

42. Enter interviewer code.

43. Enter interview date.

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 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".

Enter the participants SHS ID and Family ID across the top.

Chest Pail on Effort

1. Inquire if the participant has ever had pain or discomfort in their chest. If “no” skip to question 10.

2. Inquire if the participant gets chest pain or discomfort when they walk uphill, upstairs or when they hurry. If “no” or “unable to walk” skip to question 9.

3. Ask if the participant gets chest pain or discomfort when walking at an ordinary pace on level ground.

4. Ask the participant what they do if they get chest pain or discomfort while walking. If they answer “carry on” skip to question 9.

5. Ask what happens if they stand still. If they answer “not relieved” skip to question 9.

6. Ask how soon they feel relief if they stand still. If they answer “More than 10 minutes” skip to question 9.

7. Ask the participant to use the diagram to indicate all areas where they feel the pain.

8. Ask if they feel the pain anywhere else. If “yes” be sure to record the additional information and location.

Possible Infarction

9. Ask the participant if they have every had a server pain across the front of their chest lasting for half an hour or more?

Intermittent Claudication

10. Ask the participant if they get pain in either leg on walking. If "no" or "unable to walk" skip to question 19.

11. Ask the participant if this pain ever begins when they are standing still or sitting. If "yes" skip to question 19.

12. If "no", ask the participant to indicate what in part of the leg they feel the pain.
    a. If calves of legs are not mentioned, ask if they feel the pain "anywhere else"? Be sure to be specific and write in location on line provided.

13. Ask if the participant feels the pain when they walk uphill or hurry. If "no" skip to question 19.

14. Ask if the participant feels the pain if they walk at an ordinary pace on the level.

15. Ask if the pain disappears when walking. If "yes" skip to question 19.

16. Ask the participant what they do if they get the pain when walking. If "carry on" skip to question 19.

17. Ask what happens if they stand still. If "carry on" skip to question 19.

18. Ask how soon the pain is relieved?

ADMINISTRATIVE INFORMATION

19. Write in your interviewer code

20. Write in the date of the interview.

Perceived Stress Scale

Refer to SHS Psychological Questionnaire Manual of Operations (Volume V) for more information.

Quality of Life

Enter the participants SHS ID and Family ID across the top. Indicate how the questionnaire was administered.

Explain that the next set of questions ask about how the participant feels about their own health.

1. Ask the participant to indicate in general how they would say that their health is? The participant should choose only one answer.

The next questions are about activities that the participant might do during a typical day.

2-3. Ask if their health now limits them in the following activities and if so how much? As you read question 2 and question 3, be sure to read the options in full for each question. The participant should only mark one response.

4-5. The next questions are about problems that the participant might have had over the PAST 4 WEEKS as a result of their PHYSICAL HEALTH. Be sure to read each question in full and have the participant indicate only one response per question.

6-7. The next questions are about problems the participant might have had over the PAST 4 WEEKS with their work or regular activities as a result of any EMOTIONAL PROBLEMS such as feeling depressed or anxious. Be sure to read each question in full and have the participant indicate only one response per question.

8. Ask the participant how much pain has interfered with their normal work - both work outside the home and housework during the PAST 4 WEEKS.

9-11. These questions are about how the participant has been feeling and how things have been with them during the PAST 4 WEEKS. Be sure to read each question in its entirety and read all of the choices for every question. Have the participant to give only one response for each question.

12. Ask the participant how much of the time in the PAST 4 WEEKS has their PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with their social activities (like visiting friends, relatives, etc.) Have the participant to give only one response for each question.

ADMINISTRATIVE INFORMATION

13. Write in the interviewer code.

14. Write in the interview date.

Refer to SHS Psychological Questionnaire Manual of Operations (Volume V) for more information.

CES-D SCALE

Enter the participants SHS ID and Family ID across the top. Indicate how the questionnaire was administered.

1-12. These questions are about the participants feelings during the PAST WEEK. Read each question and all response options in their entirety for every question. Ask the participant to only mark one answer for each question.

13-20. These questions are also about how the participant felt during the PAST WEEK Read each question and all response options in their entirety for every question. Ask the participant to only mark one answer for each question.

21. Ask the participant if they have felt depressed or sad during the PAST YEAR. Read all of the options and ask the participant to mark only one.

ADMINISTRATIVE INFORMATION

22. Enter the interviewer code.

23. Enter the interview date.

Refer to SHS Psychological Questionnaire Manual of Operations (Volume V) for more information.

MHLC Scale

Refer to SHS Psychological Questionnaire Manual of Operations (Volume V) for more information.

Other Questions About Your Life

Enter the participants SHS ID and Family ID across the top. Indicate how the questionnaire was administered.

Posttraumatic Stress Disorder (PTSD)
Explain to the participant that the following questions are about frightening events that might have occurred during their lives that might have impacted their health. Read the explanation to them in full and give them the option to not answer the questions if they chose not to. It is good to have a resource sheet available to give the participant in the event that in reviewing the experience brings up or reminds them of that event.

1. Ask if the participant has ever had a frightening, traumatic or horrible experience. Read the question to the participant in full. If "no", skip to question 7.

If yes – answer yes or no to the following questions about the past month

2. Ask if the participant relived the traumatic experience through recurrent dreams, preoccupation or flashbacks.

3. Ask if the participant has seemed less interested than usual in important things, felt out of it or had a hard time with their feelings or emotions in the past month.

4. Ask the participant if they have had problems with sleeping, concentrating or with having a short temper in the past month.

5. Ask the participant if in the past month they have avoided places or reminders of the original horrible event.

6. Ask the participant if they have had some of the above problems for more than one month.

Inclusion of Community in the Self (ICS) Scale

7. Ask the participant to circle the one picture (1 through 6) that best describes the participants relationship with the community. The red Y represents the participant and the blue C represents the community at large.

Administrative Information

8. Enter the interviewer code.

9. Enter the interview date.

Refer to SHS Psychological Questionnaire Manual of Operations (Volume V) for more information.

Food Assistance and Food Security

Enter the participants SHS ID and Family ID across the top. Indicate how the questionnaire was administered.

1. Ask the participant to indicate if they or members of their household participated in any food services in the past 12 months. Select all services that were used.

2. This question asks about how affording food if the food didn't last for the last 12 months. Be sure to read the question in full and have the participant indicate only one response.

3. This question asked about affording balanced meals in the last 12 months. Be sure to read the question in full and have the participant indicate only one response.

4. This question asks about cutting the size or skipping meals in the last 12 months. Be sure to read the question in full and have the participant indicate only one response. If No, skip to question 5. If "yes"
   a. Indicate how often this occurred

5. This question asks about eating less than you felt because there wasn't enough money for food. Be sure to read the question in full.

6. This question asks about being hungry because there wasn't enough money for food. Be sure to read the question in full.

Administrative Information

7. Enter interviewer code

8. Enter interview date.

Appendix 4 Checklists and Sample Letters

THE STRONG HEART STUDY VII
Post Exam Activities Checklists

Same Day:

Process blood specimens
Review morbidity (chart review at clinic site)
Review and correct for missing data
Referral(s) review

Later:

Make routine referrals to medical providers if participant indicate preference to do so
Mail referral and result letters to participants
Mail laboratory specimens

THE STRONG HEART STUDY VII
Clinical Examination – Checklist
(Site specific)

Participant's name: _____

ID Number: _____ Date: _____
month day yr.

	Items	If done, date and initial	
1.	Screening for COVID/pregnancy	_____	_____
2.	Consent, HIPAA ROIs form signed	_____	_____
3.	Sample collection Checklist (circle if QC)	_____	_____
4.	Physical exam form (circle if QC)	_____	_____
5.	Personal interview forms I and II	_____	_____
6.	Medical history form	_____	_____
7.	Medication reception form	_____	_____
8.	Reproduction and hormone use (women)	_____	_____
9.	Rose questionnaire	_____	_____
10.	Perceived Stress	_____	_____
11.	Quality of Life (SF-12)	_____	_____
12.	CES-D Scale	_____	_____
13.	Montreal Cognitive Assessment	_____	_____
14.	Multidimensional Health Locus of Control	_____	_____
15.	Other Questions About Your Life	_____	_____
16.	Food Assistance and Food Security	_____	_____

17. 14 – Item Resilience scale _____ _____
18. Multidimensional and Interpersonal Resilience _____ _____
19. Multigroup Ethnic Identify Scale _____ _____
20. Orthogonal Cultural Identity Scale _____ _____
21. Rosenberg Self-Esteem Scale _____ _____
22. Social Support and Social Undermining _____ _____
23. Social Network Index _____ _____
24. Functional Activities Questionnaire _____ _____
25. NIH Toolbox _____ _____
26. Bristol Stool Chart _____ _____
27. CBC Results _____ _____
28. Food and Activity Questionnaire (FFQ) _____ _____
29. Copies of consent and HIPAA forms to participant _____ _____
30. Payment or payment form _____ _____
31. review of referrals and participant preference

Referral type	Review with participant	Sent to provider/yes/no/

THE STRONG HEART STUDY VII
Checklist for Blood Pressure

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed ____/____/____ **(Month/Day/Year)**

YES ( ) NO ( ) Provide subject instruction, allowing opportunity for questions.
YES ( ) NO ( ) Measure right arm for correct cuff size.
YES ( ) NO ( ) Palpate brachial artery, medial to and above antecubital fossa.
YES ( ) NO ( ) Mark pulse point.
YES ( ) NO ( ) Place cuff correctly.
YES ( ) NO ( ) Leave subject for 5 minutes rest.
YES ( ) NO ( ) Subject positioned correctly.
YES ( ) NO ( ) Provide environment free of excessive noise.
YES ( ) NO ( ) Finds pulse obliteration point.
YES ( ) NO ( ) Calculate peak inflation.
YES ( ) NO ( ) Place stethoscope in ears.
YES ( ) NO ( ) Inflate cuff rapidly to calculated peak.
YES ( ) NO ( ) Hold pressure steady for full 5 seconds.
YES ( ) NO ( ) Place bell on brachial pulse
YES ( ) NO ( ) Deflate cuff slowly, 2 mm per second.
YES ( ) NO ( ) Deflate cuff rapidly after 2 absent sounds.
YES ( ) NO ( ) Record readings.
YES ( ) NO ( ) Disconnect tubes.
YES ( ) NO ( ) Instructs subject to hold right arm vertical for full five seconds.
YES ( ) NO ( ) Wait at least 30 seconds before proceeding to 2nd and 3rd readings.
YES ( ) NO ( ) Average 2nd and 3rd readings, informs subject of average BP.

Comments**:** _____

_____

_____

_____

THE STRONG HEART STUDY VII
Quality Control

Aneroid Sphygmomanometers Checklist

DATE	INIT.	SPHYGMO MANOMETER Write the number of the equipment	LEVEL IS AT ZERO WITH NO PRESSURE	CHECK FOR AIR LEAKS WITH PRESSURE AT 200 mmHg	CHECK CAP FOR TIGHTNESS	COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.

THE STRONG HEART STUDY VII
Quality Control

Scale Checklist

MONTH	DATE/ YEAR	INIT.	PORTABLE SCALE	CALIBRATED WEIGHTS
JAN				
FEB				
MAR				
APR				
MAY				
JUN				
JUL				
AUG				
SEP				
OCT				
NOV				
DEC				

QUALITY ASSURANCE: MONTHLY TAPE MEASURE QUALITY CONTROL LOG

Each month tape measures will be calibrated against the stadiometer to check for signs of wear and stretching. One person will hold the zero mark of the tape against the height ruler at the 5 feet (60 inch) level. The second person will flatten the tape against the height ruler without stretching, and record the stadiometer heights that correspond to the 12-inch and 42-inch marks on the tape measure (to the nearest 0.25 inch). If the measurers fall outside the 3' 11 ¾" - 4' ¼" (47 ¾" – 48 ¼") or 1' 5 ¾" – 1' 6 ¼" (17 ¾" - 18 ¼") ranges respectively, the tape is replaced.

Tape Measure Quality Control Log

Date	Initials	Tape	Stadiometer Measure (inches)	Acceptable Range (Y/N)
			Tape 12": _____ Tape 42": _____	
			Tape 12": _____ Tape 42": _____	
			Tape 12": _____ Tape 42": _____	
			Tape 12": _____ Tape 42": _____	
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			Tape 12": _____ Tape 42": _____	
			Tape 12": _____ Tape 42": _____	

Mercury Sphygmomanometers Checklist
(only for use in calibrating aneroid equipment)

DATE	INIT	SPHYGMO MANOMETER Write the number of the equipment	LEVEL IS AT ZERO WITH NO PRESSURE	CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHg	CHECK CAP FOR TIGHT NESS	CHECK TUBE FOR OXIDE DUST	COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.

THE STRONG HEART STUDY VII
Simultaneous Blood Pressure Observation Form

Quarterly, each technician should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to this form and should calculate the differences between the two sets of measurements. The acceptable margin of error is 4 mm for each individual measurement and 3 mm for the average of the three readings.

Technician #1 Code # / Initials _____

Technician #2 Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

	Tech #1	**Tech #2**	**Difference**
Arm circumference	_____	_____	_____
Cuff size	_____	_____	_____
Pulse obliteration pressure	_____	_____	_____
SBP #1	_____	_____	_____
DBP #1	_____	_____	_____
SBP #2	_____	_____	_____
DBP #2	_____	_____	_____
SBP #3	_____	_____	_____
DBP #3	_____	_____	_____
Average SBP	_____	_____	_____
Average DBP	_____	_____	_____

Comments**:** _____

_____

Testing Accuracy Aneroid Sphygmomanometer

You will need a Baumanometer instrument (mercury-gravity standard) and a "Y" connector with an inflation bulb and valve attached. Connect the Baumanometer instrument and the other instrument to be tested as shown below. Cuffs and bags are not used in this test.

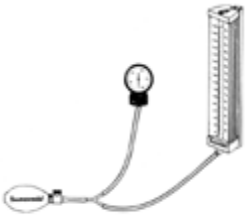


Diagram of a Wall Unit 33 connected to an aneroid with a "Y" connector

The Pressure Standard

A Baumanometer® instrument is to be used as the pressure standard if:

- The mercury meniscus is at zero with no pressure applied to the instrument.
- The instrument is in a vertical position.
- The instrument responds promptly to pressure changes. Any two Baumanometer® instruments, regardless of age, will provide accurate, linear pressure readings at every pressure level if they meet the stated criteria for a correctly functioning manometer.

Test Procedure

Check each instrument to be sure that it is at zero. Slowly inflate the instruments to 250 mm Hg and compare the readings. They should be the same, however, a deviation of ± 3 mm Hg is acceptable. Repeat this procedure at 200 mm Hg, 150 mm Hg, 100 mm Hg, 50 mm Hg, 10 mm Hg and 0 mm Hg. If the deviation is greater than ± 3 mm Hg at any of these points, the instrument being tested is inaccurate and needs adjustment or repair.

Test Kit (2941) needed for testing instrument accuracy

THE STRONG HEART STUDY VII
Sample Letter to Participant after Physical Examination.

Results entered into the SHS Redcap physical exam form will populate the participant letter. The following are responses and referral guidelines that will inform participants of their SHS screening results.

Dear "_____":

Thank you very much for taking part in the Strong Heart Study today.

Blood Pressure

When your blood pressure is too high, it causes extra "wear and tear" on your heart and blood vessels. Over the years this can lead to hardening of the arteries and then stroke, heart attacks and kidney damage. Doctors have known for many years now that properly controlling blood pressure helps to prevent these medical problems.

Strong Heart Study Phase VII
Blood Pressure Referral Guidelines

Blood Pressure Measurements	Referral Guidelines
SBP ≥ 200 mm or DBP ≥ 120 mm	**Emergency Referral**: "Your BP is extremely high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) immediately, or accompany participant to acute care setting for MD evaluation before continuing examination.
SBP 180-199 mm or DBP 110-119 mm	Ask Additional Questions*:* 1) Do you have a severe headache? 2) Do you have chest pain or pressure? 3) Are you short of breath? 4) Do you have a new problem with your vision? If "Yes" to ANY of the Additional Questions - **Emergency Referral** "Your BP is extremely high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) immediately, or accompany participant to acute care setting for MD evaluation before continuing examination. If "No" to ALL of the Additional Questions - Ask if participant has had any previous treatment for hypertension. If "No" to previous treatment for hypertension - **Immediate Referral**: "Your BP is very high, which can put you at risk now for serious complications." Have participant consult with physician (M.D.) on the same day, to obtain treatment for hypertension. If "Yes" to previous treatment for hypertension - **Immediate Referral**: "Your BP is very high. This means it is not in control. If you have used hypertension medications, you should restart them now to avoid serious complications." Have participant restart their medication the same day, and consult with physician (M.D.) within 2-3 days to see whether medication is working.

SBP 160-179 mm or DBP 100-109 mm	Ask if participant has had previous treatment or medication for hypertension. If "No" to previous treatment for hypertension - **Urgent Referral**: "Your BP is very high. This means it not in control and may require treatment to avoid serious complications." Have participant consult with physician (M.D.) within 1 week to confirm hypertension and decide need for treatment. If "Yes" to previous treatment for hypertension - **Urgent Referral**: "Your BP is very high. This means it not in control. If you have used hypertension medications, you should restart them now to avoid serious complications." Have participant restart their medication the same day, and consult with physician (M.D.) within 1 week to see whether medication is working.
SBP 140-159 mm or DBP 90-100 mm	**Routine Referral**: "Your BP is not well controlled and may need additional treatment if it remains abnormal." Suggest participant consult with physician (M.D.) within next 1-4 weeks.
SBP 130-139 mm or DBP 80-89 mm	Ask if participant has been diagnosed with diabetes, increased CVD risk or chronic kidney disease. If "Yes" to diagnosed diabetes or chronic kidney disease - **Routine Referral**: "Your BP is not well controlled for someone with [diabetes / kidney disease] and may need additional treatment if it remains abnormal." Suggest participant consult with physician (M.D.) within next 1-4 weeks. If "No" to diagnosed diabetes or chronic kidney disease - **Routine Referral**: "Your BP is in a range that puts you at risk for hypertension. There may be things you can do to bring it into a better range." Suggest participant consult with physician (M.D.) within next month.

Body Weight and "Body Mass Index" or "BMI"

We have measured your body weight and height. We have done a calculation from these two numbers that give us another number called the "BMI". This can be compared to the BMI of other people and gives you information about your health risk from obesity.

"Your BMI was_____(less than 25), which is considered normal. We hope you will continue to balance your diet and exercise to maintain this healthy level."

"Your BMI was_____(more than 25 but less than 30), which is higher than normal. We suggest that you think carefully about ways that you can reduce the foods that have a lot of calories and increase the amount of exercise that you do each day. If you want help with planning these changes, we can assist you with literature or a referral to a nutrition specialist".

"Your BMI was_____(more than 30), which is definitely higher than normal. We suggest that you let us help you make an appointment to see a dietician who can advise you about ways to change you eating habits. We would also suggest that you discuss with your medical provider ways to increase your exercise."

Smoking

One of the areas that we have asked some questions about today is smoking. While occasionally smoking tobacco as a religious practice probably causes no harm; smoking cigarettes or using other tobacco as a daily habit carries many health risks. Most people think of the risk of lung and other cancers, which is very important; but actually, the risk of death and illness from heart disease is a much greater risk from smoking. If you currently smoke, or are around people who do smoke, we would like to tell you about some methods that could help you or encourage others to quit.

We hope this information has been helpful. There will be results from your blood tests, coming back in the next days and weeks. You will be contacted and advised if these tests are normal or abnormal. If there are problems with your results, we will tell you how to get help from your medical providers to take care of your health.

In the meantime, remember these 8 important ways to keep your heart healthy:

1. Eat sensibly – (add fruits and vegetables to your diet), keep your weight normal, watch the amount of fat in your diet (avoid processed foods)
2. Exercise sensibly and regularly
3. Know that your blood pressure is normal, or work with your provider to control it
4. Know that your blood sugar is normal, or work to control it
5. If you use tobacco as a habit, please stop
6. Abstain from alcohol, or drink in moderation with only one or two drinks per day
7. See your medical provider for routine medical checks and do not wait until there is a problem. Be proactive and be sure that if you are prescribed medications to take them as directed.
8. Try to get the rest and relaxation that you need, and enjoy every day!

We look forward to working with you to learn more about your health.

Sincerely,

The Strong Heart Staff

THE STRONG HEART STUDY VII
Sample Letter to be for Emergent, Immediate, and Urgent Referrals

Date: _____

Dear Clinic staff and Strong Heart Study participant_____(name),

Normally we would have contacted you in person about this problem; but we were just not able to reach you, and so have needed to send this in the mail. If we had been able to talk with you in person, there would have been other details we would have told you about; we hope you will bring this with you to your clinic so they will be able to help you better.

If you would like help making an appointment with your clinic, please contact us at the SHS office in **[Eagle Butte at 605-964-1260, or Pine Ridge at 605-455-1395].** If this problem involves a specific test, we can get copies of the actual results for your clinic to use or send to their consultants, if they wish. Please remember that research results **cannot be** substituted for seeing your medical provider.

We are suggesting that you contact your regular medical care provider because of the following abnormalities that we have found during your testing:

_____

_____

_____

_____

We think it is best for you to talk with your doctor or clinic about this problem:
right now, or within the next: 24 hours week.

Thank you again for participating in the Strong Heart Study, and we hope that this information has helped you and your doctors improve your health.

Sincerely,

Amanda Fretts, PhD, PI,
Lyle Best, MD
Marcia O'Leary, RN
605-964-1260

THE STRONG HEART STUDY VII
Sample Letter to Participant Concerning Test Results for Normal Results or Routine Referrals Following the Return of Lab Results

Participants Name
Participant Address

Dear [participant name]

Thank you for participating in the Strong Heart Study on [insert date]. The results of your blood tests from your visit are now available. This letter summarizes this medical information.

Blood Sugar (Glucose) Test:
Blood sugar is a measure of the amount of glucose in your blood, and is used to identify conditions such as diabetes or pre-diabetes. If you are already known to have diabetes, then your blood sugar can help to decide if your diet and medications are in an effective range. Your blood sugar will depend on whether you were fasting (had not eaten for 12 hours) at the time of your blood draw and can be higher after you eat.
Your blood glucose was:_____ mg/dL

- □ This is within the desirable range
- □ This is higher than expected. This may be because you had recently eaten before your blood draw, or because you have high blood sugar. We advise you to share this information with your medical provider.

Hemoglobin A1C Test:
Hemoglobin A1C is a measure of the average amount of extra glucose in your blood over the past 3 months, and is used to identify conditions such as diabetes or pre-diabetes. If you are already known to have diabetes, then your Hemoglobin A1C can help to decide if your diet and medications are in an effective range. Unlike your blood glucose, your Hemoglobin A1C does not change with food intake before your blood draw
Your Hemoglobin A1C was: _____%

- □ This is within the desirable range
- □ This is higher than expected. This may be because you have known diabetes or pre-diabetes or that your diet and medications may need to be adjusted. We advise you to share this information with your medical provider.

Total Cholesterol:
This is a fatty substance in your blood that may clog arteries if it is too high. In people with very low risk for CVD, it is best to have your cholesterol below 200 mg/dl. In most cases, physicians will help you make most treatment decisions based on LDL-cholesterol, instead of total cholesterol. Ways to reduce your total cholesterol may include eating less animal and dairy fats or increasing your physical activity.

Your total cholesterol was: _____mg/dl

- □ This is within the desirable range, and we encourage you to maintain a healthy diet and stay active.
- □ This is above the desirable range. We advise you to have your cholesterol checked again within 3-6 months.

LDL Cholesterol:
This is the "bad" cholesterol. It is best for most people to have LDL cholesterol below 100 mg/dl, but there are benefits to much lower levels in people with high risk of CVD due to other risk factors or family history. Ways to reduce your LDL cholesterol may include eating less animal and dairy fats, increasing your physical activity, or medications.

Your LDL cholesterol was: _____mg/dl

- □ This is within the desirable range for low-risk people, but it may not be right for you. This will depend on your own medical history and other risk factors so we encourage you to discuss this with your healthcare provider and also to maintain a healthy diet and stay active so that your cholesterol stays low.
- □ This is above the desirable range for low-risk people. We advise you to have your cholesterol checked again within 3-6 months and discuss treatment with your healthcare provider

HDL Cholesterol:
This is the "good" form of cholesterol. It is best to have HDL cholesterol above 40 mg/dl for men and above 50 above for women. Ways to increase your HDL cholesterol may include eating more fish, increasing your physical activity, or medications.

Your HDL cholesterol was: _____ mg/dl

- □ This is within the desirable range, and we encourage you to maintain a healthy diet and stay active.
- □ This is below the desirable range. We advise you to have your cholesterol checked again within 3-6 months.

Triglycerides:
This is a type of fat in your blood that may cause problems in the pancreas if it is too high. It is best to have triglycerides below 150 mg/dl. Ways to reduce your triglycerides may include improving control of your blood sugar (if you are diabetic) and avoiding alcohol.
Your blood triglycerides were:_____ mg/dl

- □ This is within the desirable range.
- □ This is above the desirable range. We advise you to have your triglycerides checked again in 3-6 months.

Urine Albumin to Creatinine Ratio:
The urine albumin-to-creatinine ratio (UACR) test is used to screen for kidney problems. It is best to have levels less than 30 mg/g.
Your urine albumin to creatinine ratio was: mg/g creatinine

- □ This is within the desirable range.
- □ This is above the desirable range. We advise you share this number with your medical provider, and ask for a referral to a nephrologist (kidney specialist)

We thank you again for participating in the Strong Heart Study. Please call the local Strong Heart Study staff at [site staff phone number if you have any questions about these study results.

Sincerely,

[Site staff name]

**If we have suggested that you see your medical provider in the coming week or sooner, we will have also tried to reach you by phone. We would like to help you make arrangements for an appointment or for a ride to the clinic, if that is needed.

If you have any questions about these results, contact your health care provider or the staff at the SHS office in **[Field site information]**. The attached sheet describes the purpose of each test.

Thank you for your participation in the Strong Heart Study and for helping us learn more about heart disease and strokes in Indian people.

****If participant requests results to not be sent to their health care provider - substitute the following for the first paragraph above:**

"Honoring your request as stated in your consent form, the attached lab results were not sent to the IHS or any other medical facility or healthcare provider. It may be in your best interest for you to show your healthcare provider these results during your next visit."

THE STRONG HEART STUDY VII
Infection Control Policy

COVID-19 Prevention Guidelines for In-person Contact with Participants

1. In-person Contact with Participant Who Had Positive COVID-19 Test (SYMPTOMATIC):
   a. Mild to moderate illness – Those whose symptoms do not persist past 10 days.
      i. At least 10 days have passed since symptoms first appeared AND
      ii. At least 24 hours have passed since last fever without the use of fever-reducing medications AND
      iii. Symptoms (e.g. cough, shortness of breath) have improved, as reported by the employee
      iv. Must wear a mask provided by the facility during the visit.
   b. Severe to critical illness – Those with severe to critical illness and whose symptoms persisted past 10 days (including immunocompromised individuals):
      i. At least 10 days and up to 20 days have passed *since symptoms first appeared* AND
      ii. At least 24 hours have passed *since last* fever without the use of fever-reducing medications AND
      iii. Symptoms (e.g., cough, shortness of breath) have improved, as reported by the employee
      iv. Must wear a mask provided by the facility during the visit.

2. In-person Contact with Participant Who Had Positive COVID-19 Test (ASYMPTOMATIC)
   a. Those who are not severely immunocompromised and were asymptomatic throughout their COVID-19 infection may be seen when at least 10 days have passed since the date of their first positive viral diagnostic test. Must wear a mask provided by the facility during the visit.
   b. Those who are severely immunocompromised but who were asymptomatic throughout their infection may be seen when at least 10 days and up to 20 days have passed since the date of their first positive viral diagnostic test. Must wear a mask provided by the facility during the visit.

3. In-person Contact with Participant After They Had High Risk Activities
   a. Domestic and International Cruises AND/OR International Travel
      i. VACCINATED person that is ASYMPTOMATIC:
         1. No quarantine required.
         2. Must wear a mask provided by the facility during the visit.
      ii. UNVACCINATED persons that is ASYMPTOMATIC:
         1. No quarantine required if they have remained asymptomatic
         2. Self-monitor for symptoms.
         3. PCR testing required 5 days after return from travel.
         4. Self-quarantine for 10 days if participant did not get tested.
         5. Must wear a mask provided by the facility during the visit.

4. In-person Contact with Participant - High Risk Exposures
   a. VACCINATED person that is ASYMPTOMATIC
      i. No quarantine is required if they have remained asymptomatic.
      ii. Self-monitor for symptoms.
      iii. PCR testing required 3-5 days from date of high-risk exposure.
      iv. Self-quarantine for 10 days if participant did not get tested.
      v. Must wear a mask provided by the facility during the visit.
   b. UNVACCINATED person:
      i. Self-monitor for symptoms
      ii. Quarantine for five (5) days after exposure and PCR test 5 days from date of high-risk exposure.
      iii. Self-quarantine for 10 days if participant did not get tested.
      iv. Must wear a mask provided by the facility during the visit.

Refer to CDC guidelines for additional details: https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to- work.html

Facility/Patient Exam Room/Laboratory Safety:

1. Scheduling Clients: shared calendar/area to limit clients to (1) person (maximum 2 if client with special needs, children, etc) at a time within clinic facility
2. Designate Participants/Patient waiting area with Disinfect-able Area. Limit areas that participants are exposed to as much as possible. For example, if the participant is able to fill out paperwork, sign consents etc in their car, at home or outside, ask participant if they are comfortable doing so rather than coming into the facility.
3. Utilize Hepa filtration air exchange equipment during office hours.
4. Increase Cleaning and Disinfection Procedures – everyone is responsible to assist
5. Examine Patient Room areas for removal of unnecessary objects [cloth seats, rugs, unnecessary objects, un-cleanable artwork/posters/etc.,] and replace with items that can be disinfected and cleaned.
6. Addition of ventilation fans to patient rooms
7. Develop a checklist to wipe down patient rooms between clients
8. Clean equipment (blood pressure cuffs, weight, height, thermometer) between clients
9. Lab Procedures: Facemask, face shield, gown, etc.; disinfection between clients, UV light patient visits (10 to 20 minutes)
10. Counseling and extended length exams: whenever possible conduct interviews by phone or zoom, if client is not comfortable with these options, do interviews outside or utilize the outdoor facility either giving participant an iPad to zoom or with adequate space to insure CDC guidelines are achieved. Limit interaction to 10 minutes or less whenever possible (use time to set up zoom connection)
11. Develop outdoor Clients Areas: Table, chairs, tent and small outdoor building with disinfection procedures applied, ensure that Patient privacy/confidentiality maintained

Overall Staff Conduct:

1. Maintain 6 feet distance between self and others
2. Wear masks if in common areas or at any time indoors or outdoors with participants or other staff members.
3. Limit face to face time with both staff and participants to less than 10 minutes.
4. Call in sick if self or family members are not feeling well.
5. Work with supervisor to arrange for work from home when appropriate or set hours that are different from others work hours.

Human Immunodeficiency Virus (HIV) and Hepatitis B

INTRODUCTION
The virus that causes AIDS is a human retro virus that has been named HIV (human immuno-deficiency virus). The virus primarily infects cells of the T-lymphocyte system, but is also able to infect other cells such as macrophages and those of the central nervous system. The virus destroys the cellular immunity of infected people, leaving them susceptible to a variety of opportunistic diseases.

It has been established that the virus can be transmitted: (1) through sexual contact; (2) through parenteral exposure, including sharing needles and syringes when injecting illicit drugs, transfusion of blood or its components, and infusion of clotting factors concentrates; and (3) through perinatal exposure, probably both transplacental and intra-partum transmission and postpartum transmission.
To date, there is no evidence that the HIV virus can be transmitted by casual social contact, not even among people living in the same household. Recent reports by the CDC suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known.

Hepatitis B virus (HBV) is transmitted in ways similar to HIV.

PURPOSE:

To stress the importance of following recommended precautions to prevent exposure to the AIDS and HBV virus.

PREVENTION:

1. Before initiating work, all bench areas should be cleaned and sanitized daily with an appropriate disinfectant.

2. All laboratory specimens should be treated as if they were contaminated with either HIV or HBV. Any specimens specifically taken from known AIDS or hepatitis patients should be clearly marked as requiring isolation and transported in a leak proof container.

3. Specimens leaking from their containers should be discarded after requesting a replacement. In those cases, in which the specimen is not replaceable, the outside of the soiled container should be disinfected with either a 1: 10 sodium hypochlorite solution (household bleach) or Lysol spray and left standing for at least ten minutes before performing any laboratory procedures).

4. Every laboratorian should wear gloves and be dressed in a laboratory gown or uniform when handling and processing specimens. This will minimize the risk of contamination to exposed body parts or street clothing. Gloves should be worn and disposed of in accordance with the "Gloves (Proper Use and Disposal)" policy. Hands and other skin surfaces should be washed thoroughly and immediately after coming into contact with blood or body fluids.

5. Wear masks, gowns (or aprons), and goggles (or glasses) when there is a possibility that blood or body fluids may splash or splatter on you.

6. All laboratory specimens that must be manipulated before processing (i.e., body fluids to be diluted, caps on tubes of blood to be opened, specimens to be split or transferred, etc.) should be handled cautiously.

7. Centrifuge carriages should be sanitized daily (or after each use if possible HBVs or AIDS specimen is being centrifuged) with a germicide. After weekly use, centrifuge interiors should be sprayed with an appropriate disinfectant.

8. To prevent needle stick injuries, needles should never be recapped, separated from syringes, or otherwise manipulated. Instead, used needles should be placed intact into puncture-resistant containers. The same criteria should be applied to used scalpel blades and any other sharp device that may be contaminated by a patient.

9. To prevent transmission of HIV or HBV, the platform on the finger prick device (Autoclik, etc.) should be changed between patients.

10. Reusable devices, such as tissue grinders, pipettes, etc, should be placed into vesicles containing an appropriate germicide prior to being autoclaved and cleaned.

11. Mouth pipetting of blood or serum or plasma is forbidden for any clinical laboratory procedure. Mechanical pipetting devices are available and must be routinely used.

12. All laboratory specimens and disposables should be discarded in biohazard 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 handle blood should receive three dose of hepatitis B vaccine.

REFERENCES:

Tiemo, PM: Preventing Acquisition of Human Immunodeficiency Virus in the Laboratory: Safe Handling of AIDS Specimens. Laboratory Medicine 1986; 11: 696-698.

Standard Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture. National Committee for Clinical Laboratory Standards March 1980.

So, you're Going to Collect a Blood Specimen. College of American Pathologists, 1980. Rose SL: Clinical Laboratory Safety Philadelphia, J.B. Lippincott Company, 1984

Appendix 5 HIPAA Authorization Form

STRONG HEART STUDY
HIPAA AUTHORIZATION FORM

A. Purpose of this form:

The purpose of this form is to give permission to the research team to obtain and use your patient information for the Strong Heart Study and funded ancillary studies.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

By signing this form, you also allow the research team to use and disclose your (PHI) for the purpose of the research study named above, and the future add-on studies in which you may choose to participate, including:

- The Epitranscriptome as a Novel Mechanism of Arsenic-Induced Diabetes
- Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study
- Gut microbiome and cardiometabolic health in American Indians
- Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study

B. The patient information that will be obtained and used:

"Patient information" means the health information in your medical or other healthcare records, including information about laboratory and diagnostic tests, physical examinations, and medical history. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, social security number, and medical record number.

To provide the best research results, it is necessary to share some of your personal health information with researchers working with the Strong Heart Study. **Your name, address and social security number will only be used when it is absolutely necessary.** Otherwise, we will label your samples and the information about you with a number, not your name. For instance, sometimes it is necessary to send samples of your blood, DNA or urine to other laboratories (sometimes in other countries) for special testing. When this is done, **your sample is only identified by a number.** The laboratories sign written agreements to do only tests approved by the Strong Heart Study, and to return any left-over samples to the Strong Heart Study.

C. How your patient information will be used:

1. Who may receive your patient information:
    - Strong Heart Study investigators and their research institutions
    - Missouri Breaks Industries Research, Inc.
    - National Institutes of Health (sponsor of this research) and other Department of Health and Human Services (DHHS) agencies
    - U.S. Food and Drug Administration (FDA)
    - Great Plains Indian Health Services Institutional Review Board (GPIRB)
    - Other research regulatory agencies in the USA or abroad

Other researchers who may use your information for future research studies (with approval from the Strong Heart Study and GPIRB).

2. Why your patient information will be used and/or given to others:
    - To do the research
    - To study the results, and
    - To see if the research was done right

If the results of this study are made public, information that identifies you will not be used. The Strong Heart Study will use your patient information only in the ways that are described in the research consent form that you sign and as described in this HIPAA Authorization.

Federal and state laws require the research team to protect the privacy of your records. However, absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. The privacy laws do not always require the receiver of your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission.

You can ask questions about what the research team will do with your information and how they will protect it. If you would like to know how the (GPIRB) will protect the privacy of your records, you can contact the GPIRB toll-free at 866-331-5794.

You have the right to request and obtain your patient information related to this study by contacting the Strong Heart Study at 1-866-865-3418.

D. Expiration
None

E. Canceling your permission
You may change your mind at any time. To take back your permission, you must send your **written** request to:

Missouri Breaks Industries Research, Inc.
Attn: Strong Heart Study
118 S Willow St.
Eagle Butte, SD 57625

Please call 1-866-865-3418 for more information. If you take back your permission, the Strong Heart Study will no longer use or disclose your records.

AUTHORIZATION

I authorize the release of my medical records and health information related to this study, including my signed consent form and this document to the sponsor and its representatives, the FDA, the GPIRB and other regulatory agencies as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I understand that I will receive a signed copy of this authorization for my records.

Printed Name of Participant_____

Signature of Participant_____

I certify that under state law I am the legally authorized representative of the Participant named above and that I am authorized to sign this form to release the Participant's medical records and health information as described above.

Printed Name of Legal Representative_____

Signature of Legal Representative_____

Date_____

Appendix 6 SHS Phase VII Exam Forms

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SCREENING FOR COVID-19 AND PREGNANCY

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

Screening for COVID-19 (Field staff should refer to SHS MOOP Vol 3 for guidelines for in-person contact with participants)

1. Are you currently experiencing, or have you experienced in the past 10 days, any of the following symptoms? (***Please take your temperature before you answer this question.)***

   Yes ☐ N o ☐ Fever (100.4° F or greater)

   Yes ☐ No ☐ Cough

   Yes ☐ N o ☐ Shortness of breath or difficulty breathing

   Yes ☐ N o ☐ Sore throat

   Yes ☐ No ☐ New loss of taste or smell

   Yes ☐ No ☐ Chills

   Yes ☐ N o ☐ Head or muscle aches

   Yes ☐ No ☐ Nausea, diarrhea, vomiting

2. In the past 10 days, have you been in close proximity to anyone who was experiencing any of the above symptoms or has experienced any of the above symptoms since your contact?

   Yes ☐ No☐ Not sure/I don't know☐

3. In the past 10 days, have you been in close proximity to anyone who has tested positive for COVID-19?

   Yes ☐ No☐ Not sure/I don't know☐

4. Have you been tested for COVID-19 and are waiting to receive test results?

   Yes ☐ No☐

5. Have you have tested positive for COVID-19, or are you presumptively positive for COVID-19 based on your health care provider's assessment or your symptoms?

   Yes ☐ No☐

Screening for Pregnancy:

6. Are you Currently Pregnant? Yes |___| No |___| (If Yes, field staff should schedule participant's visit six weeks postpartum)

6a. Please specify six-week postpartum visit date for participant

|___|___|/|___|___|/|___|___|___|___|
month day year

Recruitment Tracking

The following questions will be used to track and document the status of the attempt to recruit SHS participants for Phase 7 exam. These questions are not to be asked to the participant. They should be filled using the best judgement of the SHS field staff who screened the participant.

7. Has the participant completed screening?

Yes ☐ No ☐ (if Yes, proceed to **Q10**)

8a. Reason for refusal to participate in SHS Phase 7 visit (please select the most appropriate reason):

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

9. Any additional comments:

_____

_____

10. Does the participant want to participate in the following ancillary or sub-studies:

a. Resilience, Cultural Alignment, and Social Support in Brain Aging (PI: Astrid Suchy-Dicey) Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

b. Psychological Risk Factors, Quality of life, Community and Brain Aging in American Indians (PI: Astrid Suchy-Dicey)

Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

c. Gut Microbiome, Aging and Cardiometabolic Disease in American Indians (PI: Jinying Zhao)

Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

d. The Epitranscriptome as Novel Mechanism of Arsenic Induced Diabetes (PI: Ana Navas-Acien)

Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9

Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

e. Health Effects of Metals in Native American Communities: A Longitudinal Multi-Omics Study (PI: Ana Navas-Acien) Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

f. Chronic Respiratory Diseases in American Indians (OK site only) (PI: Huimin Wu)
Yes ☐ No ☐

If No, please indicate the most appropriate reason why the participant does not want to participate in this ancillary or sub-study:

Too busy	|___| 1
Exam too long / requires too much time	|___| 2
Not interested / doesn't want to	|___| 3
Fearful of study procedure	|___| 4
Family responsibilities / caring for relative	|___| 5
Too ill / too old / disabled	|___| 6
Hearing impaired	|___| 7
Cognitively impaired	|___| 8
Out of area	|___| 9
Incarcerated/ In prison	|___| 10
Cannot reach / lost to follow-up	|___| 11
Other (please specify)	_____

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SAMPLE COLLECTION CHECKLIST

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

1. 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

2. When was the last time you ate? *(use military time)* |___|___|:|___|___|

3. Time of collection of fasting samples. *(use military time)* |___|___|:|___|___|

4. Is urine sample taken? Yes |___| 1 ***(go to Q7)*** No |___| 2

5. If no, why?

   On dialysis ..... |___|1

   Cannot urinate ..... |___|2

   Other, specify: _____ |___|3

6. Time of collection of urine sample *(use military time)* |___|___|:|___|___|

7. Blood Samples/Urine Checklist. Check the box(es) if samples were collected.

Item	Purpose	Type	Check
a) Three 10 ml SST	Chem Profile Lipids, Insulin, CRP, FFA	Serum	|___|
b) One 4.5 ml Lt Blue	Fibrinogen	Plasma	|___|
c) One 4 ml Gray	Fasting glucose	Plasma	|___|
d) Three 10 ml Purple	HbA1c, Leptin, DNA	Whole blood/Plasma/ Buffy coat	|___|
e) One Purple (size site specific)	CBC	Whole blood	|___|
f) Two PAXgene	RNA	Whole blood	|___|
g) Urine (One cup)	Albumin/Creatinine	Urine	|___|

8. Is this participant also a volunteer for blood/urine QC? Yes |___|1 No |___|2 (***go to Q12)***

9. **QC ID (second digit is "3"):** |___|___|___|___|___|___|

10. QC samples checklist. Check the box(es) if samples were collected.

Item	Purpose	Type	Check
a) One 10 ml SST	Chem Profile Lipids, Insulin, CRP, FFA	Serum	|___|
b) One 4 ml Gray	Fasting glucose	Plasma	|___|
c) One 10 ml Purple	HbA1c/Leptin	Whole blood/Plasma	|___|
d) Urine (One cup)	Albumin/Creatinine	Urine	|___|

11. Instructions: We request that you abstain from using any tobacco or alcohol until you have finished your visit with us today. Additionally, please avoid consuming caffeinated beverages until after your lab samples have been collected and your blood measurements have been taken. These precautions are in placed to ensure that your test results are not influenced by use of these substances." If you did, when and what:

ADMINISTRATIVE INFORMATION:

12. SHS Code of person completing this form: |___|___|___|

13. Today's Date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PHYSICAL EXAMINATION

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

EXAMINATION OF EXTREMITIES FOR AMPUTATIONS

1. Are any extremities missing? Yes |___|1 No |___|2 ***(go to Q2)***

If "YES" to amputation, please code the cause of amputation:

1 = Diabetes
2 = Trauma
3 = Congenital
4 = Other, please specify
9 = Unknown

	Extremities	Check if Missing		Cause	If Other, please specify
a)	Right arm	|___|		|___|	_____
b)	Right hand	|___|		|___|	_____
c)	Right finger(s)	|___|	_____ # missing	|___|	_____
d)	Left arm	|___|		|___|	_____
e)	Left hand	|___|		|___|	_____
f)	Left finger(s)	|___|	_____ # missing	|___|	_____
g)	Right leg above knee	|___|		|___|	_____
h)	Right leg below knee	|___|		|___|	_____
i)	Right foot	|___|		|___|	_____
j)	Right toe(s)	|___|	_____ # missing	|___|	_____
k)	Left leg above knee	|___|		|___|	_____
l)	Left leg below knee	|___|		|___|	_____
m)	Left foot	|___|		|___|	_____
n)	Left toe(s)	|___|	_____ # missing	|___|	_____

BLOOD PRESSURE

2. Right arm circumference, measured in centimeters (cm) |___|___|___|
Midway between acromion and olecranon.

3. Cuff size (arm circumference in brackets)

Pediatric (under 24cm) |___|1
Regular arm (24 – 32cm) |___|2
Large arm (33 – 41cm) |___|3
Thigh (>41cm) |___|4

4. Pulse obliteration pressure |___|___|___|

5. Seated Blood Pressure:

	Systolic BP	***Diastolic BP***
a) **First** Blood Pressure Measurement	|___|___|___|	|___|___|___|
b) **Second** Blood Pressure Measurement	|___|___|___|	|___|___|___|
c) **Third** Blood Pressure Measurement	|___|___|___|	|___|___|___|

6. Were the above blood pressures taken from RIGHT arm?

Yes |___|1
No |___|2

Specify: _____

7. Recorder ID (For the SHS staff who took BP): |___|___|___|

ANTHROPOMETRIC MEASUREMENTS:
(Take off shoes and remove heavy objects from pockets.)

		METRIC SYSTEM (centimeters/kilograms)	***ENGLISH SYSTEM*** (inches/pounds)
8.	Height (Standing)	**|___|___|___|** centimeters	|___|___|___| inches
9.	Weight (Standing)	**|___|___|___|** kilograms	|___|___|___| pounds
10.	Hip circumference (Standing)	**|___|___|___|** centimeters	|___|___|___| inches
11.	Waist measurement at umbilicus (Supine) ...	**|___|___|___|** centimeters	|___|___|___| inches

PEDAL PULSES AND EDEMA

		PRESENT	ABSENT	MISSING LIMBS	UNABLE TO ASSESS
12.	Right posterior tibial pulse	|___|1	|___|2	|___|3	|___|9
13.	Right dorsalis pedis pulse	|___|1	|___|2	|___|3	|___|9
14.	Left posterior tibial pulse	|___|1	|___|2	|___|3	|___|9
15.	Left dorsalis pedis pulse	|___|1	|___|2	|___|3	|___|9

16. Pedal edema Absent |___|1 Mild |___|2 Marked |___|3

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 (over 250 mmHg).

			Right arm	Right ankle	Left ankle
17.	a)	First systolic B.P.	|___|___|___|	|___|___|___|	|___|___|___|
	b)	Second systolic B.P.	|___|___|___|	|___|___|___|	|___|___|___|
	c)	Location	Posterior tibial |___|1 Dorsalis pedis |___|2	Posterior tibial |___|1 Dorsalis pedis |___|2	

18. Was ECG completed? Yes |___|1 No |___|2

ADMINISTRATIVE INFORMATION

19. Examiner code: |___|___|___|

20. Examination date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PHYSICAL EXAMINATION – QC DUPLICATE MEASUREMENT

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

BLOOD PRESSURE:

1. Right arm circumference, measured in CENTIMETERS (cm) |___|___|___|
   Midway between acromion 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 |___|___|___| |___|___|___|

   b) Second Blood Pressure Measurement |___|___|___| |___|___|___|

   c) Third Blood Pressure Measurement |___|___|___| |___|___|___|

5. Were the above blood pressures taken from RIGHT arm? Yes |___|1 No |___|2

   a) If no, why? Amputation |___|1 Wound/dressing |___|2 Cast |___|3 Refusal |___|8

6. Recorder ID: |___|___|___|

ANTHROPOMETRIC MEASUREMENTS:

		METRIC SYSTEM (centimeters/kilograms)	***ENGLISH SYSTEM*** (inches/pounds)
7.	Weight (Standing)	|___|___|___| kilograms	|___|___|___| pounds
8.	Height (Standing).....	|___|___|___| centimeters	|___|___|___| inches
9.	Waist (Supine)	|___|___|___| centimeters	|___|___|___| inches
10.	Hip circumference (Standing).....	|___|___|___| centimeters	|___|___|___| inches

ADMINISTRATIVE INFORMATION:

11. Interviewer code: |___|___|___|

12. Interviewer date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PERSONAL INTERVIEW I

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

Date of Birth: |___|___|/|___|___|/|___|___|___|___|
month day year

DEMOGRAPHIC INFORMATION:

1. Your Name:

a. Last: |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

b. First: |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

c. Middle: |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

d. Nickname/Other Name: |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

2. If ever married, what was your maiden name?

|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

3. If married, what is your spouse's name? ***(if not married, go to Q4)***

_____
Last First Middle

4. 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.*

	Hospital	Chart number	IHS 1=yes, 2=no
a.	_____	_____	_____
b.	_____	_____	_____

5. What is your current mailing address?

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
Street/P.O. Box

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
City/town

c. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
County

d. State and zip code: |___|___|—|___|___|___|___|___|

6. Is your residential address the same as above?

Yes |___|1 No |___|2 ***If no, what is your current residential address?***
If yes, skip to Q6e

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
Street

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
City/town

c. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
County

d. State and zip code: |___|___|—|___|___|___|___|___|

e. Geo codes for the residential address **(To be filled-in by SHS staff by using Google Satellite Maps. Locate the participant's home, click right on that location to identify the global position system (GPS) code. Be sure to include all decimals and positive or negative symbols as indicated on the map.)**

Latitude: _____

Longitude: _____

7. For how long have you being living at the residential address above? _____ months _____ years

8. Is the residential address above where you have lived the longest?

Yes |___|1 No |___|2 ***If no, provide the address where you have lived the longest***
If yes and consented to participate in "The Health effects of Metals in Native American Communities" study, skip to Q9
If yes, and did not consent to participate in "The Health effects of Metals in Native American Communities" study, skip to Q16

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
Street

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
City/town

c. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
County

d. State and zip code: |___|___|—|___|___|___|___|___|

e. Geo codes for the residential address where you have lived the longest **(to be filled-in by SHS staff)**

Latitude: _______________

Longitude: _______________

Please administer questions 9-15 to participants who have consented to participate in "The Health effects of Metals in Native American Communities" study.

9. Is your current residence or the residence where you have lived the longest located in the same city/town where you lived

When you were born?	Yes |___|1	No |___|2
During childhood (1 to 11 years)?	Yes |___|1	No |___|2
During adolescence (12 to 17 years)?	Yes |___|1	No |___|2

If YES to these 3 questions, skip the next 3 questions. If NO to one or more of these 3, ask the corresponding question(s):

Can you provide the name of the city/town, county, state (and zip code if possible) where you lived for the following periods?

10. First year of life (<1 year):

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

City/town

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

County

c. State and zip code: |___|___|—|___|___|___|___|___|

11. During childhood (1 to 11 years):

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

City/town

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

County

c. State and zip code: |___|___|—|___|___|___|___|___|

12. During adolescence (12 to 17 years):

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

City/town

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

County

c. State and zip code: |___|___|—|___|___|___|___|___|

If you lived in multiple places within each of those periods, tell us the location where you lived the longest.

a. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
Street

b. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
City/town

c. |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|
County

d. State and zip code: |___|___|—|___|___|___|___|___|

13. What is the source of drinking water in your home that is used for drinking and/or cooking? (mark all options that apply)

Drilled or dug well |___|

Public or community system |___| Name of the system: _____

Spring |___|

Cistern |___|

Hauling water |___|

Bottled or other purchased water |___|

Other |___| Please specify: _____

Don't Know |___|

14. Do you treat or filter the drinking water in your home??

Yes |___|

No |___|

Don't Know |___|

If yes, which of these water treatment systems do you use? (mark all option that apply)

Softener |___|

Sediment filter |___|

UV Ultraviolet light |___|

RO Reverse Osmosis |___|

Pitcher or faucet filter (example: Brita, Aquagear, Zero Water) |___|

Other |___| Specify: _____

Don't know |___|

15. In a typical day, approximately what percentage of the water that you drink is tap water vs. bottled water? (please note: total should add up to 100%)

Tap water _____%

Bottled water _____%

16. What is your home telephone number or at what telephone number can we reach you or leave a message?
|___|___|___|—|___|___|___|—|___|___|___|___|
area code
0 = If unlisted
9 = If no phone

17. What is your work or other contact telephone number?
|___|___|___|—|___|___|___|—|___|___|___|___|
area code
0 = If same as home phone
9 = If not applicable or unknown

18. Please list two of your relatives or friends not living with you who would be able to help us find you in the future:

Contact #1: _____
Name

_____
PO Address Residential (Physical) Address

_____
City/Town State, ZIP code

_____
Phone with area code Cell e-mail address

Contact #2: _____
Name

_____
PO Address Residential (Physical) Address

_____
City/Town State, ZIP code

_____
Phone with area code Cell e-mail address

ADMINISTRATIVE INFORMATION:

19. Interviewer code: |___|___|___|

20. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PERSONAL INTERVIEW II

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

BASIC INFORMATION:
Gender:

1. Sex Assigned at Birth:

|___| Male

|___| Female

|___| Intersex (born with reproductive or sexual anatomy that doesn't fit the boxes of "female" or "male.")

|___| Don't know/Not Sure

|___| Prefer not to answer

|___| Other (please specify): _____

2. As you know, not everyone identifies with a gender that's consistent with their sex assigned at birth, so which of the following best describes your gender identity? **(Give participants a chance to offer the information on their own, then read response options, and provide the explanations of each category if the participants ask)**.

|___| Male- current gender identity matches sex assigned at birth.

|___| Female- current gender identity matches sex assigned at birth.

|___| Transgender- current gender identity differs from sex assigned at birth

|___| Gender non-conforming– a term used to describe gender identities that fall outside the defined categories of male and female.

|___| Two-spirit- an umbrella term used to describe gender roles and sexual identities that existed prior to colonization.

|___| Don't know/Not Sure

|___| Prefer not to answer

|___| Other (please specify): _____

3. What is your current marital status? |____|

1 = Never married
2 = Currently married
3 = Divorced
4 = Separated
5 = Widowed
6 = Adult roommate/partner/significant other

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

4. How many years of education have you completed? (start with the first grade) |___|___|___|
   0-12 = Vo-tech or years of school (Vo-tech/GED = 12)
   14 = Junior college 16 = Bachelors
   18 = Masters 19 = Law Degree
   20 = Doctorate 999 = Unknown

5. Did you attend preschool, or kindergarten, or participate in Head Start Program?
   Yes |___| 1 No |___| 2 Unsure |___| 9

Sleep Health

5a. On average, about how many hours of sleep do you get when you go to bed (not including naps

|_____|

FAMILY INCOME:

6. Does your household income meet your family's needs?

   Yes |___| 1 No |___| 2 Unsure |___| 9

7. Are you going to school? Yes |___| 1 No |___| 2

8. 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)* |___|___|___|

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

Less than 5,000	|___| 1	20,000 to 24,999	|___| 5	Don't know/not sure	|___| 9
5,000 to 9,999	|___| 2	25,000 to 34,999	|___| 6	Refused	|___| 0
10,000 to 14,999	|___| 3	35,000 to 50,000	|___| 7		
15,000 to 19,999	|___| 4	Over 50,000	|___| 8		

TOBACCO:

10. During your lifetime have you smoked 100 cigarettes or more total?

Yes |___| 1 No |___| 2 (***go to Q18)***

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

12. Did you quit smoking? Yes |___| 1 No |___| 2 (***go to Q13)***

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)	Family pressure	|___| 1	|___| 2
v)	Peer pressure	|___| 1	|___| 2
vi)	Other	|___| 1	|___| 2

specify: _____

13. On the average, how many cigarettes do/did you usually smoke per day? |___|___|___|
(Please give an average for a typical week)
0 = Less than one cigarette per day

a) If the average is less than one cigarette per day,
number of cigarettes per month? |___|___|___|

14. 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	|___| 1	|___| 2
b)	casinos	|___| 1	|___| 2
c)	wakes/funerals	|___| 1	|___| 2
d)	when drinking alcohol	|___| 1	|___| 2
e)	social meetings	|___| 1	|___| 2
f)	when you have extra money	|___| 1	|___| 2
g)	bingo	|___| 1	|___| 2
h)	school	|___| 1	|___| 2
i)	other, specify: _____	|___| 1	|___| 2

15. On the occasions that your smoking increased, how many total cigarettes do/did you smoke per day? |___|___|___|

16. Do you smoke cigarettes now? Yes |___| 1 No |___| 2
(If No, go to Q18)

17. If you currently smoke, would you like to change your smoking habit?

Yes |___| 1 No |___| 2
(If No, go to Q18)

a) If yes, would you prefer to…		Yes	No
i)	Reduce the number of cigarettes per day	|___| 1	|___| 2
ii)	Switch to lower "tar" or "nicotine" cigarettes	|___| 1	|___| 2
iii)	Use nicotine patch/chewing gum/medications	|___| 1	|___| 2
iv)	Quit	|___| 1	|___| 2
v)	Other, specify: _____	|___| 1	|___| 2

18. Do you use chewing tobacco/snuff now? Yes |___| 1 No |___| 2
(If No, go to Q20)

19. If yes, how many times a day do you use it? _____ times/day. (Enter 0 if less than once a day or used sporadically.)

PASSIVE SMOKING:

20. 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.)

E-CIGARETTE OR OTHER ELECTRONIC VAPING PRODUCT

21. Have you ever used an e-cigarette or other electronic vaping product, even just one time in your entire life?

Yes |___| 1 No |___| 2 Don't know/Unsure |___| 9 ***if "NO" or "Don't know/Unsure, go to next section***

22. During the past 30 days, on how many days did you use e-cigarettes or other electronic vaping products? (0 – 30)

|___|___|
# of days

ALCOHOL:

PLEASE READ THE FOLLOWING TO THE PARTICIPANT:
ALCOHOL QUESTIONS

The next few questions are about the use of wine, beer or liquor, including all kinds of alcoholic beverages. We are asking these questions about alcohol because we think alcohol consumption may be related to heart disease. We assure you that this information is strictly confidential and that we are not judging your drinking habits and do not intend to report them to anyone. GIVE DRINKS CHART TO PARTICIPANT. Sometimes it's hard to count drinks, so here is a chart to show you what we mean. REVIEW CHART WITH PARTICIPANT: READ IF NECESSARY.

One whole 12 ounces can of beer = 1 drink
A whole six-pack of beer = 6 drinks
One case of beer = 24 drinks
One quart of beer = 2.5 drinks
One pint of beer = 1.3 drinks
One 40 ounces of beer = 3.3 drinks
A glass (4 ounces) of wine = 1 drink
One pint (16 ounces) of wine = 4 drinks
One quart (32 ounces) of wine = 8 drinks
A shot or gulp of straight hard liquor, like whiskey = 1 drink
One pint (16 ounces) of hard liquor = 12 drinks
One quart (32 ounces) of hard liquor = 24 drinks
A full glass of a mixed drink, like ever clear in punch = 1 drink

23. Have you ever consumed alcoholic beverages?
Yes |___| 1 No |___| 2 ***(go to Q30)***

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 ***(go to Q30)***

24. How many alcoholic drinks do you have in a typical week? |___|___|___|

25. How many days in a typical month do you have at least one drink? |___|___|___|
(Indicate the number of days per month.)

26. 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.)* |___|___|___| (# of Drinks)

27. When you drink more than your usual amount, how many **total** drinks do you have? |___|___|___| (# of Drinks)

28. How many times during the **PAST MONTH** did you have 5 or more drinks on an occasion? Indicate times per month. *(Enter zero if participants has quit drinking more than one month ago.)* |___|___|___|

29. How many times during the **PAST YEAR** did you have 5 or more |___|___|___| drinks on an occasion

LANGUAGE QUESTIONS

30. Can you speak your native language? (interviewer should specify the language)?

Yes, fluently |___|1 Yes, but not fluently |___|2 No |___|3 (**If no Skip to Q32)**

31. 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

US MILITARY OR ARMED FORCES SERVICE

32. Have you ever served or are you currently serving in the US military or Armed Forces? ***(If yes, answer 33 &34. If no, skip to next section)***

Yes |___| 1 No |___| 2

33. If "YES," in which branch of the military did you serve?

|___| 1 Air Force

|___| 2 Army

|___| 3 Marines

|___| 4 Navy

|___| 5 Coast Guard

|___| 6 National Guard

34. For how long did you serve in the military? |___|___| |___|___|
years months

ADMINISTRATIVE INFORMATION:

35. Interviewer code: |___|___|___|

36. Interview date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MEDICAL HISTORY

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

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. a) High blood pressure?

   Yes |___| 1 No |___| 2 Only during pregnancy |___| 3 Unknown |___| 9

   b) 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 |___|___|___|

   c) If "YES," are you taking any medication to control your blood pressure?

   Yes |___| 1 No |___| 2 Unknown |___| 9

		YES	NO	UNKNOWN
2.	Arthritis?	|___| 1	|___| 2	|___| 9
3.	Any fractures associated with brittle bone disease or osteoporosis?	|___| 1	|___| 2	|___| 9
	a) If "YES," where? _____			
4.	Rheumatic heart disease?	|___| 1	|___| 2	|___| 9
5.	Gallstones?	|___| 1	|___| 2	|___| 9
6.	Cancer, including leukemia and lymphoma?	|___| 1	|___| 2	|___| 9
	a) If "YES," specify type of cancer: _____			

7. Diabetes? Yes |___| 1 No |___| 2 Only during pregnancy |___| 3 Unknown |___| 9
(If No or Unknown, go to Q8)

a) How old were you when you were first told by a medical person that you had diabetes? *Indicate the actual age.* Don't know = 999 |___|___|___|

b) What type of treatment are you taking for your diabetes? *(Check appropriate answer.)*

		YES	NO
i)	insulin	|___| 1	|___| 2
ii)	oral hypoglycemic agent	|___| 1	|___| 2
iii)	by dietary control	|___| 1	|___| 2
iv)	by exercise	|___| 1	|___| 2
v)	do nothing	|___| 1	|___| 2
vi)	other: _____	|___| 1	|___| 2

	YES	NO	UNKNOWN
8. Has a medical person ever told you that you had kidney failure? ***(If No or Unknown, go to Q11)***	|___| 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 a kidney transplant?	|___| 1	|___| 2	|___| 9
a) If "YES," is the new kidney working well?	|___| 1	|___| 2	|___| 9
b) If "NO," are you waiting for a kidney transplant?	|___| 1	|___| 2	|___| 9
11. Cirrhosis of the liver?	|___| 1	|___| 2	|___| 9

HEART PROBLEMS:

12. Have you had a heart catheterization? Yes |___| 1 No |___| 2 Unknown |___| 9

(A heart catheterization is a study in which a tube is inserted into the heart through the groin or arm to see how the heart works.)

a) If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

13. Have you ever had an angioplasty (balloon, PCTA or Stent procedure)?

(Coronary angioplasty is a procedure used to open clogged heart arteries. It uses a tiny balloon catheter that is inserted in a blocked blood vessel to help widen it and improve blood flow to the heart.)

Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

14. Have you ever had an exercise or Chemical Stress test to check your heart?

Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," when and where? |___|___|/|___|___|/|___|___|___|___|
month day year

i) 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. Congestive heart failure? Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," when and where? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

b) If "YES," do you still have heart failure now? Yes |___| 1 No |___| 2 Unknown |___| 9

16. Heart attack? Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," when and where? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

17. Any other heart troubles? Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," please specify type: _____

b) If "YES," when and where? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

18. Stroke? Yes |___| 1 No |___| 2 Unknown |___| 9

a) If "YES," when and where? |___|___|/|___|___|/|___|___|___|___|
month day year

i) hospital/clinic: _____

19. Have you ever had surgery on your chest? Yes |___| 1 No |___| 2
(go to Q20)

a) Was it heart surgery? Yes |___| 1 No |___| 2 Unknown |___| 9
(go to Q20)

If "YES," which surgery have you had?

i) Bypass? Yes |___| 1 No |___| 2 Unknown |___| 9

If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
month day year

hospital/clinic: _____

ii) Valvular repair/replacement? Yes |___| 1 No |___| 2 Unknown |___| 9

If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
Month day year

hospital/clinic: _____

iii) Pacemaker? Yes |___| 1 No |___| 2 Unknown |___| 9

If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
month day year

hospital/clinic: _____

iv) Other? Yes |___| 1 No |___| 2

If "YES," when and where *(most recent)*? |___|___|/|___|___|/|___|___|___|___|
month day year

Please specify: _____

hospital/clinic: _____

20. Are you taking aspirin daily to prevent a heart attack or a stroke?

Yes |___| 1 No |___| 2 Unknown |___| 9

21. Has a medical person **ever** told you that you had COVID-19?
(Yes, probably or suspected is without having had a positive test but experienced COVID symptoms)

Yes |___| 1 Yes, probably or suspected |___| 2 No |___| 9

ORAL HEALTH QUESTION

22. How many natural teeth do you have?

a) All |___| Most |___| Some |___| None |___|

23. Describe how your chew your food? (please choose only one)

a) I use natural teeth to chew |___|
b) I use natural teeth with caps/crowns to chew |___|
c) I have natural teeth and a denture or partial. I use them both together to chew |___|
d) I use dentures to chew |___|
e) I chew with my gums |___|

24. Rate your ability to chew food (please choose only ONE)

a) Good |___| Fair |___| Poor |___|

25. Overall, how would you rate the health of your teeth and gums?

a) Excellent |___|
b) Very good |___|
c) Good |___|
d) Fair |___|
e) Poor |___|

26 Have you ever had treatment for gum disease, such as scaling and root planning, (sometimes called "deep" cleaning?)
a) Yes |___| b. No |___|c. Unknown |___|

27 Have you ever been told by a dental professional that you lost bone around your teeth?
a) Yes |___| b. No |___|c. Unknown |___|

ADMINISTRATIVE INFORMATION:

28. Interviewer code: |___|___|___|

29. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

IF THE PARTICIPANT IS FEMALE GO TO REPRODUCTION AND HORMONE USE.

IF THE PARTICIPANT IS MALE GO TO ROSE QUESTIONNAIRE.

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MEDICATION RECEPTION

SHS I.D.: |___|___|___|___|___|___|___| **SHS Family I.D.:** |___|___|___|___|___|___|___|

MEDICATION RECEPTION

As you know, the Strong Heart Study will be describing all medications its participants are using, both prescription and over- the-counter, and traditional remedies. These include pills, liquid medications, skin patches, eye drops, creams, salves, inhalers and injections, as well as cold or allergy medications, vitamins, herbal, homeopathic or traditional medicines and other supplements. Prior to your clinic visit we asked that you bring all your medications into the clinic in their original bottles.

1. Have you brought your medications with you? Are these all the medications that you have taken in the past two weeks?

Yes |___| ***(May I see them?)***

No |___| ***(Make arrangements to obtain)***

Took no meds |___|

Refused |___| ***(Cite reasons for refusal in the space below)***

Reasons for refusal:_____

Interviewer, please observe:

1. Are there any prescription medications? Yes |___| No |___|
2. Are there any over the counter (OTC) medications? Yes |___| No |___|

MEDICATIONS (Prescription & Non-Prescription)

Copy the name of medicine, the strength (include units), and the total number of doses for prescription and non-prescription. Include all pills, skin patches, creams, salves, inhalers, nebulizers, injections, vitamins and supplements, cold and allergy medication, and any over-the-counter medications.

In the compliance column: In the last month, how much of the medication did you take approximately?

	Medication Name (Clearly print the first 20 letters only)	**Strength (mg IU, etc.)** (Include decimal)	**Frequency:** (Circle day, week, month)	**PRN** (Circle Y or N)	**Compliance: # of meds** (Circle day, week, month)
1.	_____	_____	_____ D W M	Y N	_____ D W M
2.	_____	_____	_____ D W M	Y N	_____ D W M
3.	_____	_____	_____ D W M	Y N	_____ D W M
4.	_____	_____	_____ D W M	Y N	_____ D W M
5.	_____	_____	_____ D W M	Y N	_____ D W M
6.	_____	_____	_____ D W M	Y N	_____ D W M
7.	_____	_____	_____ D W M	Y N	_____ D W M
8.	_____	_____	_____ D W M	Y N	_____ D W M
9.	_____	_____	_____ D W M	Y N	_____ D W M
10.	_____	_____	_____ D W M	Y N	_____ D W M
11.	_____	_____	_____ D W M	Y N	_____ D W M
12.	_____	_____	_____ D W M	Y N	_____ D W M
13.	_____	_____	_____ D W M	Y N	_____ D W M
14.	_____	_____	_____ D W M	Y N	_____ D W M
15.	_____	_____	_____ D W M	Y N	_____ D W M

Number unable to transcribe: _____

TRADTIONAL REMEDIES, THERAPIES, & PRACTICES

Copy the name of the medicine, the strength (include units, if applicable), and total number of doses per day/week/month.

In the compliance column: In the last month, how many did you take approximately?

	Medication Name (Clearly print the first 20 letters only)	**Strength (mg IU, etc.)** (Include decimal)	**Frequency:** (Circle day, week, month)	**PRN** (Circle Y or N)	**Compliance: # of meds** (Circle day, week, month)
1.	_____	_____	_____ D W M	Y N	_____ D W M
2.	_____	_____	_____ D W M	Y N	_____ D W M
3.	_____	_____	_____ D W M	Y N	_____ D W M
4.	_____	_____	_____ D W M	Y N	_____ D W M
5.	_____	_____	_____ D W M	Y N	_____ D W M
6.	_____	_____	_____ D W M	Y N	_____ D W M
7.	_____	_____	_____ D W M	Y N	_____ D W M
8.	_____	_____	_____ D W M	Y N	_____ D W M
9.	_____	_____	_____ D W M	Y N	_____ D W M
10.	_____	_____	_____ D W M	Y N	_____ D W M
11.	_____	_____	_____ D W M	Y N	_____ D W M
12.	_____	_____	_____ D W M	Y N	_____ D W M
13.	_____	_____	_____ D W M	Y N	_____ D W M
14.	_____	_____	_____ D W M	Y N	_____ D W M
15.	_____	_____	_____ D W M	Y N	_____ D W M

Number unable to transcribe: _____

3 . Who is the primary respondent? Study participant |__| Family member |__| Other |__|

ADMINISTRATIVE INFORMATION:

4. Interviewer/reviewer code: |___|___|___|

6 Interview/review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

REPRODUCTION AND HORMONE USE (WOMEN ONLY)

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

"The following questions are related to your childbearing history and childbearing organs."
(For Q1 – Q4, use 999 for Unknown.)

1. How many times have you been pregnant (gravidity)? |___|___|___|
(If never pregnant, go to Q25.)

2. How many of your pregnancies resulted in a live birth (parity)? |___|___|___|

3. How many living children do you have? |___|___|___|

4. How many pregnancies did you lose (including miscarriage or stillbirth)? |___|___|___|

Next set of questions (Q5 to Q14) pertain to the first pregnancy or pregnancy loss

5. Did your first pregnancy result in a live birth?
Yes |___| 1 No |___| 2 Not sure |___| 3

6. What was the date of delivery or pregnancy loss for your first pregnancy?
|___|___|/|___|___|/|___|___|___|___|
Month day year

7. How many weeks pregnant were you when you delivered or lost your first pregnancy?
(*full term pregnancy is about 40 weeks, use 999 for unknown)*?
|___|___|___|

8. Hospital of delivery: _____ City: _____

9. During your first pregnancy, were you told you had high blood pressure for the first time? Please answer NO, if you were told before your first pregnancy you had high blood pressure.
(If NO, go to Q11.)
Yes |___| 1 No |___| 2 Not sure |___| 3

10. During your first pregnancy, how many weeks pregnant were you when you were first diagnosed with high blood pressure? (*full term pregnancy is about 40 weeks, use 999 for unknown)*?
|___|___|___|

Preeclampsia (pree-i-CLAMP-see-ah), also called toxemia, is a condition that typically starts after the 20th week of pregnancy and is related to increased blood pressure and protein in the mother's urine.

11. During your first pregnancy, were you told you had preeclampsia, toxemia or protein in your urine? **(If NO, go to Q13)**
Yes |___| 1 No |___| 2 Not sure |___| 3

12. During your first pregnancy, how many weeks pregnant were you when you were first diagnosed with preeclampsia, toxemia or protein in your urine? (*full term pregnancy is about 40 weeks, use 999 for unknown)*? |___|___|___|

13. During your first pregnancy, were you told for the first time that you had diabetes? Please answer NO, if you were told before your first pregnancy you had diabetes. **(If NO, go to Q15.)**

Yes |___| 1 No |___| 2 Not sure |___| 3

14. During your first pregnancy, how many weeks pregnant were you when you were first diagnosed with diabetes? (*full term pregnancy is about 40 weeks, use 999 for unknown)*?

|___|___|___|

<u>Questions 15 and 16 pertain to any other pregnancies</u>

15. Did you have preeclampsia, toxemia, or both hypertension and protein in your urine in one or more <u>later pregnancies</u>? **(If No, go to Q17)**

Yes |___| 1 No |___| 2 Not sure |___| 3

16. If yes, please answers questions below:

	Pre-eclampsia or toxemia?	Date and location of delivery or pregnancy loss	Number of weeks pregnant
pregnancy #2	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #3	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #4	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #5	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|

17. Did you ever have eclampsia, i.e. a seizure (convulsion or “fit”) along with hypertension during a pregnancy or around the time of delivery?

Yes |___| 1 No |___| 2 Not sure |___| 3

18. Did your mother or sister ever have preeclampsia?

Yes |___| 1 No |___| 2 Not sure |___| 3

19. Did you have diabetes in one or more later pregnancies? **(If No, go to Q21)**

Yes |___| 1 No |___| 2 Not sure |___| 3

20. If yes, please answers questions below:

	Diabetes?	Date of delivery or pregnancy loss	Number of weeks pregnant
pregnancy #2	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #3	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #4	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|
pregnancy #5	Yes |___| 1 No |___| 2 Not sure |___| 3	|___|___|/|___|___|/|___|___|___|___| Month day year Hospital: _____ City: _____	|___|___|___|

21. Approximately how many cigarettes/ day did you smoke during your first pregnancy *(enter "0" if you did not smoke, use 999 for unknown)*?

|___|___|___|

22. E-cigarettes are battery powered devices that provide inhaled doses of nicotine. Approximately how many e-cigarettes/ day did you use during your first pregnancy *(enter "0" if you did not smoke, use 999 for unknown)*?

|___|___|___|

23. Did you use chewing tobacco/snuff during your first pregnancy? Yes |___| 1 No |___| 2
(If NO, go to Q25.)

24. If yes, how many times a day did you use it? (Enter 0 if less than once a day or use sporadically.)

|___|___|___|

25. Have you ever used birth control pills? Yes |___| 1 No |___| 2 Not sure |___| 3
(If NO or NOT SURE, go to Q26.)

a) Are you still using birth control pills? Yes |___| 1 No |___| 2

b) How old were you when you started to use birth control pills?
Indicate the age in years. 999 = unknown |___|___|___|

c) How many years altogether did you use them? |___|___|
*Specify the duration **in years**. 0 = less than 6 months, 1 = 6–12 months, 99 = unknown.*

26. Have you ever had a birth control implant (such as Norplant)?

Yes |___| 1 No |___| 2 Not sure |___| 3
(If NO or NOT SURE, go to Q27.)

a) Are you still using a birth control implant? Yes |___| 1 No |___| 2

b) How old were you when you started to use a birth control implant?
Indicate the age in years. 999 = unknown, can't remember |___|___|___|

c) How many years altogether did you use it? |___|___|___|
*Specify the duration **in years**. 0 = less than 6 months, 1 = 6-12 months, 999 = unknown.*

27. Have you ever used birth control shots (such as Depo Provera)?

Yes |___| 1 No |___| 2 Not sure |___| 3
(If NO or NOT SURE, go to Q28.)

a) Are you still using birth control shots? Yes |___| 1 No |___| 2

b) How old were you when you started to use birth control shots?
Indicate the age in years. 999 = unknown, can't remember |___|___|___|

c) How many years altogether did you use them? |___|___|___|
*Specify the duration **in years**. 0 = less than 6 months, 1 = 6-12 months, 999 = unknown*

28. How old were you when you started to have regular menstrual cycles (periods)?
Indicate the age in years. 999 = unknown |___|___|___|

29. Have your menstrual cycles (periods) stopped? Yes |___| 1 No |___| 2
(go to Q30)

a) If "YES," have they stopped for 12 months or more? Yes |___| 1 No |___| 2
(go to Q30)

i) How old were you when your periods stopped completely?
Indicate the age in years. 999 = unknown, can't remember |___|___|___|

ii) Did your periods stop naturally, or because of surgery or hormone use, or for some other reason?
Natural |___| 1 ***(go to Q30)***
Surgery |___| 2
Hormonal |___| 3 ***(go to Q30)***
Other, specify: _____|___| 4 (***go to Q30)***

iii) If **SURGERY**, were <u>both</u> of your ovaries removed?

Yes |___| 1 No |___| 2 Unknown |___| 9

"ESTROGEN and PROGESTERONE are types of female hormones that may be taken for many reasons, including after a hysterectomy or menopause, to regulate your periods or for any other reasons."

30. Except for birth control pills, have you ever taken estrogen – either pills, as a patch or by shot – for any reason?

Yes |___| 1 No |___| 2 Not sure |___| 3
(If NO or NOT SURE, go to Q38.)

31. How old were you when you started using estrogen? *Indicate age in years.* |___|___|___|

32. 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.)

33.	Do/Did you use estrogen for (answer all applicable)	YES	NO	NOT SURE
a)	post-surgery (hysterectomy and removal of ovaries)	|___| 1	|___| 2	|___| 3
b)	relief of menopause symptoms	|___| 1	|___| 2	|___| 3
c)	prevent bone loss	|___| 1	|___| 2	|___| 3
d)	protect against heart disease	|___| 1	|___| 2	|___| 3
e)	doctor's advice	|___| 1	|___| 2	|___| 3
f)	other: _____	|___| 1	|___| 2	|___| 3

34. Do/Did you take progesterone in addition to, or in combination with, your estrogen treatment?

Yes |___| 1 No |___| 2 Not sure |___| 3

35. What form of estrogen are you taking? Is it a pill, patch, shot or other type?

pill |___| 1 patch |___| 2 shot |___| 3 other |___| 4 Not sure |___| 5

36. Are you still taking estrogen? Yes |___| 1 ***(go to Q38)*** No |___| 2 ***(go to Q37)***

37.	Why did you stop taking estrogen?	YES	NO	UNKNOWN
a)	Caused bleeding	|___| 1	|___| 2	|___| 9
b)	Made breasts tender	|___| 1	|___| 2	|___| 9
c)	Made you feel bloated	|___| 1	|___| 2	|___| 9
d)	Made you feel "funny," didn't like the way you felt	|___| 1	|___| 2	|___| 9
e)	Do not like taking any medicines	|___| 1	|___| 2	|___| 9
f)	Too expensive	|___| 1	|___| 2	|___| 9
g)	Doctor's advice	|___| 1	|___| 2	|___| 9
h)	Concerned about long-term side effects	|___| 1	|___| 2	|___| 9
i)	Other: _____	|___| 1	|___| 2	|___| 9

38. Other than in combination with estrogens, have you ever taken progesterone by itself for any reason?
Yes |___| 1 No |___| 2 Not sure |___| 3
(If NO or NOT SURE, go to Q42.)

39. How old were you when you started using progesterone? *Indicate age in years.* |___|___|___|

40. How many years altogether did you take progesterone? *Specify duration in years.* |___|___|___|
(If less than 3 months, record 0. If more than 3 months, but less than 1 year, record 1.)

41. Are you still taking progesterone? Yes |___| 1 No |___| 2 Not sure |___| 3

ADMINISTRATIVE INFORMATION:

42. Interviewer code: |___|___|___|

43. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

ROSE QUESTIONNAIRE FOR ANGINA AND INTERMITTENT CLAUDICATION

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

Chest Pain on Effort

1. Have you ever had any pain or discomfort in your chest? Yes |___|1
   No |___|2 ***(go to Q10)***

2. Do you get it when you walk uphill, upstairs or hurry? Yes |___|1
   No |___|2 ***(go to Q9)***
   Never hurries or walks uphill or upstairs |___|3
   Unable to walk |___|4 ***(go to Q9)***

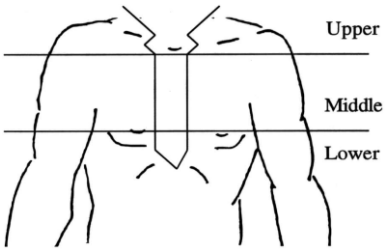
3. Do you get it when you walk at an ordinary pace on the level? Yes |___|1 No |___|2

4. What do you do if you get it while you are walking? Stop or slow down |___|1
   (*Record "stop or slow down" if participants carries on after taking nitroglycerine.*)
   Carry on |___|2 ***(go to Q9)***

5. If you stand still, what happens to it? Relieved |___|1 Not relieved |___|2 ***(go to Q9)***

6. How soon? 10 minutes or less |___|1 More than 10 minutes |___|2 ***(go to Q9)***

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

a) If "YES," record additional information: _____

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

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

a) If calves not mentioned, ask: "Anywhere else?" *Please specify*: _____
_____ ***(go to Q19)***

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

ADMINISTRATIVE INFORMATION:

19. Interviewer code: |___|___|___|

20. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PERCEIVED STRESS

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|___|

Perceived stress refers to how much the everyday situations in life may be causing psychological distress or difficulty. Higher stress has been linked to higher risk of depression, mortality, and cardiovascular disease.

***Instructions**: For the following questions, please check the closest answer according to the following scales.* ***Mark only one answer for each question**.*

In the past month, how often have you (Q1- 7)

		Not at all	Rarely	Sometimes	Often	Most of the time	Not Sure
1.	been upset because of something that happened unexpectedly?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
2.	felt nervous or "stressed"?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
3.	dealt well with irritating life hassles?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
4.	felt that things were going your way?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
5.	felt unable to control irritations in your life?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
6.	felt that you were on the top of things?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9
7.	felt difficulties or problems were piling up so high that you could not handle them?	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 9

Time Spent Watching TV/Social Media

8. On the average, how much time per day do you watch TV/Social Media? |___|___|: |___|___|
hours minutes

ADMINISTRATIVE INFORMATION:

9. Interviewer/reviewer code: |___|___|___|

10. Interview/review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

QUALITY OF LIFE

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

How is this questionnaire administered? By interviewer |___|1 By self |___|2 Refused |___|8

The SF-12 health-related quality of life scale measures quality of life in physical and mental health.

***Instructions**: For the following questions, please check the closest answer according to the following scales.*
Mark only one answer for each question

These next questions ask how you feel about your own health.

1. In general, would you say your health is? **(Please check only one.)**

   Excellent ..... |___|1

   Very good ..... |___|2

   Good ..... |___|3

   Fair ..... |___|4

   Poor ..... |___|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?

		Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
2.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.....	|___|1	|___|2	|___|3
3.	Climbing **several** flights of stairs (or climbing a hill) ...	|___|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?

		Yes	No
4.	**Accomplished less** than you would like.....	|___|1	|___|2
5.	Were limited in the kind of work or other activities.....	|___|1	|___|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)?

		Yes	No
6.	**Accomplished less** than you would like.....	|___|1	|___|2
7.	Didn't do work or other activities as carefully as usual.....	|___|1	|___|2

8. **During the PAST 4 WEEKS, how much did pain interfere with your normal work, (including both work outside the home and housework)?**

Not at all.....	|___|1
A Little Bit.....	|___|2
Moderately	|___|3
Quite a bit.....	|___|4
Extremely	|___|5

These questions are about how you feel and how things have been with you during the PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *PAST 4 WEEKS*

		All of the Time	Most of the Time	a Good Bit of the Time	Some of the Time	a Little of the Time	None of the Time
9.	Have you felt calm and peaceful? .	|___|1	|___|2	|___|3	|___|4	|___|5	|___|6
10.	Did you have a lot of energy?.....	|___|1	|___|2	|___|3	|___|4	|___|5	|___|6
11.	Did you feel downhearted and blue?.....	|___|1	|___|2	|___|3	|___|4	|___|5	|___|6

12. **During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH or EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?**

(Please check one number.)

All the time ..... |___|1

Most of the time..... |___|2

Some of the time ..... |___|3

A Little of the time..... |___|4

None of the time..... |___|5

ADMINISTRATIVE INFORMATION:

13. Interviewer/reviewer code: |___|___|___|

14. Interview/review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CES-D SCALE

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|___|

How is this questionnaire administered? By interviewer |___|1 By self |___|2 Refused |___|8

The CES-D scale is a general screening measure of symptoms of depression. Measuring depression can be useful to assess mood, as well as health and cardiovascular risk.

Here are some questions (Q1-Q20) about your feelings during the <u>past week</u>. For each of the following statements, please respond as to whether you felt that way.

During the **past week** . . .	Rarely or Not at ALL < 1 day 1	Some 1-2 days 2	Often 3-4 days 3	Most of the Time 5-7 days 4	Not Applicable 9
1. I was bothered by things that don't usually bother me.	|___|1	|___|2	|___|3	|___|4	|___|9
2. I did not feel like eating; my appetite was poor.	|___|1	|___|2	|___|3	|___|4	|___|9
3. I felt that I could not shake the blues even with help from my family or friends.	|___|1	|___|2	|___|3	|___|4	|___|9
4. I felt that I was just as good as other people.	|___|1	|___|2	|___|3	|___|4	|___|9
5. I had trouble keeping my mind on what I was doing.	|___|1	|___|2	|___|3	|___|4	|___|9
6. I felt depressed	|___|1	|___|2	|___|3	|___|4	|___|9
7. I felt that everything I did was an effort.	|___|1	|___|2	|___|3	|___|4	|___|9
8. I felt hopeful about the future.	|___|1	|___|2	|___|3	|___|4	|___|9
9. I thought my life had been a failure.	|___|1	|___|2	|___|3	|___|4	|___|9
10. I felt fearful.	|___|1	|___|2	|___|3	|___|4	|___|9
11. My sleep was restless.	|___|1	|___|2	|___|3	|___|4	|___|9
12. I was happy.	|___|1	|___|2	|___|3	|___|4	|___|9

For each of the following statements, please respond as to whether you felt that way: Rarely or Not at All, Some of the time, Often, or Most of the time.

During the **past week** . . .	Rarely or Not at ALL < 1 day 1	Some 1-2 days 2	Often 3-4 days 3	Most of the Time 5-7 days 4	Not Applicable 9
13. I talked less than usual.	|___|1	|___|2	|___|3	|___|4	|___|9
14. I felt lonely.	|___|1	|___|2	|___|3	|___|4	|___|9
15. People were unfriendly.	|___|1	|___|2	|___|3	|___|4	|___|9
16. I enjoyed life.	|___|1	|___|2	|___|3	|___|4	|___|9
17. I had crying spells.	|___|1	|___|2	|___|3	|___|4	|___|9
18. I felt sad.	|___|1	|___|2	|___|3	|___|4	|___|9
19. I felt that people disliked me.	|___|1	|___|2	|___|3	|___|4	|___|9
20. I felt like I couldn't do what I needed to do.	|___|1	|___|2	|___|3	|___|4	|___|9

During the **past year** . . .	Rarely or Not at ALL 1	Some 2	Often 3	Most of the Time 4	Not Applicable 9
21. I have felt depressed or sad.	|___|1	|___|2	|___|3	|___|4	|___|9

ADMINISTRATIVE INFORMATION:

22. Interviewer/reviewer code: |___|___|___|

23. Interview/review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MHLC SCALE

SHS Family I.D. |___|___|___|___|___|___|___|___| SHS I.D.: |___|___|___|___|___|___|

How was the questionnaire administered?

|___| 1=By interviewer |___| 2=By self |___| 3=Refused

Multidimensional Health Locus of Control Scale

Each item below is a belief statement about your medical condition with which you may agree or disagree. Each statement is a scale which ranges from strongly disagree (0) to strongly agree (3). For each item we would like you to select the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you select. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

	Strongly Disagree 0	Disagree 1	Agree 2	Strongly Agree 3
1. If I become sick, I have the power to make myself well again.	|___| 0	|___| 1	|___| 2	|___| 3
2.Often I feel that no matter what I do, if I am going to get sick, I will get sick.	|___| 0	|___| 1	|___| 2	|___| 3
3. If I see an excellent doctor regularly, I am less likely to have health problems.	|___| 0	|___| 1	|___| 2	|___| 3
4. Most things that affect my health happen by accidental happenings.	|___| 0	|___| 1	|___| 2	|___| 3
5. I can only maintain my health by consulting health professionals.	|___| 0	|___| 1	|___| 2	|___| 3
6. I am directly responsible for my health.	|___| 0	|___| 1	|___| 2	|___| 3
7. Other people play a big part in whether I stay healthy or become sick.	|___| 0	|___| 1	|___| 2	|___| 3
8. Whatever goes wrong with my health is my own fault	|___| 0	|___| 1	|___| 2	|___| 3
9. When I am sick, I just have to let nature run its course.	|___| 0	|___| 1	|___| 2	|___| 3

	Strongly Disagree 0	Disagree 1	Agree 2	Strongly Agree 3
10 Health professionals keep me healthy.	|___| 0	|___| 1	|___| 2	|___| 3
11. When I stay healthy, I'm just plain lucky.	|___| 0	|___| 1	|___| 2	|___| 3
12. My physical well-being depends on how well I take care of myself.	|___| 0	|___| 1	|___| 2	|___| 3
13.When I feel ill, I know it is because I have not been taking care of myself properly.	|___| 0	|___| 1	|___| 2	|___| 3
14 The type of care I receive from other people is what is responsible for how well I recover from an illness.	|___| 0	|___| 1	|___| 2	|___| 3
15.Even when I take care of myself, it's easy to get sick.	|___| 0	|___| 1	|___| 2	|___| 3
16.When I become ill, it's a matter of fate.	|___| 0	|___| 1	|___| 2	|___| 3
17.I can pretty much stay healthy by taking good care of myself.	|___| 0	|___| 1	|___| 2	|___| 3
18. Following doctor's orders to the letter is the best way for me to stay healthy.	|___| 0	|___| 1	|___| 2	|___| 3

ADMINISTRATIVE INFORMATION:

19. Interviewer code: |___|___|___|

20. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

OTHER QUESTIONS ABOUT YOUR LIFE

SHS I.D.: |___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

Posttraumatic Stress Disorder (PTSD)

Many people experience very frightening events sometime during their lives. Sometimes these experiences can upset them so much that their health suffers. The following six questions ask whether you have experienced such an event, and, if so, whether it has led to lasting problems. If you prefer not to answer a question, you can skip it.

1. Have you ever had an extremely frightening, traumatic or horrible experience like being a victim of a violent crime, seriously injured in an accident, being assaulted, seeing someone seriously injured or killed, or being a victim of a natural disaster?

   Yes |___|1 No |___|2
   (If you answered "NO," go to question 7)

   During the past month:

2. Did you relive the traumatic experience through recurrent dreams, preoccupation or flashbacks?

   Yes |___|1 No |___|2

3. Did you seem less interested than usual in important things, feel "out of it," or did you have a hard time with your feelings or emotions?

   Yes |___|1 No |___|2

4. Did you have problems sleeping, concentrating, or having a short temper?

   Yes |___|1 No |___|2

5. Did you avoid any place or anything that reminded you of the original horrible event?

   Yes |___|1 No |___|2

6. Did you have some of the above problems for more than one month?

   Yes |___|1 No |___|2

Please administer question 7 to participants who have consented to participate in Psychological risk factors, quality of life, community, and brain aging in American Indians: The Strong Heart Study

Inclusion of Community in the Self (ICS) Scale

7. Please circle the picture that best describes your relationship with the community at large. (Y=You; C=Community at Large)

1 2 3 4 5 6

ADMINISTRATIVE INFORMATION:

8. Interviewer code: |___|___|___|

9. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

FOOD ASSISTANCE AND FOOD SECURITY

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

1. In the past 12 months, have you or other members of your household participated in any of the following services? (*please check all you have used*)
    i. □ WIC – Women Infants & Children Program
    ii. □ SNAP/EBT – Supplemental Nutrition Assistant Program
    iii. □ Tribal Food Distribution Program (commodities)
    iv. □ Elderly Nutrition Program
    v. □ Food Pantry, Soup Kitchen
    vi. □ Free/Reduced School Breakfast or Lunch, or Summer Meals Program
    vii. □ Do Not Participate in any of these programs
    viii. □ I choose not to answer

2. In the past 12 months, the food that your household bought just didn't last, and your household didn't have money to get more.
    i. □ Often true
    ii. □ Sometimes true
    iii. □ Never true
    iv. □ I choose not to answer

3. In the past 12 months, your household couldn't afford to eat balanced meals.
    i. □ Often true
    ii. □ Sometimes true
    iii. □ Never true
    iv. □ I choose not to answer

4. In the last 12 months, did your household ever cut the size of your meals or skip meals because there wasn't enough money for food?
    i. □ Yes
    ii. □ No
    iii. □ I choose not to answer

    iv. IF YES How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months?
        a. □ Almost every month
        b. □ Some months but not every month
        c. □ Only 1 or 2 months
        d. □ I choose not to answer

5. In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food?
   a. □ Yes
      □ No
      □ I choose not to answer

6. In the last 12 months, were you ever hungry but didn't eat because there wasn't enough money for food?
   □ Yes
   □ No
   □ I choose not to answer

ADMINISTRATIVE INFORMATION

7. Examiner code: |___|___|___|

8. Examination date: |___|___|/|___|___|/|___|___|___|___|
   Month day year

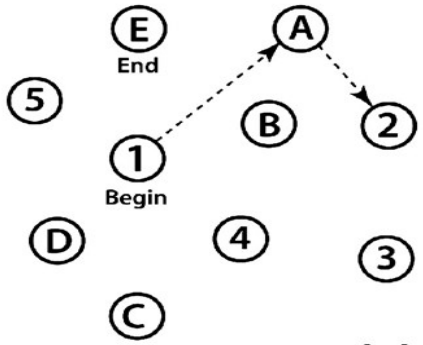
Montreal Cognitive Assessment (MOCA)

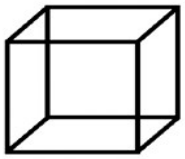
[To be administered by trained personnel]

SHS I.D.: |___|___|___|___|___|___|___| Interviewer code: |___|___|___|

Interview date: |___|___|/|___|___|/|___|___|___|___|

VISUOSPATIAL / EXECUTIVE





Copy cube

[ ] [ ]

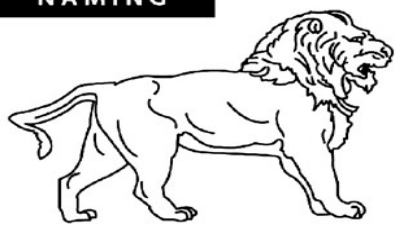
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS

___/5

NAMING



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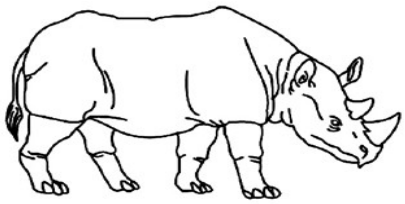

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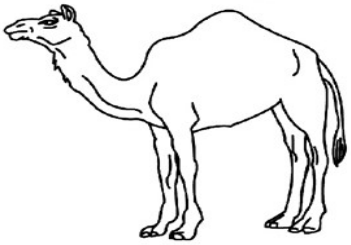


[ ]

___/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

___/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

© Z.Nasreddine MD **www.mocatest.org** Normal ≥ 26 / 30

TOTAL ___/30

Add 1 point if ≤ 12 yr edu

MOCA Continued: *Scratch page for interviewer*

Attention-Digits: _____

Attention-Subtraction (Serial 7): ____ _____ _____ _____ _____

Language Fluency - F test:

1. _____	11. _____	21. _____
2 _____	12 _____	22 _____
3. _____	13. _____	23. _____
4. _____	14. _____	24. _____
5 _____	15 _____	25 _____
6 _____	16 _____	26 _____
7. _____	17. _____	27. _____
8. _____	18. _____	28. _____
9 _____	19 _____	29 _____
10 _____	20 _____	30 _____

Abstraction- train/bicycle: _____

Abstraction- watch-ruler: _____

Orientation-Date: _____

Orientation-Month: _____

Orientation-Year: _____

Orientation-Day: _____

Orientation-Place: _____

Orientation-City: _____

Other Notes: _____

STRONG HEART STUDY PHASE 7

RESILIENCE STUDY QUESTIONNAIRE

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

Date:|___|___| / |___|___| / |___|___|

Interviewer Code: |___|___|___|

Please administer questions in sections S13- S20 to participants who have consented to participate in Resilience, cultural alignment, and social support in brain aging: Data from the Strong Heart Study

14-Item Resilience Scale (RS-14)

Resilience may be defined as the ability to regulate emotions, maintain positive attitude, or see failure as helpful feedback despite conditions of extreme stress. The RS-14 measures traits of individual resilience, including self-reliance, perseverance, self-regard, engagement, humor, resourcefulness, meaningfulness, and composure.

***Instructions**: For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

	Strongly disagree	Disagree	More or less disagree	Neutral	More or less agree	Agree	Strongly agree
1. I usually manage one way or the other	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
2. I feel that I can handle many things at a time	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
3. I can get through difficult times because I have experienced difficulty before	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
4. In an emergency, I am someone people can generally rely on	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
5. When I am in a difficult situation, I can usually find my way out of it	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
6. I feel proud that I have accomplished things in life	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
7. I keep interested in things	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
8. My life has meaning	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
9. I usually take things in stride	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
10. I can usually find something to laugh about	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
11. I am determined	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
12. I have self-discipline	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
13. I am friends with myself	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7
14. My belief in myself gets me through hard times	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5	|___| 6	|___| 7

Multidimensional and Interpersonal Resilience Measure (MIRM)

There are many aspects of resilience. Some scientists believe that resilience is also feature of community, both defined by and improved by social support. The MIRM scale covers more complex concepts of resilience, including access to a support network, optimism, access to economic and social resources, spirituality and religiosity, relational accord, emotional regulation, emotional expression, and communication.

Instructions*: For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

	Not true at all	Rarely True	Sometimes True	Often True	True nearly all the time
1. I can deal with whatever comes my way	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
2. I am able to adapt to change	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
3. I tend to bounce back after illness or hardship	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
4. When I am confused by a problem, one of the first things I do is survey the situation and consider all the relevant pieces of information	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
5. Before criticizing somebody, I try to imagine how they would feel if I were in their place	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
6. I sometimes find it difficult to see things from another person's point of view	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
7. I often have not comforted another when he or she needed it	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
8. Sometimes when people are talking to me, I find myself wishing that they would leave	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5

For the following questions, please select one answer. If you are unsure, please give the best answer you can. Mark only one answer for each question.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
9. Overall, I expect more good things to happen to me than bad	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
10. I'm always hopeful about my future	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
11. In unclear times, I usually expect the best	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5

MIRM Continued: *Please select the closest answer according to the following scales.*

Select the answer option that you feel is currently the most accurate. The scale runs form Lowest (1) to Highest (10).

	Lowest ……Highest									
12. Where do you think you stand at this time in your life, relative to other people in the United States? (10 = People with most money, education, or most respected jobs)	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
13. In general, how satisfied are you with your finances? (10=Very Satisfied)	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*

	Never	A Little of the Time	Sometimes	Frequently
14. How often do you feel lonely?	|___| 1	|___| 2	|___| 3	|___| 4
15. How often do your spouse, children, close friends, and relatives give you advice or information about medical, financial, or family problems?	|___| 1	|___| 2	|___| 3	|___| 4
16. How often do your spouse, children, close friends, and relatives help with daily tasks like shopping, giving you a ride, or household chores?	|___| 1	|___| 2	|___| 3	|___| 4
17. How often are your spouse, children, close friends, or relatives willing to listen when you need to talk about your worries or problems?	|___| 1	|___| 2	|___| 3	|___| 4
18. How often do your spouse, children, close friends, and relatives make you feel loved and cared for?	|___| 1	|___| 2	|___| 3	|___| 4
19. How often do your spouse, children, close friends, and relatives make too many demands on you?	|___| 1	|___| 2	|___| 3	|___| 4
20. How often are your spouse, children, close friends, and relatives critical of what you do?	|___| 1	|___| 2	|___| 3	|___| 4

	Not at all	Slightly	Moderately	Very
21. To what extent do you consider yourself a religious person?	|___| 1	|___| 2	|___| 3	|___| 4
22. To what extent do you consider yourself a spiritual person?	|___| 1	|___| 2	|___| 3	|___| 4

Revised Multigroup Ethnic Identity Scale (MEIM-R)

Identity is complex, and has been associated with resilience, social support, and health. Cultural, social, and ethnic identities may not be restricted to a single group, but can be fluid, variable, overlapping, or mixed. The MEIM-R includes self-categorization on ethnic identity as well as exploration and commitment to that identity.

Instructions: *Please fill in the blank. If you are unsure, please give the best answer you can.*

1. I consider myself as belonging to _____ race/ethnic group.

Instructions*: For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
2. I have spent time trying to find out more about my ethnic group, such as its history, traditions, and customs	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
3. I have a strong sense of belonging to my own ethnic group	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
4. I understand pretty well what my ethnic group membership means to me	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
5. I have often done things that will help me understand my ethnic group background better	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
6. I have often talked to other people in order to learn more about my ethnic group	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5
7. I feel a strong attachment towards my own ethnic group	|___| 1	|___| 2	|___| 3	|___| 4	|___| 5

Instructions*: Please select all that apply. To remove an answer, fully black out the incorrect answer.*

8. I consider myself and/or my parents as belonging to:

	Yes	No
American Indian	|___|1	|___|0
Alaska Native, First Canadian	|___|1	|___|0
Pacific Islander, Native Hawaiian	|___|1	|___|0
Asian, Asian-American	|___|1	|___|0
Black, African-American	|___|1	|___|0
Hispanic, Latino	|___|1	|___|0
White, Caucasian, European	|___|1	|___|0
Other	|___|1	|___|0

- Other (Specify)

_____

Orthogonal Cultural Identity Scale (OCIS)

The degree of alignment and participation in one's own culture can have potential consequences for resilience and positive healthy aging. The OCIS measures annual family activities, personal and family involvement in traditional culture, and personal and family success in traditional culture.

Instructions*: Mark only one answer for each question. For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

	None	A Few	Some	A Lot
1. Some families have special activities or traditions that take place every year at particular times (holiday parties, special meals, religious activities, trips). How many of these special activities did your family have when you were growing up that were based on *Native American* or *American Indian* culture?	|___| 1	|___| 2	|___| 3	|___| 4
2. In the future, with your own family, will you do special things together or have special traditions that are based on *Native American* or *American Indian* culture?	|___| 1	|___| 2	|___| 3	|___| 4

Please select the option that infers to you.

	Not at All	Not Much	Some	A Lot
3. Does your family live by or follow the *Native American* or *American Indian* way of life?	|___| 1	|___| 2	|___| 3	|___| 4
4. Do you live by or follow the *Native American* or *American Indian* way of life?	|___| 1	|___| 2	|___| 3	|___| 4
5. Is your family a success in the *Native American* or *American Indian* way of life?	|___| 1	|___| 2	|___| 3	|___| 4
6. Are you a success in the *Native American* or *American Indian* way of life?	|___| 1	|___| 2	|___| 3	|___| 4

Reservation

7. Ever lived on the reservation	Yes |___|1	No |___|0
8. Live on the reservation now	Yes |___|1	No |___|0
9. Parents ever lived on reservation	Yes |___|1	No |___|0
10. Parents or family members living on reservation now	Yes |___|1	No |___|0

Please fill in the blanks: (Enter N/A to Q 9-10 if participant never lived on a reservation)

11. Number of years lived on the reservation	
12. Age moved off of the reservation	
13. Recency of last visit to reservation (# of years)	
14. Days spent on reservation in the past year	

OCIS continued: *Please select the best answer by circling the correct answer, as relevant.*

Social

15. Contact with *Native American* or *American Indian* relatives living on the reservation in past year	Yes |___|1	No |___|0	N/A
16. Contact with *Native American* or *American Indian* relatives living outside of the reservation in past year	Yes |___|1	No |___|0	N/A
17. Presence of *Native American* or *American Indian* neighbors	Yes |___|1	No |___|0	N/A

Activities

18. Engage in traditional behaviors in past year (beading, singing, dancing)	Yes |___|1	No |___|0			
19. Frequency of engaging these behaviors in past year (beading, singing, dancing)	*Daily* |___| 1	*Weekly* |___| 2	*Monthly* |___| 3	*Less Often* |___| 4	*NA*
20. Attend traditional activities/events in past year (pow wows, fiestas)	Yes |___|1	No |___|0			
21. Number of these activities/events attended in past year (pow wows, fiestas)	*Daily* |___| 1	*Weekly* |___| 2	*Monthly* |___| 3	*Less Often* |___| 4	*NA*
22. Practiced *Native American* or *American Indian* religion attended in past year (sweat lodge, wake ceremony)	Yes |___|1	No |___|0			
23. Number of *Native American* or *American Indian* religious ceremonies attended in past year (sweat lodge, wake ceremony)	*Daily* |___| 1	*Weekly* |___| 2	*Monthly* |___| 3	*Less Often* |___| 4	*NA*
24. Currently belong to a *Native American* or *American Indian* organization	Yes |___|1	No |___|0			
25. Ever belong to a *Native American* or *American Indian* organization	Yes |___|1	No |___|0			

Rosenberg Self-Esteem Scale (R-SES)

Self-esteem is commonly thought to have significant associations with life, social, and health success***;*** however, these effects can vary widely and may be dependent on degree of social support. The RSES self-worth by measuring both positive and negative feelings about the self, and is believed to be objective and independent.

Instructions*: Mark only one answer for each question. For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

	Strongly agree	Agree	Disagree	Strongly disagree
1. On the whole, I am satisfied with myself	|___| 4	|___| 3	|___| 2	|___| 1
2. At times I think I am no good at all	|___| 1	|___| 2	|___| 3	|___| 4
3. I feel that I have a number of good qualities	|___| 4	|___| 3	|___| 2	|___| 1
4. I am able to do things as well as most other people	|___| 4	|___| 3	|___| 2	|___| 1
5. I feel I do not have much to be proud of	|___| 1	|___| 2	|___| 3	|___| 4
6. I certainly feel useless at times	|___| 1	|___| 2	|___| 3	|___| 4
7. I feel that I'm a person of worth	|___| 4	|___| 3	|___| 2	|___| 1
8. I wish I could have more respect for myself	|___| 1	|___| 2	|___| 3	|___| 4
9. All in all, I am inclined to feel that I am a failure	|___| 1	|___| 2	|___| 3	|___| 4
10. I take a positive attitude toward myself	|___| 4	|___| 3	|___| 2	|___| 1

Social Support and Social Undermining Items (SS/U)

Social support and its reverse—social undermining—are known to be significant factors in health and resilience. Just as with resilience, social support and undermining are complex and may be defined multiple ways. The SS/U scale evaluates emotional (perceived) and instrumental (received) support; critical appraisal; and isolation.

Instructions*: For the following questions, please select one answer. If you are unsure, please give the best answer you can.*

Emotional Support

	Often	Sometimes	Never
1. How much do your friends or relatives really care about you?	|___| 3	|___| 2	|___| 1
2. How much do they understand the way you feel about things?	|___| 3	|___| 2	|___| 1
3. How much do they appreciate you?	|___| 3	|___| 2	|___| 1
4. How much can you rely on them for help if you have a serious problem?	|___| 3	|___| 2	|___| 1
5. How much can you talk to them about your worries?	|___| 3	|___| 2	|___| 1
6. How much can you relax and be yourself around them?	|___| 3	|___| 2	|___| 1

Instrumental Social Support

Among the people you know, is there someone:	Yes	No
1. You can go with to play cards, bingo, a powwow, or a community meeting?	Yes |___|1	No |___|0
2. Who would lend you money if you needed it in an emergency?	Yes |___|1	No |___|0
3. Who would lend you a car or drive you somewhere else if you really needed it?	Yes |___|1	No |___|0
4. You could call who would bail you out if you were arrested and put in jail?	Yes |___|1	No |___|0
5. You could count on to check in on you regularly?	Yes |___|1	No |___|0

Critical Appraisal

	Often	Sometimes	Never
1. How often do your friends or relatives make too many demands on you?	|___| 3	|___| 2	|___| 1
2. How often do they argue with you?	|___| 3	|___| 2	|___| 1
3. How often do they criticize you?	|___| 3	|___| 2	|___| 1
4. How often do they let you down when you are counting on them?	|___| 3	|___| 2	|___| 1
5. How often do they get on your nerves?	|___| 3	|___| 2	|___| 1
6. How often do they drink or use drugs too much?	|___| 3	|___| 2	|___| 1

Isolation

	Very Isolated	Somewhat Isolated	Not very isolated at all
1. How isolated do you feel?	|___| 3	|___| 2	|___| 1
	A lot	Sometimes	Not very much at all
2. How often do you purposely avoid family gatherings?	|___| 3	|___| 2	|___| 1
	Very	Somewhat	Not at all
3. Of those family gatherings you go to, how likely are you to leave early?	|___| 3	|___| 2	|___| 1

Social Network Index (SNI)

Another feature of social support is the size and complexity of a social network. This is important because social effects for people with a large, surface network (lots of casual acquaintances) may be different than those who have a small, deep network (few close friends). The SNI assesses 12 types of social relationships.

***Instructions**: For the following questions, please select one answer. If you are unsure, please give the best answer you can. Enter N/A were appropriate.*

1. *[Marital status from main questionnaire]*

2. How many children do you have? _____

2b. How many of your children do you see or talk to on the phone at least once every 2 weeks? _____

3. Are either of your parents living? |___|1 Mother |___|2 Father |___|3 Both |___|0 Neither

3b. Do you see or talk to either or both of your parents at least once every 2 weeks? Yes |___|1 No |___|0

4. Are either of your in-laws (or partner's parents) living? |___|1 Mother |___|2 Father |___|3 Both |___|0 Neither

4b. Do you see or talk to either or both of your partner's parents at least once every 2 weeks? Yes |___|1 No |___|0

5. How many other relatives (other than your spouse, parents & children) do you feel close to? _____

5b. How many of these relatives do you see or talk to on the phone at least once every 2 weeks? _____

6. How many close friends do you have? _____

6b. How many of these friends do you see or talk to at least once every 2 weeks? _____

7. Do you belong to a church, temple, or other religious group? Yes |___|1 No |___|0

7b. How many members of your church or religious group do you talk to at least once every 2 weeks? _____

8. Do you attend any classes (school, university, adult education) on a regular basis? Yes |___|1 No |___|0

8b. How many fellow students or teachers do you talk to at least once every 2 weeks? _____

9. Are you currently employed either full or part-time? Yes |___|1 No |___|0

9b. How many people do you supervise? _____

9c. How many people at work (other than those you supervise) do you talk to more than once every 2 weeks? _____

10. How many of your neighbors do you see or talk to at least once every 2 weeks? _____

11. Are you currently involved in regular volunteer work? Yes |___|1 No |___|0

11b. How many people involved in this volunteer work do you talk to about volunteering-related issues at least once every 2 weeks? _____

12. Do you belong to any groups where you talk to members about group-related issues at least once every 2 weeks? (Examples: social clubs, recreational groups, trade unions, commercial groups, professional organizations, groups with children like PTA or Boy Scouts, community service groups) Yes |___|1 No |___|0

13. Consider those groups where you talk to a fellow member at least once every 2 weeks. Please provide the following for each: the name or type of group, the number of members that you talk to > once every 2 weeks.

Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____
Group _____ # Members you talk to at least every 2 weeks _____

Functional Activities Questionnaire (FAQ)

Dementia is a clinical syndrome wherein the patient is unable to perform the usual activities of their daily lives, such as preparing balanced meals or managing personal finances. Dementia can be caused by caused by cardiovascular, cerebrovascular, neurodegenerative, or other disease. The Functional Activities Questionnaire (FAQ) measures the ability to perform these instrumental activities of daily living (IADLs).

***Instructions**: Please rate your ability to complete the following daily tasks, according to the following scale. If you **never did** the task or activity, rate **how well you think you would do, if you were to do it now**. For each task or activity, also indicate whether your ability has changed **over the past year**. Mark only one answer for each question. If you are unsure, please give the best answer you can.*

	Normal or Never Did (1)	*Have Difficulty But Can Do By Myself (2)*	*Can Do But Need Assistance (3)*	*Dependent on Others (4)*
1. Write checks, pay bills, balance checkbook	|___|1	|___| *2*	|___| *3*	|___| *4*
2. Assemble business affairs, papers, tax records	|___|1	|___| *2*	|___| *3*	|___| *4*
3. Shop alone for clothes, household necessities, or groceries	|___|1	|___| *2*	|___| *3*	|___| *4*
4. Play a game of skill, work on a hobby	|___|1	|___| *2*	|___| *3*	|___| *4*
5. Heat water, make a cup of coffee, turn off stove after use	|___|1	|___| *2*	|___| *3*	|___| *4*
6. Prepare a balanced meal	|___|1	|___| *2*	|___| *3*	|___| *4*
7. Keep track of current events	|___|1	|___| *2*	|___| *3*	|___| *4*
8. Pay attention to & understand TV, books, magazines	|___|1	|___| *2*	|___| *3*	|___| *4*
9. Remember appointments, family occasions, holidays, medications	|___|1	|___| *2*	|___| *3*	|___| *4*
10. Travel out of neighborhood, drive, arrange to take the bus	|___|1	|___| *2*	|___| *3*	|___| *4*

11. Have any of these abilities declined due to a cognitive or memory problem?	Yes |___|1	No |___|0
12. Are any of these limitations due to a physical limitation such as use of a cane, walker, or wheelchair?	Yes |___|1	No |___|0

The Bristol Stool Chart - A Tool to Track Your Bowel Movement

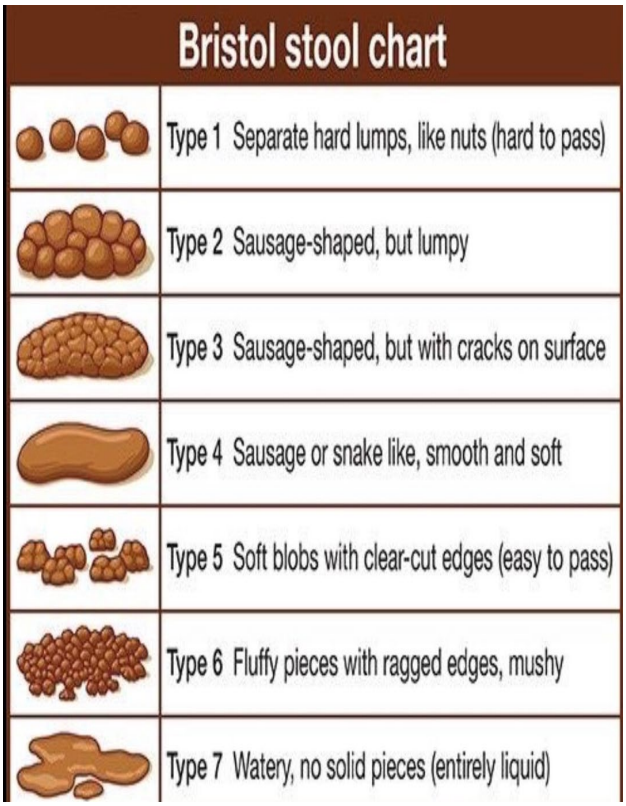
What is the Bristol Stool Chart

The bowel is a part of the digestive system that allows people to absorb nutrients from food and expel the waste that the body cannot use. If feces pass too quickly or too slowly, it may indicate a problem with the bowels.

The Bristol Stool Chart is a quick, inexpensive, and reliable way to assess how long a stool has spent in the bowels. The tool breaks down stools into seven types based on their appearance, ranging from type 1 (hard) to type 7 (loose). The scale was created in 1997 by a team of healthcare providers at the British Royal Infirmary in Bristol, England. Doctors can use the tool as a practical guide to identify problems with bowel movements and know if your bowel movement is healthy. Researchers have also used the chart to identify problematic foods, supplements, digestive health and other lifestyle stressors, and assess how well various treatments work for people with certain GI problems.

Why Stool Type Matters

Why does your type of stool matter? It can help you to identify what is normal and if you are experiencing constipation or diarrhea. It can also help you to describe to your doctor what you are experiencing when you are using the restroom.



Types of Stool and What They Mean

The Bristol Stool Chart classifies stools into seven groups. Types 1-2 indicate constipation. Types 3-5 are considered normal, and types 6-7 indicate diarrhea.

Regular Bowel Movements

So, what is normal? When it comes to your bowel movements everyone seems to have their own normal. We are all unique. But, in general your bowel movements should pass easily and be well formed. You should be using the restroom on a regular basis, and using the restroom should not be a struggle.

When to Speak with a Doctor

If a person is persistently passing stools at either end of the Chart or switching from one end of the scale to the other, it is advisable that they consult with a doctor.

A healthcare professional can help identify the potential cause of the abnormal bowel movements and recommend suitable treatments to allow an individual to pass regular and healthy stools.

Maintaining Good Bowel Health

Maintaining good bowel health typically includes three steps:

- Eating plenty of fiber. Fiber provides bulk to help stool pass
- Drinking enough fluid. Fluids help keep things lubricated and moving
- Being physically active. Physical activity helps to keep the body and bowels healthy.

Bristol Stool Chart

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

Please administer Bristol stool chart questions to participants who have consented to participate in Gut microbiome, aging and cardiometabolic
diseases in American Indians study
Please indicate the type of stool passed by putting a check mark in the appropriate box for each of the 3 days listed below

Date	**Type 1** Separate hard lumps like nuts (hard to pass) 	**Type 2** Sausage shaped but lumpy 	**Type 3** Like a sausage but with cracks on surface 	**Type 4** Like a sausage or snake, smooth and soft 	**Type 5** Soft blobs with clear-cut edges (passed easily) 	**Type 6** Fluffy pieces with ragged edges, a mushy stool 	**Type 7** Watery, no solid pieces (entirely liquid) 
Day 1 (2 days BEFORE stool sample was collected) __ __/__ __/__ __ __ __ Month Day Year							
Day 2 (1 day BEFORE stool sample was collected) __ __/__ __/__ __ __ __ Month Day Year							
The day ON which stool sample was collected __ __/__ __/__ __ __ __ Month Day Year							

Adapted from the Bristol Stool Scale developed by KW Heaton and SJ Lewis at the University of Bristol, 1997

THE STRONG HEART STUDY VII
CHRONIC RESPIRATORY DISEASE STUDY

RESPIRATORY QUESTIONNAIRE

SHS I.D.: |___|___|___|___|___|___| SHS Family I.D: |___|___|___|___|___|___|___|

Participant ID _____

1. a. Do you usually have a cough?
|___| 1=Yes |___| 0=No **(skip to Q 2)**

   b. Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week?
|___|1=Yes |___|0=No

   c. Do you usually cough at all on getting up, or first thing in the morning?
|___|1=Yes |___|0=No

   d. Do you usually cough like this on most days for 3 consecutive months or more during the year?
|___|1=Yes |___|0=No

   e. How long have you had this cough?
_____ year(s) _____month(s)

   f. Do you usually bring up phlegm from your chest when you cough?
|___|1=Yes |___|0=No

2. Does your chest ever sound wheezy or whistling?

a. when you have a cold	|___|1=Yes	|___| 0=No
b. occasionally apart from colds	|___|1=Yes	|___| 0=No **(skip to Q 3)**
c. most days	|___|1=Yes	|___| 0=No
d. most nights	|___|1=Yes	|___| 0=No

3. At any time during the last 12 months, have you had wheezing or whistling in your chest?
|___|1=Yes |___|0=No

4. Have you ever had an attack of wheezing that has made you feel short of breath?
|___|1=Yes |___|0=No

5. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?
|___|1=Yes |___|0=No **(skip to Q 10)** |___|2=Unable to walk **(skip to Q 10)**

6. Do you have to walk slower on the level than people of your age because of breathlessness?
|___|1=Yes |___|0=No

7. Do you ever have to stop for breath when walking at your own pace on the level?
|___|1=Yes |___|0=NO

8. Do you ever have to stop for breath after walking about 100 yards (the length of a football field) or after a few minutes on the level?
|___|1=Yes |___|0=No

9. Are you too breathless to leave the house or breathless on dressing or undressing?
|___|1=Yes |___|0=No

10. Did you have any lung trouble before the age of 16?
|___|1=Yes |___|0=No

11. Have you ever been told you snore?
|___|1=Yes |___|0=No

12. Have you ever been told you have any of the lung diseases?

a. Asthma |___|1=Yes |___|0=No |___| 2=Unknown

If 'Yes' for asthma, do you still have it now? |___|1=Yes |___|0=No |___|2=Unknown

b. COPD (chronic obstructive pulmonary disease) |___|1=Yes |___|0=No |___|2=Unknown

c. Chronic bronchitis |___|1=Yes |___|0=No |___|2=Unknown

d. Emphysema |___|1=Yes |___|0=No |___|2=Unknown

e. Lung fibrosis |___|1=Yes |___|0=No |___|2=Unknown

f. Lung cancer |___| 1=Yes |___|0=No |___|2=Unknown

g. Obstructive sleep apnea |___|1=Yes |___|0=No |___| 2=Unknown

h. Other _____

13. Are you currently on any treatment for above lung disease(s)?
|___|1=Yes |___| 0=No

ADMINISTRATIVE INFORMATION:

14. Interviewer/reviewer code: |___|___|___|

15. Interview/review date: |___|___|/|___|___|/|___|___|___|___|
Month Day Year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CBC RESULTS

SHS I.D.: |___|___|___|___|___|___| SHS Family I.D.:|___|___|___|___|___|___|___|

Each center's results may appear in different order. Please be careful when entering the results.

1. WBC (10^9/L or K/cmm or K/uL) .....|___|___|. |___|___|
2. RBC (10^{12}/L or M/cmm or M/uL).....|___|___|. |___|___|
3. HGB (g/dL).....|___|___|. |___|___|
4. HCT (%).....|___|___|___|. |___|___|
5. MCV (fL) .....|___|___|___|. |___|___|
6. MCH (pg) .....|___|___|. |___|___|
7. MCHC (g/dL).....|___|___|. |___|___|
8. RDW (%).....|___|___|. |___|___|
9. Platelet count (PLT. 109/L or K/cmm or K/uL) ..... |___|___|___|___|. |___|___|
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 (%) .....|___|___|. |___|___|

ADMINISTRATIVE INFORMATION:

16. Did the participant have a CBC? Yes |___|1 No |___|2
17. Completer code: |___|___|___|
18. Completion date: |___|___|/|___|___|/|___|___|___|___|
    Month day year

Laboratory Procedures

Manual of Operations Volume IV

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

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Tracking of Revisions to Manual of Operations Volume IV: Laboratory Procedures

Date of Revision	Revised Section	Revision	Approved by, Date
5/3/2023	Entire document	Fixed formatting issues	SHS CC, 11/1/2022

Table of Contents

IV. Laboratory Procedures

1. General Precautions for Handling of Blood

Lab testing in research is important. Your work brings new and important information to the scientific and medical community. The special equipment and skills such as attention to detail, organization and phlebotomy are critical to the success of this project. Your work on this project will probably expose you to a variety of potentially hazardous situations. The following learning modules are designed to help you keep safe on the job.

Each site should have at least one staff member who will be actively involved in this process attend the initial training session. This person, in turn will be responsible for training additional personnel at his/her facility. The training session will cover all procedures related to supplies, equipment, and preparation of log sheets, labeling, collection, processing, storage, packing and shipping of specimens.

Throughout the study, a qualified observer should regularly monitor and evaluate the work of those involved in the collection and processing of blood samples. Specific plans should be made to train new staff members at each facility. Training should include a detailed review of the Strong Heart Study laboratory manual as well as supervised practice in the application of the techniques required by the protocol.

This section will provide knowledge to protect you and others. In addition to these instructions, use commonsense on the job every day.

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don’t take chances
- Don’t operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
- Avoid direct contact with blood, serum or plasma. Cover any scratches or cuts on fingers and hands very carefully and use gloves in the handling of specimens.

All tubes, containers and other materials exposed to blood must be disposed of in appropriately labeled waste receptacles for biohazardous materials

- When removing stoppers from vacutainers, use a splash shield to prevent droplets from spraying onto your skin or eyes.
- All samples should be stored in sealed containers or tubes.
- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.

- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.
- Avoid working alone
- Post important phone numbers and emergency numbers prominently
- Know before an accident where to go and what to do
- Know the location of safety showers, eye washes and fire extinguishers

1.1 Safety Precautions

This section will provide knowledge to protect you and others, as well as demonstrate common procedures that will be used on the job every day.

Safety guidelines:

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don’t take chances
- Don’t operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
- Avoid direct contact with blood, sera or plasma. Cover any scratches or cuts on fingers and hands very carefully and use gloves in the handling of specimens.
- All tubes, containers and other materials exposed to blood must be disposed of in appropriately labeled waste receptacles for biohazardous materials.
- When removing stoppers from vacutainers, use a splash shield to prevent droplets from spraying onto your skin or eyes.
- All samples should be stored in sealed containers or tubes.
- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.
- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.

Emergencies can happen, so be prepared:

- Avoid working alone
- Post important phone numbers and emergency numbers prominently
- Know before an accident where to go and what to do
- Know the location of safety showers, eye washes and fire extinguishers

Equipment Precautions:

- **Glassware** like vacutainers can break, causing chemical and cut hazards. Some of the chemicals contained in the vacutainers are EDTA and heparin. Although serious hazards are unlikely if exposed, still follow procedures if an accident occurs. To avoid contact, use the right type of glassware for each job, and discard chipped or cracked vacutainers in an approved receptacle. Don't force anything made of glass.
- **Electrical equipment** always carries the potential of shock or fire. Don't touch it with wet hands or while standing on a wet floor. Report any shocks, and don't attempt to do repairs if you haven't been trained.
- **Centrifuges** and other equipment with moving parts can catch your clothing or open up suddenly, showering you with dangerous material. Keep clothing or long hair away from them. Make sure the load is balanced, the top is locked down, and the equipment has stopped before you open it.

1.2 Personal Protective Equipment

This module will include information on proper use of protective clothing and first-aid instructions.

Let protective equipment work for you.

For this aspect of the study, always use assigned protective clothing and equipment. Always check that it is in good condition before putting it on. For this study the following are required:

- **Goggles or side shield safety glasses** to protect against splashes or flying objects are required any time you are working with specimens or performing phlebotomy.
- **Gloves** must be worn to protect against any chemicals or exposure to samples
- **Long sleeves** are required to the length of your wrist and meet the glove.
- **Lab coats** must be full length and fully buttoned down the front.
- **Sturdy closed toed shoes** are required to cover your feet in case of spills or accidents

If you are exposed to a hazardous substance or samples, take the following actions:

- **Eyes:** Flush with water for 15 minutes.
- **Ingestion:** Follow labels and MSDS instructions MSDS is an abbreviation for Materials Safety Data Sheet and is available from the manufacturer for every chemical produced.
- **Skin Contact:** If limited to a small area of the body such as the hands, remove any contaminated gloves or clothing and wash with copious amounts of water. If there is greater exposure, stand under emergency shower and remove contaminated clothing immediately.
- **Inhalation:** Get to fresh air and get prompt medical attention.

You should check with your supervisor for specific instructions at your institution prior to an accident.

1.3 Preventing Exposure to Blood Borne Pathogens

Your chance of being directly exposed to bloodborne pathogens on the job is small. But keeping exposure minimal can only succeed if staff members use the tools to protect themselves on the job.

Universal Precautions are your best protection against any risk to exposure. This means all staff must treat all blood, urine, and other potentially infectious body fluids as if they are infected.

ALL SPECIMENS SHOULD BE REGARDED AS POTENTIALLY HAZARDOUS.

DO:

- Wash hands and exposed skin with soap and water immediately after exposure to infectious materials or after taking off gloves or other personal protective equipment.
- Use antiseptic or cleansers or towelettes only if washing facilities aren't available.
- Minimize splashing, spraying, or spattering of blood or other potentially infectious materials.
- Place contaminated sharps in assigned labeled, puncture-resistant, leak-proof containers.

DON'T:

- Don't shear or break contaminated needles or other sharps, and don't bend, recap, or remove unless specifically instructed.
- Don't keep food, drink, medication or makeup in work areas with exposure potential.
- Don't eat, drink, smoke apply cosmetics or lip balm, or handle contact lenses in work areas with exposure potential.
- Don't pipette or suction anything by mouth.

Protective Clothing:

- ***BEFORE you*** put on protective clothing, make sure it's in good condition. Don't wear anything that's damaged or does not fit properly.
- ***AFTER tasks*** in the area are completed, remove all protective clothing before leaving that area. Remove protective clothing in such a manner as to minimize exposure and avoid contamination. Place protective clothing in a specially assigned area or container for decontamination, washing, storage or disposal.

Housekeeping:

- Written procedures and a cleaning schedule help keep the workplace free of infection.

Cover equipment and surfaces with plastic wrap, aluminum foil, or impervious absorbent paper. Remove and replace covering that is, or may be, contaminated.

1.4 Proper Labeling

Proper labeling of containers for regulated waste must be labeled with fluorescent orange or orange-red biohazard warning labels.

Examples in the clinical area or lab are: refrigerators and freezers containing blood and other potentially infectious materials and other containers used to store, transport or ship blood and other potentially infectious materials

Biohazard labels **ARE** required for the following:

- waste containers used for disposal of contaminated needles
- refrigerator or freezer holding blood or other potentially infectious material
- individual specimen containers for storage or shipment zip-lok biohazard bags

Biohazard labels **ARE NOT** required for the following:

- when red bags or red containers are used
- on individual containers or blood of other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal

The risk of exposure is very small and most encounters with an HIV or HBV carrier poses no risk. AIDS and Hepatitis B can be transmitted through:

- Sexual contact
- Shared needles
- Needlestick injuries from infected needles or sharps
- Direct contact between broken or chaffed skin and infected body fluids.
- Hepatitis B can also be transmitted through dried blood and contaminated surfaces.

Neither AIDS (HIV) nor Hepatitis B are transmitted by:

- Coughing or sneezing
- Touching an infected person
- By using the same equipment, materials, toilets, showers, or water fountains.

Be safe!!! Your employer must make available, free of charge or at a reasonable time and place, the hepatitis B vaccine and vaccination series to all employees at risk. Any booster doses recommended by the US Public Health Service also must be provided. You are not required to participate in a prescreening program to receive the vaccine series. Also, the vaccine can be available at a later time if initially declined. If you choose to not receive the vaccine, your facility will ask you to complete and sign a form stating your refusal. This is required by law.

If you are directly exposed, REPORT IT IMMEDIATELY!!!

An exposure incident is specific to eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. A common example of exposure would be a puncture from a used needle.

If exposed, you should contact your supervisor immediately. This allows for timely medical evaluation and follow up as well as for timely testing of the source. Your facility will provide immediate, confidential assistance and medical evaluation, including a blood test. All information will be treated with the strictest of confidence.

2. Sample Collection Instructions

Personnel involved in sample collection should be highly experienced with vacutainer and butterfly blood collections, and be prepared to handle common problems, such as difficult blood collection and situations such as fainting. The phlebotomist should also be familiar with precautions to avoid exposing themselves to blood and be trained in the following:

- Ideally staff will have cardiopulmonary resuscitation (CPR) certification.
- It is suggested that they read "Collection and Handling of Laboratory Specimens: A Practical Guide"[1] or a similar phlebotomy manual.
- Personnel should wear clean white lab coats (with no blood stains) and maintain a neat appearance. Lab coats will be full length, with long sleeves. Lab coats will be buttoned closed down the full length of the coat.
- Personnel will wear protective eyewear. Safety glasses are required when performing phlebotomy, processing specimens and preparing samples for storage and/or shipment.
- Staff should wear nametags and introduce themselves (if necessary) before a blood draw.
- Long hair and bangs should be pulled back.
- Phlebotomists and assistants should not chew gum or have any food in their mouths during blood draws. Food and drink must never be brought into areas used for blood drawing or processing. Staff will attempt no more than three venipunctures on the same subject. After three failed attempts, another person will be asked to try.

2.1 Sample Collection Facilities

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.

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
- 2x2 sterile gauze pads
- band aids
- adhesive tape
- urine collection cups
- disposable latex gloves

[1] Slockbower, J.M., and Blumenfeld, T.A., (Eds.). Collection and Handling of Laboratory Specimens: A Practical Guide. Philadelphia: J.B. Lippincott Company, 1983.

- ammonia inhalants
- paper cups
- emesis basin
- tourniquets
- biohazard labels
- biohazard needle disposal boxes
- biohazard bags
- Tube racks or supports
- Waterproof marking pen
- Refrigerator
- Centrifuge
- -70ºC Freezer (or lower temperature Freezer than -70ºC)

2.2 Sample Collection and Processing

2.2.1 Sample Collection and Laboratory Requisition Form

Clinic personnel should carefully review the description of collection requirements to ensure that specimens are collected in the proper order and use the proper technique. Each clinic should set up a blood collection and blood processing notebook or a laboratory logbook in advance. It should be located in the blood collection/processing area. This should be a hardbound notebook from which pages cannot be easily removed. Pages should have columns headed for date, visit number, participant name and ID, barcode labels, redraw labels and room to write "comments" about any problems with blood draws or processing, including hemolysis of samples, etc.

In addition to the logs for the clinical area, it will be necessary to complete a laboratory requisition form for each subject (see example of this PARTICIPANT SAMPLE FORM in **Appendix 4** below). The completed requisition form should include the following:

- SHS ID
- Collection Date
- Under left column marked “write the number of samples sent” record the actual number of samples sent.

After proper completion of requisition form, affix barcode label to both copies of the form and one label in the laboratory log book.

If sample collection is a redraw, indicate “yes” in the Redraw box on a new requisition form and take the following steps:

- Affix original barcode label to both copies of the requisition form
- Affix redraw barcode label to both copies of the requisition form
- Place redraw label by the appropriate participant ID in laboratory log book

2.2.2 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.

Pre-numbered and bar-coded labels will be provided to the study sites. Take care to select the correct number depending on whether the samples are being collected from the participant as a QA sample or for a Courtesy visit.

To properly label vacutainers and shipping vials, the white section of the label must be applied (first) to the tube laterally with the clear end wrapped over the white section of the label after the label is wrapped around the tube.

2.3 Venipuncture Procedure

2.3.1 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.

2.3.2 Difficult Venipunctures:

There will be several common situations in which vascular access may be difficult. These will include but are not limited to the following:

- Palpated vein feels small or rolls.
- Excess subcutaneous tissue and fat lies over veins.
- Participant complains of being stuck more than once on a previous visit (no single staff person will attempt more than three venipunctures on a single participant at a single clinic visit) or has had a bad experience elsewhere.
- Participant has been stuck once already and none of the usual veins are palpable.

All reasonable efforts should be made to collect a blood sample, including use of a 23-gauge needle if that is the only means available to obtain a sample, e.g., in the case of a child or elderly person. If the participant experiences any of the above problems, and is agreeable to a repeat attempt, you may try the following procedure:

- Check back of hand and forearm for venipuncture sites with larger veins.
- Attempt one or more vein dilation methods:
    - Hot pack venipuncture site with a warm, wet towel or apply heating pad for 3-5 minutes.
    - Have participant hold hand in warm water for 3-5 minutes.
    - Have participant dangle arm at side with tourniquet in place for one minute.
    - Use blood pressure cuff as a tourniquet by pumping pressure to 60-80 mm Hg.
    - Be sure room is not too cool.

2.3.3 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 was consumed. If subject is not fasting, record time and note in comment section what foods or beverages were consumed that morning. Be sure to include any additives like cream, sugar, or artificial sweeteners if a beverage was consumed. Regardless of fasting state, proceed with drawing procedure.

3. Inform the participant about the procedure. Explain the procedure to the participant, e.g., "I will be drawing a blood sample from your arm today. You will probably feel a small prick when I insert the needle."

4. Assemble all materials; have extra tubes within reach.

5. Blood samples will be collected from Strong Heart Study participants using conventional vascular access with a multi-draw Vacutainer (butterfly) needle and collection of the blood sample into Vacutainer tubes.

6. The antecubital site of the left arm will be used as the first choice for venipuncture. The median cubital vein is the one most frequently used. If the venipuncture of this vein is unsuccessful, the cephalic and basilic may be the next appropriate choice, followed by veins on the back of the hand. For known mastectomy participants, avoid use of an arm where there was axillary lymph node dissection.

7. Be sure all necessary supplies and equipment are available and set up in advance. Note visit type and type of Vacutainer tubes required. Label tubes with participant ID# and date and time of collection. Complete all lab forms before specimen collection. Ensure that all necessary equipment is functioning properly.

8. Be sure a full-length lab coat is worn and buttoned. Wash hands and put on protective gloves.

9. Fit luer adapter needle at end of collection set into Vacutainer sleeve and place the first collection tube into sleeve/hub.

10. Position participant's arm on the drawing table. Extend the arm toward you, palm up.

11. Apply tourniquet 3 inches above a venipuncture site. If it is necessary to apply a tourniquet for preliminary vein selection, release it for two minutes and reapply immediately before entering the vein.

    If no radial pulse can be felt, the tourniquet is too tight. Tourniquet must not be in place for 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 multi-draw 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:
    1. Move the needle slightly in or out.
    2. Rotate needle slightly or lift needle to move bevel away from the wall of the vein.
    3. Try another tube.
    4. Loosen tourniquet; blood flow may be impeded if tourniquet is too tight.
    5. Be sure to watch for signs of hematoma or swelling from the vein. If there is any indication of hematoma or swelling, immediately remove tourniquet and needle. Place 2x2 gauze over the site, and apply pressure and/or ice pack on site for 5 minutes. If the first attempt to obtain blood is unsuccessful (with the subject's permission) try again on the opposite arm. **The same technician should not attempt a venipuncture more than three times.**

17. When first tube is filled, remove tube and replace with the next tube. Invert all filled tubes **except SST tubes** 8-10 times and place on ice. **DO NOT** place SST tube on ice.

18. Proceed with collection of tubes in this order. Label all tubes:
    Fasting:
    1. (3) Red top (SST) tubes
    2. (1) Light Blue top (Citrate) tubes
    3. (1) Gray top (Sodium fluoride) tubes
    4. (4) Lavender top (EDTA) tubes
    5. (2) PAXgene RNA tubes (last tubes collected)

19. After drawing the last tube, remove the tourniquet. Use clean gauze to apply slight pressure to arm and withdraw needle, then immediately apply pressure to site. Apply gentle pressure to the site.

20. Request participant apply pressure at site for 3-5 minutes while leaving the arm straight at the elbow. This is more important than elevating the arm or bending the elbow, which some participants might do automatically.

21. Confirm that bleeding has stopped, and apply a pressure bandage at venipuncture site. If bleeding has not stopped, elevate arm and continue to apply pressure until it stops.

22. Check preprinted labels and tubes, making sure the ID# and tube designations are correct.

23. Dispose of entire needle set-up into a proper biohazard disposal container. *Never try to re-cap a needle since this puts you at risk for a needle puncture.*

24. Check site. If blood oozes from the site, have the participant apply pressure to the site 1-2 minutes longer or as long as is necessary, elevating arm above head. Apply Band-Aid.

25. Give the participant labeled urine specimen cup and instruct him to void into the container. Inform him/ her where to leave the container.

26. Remove gloves, wash hands, and proceed to next participant.

Realize that the participant might be disoriented, embarrassed, or irritable and may need additional attention. Recognize also that this incident will have an impact on future blood drawing, and possible adherence through the study, and must be handled with reassurance. Make a note in the participant's file so that clinic staff will be aware of the situation in the future.

Finish venipuncture following procedures outlined above, if possible. If multiple attempts at venipuncture are unsuccessful, do not reschedule the participant unless both the technician and the participant agree that this is an unusual situation and that there is a high probability of obtaining a sample on the first try at another visit.

Note: If sample is not collected, try to reschedule the visit especially if the technician and participant agree that this is an unusual situation and that is not likely to occur again. If participant does not wish to reschedule, indicate in the comment section on the visit form that the samples were not collected

2.3.4 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

2.4 Urine Sample Collection

Containers for routine collection should be clean and hold about 50 ml in volume and must have a tight-fitting lid. The participant's privacy should be assured and a clean bathroom available.

- Instruct the participant to perform the following steps:
- Remove cap from the labeled container before beginning urination
- Void directly into toilet and after stream is steady, pause.
- Begin stream again and fill approximately half of the cup.
- Finish urinating, firmly place cap on container and return sample to the study person.

Flow charts summarizing processing procedures are in Appendix 1.

2.5 Sample Collection Instructions

Table 1: General Instructions for Sample Processing of Blood & Urine Samples

Collection Tubes	Specifications
3 10ml SST * Lipids and Serum Storage	1. Let stand at room temperature for 30 minutes so blood can clot. If samples cannot be processed within the hour, refrigerate sample or place on ice. 2. Centrifuge at 3000 rpm (1000xG) for 10 minutes. 3. Place approximately 0.3 ml of serum sample in each of the appropriate 2ml-cryovials and label.
1 4.5ml Lt blue ** Na Citrate Plasma Storage	*1. This vacutainer must be allowed to fill completely with blood at the time of collection.* 2. After collection gently invert 8-10 times. Place on ice or refrigerate immediately. 3. Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. 4. Place approximately 0.5 ml of plasma sample in each of the appropriate 2ml- cryovials and label.
1 4ml Gray *** Fasting Glucose and NaFl Plasma Storage	1. After collection gently invert 8-10 times. Place on ice or refrigerate immediately. 2. Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. 3. Place approximately 0.5 ml of plasma sample in each of the appropriate 2ml-cryovials and label.
3 10 ml Purple HemoglobinA1c DNA Isolation EDTA Plasma Storage **1** 4 ml **P**urple for CBC at local lab	1. After collection, gently invert 8-10 times, place on ice or refrigerate immediately. 2. Tube #1: Prior to centrifuging, mix well and pipette approximately 0.5 ml of whole blood and place in each appropriate 2-ml cryovial and label. Re-cap tube #1. 3. All three tubes: Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. First, place approximately 0.5 ml of plasma sample in each of the appropriate 2-ml cryovials and label. Then, remove the buffy coat using the *purple top tube buffy coat isolation protocol* as follows: **Buffy Coat:** 1. After plasma has been removed, there should be about 1/8th inch of plasma remaining on top of the buffy coat. 2. With either a glass or plastic pipette, place the tip of the pipette at the bottom of the small plasma layer just *slightly above* the buffy coat. Also, rest the pipette against the glass inside edge of the vacutainer tube. 3. Slowly draw up the buffy coat by moving the pipette in a circular motion around the inside of the vacutainer. 4. Remove all of the buffy coat from one tube and place in a 2.0 ml cryovial (orange cap). 5. Cap cryovial firmly, apply label. 6. With each tube repeat steps 1-4 using a different pipette for each tube. Use a new clean pipet for each tube. Do not mix the buffy coats between cryovials, ie only one buffy coat from one tube per cryovial.

*If the 10 ml SST collection tube is not available, use 4 x 8.5 ml SST and place 0.3 ml serum in each cryovial. Or using 3 x 8,5 ml for collection, but place 0.25 ml serum in each cryovial.
** For 1 x 4.5ml Lt blue collection, place 0.3 – 0.5 ml Cit Na plasma in each cryovial.
*** For 1 x 4ml Gray collection, place 0.3 – 0.5 ml NaFl plasma in each cryovial.

Table 1 Continued: General Instructions for Sample Processing of Blood & Urine Samples

Collection Tubes	Specifications
2 10ml PAXgene RNA tubes (2.5 ml blood + 7.5 ml RNA stabilizer) RNA	PAXgene RNA tubes to collect whole blood directly into an RNA preservative are labeled ending in RN1 and RN2. Follow these instructions: • A blood collection set with a catheter (i.e. blood collection kit) connecting the needle to the tube holder must be used to prevent backflow of the preservative into the vein. • Collection: 1. Using standard blood draw procedures, fill all other tubes to be collected – the PAX tube should be the last tube collected (this ensures that the interior volume of the blood collection set is properly primed so that the full volume is drawn). 2. Keep donor's arm in a downward position. 3. Hold tube in a **vertical position** below the donor's arm during collection. 4. Release tourniquet as soon as blood starts to flow into the tube. 5. Make sure that the additives in the tube do not touch the stopper or end of the needle during venipuncture. 6. Allow at least **10 seconds** for a complete blood draw to take place. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The PAX tube with its vacuum is designed to draw 2.5ml of blood into the tube. 7. Ensure the tube is properly **filled to capacity** is essential. Underfilling leads to an incorrect blood-to-additive ratio that can bias the analytical results. • Processing and Storage: 1. Immediately after collection, gently invert the PAX tube **10 times** to fully mix the blood with the additives. Stand tube upright in a rack. 2. Keep tubes at controlled room temperature (18-25°C) for at least two hours to allow the reagent to fully react with the blood. Tubes can be kept at room temperature overnight if that is convenient. 3. Keep the tubes away from sunlight or strong light source. If prolonged exposure to strong light is unavoidable, cover with aluminum foil. 4. Transfer the tubes to the designated cardboard collection box for storage at -80oC. 5. Storage boxes must be taller than the PAXgene tubes to keep pressure off the tops of the tubes when stacking in the freezer.

Table 1 Continued: General Instructions for Sample Processing of Blood & Urine Samples

Collection Tubes	Specifications
1 cup Random Urine Creatinine & Albumin Urine Storage	1. Do not centrifuge. 2. After collection, place on ice or refrigerate immediately. 3. Mix gently by swirling, and then transfer to cryovials using pipette. 4. Place 1 ml of urine sample in each of the appropriate 2-ml cryovials and label.

Table 2: Collection and Storage and Instructions

Collection Tubes	Test	Sample Type	Storage/Shipping Requirement	Cryovial Type
3 10 ml SST (red/gray tiger top)	Lipids Storage	Serum	Frozen	**40** 2 ml-red cap vial
1 4.5 ml Lt blue	Storage	Na Citrate Plasma	Frozen	**4** 2 ml-blue cap vial
1 4.0 ml Gray	Fasting glucose Storage	NaFl Plasma	Frozen	**4** 2 ml-black cap vial
3 10 ml Purple	HemoglobinA1c DNA Isolation EDTA Storage	Whole Blood Buffy coat EDTA Plasma	Frozen Frozen Frozen	**4** 2 ml-neutral cap vial **2** 2 ml-orange cap vial **16** 2 ml-purple cap vial
1 4ml Purple for CBC at local lab	**CBC**	Whole Blood	Fresh	**1** 4ml Purple top
2 10 ml PAXgene RNA tubes	RNA	PAX Blood	Frozen	**2** 10 ml-PAXgene RNA tube
1 cup Random Urine	Albumin/Creatinine Storage	Urine	Frozen	**10** 2 ml-yellow cap vial

Table 3: QA Collection Instructions

Collection Tubes	Test	Sample Type	Storage/Shipping Requirement	Cryovial Type
1 10 ml SST	Lipids	Serum	Frozen	**4** 2 ml-red cap vial
1 4 ml Gray	Fasting glucose	NaFl Plasma	Frozen	**2** 2 ml-black cap vial
1 4 ml Purple	HemoglobinA1c	Whole Blood	Frozen	**2** 2 ml-neutral cap vial
1 cup Random Urine	Albumin/Creatinine	Urine	Frozen	**2** 2 ml-yellow cap vial

2.6 Quality Assurance Sample Collection

As part of the Quality Assurance process of this study, there is a need to assure that all the steps from the time that blood is collected to the time that results are reported are correct. To accomplish this, replication of unknown samples will be necessary by performing blind duplicate testing of samples. Blind duplicate samples, otherwise known as quality assurance (QA) samples, will be obtained from participants as follows:

1. Collect blind duplicate samples at a frequency of every 20th participant.

2. Collect blind duplicate samples only for the tests listed in **Table 3** above.

3. In order to label the blind duplicate samples, the Coordinating Center created a set of blinded IDs that were sent to each field center. This list should not be made available to the Core Laboratory.

2.6.1 Processing and Shipping QA samples

These samples should be treated the same as the regular participant samples and be included in regular shipments with the participant and courtesy samples. DO NOT note the corresponding (regular) participant number anywhere on the form to go to the lab.

3. Sample Storage and Shipment

3.1 Equipment Maintenance

3.1.1 Proper maintenance of equipment

The proper care of equipment promotes the life of any piece of equipment and will reduce the possibility of downtime while waiting for repair. Included in the proper maintenance of equipment is the requirement of taking temperatures of refrigerators and freezers.

3.1.2 Refrigerators and Freezers

Storage requirements for samples include keeping samples at the proper temperature until samples are shipped. Never store samples in a self-defrost freezer. At each site, there should be a temperature log to record the temperatures of the room, all refrigerators and all freezers that hold samples. By recording and evaluating temperatures each day, you will see temperature fluctuation that is a signal that some part is not working properly and downtime is inevitable. It is also advisable to locate a maintenance/repair company that services your unit in the area before a problem is experienced. If temperatures begin to fluctuate, the repair service should be called in to evaluate the problem. It may be a simple repair like a door seal or it may require ordering a part. In any case, detecting the problem early will give you time to have the repair done while still maintaining samples at proper temperatures. In addition to recording temperatures, all refrigerators and freezers require routine maintenance. Follow manufacturer guidelines.

3.1.3 Centrifuges

Like refrigerators and freezers, there are many makes and models of centrifuges. Follow manufacturer guidelines for the care of your centrifuge. In addition, locate a service company that can do the maintenance and repairs. Find this company before a problem occurs. In addition, once a month the inside bowl of the centrifuge should be cleaned with a disinfectant. Always wear gloves, safety glasses and a lab coat when performing this task.

3.2 Storage Requirements

One important precaution which should always be kept in mind when handling samples is that all blood, **except for the SST tube,** should be cooled (either in the refrigerator or on ice) as soon as the samples are collected. They should be kept cold until processing is complete and samples are properly stored. After the SST tube is completely clotted (20-30 minutes) it should also be kept cool if it cannot be processed within the hour. Plasma should be separated from the cells within the hour. Plasma samples should not be allowed to freeze and thaw during any of the handling steps.

3.3 Shipping Instructions

Table 4: Shipping Instructions for All Visit Types (Participant, QA)

Collection Tubes	Test	Sample Type	Shipping to	Cryovial Type
3 10 ml SST (red/gray tiger top)	Lipids Storage	Serum	Frozen, to PML	**40** 2 ml-red cap vial
1 4.5 ml Lt blue	Storage	Na Citrate Plasma	Frozen, to PML	**4** 2 ml-blue cap vial
1 4.0 ml Gray	Fasting glucose Storage	NaFl Plasma	Frozen, to PML	**4** 2 ml-black cap vial
3 10 ml Purple	HemoglobinA1c DNA Isolation EDTA Storage	Whole Blood Buffy coat EDTA Plasma	Frozen, to PML Frozen, to PML Frozen, to PML	**4** 2 ml-neutral cap vial **2** 2 ml-orange cap vial **16** 2 ml-purple cap vial
1 4ml Purple for CBC at local lab	CBC	Whole Blood	Fresh, to local Lab	**1** 4ml Purple top
2 10 ml PAXgene RNA tubes	RNA	PAX Blood	Frozen, One to Columbia U, and one to PML	**2** 10 ml-PAXgene RNA tube
1 cup Random Urine	Albumin/Creatinine Storage	Urine	Frozen, to PML	**10** 2 ml-yellow cap vial

PML = Penn Medical Laboratory

The SHS7 sample shipment from the field to the Central lab is by the batch and splitting samples.

3.4 Supplies Required for Shipping

3.4.1 Frozen Samples:

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- FedEx Shipping Labels
- Biohazard bags
- Dry Ice
- Paper Towels for wrapping Storage Boxes
- Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
- 3/4" Scotch Brand Filament Tape

Note: 20 lbs of dry ice gives some insurance against thawing if the package is delayed a few hours.

3.4.2 Preparation of Samples for Shipment to Penn Medical Lab:

- Study laboratory requisitions stapled to extra unused labels for each set of samples must accompany each shipment.
- Each is printed on two-part carbonless form.
- Keep the last copy for your records and send the original with the samples.
- When your shipment is received, lab technicians at each laboratory will perform an inventory to be certain that all samples in the box correspond to those indicated on the shipping log. If the lab finds any discrepancies, they will call you to ask for your assistance in identifying extra samples or find lost samples.

3.4.3 • Packing Shipping Containers

All samples are to be packed according to DOT regulations and in compliance with shipper's requirements. This includes the following:

- Label the exterior of all shipping boxes according to the shipper's requirements. Boxes must have dry ice labels with the amount of dry ice marked on the label and orange-red labels with "Perishable" printed.

- Place approximately 20 pounds of dry ice at the bottom of the shipping box.

- Place packing material (i.e., chux, Styrofoam "peanuts" or newspaper) on top of dry ice.

- Place samples in biohazard bags with forms in pocket of bag on top of packing.

- Check all of the specimens in the box against the Shipping Log Form to be sure there are no transcription errors or missing specimens.

- Add more packing material if there is additional space so samples cannot bounce around the box while in shipment.

- Place "Class 9" (dry ice) labels on the outside of the cardboard shipping carton and record the amount enclosed.

- Place polyfoam lid on box.

- Close cardboard lids.

- With ¾" tape secure the cardboard lid closed.

- Prepare FedEx air bill.

- Samples will be shipped by priority air so that they arrive at the laboratory *WITHIN 24 HOURS*. ONLY SHIP SAMPLES MONDAY through WEDNESDAY.

- Retain a copy of the air bill as a receipt for tracking and auditing purposes.

- The day of shipment, email the laboratory to inform them that a package is being sent. Please give the following information:
  - Date samples will be shipped
  - The name of the person responsible for shipping the package and a phone number where the call can be returned if needed
  - Number of shipping boxes sent
  - FedEx tracking number

3.5 Contact Information

This information will allow the lab to track the package quickly if it does not arrive as planned.

If you have any question regarding samples or shipment to Penn Medical Lab:

Nima Nur, Nima,Nur@medstar.net
Phone: 301-560-2957
Fax: 301-560-7325

Shipping/Receiving Dept: Phone: 301-560-2957

Technical Area: Phone: 301-560-2957

3.6 Holiday Schedule

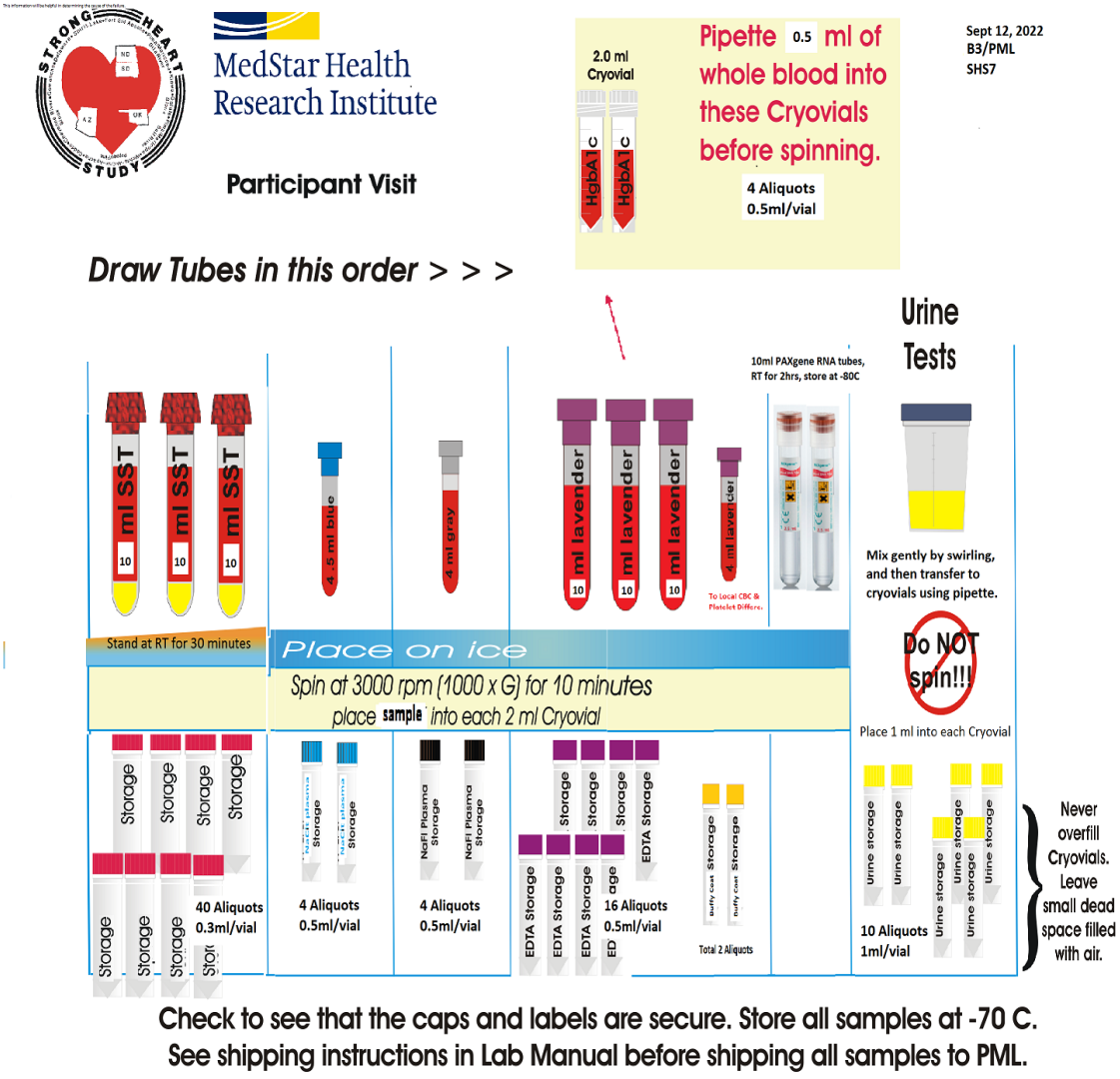
Penn Medical Laboratory is closed on the following holidays:

New Year's Day
ML King Day
Memorial Day
Independence Day
Labor Day
Thanksgiving
Christmas Day

Appendices

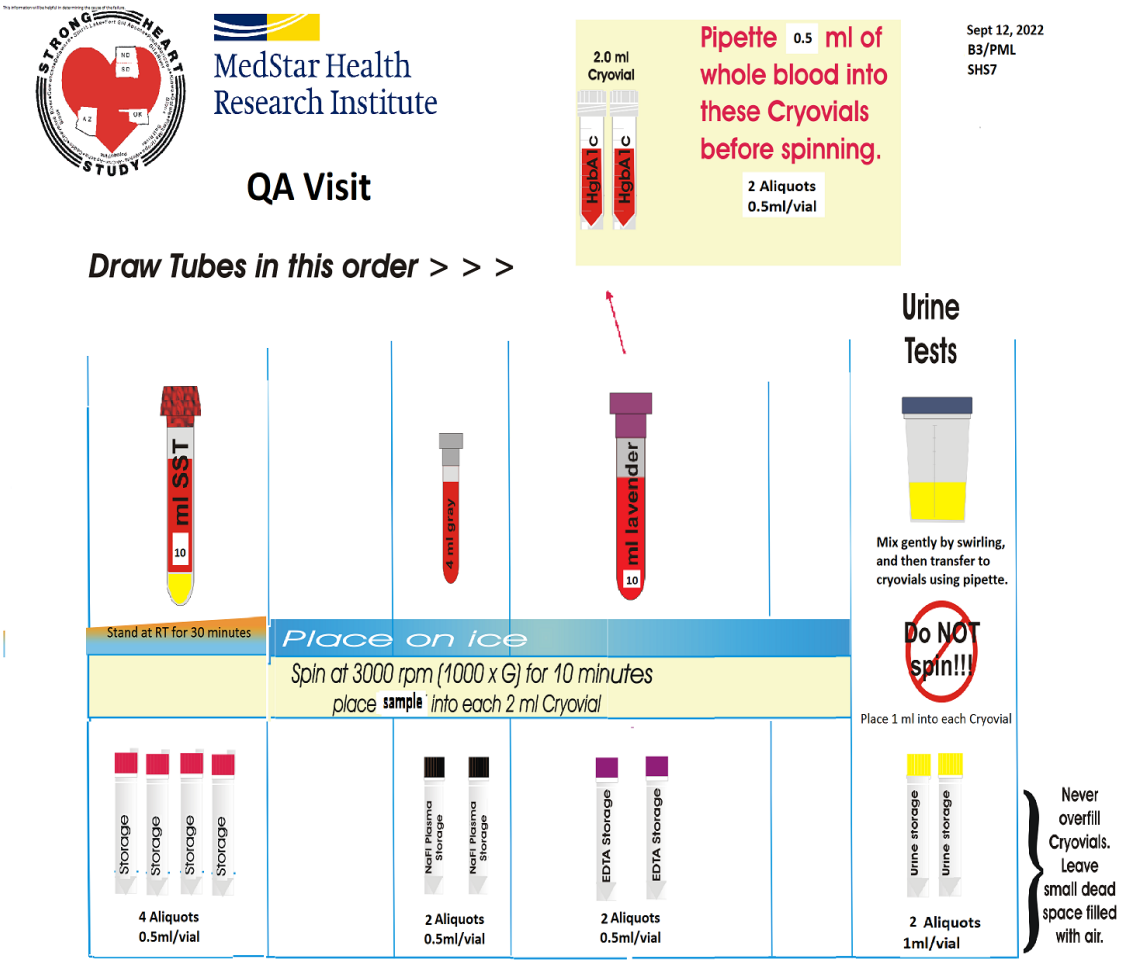
Appendix 1 Processing Procedures

A1.1 SHS Phase VII Examination



Check to see that the caps and labels are secure. Store all samples at -70 C.
See shipping instructions in Lab Manual before shipping all samples to PML.

A1.2 SHS Phase VII QC/QA Visit



Check to see that the caps and labels are secure. Store all samples at -70 C.
See shipping instructions in Lab Manual before shipping all samples to PML.

Appendix 2 Strong Heart Study DNA and Sample Storage Policy and Procedures

Presented by the SHS Ethics Committee
and adopted by the SHS Steering Committee
New York City
February 14, 2002

1. Objectives

Penn Medical Laboratory (Maryland) is the custodian for plasma, serum, and urine samples of participants in all phases of the Strong Heart Study. Southwest Foundation for Biomedical Research (San Antonio, Texas) is the custodian for DNA samples. Henceforth the term "PML/SWF" will refer to the respective laboratories with regard to either blood or urine derived samples (Penn Medical Laboratory) or DNA samples (Southwest Foundation for Biomedical Research). PML/SWF are charged with inventory and safe storage of these samples under optimal conditions to insure stability of analytes. PML/SWF cannot release these samples unless directed by the Strong Heart Study Steering Committee and under current guidelines of the Indian Health Service, National Heart Lung and Blood Institute and all relevant Institutional Review Boards (Human Use). Samples can be released to foster specific meritorious and ethical research of cardiovascular disease and pulmonary disease and their risk factors as outlined in the Strong Heart Study consent forms. The specific use is subject to scientific review of the Strong Heart Study Steering Committee and the NHLBI. Released samples can only be used for the approved measurements by the designated investigator, and unused samples are to be returned in good condition to the PML/SWF with documented history of the uses of each sample including a log of freeze thaw cycles. Consistent with SHS consent forms, the samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

Policies and procedures described in this document are designed to:

- Release authorized samples only after appropriate review as laid out in Section 4 of this document.
- Release samples after receipt of the signed ***Strong Heart Study Sample Use Agreement*** (**Appendix 3** below).
- Insure sample integrity by keeping the samples in appropriate storage conditions and documenting the history of those storage conditions.
- Insure that the samples are secure and safe from unauthorized use.
- Insure confidentiality of the sample donor in accordance with study guidelines.
- Maintain records of samples stored, removal, freeze thaw cycles, and their placement to insure efficient retrieval.
- Follow procedures to ensure that samples are released appropriately and transferred under conditions, which insure sample integrity.
- Maintain records indicating where, when and why samples were released.
- Insure that disposal or destruction of samples is done in accordance both with good laboratory practice and the guidelines of the Strong Heart Study participants.

2. Sample Storage Conditions:

A. Buffy Coats, plasma, urine, serum, and DNA

Samples are stored in airtight, gasketed vials at -70 to -80º C (-20º C for DNA). Vials are filled leaving at least 0.5 cc airspace at the top of each vial. DNA is stored under conditions known to preserve integrity and quality of DNA (i.e. a non-frostless freezer). Vials are marked in indelible ink on freezer-safe labels with Strong Heart Study participant number, date of collection and PML/SWF Sequence number. The freezers are locked and the key is the responsibility of the laboratory supervisor.

B. Database, sample inventory

The laboratory maintains a computerized database containing the following data on each stored sample: date of receipt, condition on receipt, number of vials, approximate volumes of each sample, freezer location, sample type (DNA, buffy coat, serum, plasma, urine, etc.), release date, release destination, release purpose, return date, return volume, freeze thaw cycles logged, misc. notations. PML/SWF will maintain records of freezer temperatures. Temperatures are manually logged on all workdays by the technical staff and reviewed for drift. Periodic maintenance as recommended by the freezer manufacturer will be kept available for inspection. Records of freezer malfunction and maintenance will also be made available.

C. Damaged storage samples

Communication to the Strong Heart Study Steering Committee: At the request of the Steering Committee, PML/SWF will notify the Steering Committee of sample damage evidenced by thawing or breakage of samples. Computerized and paper logs of samples will include such events.

3. Disposal of Samples

Samples will be disposed at the direction of the Steering Committee by routine laboratory methods. Prior to this, a request will be made to appropriate tribes regarding culturally correct methods of disposal of damaged or non-usable samples and the laboratory will make a reasonable attempt to cooperate with those requests. Any procedures used for disposal of samples must be consistent with *Good Laboratory Practice*, and minimize biohazard contamination.

4. Release of samples

A. Procedures for acting on requests. Administrative pathway for release of samples:

Requests are presented in writing to the Strong Heart Study Steering Committee. Requests are judged by their scientific merit1[2,] potential benefit to the Indian Communities, and consistency with human use guidelines (as outlined in the signed consent) specific to the Strong Heart Study. Requests for Strong Heart Study samples must be specific. Strong Heart Study samples must not be used for additional measurements unless additional written approval is received from the Strong Heart Study Steering Committee. All uses must be consistent with the participant consent of the Strong Heart Study.

Request for Strong Heart Study samples must be made in writing to the Strong Heart Study Steering Committee and should justify the volume of sample requested and whether previously unused (never thawed) samples are necessary. Requests should be brief and generally follow guidelines used in scientific proposals:

- rationale,
- hypotheses,
- specific aims,
- background,
- methods and
- planned analyses.

Study participants and participating tribes will be notified by the Strong Heart Study Newsletter when new tests are done using stored specimens. The investigators will write articles in the newsletter describing what tests are being done and how they will increase understanding of CVD or pulmonary disease in American Indians. Scientific articles resulting from the laboratory studies of the stored specimens will be reviewed and approved by the SHS publications committee, all participating tribes, by NHBLI and by the Phoenix, Aberdeen and Oklahoma Area IRBs prior to publication.

This policy will not preclude obtaining explicit tribal and/or IRB approvals in the event that ancillary studies are proposed which would require re-contact of participants or other issues that would suggest consultation with appropriate IRBs or tribal governments.

[2] Scientific merit will include the originality of the research, value to the tribal communities and participants, and quality of the measurements proposed.

B. Release instructions to PML/SWF:

Written requests to release samples (***Request to Release Samples*** **Appendix 3** below) will be made by the Strong Heart Study Steering Committee after review of scientific merit and ethical considerations. The written request must confirm that all appropriate reviews have been made. Samples to be released must be identified by date or phase of collection, volume or number of vials to be released, shipping destination and contact person, and Strong Heart Study IDs.

PML/SWF will maintain records of requests for a period of 15 years. These records will be made available to the Strong Heart Study sponsor and tribal governments upon request.

C. Technical procedure for releasing samples

Samples are removed from storage only by PML/SWF employees who are trained in safe sample handling. Written logs of the samples requested are used to locate and remove samples. Each sample found is logged onto the table and these data are promptly transferred into the computer database. The removed samples and the list are reviewed by the PML/SWF technical supervisor. Discrepancies are logged and resolved. Samples requested which are not found are logged and investigated to insure consistency between the data base and sample inventory. See ***PML/SWF Sample Request Log*** – **Appendix 3** below.

The sample shipment is coordinated with the receiving laboratory to insure safe receipt of the requested samples. The requesting laboratory must acknowledge the receipt and condition of the samples upon arrival. Any discrepancies between the numbers and amounts of samples approved for use by the requesting laboratory and those received must be reported by the requesting laboratory within one month of receipt of the samples.

Appendix 3 Strong Storage Policy

Strong Heart Study Sample Use Agreement

Strong Heart Study release tracking number_____

The release of Strong Heart Study samples is subject to the following policies and procedures. No samples will be released until the investigator agrees to the following policies and procedures approved by the Strong Heart Study Steering Committee:

1. Samples can be released to foster specific meritorious and ethical research as outlined in the Strong Heart Study consent forms. The specific use is subject to prior approved scientific review of the Strong Heart Study Steering Committee and the NHLBI. The laboratory releases samples only after written instructions are received from the Steering Committee.
2. Released samples can only be used for the approved measurements in the specified laboratory and unused samples are to be returned in good condition to PML/SWF with documented history of the uses of each sample including a log of freeze thaw cycles. The investigator must supply PML/SWF with the name, phone number, E-mail address and shipping address of the person responsible for receiving the samples.
3. The samples will be released for a period of ___ days ending on _____(dd/mm/yyyy). At the termination of this period, the investigator must either return the samples to PML/SWF or request and receive permission from the Strong Heart Study Steering Committee for a specified extension to complete the analyses.
4. Samples must be returned to the PML/SWF with any remaining material at the completion of the approved use period as described above. Samples should be returned in their original containers with the original label. Samples are to be shipped under conditions specified by the Medical or Technical Director of the PML/SWF. Unused samples must not be discarded.
5. Data derived from the use of these samples is the joint property of the Strong Heart Study Steering Committee and the investigator. Publication of the results of these investigations is subject to the policies and prior approval of the Strong Heart Study Publications Committee, the NIH and the appropriate tribal councils.
6. The investigator acknowledges and abides by the informed consent document limiting use of these specimens for the study of cardiovascular and lung diseases and their risk factors and specimens will only be used for those purposes. The samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

I have read the Strong Heart Study Sample Storage policies and understand that the samples must be used only for uses approved in writing by the Strong Heart Study Steering Committee. I agree to abide by the limitations set forth in these policies.

_____ _____

printed name date

_____

signature

_____address

_____address

_____city, state, zip

_____phone number

_____e-mail address

Request to Release Samples

Date: _____

A request to the Penn Medical Laboratory is made to release the following samples (attach list or table if necessary):

Minimum volume needed for each sample: _____ µL.

Type of sample: □ plasma □ serum □ buffy coat □ urine □ other:_____

OK to use previously thawed samples? □ Yes □ No

To:
name of investigator: _____
shipping address: _____
_____
_____
_____
phone contact: _____
E-mail address: _____

Purpose of the Request:

Steering Committee Chair_____ _____
signature date

When should the samples be returned to the Penn Medical Laboratory?_____
date

_____

for PML lab use (attach log of sample request v. those actually sent):

samples pulled and shipped on: _____(mm/dd/yyyy)

Technician _____signature

Supervisor _____signature

PML/SWF Sample Request Log

Sample Request Tracking number:_____
Technician:_____(pulling samples)
Technician:_____(replacing samples)

sample requested SHS ID, phase	found?	Sent (date)	Notes	returned date/volume

Appendix 4 Strong Heart Study VII Participant Sample Form

B3/Penn Medical Laboratory 6525 Belcrest Road, Suite 700 Hyattsville, MD 20782 Phone: 301-560-2999 Fax: 301-560-7325	**PARTICIPANT SAMPLE FORM**

SHS ID: (Place *Barcode Label* here. Attach any extra *Barcode labels* to this form and return to PML)	Collection Date: (mm/dd/yy)
	Shipment: First ☐ Second ☐
	Redraw: Yes ☐ No ☐

write the number of samples sent	Test	Sample Condition	Sample Type	Lab to Receive Samples	Transfer Vial Type (total # & color cap)
	Lipids and storage	Frozen	Serum	PML	40 2ml-red cap vial
	Storage	Frozen	NaCitr Plasma	PML	4 2ml-blue cap vial
	Fasting Glucose and storage	Frozen	NaFl Plasma	PML	4 2ml-black cap vial
	Hemoglobin A1c and storage	Frozen	Whole Blood	PML	4 2ml-neutral cap vial
	Storage	Frozen	EDTA Plasma	PML	16 2ml-purple cap vial
	Buffy coat (DNA isolation)	Frozen	Buffy Coat	PML to SFBR	2 2ml-orange cap vial
	RNA	Frozen	PAX Blood	PML	1 PAX RNA tube
	Urine Creatinine & mAlb and storage	Frozen	Urine	PML	10 2ml-yellow cap vial

Site Comments:	
Lab Comments:	Date and Time Samples received:
	Processing Technician Initials:

Psychosocial Questionnaires

Manual of Operations Volume V

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

Strong Heart Study Coordinating Center

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The University of Oklahoma Health Sciences Center

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Oklahoma City, OK 73190

Tracking of Revisions to Manual of Operations Volume V: Psychosocial Questionnaires

Date of Revision	Revised Section	Revision	Approved by, Date
5/9/2023	Section 16: MOCA Section 17: NIH Toolbox	Add additional scripts for the field centers to use	SHS CC, 11/1/2022
5/3/2023	Entire document	Fixed formatting issues	SHS CC, 11/1/2022

Table of Contents

V. Psychological Questionnaires

1. Rationale for Psychosocial Questionnaires of Psychosocial Factors

Over the last twenty years, scientists and clinicians alike have been looking at the relationship between psychosocial factors and health outcomes. To date, there has been increasing recognition among the medical community that psychosocial factors (e.g., stress, depression and social isolation) contribute to many forms of disease. One of the most well documented areas in this research has been in the associations between psychosocial variables and cardiovascular disease.

The idea that psychosocial variables could affect health is not a new concept. In 1628, while describing the circulatory system, William Harvey noted that emotions affect the heart. William Osler, often described as the father of internal medicine, described the typical heart disease patient as "a keen and ambitious man, the indicator of whose engine is always at full speed ahead." (Clay, 2001). Since then, our knowledge of the effects of psychosocial variables and disease outcome has increased considerably. In recent years, it has been found that the personality trait of cynical hostility predisposes individuals for cardiovascular disease. A recent report using Strong Heart Family Study Data has identified that cynicism and hostility are correlated strongly with depression and inversely with social support, which were associated with higher and lower risk of early mortality and cardiovascular disease, respectively (Suchy-Dicey, 2021). Depression and social support may influence mortality and health outcomes after the onset of heart disease, and several intervention studies have shown efficacy in psychosocial intervention improving both the outcome and the quality of life for individuals suffering from heart disease (Clay, 2001). Postulated biological mechanisms for these associations include systemic inflammation, autonomic nervous system dysfunction, and endothelial dysfunction. In addition, adaptive behaviors resulting from traumas or stress exposures may also contribute, such as poor sleep hygiene, reluctance to change unhealthy lifestyle behaviors, and non-adherence to medical treatments.

In contrast to risk features, protective features such as social support and psychological resilience may protect against negative aging or health outcomes. Overall, up to 30% of the variance in physical and emotional health in studies of youth may be accounted for by psychological resilience and related features, with a substantial portion attributable to family caring and social support. However, the psychosocial factors that might confer such protections in elders have not been fully examined.

Many of these psychosocial factors appear to have a strong environmental foundation. For example, most people encounter stress in their daily life and will also experience at least one major stressful or traumatic situation that may even be life threatening. However, when such experiences are particularly common, frequent, ongoing, or severe—such as circumstances of discrimination, bullying, harassment, poverty, dysfunctional family relationships, or in the context of historical traumas to communities—then the resulting stress is more likely to be more intense, chronic, and overwhelming. However, resilience against stress and trauma can also be environmental features: for example, Diné (Navajo) people employ a wellness philosophy to emphasize harmony of person and community, fostering better intergenerational relationships,

developing social networks, participating in community events, engaging in traditional practices, cultivating spirituality, and affirming cultural identity. These perspectives and values are reported to have significant positive consequences on psychology of community members.

This psychosocial portion of Phase VII of the Strong Heart Study is especially aimed at examining these questions: with a particular interest in whether such positive aging features may be enough to improve or prevent the negative environmental features that may also be present and otherwise unavoidable in SHS communities and members.

The forms are designed to be self-administered, but SHS Staff should check all the forms for completeness and ask questions that have not been answered. The following questionnaires are administered to all Phase VII SHS participants: Perceived Stress; Quality of Life – SF-12; CES-D depression scale; Multidimensional Health Locus of Control (MHLC); Other Questions About Your Life (Traumatic Experience and Inclusion of Community in the Self Scale); Resilience (RS-14) Scale; Multidimensional and Interpersonal Resilience Measure (MIRM), Multigroup Ethnic Identity Scale; Orthogonal Cultural Identity Scale; Rosenberg Self-Esteem Scale; Social Support and Social Undermining Items; Social Network Index; Functional Activities Questionnaire; and MoCA.

1.1 References

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2. Perceived Stress Scale (PSS)

2.1 Individual experience of stress

Perceived stress refers to the degree that everyday situations in a person's life are considered stressful. Changes in brain chemistry (serotonin 5-HT, cortisol "stress hormones") can result from exposure to chronic or repeated stressful situations. Such chemical changes may be similar to the changes that occur as a result of depression, and can result in long-term negative health outcomes, including premature mortality, cardiovascular disease, and psychological consequences.

2.2 Data in SHS / American Indian populations

This scale has adequate reliability in healthy adults, although the psychometric performance in American Indians has not been evaluated. This scale was previously used as part of the Family Study; this Phase VII study will be the first to directly estimate scale reliability and validity for the PSS scale in American Indian adults. Higher symptoms of stress have been reported for American Indian adults, as have the conditions that cause higher life stress, including traumatic and negative historical, social, and economic conditions. American Indian adults also have reported higher frequency of consequences of high stress, such as more severe symptoms of depression.

2.3 Scoring

PSS items are rated on a 5-point scale of occurrence over the past 4 weeks (0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, 4 = very often). Sic items are positively coded and four are negatively coded ; all are summed to create a total score ranging from 0 to 40. Scores of 13 are considered typical; scores of 20 or higher are considered to represent high experience of stress. Previous SHS examinations included 7 of the original 10 PSS questions, and so total scores were adjusted by a factor of 10/7 to allow for comparability with other population studies.

2.4 Strong Heart Study Form

Refer to Perceived Stress form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

2.5 References

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3. Short form 12 (SF-12) Scale

3.1 Health-related quality of life

The SF-12 health-related quality of life scale will be used in Phase VII of the Strong Heart Study; this scale is similar to the SF-36 health-related quality of life scale, which was used in some of the other SHS examinations (Phases II and III). The main reason for using the SF-12 instead of the SF-36 is to save time with shorter version. Psychometric work by SHS investigators to validate the longer SF-36 has shown that the full version is not necessary in order to capture all important information about quality of life. The SF-12 version generates two main measures, physical health and mental health. These two measures, the physical component (PCS-12) and the mental component (MCS-12), are compatible to those generated by the SF-36 and have been validated in other populations.

3.2 Relevance to health outcomes

Subjective health, or how people see their own health, is increasingly recognized as an important factor in whether people take the necessary steps to either prevent health problems or to seek services for such problems. The SF-12 is an important measure of subjective health.

3.3 Data in SHS / American Indian populations

Analyses of SHS SF-36 scale have been published (Beals, Welty et al. 2006; Barbosa-Leiker, et al 2021), as a first step to assess whether the SF-36 works well in SHS populations–and it did. Interestingly, however, the physical and mental health dimensions were more highly related to one another than in many other samples; this may reflect a more holistic view of health.

3.4 Scoring

The SF-12 scale has varying item coding among its multiple subscales, including general health perceptions, vitality, bodily pain, physical function, emotional function, social function, and mental health. Items are coded, or reverse coded, so that higher scores corresponding to worse health, and each item is scored with a minimum score of 1, so that the total possible summary scores range from 12 to 47. In comparison to the longer SF-36, SF-12 had similar score performance but larger standard errors.

3.5 Strong Heart Study Form

Refer to Quality of Life form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

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4. Centers for Epidemiological Studies Depression (CES-D) Scale

4.1 Symptoms of depression and health

A vast research literature has established relationships between depression and health. Measurements of depression can be useful to assess health and mood, as well as risk for cardiovascular disease and mortality.

4.2 Assessment of depression

Designed for self-administration or interview, the Center for Epidemiologic Studies of Depression Scale (CES-D) scale was originally developed as a general screening measure for depression (Radloff, 1977). It is a 20-item instrument designed to measure current depressive symptomatology, and especially depressive affect. The items were chosen to represent major components of major depression, including: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, loss of appetite, sleep disturbance, and psychomotor retardation. The scale can distinguish clinical groups with high sensitivity and specificity, and various cutoff scores have been established for clinical depression in different populations (Beals et al, 1991).

4.3 CES-D Utilized by Similar Studies

The CES-D is the standard scale used in numerous large, population studies, including the Honolulu Heart Program, the Inter-Tribal Heart Project (Menominee, Red Lake & White Earth), Cardia, and the Stanford Coronary Prevention Project. The CES-D has been found in other populations to have good test-retest reliability, and internal consistency; internal reliability (Cronbach's Alpha) = 0.89.

4.4 Data in SHS / American Indian populations

The CES-D has been administered in most phases on SHS, including Phases 1-3, Family Study, and Stroke Study. Analysis of these data showed that the 20-item CESD is a poor fit for elderly, but a 12-item subscale has adequate reliability and validity. Females have significantly higher (worse) depression scores on both the full and abbreviated versions of the scale, as well as on all formal subscales (depressed affect, somatic symptoms, well-being). Overall, symptoms of clinical depression (scores ≥16) were present in 20% of elders over age 65, and were associated with lower income, lower education, and with poorer cognition and physical health. Administration of CES-D in all SHS phases appears necessary in order to capture a significant and important risk factor for cardiovascular and cerebrovascular health.

4.5 Scoring

CES-D items are rated on a 4-point (0-3) Likert scale indicating frequency of occurrence during the last week, ranging from "rarely or not at all" to "most of the time." Four items are reverse-coded: #'s 5, 9, 13, and 17, and items are then summed for a total score ranging from 0-60. Note: item #21 is not a part of the CES-D scale, and should be scored separately.

4.6 Score Interpretation

Upon completion of the survey, a staff member will sum the scores, taking in to account the reverse coded items. If the total score for the 20-item scale is above the cutoff score for clinical depression (**≥16**), the staff member will ask the participant if they are interested in a referral for follow-up. The staff member will then note in the chart that the verbal offer of a referral had been given to the participant.

4.7 Strong Heart Study Form

Refer to CES-D form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

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5. Multidimensional Health Locus of Control (MHLC) Scale

The construct of Health Locus of Control was derived from the Social Learning Theory developed by Rotter in 1966. This theory states that an individual learns on the basis of his of her history of reinforcement. Health Locus of Control (HLC) is the degree to which individuals believe that their health is controlled by internal or external factors. Whether a person is internal or external is based on a series of statements. The statements are scored and summed to determine whether the individual has internal or external health beliefs.

There have been multiple studies done that have suggested that HLOC can play a major role in health outcome. Individuals who have a more internal HLOC perceive that they retain power over health-related rewards are prone to obtain proper nutrition, exercise, rest, stress reduction, and to adopt prevention/ enhancement strategies to maintain/ improve the state of their health. Those who have a more external HLOC believe that chance, god, or doctors, etc., control their health; they are liable to exhibit behaviors which are less action oriented (more reaction oriented). This can be especially important in diseases that have a strong behavioral component such as diabetes or heart disease.

The MHLC scale has three subscales designed to measure the construct of HLOC.

1. Internal HLC (IHLC) is the extent to which one believes that internal factors are responsible for health/illness.
2. Powerful Others HLC (PHLC) is the belief that one's health is determined by powerful others.
3. Chance HLC (CHLC) measures the extent to which one believes that health illness is a matter of fate, luck or chance.

5.1 Reliability & Validity

The MHLC subscales have been shown to be reliable in many studies. They have been shown to have Cronbach alphas in the .60-75 range and test-retest stability coefficients ranging from .60 - .70. The MHLC scale is widely considered to be the instrument of choice when measuring the construct HLC.

5.2 Administration

This scale was designed for self-administration, or in interview format. Each item is to be answered on a 4 point Likert scale where "Strongly Disagree" is 0, "Disagree" is 1, "Agree" is 2, and "Strongly Agree" is 3.

5.3 Scoring

The score on each subscale is the sum of the values for each item on the subscale. All of the subscales are independent of one another, so there is no such thing as a "total" MHLC score. The items for the three subscales are as follows:

Internal:	1, 6, 8, 12, 13, 17
Chance:	2, 4, 9, 11, 15, 16
Powerful Others	3, 5, 7, 10, 14, 18

5.4 Strong Heart Study Form

Refer to MHLC form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

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6. Posttraumatic Stress Disorder

6.1 Post-traumatic stress disorder and health (PTSD)

PTSD describes the set of symptoms some people have after experiencing or witnessing a horrible event, or after chronic and uncontrolled experiences of extreme stress. The symptoms are broken out into 3 types: re-experiencing or reliving the event; avoidance of places, people or things that might remind the person of the trauma, and increased vigilance or arousal. These reactions have to last at least a month to qualify as being PTSD.

Recent research has indicated that psychiatric disorders such as major depression are risk factors for cardiovascular disease (Bankier and Littman 2002; Schnittker 2005; Simon and Von Korf 2006). More recently the role of PTSD and cardiovascular diseases has also received attention (Sawchuk, Roy-Byrne et al. 2005). Given the symptoms of hyper-excitability, increased vigilance, and overall anxiety associated with this disorder, PTSD promises to be an important risk factor for cardiovascular disease.

6.2 Trauma, anxiety exposures in American Indian populations

American Indian populations are exposed to more trauma and stress than many other Americans. American Indian study participants report both more types and higher frequency of traumatic exposures (Manson, Beals et al. 1996; National Center for Posttraumatic Stress Disorder and the National Center for American Indian and Alaska Native Mental Health Research 1996; Ritsher, Struening et al. 2002; Manson, Beals et al. 2005). Additionally, mortality statistics indicate greater risk of death from unintentional injuries and violence for American Indians compared with other groups (U. S. Department of Health and Human Services 2001). Therefore, it is not surprising that social and psychological problems associated with trauma, (American Psychiatric Association 1994) are also found at higher proportion in American Indian populations.(Manson, Beals et al. 1996; Beals, Manson et al. 2002; Beals, Manson et al. 2005; Beals, Novins et al. 2005)

6.3 PTSD data in SHS / American Indian populations

Preliminary analyses of American Indian and Alaska Native Programs data at the University of Colorado suggest that American Indians may have higher frequency of PTSD (Sawchuk, Roy-Byrne et al. 2005) although additional research is in progress. However, that research is all cross-sectional and cannot evaluate changes over time. The SHS has previously collected data on PTSD and anxiety as well. These items have been examined in association with measures of stress, resilience, and mortality in the SHS Family study, and were found to be highly correlated with stress and social isolation. Thus, addition of PTSD items to Phase VII of the SHS will provide a critical opportunity to examine the relationship between PTSD and cardiovascular disease over time.

6.4 Measuring PTSD

The PTSD measure has 6 items. The first asks whether or not the person has experienced a trauma. While examples of possible traumas are provided (victim of violent crime, seriously injured in an accident, being assaulted, seeing someone seriously injured or killed, or being the victim of a natural disaster), the participant is not asked to describe the event at all. If they have experienced a trauma, the remaining 5 questions ask about: 1) reliving the experience, 2) being less interested in things, 3) problems sleeping or concentrating, 4) avoiding places or things that remind one of the traumas, and 5) whether some of these problems have lasted more than 1 month.

Staff may be worried about a participant's reactions to these questions. Most people, even those with PTSD, will answer them with no problem. Also, prior phases of SHS have not had significant problems with respondents to these same questions. However, due to the sensitive nature of these questions, staff should be prepared with a list of referrals in case a participant wants to talk to someone about their trauma and symptoms.

6.5 Strong Heart Study Form

Refer to Other Questions About Your Life form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

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14. Suchy-Dicey A, Eyituoyo H, O'Leary M, Cole SA, Traore A, Verney S, Howard B, Manson S, Buchwald D, Whitney P. (2021, under review). *Psychological and social support associations with mortality and cardiovascular disease in middle-aged American Indians: data from The Strong Heart Study*. Social Psychiatry and Psychiatric Epidemiology

7. Inclusion of Community in the Self (ICS) Scale

7.1 Community connectedness

Community connectedness refers to a sense of belonging and social connectedness for members of a given community. Public health programs focused on improving community connectedness, especially with cultural-specific adaptations, can increase accountability, community, belonging, and identity. These associations are especially strong for communities that have been exposed to historical traumas.

7.2 Community connectedness and health

Furthermore, community connectedness can moderate the relationship between depressive symptoms and suicidality in adolescents. Research on youth in Canada finds that cultural connectedness is linked to less substance use and better mental health. A sense of community belonging is also associated with better physical and mental health. Community connectedness is also protective and strongly related to health-related behavior changes; these changes are strongest among seniors.

7.3 Data in SHS / American Indian populations

The ICIS has excellent test-retest reliability, convergent validity, and discriminant validity in Canadian First Nations and other populations. However, it has not been measured in US American Indians. For application to the SHS Phase VII study, based on previous work with AI communities, we have made minor changes, including adding color and changing “self” to “you”.

7.4 Scoring

This is a single-item, pictorial, categorical measure.

7.5 Strong Heart Study Form

Refer to Other Questions About Your Life form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

7.6 References

1. Hystad P, Carpiano RM. Sense of community-belonging and health-behaviour change in Canada. J Epidemiol Community Health. 2012;66(3):277-283.
2. Kitchen P, Williams A, Chowhan J. Sense of Community Belonging and Health in Canada: A Regional Analysis. Soc Indic Res. 2012;107(1):103-126.
3. Mashek D, Cannaday LW, Tangney JP. Inclusion of community in self scale: A single-item pictorial measure of community connectedness. Journal of Community Psychology. 2007;35(2):257-275.
4. Matlin SL, Molock SD, Tebes JK. Suicidality and Depression Among African American Adolescents: The Role of Family and Peer Support and Community Connectedness. Am J Orthopsychiat. 2011;81(1):108-117.
5. Ross N. Community belonging and health. Health Rep. 2002;13(3):33-39.

6. Shields M. Community belonging and self-perceived health. Health Rep. 2008;19(2):51-60.
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8. Snowshoe A, Crooks CV, Tremblay PF, Hinson RE. Cultural Connectedness and Its Relation to Mental Wellness for First Nations Youth. J Prim Prev. 2017;38(1-2):67-86.
9. Stone RAT, Whitbeck LB, Chen XJ, Johnson K, Olson DM. Traditional practices, traditional spirituality, and alcohol cessation among American Indians. J Stud Alcohol. 2006;67(2):236-244.

8. Resilience Scale (RS-14)

8.1 Individual Resilience

Resilience may be defined as the ability of an individual to regulate emotions, maintain a positive attitude, and see failure as helpful feedback under conditions of extreme stress. Most people will be exposed to at least one major life trauma; daily life may additionally contribute to stress, such as exposure to bullying, harassment, dysfunctional relationships, poverty, or other environmental conditions. When stress is especially intense, chronic, or overwhelming, conditions like post-traumatic stress disorder (PTSD), depression, burnout, anxiety, physical ramifications such as inflammation or illness can occur. Resilience against such responses comprises a complex psychological construct and can be challenging to define; however, in simplest terms, resilience can be viewed as a stable trajectory of healthy functioning despite highly adverse conditions. Resilience may be considered as a trait, a process, or an outcome.

8.2 Measuring Resilience

The 14-item Resilience Scale (RS-14) measures individual trait-based resilience, including sub-items self-reliance, perseverance, self-regard, engagement, humor, resourcefulness, meaningfulness, and composure, and has been translated into more than 40 languages with excellent factor validity across a broad cultural range.

8.3 Data in SHS / American Indian populations

In general, American Indian peoples amd populations have historically shown remarkable resilience to stress and trauma. In studies among Diné people, resilience has been attributed to *Hózhó*, a strength-based wellness philosophy that emphasizes the wholeness of person and community, which values engagement in cultural, social, and familial structures. However, the psychological features and consequences that might define or be associated with such resilience have not been measures in American Indian or SHS adults. This study will be the first to collect data on resilience and other, similar positive health features.

8.4 Scoring

The 14 items are coded on a 7-point scale (from 1, strongly disagree, to 7, strongly agree), with summary score ranging 14 to 98. Scores higher than 90 indicate high resilience, 82-90 moderate-high, 65-81 moderate-low, 57-64 low, and below 56 very low.

8.5 Strong Heart Study Form

Refer to RS-14 form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

8.6 References

1. Southwick SM, Bonanno GA, Masten AS, Panter-Brick C, Yehuda R. Resilience definitions, theory, and challenges: interdisciplinary perspectives. Eur J Psychotraumatol 2014;5
2. Aiena BJ, Baczwaski BJ, Schulenberg SE, Buchanan EM. Measuring resilience with the RS-14: a tale of two samples. J Pers Assess 2015;97:291-300.

3. Wagnild G. A review of the Resilience Scale. J Nurs Meas 2009;17:105-13.
4. Wagnild GM, Collins JA. Assessing resilience. J Psychosoc Nurs Ment Health Serv 2009;47:28-33.

9. Multidimensional and Interpersonal Resilience Measure (MIRM)

9.1 Interpersonal Resilience

There are many facets of resilience, which is described more fully above. One of these facets or concepts are that resilience is a feature of community, both defined by and improved by social support. Some scientists argue that resilience is not an individual characteristic, but moreover a collective trait, "residing in durability of interpersonal relationships in extended family and wider social networks of support".

9.2 Measuring complex and community resilience

This 22-item scale covers multiple, more complex concepts of both community and individual resilience, with sub-items including access to a social support network, optimism, perceived access to economic and social resources, spirituality and religiosity, relational accord, emotional regulation, emotional expression, and communication.

9.3 Data in SHS / American Indian populations

This scale has not been administered in SHS populations; this will be the first study to assess resilience and its features and health consequences in AI adults and communities.

9.4 Scoring

Items are scored on a 5-point scale (from 1, not at all, to 5, nearly all the time), with summary scores indicating higher degrees of resilience; 6 items are reverse coded. Thresholds for diagnostic or risk prediction have not yet been identified.

9.5 Strong Heart Study Form

Refer to MIRM form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

References

1. Teufel-Shone NI, Tippens JA, McCrary HC, Ehiri JE, Sanderson PR. Resilience in American Indian and Alaska Native Public Health: An Underexplored Framework. Am J Health Promot. 2016
2. Phinney, Jean S. Multigroup Ethnic Identity Measure: A New Scale for Use with Diverse Groups. Journal of adolescent research, 1992-04, Vol.7 (2), p.156-176
3. Martin AS, Distelberg B, Palmer BW, Jeste DV. Development of a new multidimensional individual and interpersonal resilience measure for older adults. Aging Ment Health 2015;19:32-45.

10. Revised Multigroup Ethnic Identity Scale (MEIM-R)

10.1 Multiple/Complex Identity

Identity is a complex construct, which has been associated with resilience, social support, and health outcomes. Furthermore, cultural, social, and ethnic identities may not be restricted to a single group, but can be fluid, variable, overlapping, heterogeneous, or otherwise complex.

10.2 Data in SHS / American Indian populations

Reviews of literature identify cultural engagement and ethnic identity as attributes of individual resilience in American Indian youth, but little is known about adults or for across the life-course. Although identification as American Indian or from North American Indigenous peoples is a component of participating in the SHS cohort, more complex data on identity—especially fluidity or overlap with other ethnic or cultural groups—has not been collected. The Revised Multigroup Ethnic Identity Measure (MEIM-R) includes self-categorization on ethnic identity as well as exploration and commitment to that identity

10.3 Scoring

Items are scored on a 5-point scale (from 1, strongly disagree, to 5, strongly agree). The revised version performs similarly to the original, except in settings defined by very limited education, such as in elementary schools.

10.4 Strong Heart Study Form

Refer to MEIM-R form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

10.5 References

1. Herrington HM, Smith TB, Feinauer E, Griner D. Reliability generalization of the Multigroup Ethnic Identity Measure-Revised (MEIM-R). J Couns Psychol 2016;63:586-93.
2. Brown SD, Unger Hu KA, Mevi AA, et al. The multigroup ethnic identity measure-revised: measurement invariance across racial and ethnic groups. J Couns Psychol 2014;61:154-61.

11. Orthogonal Cultural Identity Scale (OCIS)

11.1 Acculturation & Cultural Participation

The degree of alignment (acculturation) and participation in American Indian or other culture also have potential consequences for resilience and positive healthy aging. In youth, enculturation and social support from peers account for 34% of variance in resilience; although less is known about adults, especially American Indian and other cultural minorities.

11.2 Scoring

The OCIS includes 6 items on annual family activities, personal and family involvement, and personal and family success in traditional culture over several different ethnic / cultural groups (e.g., Anglo, Latino, Native American). Items are scored on a 4-point scale (from 1, lowest level of identification, to 4, highest) and then summed for each group.

11.3 Strong Heart Study Form

Refer to OCIS form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

11.4 References

1. Venner KL, Wall TL, Lau P, Ehlers CL. Testing of an orthogonal measure of cultural identification with adult mission Indians. Cultur Divers Ethnic Minor Psychol 2006;12:632-43.
2. Stumblingbear-Riddle G, Romans JS. Resilience among urban American Indian adolescents: exploration into the role of culture, self-esteem, subjective well-being, and social support. *Am Indian Alsk Native Ment Health Res.* 2012;19(2):1-19.

12. Rosenberg Self-Esteem Scale (R-SES)

12.1 Self esteem

Self-esteem is commonly understood to have significant associations with life, social, and health success. High self-esteem may be partly due to as well as result from good performance in school, life, work, or other endeavors. However, these effects can vary widely, and effects from interventions aimed at improving self-esteem directly are frequently ineffective, confirming it as a complex, albeit important, social and cognitive construct. Those high in self-esteem are believed to be more likable and attractive, to have better relationships, and to make better impressions on others than people with low self-esteem, but objective measures may conflict with these beliefs. Those with very high self-esteem may alienate others, be more willing to speak up in groups and to criticize the group's approach, and show stronger in-group favoritism which may increase prejudice and discrimination. All of these effects may decrease social support.

12.2 Measuring self-esteem

Measurement of self-esteem and evaluation of these effects is complicated by several factors. Because many with high self-esteem may exaggerate successes (and those with low self-esteem may minimize them) and positive (or negative) personality traits, objective information is critical. High self-esteem may also be heterogeneous in its features, and may include those who view negativity in a positive light. This 10-item scale measures self-worth by measuring both positive and negative feelings about the self, and is believed to be unidimensional.

12.3 Data in SHS / American Indian populations

This will be the first study using this scale in American Indian adults, and it will provide the first information about self-esteem in relation to social support, community, stress, and resilience.

12.4 Scoring

All items are answered using a 4-point Likert scale format ranging from strongly agree to strongly disagree. Items 2, 5, 6, 8, 9 are reverse scored. Give “Strongly Disagree” 1 point, “Disagree” 2 points, “Agree” 3 points, and “Strongly Agree” 4 points. Sum scores for all ten items. Keep scores on a continuous scale. Higher scores indicate higher self-esteem.

12.5 Strong Heart Study Form

Refer to R-SES form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

References

1. Rosenberg, M. (1965). Society and the adolescent self-image. Princeton, NJ: Princeton University Press.
2. Gray-Little, B., Williams, V.S.L., & Hancock, T. D. (1997). An item response theory analysis of the Rosenberg Self-Esteem Scale. *Personality and Social Psychology Bulletin*, *23*, 443-451.

3. Baumeister, R. F., Campbell, J. D., Krueger, J. I., & Vohs, K. D. (2003). Does high self esteem cause better performance, interpersonal success, happiness, or healthier lifestyles? *Psychological Science in the Public Interest, 4*, 1-44.

13. Social Support and Undermining Scale (SS/U)

13.1 Social support and social undermining

Social support has been examined for more than 20 years as a significant factor in health, resilience, and disease. Just as with resilience, social support is a complex construct which may be conceptualized in multiple ways: as a network, as perceived available support, or as received support from others (transactional). However, it is conceptualized, social support generally appears to have beneficial or protective effect on both physical and mental well-being, on long-term health outcomes, and on community. Its converse—social undermining—may contribute negatively to all of these outcomes, and may be conceptualized as hindrance, conflict, or isolation.

13.2 Measuring social support

This scale, SS/U, evaluates perceived and received social support with positive subscales including emotional support and instrumental support; and social undermining with negative subscales including critical appraisal and isolation. These items have been derived from the National Comorbidity Survey, tailored specifically for American Indian populations, and then validated by the American Indian Service Utilization and Psychiatric Epidemiology Risk and Protective Factors Project.

13.3 Data in SHS / American Indian populations

This scale was previously administered in SHS Family study, and has also been administered to AI-SUPERPFP cohort in the Northern Plains and Southwest. Findings from these studies have identified that social support and undermining may function independently of each other—rather than acting as opposite constructs. Cynicism, depression, and substance use have been associated with both constructs; although undermining may have a stronger effect. Social support appears to have a strong protective effect on both cardiovascular disease and mortality in American Indian elders. However, the scale validity has not been directly examined, and there has not been any option to examine social support in relation to positive aging such as resilience compared with negative aging such as stress. This study will allow SHS investigators to directly examine these questions.

13.4 Scoring

Positive subscales cover emotional support (6 items coded 1 to 3) and instrumental support (5 items coded 0,1), with higher scores connoting better social support; negative subscales include critical appraisal (6 items coded 1 to 3) and isolation (3 items coded 1 to 3), with higher scores connoting poorer social support or greater isolation. Summary scores accounting for reverse (negative item) coding included the four subscales together, with a possible range 15 to 50 and higher scores indicating better support.

13.5 Strong Heart Study Form

Refer to SS/U form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

13.6 References

1. Vinokaur A, Van Ryn M. Social support and undermining in close relationships: their independent effects on mental health of unemployed persons. Journal of Personality and Social Psychology. 1993: 65(2): 350-359.
2. Oetzel J, Duran B, Jiang Y, Lucero J. Social support and social undermining as correlates for alcohol, drug, and mental disorders in American Indian women presenting for primary care at an Indian Health Service hospital. *J Health Commun.* 2007;12(2):187-206.
3. Kessler RC, McGonagle KA, Zhao S, et al. Lifetime and 12-month prevalence of DSM-III-R psychiatric disorders in the United States. Results from the National Comorbidity Survey. *Arch Gen Psychiatry.* 1994;51(1):8-19.
4. Beals J, Manson SM, Mitchell CM, Spicer P, Team A-S. Cultural specificity and comparison in psychiatric epidemiology: walking the tightrope in American Indian research. *Cult Med Psychiatry.* 2003;27(3):259-289.
5. Suchy-Dicey A, Eyituoyo H, O'Leary M, Cole SA, Traore A, Verney S, Howard B, Manson S, Buchwald D, Whitney P. (2021, under review). *Psychological and social support associations with mortality and cardiovascular disease in middle-aged American Indians: data from The Strong Heart Study*. Social Psychiatry and Psychiatric Epidemiology

14. Social Network Index (SNI)

14.1 Social network size

One of the features of social support that is not covered by the SS/U scale is the size, depth, and complexity of the social network. This concept is important because it can provide a different facet of social support, allowing comparisons of people with a large, surface network (e.g., lots of casual acquaintances) with those who have a small, deep network (e.g., few close friends). The Social Network Index (SNI) assesses participation in 12 types of social relationships.

14.2 Data in SHS / American Indian populations

SNI has not been studied in American Indians, although it may be important for different ways that social support varies among different people. This will be the first study to examine these questions.

14.3 Scoring

One point is assigned for each type of relationship (possible score of 12) for which respondents indicate that they speak (in person or on the phone) to persons in that relationship at least once every two weeks.

14.4 Strong Heart Study Form

Refer to SNI form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

14.5 References

1. Cohen, S., Doyle, W. J., Skoner, D. P., Rabin, B. S., and Gwaltney, J. M., Jr. (1997). Social ties and susceptibility to the common cold. Journal of the American Medical Association, 277, 1940-1944. Journal of the American Medical Association, 277, 1940-1944.
2. Bickart, K. C., et al (2011). Amygdala volume and social network size in humans. Nature Neuroscience, 14, 163-164.
3. (2.) Bickart, K. C., et al (2012). Intrinsic amygdala–cortical functional connectivity predicts social network size in humans. Journal of Neuroscience, 32, 14729-14741.

15. Functional Activities Questionnaire (FAQ)

15.1 Instrumental activities of daily living (IADL)

Dementia is a clinical syndrome (set of functional and cognitive symptoms) wherein the patient is unable to perform the usual activities of their daily lives. Dementia can be caused by caused by cardiovascular, cerebrovascular, or neurodegenerative disease. Compromised functional ability can be unsafe, anxiety provoking, and costly, as it may require close care or even hospitalization. Valid and reliable information about function and ability to perform these instrumental daily activities is often used to identify those who may be affected by dementia, as well as to individualize care, and to design safe and supportive environments for elders living with dementia.

The Functional Activities Questionnaire (FAQ) measures instrumental activities of daily living (IADLs), such as preparing balanced meals and managing personal finances. Since functional changes are noted earlier in the dementia process than other cognitive changes, this tool is also useful to monitor functional changes over time and to differentiate those with mild cognitive impairment vs more severe outcomes. The FAQ is used in combination with the Montreal Cognitive Assessment (MOCA) as part of the National Alzheimer's Coordinating Center research studies to assess participant status and trajectories.

15.2 Validity and reliability

The FAQ has good sensitivity (85%) to identify functional impairment in dementia, and high reliability (exceeding 0.90)—all among general population. Tests of validity have established it can discriminate among different functional levels, predict neurological and mental status, and demonstrate sensitivity to change. As with other instruments that use indirect approaches in a population affected by cognitive decline, there may be substantial measurement error and bias. None of these measures have been assessed in American Indian populations.

15.3 Data in SHS / American Indian populations

The FAQ was administered to the SHS Stroke study cohort, which was an ancillary follow-up to Phase 1 survivors conducted in 2017-19 (N=400). During this examination, it was observed that the FAQ may not have the same precision and accuracy with cognitive status as in the general population, but these analyses are still underway. However, the FAQ is still the standard for assessment of IADLs. Therefore, we have made minor changes to the format of the scale and instrument, and to the instructions, in hopes that these modifications will change the reliability and accuracy of reporting. This study will provide the first opportunity to directly evaluate scale validity and reliability; as well as allow evaluation with the resilience, social support, and stress features also being collected in Phase VII.

15.4 Scoring

The scale's 10 items ask informant (self or family member) to rate patient's ability using the following scoring system: able to do, or could do (0); has some difficulty but can do by self (1); requires assistance but can still do (2); dependent on others (3). Items are then summed for a total score ranging from 0-30. Dependency in 3 or more activities is typically considered to indicate

significantly impaired function and possible dementia. Note that score=3 for 3+ items is not equivalent to score=1 for 9-10 items; continuous assessment may not be informative for adjudication of clinical syndromes.

15.5 Strong Heart Study Form

Refer to FAQ form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

15.6 References

1. Peres, K., Helmer, C., Amieva, H., Orgogozo, J., Rouch, I., Dartigues, J., & Barberger-Gateau, P. (2008). Natural history of decline in instrumental activities of daily living performance over the 10 years preceding the clinical diagnosis of dementia: A prospective population-based study. JAGS, 56(1), 37-44.
2. Pfeffer, R.I., Kurosaki, T.T., Harrah, C.H. Jr., Chance, J.M., & Filos, S. (1982). Measurement of functional activities in older adults in the community. Journal of Gerontology, 37(3), 323-329.
3. Weintraub, S., Salmon, D., Mercaldo, N., Ferris, S., Graff-Radford, N.R., Chui, H., & et al. (2009). The Alzheimer's Disease Centers' Uniform Data Set (UDS): The neuropsychologic test battery. Alzheimer's Disease and Associated Disorders, 23(2), 91-101.

16. Montreal Cognitive Assessment (MOCA)

16.1 Cognition and dementia

Dementia is not a singular disease, but rather a clinical term for the impaired ability to remember, think, make decisions, or complete the activities of everyday living. The most common risk factor for dementia is older age, but dementia is not a part of normal aging. Alzheimer's disease is the most common type of dementia, but vascular and other forms are also common and may co-exist, especially in populations with high rates of cardiovascular disease and cardiovascular risk factors such as diabetes, hypertension, dyslipidemia, and kidney disease. Doctors diagnose dementia on the basis of cognitive and functional symptoms. For patients who have Alzheimer's disease or (cerebro)vascular disease, cognitive and functional symptoms may not yet be present, or may still be too mild to be called dementia.

16.2 Assessment of cognition

One of the most common tools to screen for cognitive impairment is the Montreal Cognitive Assessment (MoCA). The MOCA is a 10-minute, 1-page tool that can assess a multiple different cognitive domain, including executive function, attention, phonemic and semantic fluency, abstraction, delayed verbal memory, and orientation. MOCA has broad clinical utility for both mild cognitive impairment and dementia, including Alzheimer's disease type, and is used in most Alzheimer's disease research by the National Alzheimer's Coordinating Center.

16.3 Data in SHS / American Indian populations

The MOCA is designed to be administered by persons with special training, and was previously given to participants of the SHS Stroke Study in 2017-2019 (N=400). These data are being analyzed, and will be reported soon.

All of the Strong Heart Study field centers have given this test previously, and have been trained in its administration. The field staff who will be giving this test as part of Phase VII will need to be trained too, which can be done here: https://www.mocatest.org/training-certification.

Phase VII study will be the first opportunity to examine change over time in MOCA scores, as well as to examine MOCA scores in younger adults. Additionally, score validity and reliability will be directly assessed, which will provide information about ability of this test instrument to provide information for assessment of MCI and dementia in clinic, and in association with both protective and risk features.

16.4 Brief Scoring

Executive function is assessed via a mini trail-making test, a cube copy test, and a clock drawing test (total: 5 points). Semantic or recognition memory is evaluated via a naming test for three pictographic animals (total: 3 points). Phonemic or working memory is measured using a memory test of five words, which are given over two short delay trials used to assess learning (no points), followed by a long-delay free recall after 5 minutes to assess retrieval (5 points) and then a multiple-choice cued recall (no points). Attention is evaluated with three tasks, including a

digit repeat task, both forward and backward (2 points); a letter recognition task (1 point); and serial subtraction of 7 starting at 100 (3 points). Verbal fluency is reviewed based on two phrase repeat tasks (2 points) and a verbal naming task where the participant is asked to name as many words starting with the letter F as possible in one minute (1 point if N>11 words). Abstraction is evaluated based on the participant's ability to describe the ways in which two methods of conveyance and two tools for measurement are similar (2 points). Finally, orientation is determined based on the ability of the participant to recite the date, month, year, weekday, specific location, and city (1 point each; 6 total). Altogether, these subitems are summed to provide a range of 0-30 possible points. A score threshold of 26 or lower has a sensitivity of 90% for MCI and 100% for mild AD in the general population. However, subdomains can be assessed individually to determine specific cognitive deficits. Also, preliminary data suggest that lower cutoff scores for both MCI and dementia are needed for minority populations.

16.5 Administration & Detailed Scoring

16.5.1 Version 8.1

The Montreal Cognitive Assessment was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. The MoCA may be administered by anyone who understands and follows the instructions, however, only a health professional with expertise in the cognitive field may interpret the results.The time to administer the MOCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

Interviewers will be trained using a standardized procedure for administering the MOCA questionnaire. All field staff will be certified to administer the MOCA. The certification will take about 1 hour to complete. The Washington State University Coordinator will coordinate the certification of field staff.

16.5.2 Materials Needed

- Quiet testing room with a small table and two chairs.
- Legal notepad with large clips
- Two pencils: one for the examiner and one without an eraser for the participant
- Stopwatch or clock
- MOCA test questionnaire

See **Appendix 1** for Administration and Scoring Instructions

16.6 Strong Heart Study Form

Refer to MOCA form in **Appendix 6** of the Personal Interview and General Examination Manual of Operations (Volume III).

16.7 MOCA Cognitive Assessment Summary

The following can be used as a script by the field centers when administering the MOCA.

Background and Importance

MoCA (2005, Nasreddine) was developed to be more sensitive to mild changes in cognition than the older, more widely-used MMSE/3MSE (1983, Folstein). MoCA evaluates several cognitive domains (areas of cognitive function), including executive function, immediate and delayed memory, visuospatial ability, attention, working memory, language, and orientation. These domains are targeted/affected by Alzheimer's disease and related dementias, vascular injury, frontotemporal dementia, Lewy body disease, structural lesions, and traumatic injury. The MoCA cutoff score <26 to identify impaired functioning in middle-age non-Hispanic Whites does not work well in other populations, as it does not account for important differences by age, sex, race, and education. Cutoffs for dementia that are less prone to false positives include: Hispanic/Latinos <19 and African Americans <16 (2010, Milani). Cutoffs appropriate for American Indian populations have not been established.

MoCA Section 1: Visuospatial & Executive function

- Mini trail making: thought flexibility, planning, comprehension
- Cube copy: visual/spatial, abstraction, planning
- Clock drawing: visual/spatial, memory, organization, visual neglect

MoCA Section 2: Naming

- Pictorial animal naming: language, lexical (word) retrieval, memory, perceptual

MoCA Section 3: Memory

- Word list trials & short recall (no points): encoding memory

MoCA Section 4: Attention

- Digit span: attention, working memory, storing and managing information
- Letter tap: concentration, processing speed
- Serial 7 subtraction: concentration, calculation, working memory

MoCA Section 5: Language

- Repeat phrase: pronunciation, fluency, memory storage
- Letter F word list: phonemic fluency, executive function and planning

MoCA Section 6: Abstraction

- Similarities: abstract vs concrete thinking

MoCA Section 7: Delayed Recall

- Word list long recall, cue, recognition: verbal memory, retrieval, encoding

MoCA Section 8: Orientation

- Time, place: ability to place self in time and space

Reason why a score is not returned

MoCA is often used in clinical setting, but the appropriate MoCA cutoff score to define cognitive impairment or dementia in American Indians--and any test adaptations needed to account for local social environment, language, or culture-- are **not yet known**. Therfore, the test scores may not mean what we think they mean. Our research teams are actively working on these questions, and this research project is intended to help answer these questions. Our goal is to provide normative and diagnostic data so that correct identification of cognitive (dementia) status can be achieved for all American Indian elders.

How to encourage during testing

• "You are doing great with your effort, keep it up!"
• "Remember, just do your best. Some questions are easy, and some are hard. We just want you to try your best"
• [at the end] "Wow! That was a complex test, and you completed it! Thank you for your efforts!"

16.8 References

1. Nasreddine ZS, Phillips NA, Bedirian V, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc 2005;53:695-9.
2. Morris JC, Weintraub S, Chui HC, et al. The Uniform Data Set (UDS): clinical and cognitive variables and descriptive data from Alzheimer Disease Centers. Alzheimer Dis Assoc Disord 2006;20:210-6.

17. National Institutes of Health Cognitive Toolbox (NIH Toolbox)

17.1 Standardized assessment of cognition and dementia

Similar to the MOCA cognitive assessment, the NIH Toolbox Cognition Battery is designed to collect and assess cognitive status continuously across multiple domains of function. The NIH Toolbox measures 5 cognitive domains, including language, executive function, episodic memory, processing speed, and working memory; these measures are also used together to derive a total cognition composite score. These continuous scores can be used to establish risk and diagnostic thresholds for mild cognitive impairment and dementia, although thresholds may vary by population an validity of test. This battery of tests is fully computerized, and can be administered via tablet.

17.2 Data in SHS / American Indian populations

The NIH Toolbox has not been administered to American Indian populations or studies; this will be the first study to collect these data in American Indian adults. This study will also be the first to validate these cognitive tests, and to establish appropriate clinical thresholds for cognitive impairment and dementia using this toolbox.

17.3 Content of NIH Toolbox

The Picture Vocabulary test uses an audio recording of words and photographic images on the computer screen. The Oral Reading Recognition test, participants are asked to read and pronounce letters and words. Dimensional Change Card Sorting ask participants to set-shift by selecting a target picture between two pictures that vary along two dimensions. The Flanker Inhibitory Control and Attention Test ask participants to focus on a target middle stimulus in a series and respond quickly while inhibiting attention to similar stimuli flanking it. The Picture Sequence Memory Test involves recalling the order of increasingly longer series of pictured objects after delay periods. For the List Sorting Test, pictures of different foods and animals are presented that must be mentally sequenced in a given order. Finally, for the Pattern Comparison Test, participants must decide whether pairs of pictures and designs are the same or not. Scoring is done automatically by the testing software for each of the cognitive tests, domains, and for the overall composite score(s).

17.4 NIH Toolbox Script

The following can be used as a script by the field centers when administering the NIH Toolbox.

Additions to the Script:

Background and importance

- Some thinking and memory games are designed to screen for thinking problems. This task is intended to measure a wide range of thinking skills, like memory, attention, and language. We all have areas of strengths and weaknesses when it comes to thinking skills. This task is not intended to measure problems, but rather to understand your current areas of relative strengths and weaknesses across a range of areas of thinking.
- You will find some of the questions are pretty easy, but there will often come a point on many of the tasks when it becomes difficult. This is normal! We aim to push the brain *further* than the brain can go in order to understand your areas of relative strengths and challenges. There is no pass or fail. We just ask that you try your best so we can get the best picture. Your effort to do your best is the most important thing.
- This research is important to our community because many of these thinking tasks were developed in specific groups of people from the majority culture in the U.S. We aim to understand how these tasks work in a wider range of people, including American Indian populations. This will ultimately help us better diagnose and treat thinking challenges across a wider range of people with more diverse backgrounds. This study is aligned with our broader goal of having equitable and data-informed health care for all individuals, particularly American Indian individuals.

What the memory and thinking tasks are for

- There are 7 separate parts to this task which aim to measure different thinking skills, ranging from things like memory and language to problem-solving and thinking speed.
- The reason why we measure each different thinking skill more in-depth is because we learn specific things about how the brain works using this approach.

Only if participant asks:

Reason why they do not get a score

- We cannot give you a score because this memory and thinking task is a research tool and was not developed to provide clinical information for patients yet. Part of our goal is to understand how this works. We need your data to help us understand more! We hope that this research will lead to better, more precise, and equitable tasks to better treat patients from a range of backgrounds, including American Indian, in the clinic soon.

What each task measures

- If participant asks what each task is about:
    - 1: Picture Vocabulary: looks at verbal fluency and general vocabulary in standard American English
    - 2: Flanker Inhibitory Control and Attention: looks at ability to ignore distractions and pay selective attention to a goal, i.e. executive function, inhibitory control, attention

- 3: List Sorting Working Memory: a sequencing task, looks at the ability to store and sort short term information , i.e. working memory
- 4: Dimensional Change Card Sort Test- ability to shift between instruction goals, i.e. executive function, cognitive flexibility
- 5: Pattern Comparison: measures processing speed
- 6: Picture Sequence Memory: looks at episodic memory, which is involved with adding, storing, and retrieving new information in a specific order
- 7: Oral Reading Recognition: looks at measure ability to read, decode, and pronounce a set of increasingly difficult words, i.e. language, oral reading skills

Other notes:

How to encourage during the Toolbox

- Please feel free to give enthusiastic feedback during **practice trials**. E.g., "You got it!", "That's exactly right!" "Now let's keep going!"
- Although it is important to give the tests in a standardized way, you can and should be attentive to the needs of the participant in the moment. Feel free to check in with the patient part of the way through or if s/he looks anxious, "How are you doing?", "Do you need a quick break?", "How about we grab some water or take a walk?"
- Normalize the weirdness of the testing experience: "I know these are strange games. They give us a lot of great information. I really appreciate you going through this with me."
- "You're a great sport, thanks for sticking through these with me!"
- "Keep it up, these games are meant to feel hard!"
- If asked a question or if you can give feedback: "Unfortunately I am not allowed to tell you much as we are going through the tasks. I know that can be very unsatisfying/frustrating." (You may even consider adding this into the general intro to the tests for everyone).
- "You are doing great going through these, keep it up!"
- "Remember, just do your best. Some questions are easy, and some are very hard"
- [after picture vocabulary] You are more than halfway done!
- [after each item on the oral reading] "Thank you!"
    - If you need to check the pronunciation: "Can you say the word again, as you said it before?"
- [at the end] "Wow! That was a long game, and you completed it! That game is not easy, so thank you for all of that effort!"

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Appendices

Appendix 1 Montreal Cognitive Assessment (MOCA) Version 8.1

Administration and Scoring Instructions

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. The MoCA may be administered by anyone who understands and follows the instructions, however, only a health professional with expertise in the cognitive field may interpret the results. For administration of the Visuospatial/Executive section, fold the MoCA sheet so only the first row is visible while participant is drawing. During the Naming section, cover the rest of the sheet with the clipboard while showing the different animals. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

All instructions may be repeated once.

1. **Alternating Trail Making:**
   Administration: The examiner instructs the subject: "Please draw a line going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)]."

   Scoring: One point is allocated if the subject successfully draws the following pattern: 1- A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected (meaning corrected before moving on to the Cube task) earns a score of 0. A point is not allocated if the subject draws a line to connect the end (E) to the beginning (1).

2. **Visuoconstructional Skills (Cube):**
   Administration: The examiner gives the following instructions, pointing to the cube: "*Copy this drawing as accurately as you can.*"

   Scoring: One point is allocated for a correctly executed drawing.
   - Drawing must be three-dimensional.
   - All lines are drawn.
   - All lines meet with little or no space.
   - No line is added.
   - Lines are relatively parallel and their length is similar (rectangular prisms are accepted).
   - The cube's orientation in space must be preserved.

   A point is not assigned if any of the above criteria is not met.

3. **Visuoconstructional Skills (Clock):**
   Administration: The examiner must ensure that the subject does not look at his/her watch while performing the task and that no clocks are in sight. The examiner indicates the appropriate space and gives the following instructions: *"Draw a clock. Put in all the numbers and set the time to 10 past 11."*

   Scoring: One point is allocated for each of the following three criteria:
   - Contour (1 pt.): the clock contour must be drawn (either a circle or a square). Only minor distortions are acceptable (e.g., slight imperfection on closing the circle). If the numbers are arranged in a circular manner but the contour is not drawn the contour is scored as incorrect.
   - Numbers (1 pt.): all clock numbers must be present with no additional numbers. Numbers must be in the correct order, upright and placed in the approximate quadrants on the clock face. Roman numerals are acceptable. The numbers must be arranged in a circular manner (even if the contour is a square). All numbers must either be placed inside or outside the clock contour. If the subject places some numbers inside the clock contour and some outside the clock contour, (s)he does not receive a point for Numbers.
   - Hands (1 pt.): there must be two hands jointly indicating the correct time. The hour hand must be clearly shorter than the minute hand. Hands must be centered within the clock face with their junction close to the clock center.

4. **Naming:**
   Administration: Beginning on the left, the examiner points to each figure and says: *"Tell me the name of this animal."*

   Scoring: One point is given for each of the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. **Memory:**
   Administration: The examiner reads a list of five words at a rate of one per second, giving the following instructions: "This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn't matter in what order you say them." The examiner marks a check in the allocated space for each word the subject produces on this first trial. The examiner may not correct the subject if (s)he recalls a deformed word or a word that sounds like the target word. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, the examiner reads the list a second time with the following instructions: "I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time." The examiner puts a check in the allocated space for each word the subject recalls on the second trial. At the end of the second trial, the examiner informs the subject that (s)he will be asked to recall these words again by saying: "I will ask you to recall those words again at the end of the test."

Scoring: No points are given for Trials One and Two. Place a check mark (☑) in the allocated space for each word and trial for correctly repeated words.

6. **Attention:**

Forward Digit Span: Administration: The examiner gives the following instructions: "*I am going to say some numbers and when I am through, repeat them to me exactly as I said them.*" The examiner reads the five numbers sequence at a rate of one digit per second.

Backward Digit Span: Administration: The examiner gives the following instructions: "*Now I am going to say some more numbers, but when I am through you must repeat them to me in the backward order.*" The examiner reads the three numbers sequence at a rate of one digit per second. If the subject repeats the sequence in the forward order, the examiner may not ask the subject to repeat the sequence in backward order at this point.

Scoring: One point is allocated for each sequence correctly repeated (N.B.: the correct response for the backward trial is 2-4-7).

Vigilance: Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instructions: "*I am going to read a sequence of letters. Every time I say the letter A, tap your hand once. If I say a different letter, do not tap your hand.*"

Scoring: One point is allocated if there is zero to one error (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s: Administration: The examiner gives the following instructions: *"Now, I will ask you to count by subtracting 7 from 100, and then, keep subtracting 7 from your answer until I tell you to stop."* The subject must perform a mental calculation, therefore, (s)he may not use his/her fingers nor a pencil and paper to execute the task. The examiner may not repeat the subject's answers. If the subject asks what her/his last given answer was or what number (s)he must subtract from his/her answer, the examiner responds by repeating the instructions if not already done so.

Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correct subtraction, 2 points for two or three correct subtractions, and 3 points if the subject successfully makes four or five correct subtractions. Each subtraction is evaluated independently; that is, if the subject responds with an incorrect number but continues to correctly subtract 7 from it, each correct subtraction is counted. For example, a subject may respond "92 – 85 – 78 – 71 – 64" where the "92" is incorrect, but all subsequent numbers are subtracted correctly. This is one error and the task would be given a score of 3.

7. **Sentence repetition:**
   Administration: The examiner gives the following instructions: *"I am going to read you a sentence. Repeat it after me, exactly as I say it* [pause]: ***I only know that John is the one to help today.****"* Following the response, say: *"Now I am going to read you another sentence. Repeat it after me, exactly as I say it* [pause]: ***The cat always hid under the couch when dogs were in the room.****"*

   Scoring: One point is allocated for each sentence correctly repeated. Repetitions must be exact. Be alert for omissions (e.g., omitting "only"), substitutions/additions (e.g., substituting "only" for "always"), grammar errors/altering plurals (e.g. "hides" for "hid"), etc.

8. **Verbal fluency:**
   Administration: The examiner gives the following instructions: *"Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready?* [Pause] Now, tell me as many words as you can think of that begin with the letter F. [Time for 60 sec.] *Stop."* If the subject names two consecutive words that begin with another letter of the alphabet, the examiner repeats the target letter if the instructions have not yet been repeated.

   Scoring: One point is allocated if the subject generates 11 words or more in 60 seconds. The examiner records the subject's responses on the scratch sheet .

9. **Abstraction:**
   Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: *"I will give you two words and I would like you to tell me to what category they belong to* [pause]: *an orange and a banana.*" If the subject responds correctly the examiner replies: *''Yes, both items are part of the category Fruits.''* If the subject answers in a concrete manner, the examiner gives one additional prompt: *"Tell me another category* to *which these items belong to."* If the subject does not give the appropriate response *(fruits)*, the examiner says: *"Yes, and they also both belong to the category Fruits."* No additional instructions or clarifications are given. After the practice trial, the examiner says: *"Now, a train and a bicycle."* Following the response, the examiner administers the second trial by saying: *"Now, a ruler and a watch."* A prompt (one for the entire abstraction section) may be given if none was used during the example. Record the responses on the scratch sheet

Scoring: Only the last two pairs are scored. One point is given for each pair correctly answered.

The following responses are acceptable:

- train-bicycle = means of transportation, means of travelling, you take trips in both
- ruler-watch = measuring instruments, used to measure

The following responses are **not** acceptable:

- train-bicycle = they have wheels
- ruler-watch = they have numbers

10. Delayed recall:

Administration: The examiner gives the following instructions: *"I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember."* The examiner makes a check mark (√) for each of the words correctly recalled spontaneously without any cues, in the allocated space. If the subject fails to freely recall one or more, proceed to cueing, as indicated below.

Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (☑) in the allocated space. If the subject does not recall the word after the category cue, give him/her a multiple-choice trial. For example, if the word FACE was not freely recalled with the category cue, ask, "Which of the following words do you think it was, NOSE, FACE, or HAND?" Use the following category and/or multiple-choice cues for each word, when appropriate:

	Category Cue	Multiple Choice
FACE	Part of the body	Nose, face, hand
VELVET	Type of fabric	Denim, cotton, velvet
CHURCH	Type of building	Church, school, hospital
DAISY	Type of flower	Rose, daisy, tulip
RED	A color	Red, blue, green

Scoring: **One point is allocated for each word recalled freely without any cues.** No points are allocated for words recalled with a cue. A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

11. Orientation:

Administration: The examiner gives the following instructions: "*Tell me today's date.*" If the subject does not give a complete answer, the examiner prompts accordingly by saying: *"Tell me the [year, month, exact date, and day of the week]."* Then the examiner says: *"Now, tell me the name of this place, and which city it is in."*

Scoring: One point is allocated for each item correctly answered. The date and place (name of hospital, clinic, office) must be exact. No points are allocated if the subject makes an error of one day for the day and date.

TOTAL SCORE

Sum all subscores listed on the right-hand side. DO NOT add an additional one (1) point if the participant has 12 or fewer years of formal education, this will be done by the analysis team after data collection. Just note the raw score based on the scores in the right column. The maximum score is 30 points. A final total score of 26 and above is considered normal.

Please refer to the MoCA website at www.mocatest.org for more information on the MoCA.

Food Frequency Questionnaire

Manual of Operations Volume VI

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

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Tracking of Revisions to Manual of Operations Volume VI: Food Frequency Questionnaire

Date of Revision	Revised Section	Revision	Approved by, Date
4/20/2023	Entire document	Fixed formatting issues	SHS CC, 11/1/2022

Table of Contents

VI. Food Frequency Questionnaire

1. Block 2014 Food Frequency Questionnaire (FFQ)

The following pages are extracted from the Instructions Manual for the Block 2014 FFQ.

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BLOCK 2014

Food Frequency Questionnaire

Interviewer Instructions for the 2014 Questionnaire

Food Frequency Questionnaire

Mechanics

Use # 2 pencil	To ensure that the scanner reads correctly, the questionnaire must be completed using a #2 pencil. A hard pencil may produce too light a mark, and may be scanned as missing.
No other marks on questionnaire	Comments or notes should not be written on the questionnaire, as they may confuse the scanner. Comments must be on a separate page.
Bubble completely	Fill in the answer bubbles completely. Do not simply make a checkmark or an "X" over the bubble.
One bubble per answer	Never mark two bubbles for the same answer -- both will be lost as an error.
No staples	Staples would have to be removed, and if inadvertently not removed could damage the scanner. Marks left by staples can interfere with the scanner reading of tracking marks, booklet number marks or page number marks, and necessitate someone copying over the entire questionnaire.
No extra pages	Do not insert any extra pages or papers with notes on them into the booklet, or attach yellow stickies. If not noticed prior to scanning, they might interfere with the scanning.
No folds	Do not fold the questionnaire.
No 3-hole punch	Holes might interfere with the scanning process.
Portion size pictures	A single page of portion size pictures is attached as the last sheet of the questionnaire booklet. Carefully detach this page. This sheet is **not** to be returned to NutritionQuest with completed FFQ booklets sent for analysis.

General Instructions

Introducing the Food questionnaire	Provide a transition from the other parts of the interview to the Food Questionnaire section, with a phrase such as the following: "Now I'd like to ask you some questions about the foods you usually eat." Do not use phrases that include the word "diet", as some respondents may think we mean "dieting", rather than simply their usual food habits. Do not spend too much time at this initial introduction.
Read questions as written	The words are not optional. Do not paraphrase. Do not omit any words. For example, "in season" is an essential part of the prompt for the foods in which it is used. Some foods that may be unfamiliar to you are being marketed nationally; do not omit them. Read the entire question before accepting a response from the subject; there may be foods at the end of the list that he/she needs to know are included.
Respondent questions	If respondent asks a question for clarification, and you know the answer because it is in this manual, you may give her the answer; it is not necessary to reread the entire question. For example, in the general question "How often do you use fat or oil, to fry, stir fry....?": If respondent asks, "Does that include butter I put on bread?" you may answer "No, just fat you may use to, stir-fry...", without rereading the whole question.
Foods not on the food list	The food list represents the most important nutrient sources in most people's diets. It does not and is not intended to include all possible foods that people ever eat. Thus, it is likely that some foods that a person eats will not be on the list. Do not attempt to force unmentioned foods into categories by guessing at their similarity.

Instructions About the Frequency Part of the Food Questions

Importance of frequency

Although portion size improves the accuracy of the nutrient estimates, the interviewer should be aware that frequency of consumption is much more important than exact portion size in determining long-term usual intake.

Frequency categories

Note the frequency categories at the top of the columns. Be careful to mark the correct column, since being off by a column can make a large difference in the nutrient estimate.

Although you will ask the question in an open-ended way ("How often do you eat..."), encourage the respondent to give her answers in terms of one of the predefined categories. Respondents easily get the idea, and will quickly learn to give answers in the categories shown.

Should I read all the response categories?

In this Food Questionnaire, the answers are all in categories, such as "Once per month", "5-6 times per week",....

In most cases it is not necessary to read the response categories every time, although you may do so if the respondent is hesitating or unclear. Instead, you will first show the respondent an example of the type of categories you will be using to record her answers. Then, you will simply ask the question in an open-ended way, wait for a response (such as "5 times a week"), and record it in the appropriate category.

Section dividers

Questions are grouped together by type of food, such as “Cereals, grains, breads”, or “sweets and desserts”. Introduce each section with a phrase such as this: “The next questions are about fish and seafood”.

Some sections also include additional instructions to introduce the foods in that section. Read the text as written. E.g., “Next, I’m going to ask about fruits. How often do you eat the following 2 items, just during the summer months when they are in season?”

Wording of the frequency questions

It is not necessary to say "How often do you eat ...." for every food. You can repeat the introductory phrase from time to time, but most often you should just read the next food, without the "How often...." This will make the interview go a little faster, be less boring, and perhaps encourage the respondent to pick up the pace. Similarly, avoid repetitively saying "[name of food].... How often do you eat that?" It is okay to say that occasionally to vary the wording and pace, but not for every food. Do not, however, just say "Do you eat ..."; this unnecessarily lengthens the interview, because then if the respondent says “yes,” you still have to ask the "How often" question.

How often vs. How many

There is a potential confusion between “how often” and “how many”, particularly for fruits. Make sure to keep them separate for the respondent. For example, when you ask “bananas”, some respondents may say "I eat two a week"; this could lead to double-counting if you marked “2/wk”, then asked “how many” and she said “2”. So if the respondent is answering fruits as "I eat two a week", explain that you will ask "How many" in a subsequent question; right now, you want her to tell you “how often” per week, meaning "how many days", not how many bananas per week.

Always get the frequency ("How often") before asking about portion size ("How much" or "How many"). While the respondent is thinking about her answer to "How often", do not interrupt with any mention of portion size. Do not point to the portion size pictures until after you know her answer to "How often".

Seasonality

For the first two questions in the fruit section -- “Watermelon...”, and “Strawberries...” -- ask specifically about intake <u>just during the summer months</u> when the fruits are “in season”. The respondent should give the frequency with which that food is consumed, just in the few-months period when it is in season.

All other foods require an estimate of average year-round frequency of consumption. If the respondent eats some of these “year-round” items more in one season than another, the reported frequency should still be a rough average over the whole year. For example, if respondent says "I eat apples 3 to 4 times a week now that they're in season", you should say something like, "Please try to estimate how often that would average out to over the whole year."

If the respondent is unable to do the conversion herself, then the interviewer may use the following chart to estimate for her.

Average use in season	**Conversion**	**Average use year-round**
Every day	Shift 3 columns to left	Twice per week
5-6 times per week	Shift 3 columns to left	Once per week
3-4 times per week	Shift 3 columns to left	2-3 times per month
2 times per week	Shift 2 columns to left	2-3 times per month
Once per week	Shift 2 columns to left	Once a month
2-3 times per month	Shift 2 columns to left	A few times per year
Once a month	Shift 1 column to left	A few times per year
A few times per year	Shift 1 column to left	Never
Never	No change	Never

Buying in bulk	Some respondents will say something like "I buy a gallon and then drink it until I'm done with it". Again, you should ask her to try to average her intake over the whole year. Something like, "Please estimate how many glasses per day or per week you think you drink, on average over the whole year."
Items with more than one food	For example, "Tacos, burritos, enchiladas...". Do not try to get separate estimates of either frequency or portion size for these foods. Just ask the respondent to answer their frequency for the group of foods. And don't worry about the foods having different sizes; just ask the respondent to pick the portion size picture that that best approximates how much she usually eats of that group of foods.
Answers that straddle response categories	If the respondent answers with a range that does not fit exactly into one of the available response categories, ask the respondent to choose which of the available categories is closer to how often she uses that item. For example, suppose you ask the respondent "How often do you eat bananas", and she answers "once or twice a week". You would then say, "Would that be closer to "once per week or twice per week?"
"Never" frequency	Use the "Never" column for any foods either literally never eaten, or eaten by the respondent less often than "a few times per year". They will be counted as zero.
Responses with different wording	Apply common sense. "Less than once a year" or "3 to 4 times in my life", code as "Never" without further probing. Answers such as "I eat that on most days" should be further probed to identify the exact frequency response: "Would you say that's closer to "5-6 time per week", or "Every day"?

Instructions about the *Portion Size* Part of the Food Questions

Portion size is easy in this interview

Ask the portion size before moving on to frequency of the next food. You don't need to worry about converting to half cups, ounces, etc.

Just mark the bubble corresponding to the respondent's portion size choice:
"A" = 1st bubble
"B" = 2nd bubble
"C" = 3rd bubble
"D" = 4th bubble

Wording of the portion size questions

It is not necessary to make a full sentence out of the portion size section each time. I.e., do not say, for every food, "When you have ..., about how much/many do you have each time?" Instead, for the "how many", just say "How many teaspoons", etc. For the foods with "How much", you can say "How much on those days?" and point to the pictures; or, after a while, just say "A, B, C or D?"; or you can say "Which bowl?"

"XXL"

If the respondent says that his/her usual portion is larger than the largest model (which corresponds to the fourth bubble), record the answer as the fourth bubble.

How important is portion size?

Although portion size will definitely improve the accuracy of the answers, you should not permit the respondent to spend undue time on the portion size answers. This section should move along quite quickly, with a breezy "How many" or "A, B, C or D?"

Note on beverage "portion sizes"

The portion size part of the beverages section is designed to capture the *number* of glasses, bottles, cans, etc. that the respondent usually drinks, on the days she drinks the beverage.

Rather than asking an additional question about *the size* of the beverage that the respondent drinks, to simplify administration of the questionnaire several standard sizes of bottles, cans, etc. are listed in the portion size section for several beverages.

For the beverage items listing portion size in "glasses", one glass size is assumed to be an 8 oz. serving, for the following beverages: milk (not including chocolate milk), tomato/V8 juice, 100% juices, all other fruit juices.

A 12 oz. glass or bottle size is assumed for the following beverages: chocolate milk, drinks like cranberry juice cocktail, drinks like Sunny Delight.

A 16 oz. glass or bottle size is assumed for iced tea.

A 6 oz. glass is assumed for wine.

A 9 oz. cup is assumed for coffee and tea.

These portion sizes are provided as clarification for you, the interviewer, so that you will be able to answer questions if the respondent asks. **The interviewer does not need to offer the respondent this information, but if he/she asks, you may respond to questions using the information provided here.**

Correct wording for asking the portion size questions

Each food has a correct wording for asking the portion size question ("how many", "how much" etc). The correct wording is given in the column just preceding the portion size bubbles. The cue about the correct wording is in the words underneath the portion size bubbles.

SUMMARY OF HOW TO ASK PORTION SIZE

What is under the portion size bubbles:	How to ask the question:
A number	Ask "HOW MANY?" or "HOW MUCH?" and get an answer in number of items.
A-B-C-D	Ask "HOW MUCH?" and get an answer as A-B-C-D referring to the pictures.
"How many" questions	Ask "How many on those days" or sometimes just "How many". Use the unit that is the name of the food (e.g., "bananas") or that is shown in the "Portion Size" column (e.g. "slices", "teaspoons", "bowls"). If the portion size descriptor lists additional information, such as the unit, read that too. For example, "How many 12-ounce servings?" Code response according to respondent's answer ("1", "2", "3", etc.). For example, look at "Bananas": ask portion size in an open-ended way, as "How many in a day?" You then record the answer in the appropriate bubble, "1/2", "1", "2". If the number reported is larger than shown for any of the bubbles, use the fourth bubble. Acceptable phrasing: "How many bananas in a day?" "How many in a day?" "How many each time?" "How many, on the days you eat them?" Some questions, like "breakfast pastries", include portion size responses in both small and medium units. For these items, read the portion sizes choices to the respondent. For example, "How many pieces in a day? 1 small, 1 medium, 2 pieces or three?"

"How much" questions

Ask "How **much on those days,** A, B, C or D?", or just "A, B, C or D?", or "Which picture, A, B, C or D?" Code A-B-C-D as 1st bubble, 2nd bubble, 3rd bubble, 4th bubble, without any kind of conversion, calculation or interpretation.

For example, "Strawberries or other berries, in season": In the "How Much" section, you see "A,B,C,D". For these foods, indicate the portion size pictures and ask the respondent to choose the picture closest to her usual portion. Again, **the respondent may use either the plates or the bowls to give his/her answer**.

Acceptable phrasing:
"How much on those days? A, B, C, or D?"
"How much each time?"
"Which of these pictures is closest to your usual portion?"
"Which picture is closest to the amount you usually eat?"

Eventually, you can say simply say "A, B, C or D?"

Q by Q (question by question) – Introduction

Respondent ID Number	The Respondent ID number must always be filled in. This number must be unique to the subject and only include 10 numeric characters. This ID is the only variable that will make it possible to connect the nutrient estimates with the right individual. Write in the Respondent ID and be sure the correct bubbles are filled in completely and accurately. If there are fewer than 10 digits in the subject's study ID, ask the study coordinator how to enter the digits – either left- or right-justified.
Today's date	The date the questionnaire is completed. Write in date and fill correct bubbles completely.
Sex	"Sex" must be answered. The analysis program uses it to calculate subject's Dietary Reference Intakes (DRIs) and Recommended Dietary Allowances (RDAs).
Pregnant or Breast feeding	"Pregnant/breast feeding" must be answered. The analysis program uses it to calculate subject's DRIs and RDAs.
Age	Age must always be filled in, and bubbled in. The analysis program uses it to calculate subject's DRIs and RDAs.
Weight	Weight should always be filled in. It's used to determine the subject's Basal Metabolic Index (BMI), which is essential for the calculation of energy **expenditure**. The bubbles must be filled in, not just written in at the top.
Height	Height should always be filled in. It's used to determine the subject's BMI, which is essential for the calculation of energy **expenditure**. The bubbles should be filled in, not just written in at the top. Note that the first bubble is for height in feet, and the second bubble is for inches. In case of a "1/2 inch", *round down.*

Introducing the Main Food List

Read the introduction to the food list, on page 1:
This form is about the foods you usually eat.... Please tell us:"

1. "*HOW OFTEN, on average, did you eat the food*"

   After the last sentence you should point to the questionnaire and prompt: "Is it 'Never', 'A few times per year', 'Once per month', '2-3 times per month', 'Once per week', '2 times per week', '3-4 times per week', '5-6 times per week', or ' Every day'."

2. Continuing with the introduction, read the next section: "*HOW MUCH of the food did you usually eat on the days you ate it?*

   "Sometimes we ask "how much" as A, B, C, or D. LOOK AT THE PORTION PICTURES." At this point, you should hand them the page of portion size pictures, and continue with the introduction: *"Pick the picture that looks the most like the serving size you usually eat."*

   The respondent can use either the plates or the bowls to choose her serving size, but generally, she should refer to the bowl pictures for foods that are usually eaten in bowls (breakfast cereal, soups...), and the plate pictures for foods that are usually eaten on plates. Note that there is no "A" bowl.

   Finally, if you refer to the portions as A, B, C, or D, it will encourage the respondent to refer to them that way, thus speeding up the process.

3. WHAT TYPE. *"For some foods we ask the type, for example, low-fat or low-sugar. We'll ask these TYPE questions near the end of the questionnaire."*

   The **time frame** covers "the past year or so". This is deliberately a little vague, because it is not expected that anyone could remember exactly what he or she ate during exactly the past year. The idea is just to get a usual pattern -- their current diet at this point in their life. Some people raise the objection, "Oh, I can't even remember what I ate yesterday; how could anyone answer what they ate in the past year?" If respondents have this concern, it's important to make clear to them that the idea is not to remember, but to think about their usual pattern of frequency. For example, they don't have to remember how many times they had eggs in the past year. Instead, what they can tell you with reasonable accuracy is, "Oh, I have eggs about twice a week."

   For some items, people may indicate that they have changed their habits in the past year. In that case, ask "Do you expect that this is a lasting change?" If the new habit appears to be lasting and stable, she should report on the new pattern rather than the former pattern.

Q by Q – Eggs and Dairy Foods

Breakfast sandwiches or breakfast burritos with eggs or meat	Include egg sandwiches on biscuits, croissants, or English muffins, egg biscuits and egg burritos, whether fried, scrambled, poached or boiled. The defining ingredient of these items is the egg, for the cholesterol and protein content. Thus, do not count egg sandwiches/burritos made with egg substitutes. This food question also includes breakfast sandwiches with meat, but no eggs, such as breakfast biscuits.
Other eggs like scrambled or boiled, or quiche (not egg substitutes)	Include real eggs when eaten as eggs, including scrambled, boiled, and fried. Also, include deviled eggs, egg salad and quiche (which is largely egg). Do not count eggs used in cooking, such as in cakes, custards, etc. Do not count Egg Beaters, egg substitutes, or if only egg whites are eaten. The main point is the cholesterol, so if they scramble, for example, one egg yolk and two egg whites, just count the number of yolks.
Yogurt (not frozen yogurt)	Include all varieties, with or without fruit, regular or low-fat, sweetened or artificially sweetened. Do not code the fruit in yogurt separately as fruit.
Cottage cheese, ricotta cheese	Include whole fat, low-fat, and nonfat.
Cream cheese, sour cream, dips	Include cream cheese, sour cream, and **dairy-based dips** eaten on breads, bagels, crackers, chips and vegetables. Include all types, regular or lowfat. Do not include vegan varieties. Do not include guacamole or hummus. These dips are separate items that will be asked later.
Cheese, sliced cheese, cheese spread, including in sandwiches and quesadillas	Include all types, regular or low-fat, hard cheese or soft cheese, natural or processed. Do not include cream cheese. This refers specifically to cheese eaten as cheese. It should not include cheese eaten in lasagna, pizza, etc. Those foods will come later. Toward the end of the questionnaire, we will ask about the type of cheese usually eaten, like regular or low-fat.

Q by Q – Cereals, Grains and Breads

Cold cereals, ANY KIND, like corn flakes, fiber cereals, sweetened cereals	Frequency with which respondent eats any *cold* cereal. Toward the end of the questionnaire, we will ask about the type of cereal usually eaten.
Oatmeal, or whole grain cereal like Wheatena or Ralston	This refers to cooked whole grain hot cereals. Include steel cut, oat flakes, whole wheat hot cereals. Muesli can be eaten either hot or cold; if the respondent reports eating muesli it should be counted here. Do not include Cream of Wheat; this will be asked in the next question.
Grits, cream of wheat, cornmeal mush	This refers to all non-whole grain cooked cereals, including cream of wheat, cream of rice, barley and hominy.
Milk or milk substitutes on cereal	Ask about milk on cereal only if respondent eats either cold or hot cereal. If they NEVER eat cereal, mark NEVER for milk on cereal and move to the next question. Ask the question just like any other, "how often do you use...", if the respondent eats cereal. Do not just assume that the frequency will be the same as the frequency of cereal. (Some people eat cereal plain, as a snack.) Frequency: For most people, this will be the number of days per week or month that they eat any kind of cold or hot cereal with milk. Some respondents may say "*every time*". Do not code this as "every day". Rather, look back at her cereal frequencies and remind her of how often she said she eats cold and hot cereals; then ask her, 'so, about how often do you use milk on cereal, per week?"
Brown Rice, or dishes made with brown rice	This includes not only brown rice eaten by itself, but also dishes made with brown rice, such as fried rice, rice and beans, etc.
White rice, or dishes made with rice, like rice and beans	This includes not only white rice eaten by itself, but also dishes made with white rice such as sushi, fried rice, Rice-a-roni, beans-n-rice, rice pudding, etc.
Pancakes, waffles, French toast, crepes	With or without butter or syrup. Syrup will be added automatically by the program.

Breakfast pastries, like muffins, scones, sweet rolls, Danish, Pop Tarts, pan dulce	Also include coffee cake, croissants, sweet rolls, cinnamon rolls, etc. Muffins include kinds such as bran muffins, blueberry muffins, etc. Do not include corn muffins or English muffins. Corn muffins should be included under "Corn bread…" and English Muffins are under "Bagels…" below.
Biscuits, not counting breakfast sandwiches	Biscuits include homemade or from fast food places such as Kentucky Fried Chicken, McDonalds. Do not count biscuits counted in breakfast sandwiches above.
Corn bread, corn muffins, hush puppies	Includes cornbread, corn muffins, hush puppies, and cornmeal based breads and puddings.
Hamburger buns, hotdog buns, submarine or hoagie buns	All types, all sizes. Do not count sliced sandwich bread here. That should be counted below.
Bagels or English muffins, dinner rolls, pita, naan	Any kind, any size. Can also include flatbreads, focaccia, and injera.
Tortillas (not counting in tacos or burritos)	Includes flour and corn tortillas. Portion size is in number of tortillas each time. Do not include the tortillas eaten as part of a taco or burrito or breakfast burrito, as these have been counted elsewhere.
Any other bread or toast, including white, dark, whole wheat, and what you have in sandwiches	Includes any kind of bread that has not already been recorded, including White, French, Italian, etc., whole wheat, rye, pumpernickel, or other dark breads. Include bread eaten in sandwiches, toast, etc. In reporting portion size, the response is in "slices". The type of bread usually eaten -- e.g. whole wheat vs. regular -- will be recorded near the end of the questionnaire.

Q by Q – Vegetables

All vegetables consumed, whether fresh, frozen, canned, or in stir-fry, should be included here if the amount equals at least the "A" size portion picture (approximately equal to one quarter cup).

Vegetable soup, vegetable stew, vegetable-beef stew are their own items; the vegetables in those soups/stews should not be reported separately under the individual vegetable items. Small "incidental" amounts that may be included in salads or mixed dishes should not be reported separately under the particular vegetable, unless the amount is equal to at least a half cup. Most of the vegetables must be answered in terms of the portion size pictures. Do not let the respondent answer in ounces.

Broccoli, Chinese broccoli, or Brussels sprouts	Includes cooked or raw. Includes items from salads only if the amount comes to at least the size of a quarter cup, and then only if the frequency that this vegetable itself is actually eaten, not just the frequency that salad may be eaten.
Carrots, and mixed vegetables containing carrots	Includes cooked or raw. Include items from salads only if the amount comes to at least the size of a quarter cup, and then only the frequency that this vegetable itself is actually eaten, not just the frequency that salad may be eaten. Does not include carrots eaten in mixed dishes such as soup or stew, as those items are captured elsewhere.
Corn	Fresh, frozen or canned. Ask the respondent to estimate their year-round average, even if they report eating fresh corn mostly in the summer months. Remember that people may eat corn on the cob when it is in season, but eat canned or frozen corn during the rest of the year. One ear of corn equals approximately a "B" or medium serving (approximately onehalf cup).
Green beans, string beans, green peas	Green beans refer to canned, frozen, fresh, or in salad bars, but not to dried-type peas like black-eye peas, split peas. Green peas (canned, frozen, fresh, or in salad bars) are also counted in this category.
Cooked greens like spinach, collards, turnip greens, kale, mustard greens	This refers specifically to cooked, dark-green, strong-flavored greens. Cooked beet greens or chard, for example, may be counted here. However, lighter-green leafy vegetables such as celery tops should not be counted here. Raw spinach in *salad* (as opposed to cooked spinach) should be recorded under Green salad below.
Cabbage, cole slaw, Chinese cabbage	Includes raw or cooked cabbage, including Chinese cabbage and cole slaw, whether homemade or from a restaurant.

Green salad with lettuce or raw spinach	Includes all kinds of green salad that include some lettuce or raw spinach, whether mostly of iceberg lettuce or of other types of lettuce, and regardless of whether other vegetables are sometimes eaten in it. Mixed greens and spinach salad should be recorded here also.
Raw tomatoes	Includes raw tomatoes eaten alone or in salad. Does not include tomato sauces, which are captured under "spaghetti", etc. Does not include the tomatoes in tomato or vegetable soups, which are captured under that item. The portion size refers to 1/4, 1/2... of a medium tomato.
Salad dressing	All types, creamy or not, including oil and vinegar. The type -- regular or low-fat – is assessed later in the questionnaire.
Avocado, guacamole	Include avocado eaten alone or in a sandwich, salad, dish, or dip. Portions: Keep in mind that 1 whole Avocado = approximately 10 TBSPS; ½ Avocado = approximately 5 TBSPs; 1/5 Avocado = 2 TBSPs. If the respondent reports eating a whole avocado on the days they eat avocado, you may double the reported frequency response.
Sweet potatoes, yams	All types. Do not include the sweet potatoes eaten in pies; that question is asked later.
French fries, home fries, hash browns, tater tots	Include those eaten at home or in a restaurant – fries, home fries, hash browns and tater tots.
Potatoes not fried, like baked, boiled, mashed, or in stew or potato salad	Include all forms of potatoes that are not fried, including large amounts found in stew. Do not include sweet potatoes, as those were captured above.
Any other vegetable like squash, cauliflower, peppers, okra, nopales	Includes any other vegetables that were not mentioned previously.

Q by Q – Fruits

Seasonality: Among the fruits, 2 of the items refer to intake "in season", while 7 items refer to intake "year round". If any of these "year-round" foods are eaten more in one season than another, ask respondent for her best estimate of a year-round average.

It is essential to read the "in season" text, and respondents should report the frequency with which that fruit is eaten when it is in season (refer to the "seasonality" section above for a detailed discussion). Do not probe for length of season.

Jams and jellies should not be counted as servings of fruit. Fruit in yogurt does not count as servings of fruit.

In season (summer) fruits – FRESH only

Watermelon, cantaloupe, honeydew, other melons, in season	Fresh only. Report frequency only for the few months they are "in season".
Strawberries or other berries, in season	Fresh only. Also include blackberries, blueberries, and raspberries. Report frequency only for the few months when they are "in season".

All-year-round fruits.

Bananas	All kinds, all sizes.
Apples or pears	All kinds, all sizes; includes pears, or Asian pears. Discourage respondents from trying to do math, adding up separately their apples and their pears. An intuitive average is fine. Do not include dried, as dried fruit is asked below.
Oranges, tangerines, grapefruit	**All kinds, all sizes; includes all oranges (not as juice), tangerines, tangelos, mandarin oranges.** Orange juice is asked later in the questionnaire. If respondent only uses oranges to make juice, tell her to wait and count that as orange juice. If she sometimes eats them as oranges and sometimes as juice, just get frequency of "as oranges" in the fruit section, and then later get the "as juice" in the juice section.
Peaches and nectarines	Include fresh or frozen. Do not include canned or dried, as those are asked below.

Any other fresh fruit like grapes, plums, mango, fruit salad	ANY other fresh fruit. Do not include canned or dried.
Raisins, dates, other dried fruit	Include all types: raisins, cranberries, prunes, dates, and so on.
Canned fruit like applesauce, fruit cocktail, canned peaches or pineapple	Any kind of canned fruit.

Q by Q – Beans, Tofu, and Meat Substitutes

In this section, include those eaten alone, or in mixed dishes like burritos, chili, stir-fry, salad.

Refried beans, bean burritos, or hummus	Burritos that have meat should NOT be recorded here. Record them under the "Tacos, burritos item on page 4."
Pinto beans, black beans, kidney beans, baked beans, lentils	With or without meat. This includes all dried-type beans, regardless of whether they're mentioned here or not, such as navy beans, red beans, etc. Do not include pea or bean soups; these are asked later.
Tofu or tempeh	Refers to "fresh" tofu such as is normally served in Chinese restaurants, or bought in the refrigerator section of the supermarket. Includes all consumption, whether at home or in a restaurant. Includes regular tofu, and fermented or dry, spiced, or koritofu. Count "vegetarian meats" under the next item, "meat substitutes...".
Meat substitutes, like veggie burgers, veggie chicken, vegetarian hot dogs or vegetarian lunch meats	This includes all meat substitutes, such as "veggie-burgers" or "veggie hot dogs", whether from a restaurant, or from the refrigerated or frozen food sections of the supermarket.

Q X Q – Soups, mixed dishes, and noodles

Split pea, bean, or lentil soup	Any type of pea, bean, or lentil soups may be counted here.
Vegetable soup, vegetable beef soup, or tomato soup	Any type of vegetable soup that has lots of carrots or has a tomato base.
Any other soup including chicken noodle, cream soups, Cup-ASoup, ramen	This is the catchall for all other forms of soup, whether creamed or not. Meat soups, chowder, pozole, caldo de res, udon, etc.
Pizza or pizza pockets	All forms, all sizes, all toppings, homemade, from a restaurant or from frozen, with or without meat.
Macaroni and cheese	Macaroni and cheese.
Spaghetti, lasagna, other pasta with tomato sauce	This item should include only those pasta dishes that are eaten with tomato sauce. It can include mixed pasta items such as raviolis. The defining characteristic is the tomato sauce. When asking this question, emphasize the words "with tomato sauce".
Other noodles like plain pasta, pasta salad, sopa seca	Any other noodle or pasta dish not already answered above.
Egg rolls, won tons, samosas, empanadas	Includes savory pastries filled with meat and/or vegetables such as dumplings, dim sum, knish, savory crepes and turnovers

Q by Q – Meat and Chicken

Hamburgers, cheeseburgers, turkey burger, at home or from a restaurant	All sizes, at home or in a restaurant. Does not include the ground beef or turkey that is used in spaghetti, lasagna or pizza.
Hot dogs, or dinner sausage like Polish, Italian, chicken apple	All forms, including beef, pork, chicken or turkey varieties.
Bacon or breakfast sausage	Bacon or breakfast sausage. Includes turkey bacon. Do not count the sausage/bacon from breakfast sandwiches, as that was counted earlier.
Lunch meats like bologna, sliced ham, sliced turkey, salami	Lunch meats, all types. Ham refers to slices as for sandwiches; ham eaten as a roast or as the entree for a main meal should be reported under "pork" (as asked about below). Do not include small amounts eaten on pizza, etc. Do not include vegetarian lunch meats as those were asked earlier.
Meat loaf, meat balls	Include ground beef or meat mixtures that are mainly beef used in meatballs, meat loaf, or ground meat kebabs. If ground meat is mainly turkey or chicken, include under “Roasted or broiled chicken or turkey” (as asked about below). If ground meat is mainly pork (not sausage), include under “Pork chops” (as asked about below).
Steak, roast beef, pot roast, including in frozen dinners or sandwiches	Fresh, in frozen dinners, or on sandwiches. Do not include beef eaten as ground beef.
Tacos, burritos, enchiladas, tamales, tostadas, with meat or chicken	Includes tacos, burritos, enchiladas, tamales, tostadas, or other similar dishes that are made with meat or chicken. Do not include bean burritos here; they should be included in the previous section, under "refried beans or bean burritos".
Ribs, spareribs Pork chops, pork roasts, cooked ham (including for breakfast)	Any type, any size of ribs or spareribs. Do not include pork-based lunch meats.

Any other <u>beef or pork</u> dish like stew, pot pie, corned beef hash, chili, Hamburger Helper, curry	Include any mixed dish with <u>beef or pork</u> that has not already been counted earlier. "Mixed dishes with <u>chicken</u>" are asked about in a later question.
Liver, including chicken livers or liverwurst	All forms.
Pigs feet, neck bones, oxtails, tongue, chitlins	This item includes the listed foods as well as any other organ meats.
Veal, lamb, goat, deer meat, other game	This item includes these three types of meat and any other "game" meat but not type of fowl.
<u>Fried</u> chicken, including chicken fingers, chicken nuggets, wings, chicken patty	All parts of a chicken are included (wings, thighs, breast, etc.) provided they **are fried**. Include McNuggets, etc.
Roasted or broiled chicken or turkey	Include roasted, broiled or BBQ here, but <u>not</u> chicken or turkey eaten as part of a mixed dish (see next question).
Any other <u>chicken or turkey</u> dish, like chicken stew or curry, chicken salad, stir-fry, Chinese chicken dishes	Includes any mixed dish with chicken or turkey that has not already been counted elsewhere.

Q by Q – Fish, Seafood

Oysters	Any form, raw, fried, or in stew or soup. Portion size refers to the amount of oysters, and should not include any noodles, rice, etc., eaten with it.
Shellfish like shrimp, scallops, crab	All forms, including clams, mussels, squid, etc. Include fried, grilled, sautéed, or in soups, stews or gumbos, or in pasta. Portion size refers to the amount of shellfish, and should not include any noodles, rice, etc., eaten with it.
Tuna, tuna salad, tuna casserole	All forms of tuna, light meat or dark, canned in oil or in water, raw (sushi or sashimi), or in a casserole. Portion size refers to the amount of tuna, and should not include any noodles, rice, etc., eaten with it.
Salmon, mackerel, sea bass, trout, sardines, herring, without breading	The category includes high omega 3 fatty-acid fish – (others examples are char, anchovies, etc. Fish can be raw (sushi or sashimi), baked, steamed, poached, seared, BBQ, canned. Not fried or breaded.
Fried fish, fish sticks, fish sandwich, breaded fillets	Home-made, or from a restaurant or fast food. All types of fried or breaded fish.
Any other fish	Include all other fish that has not been counted above. Include baked, grilled, raw, sautéed, in soups, stews, or sauces for rice, pasta or noodles. Portion size refers to the amount of fish, and should not include any noodles, rice, etc., eaten with it.

Q by Q – Nuts, Seeds, Snacks

Peanut butter or other nut butters	Peanut butter or other nut butters like almond butter may be included in this item.
Walnuts or flax seeds (don't count flax seed oil)	Walnuts and flax seeds (not counting flax seed oil), and other seeds high in omega-3 and omega-6 fatty acids such as chia or hemp seed.
Peanuts, sunflower seeds, other nuts or seeds	Peanuts, and any other nuts or seeds, including almonds, cashews, pistachios, sunflower, pumpkin, etc.
Energy or protein bars like Power Bar, Clif, Balance, Luna, South Beach, Atkins	Both bars high in carbohydrate and bars high in protein may be counted here. The type of bar usually eaten is asked later.
Breakfast bars, cereal bars, granola bars (not energy or protein bars)	These do not have to be eaten for breakfast. Count them at any time of day.
Popcorn	All types, including air popped, microwave, from a movie theater, caramel and kettle corn, etc.
Whole grain crackers, like Wheat Thins, RyeKrisp, Ryvita, Wasa	Only include whole-grain types, regular or low-fat.
Any other crackers, like saltines, Ritz, Cheez-Its, cheesefilled pretzels	All other crackers or pretzels. Any kind, regular or lowfat.
Tortilla chips or corn chips, like Fritos, Doritos, corn nuts	Corn or tortilla chips or multigrain-based snacks. Regular, low-fat or baked. Do not include Cheetos or corn puffs. This is a separate item.
Any other snack chips, like potato chips, Cheetos, Chex mix	Potato chips, Cheetos, Chex mix, or other salty snacks like corn puffs, pork cracklings, snack mix, rice crackers, vegetable chips, sesame nuggets, etc.

Q X Q - Sweets and Desserts

Donuts	This is intended to capture any kind of doughnuts or sweet fried pastry, such as doughnuts, churros, etc.
Cake or snack cakes like cupcakes, Twinkies, pound cake, banana bread	All kinds of cakes, home-made or packaged, including snack cakes, etc. Do not include muffins, coffee cake, or breakfast pastries, as these were asked previously. Toward the end of the questionnaire, we will ask about the type of cake, such as whether regular or low-fat.
Cookies, brownies	All kinds. Cookies vary widely in size. The portion size questions refer to a medium-sized cookie, roughly the size of an Oreo cookie.
Pumpkin pie, sweet potato pie	Include pies or puddings made with pumpkin, sweet potato, or winter squash. However, do not double-count the frequency of sweet potato intake reported in an earlier item.
Any other pie or cobbler, including fast food pies, snack pies	All forms, fruit-filled or not. Include fast-food pies and snack pies sold at convenience stores.
Ice cream, ice cream bars, frozen yogurt, fast food milkshakes	All forms, including ice cream bars, fast-food milkshakes, etc.
Pudding, custard, rice pudding, flan	Include all pudding and custards, flan, mousse, haupia (coconut pudding), etc.
Chocolate or other flavored sauces or syrup, on ice cream	Include flavored syrups and sauces added to food just before eating, such as ice cream topping. Do not count chocolate syrup that may be used to make chocolate milk, hot chocolate or cocoa, as these drinks are asked later in the beverages section.
Popsicles, jello, frozen fruit bars, slushies, sherbet (don't count sugarfree)	Also includes ices, gelatin desserts, sorbet, gelato, etc. Do not include sugar-free varieties.
Chocolate candy, candy bars like Snickers, Hershey's, M&Ms	Only chocolate-covered or chocolate-based candy and candy bars should be included here. The point is the chocolate, not just any candy.

Any other candy, not chocolate, like hard candy, Lifesavers, Skittles, Starburst, breath mints, chew gum (NOT sugar free) Any sugar-based, non-chocolate candy. Do not include sugar-free candy

Q x Q – Spreads, Sauces, Other Foods

Margarine (not butter) on bread, rice, vegetables, or other foods	All forms of margarine, not butter, on bread or added to rice, vegetables or other foods at the table. A "pat" is about one teaspoon.
Butter (not margarine) on bread, rice, vegetables, or other foods	All forms of butter, not margarine, on bread or added to rice, vegetables or other foods at the table. A "pat" is about one teaspoon.
Mayonnaise, sandwich spreads	All types. The questionnaire asks about the type of mayonnaise/sandwich spread later in the questionnaire.
Ketchup, salsa, chili sauce, chili peppers	All kinds of tomato-based condiments or chili sauces or chili peppers.
Mustard, barbecue sauce, soy sauce	Any other condiment not captured above that contains a significant amount of sodium.
Gravy, or other rich sauces like Alfredo, white sauce, mole, peanut sauce	Gravy, or other rich sauces like hollandaise, pesto, sweet and sour, lobster sauce, black bean sauce, coconut-based sauces, etc.,
Jam, jelly, marmalade	Include all kinds of preserves and sweet fruit spreads or sauces. We ask about low-sugar types later in the questionnaire.
Pickles, picked vegetables, sauerkraut, kimchi	Include all types of pickled vegetables or chutney
Salt, added to your food at the table	Do not include salt added in cooking.

Q by Q – Beverages

Chocolate milk, cocoa, hot chocolate	Made at home or from a store or restaurant.
Glasses of milk or soy milk, not counting on cereal, in coffee, or chocolate milk	This applies to glasses of milk or milk substitutes, not to milk added to coffee or cereal. Include all types – soy milk, goat milk, almond milk, rice milk, low lactose, etc. Later in the questionnaire we ask about the type milk. Be careful that respondents do not double-count the milk they may have added to their Carnation Instant Breakfast.
Meal replacement drinks like Slim Fast, Ensure, or high protein drinks or powders	Includes any meal supplement or replacement: Boost or Ensure; any dieting milkshake, such as Sego or Slim-Fast; pre-mixed protein drinks like Muscle Milk; and home-mixed protein drinks made from protein powder.
Tomato juice, V8, other vegetable juice	Tomato juice, V8, vegetable juice, Clamato.
Real 100% orange juice or grapefruit juice. Don't count orange soda or Sunny Delight	Canned, bottled, frozen or fresh. Do not include fruit drinks, sodas, or any drink that is not 100% orange or grapefruit juice. (Sunny Delight is not 100% juice.)
Other 100% juices, like apple, grape, 100% fruit blends, or fruit smoothies	Other real 100% fruit juice, canned, bottled, frozen or fresh. Include real juice or fruit blended into smoothies.
Hi-C, cranberry juice cocktail, Hawaiian Punch, Tang	Includes drinks containing a significant amount of vitamin C, with or without real fruit.
Drinks with some juice like Sunny Delight, Knudsen	Includes drinks with some real fruit juice, whether canned, fresh, or carbonated.
Iced tea, homemade, instant or bottled, like Nestea, Lipton, Snapple, Tazo	Any kind of cold or iced tea, including instant, homemade, canned or bottled, sweetened or unsweetened. Later, we ask what type is usually consumed.

Gatorade, PowerAde, or other sports drinks	Include "sports drinks" and other electrolyte replacement drinks. Do not include fruit drinks, Kool-Aid, tea or lemonade, as these are asked elsewhere.
Energy drinks like Red Bull, Rockstar, Monster	These drinks contain significant amounts of caffeine. We ask about the type of energy drink later in the questionnaire.
Kool-Aid, lemonade, fruitflavored drinks, like Crystal Light, atole, horchata (not iced tea)	We ask about regular vs. low-sugar varieties later in the questionnaire.
Soft drinks, soda, pop, like cola, 7Up, orange soda, regular or diet	Includes cola, ginger ale, Dr. Pepper, orange or grape soda, etc. Later in the questionnaire, we ask whether soft drinks consumed are usually artificially sweetened (diet). If the respondent buys large bottles of soft drink (such as the standard 64 oz. bottle) and then drinks it in cups or glasses, have the respondent think about the total intake in a day as if it were purchased in other standard containers. For instance, two small glasses or 1 medium-large glass would add up to "1 can", two medium glasses or a large "iced tea" glass equals "1 20-ounce bottle", for 3 cups or 2 medium-large glasses in a day mark "2 cans", and for more than that mark "Big gulp or 3 cans".
Beer or nonalcoholic beer	Bottles, glasses, cans, or draft, all varieties. Respondent can indicate regular vs. low-calorie later in the questionnaire.
Wine or wine coolers	All forms, red or white, as well as champagne, and spritzers.
Liquor or mixed drinks, cocktails	Include all forms of hard alcohol, whether "straight" (as with whiskey), or in mixed drinks such as a vodka tonic. Liqueurs are to be included.
Water, bottled or tap	Include any kind of water, tap or bottled that has zero calories. Includes mineral water, artificially flavored water, water with vitamins, etc.
Milky coffee drinks like latte, mocha, cappuccino, Frappuccino	This refers to coffee and espresso drinks which are composed largely of milk, either made at home or from a café or restaurant. We ask about which type of milky drink later in the questionnaire.
Coffee (brewed or instant), regular or decaf	Include caffeinated or decaffeinated, brewed or instant

Hot tea (not including herbal tea)	Any form of regular black or green tea. Do not include herbal tea or iced tea.

Q x Q - Additions to coffee and tea

MILKY COFFEE DRINKS: What kind do you usually drink?	Mark the type of milky coffee drinks the respondent drinks most often. Mark "Some of each" if the respondent reports they drink "some of each". Mark "Don't drink them" if the respondent never drinks milky coffee drinks. Mark only one response.
What are your milky coffee drinks usually made with?	Choose the type of milk the respondent uses most often for their milky coffee drinks (e.g. latte, cappuccino, mocha, etc). Mark only one. If the respondent uses a type of milk such as rice milk or almond milk, mark "something else". Mark "Don't drink" if the respondent reported that s/he does not drink milky coffee drinks.
COFFEE: Is your coffee usually regular or decaf?	Choose the type consumed most often. Choose "I drink both kinds" if both are consumed equally. Mark only one.
What do you usually add to your regular or decaf coffee?	Choose the type of milk/creamer that is *usually* added to coffee (regular or decaf). If the respondent uses more than one type, have her pick the one she uses most often. Mark only one.
Do you usually add sugar (or honey) to coffee?	Refers to only real sugar or honey, not sugar substitutes. Fill in the Yes/No question. If "Yes", also fill in the number of teaspoons in each cup.
HOT TEA: Is your hot tea usually regular or decaf?	Choose the type consumed most often. Choose "I drink both kinds" if both are consumed equally.
What do you usually add to your hot tea?	Choose the type that is *usually* added to tea. If the respondent uses more than one type, have her pick the one she uses most often. Mark only one.
Do you usually add sugar (or honey) to tea?	Refers to only real sugar or honey, not sugar substitutes. Fill in the Yes/No question. If "Yes", also fill in the number of teaspoons in each cup

Q x Q –If you eat the following foods, what type do you usually eat?

This section includes 31 questions that refine the specific types of foods and beverages the respondent usually consumes. **Mark only one answer for each type of food.** Multiple answers will be scored as "errors" and no information will be recorded.

The end of this section includes questions about cereal brands, and about type of fats and oils used in cooking. The respondent should select one or two cereals, and one or two types of cooking fat.

"Don't drink" or "Don't eat" is a valid answer choice for some of the items in this section; it should be used only if the respondent reported never eating consuming the food/beverage in the main food list.

Have the respondent try to remember the usual or most frequent form of the food before marking "Don't know". If necessary, "Don't know" is a valid choice for respondents who do not do the shopping and really do not know what type he/she consumes.

Milk	The respondent should mark the ONE type she uses most often. If she drinks more than one type of milk, ask her to choose the one she drinks most often. The analysis program will use the answer to select the type of milk to apply to the "glasses of milk" item reported in the main food list. *Note that this response applies to "glasses of milk", not to milk added to coffee or cereal.*
Slim Fast, Ensure, or high protein drinks	The program will use the answer to this question to assign the type of liquid meal to use for the frequency reported earlier.
Real 100% orange or grapefruit juice	The program will use the answer to this question to assign the type of juice to use for the frequency of orange/grapefruit juice reported earlier.
Iced tea	The program will use the answer to this question to assign the type of iced tea to use for the frequency reported above.
Drinks like Kool-Aid, lemonade, Crystal Light	The program will use the answer to this question to assign the type of Kool-Aid, lemonade, etc. to use for the frequency reported above.
Energy Drinks like Red Bull, Monster	The program will use the answer to this question to the type of energy drinks to use for the frequency reported above.
Soft drinks, soda pop	The program will use the answer to this question to assign the type of soda or pop (regular or diet) to use for the frequency reported above.

***(Soft drinks, soda pop)* Do they usually have caffeine?**	The program will use the answer to this question to assign the type of soda or pop to use for the frequency reported above.
Beer	The program will use the answer to this question to assign the type of beer to use for the frequency reported above.
Wine or wine cooler	The program will use the answer to this question to assign the type of wine to use for the frequency reported above.
Cheese	"Cheese" here refers specifically to cheese by itself, not as part of pizza, lasagna, etc. The program will use the answer to this question to assign the fat content of cheese, for the frequency reported above.
Yogurt	The program will use the answer to this question to assign the sugar content of the yogurt reported in the main food list
Yogurt	The program will use the answer to this question to assign the fat content of the yogurt whose frequency was reported above
Salad dressing	The program will use the answer to this question to assign the fat and sugar content of salad dressing, for the frequency reported above.
Spaghetti or lasagna	The program will use the answer to this question to assign the meat content of the spaghetti or lasagna dishes, for the frequency reported above.
Noodles, pasta	The program will use the answer to this question to assign the type of pasta (whole grain or regular) to apply in the nutrient analysis. Choose the type eaten most often.
Burgers	Choose the one the respondent eats most often. The program will use the answer to this question to assign the type of burger to use for the frequency reported in the Hamburgers, cheeseburgers, etc. item in main food list.
Beef or pork	The program will use the answer to this question to assign the fat content of these meats, for the frequency reported above.
Chicken or turkey	The program will use the answer to this question to assign the fat content of the chicken/turkey item, for the frequency reported above.
Hot dogs, dinner sausage	The program will use the answer to this question to the meat type for the hot dogs and dinner sausage reported above.
Lunch meats	The program will use the answer to this question to assign the meat type of the lunch meats reported above.

Cake, snack cakes, cupcakes	The program will use the answer to this question to assign the fat and sugar content of the "Cake…" item in the main food list. If respondent usually eats low-fat cakes but eats regular-fat varieties of other foods in the item above, this question should be answered based on the food he or she eats most often.
Cookies, brownies	The program will use the answer to this question to assign the fat and sugar content of cookies, for the frequency reported above.
Ice cream, frozen yogurt	The program will use the answer to this question to assign the fat and sugar content of ice cream and frozen yogurt, for the frequency reported above. Again, this question should be answered based on the type of ice cream he or she eats most often.
Energy or protein bars	The program will use the answer to this question to assign the fat and sugar content of energy or protein bars, for the frequency reported above. This question should be answered based on the kind he or she eats most often.
Bagels, English muffins, rolls	The program will use the answer to this question to choose the type of bagel, English muffin, etc. to apply in the nutrient analysis. This question should be answered based on the kind he or she eats most often
Burger, hot dog, submarine buns	The program will use the answer to this question to assign the type of buns to apply in the nutrient analysis. This question should be answered based on the kind he or she eats most often
Bread	The program will use the answer to this question to assign the type of bread to apply in the nutrient analysis. This question should be answered based on the kind he or she eats most often
Tortillas	The program will use the answer to this question to assign the type of tortilla to apply in the nutrient analysis. This question should be answered based on the kind he or she eats most often
Popcorn	The program will use the answer to this question to assign the fat and sugar content of popcorn for the frequency reported above.
Crackers, pretzels	The program will use the answer to this question to assign the fat content of crackers, pretzels, rice cakes, etc. for the nutrient analysis
Mayonnaise or sandwich spreads	The program will use the answer to this question to the fat content of mayonnaise or sandwich spreads for the frequency reported above
If you eat cold cereals, what do you usually eat?	**Mark only one or two answers**. Respondent should select the one or two cereals he/she most commonly eats. If the respondent's cereal brand is is not listed, ask the respondent to choose from the 4 generic cereal types shown in italics at the end of the list.

Which fats or oils are used most often for cooking or frying (not baking) in your home?

Mark only one or two answers. The respondent should select the one or two fats or oils that she most commonly uses when cooking or frying foods at home. Mark the kind of fat or oil used to fry, stir-fry, simmer or sauté. This question does not include: fat used in baking; oil used for salad dressing; and butter or margarine used on bread.

Do not read "Mark only one or two." Do not read the response categories. Leave it open-ended, and then fill in the bubble that matches the respondent's answer.

If respondent names only one, mark only one without further probing.

If she names two, mark two. If the respondent names more than two kinds of fats/oils, ask which two are used most often.

"Crisco" refers to Crisco shortening. If subject specifies Crisco oil, mark it under "vegetable oil

If subject uses "Coconut oil", mark "Other oil".

Sesame oil: If respondent reports "sesame oil", ask if she uses it in large quantities such as 1-2 tablespoons; if so, code as vegetable oil. If she only uses a few drops for flavoring, do not code as oil at all.

Later, at the end of the questionnaire, under "Some last questions about you", the subject is asked how often she eats foods that are cooked at home with this type of oil.

Q x Q – What vitamin supplements taken do you take fairly regularly

"Fairly regularly" means **at least** a few days per month.

If the respondent did not take vitamin supplements in the past year, or took them less often than a few days per month, you should mark "didn't take" for all of the listed vitamins.

Multiple vitamins

Prenatal vitamins	"Prenatal vitamins" are the kind prescribed for pregnant women. They include a very long list of nutrients, and may include higher amounts of some nutrients than other types of multiple vitamins.
Regular One-ADay, Centrum, "senior" vitamins, or house brands of multiple vitamins	Multiple vitamins typically contain all of the vitamins (A, B1, B2, C, D, E and others) and often contain minerals (iron, zinc, calcium and others). One-a-Day, Theragran, Centrum, Centrum Silver, and any local brand (e.g., Safeway Multivits) count here. The key characteristic is that it contains many different vitamins; it is thought to be a general purpose supplement, covering all the bases at least at a basic level.
Stress-tabs or BComplex type	These will have "stress", or "B-Complex", or "High-B" in the name. They all have B vitamins at levels substantially higher than the RDA.
Antioxidant combination, eye formula	These will have "antioxidant", "eye formula", "vision formula" or "Areds formula" in the name. These multiple vitamins are significantly higher in antioxidants than a regular multiple vitamin.

Single Vitamins or Minerals, not part of multiple vitamins

In general, these are supplements where each pill contains only the one vitamin or mineral listed. Thus, we are asking here about single supplements that are not part of multiple vitamins. Don't "double count" the multiple vitamins already mentioned above.

An exception: Occasionally a pill may contain just two minerals, such as calcium & zinc. Since we don't have a place for "multiple minerals", it is okay for respondent to record the frequency of consumption under both "calcium" and "zinc" separately.

Vitamin A (not beta-carotene)	For Vitamin A, it is important to note that this is "not beta-carotene". Many respondents have learned that vitamin A and beta-carotene are in some way related. However, the "Vitamin A" line is asking specifically about preformed vitamin A, also known as retinol.
Vitamin B-6	Includes only vitamin B-6 taken as a single supplement

Vitamin B-12	Includes only vitamin B-12 taken as a single supplement
Vitamin C	Includes only vitamin C taken as a single supplement.
Vitamin D	Includes only vitamin D taken as a single supplement.
Vitamin E	Includes only vitamin E taken as a single supplement.
Folic Acid, folate	Includes only folate or folic acid taken as a single supplement.
Calcium or antacids with calcium, like Tums	Includes only calcium, antacids or Tums taken as single supplements. If the respondent's calcium tablets include another mineral listed in this section, such as "zinc", you may mark both frequency responses.
Iron	Includes only iron taken as a single supplement. If the respondent's iron tablets include another nutrient listed in this section, such as "Vitamin C", you may mark both frequencies.
Zinc	Includes only zinc taken as a single supplement. If the respondent's zinc tablets include another mineral listed in this section, such as "calcium", you may mark both frequency responses.
Cod liver oil, other fish oils, omega-3, flax seed oil, algae	Includes only omega-3 sources taken as a single supplement. These items are commonly available in capsules. Note that "flax seeds" should have been reported previously, in the nuts/seeds section of the questionnaire. Only flax seed oil should be reported here.
Fiber supplements like Benefiber, Metamucil	This refers to fiber supplements that are taken as a single supplement, either in pill form or in as a powder.

More information about supplements …

If you take One-A Day, Centrum or other types of multiple vitamins...	This need only be filled in if respondent reported taking One-A-Day type multiple vitamins. (If respondent doesn't know, the program will assume "with minerals", since that is 80% of the market.)
If you take vitamin C...	This need only be filled in if respondent takes vitamin C as a single supplement (not part of multiple vitamins). The doses shown are commonly available pill sizes. Note that this refers to the total milligrams of vitamin C the respondent usually takes **in an entire day**, on the days this supplement is taken.

If you take vitamin E...	This need only be filled in if respondent takes vitamin E as a single supplement (not part of multiple vitamins). The doses shown are commonly available pill sizes. Note that this refers to the total IUs of vitamin E the respondent usually takes **in an entire day**, on the days this supplement is taken.
If you take calcium...	This need only be filled in if respondent takes calcium as a single supplement (not part of multiple vitamins). The doses shown are commonly available pill sizes. Note that this refers to the total milligrams of calcium the respondent usually takes **in an entire day**, on the days this supplement is taken.
If you take vitamin D....	This need only be filled in if respondent takes vitamin D as a single supplement (not part of multiple vitamins). The doses shown are commonly available pill sizes. Note that this refers to the total IUs Of vitamin D the respondent usually takes **in an entire day**, on the days this supplement is taken
If you take omega3 supplements...	This need only be filled in if respondent takes omega-3 supplements as a single supplement (not part of multiple vitamins). Ask the subject about the one or two omega-3 supplements taken most often.

"Some last questions about you"

The following questions are used by the program to compare and if necessary, adjust the frequencies of food responses in the main food list.

About how many servings of vegetables do you eat, not counting salad or potatoes? 1 serving = 1/2 cup

Servings of vegetables: This doesn't mean "how many different kinds".

Here, we mean how many 1/2 cup servings show up on your plate during the day. So green beans with lunch and squash with dinner would be 2 per day; green beans with lunch and green beans with dinner would be 2 per day; nothing with lunch and both squash and green beans with dinner would be 2 per day.

Salad and potatoes are excluded from these questions simply to clarify which foods we are asking about.

Acceptable answers to respondent questions:

Q: "Do you mean different kinds of vegetables?"
A: "No, just how many total servings of vegetables, of any kind."

Q: "Should I count second helpings as two servings?" A: "Yes"

Q: "What if I have a big salad with lots of stuff in it?"
A: "**Not counting the salad greens**, how many 1/2 cup servings of vegetables are in your salad"

About how many servings of fruit do you eat, not counting juices? 1 serving = ½ cup or 1 medium fruit

See discussion of vegetables above.

How often do you eat foods prepared at home that are cooked or fried in fat or oil? During a regular day, how many meals and snacks do you usually eat?

Frequency of fat or oil used in cooking: Note that fat or oil use is in frying, stir-frying, simmering, etc. Do not include fat used in baking. This also does not include oil used on salads, and does not include butter or margarine used on bread.

Meals per day...

Meals per day: This refers to how many meals the respondent usually eats in a typical day. What is a meal? A meal is usually a larger portion of food that is eaten at regular parts of the day, such as breakfast, lunch and dinner.

Snacks per day... Snacks per day: What is a snack? A snack is a portion of food often smaller than a regular meal and is generally eaten between meals. Snacks can be pre-packaged, or made from fresh ingredients like fruit, veggies, nuts, etc.
Note: If respondent eats only an orange or apple for lunch, then their lunch is more of a snack than a meal.

Q X Q -- PHYSICAL ACTIVITY SURVEY

The activities on the physical activity survey are grouped by similarity of activity (e.g. cooking and cleaning), and by the level of energy expenditure required to perform the activities. There are two questions for each activity: How often, on average, the respondent participates in the listed activity; how many minutes per day (duration) they do the listed activity on the days they do them. Read the introductory question: "Think about the last 12 months. How often did you do the following activities?". Then read the items in the first question. After the respondent answers, and if the respondent does the activity at least a few times per month, ask them the duration question for that item: "On the days you do that, how much time do you spend doing the activity? Is it less than 30 minutes, 30-60 minutes, 1-2 hours, or 3 or more hours?

Cooking, shopping, light cleaning like doing laundry or dusting, or running errands	These items are all considered to be low intensity activities.
Slow walking like walking the dog, or light work around the house like watering.	These items are all considered to be low intensity activities. Slow walking and light work refers to slow walking and activities that do not require much effort nor increase your heart rate.
Work on the job involving standing, like store clerk, or work involving driving (like truck driver)	These items are all considered to be low intensity activities. This refers to work and activities that do not increase your heart, do not require much physical exertion, and may be sedentary.
Taking care of children (feeding, dressing), or moderate housework like sweeping, mopping, cleaning the tub	These items are all considered to be moderate intensity activities. By moderate housework, we mean activities that require a moderate amount of effort and accelerate the heart rate somewhat.
Weeding, raking, mowing the lawn, or light house repairs	These items are all considered to be moderate intensity activities. Moderate effort for activities done around the house like weeding, raking, mowing the lawn, or light house repairs.
Brisk walking, dancing, hunting or fishing, golf (NOT using a golf cart), or 'friendly' outdoor games like softball	These items are all considered to be moderate intensity activities.
Factory work, mechanic, restaurant work, or work involving	These items are all considered to be moderate intensity activities. This category is for work like factory work, mechanic, restaurant work, or work involving walking, like mail carrier that requires moderate effort and accelerates the heart rate to a moderate extent.

walking, like mail carrier	
Construction, painting, feeding livestock, or homecare like caring for an adult family member	These items are all considered to be moderate intensity activities. This category is for work like construction, painting, feeding livestock, or homecare like caring for an adult family member that requires moderate effort and accelerates the heart rate to a moderate extent.
Heavy work like moving boxes, heavy digging or shoveling snow, farm chores like baling hay, or other HARD labor	These items are all considered to be vigorous intensity activities. These household activities include heavy work like moving boxes, heavy digging or shoveling snow, farm chores like baling hay, or other HARD labor. They require a large amount of effort, cause rapid breathing and a substantial increase in heart rate.
Exercising at the gym or at home, aerobics, weight training, jogging, or vigorous sports like basketball, soccer, tennis	These items are all considered to be vigorous intensity activities. This question includes aerobic activities that require vigorous effort. They require a large amount of effort, cause rapid breathing and a substantial increase in heart rate.
Bicycling or swimming for exercise	These items are all considered to be vigorous intensity activities. This question includes aerobic activities that require vigorous effort. They require a large amount of effort, cause rapid breathing and a substantial increase in heart rate. Note: Bicycling and swimming are asked separately from the other vigorous intensity exercises to permit the physical activity questionnaire to be more easily compared with accelerometer-based assessments of physical activity. Accelerometers are typically worn on the hip and therefore do not capture the activity from bicycling; and they're not typically worn when swimming.

Race and Ethnicity

Are you Hispanic or Latino?	This question is part of the new federal standard for asking "race- ethnicity", in two questions. Race-ethnicity is an important covariate for many health conditions and risk factors.
What race do you consider yourself to be?	This is the second question in the set of two federal standard questions for asking "race-ethnicity". Multiple answer marks are allowed in this question. Mark all that apply.

End of questionnaire

REVIEW

Interviewer should take a few moments to review the questionnaire for missing answers or multiple marks, and ask for clarification before the respondent departs

2. Cue Cards for Block 2014 FFQ

This survey asks about foods you usually eat. Think about your usual intake over the last year. This includes all meals or snacks, at home, in a restaurant, or carry-out. … Answer each question as well as you can. Estimate if you are not sure.

There are two kinds of questions for each food:
HOW OFTEN? and HOW MUCH?

HOW OFTEN (in the past year)								
NEVER	A FEW TIIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK R	EVERY DAY

HOW MUCH <u>on those days</u>? SEE PORTION SIZE PICTURES FOR A-B-C-D				
How much	A	B	C	D
	¼ cup	½ cup	1 cup	2 cups

What type of milk do you usually drink or put on your cereal?
(Choose ONLY ONE.)

o Whole milk o Reduced fat 2% milk
o Low-fat 1% milk
o Skim milk or non-fat
o Soy milk
o Rice milk
o Almond milk, other
o Don’t drink or don’t know

If you eat cold cereals, what do you usually eat?

(Choose ONE or TWO that you eat most often. If you usually eat just one kind, only choose one.)

- O All-Bran Original
- O All-Bran Complete
- O Apple Jacks, Cookie Crisp
- O Bran Flakes
- O Cap'n Crunch o Cheerios, plain or Multi-Grain
- O Cheerios, Honey Nut, flavors
- O Chex, Wheat
- O Chex, other
- O Cinnamon Toast Crunch
- O Cocoa Krispies, Pebbles, Puffs
- O Corn Flakes, Corn Puffs
- O Corn Pops
- O Fiber-One, Bran Buds
- O Froot Loops
- O Frosted Flakes
- O Frosted Mini-Wheats
- O Granola
- O Grape Nuts
- O Honey Bunches of Oats
- O Kashi GOLEAN, Heart to Heart
- O Life
- O Lucky Charms, Fruity Pebbles
- O Oatmeal Squares, Oat Bran
- O Raisin Bran o Rice Krispies, puffed rice
- O Shredded Wheat o Special K, plain
- O Special K, flavors
- O Total
- O Wheaties
- O *Other sweet cereal*
- O *Other unsweetened cereal*
- O *Other whole grain cereal*
- O *Other bran or fiber cereal*
- O Don't eat cereal

What kinds of fat or oil did you usually use for cooking?
(Choose ONLY ONE or TWO.)

- O Non-stick spray or None
- O Butter or ghee
- O Butter/margarine blend
- O Stick margarine
- O Soft tub margarine
- O Low-fat margarine
- O Olive oil
- O Canola oil, safflower oil
- O Corn oil, vegetable oil and blends
- O Peanut oil
- O Lard, fatback, or bacon fat
- O Vegetable shortening, Crisco
- O Other oil
- O Don’t know

What vitamin supplements do you take fairly regularly?

<u>Multiple Vitamins</u> – Do you take …

Prenatal Vitamins
Regular Once-A-Day, Centrum, "senior" vitamins or house brands
Stress-tabs or B-complex type
Antioxidant combination, eye formula

<u>Single Vitamins or Minerals</u> – Taken alone or in combination.
(Do not count what is in your multiple vitamins above.)

Vitamin A (not beta-carotene)
Vitamin B-6
Vitamin B-12
Vitamin C
Vitamin D
Vitamin E
Folic acid, folate
Calcium or antacids with calcium, like Tums
Iron
Zinc
Cod liver oil, other fish oils, omega-3, flax seed oil, algae
Fiber supplements like Benefiber, Metamucil

If taking vitamin supplements fairly regularly …

HOW OFTEN?

DIDN'T TAKE	A FEW DAYS per MONTH	1 DAY PER WEEK	2 DAYS PER WEEK	3-4 DAYS PER WEEK	5-6 DAYS PER WEEK	EVERY DAY

FOR HOW MANY YEARS?

LESS THAN 1 YEAR	1-4 YEARS	5-9 YEARS	10 + YEARS

If you take One-A-Day, Centrum or other type of multiple vitamins, do you usually take types that …

o Contain minerals, iron, zinc, etc. o Do not contain minerals o Don't know

If you take …
VITAMIN C … How many milligrams do you usually take?

100	250	500	750	1000	1500	2000	3000+	DON'T KNOW

If you take …
VITAMIN E … How many IUs do you usually take?

100	200	300	4000	600	800	1000	2000+	DON'T KNOW

If you take …
Calcium … How many milligrams do you usually take?

100	350	650	1250+	DON'T KNOW

If you take …
VITAMIN D … How many IUs do you usually take?

400	600	800	1000	2000	3000	4000	5000+	DON'T KNOW

If you take omega-3 supplements, what type do you usually take?
(Mark all that apply.)

- O Fish oil
- O Flax oil, hemp oil, other seed oil
- O Krill oil
- O Algae
- O Don't know

A few last questions about your eating patterns.

How many servings of vegetables do you eat (not counting salad or potatoes)**?**

How many servings of fruit do you eat (not counting juices)**?**

How often do you eat foods prepared at home that are <u>cooked or fried</u> in fat or oil?

RARELY	1-2 Per WEEK	3-4 Per WEEK	5-6 Per WEEK	1 Per DAY	1 1/2 Per DAY	2 Per DAY	3 Per DAY	4+ Per DAY

During a regular day, how many meals and snacks do you usually eat?

<u>Meals</u> per day

o 1 o 2 o 3 o 4 o 5+

<u>Snacks</u> per day

o 1 o 2 o 3 o 4 o 5+

Physical Activity

Think about the last 12 months. How often did you do these activities in the past year? And, if you did them, how much time on those days?

HOW OFTEN in the past year					
RARELY OR NEVER	A FEW TIIMES A MONTH	ONCE OR TWICE A WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	ALMOST EVERY DAY

HOW MUCH TIME on those days?			
LESS THAN 30 MINUTES	30-60 MINUTES	1-2 HOURS	3 OR MORE HOURS

A few more questions about you before we are done.

Are you?
(Choose one)

O Hispanic or Latino

O Not Hispanic or Latino

What race do you consider yourself to be?
(Indicate all that apply)

O White

O Black or African American

O Asian

O American Indian or Alaska Native

O Native Hawaiian or other Pacific Islander

3. Food And Activity Questionnaire

FOOD AND ACTIVITY QUESTIONNAIRE

RESPONDENT ID #

TODAY'S DATE

	DAY	YEAR
Jan		
Feb		
Mar	01	2022
Apr	02	2023
May	03	2024
Jun	04	2025
Jul	05	2026
Aug	06	2027
Sep	07	2028
Oct	08	2029
Nov	09	2030
Dec	10	2031

ABOUT THIS SURVEY

Please answer each question as best you can. Estimate if you aren't sure.

- **DETACH THE LAST PAGE OF THIS BOOKLET.** These are your portion pictures.
- **USE ONLY A NUMBER 2 PENCIL.**
- **FILL IN THE CIRCLES COMPLETELY** and erase completely if you make any changes.

ABOUT YOU

SEX
- Male
- Female

If female, are you pregnant or breast feeding?
- No
- Yes
- Not female

AGE

WEIGHT pounds

HEIGHT feet inches

INSTRUCTIONS

This form is about the foods you usually eat. Think about your usual intake over the last year. This includes all meals or snacks, at home, in a restaurant, or carry-out.

Please tell us...

1. **HOW OFTEN,** on average, did you eat the food?
   DO NOT SKIP any foods. Mark "Never" if you didn't eat any of the food.
2. **HOW MUCH** of the food did you usually eat on the days you ate it?
   Sometimes we ask "how much" as A, B, C or D. **LOOK AT THE PORTION PICTURES.**
   Pick the picture that looks the most like the serving size you usually eat.
   (If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.)
3. **WHAT TYPE?** For some foods we ask the type (low-fat, low-sugar...) near the end of the survey.

EXAMPLE: This person drank orange juice twice a week, and had one glass each time.
Once a week this person ate a "C"-sized serving of cold cereal (about 1 cup).

	HOW OFTEN in the past year? NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Orange juice	○	○	○	○	○	●	○	○	○	How many glasses: ○1 ○2 ○3 ○4
Cold cereal	○	○	○	○	●	○	○	○	○	Which bowl: ○A ○B ●C ○D

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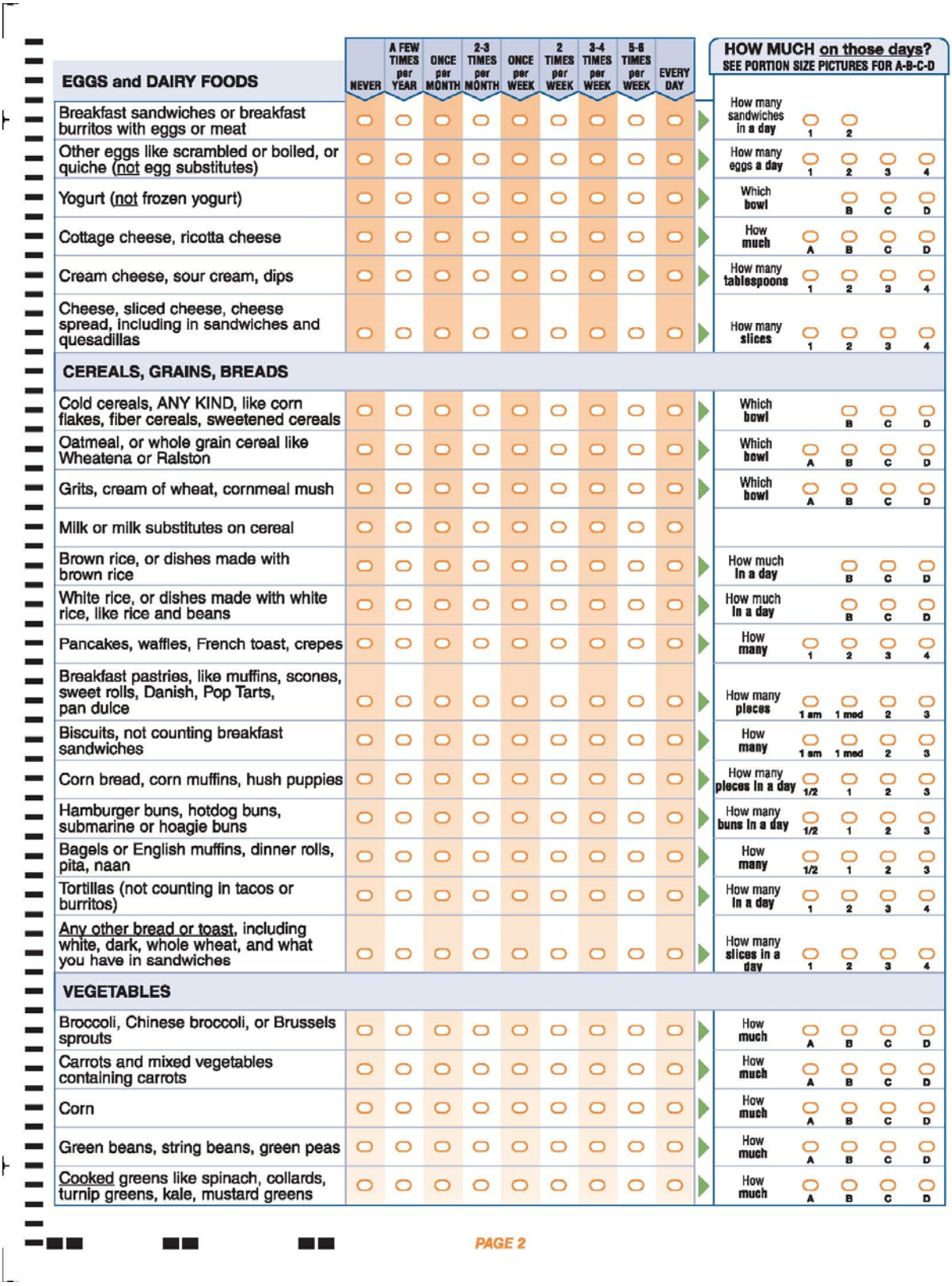
SERIAL #

Block 2014.1 – Strong Heart ©www.NutritionQuest.com



EGGS and DAIRY FOODS	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Breakfast sandwiches or breakfast burritos with eggs or meat										How many sandwiches in a day: 1 2
Other eggs like scrambled or boiled, or quiche (not egg substitutes)										How many eggs a day: 1 2 3 4
Yogurt (not frozen yogurt)										Which bowl: B C D
Cottage cheese, ricotta cheese										How much: A B C D
Cream cheese, sour cream, dips										How many tablespoons: 1 2 3 4
Cheese, sliced cheese, cheese spread, including in sandwiches and quesadillas										How many slices: 1 2 3 4
CEREALS, GRAINS, BREADS										
Cold cereals, ANY KIND, like corn flakes, fiber cereals, sweetened cereals										Which bowl: B C D
Oatmeal, or whole grain cereal like Wheatena or Ralston										Which bowl: A B C D
Grits, cream of wheat, cornmeal mush										Which bowl: A B C D
Milk or milk substitutes on cereal										
Brown rice, or dishes made with brown rice										How much in a day: B C D
White rice, or dishes made with white rice, like rice and beans										How much in a day: B C D
Pancakes, waffles, French toast, crepes										How many: 1 2 3 4
Breakfast pastries, like muffins, scones, sweet rolls, Danish, Pop Tarts, pan dulce										How many pieces: 1 sm 1 med 2 3
Biscuits, not counting breakfast sandwiches										How many: 1 sm 1 med 2 3
Corn bread, corn muffins, hush puppies										How many pieces in a day: 1/2 1 2 3
Hamburger buns, hotdog buns, submarine or hoagie buns										How many buns in a day: 1/2 1 2 3
Bagels or English muffins, dinner rolls, pita, naan										How many: 1/2 1 2 3
Tortillas (not counting in tacos or burritos)										How many in a day: 1 2 3 4
Any other bread or toast, including white, dark, whole wheat, and what you have in sandwiches										How many slices in a day: 1 2 3 4
VEGETABLES										
Broccoli, Chinese broccoli, or Brussels sprouts										How much: A B C D
Carrots and mixed vegetables containing carrots										How much: A B C D
Corn										How much: A B C D
Green beans, string beans, green peas										How much: A B C D
Cooked greens like spinach, collards, turnip greens, kale, mustard greens										How much: A B C D

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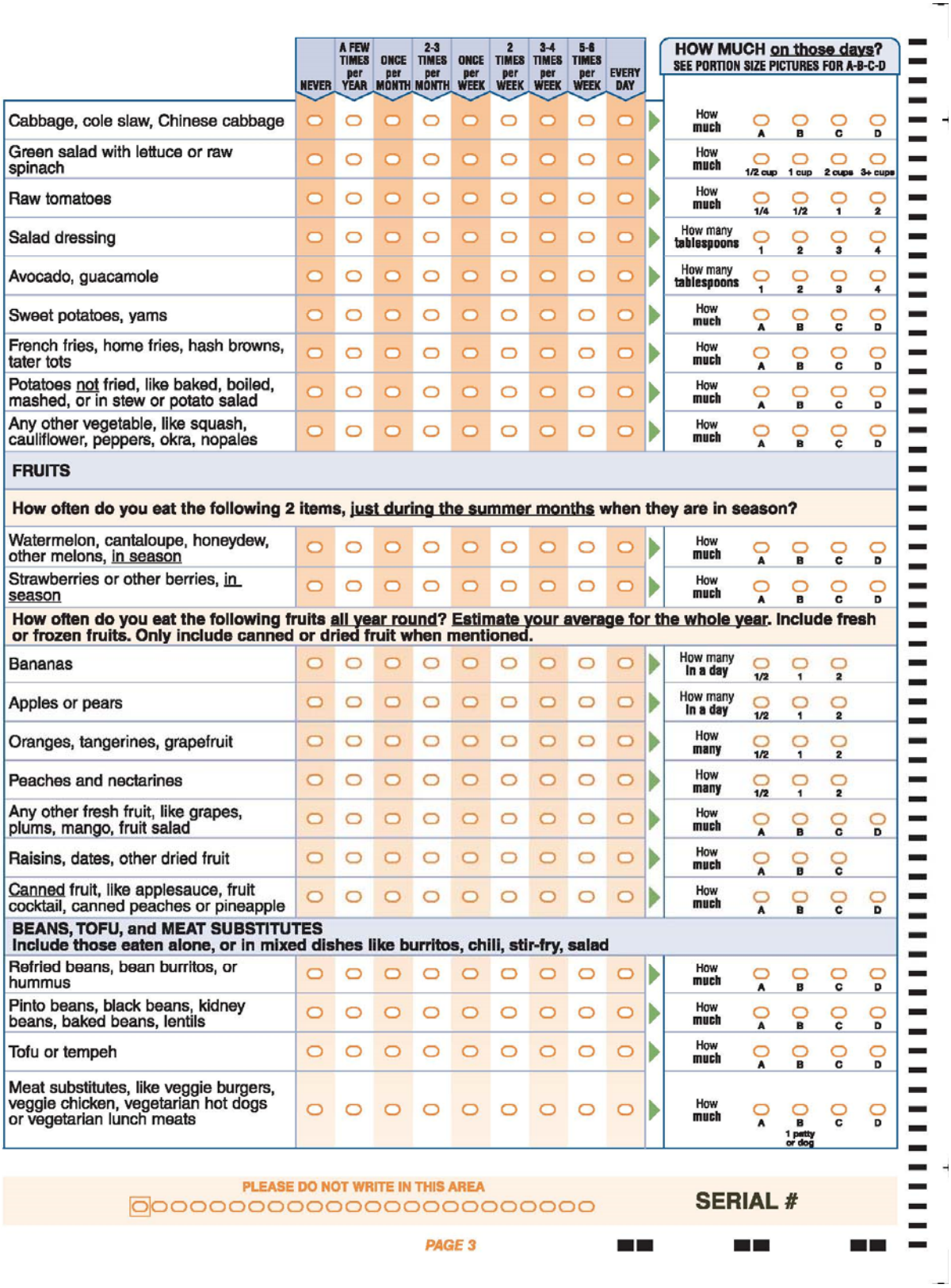

	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Cabbage, cole slaw, Chinese cabbage	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Green salad with lettuce or raw spinach	○	○	○	○	○	○	○	○	○	How much ○1/2 cup ○1 cup ○2 cups ○3+ cups
Raw tomatoes	○	○	○	○	○	○	○	○	○	How much ○1/4 ○1/2 ○1 ○2
Salad dressing	○	○	○	○	○	○	○	○	○	How many tablespoons ○1 ○2 ○3 ○4
Avocado, guacamole	○	○	○	○	○	○	○	○	○	How many tablespoons ○1 ○2 ○3 ○4
Sweet potatoes, yams	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
French fries, home fries, hash browns, tater tots	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Potatoes not fried, like baked, boiled, mashed, or in stew or potato salad	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Any other vegetable, like squash, cauliflower, peppers, okra, nopales	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
FRUITS										
How often do you eat the following 2 items, just during the summer months when they are in season?										
Watermelon, cantaloupe, honeydew, other melons, in season	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Strawberries or other berries, in season	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
How often do you eat the following fruits all year round? Estimate your average for the whole year. Include fresh or frozen fruits. Only include canned or dried fruit when mentioned.										
Bananas	○	○	○	○	○	○	○	○	○	How many in a day ○1/2 ○1 ○2
Apples or pears	○	○	○	○	○	○	○	○	○	How many in a day ○1/2 ○1 ○2
Oranges, tangerines, grapefruit	○	○	○	○	○	○	○	○	○	How many ○1/2 ○1 ○2
Peaches and nectarines	○	○	○	○	○	○	○	○	○	How many ○1/2 ○1 ○2
Any other fresh fruit, like grapes, plums, mango, fruit salad	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Raisins, dates, other dried fruit	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C
Canned fruit, like applesauce, fruit cocktail, canned peaches or pineapple	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
BEANS, TOFU, and MEAT SUBSTITUTES **Include those eaten alone, or in mixed dishes like burritos, chili, stir-fry, salad**										
Refried beans, bean burritos, or hummus	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Pinto beans, black beans, kidney beans, baked beans, lentils	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Tofu or tempeh	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Meat substitutes, like veggie burgers, veggie chicken, vegetarian hot dogs or vegetarian lunch meats	○	○	○	○	○	○	○	○	○	How much ○A ○B 1 patty or dog ○C ○D

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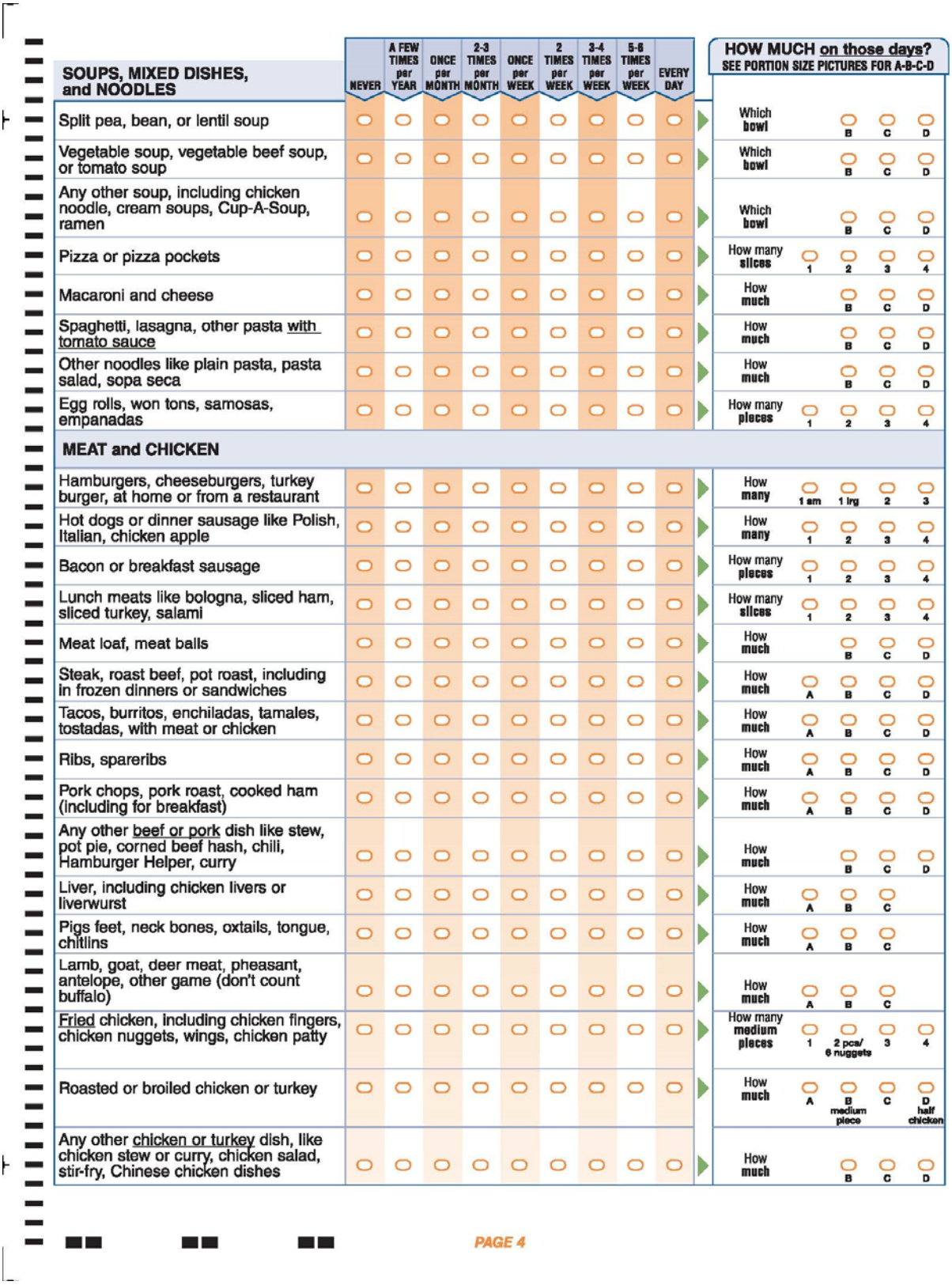

SOUPS, MIXED DISHES, and NOODLES	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Split pea, bean, or lentil soup	○	○	○	○	○	○	○	○	○	Which bowl: B C D
Vegetable soup, vegetable beef soup, or tomato soup	○	○	○	○	○	○	○	○	○	Which bowl: B C D
Any other soup, including chicken noodle, cream soups, Cup-A-Soup, ramen	○	○	○	○	○	○	○	○	○	Which bowl: B C D
Pizza or pizza pockets	○	○	○	○	○	○	○	○	○	How many slices: 1 2 3 4
Macaroni and cheese	○	○	○	○	○	○	○	○	○	How much: B C D
Spaghetti, lasagna, other pasta with tomato sauce	○	○	○	○	○	○	○	○	○	How much: B C D
Other noodles like plain pasta, pasta salad, sopa seca	○	○	○	○	○	○	○	○	○	How much: B C D
Egg rolls, won tons, samosas, empanadas	○	○	○	○	○	○	○	○	○	How many pieces: 1 2 3 4
MEAT and CHICKEN										
Hamburgers, cheeseburgers, turkey burger, at home or from a restaurant	○	○	○	○	○	○	○	○	○	How many: 1 sm 1 lrg 2 3
Hot dogs or dinner sausage like Polish, Italian, chicken apple	○	○	○	○	○	○	○	○	○	How many: 1 2 3 4
Bacon or breakfast sausage	○	○	○	○	○	○	○	○	○	How many pieces: 1 2 3 4
Lunch meats like bologna, sliced ham, sliced turkey, salami	○	○	○	○	○	○	○	○	○	How many slices: 1 2 3 4
Meat loaf, meat balls	○	○	○	○	○	○	○	○	○	How much: B C D
Steak, roast beef, pot roast, including in frozen dinners or sandwiches	○	○	○	○	○	○	○	○	○	How much: A B C D
Tacos, burritos, enchiladas, tamales, tostadas, with meat or chicken	○	○	○	○	○	○	○	○	○	How much: A B C D
Ribs, spareribs	○	○	○	○	○	○	○	○	○	How much: A B C D
Pork chops, pork roast, cooked ham (including for breakfast)	○	○	○	○	○	○	○	○	○	How much: A B C D
Any other beef or pork dish like stew, pot pie, corned beef hash, chili, Hamburger Helper, curry	○	○	○	○	○	○	○	○	○	How much: B C D
Liver, including chicken livers or liverwurst	○	○	○	○	○	○	○	○	○	How much: A B C
Pigs feet, neck bones, oxtails, tongue, chitlins	○	○	○	○	○	○	○	○	○	How much: A B C
Lamb, goat, deer meat, pheasant, antelope, other game (don't count buffalo)	○	○	○	○	○	○	○	○	○	How much: A B C
Fried chicken, including chicken fingers, chicken nuggets, wings, chicken patty	○	○	○	○	○	○	○	○	○	How many medium pieces: 1 2 pcs/6 nuggets 3 4
Roasted or broiled chicken or turkey	○	○	○	○	○	○	○	○	○	How much: A B medium piece C D half chicken
Any other chicken or turkey dish, like chicken stew or curry, chicken salad, stir-fry, Chinese chicken dishes	○	○	○	○	○	○	○	○	○	How much: B C D

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FISH, SEAFOOD	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Oysters	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C
Shellfish like shrimp, scallops, crab	○	○	○	○	○	○	○	○	○	How much fish: ○ A ○ B ○ C ○ D
Tuna, tuna salad, tuna casserole	○	○	○	○	○	○	○	○	○	How much of the tuna: ○ A ○ B ○ C
Salmon, mackerel, sea bass, trout, sardines, herring, without breading	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Fried fish, fish sticks, fish sandwich, breaded fillets	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Any other fish	○	○	○	○	○	○	○	○	○	How much fish: ○ A ○ B ○ C ○ D
NUTS, SEEDS, SNACKS										
Peanut butter or other nut butters	○	○	○	○	○	○	○	○	○	How many tablespoons: ○ 1/2 ○ 1 ○ 2 ○ 3
Walnuts or flax seeds (don't count flaxseed oil)	○	○	○	○	○	○	○	○	○	How much: ○ 1 Tbsp ○ 2 Tbsp ○ 1/4 cup ○ 1/2 cup
Peanuts, sunflower seeds, other nuts or seeds	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Energy or protein bars, like Power Bar, Clif, Balance, Luna, South Beach, Atkins	○	○	○	○	○	○	○	○	○	How much: ○ Small ○ Medium ○ Large
Breakfast bars, cereal bars, granola bars (not energy or protein bars)	○	○	○	○	○	○	○	○	○	How many: ○ 1 ○ 2 ○ 3
Popcorn	○	○	○	○	○	○	○	○	○	How many cups: ○ 1-2 ○ 3-6 ○ 7-9 ○ 10-12
Whole grain crackers, like Wheat Thins, RyeKrisp, Ryvita, Wasa	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Any other crackers, like saltines, Ritz, Cheez-Its, cheese-filled pretzels	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Tortilla chips or corn chips, like Fritos, Doritos, corn nuts	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Any other snack chips, like potato chips, Cheetos, Chex mix	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
SWEETS AND DESSERTS										
Donuts	○	○	○	○	○	○	○	○	○	How many: ○ 1 mini ○ 1 med ○ 2 ○ 3
Cake or snack cakes like cupcakes, Twinkies, pound cake, banana bread	○	○	○	○	○	○	○	○	○	How many pieces: ○ 1 sm ○ 1 med ○ 2 ○ 3
Cookies, brownies	○	○	○	○	○	○	○	○	○	How many: ○ 1-2 ○ 3-4 ○ 5-6 ○ 7+
Pumpkin pie, sweet potato pie	○	○	○	○	○	○	○	○	○	How many pieces: ○ 1/2 ○ 1 ○ 2 ○ 3
Any other pie or cobbler, including fast food pies, snack pies	○	○	○	○	○	○	○	○	○	How many pieces: ○ 1/2 ○ 1 ○ 2 ○ 3
Ice cream, ice cream bars, frozen yogurt, fast food milkshakes	○	○	○	○	○	○	○	○	○	How much: ○ B ○ C ○ D
Pudding, custard, rice pudding, flan	○	○	○	○	○	○	○	○	○	How much: ○ B ○ C ○ D
Chocolate or other flavored sauces or syrup, on ice cream	○	○	○	○	○	○	○	○	○	How much: ○ 1-2 Tbspn ○ 3-4 Tbspn ○ 1/2 cup

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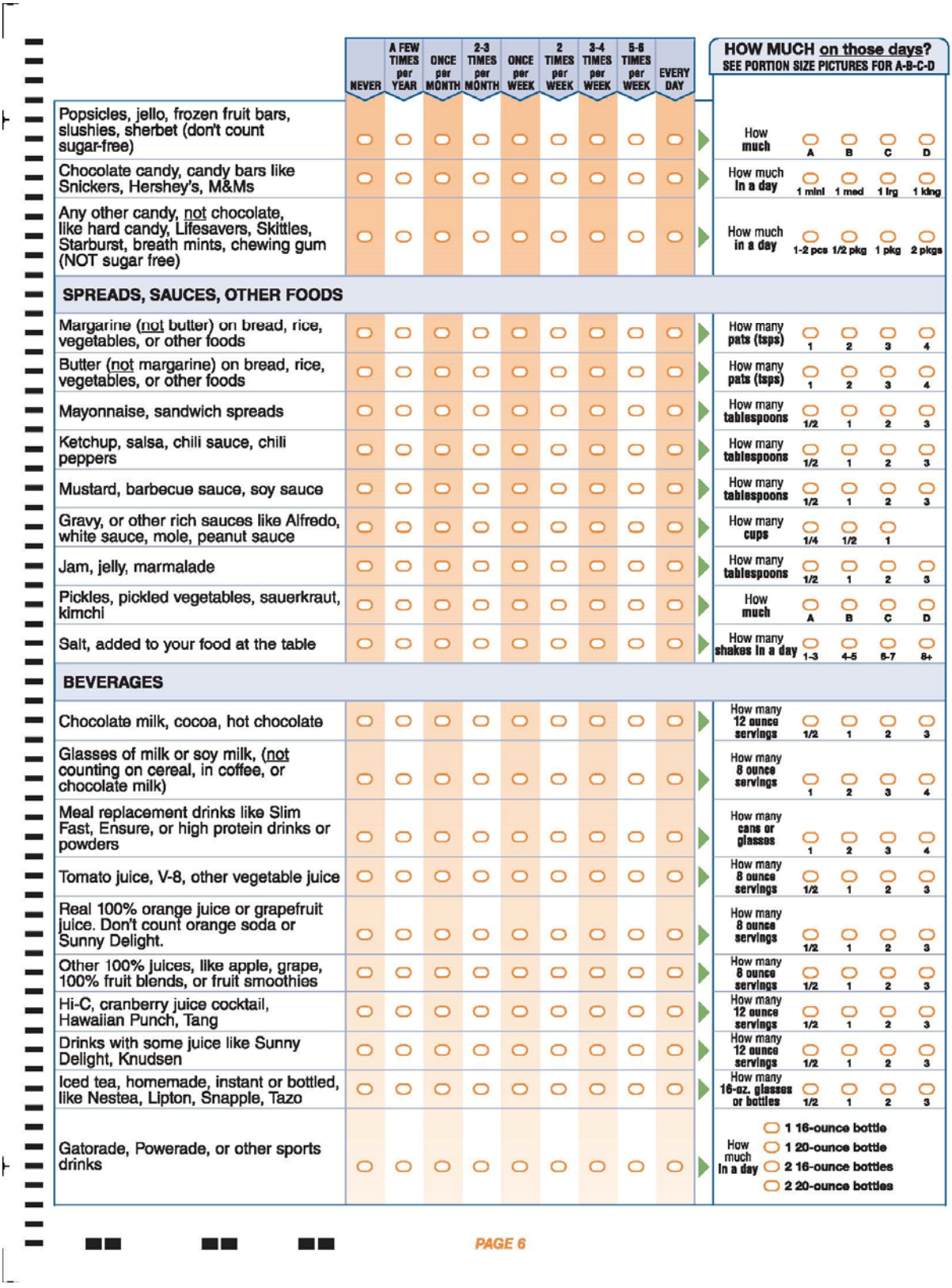

	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Popsicles, jello, frozen fruit bars, slushies, sherbet (don't count sugar-free)	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Chocolate candy, candy bars like Snickers, Hershey's, M&Ms	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1 mini ○ 1 med ○ 1 lrg ○ 1 klng
Any other candy, not chocolate, like hard candy, Lifesavers, Skittles, Starburst, breath mints, chewing gum (NOT sugar free)	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1-2 pcs ○ 1/2 pkg ○ 1 pkg ○ 2 pkgs
SPREADS, SAUCES, OTHER FOODS										
Margarine (not butter) on bread, rice, vegetables, or other foods	○	○	○	○	○	○	○	○	○	How many pats (tsps): ○ 1 ○ 2 ○ 3 ○ 4
Butter (not margarine) on bread, rice, vegetables, or other foods	○	○	○	○	○	○	○	○	○	How many pats (tsps): ○ 1 ○ 2 ○ 3 ○ 4
Mayonnaise, sandwich spreads	○	○	○	○	○	○	○	○	○	How many tablespoons: ○ 1/2 ○ 1 ○ 2 ○ 3
Ketchup, salsa, chili sauce, chili peppers	○	○	○	○	○	○	○	○	○	How many tablespoons: ○ 1/2 ○ 1 ○ 2 ○ 3
Mustard, barbecue sauce, soy sauce	○	○	○	○	○	○	○	○	○	How many tablespoons: ○ 1/2 ○ 1 ○ 2 ○ 3
Gravy, or other rich sauces like Alfredo, white sauce, mole, peanut sauce	○	○	○	○	○	○	○	○	○	How many cups: ○ 1/4 ○ 1/2 ○ 1
Jam, jelly, marmalade	○	○	○	○	○	○	○	○	○	How many tablespoons: ○ 1/2 ○ 1 ○ 2 ○ 3
Pickles, pickled vegetables, sauerkraut, kimchi	○	○	○	○	○	○	○	○	○	How much: ○ A ○ B ○ C ○ D
Salt, added to your food at the table	○	○	○	○	○	○	○	○	○	How many shakes in a day: ○ 1-3 ○ 4-5 ○ 6-7 ○ 8+
BEVERAGES										
Chocolate milk, cocoa, hot chocolate	○	○	○	○	○	○	○	○	○	How many 12 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Glasses of milk or soy milk, (not counting on cereal, in coffee, or chocolate milk)	○	○	○	○	○	○	○	○	○	How many 8 ounce servings: ○ 1 ○ 2 ○ 3 ○ 4
Meal replacement drinks like Slim Fast, Ensure, or high protein drinks or powders	○	○	○	○	○	○	○	○	○	How many cans or glasses: ○ 1 ○ 2 ○ 3 ○ 4
Tomato juice, V-8, other vegetable juice	○	○	○	○	○	○	○	○	○	How many 8 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Real 100% orange juice or grapefruit juice. Don't count orange soda or Sunny Delight.	○	○	○	○	○	○	○	○	○	How many 8 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Other 100% juices, like apple, grape, 100% fruit blends, or fruit smoothies	○	○	○	○	○	○	○	○	○	How many 8 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Hi-C, cranberry juice cocktail, Hawaiian Punch, Tang	○	○	○	○	○	○	○	○	○	How many 12 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Drinks with some juice like Sunny Delight, Knudsen	○	○	○	○	○	○	○	○	○	How many 12 ounce servings: ○ 1/2 ○ 1 ○ 2 ○ 3
Iced tea, homemade, instant or bottled, like Nestea, Lipton, Snapple, Tazo	○	○	○	○	○	○	○	○	○	How many 16-oz. glasses or bottles: ○ 1/2 ○ 1 ○ 2 ○ 3
Gatorade, Powerade, or other sports drinks	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1 16-ounce bottle ○ 1 20-ounce bottle ○ 2 16-ounce bottles ○ 2 20-ounce bottles

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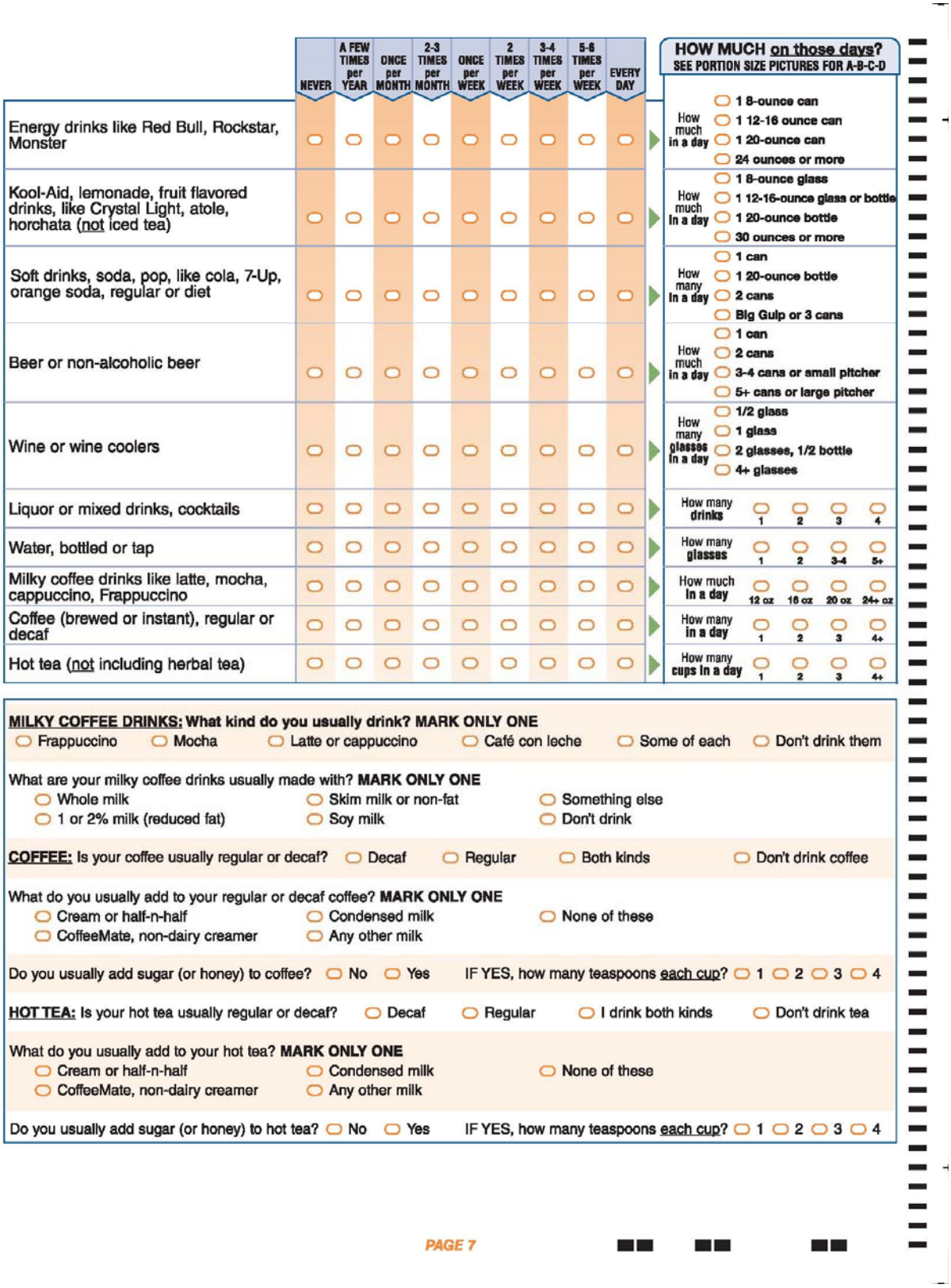

	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Energy drinks like Red Bull, Rockstar, Monster	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1 8-ounce can ○ 1 12-16 ounce can ○ 1 20-ounce can ○ 24 ounces or more
Kool-Aid, lemonade, fruit flavored drinks, like Crystal Light, atole, horchata (not iced tea)	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1 8-ounce glass ○ 1 12-16-ounce glass or bottle ○ 1 20-ounce bottle ○ 30 ounces or more
Soft drinks, soda, pop, like cola, 7-Up, orange soda, regular or diet	○	○	○	○	○	○	○	○	○	How many in a day: ○ 1 can ○ 1 20-ounce bottle ○ 2 cans ○ Big Gulp or 3 cans
Beer or non-alcoholic beer	○	○	○	○	○	○	○	○	○	How much in a day: ○ 1 can ○ 2 cans ○ 3-4 cans or small pitcher ○ 5+ cans or large pitcher
Wine or wine coolers	○	○	○	○	○	○	○	○	○	How many glasses in a day: ○ 1/2 glass ○ 1 glass ○ 2 glasses, 1/2 bottle ○ 4+ glasses
Liquor or mixed drinks, cocktails	○	○	○	○	○	○	○	○	○	How many drinks: ○ 1 ○ 2 ○ 3 ○ 4
Water, bottled or tap	○	○	○	○	○	○	○	○	○	How many glasses: ○ 1 ○ 2 ○ 3-4 ○ 5+
Milky coffee drinks like latte, mocha, cappuccino, Frappuccino	○	○	○	○	○	○	○	○	○	How much in a day: ○ 12 oz ○ 16 oz ○ 20 oz ○ 24+ oz
Coffee (brewed or instant), regular or decaf	○	○	○	○	○	○	○	○	○	How many in a day: ○ 1 ○ 2 ○ 3 ○ 4+
Hot tea (not including herbal tea)	○	○	○	○	○	○	○	○	○	How many cups in a day: ○ 1 ○ 2 ○ 3 ○ 4+

MILKY COFFEE DRINKS: What kind do you usually drink? MARK ONLY ONE

○ Frappuccino ○ Mocha ○ Latte or cappuccino ○ Café con leche ○ Some of each ○ Don't drink them

What are your milky coffee drinks usually made with? **MARK ONLY ONE**

○ Whole milk ○ Skim milk or non-fat ○ Something else
○ 1 or 2% milk (reduced fat) ○ Soy milk ○ Don't drink

COFFEE: Is your coffee usually regular or decaf? ○ Decaf ○ Regular ○ Both kinds ○ Don't drink coffee

What do you usually add to your regular or decaf coffee? **MARK ONLY ONE**

○ Cream or half-n-half ○ Condensed milk ○ None of these
○ CoffeeMate, non-dairy creamer ○ Any other milk

Do you usually add sugar (or honey) to coffee? ○ No ○ Yes IF YES, how many teaspoons each cup? ○ 1 ○ 2 ○ 3 ○ 4

HOT TEA: Is your hot tea usually regular or decaf? ○ Decaf ○ Regular ○ I drink both kinds ○ Don't drink tea

What do you usually add to your hot tea? **MARK ONLY ONE**

○ Cream or half-n-half ○ Condensed milk ○ None of these
○ CoffeeMate, non-dairy creamer ○ Any other milk

Do you usually add sugar (or honey) to hot tea? ○ No ○ Yes IF YES, how many teaspoons each cup? ○ 1 ○ 2 ○ 3 ○ 4

If you eat the following foods, what type do you usually eat? MARK ONLY ONE ANSWER FOR EACH QUESTION

Milk	○ Whole milk	○ 2% milk	○ 1% milk (low-fat)	○ Skim milk, non-fat	
	○ Soy milk	○ Rice milk	○ Almond milk, other	○ Don't drink	
Slimfast, Ensure, or high protein drinks	○ Slimfast, Ensure, regular	○ Slimfast, Ensure, light or low-carb			
	○ High protein drinks, regular	○ High protein drinks, light or low-carb	○ Don't know/Don't drink		
Real 100% orange or grapefruit juice	○ Calcium-fortified	○ Not calcium-fortified	○ Don't know	○ Don't drink	
Iced tea	○ Home-made, no sugar	○ Bottled, no-sugar	○ Don't drink		
	○ Home-made, with sugar	○ Bottled, pre-sweetened			
Drinks like Kool-Aid, lemonade, Crystal Light	○ Low-calorie, sugar-free	○ Regular	○ Don't drink		
Energy drinks like Red Bull, Monster	○ Sugar-free	○ Regular	○ Don't drink		
Soft drinks, soda, pop	○ Diet, low-calorie	○ Regular	○ Don't drink		
Do they usually have caffeine?	○ Has caffeine	○ No caffeine	○ Don't drink		
Beer	○ Regular	○ Light	○ Non-alcoholic	○ Don't drink	
Wine or wine cooler	○ Red wine	○ White wine	○ Both red and white wine	○ Don't drink	
Cheese	○ Low-fat	○ Regular-fat	○ Don't eat		
Yogurt	○ Plain (no sugar or fruit)	○ With fruit or other flavors			
Yogurt	○ Low-fat	○ Non-fat	○ Regular (whole milk)	○ Don't eat	
Salad dressing	○ Low-fat, lite	○ Fat free	○ Regular	○ Oil & vinegar	○ Don't use
Spaghetti or lasagna	○ Meatless	○ With meat sauce or meatballs	○ Don't eat		
Noodles, pasta	○ Rarely whole grain	○ Sometimes whole grain	○ Usually whole grain	○ Don't know/don't eat	
Burgers	○ Hamburger	○ Cheeseburger	○ Turkey burger	○ Don't eat	
Beef or pork	○ Avoid eating the fat	○ Sometimes eat the fat	○ Often eat the fat	○ Don't eat	
Chicken or turkey	○ Avoid eating the skin	○ Sometimes eat the skin	○ Often eat the skin	○ Don't eat	
Hot dogs, dinner sausage	○ Beef or pork	○ Chicken or turkey, low-fat	○ Don't eat		
Lunch meats	○ Beef or pork	○ Chicken or turkey, low-fat	○ Don't eat		
Cakes, snack cakes, cupcakes	○ Low-sugar, low-carb	○ Low-fat	○ Regular-fat	○ Don't eat	
Cookies, brownies	○ Low-sugar, low-carb	○ Low-fat	○ Regular-fat	○ Don't eat	
Ice cream, frozen yogurt	○ Low-sugar, low-carb	○ Low-fat or frozen yogurt	○ Regular	○ Don't eat	
Energy or protein bars	○ High energy	○ High protein	○ Some of each	○ Don't know	○ Don't eat
Bagels, English muffins, rolls	○ White	○ Multi-grain	○ 100% whole wheat	○ Eat all kinds	○ Don't eat
Burger, hot dog, submarine buns	○ White	○ Multi-grain	○ 100% whole wheat	○ Eat all kinds	○ Don't eat
Bread	○ White (not whole grain)	○ 100% whole wheat	○ Don't eat		
	○ Multi-grain, rye, or other brown bread	○ Eat some of each			
Tortillas	○ Corn tortillas	○ Flour tortillas (wheat)	○ Eat all kinds or don't know	○ Don't eat	
Popcorn	○ Air popped, fat-free	○ Low-fat or Light	○ Regular	○ Caramel corn	○ Don't know ○ Don't eat
Crackers, pretzels	○ Low-fat, including RyeKrisp, rice cakes, or plain pretzels	○ Don't know			
	○ Regular-fat crackers or filled pretzels	○ Don't eat			
Mayonnaise or sandwich spreads	○ Low-fat, light	○ Regular	○ Don't eat		

If you eat **cold cereals**, what do you usually eat? Choose **ONE or TWO** that you eat most often. If you usually eat just one kind, only choose one.

○ All-Bran Original	○ Cinnamon Toast Crunch	○ Grape Nuts	○ Special K, plain
○ All-Bran Complete, Complete	○ Cocoa Krispies, Pebbles, Puffs	○ Honey Bunches of Oats	○ Special K, flavors
○ Apple Jacks, Cookie Crisp	○ Corn Flakes, Corn Puffs	○ Kashi GOLEAN, Heart to Heart	○ Total
○ Bran Flakes	○ Corn Pops	○ Life	○ Wheaties
○ Cap'n Crunch	○ Fiber-One, Bran Buds	○ Lucky Charms, Fruity Pebbles	○ *Other sweet cereal*
○ Cheerios, plain or Multi-Grain	○ Froot Loops	○ Oatmeal Squares, Oat Bran	○ *Other unsweetened cereal*
○ Cheerios, Honey Nut, flavors	○ Frosted Flakes	○ Raisin Bran	○ *Other whole grain cereal*
○ Chex, Wheat	○ Frosted Mini-Wheats	○ Rice Krispies, puffed rice	○ *Other bran or fiber cereal*
○ Chex, other	○ Granola	○ Shredded Wheat	○ *Don't eat cereal*

Which **fats or oils** are used most often for **cooking or frying** (not baking) in your home? **MARK ONLY ONE OR TWO**

○ Non-stick spray or none	○ Soft tub margarine	○ Corn oil, vegetable oil and blends	○ Other oil
○ Butter or ghee	○ Low-fat margarine	○ Peanut oil	○ Don't know
○ Butter/margarine blend	○ Olive oil	○ Lard, fatback, or bacon fat	
○ Stick margarine	○ Canola oil, safflower oil	○ Vegetable shortening, Crisco	

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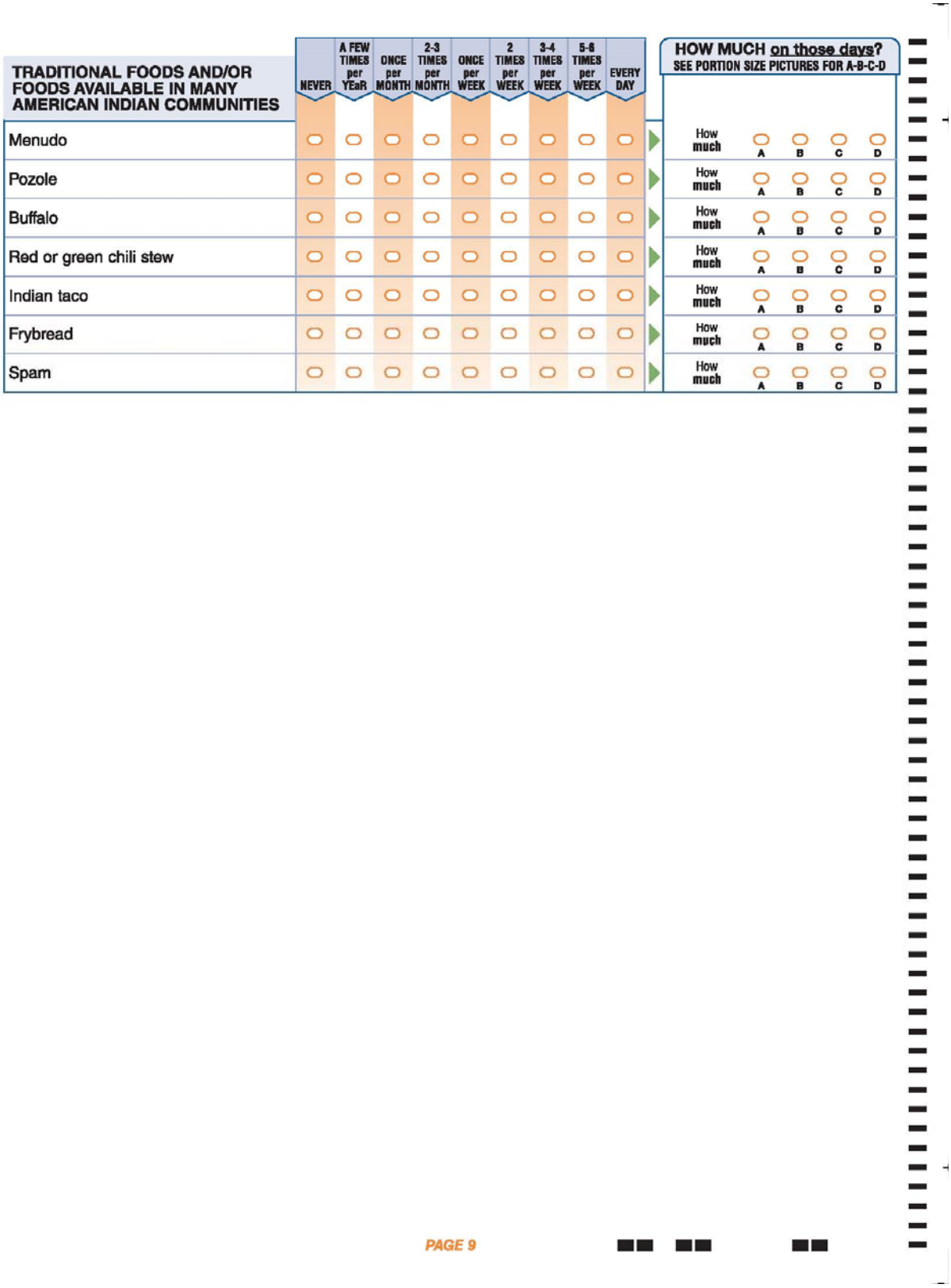

TRADITIONAL FOODS AND/OR FOODS AVAILABLE IN MANY AMERICAN INDIAN COMMUNITIES	NEVER	A FEW TIMES per YEaR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH on those days? SEE PORTION SIZE PICTURES FOR A-B-C-D
Menudo	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Pozole	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Buffalo	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Red or green chili stew	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Indian taco	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Frybread	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D
Spam	○	○	○	○	○	○	○	○	○	How much ○A ○B ○C ○D

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SOME LAST QUESTIONS ABOUT YOU

	RARELY	1-2 per WEEK	3-4 per WEEK	5-6 per WEEK	1 per DAY	1 1/2 per DAY	2 per DAY	3 per DAY	4+ per DAY
About how many servings of vegetables do you eat, not counting salad or potatoes? 1 serving = 1/2 cup.	○	○	○	○	○	○	○	○	○
About how many servings of fruit do you eat, not counting juices? 1 serving = 1/2 cup or 1 medium fruit.	○	○	○	○	○	○	○	○	○
How often do you eat foods prepared at home that are cooked or fried in **fat or oil?**	○	○	○	○	○	○	○	○	○

During a regular day, how many **meals and snacks** do you usually eat?

Meals per day	○ 1	○ 2	○ 3	○ 4	○ 5+
Snacks per day	○ 1	○ 2	○ 3	○ 4	○ 5+

During a regular week, how many times do you eat take-out (for example, fast-food, food trucks, grocery store or convenience store food court, sit-down restaurant)?

- ○ Rarely or never
- ○ A few times per month
- ○ Once or twice a week
- ○ 3-4 times a week
- ○ 5-6 times per week
- ○ Almost every day

PHYSICAL ACTIVITY SURVEY

Think about the last 12 months. How often did you do the activities listed below?

	HOW OFTEN IN THE PAST YEAR						HOW MUCH TIME ON THOSE DAYS			
	RARELY OR NEVER	A FEW TIMES A MONTH	ONCE OR TWICE A WEEK	3-4 TIMES A WEEK	5-6 TIMES A WEEK	ALMOST EVERY DAY	LESS THAN 30 MINUTES	30-60 MINUTES	1-2 HOURS	3 OR MORE HOURS
Cooking, shopping, light cleaning like doing laundry or dusting, or running errands	○	○	○	○	○	○	○	○	○	○
Slow walking like walking the dog, or light work around the house like watering	○	○	○	○	○	○	○	○	○	○
Work on the job involving standing, like store clerk, or work involving driving (like truck driver)	○	○	○	○	○	○	○	○	○	○
Taking care of children (feeding, dressing), or moderate housework like sweeping, mopping, cleaning the tub	○	○	○	○	○	○	○	○	○	○
Weeding, raking, mowing the lawn, or light house repairs	○	○	○	○	○	○	○	○	○	○
Brisk walking, dancing, hunting or fishing, golf (NOT using a golf cart), or 'friendly' outdoor games like softball	○	○	○	○	○	○	○	○	○	○
Factory work, mechanic, restaurant work, or work involving walking, like mail carrier	○	○	○	○	○	○	○	○	○	○
Construction, painting, feeding livestock, or homecare like caring for an adult family member	○	○	○	○	○	○	○	○	○	○
Heavy work like moving boxes, heavy digging or shoveling snow, farm chores like baling hay, or other HARD labor	○	○	○	○	○	○	○	○	○	○
Exercising at the gym or at home, aerobics, weight training, jogging, or vigorous sports like basketball, soccer, tennis	○	○	○	○	○	○	○	○	○	○
Bicycling or swimming for exercise	○	○	○	○	○	○	○	○	○	○

Thank you very much for filling out this questionnaire.
Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA

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1/4" SPINE PERF

Fold along this line, then carefully detach.

**Fold this page along the dotted line,
then CAREFULLY detach this page.
Your portion pictures are on the back.**

1/4" SPINE PERF

Fold along this line, then carefully detach.

Portion Size Choices

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your usual portion size.

Choose A, B, C or D: **A** = 1/4 Cup of Food **B** = 1/2 Cup of Food **C** = 1 Cup of Food **D** = 2 Cups of Food

4. Nutrition Report Example

Your Nutrition Report [redacted]

Antioxidants from diet		
Vitamin A	929.57 RAE	RDA for you: 900.00 RAE
Beta-carotene	4507.68 mcg	5000-6000 micrograms from food
Vitamin C	98.32 mg	A good diet can provide 200400 milligrams
Vitamin E	9.21 mg	RDA: 15.00 mg.
B-Vitamins from diet		
B1, B2	1.87 mg	RDA: 1.20 milligrams
Niacin	26.70 mg	RDA: 16.00 milligrams
Folate	604 66 mcg	RDA 400 00 micrograms
Vitamin B6	2.20 mg	RDA: 1.70 milligrams
Minerals from diet		
Calcium	1298.93 mg	RDA: 1000.00 milligrams
Zinc	14.96 mg	RDA: 11.00 milligrams
Iron	19.09 mg	RDA: 15 milligrams
Potassium	3544 79 mg	3000 milligrams or more
Sodium (salt)	4147.05 mg	2400 milligrams or less
Magnesium	373.08 mg	420.00 milligrams or more

***Your* Food Group Ser ıgs**		**USDA My Pyramid Recommendations**
Bread, pasta, rice	6 76 1 oz equiv	7 00 oz equiv per day
Whole grains	1.49 1 oz. equiv.	3.50 oz. -equiv per day
Vegetables group	2.24 cups	3.00 cups per day
without potatoes	1.82 cups	2.10 cups per day
Fruits, fruit juices	1 07 cups	2 00 cups per day
Milk, cheese, yogurt	1.78 cups	3.00 cups per day
Meat, eggs, or beans	12.80 1 oz. equiv.	6.00 oz. -equiv per day
Good oils, in foods	5.66 "teaspoons"	6.00 "teaspoons" per day

***Your* average intake**		***Your* Recommended levels**
Calories	2259 53 Kcal	Depends on your age, sex, body size and physical activity
Fat	97.47 g	25-35% of total calories
as % of cals	38.82%	
Saturated fat	30.90 g	Less than 7% of calories
as % of cals	12.31%	
Monounsaturated fat	36.65 g	
Polyunsaturated fat	21 39 g	
Protein as % of cals	94.51 g 16 73%	10-20% of total calories. For you 56 00 113 00 grams per day
Carbohydrate as % of cals	260 27 g 46.07%	50 60% of total calories (primarily from whole grains, vegetables and fruits)
Cholesterol	355.49 mg	Less than 200 milligrams
Dietary Fiber	23 36 g	20 35 grams or more
Alcohol % of cals	0.00%	1 drink/day or less
Sweets % of cals	14.21%	Use sparingly. Full of empty calories

Where the nutrients are coming from in *your* diet

Calories
Pizza, pizza pockets
Breakfast sandwich w egg or meat
Other beans, lentil

Total Fat
Pizza, pizza pockets
Breakfast sandwich w egg or meat
Cook fat: Corn, vegetable oil blends

Saturated Fat
Butter at table
Pizza, pizza pockets
Breakfast sandwich w egg or meat

Cholesterol
Other eggs or omelets
Breakfast sandwich w egg or meat
Steak, roast

Sodium
Pizza, pizza pockets
Breakfast sandwich w egg or meat
Lunch meats, poultry, low-fat

Fiber Other beans, lentil
Bread, whole grain
Pizza, pizza pockets

Vitamin C
OJ, grapefruit juice, calcium fortified
Cabbage, slaw, Chinese cabbages
Other 100% juice and blends

Potassium
Coffee, both kinds
Other beans, lentil
OJ, grapefruit juice, calcium fortified

Vitamins from supplements

Vitamin A	2709.00 RAE
Vitamin C	260.00 mg
Vitamin E	40 10 mg a toc
Folate	400.00 mcg
Calcium	200.00 mg
Iron	18.00 mg Zinc 31 00 mg

Suggestions about your diet:

For better health, lower your saturated fat intake to less than 7% of total calories.
To achieve this goal, eat more vegetables, fruits and grains, and fewer fatty foods. Look at your top three sources of saturated fat. Try eating these less often or switching to smaller portions or low-fat types.

Congratulations! You are getting a good amount of calcium

Keep eating those low-fat dairy products and low-fat milk, and perhaps try calcium-fortified juice. It is needed for strong bones, and for regulating blood pressure, transmitting nerve impulses, and in blood clotting. Calcium supplements are also valuable, to ensure that you are getting enough.

You're not getting your recommended servings per day of vegetables!
They can lower the risk of cancer and heart disease. And of course, they are usually low in fat. Getting at least five servings every day is not that hard! For example, have a glass of juice or a piece of fruit with breakfast (1), a salad with lunch (2), a piece of fruit for a snack (3), and potatoes and a vegetable with dinner (4,5).

My Pyramid Food Groups
Learn how your diet compares to USDA My Pyramid recommendations for your calorie level. Half of all your grain servings (breads, pasta, rice) should be whole grains. Since 2006 USDA gives fruit and vegetable advice as “cups” of food. Beneficial oils are from natural (unhydrogenated) vegetable oils and some foods, like avocados, nuts, seeds, and fish. My Pyramid has a website, http://www.mypyramid.gov.

Body Mass Index (BMI)

Your self-reported height is 6 feet 03 inches.
Your self-reported weight is
263 pounds. Your Body Mass
Index (BMI) is 32.87.

Body Mass Index (BMI) is one of many factors that may be related to developing a chronic disease such as heart disease, cancer, or diabetes.

BMI	Weight Status
Below 18.5	Underweight
18.5 to 24.9	Normal
25.0 to 29.9	Overweight
30.0 and above	Obese

If your BMI is above 25, or if you are Asian or South Asian and your BMI is above 23, you might want to talk to your health care provider about weight loss strategies. For overweight people, even a small weight loss may help to lower the risk of disease.

5. Diet Letter for SHS Participants

Insert sender information (I assume the PI at each site?)

First Name, Last Name
Participant ID
Address

MM—DD-YY
RE: Nutrition report from the dietary survey completed during your research exam performed on MM-DD-YYYY for the Strong Heart Liver Study

Dear [Mr./Mrs./Ms./Dr.] Last Name,
Thank you for participating in our research on liver disease and having a research exam on MM-DD-YYYY. The exam included a questionnaire regarding your food intake and diet. The questionnaire was developed by a company called Nutrition Quest.

Nutrition Quest converted your answers into a personalized nutrition report, which we are providing to you. It provides you with personalized suggestions about your diet, including what changes you might make to improve your diet, as well as what you are doing well regarding eating a healthy diet.

In addition, the nutrition report includes a detailed summary of your average daily intake of many different food categories and nutrients, and where the nutrients are coming from in your diet.
This report is prepared by Nutrition Quest based upon your answers to the dietary survey. For comparison, the report provides the USDA My Pyramid recommendations for daily food intake. It also provides the recommended dietary allowance (RDA) considered necessary for the maintenance of good health (by the Food and Nutrition Board of the National Research Council/ National Academy of Sciences).
We thank you again for participating in our research and we hope this report provided by Nutrition Quest is helpful to you by providing information about your diet.

Sincerely,
Insert signature
PI First Name, Last Name, Title

6. Ethnic Foods Information

Common Preparation of Ethnic Foods Included in FFQ

Food	Common Preparation
Menudo	Tripe, hominy, tomato, onion, chili powder
Pozole	Wheat kernels, boiled with tepary beans
Red or green chili stew	Beef chuck or stewing beef cooked with chili or jalapeno
Indian taco	Frybread, ground beef, beans, cheese, lettuce, tomato; or any combination of these foods
Frybread	Any frybread, whether baking powder or yeast dough
Spam	Pork and ham, salt, water, potato starch, sugar, and sodium nitrite

Data Entry and Quality Control

Manual of Operations Volume VII

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
Hudson College of Public Health
The University of Oklahoma Health Sciences Center

P.O. Box 26901
Oklahoma City, OK 73190

Tracking of Revisions to Manual of Operations Volume VII : Data Entry and Quality Control

Date of Revision	Revised Section	Revision	Approved by, Date
6/28/2023	Section 4: Quality Control	Add plan for deleting records in REDCap	SHS QC Committee, 6/28/2023
5/4/2023	Section 1: SHS REDCap Application	Change REDCap from OUHSC to SHS	SHS CC, 3/2023
4/20/2023	Entire document	Fixed formatting issues	SHS CC, 11/1/2022
11/8/2023	Section 4: Quality Control	Add lab QC label instructions	SHS QC Committee, 11/8/2023
9/3/2024	Section 3.3: Screening and Consent	Add plan for indicating inability to complete study due to dementia Revised wording	SHS CC, 8/27/2024

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VII. Data Entry and Quality Control

1. Introduction

This manual is to assist Strong Heart Study (SHS) investigators and field staff in three Field Centers (FC, the MedStar Health Research Institute, Phoenix, Arizona, the Missouri Breaks Industry Research Inc, Eagle Butte, South Dakota, and the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma) in understanding and using the REDCap data entry forms develop for SHS Phase VII.

In addition, this manual is to help staff at the SHS Data Coordinating Center (CC) manage data entered on the forms in REDCap.

2. Strong Heart Study REDCap Application

The Strong Heart Study (SHS) REDCap (**R**esearch **E**lectronic **D**ata **C**apture) application can be accessed by pointing a web browser to the following address:

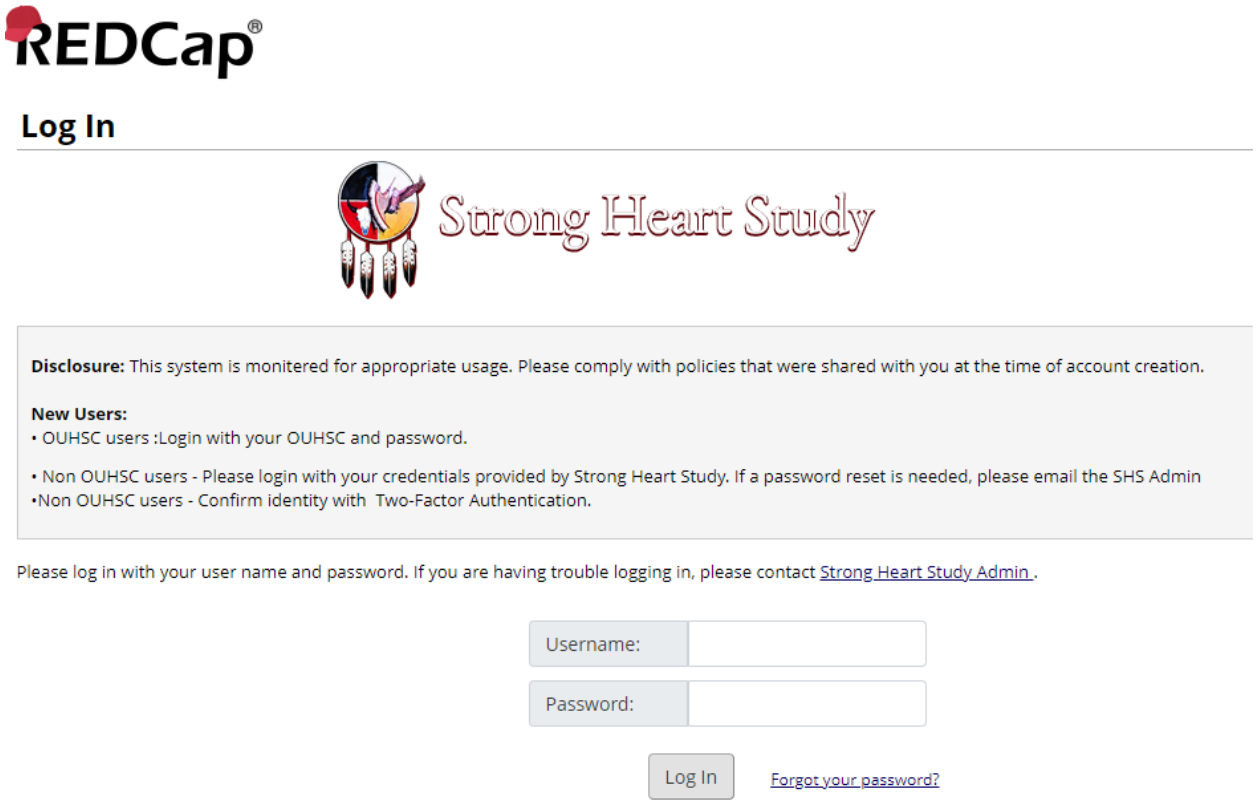
https://shsrcap.ouhsc.edu/

In order to access the application, the University of Oklahoma Health Sciences Center (OUHSC) staff may use their OUHSC user name and password. For users that do not have an OUHSC account, a user account must be created by the SHS REDCap admin, Pravina Kota, at pravina-kota@ouhsc.edu. To request accounts, the Site PI should send the names and email addresses of the requested users to the Data Coordinating Center (DCC) data manager Kimberly Malloy, at kimberly-malloy@ouhsc.edu.

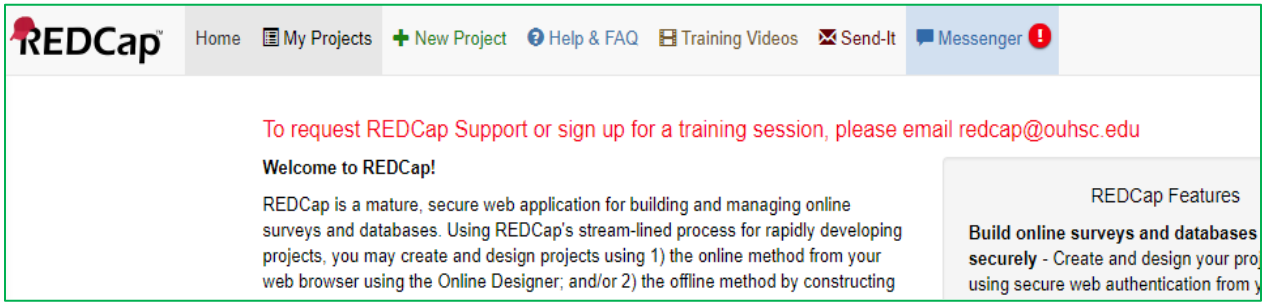
User accounts on the SHS REDCap application should be used for the following tasks:

1. Consenting participants for the Phase VII examination.
2. Entry or edits of participant data collected through Phase VII personal interview and physical examination
3. Entry or edits and completion of participant data collected for Phase VII Ancillary studies
4. Tracking study progress.

To connect to the SHS REDCap application, point your web browser to the server address provided above, then enter your user name and password into the login screen:



You will then see the main REDCap screen, where you should click on the "My Projects" tab:



2.1 REDCap Data Collection Options

To collect data using REDCap, field center staff can utilize a desktop or laptop or iPAD. When using any of these devices, the best recommendation is to use the web version of REDCap instead of using the REDCap mobile app. Users will be notified when the use of mobile app becomes available.

The web version of REDCap is used to accommodate branching logic, other special features, and external modules that have be requested and needed in the setup of this project. Some of these modules are not supported by the REDCap app version and hence staff might see limited functionality when trying to capture data using the app version. Since the app is controlled by the respective app stores of Apple and Android platforms, no timeline can be established on when such functionality will be included onto these apps. The web version of REDCap is fully functional and tested and would work best without disruptions.

2.2 Summary of REDCap Project

Select the appropriate field center SHS Phase VII Exam REDCap project

1. For Arizona, select SHS Phase VII Exam - Arizona
2. For Oklahoma, select SHS Phase VII Exam - Oklahoma
3. For Dakotas, select SHS Phase VII Exam – South Dakota

This REDCap project includes the following

1. Consent documents
   - These include consents for the Phase VII Examination, consents for each Phase VII ancillary study, HIPAA forms (if applicable), and IHS consent forms (if applicable).
   - These documents will be completed and signed by the participant and the person obtaining consent.
2. Data will be collected on the following Phase VII exam forms:
   - Participant Screening and Exit
   - Sample Collection Checklist
   - Physical Examination
   - Physical Examination – QC Duplicate Measurement for select participants
   - Personal Interview I

- Personal Interview II
- Medical History
- Medication Reception
- Medication Dosage Details
- Reproduction and Hormone Use (Women Only)
- Rose Questionnaire for Angina and Intermittent Claudication
- Perceived Stress
- Quality of Life
- CES D Scale
- MHLC Scale
- Other Questions About Your Life
- Food Assistance & Food Security
- Food Frequency Questionnaire (FFQ)
- CBC Results

3. Data will be collected from the following Ancillary Study forms:
   - Resilience, Cultural Alignment, and Social Support in Brain Aging
     - Montreal Cognitive Assessment (MOCA)
     - 14- Item Resilience Scale (RS-14)
     - Multidimensional and Interpersonal Resilience Measure (MIRM)
     - Multigroup Ethnic Identify Scale (MEIM-R)
     - Orthogonal Cultural Identity Scale (OCIS)
     - Rosenberg self-Esteem Scale (R-SES)
     - Social Support and Social undermining Items (SS/U)
     - Social Network Index (SNI)
     - Functional Activities Questionnaire (FAQ)
   - Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians
     - The NIH Toolbox Cognition Battery
   - The Epitranscriptome as a Novel Mechanism of Arsenic – Induced Diabetes
     - An extra blood sample will be taken and recorded on the sample collection checklist
   - Health Effects of Metals in Native American communities: A Longitudinal Multi-omics Study
     - Additional address information and drinking water questions are included in the Personal Interview I questionnaire
   - Gut Microbiome, Aging, and Cardiometabolic Diseases in American Indians
     - Bristol Stool Chart
   - Chronic Respiratory Diseases in American Indians (administered in Oklahoma only)
     - Respiratory questionnaire

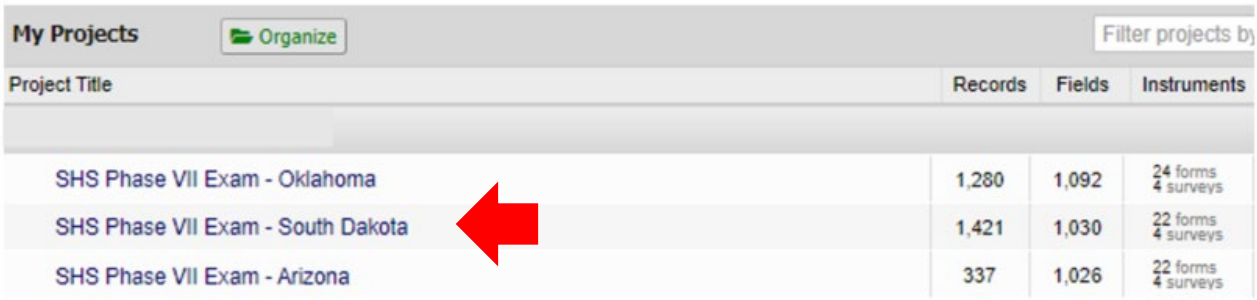
3. Data Entry Instruction

3.1 Before Starting

Before entering data, the interviewer needs to identify eligible participants. The current REDCap database includes participants who were identified by each field center as possible eligible participants. If a field center identifies an eligible participant that is not in the current list on REDCap, the field center can add this participant to REDCap. See Section 3.5 below for more details on how to add a participant.

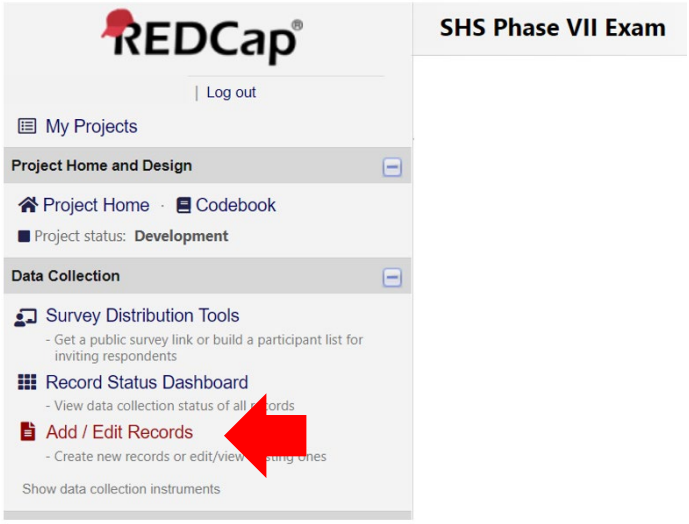
3.2 Getting Started

To screen, consent, and/or enter data for a participant, select your field sites SHS Phase VII Exam project on the REDCap front page:

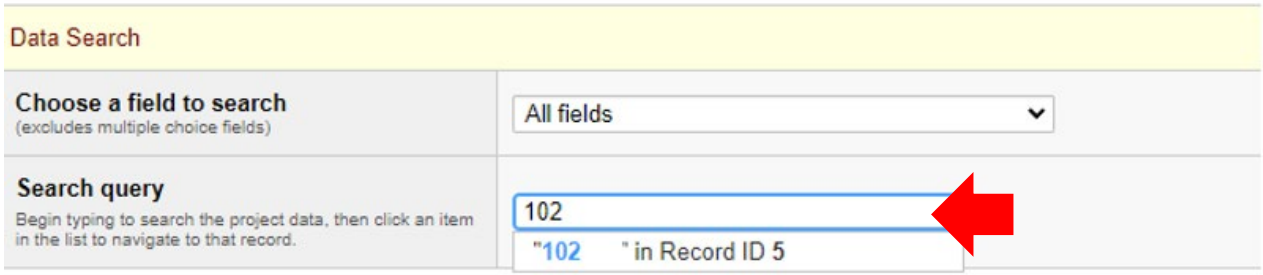


Eligible participant SHS ID and SHS Family ID (if applicable) have already been populated in the REDCap database. To find a participant, select Add / Edit Records link under the Data Collection menu on the left site of the screen.

Note: Information that has already be populated in REDCap have been redacted from this manual to preserve confidentiality.



In the Search query field, the SHS ID number or SHS Family ID number can be entered. A drop down menu will appear, and the correct record should be selected.

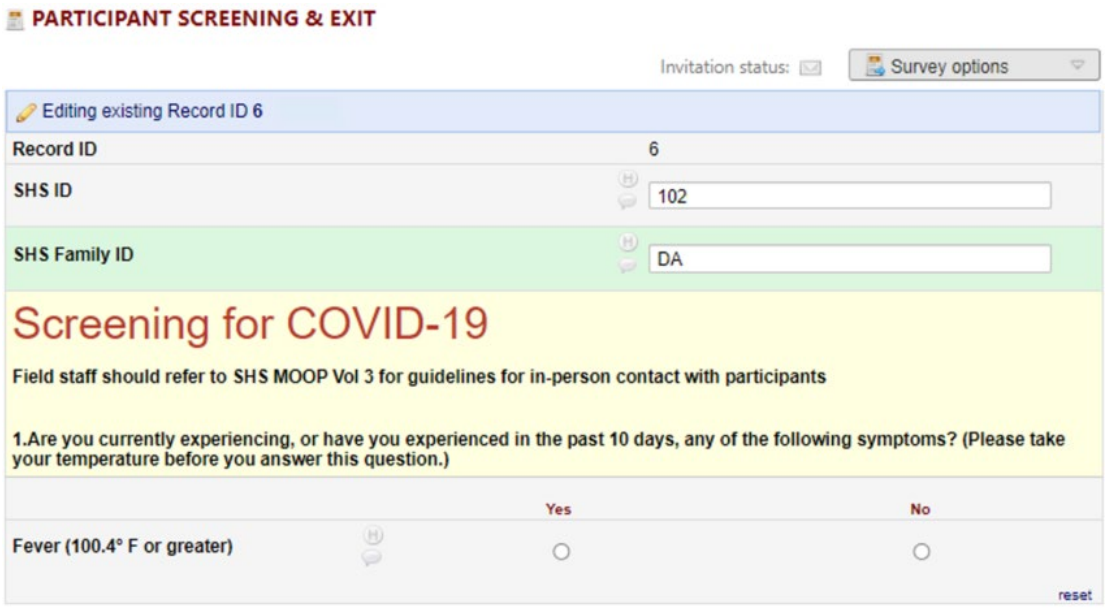


The Screening & Exit page will appear. The interviewer or FC personnel can then administer the screening questionnaire.

3.3 Screening and Consent

The Screening for COVID-19, Pregnancy, & Exit page will be used by the interviewer or FC personnel to screen for eligibility for the Phase VII examination. Screening questions include exposure to COVID-19 and pregnancy. If the participant is either COVID positive or pregnant, they cannot participate in the Phase 7 examination until they are COVID negative or 6-weeks postpartum. These participants will need to be contacted again and re-screened.

The SHS ID and SHS Family ID fields are already be populated on this form. The Record ID number is a pre-populated identification number used in the REDCap system and cannot be changed.



The Screenings for COVID-19, Pregnancy, and Exit form includes several Administrative sections that will only be used by the FC and the CC to aid in tracking which ancillary studies participants have consented too, reasons why a participant may not want to participate in the Phase 7 examination or any of the ancillary studies, allow for multiple visits for a participant to complete all of the Phase 7 examination and/or ancillary studies, and to track if consents were administered on an iPAD/computer or on paper. Answers to the questions in these sections also provides logic in REDCap for certain forms to appear or not appear based on how a question was answered.

If a participant is unable to participate in the Phase 7 examination or any of the ancillary studies due to dementia, please select 'Cognitively Impaired' from the drop-down list. Alternatively, you can select 'Other' and specify the reason as dementia.

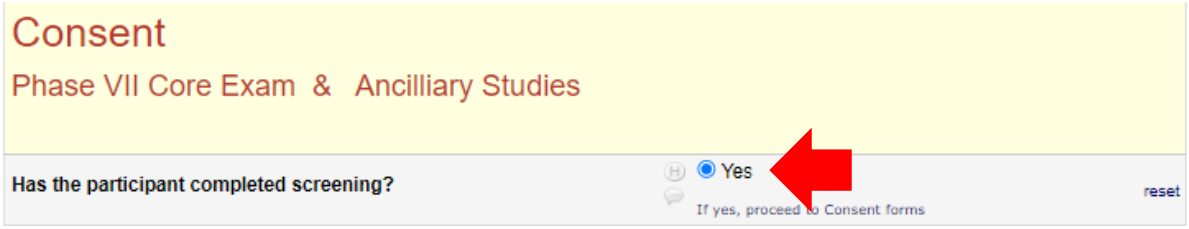
It is important to complete these sections prior to administering any questionnaire so that the logic is appropriately applied. This can be done after the consenting to Phase 7 examination and the ancillary studies. It is going to be the responsibility of the interviewer at the FC to ensure these questions are filled out properly before administering the questionnaires. This form should not be given to the participant to fill out.

Below outlines certain scenarios and how each administrative section of this form should be filled out.

3.3.1 Administering Electronic Consent (e-consent)

The participant has completed screening and wants to participate in the Phase 7 examination.

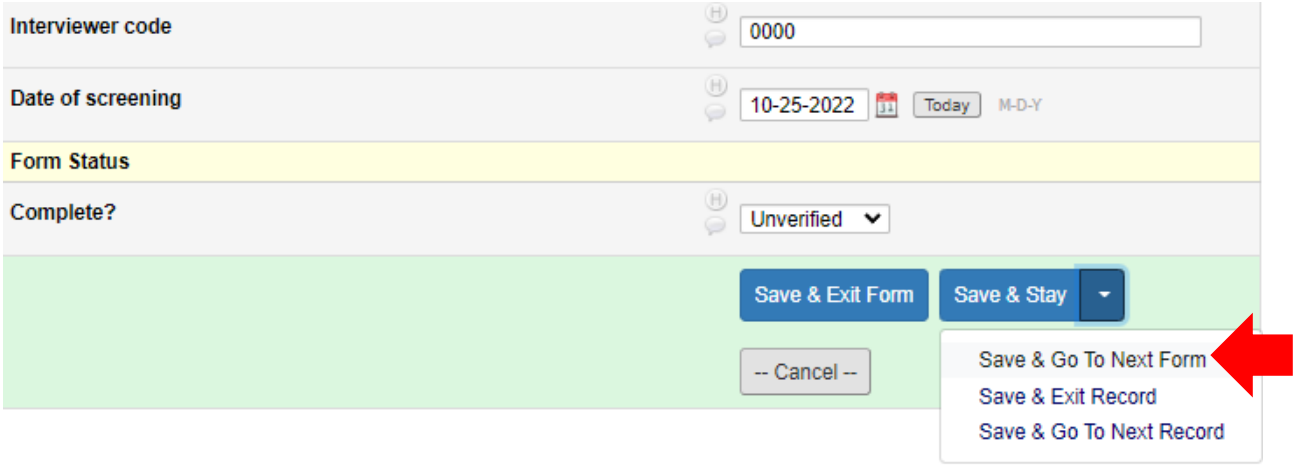
The interviewer will select Yes to the question "Has the participant completed screening?"



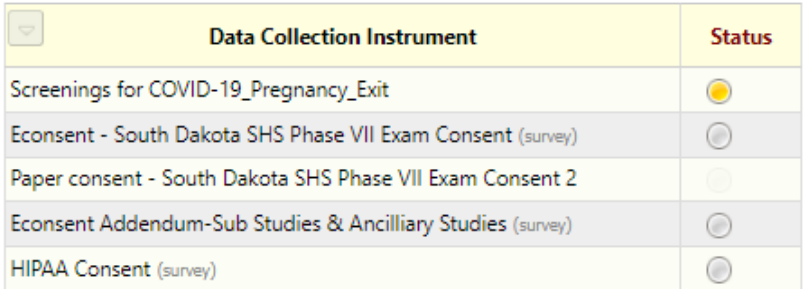
The interviewer will then scroll down to Administrative Information and select whether the consent for the Phase 7 examination will be administered on an iPAD/computer or on paper.

If the interviewer selects iPAD/Computer, the Phase 7 examination consents and ancillary study consents will be available on REDCap for the participant to fill out and sign.

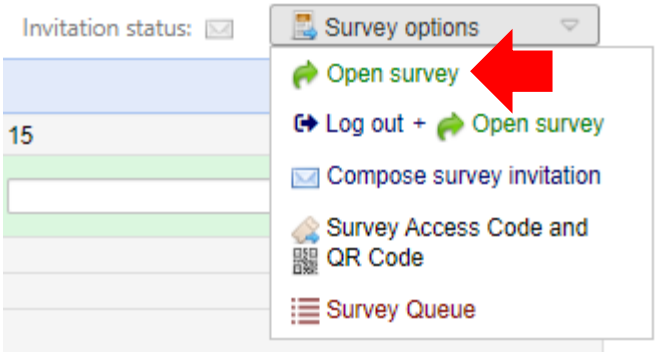
The Interviewer can then enter their code and the date of screening. And select "Unverified" under form status. The Unverified status will change the radio button for this form from RED to YELLOW. This can be used by the interviewer as a reminder that this form will need to be returned to after the consenting process to enter more information before the interviewer can administer the questionnaires. Select Save & Go to the Next Form.



The electronic consents (or e-consents) will now be available for the participant to read and sign. See Section 3.4 Complete Consent Process for more details. Note: the screen shots below are for the Dakota site consents, but the process will be the same for all three centers.



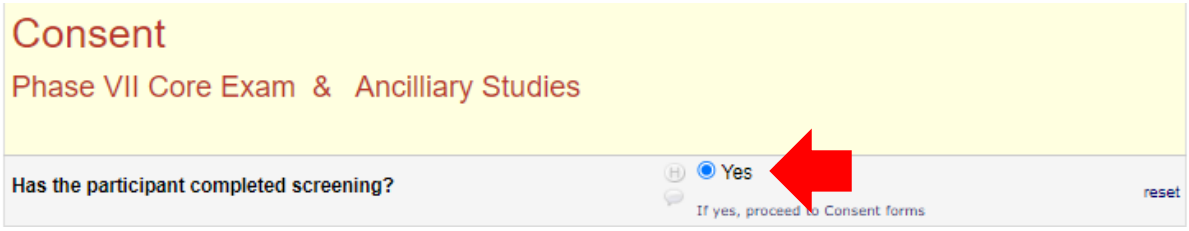
Because iPAD/Computer was selected, the next form will be the Phase 7 examination consent. To begin the administration process, the interviewer will need to select Survey options at the top of the Screen, and select Open Survey.


Invitation status:
Survey options
Open survey
Log out + Open survey
Compose survey invitation
Survey Access Code and QR Code
Survey Queue
15

3.3.2 Administering Paper Consent

The participant has completed screening and wants to participate in the Phase 7 examination.

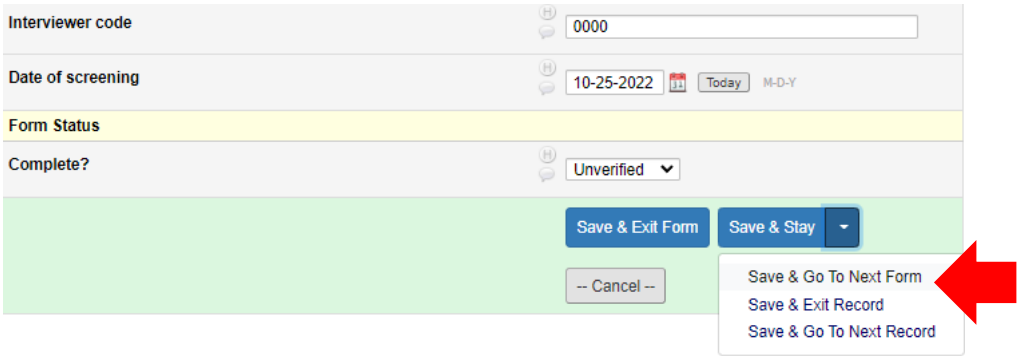
The interviewer will select Yes to the question "Has the participant completed screening?"



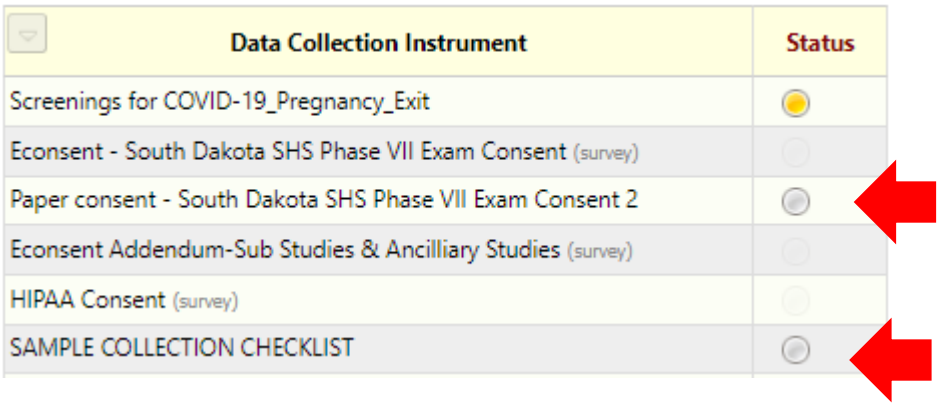
The interviewer will then scroll down to Administrative Information and select whether the consent for the Phase 7 examination will be administered on an iPAD/computer or on paper.

If the interviewer selects Paper, the Phase 7 examination consents and ancillary study consents will NOT be available on REDCap for the participant to fill out and sign. The participant will have to be given a paper copy of all of the consents to fill out and sign.

The Interviewer can then enter their code and the date of screening. And select "Unverified" under form status. The Unverified status will change the radio button for this form from RED to YELLOW. This can be used by the interviewer as a reminder that this form will need to be returned to after the consenting process to enter more information before the interviewer can administer the questionnaires. Select Save & Go to the Next Form.



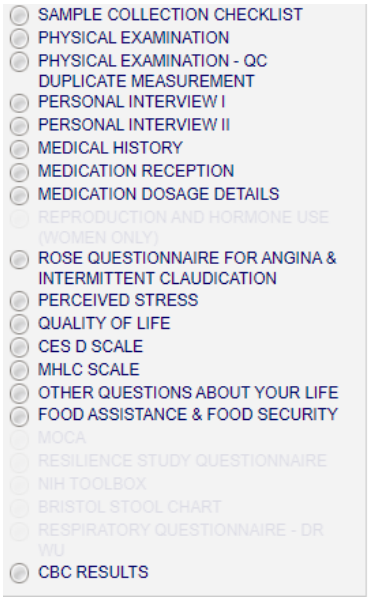
Because paper was selected, the next the consent forms will not be available. However, there will be a form call paper consent that will be available to the FC staff can enter how the participants answered all the consent questions on the paper form so that all consent questions are captured in REDCap. The next form to be filled out is the Sample Collection Checklist.



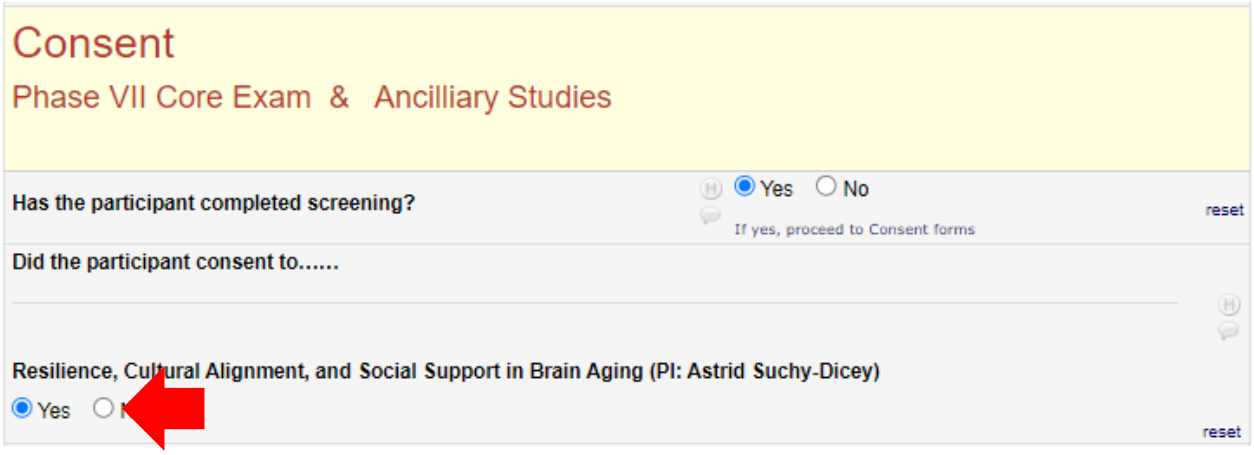
3.3.3 Completing Consent Process and Questions for Ancillary Studies

During the consent process, the participant will consent or not consent to the each ancillary study. After the participant completes the consents, the FC interviewer will need to navigate back to the screening form and complete the Consent section of this form. Answering Yes or No to each ancillary study will determine if the ancillary study questions will appear in REDCap.

If not selection is made in the Consent section of the Screening form, then all of the ancillary study forms will be greyed out and cannot be selected to enter data.

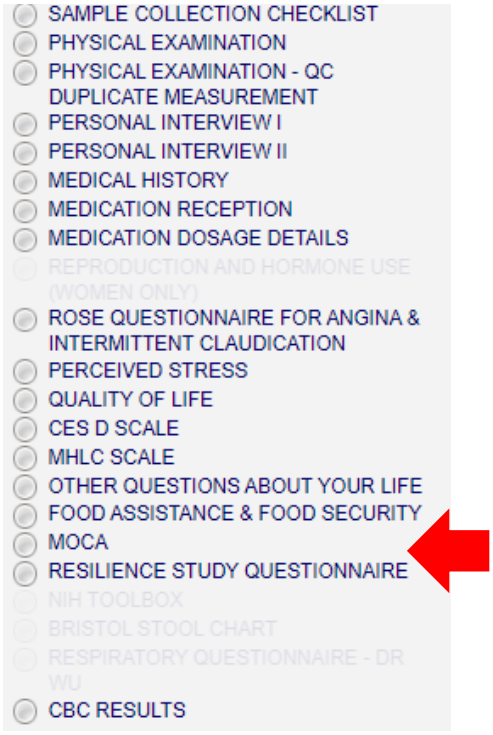


If a participant did consent to participate in an ancillary study, navigate to the Consent Section and find the ancillary study and select Yes.

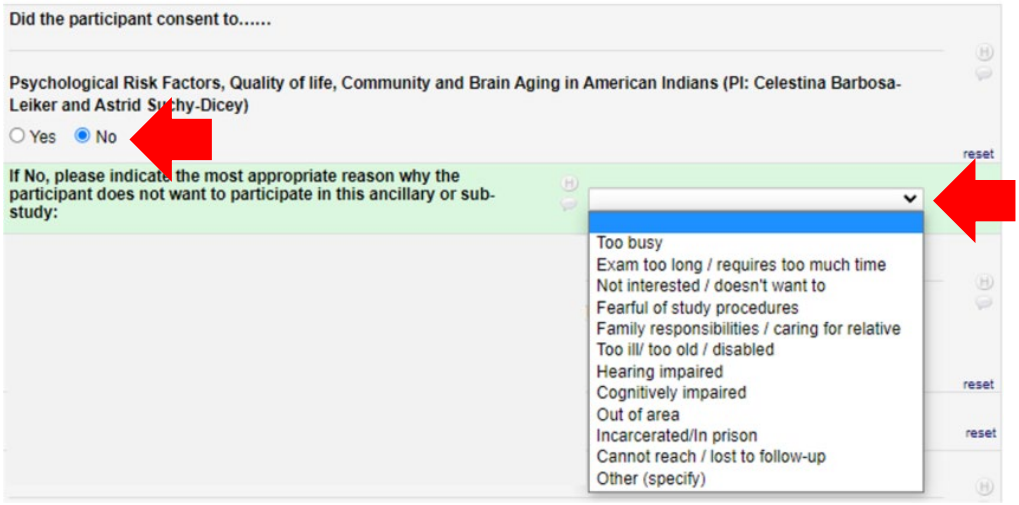


For the selection to apply, navigate to the bottom of the form and Select "Save & Stay".

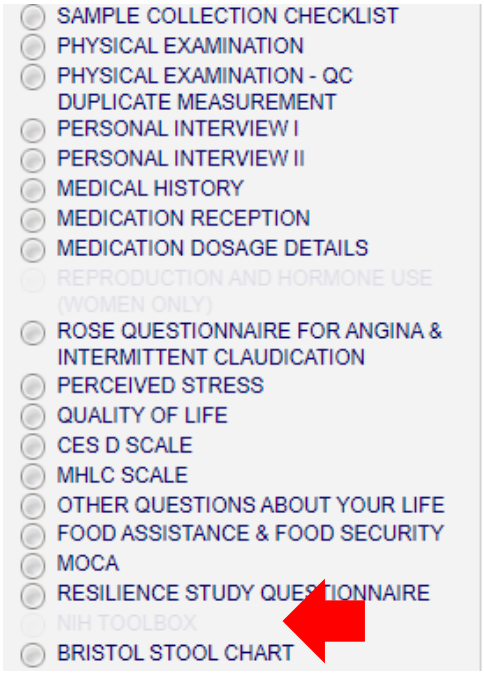
Now the forms for the selected ancillary study will appear and can be filled out.



If a participant decides not to participate in one of the ancillary studies, Select No and provide a reason (choose one that is as close to the reason as possible) as to why the participant choose not to participate in that ancillary study.



And the form that is associated with the ancillary study will not appear in REDCap. This will reduce errors in data entry so that participants who don't consent to an ancillary study don't accidently end up completing that ancillary studies forms.

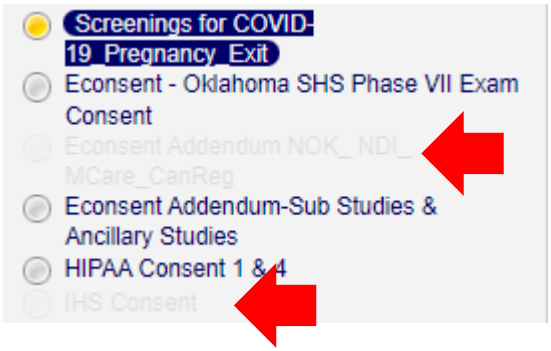


Once the consent section is complete, the FC interview can select the Sample Collection Checklist and begin the Phase 7 examination.

3.3.4 Administrative Question for Oklahoma FC Only

For the Oklahoma site only, there is an additional question in the Administrative section that identifies participants who have already signed consents for contacting next of kin, requesting data from the National Death Index, Requesting data from Medicare, requesting data from the Cancer Registry and signed the IHS consent. This question has been pre-populated for Oklahoma. The FC interviewer does not need to change the answer unless it is in error.

These participants do not need to re-sign these consents. For these participants, the two consents are greyed out and will not be available in REDCap since they are not needed.

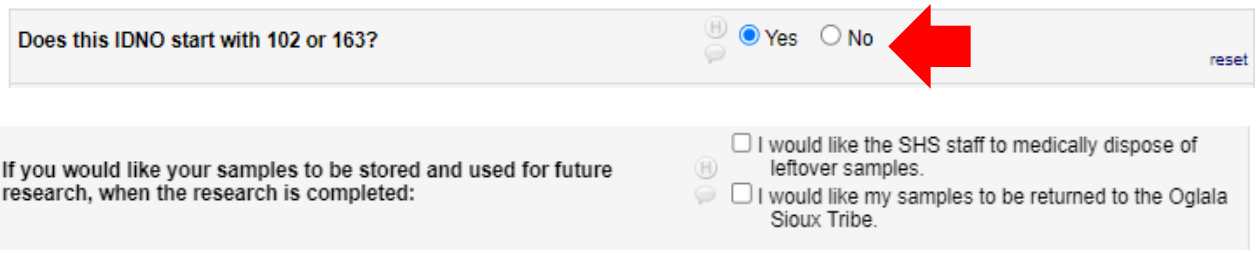


If the participant hasn't already signed these consents, then the question will say No and all of the consents will be available to sign

3.3.5 Administrative Question for Dakota FC Only

For the Dakota site only, there is an additional question in the Phase 7 consent that asks about samples storage and usage for the participants from the Oglala Sioux Tribe (OST).

If the administrative question is answered yes, then this question will appear for OST participants only. If this administrative question is answered no, then this question will NOT appear on the Phase 7 consent.

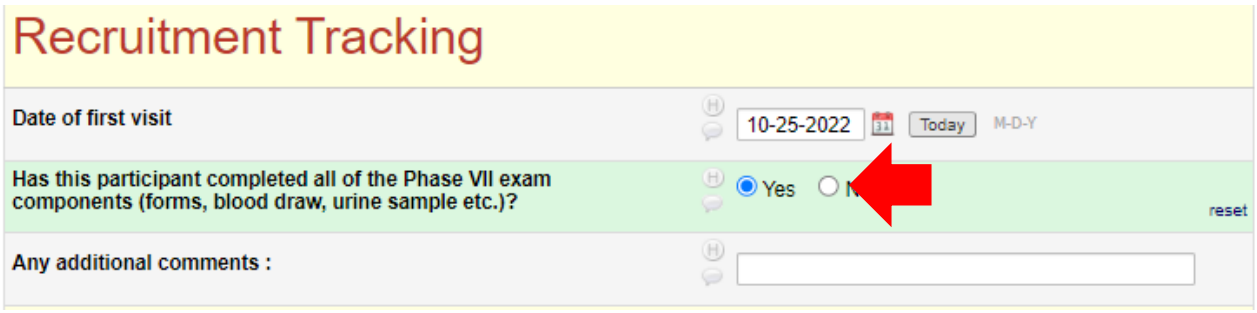


3.3.6 Recruitment Tracking

The last section in the Screening for COVID, Pregnancy, & Exit form will capture information about whether or not a participant was able to complete the Phase 7 examination and all of the consented ancillary studies in one visit.

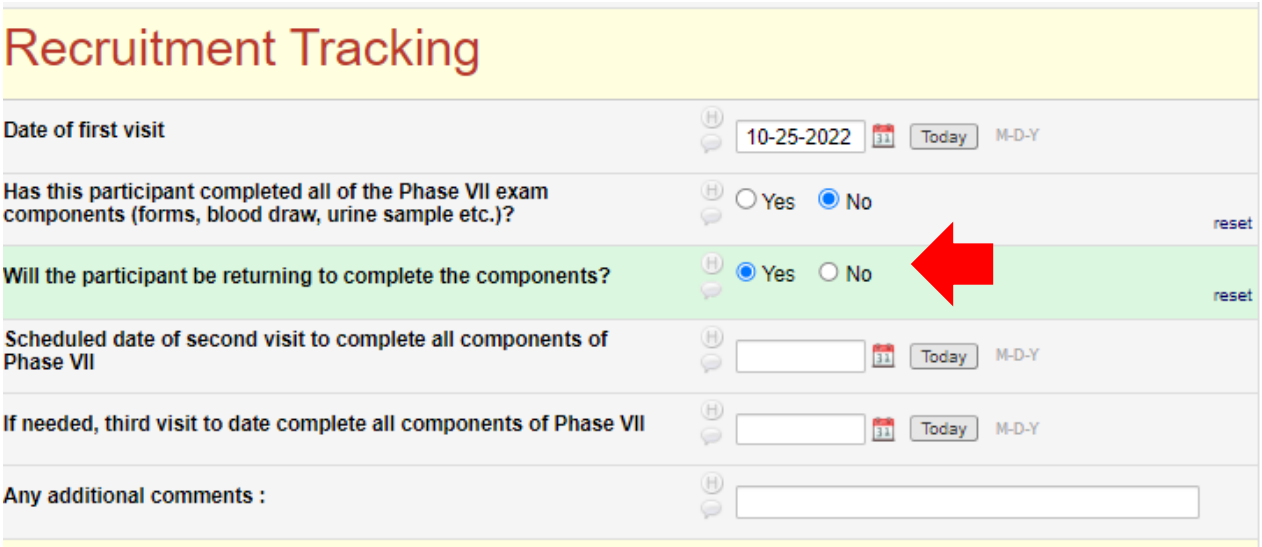
This is being collected in part to report to the NIH and to help schedule a follow-up exam for the participant if it is needed. This allows for elders and/or people who have a full time job to split the examination if needed.

If the participant has finished the Phase 7 examination and all of the components for the ancillary studies that they consented to participate in, the FC interviewer will return to the Screening for COVID, pregnancy & Exit form and complete the Recruitment Tracking section. The interviewer will enter the date of the first visit and indicate if the participant has finished all of the components of the examination.

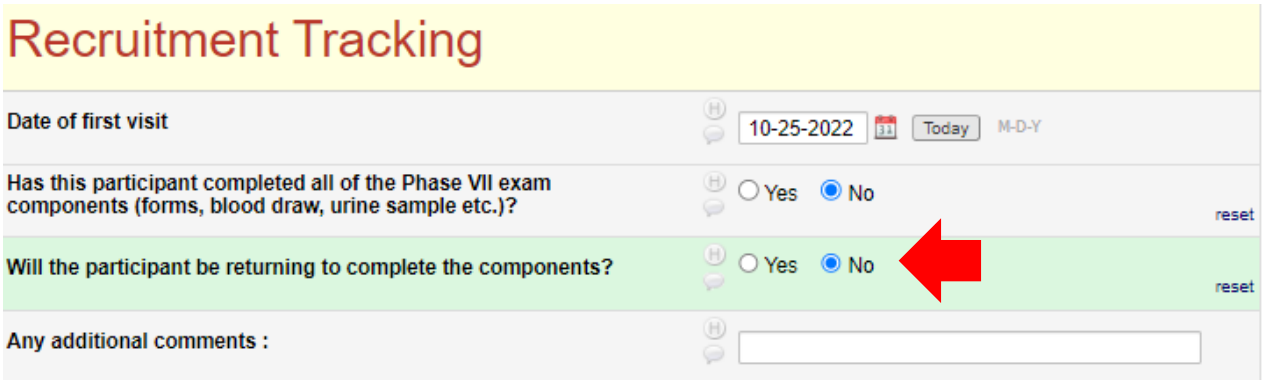


The FC interviewer will then change the form status from Unverified to Complete. Save and exit the form.

If the participant has not finished all components of the Phase 7 examination or ancillary studies, the FC will enter the date of the first visit and select No. This will bring up a second question that asks if the participant is willing to come back to finish the Phase 7 examination. If the participant answers Yes, they will return to complete the exam, there are fields available to put in the date of the scheduled second visit (and a third visit if necessary) for the FC interview to fill out. The form status will need to be changed to Complete and the form saved.



If the participant indicates they won't be returning to finish the examination, then the FC interviewer will select No and the form status changed to completed.

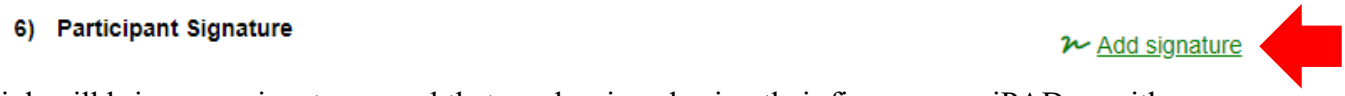


3.4 Complete e-Consent Process

After the Screening & Exit form is completed, the next form that will appear is the Phase VII Consent form for the FC. This form is a digital version of the IRB approved consent form. The consent form will have the SHS ID and SHS Family ID (if applicable) populated. The next sections will be consent form language. The interviewer or FC personnel will proceed in obtaining informed consent for each participant.

Towards the end of the form, the participant will be able to select their answers for participation in Phase VII examination.

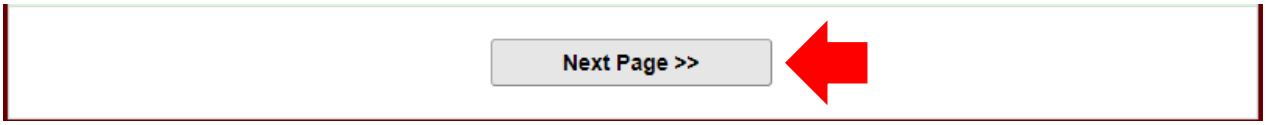
The participant will be asked to digitally sign their consent form by pressing the Add signature link in the Participant signature field.



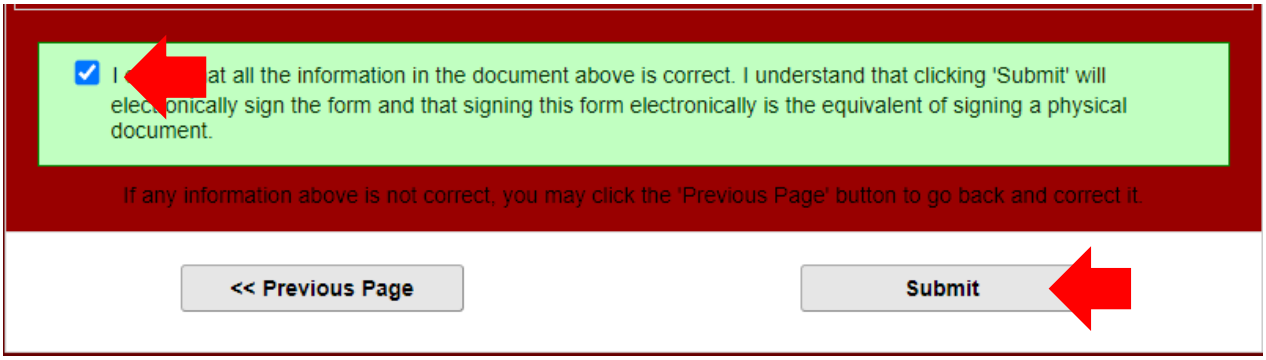
This link will bring up a signature panel that can be signed using their finger on an iPAD or with a mouse on a computer. After signing on the line, save the signature by pressing the Save signature button.

The participant will type in their name and select the date they signed this consent form.

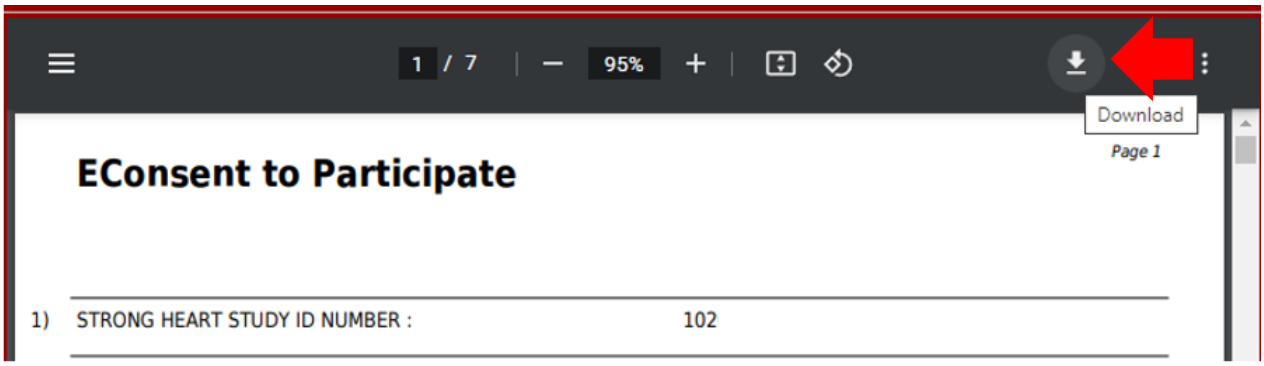
The person obtaining consent will also have to sign the digital consent document, type in their name and add the date that consent was obtained. Click the Next Page button when the consent form has been completed.



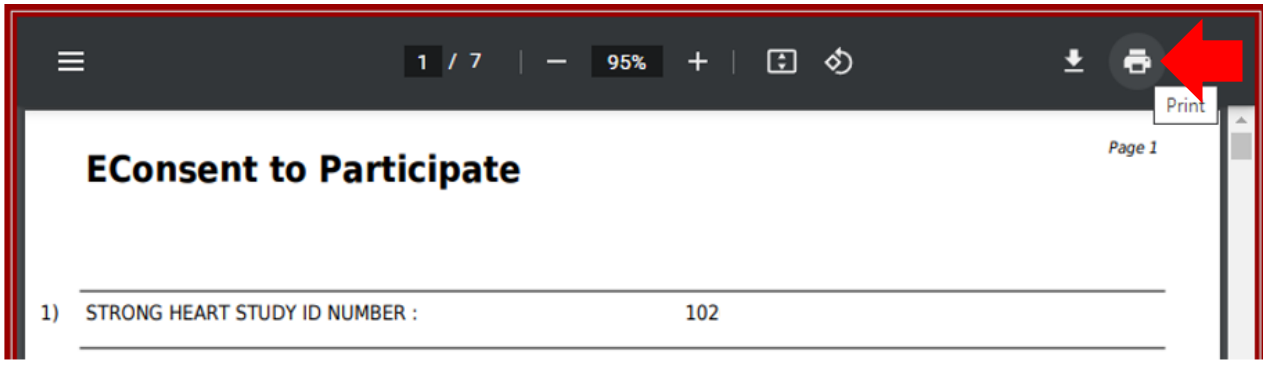
The next screen will ask to certify that all of the information in the consent document is correct. Review the consent document to verify that the participant has selected an answer for all questions and has signed and dated the consent document. If everything is correct, select the box that the information is correct and select the Submit button.



This page also allows for the consent document to be saved on a computer and/or printed out for the participant. Select the Download button to download and save this document to a folder on the computer.



Select the Print button to print a copy of this consent for the participant or to file at the FC.



The next set of consent documents will be Addendums to the consent and consents to Ancillary studies. The process is similar to the consent process above.

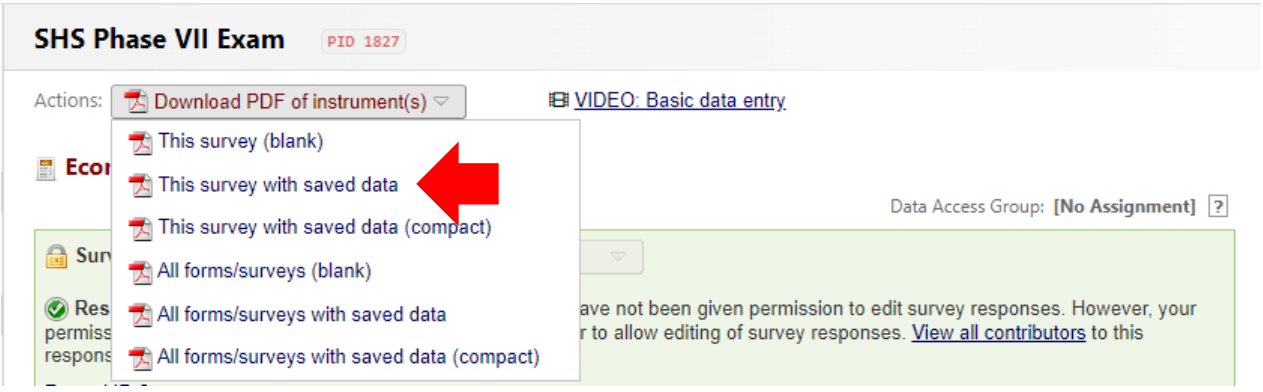
The third set of consent documents will be any HIPAA consent forms. The participant will provide their signature and date for this form.

The last consent document with be the IHS consent, if applicable. This form will need to be signed on a paper and uploaded to REDCap.

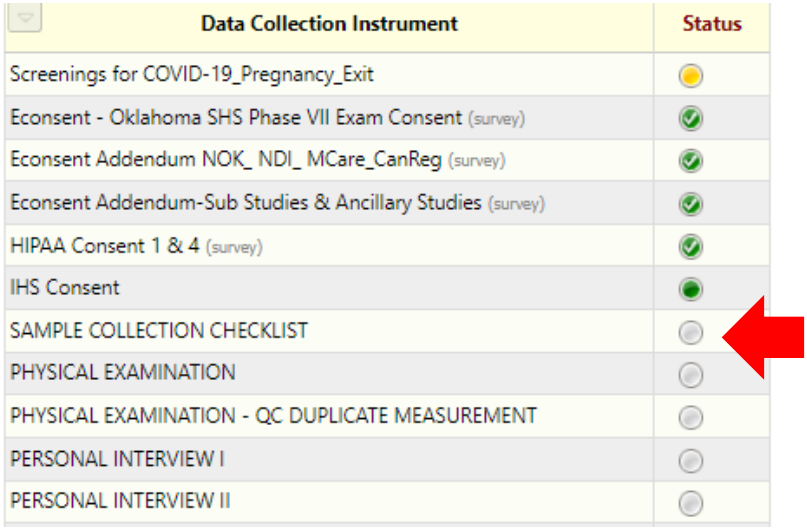
Once all of the surveys are completed, the radio buttons for the consent documents will be Green with a checkmark on the Event Grid for the participant. NOTE: The screen shot below is an example of the Oklahoma FC consents administered. Arizona and the Dakotas have different consents being administered.

Data Collection Instrument	Status
Screenings for COVID-19_Pregnancy_Exit	
Econsent - Oklahoma SHS Phase VII Exam Consent (survey)	
Econsent Addendum NOK_ NDI_ MCare_CanReg (survey)	
Econsent Addendum-Sub Studies & Ancillary Studies (survey)	
HIPAA Consent 1 & 4 (survey)	
IHS Consent	

If another copy of the consent needs to be saved or printed, click on the Green button for the consent document. This will take you to a page with the consent information. Click on the button Download PDF of instruments(s) at the top of the page and select This survey with saved data. A PDF copy of the consent document can then be downloaded to a computer and printed.



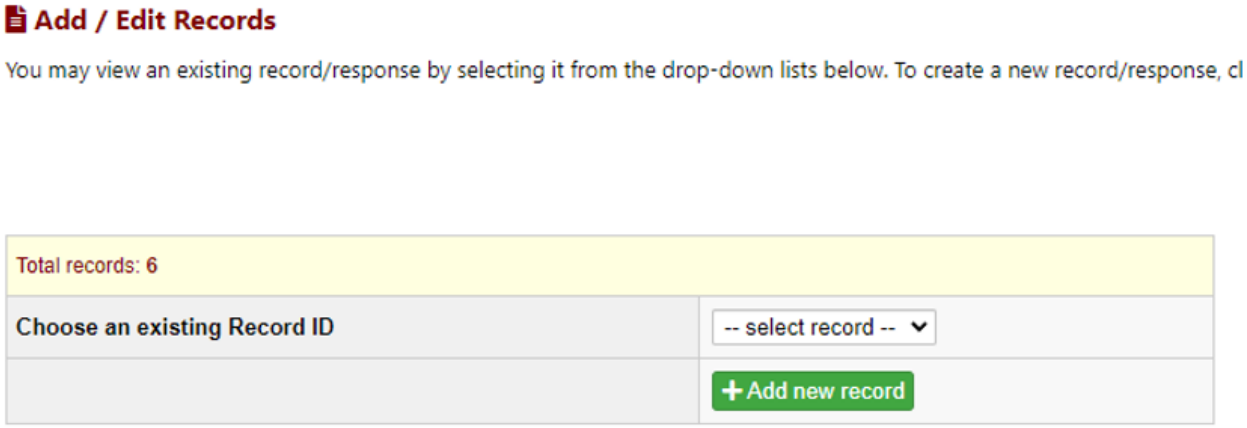
Using the Event Grid for the participant, select the next form to be entered.



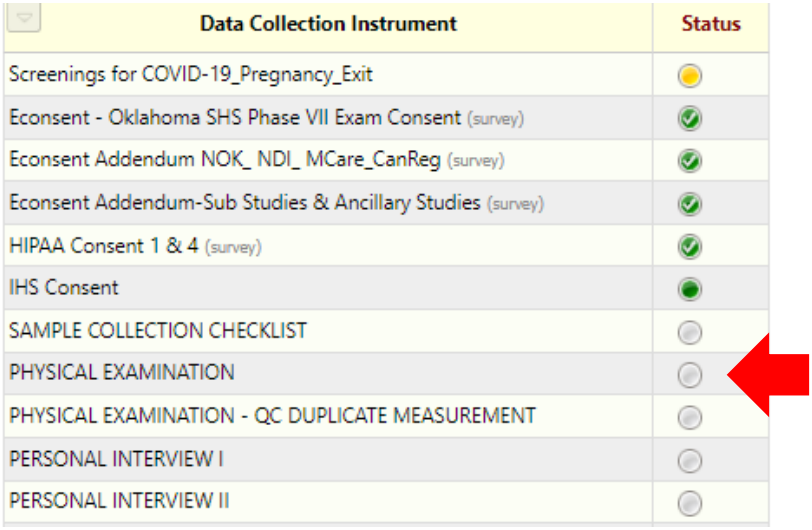
Data Collection Instrument	Status
Screenings for COVID-19_Pregnancy_Exit	
Econsent - Oklahoma SHS Phase VII Exam Consent (survey)	
Econsent Addendum NOK_ NDI_ MCare_CanReg (survey)	
Econsent Addendum-Sub Studies & Ancillary Studies (survey)	
HIPAA Consent 1 & 4 (survey)	
IHS Consent	
SAMPLE COLLECTION CHECKLIST	
PHYSICAL EXAMINATION	
PHYSICAL EXAMINATION - QC DUPLICATE MEASUREMENT	
PERSONAL INTERVIEW I	
PERSONAL INTERVIEW II	

3.5 Edit or Add to an Existing Participant

To edit data entered previously or to add new data to an already existing participant, use the Search query box on the Add/Edit Records page. You can start typing either the Strong Heart Study ID or Strong Heart Study Family ID, and a drop down menu will appear and the correct ID can be selected.



Once the ID is selected, this will take you to the participants Event Grid. You can then select which form to enter data or edit data.



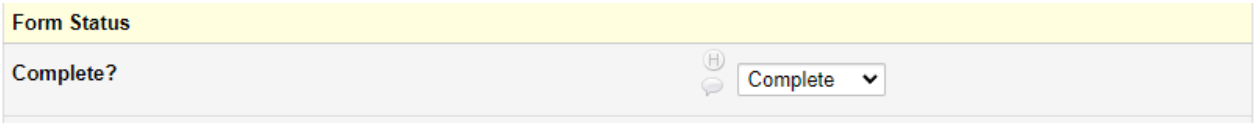
Data Collection Instrument	Status
Screenings for COVID-19_Pregnancy_Exit	
Econsent - Oklahoma SHS Phase VII Exam Consent (survey)	
Econsent Addendum NOK_ NDI_ MCare_CanReg (survey)	
Econsent Addendum-Sub Studies & Ancillary Studies (survey)	
HIPAA Consent 1 & 4 (survey)	
IHS Consent	
SAMPLE COLLECTION CHECKLIST	
PHYSICAL EXAMINATION	
PHYSICAL EXAMINATION - QC DUPLICATE MEASUREMENT	
PERSONAL INTERVIEW I	
PERSONAL INTERVIEW II	

3.6 Deleting Records and/or Data from REDCap

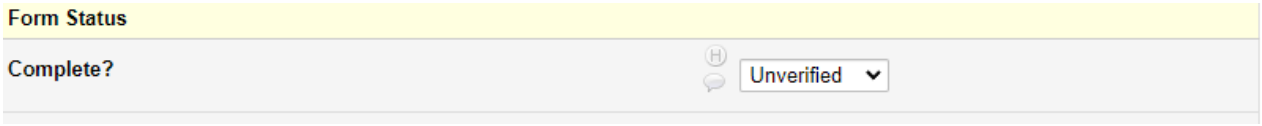
If a record or data are entered in error, the field site should contact the CC. The CC will remove the appropriate information. The field site should NOT delete or remove any information off of REDCap. Please refer to **Section 6** for the CC contact information.

3.7 Form Status

At the end of each form, there is a Form Status section. This is for tracking completion status of the form in REDCap. When the form is completed, the form status should be changed from Incomplete to Complete.

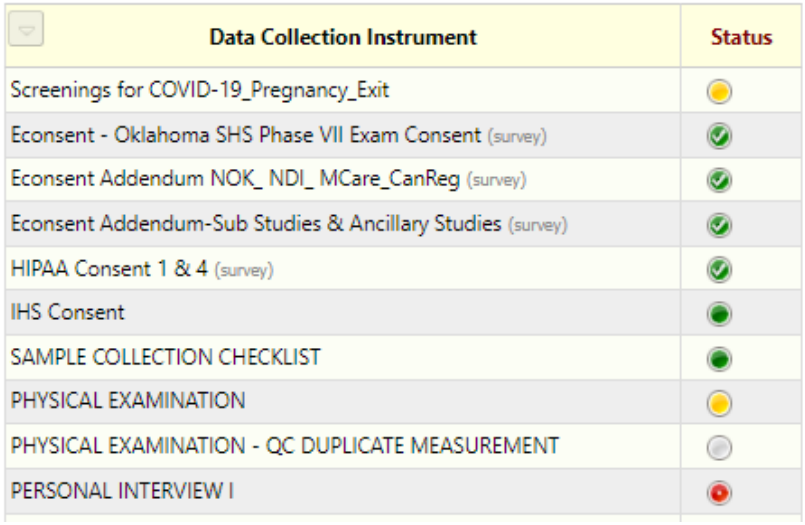


As information is entered into REDCap, there may be instances were the answers need to be verified or the form was not completed. In cases where answers need to be verified, the form status should be changed to Unverified.



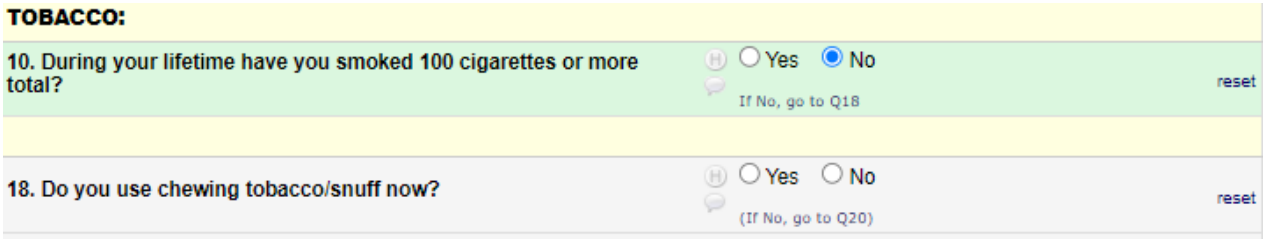
In instances where the form was not completed by the participant or if the form wasn't completely entered in the system, the form status should be Incomplete.

The participants Event Grid will also reflect the form status by the color of the radio button next to each form. If the button is Green, then the form has been marked Complete. If the button is Yellow, the form has been marked as Unverified. If the button is Red, the form has been marked Incomplete. The interviewer or FC personnel can use these colors to quickly identify which forms need more information and completed.

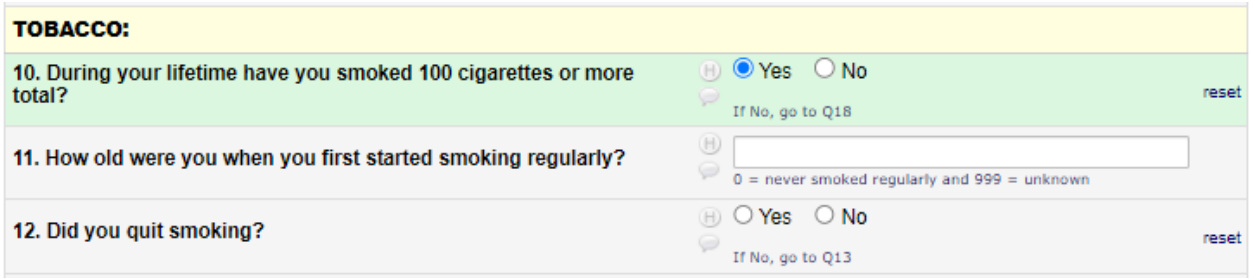


3.8 Form Logic

REDCap utilizes logic expressions to allow for skipping questions based on how previous questions were answered. For example, on the Personal Interview II form, Question 10 asks "During your lifetime have you smoke 100 cigarettes or more total?". If the participants answers no, the instructions state to go to Question 18. In REDCap, if the answer to this question is No, then Question 18 will appear as the next question.



If the person answers Yes to Question 10, then the next question to appear will be Question 11.



There is similar logic added to most of the forms for Phase VII exams.

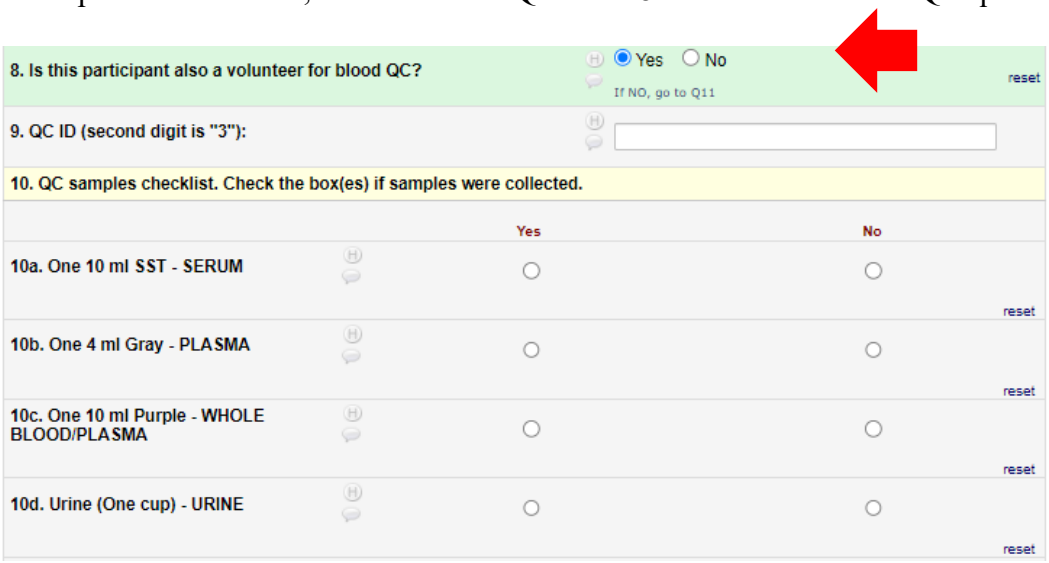
3.9 Form Specific Instructions

This section outlines how some specific Phase 7 exam forms and Phase 7 ancillary study forms should be filled out in REDCap. Additional detailed instructions for each form is provided in the Strong Heart Study Phase VII Personal Interview and General Examination Manual of Operations (Volume III).

3.9.1 Sample Collection Checklist - QC Samples

Collection of duplicate laboratory samples will be done on every 10th participant at each center until 500 participants have been enrolled in Phase 7. After 500 participants have been enrolled, collection of duplicate laboratory samples will be done on every 20th participant at each center. The blood QC checklist will need to be entered in REDCap for these participants.

If this person is selected, choose Yes on Question 8 and all of the blood QC questions will appear.



If the participant was not selected for duplicate blood collection, the answer will be No and the person entering data will be directed to the question 11 on the sample collection form.

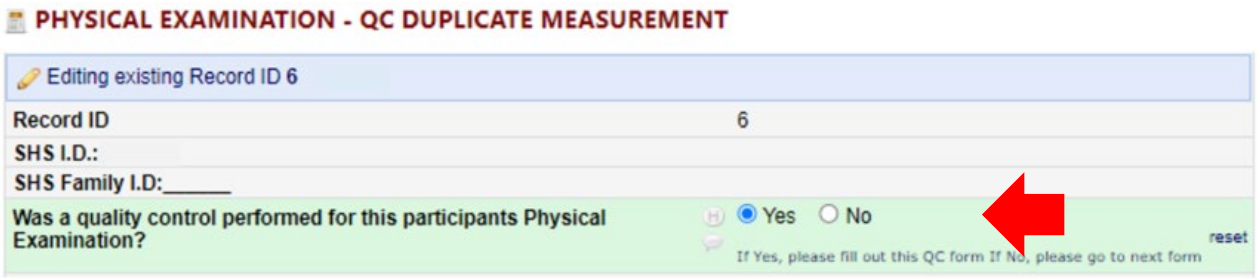
More details about quality control, including quality collection instruments and processing are provided in the Training Manual of Operations (Volume VIII).

3.9.2 Physical Examination – QC Duplicate Measurement

Collection of duplicate physical examinations will be done on every 10th participant at each center until 500 participants have been enrolled in Phase 7. After 500 participants have been enrolled, collection of duplicate laboratory samples will be done on every 20th participant at each center.

Two people at the field center will collect anthropometric measurements and blood pressure measurements. The second person will enter their readings on the Physical Examination – QC Duplicate Measurement form in REDCap.

If a participant has been selected to have their anthropometric measurements and blood pressure measurements done twice, select Yes as the answer to the first question on the Physical Examination – QC Duplicate Measure form and enter the measurements.

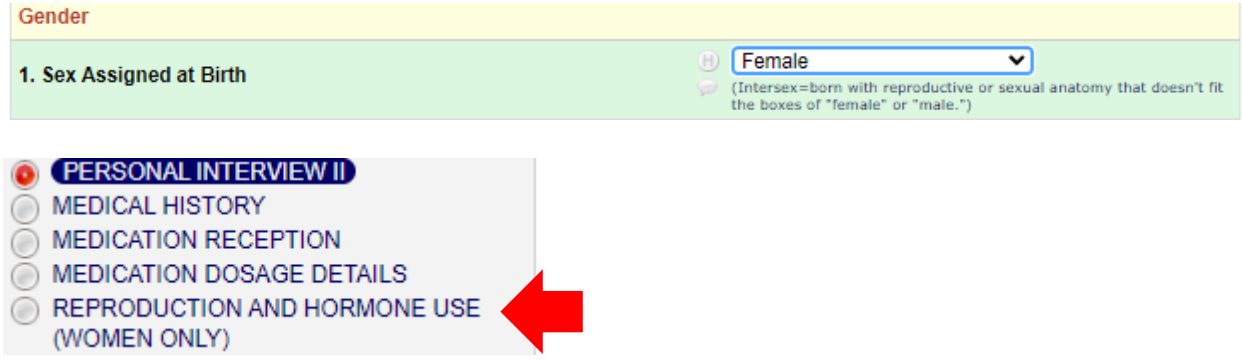


If Yes is selected, then all of the questions will appear in REDCap to be filled out. If No is selected, then the form status can be changed to completed and the person entering the data can go to the next form.

More details about quality control, including quality control logs are provided Training Manual of Operations (Volume VIII).

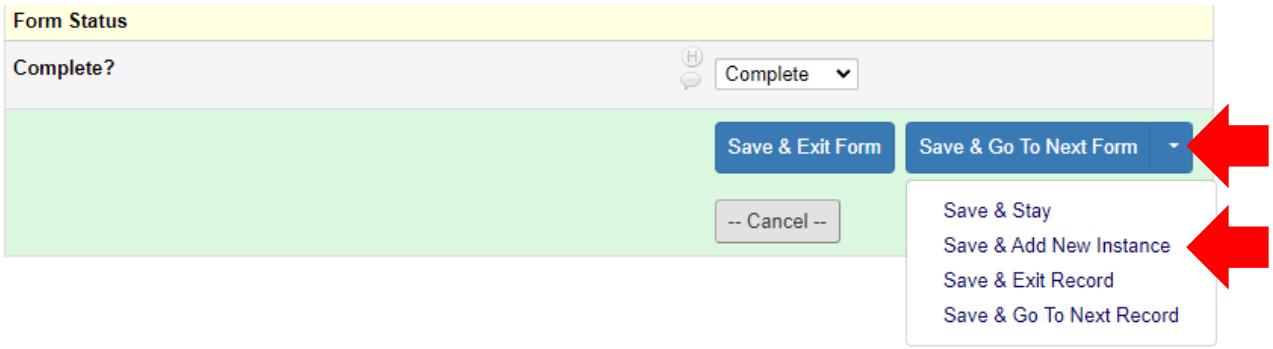
3.9.3 Reproduction and Hormone Use

This form will only appear in REDCap if the participant's answer to Question 1 from the Personal Interview Form II: Sex Assigned at Birth is "Female".



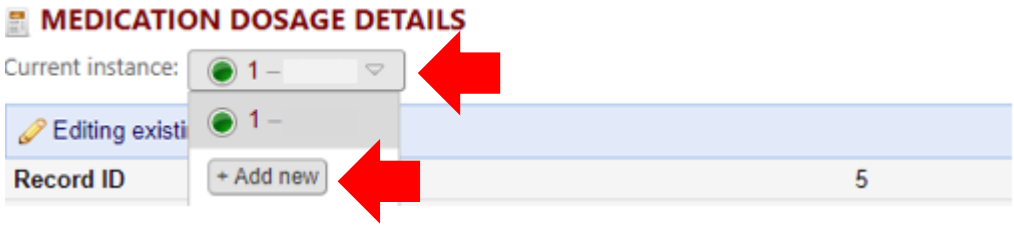
3.9.4 Medication Dosage Details

Medications (Prescription & Non-Prescription) form was designed on REDCap to accommodate the complexity of medication data. The medication form can be used multiple times to record as many medications used by the participant as necessary. The first medication will be the first form entered in REDCap. After entering the first medication, select the Down arrow on the Save & Go To Next Form. Next, select the Save& Add New Instance.



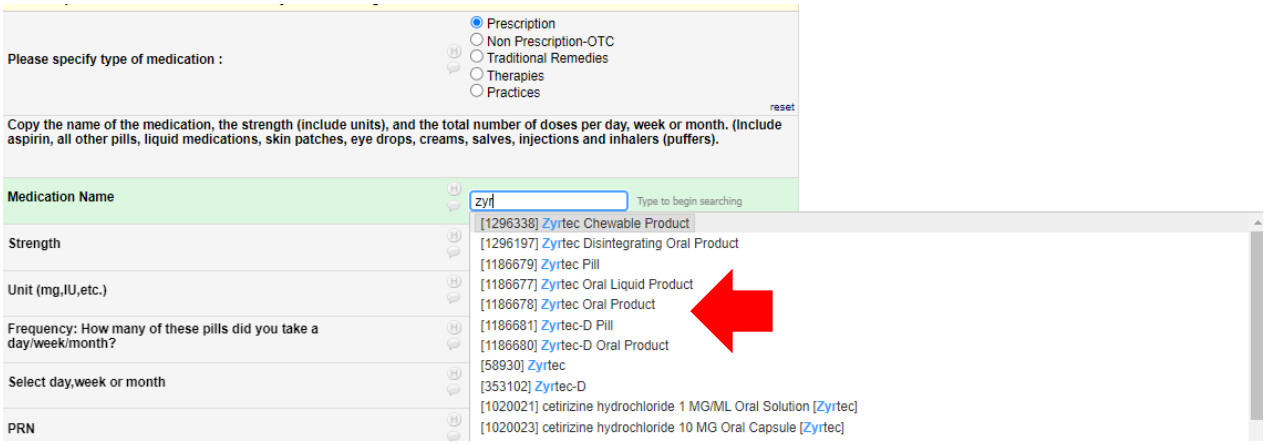
This will allow for the medications form to be repeated and the second medication details can be entered into REDCap.

To add another medication, you can also select the grey box at the top of the form next to Current Instance: and Select the Add New button to add another form to enter medication information.



Enter as many medication form as necessary.

To aid in entering medication names, a module has been added so that the Medication Name will start to auto populate when medication names are entered in the field.



The field staff entering medication data can select the correct medication name from the drop down menu. And then continue to answer the remaining questions about the medication use.

3.9.5 Food Frequency Questionnaire (FFQ)

The FFQ will be self-administered to the participants.The participant will either bring or mail this questionnaire back to the Field Center. The FC will mail these questionnaires to Block for processing.

For more about the FFQ, refer to the Food Frequency Questionnaire Manual of Operations (Volume VI).

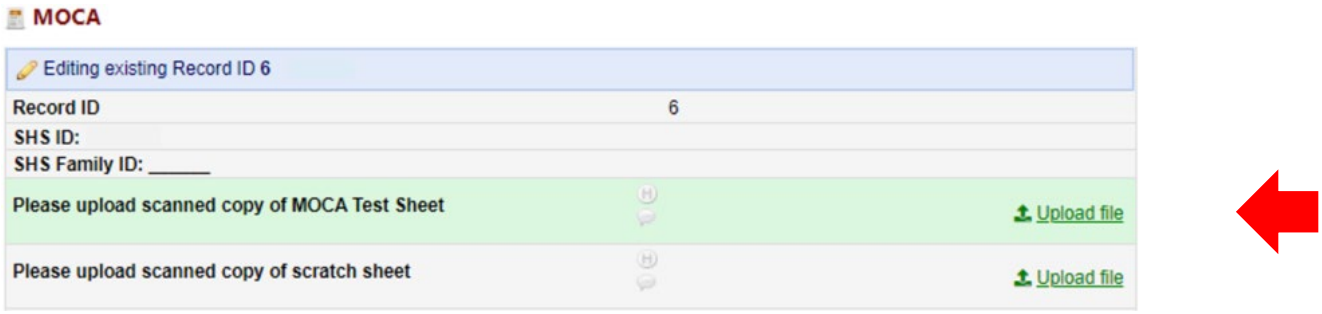
3.9.6 Ancillary Study Questionnaires

Each Ancillary Study Questionnaire or questions will appear in REDCap if the participants has consented to participate in these studies. As a reminder, the answers on the Screening for COVID, pregnancy, & Exit form will control if these questionnaires or questions appear in REDCap. For more information, please see Section 3.3 in this manual.

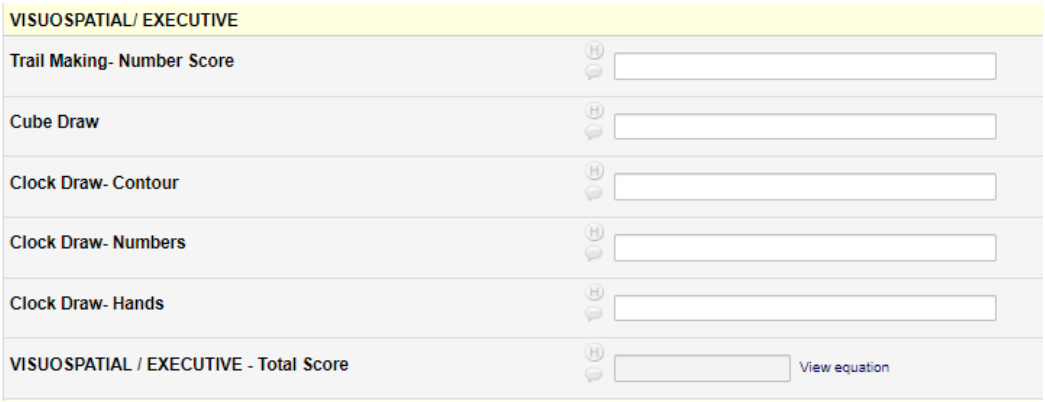
3.9.6.1 MOCA Questionnaire

The MOCA will be administered only to participants who consented to participate in the Resilience, Cultural Alignment, and Social Support in Brain Aging ancillary study.

The MOCA test will be administered on paper. The FC staff will upload a scanned copy of the MOCA test sheet and the scratch sheet to REDCap by selecting the upload file link on the MOCA REDCap page.



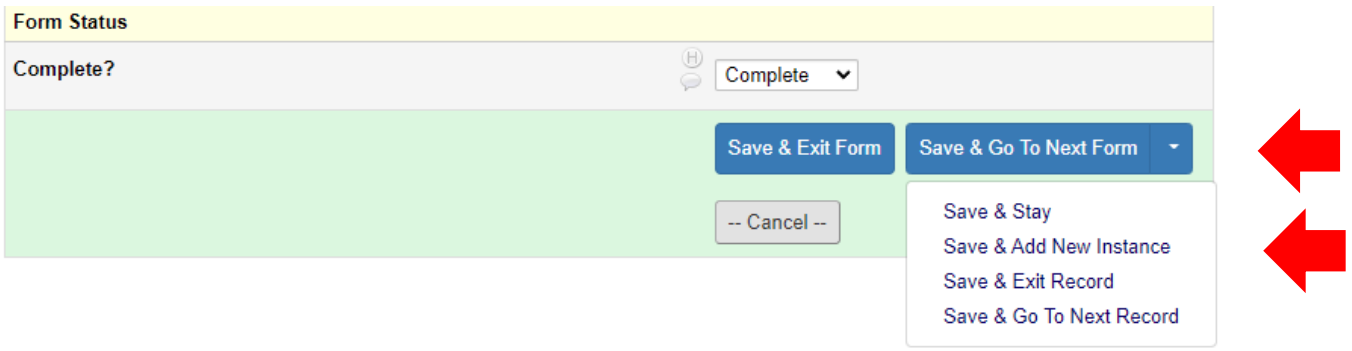
The information entered on REDCap will include the subscores for each section of the MOCA questionnaire, and the total score.



The FC staff will change the form status to complete when the data is entered and move to the next form.

Investigators and staff from the Resilience study will be able to download and review the MOCA test sheet and scratch sheet. They will also provide scoring for the MOCA. To accommodate these scores, the MOCA form has been made a repeatable form. The Resilience staff will need to navigate to the participants Record Status page and select the MOCA form. They will need to

add an new instance of this form by selecting the Down arrow on the Save & Go To Next Form and select the Save& Add New Instance.



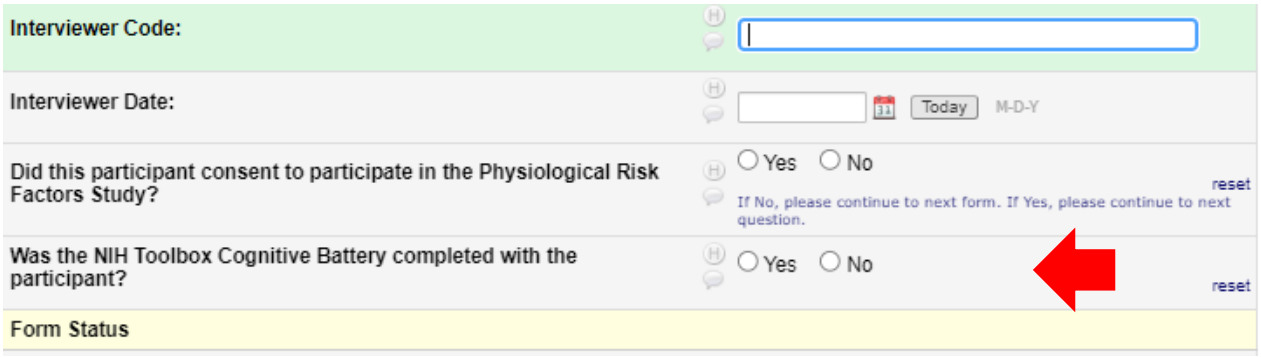
The Resilience staff will then enter their scores and can provide any feedback about the scoring process to the FC, if needed.

Training for administration for the MOCA questionnaire was provided to each FC staff who will be administering this questionnaire. For more information about administering this questionnaire, along with the other questionnaires for the Resilience study, refer to the Psychosocial Questionnaires Manual of Operations (Volume V).

3.9.6.2 NIH Toolbox Cognition Battery

The NIH Toolbox will be administered only to participants who consented to participate in the Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians ancillary study.

The NIH Toolbox will be administered on a different system. The participant will answers questions on a provided iPAD. In SHS REDCap system, if the participant consented to this ancillary study, there will be the question about whether the participant completed the NIH toolbox. This will help the CC track who is expected to have data in the NIH toolbox.

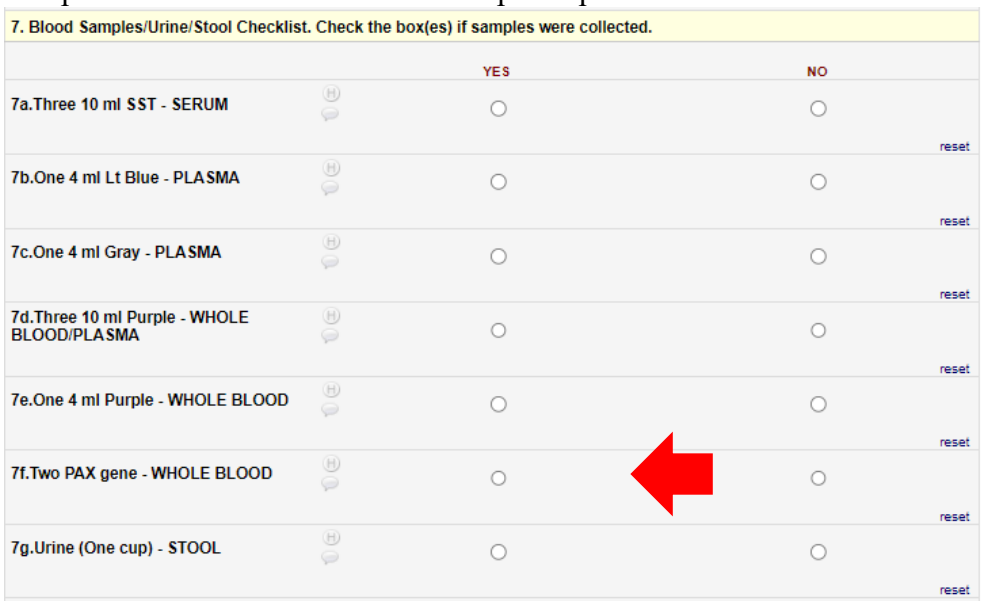


Training for administration for the NIH Toolbox was provided to each FC staff who will be administering this questionnaire. For more information about administering this questionnaire, along with the other questionnaires for the Psychological Risk Factors, Quality of Life, Community, and Brain Aging in American Indians study, refer to Psychosocial Questionnaires Manual of Operations (Volume V).

3.9.6.3 PAX gene Blood RNA tube collection

An extra blood collection will be performed for participants who consented The Epitranscriptome as a Novel Mechanism of Arsenic – Induced Diabetes ancillary study

These participants will have two PAX gene tubes collected. Select Yes to question 7f on the Sample Collection Checklist for these participants.

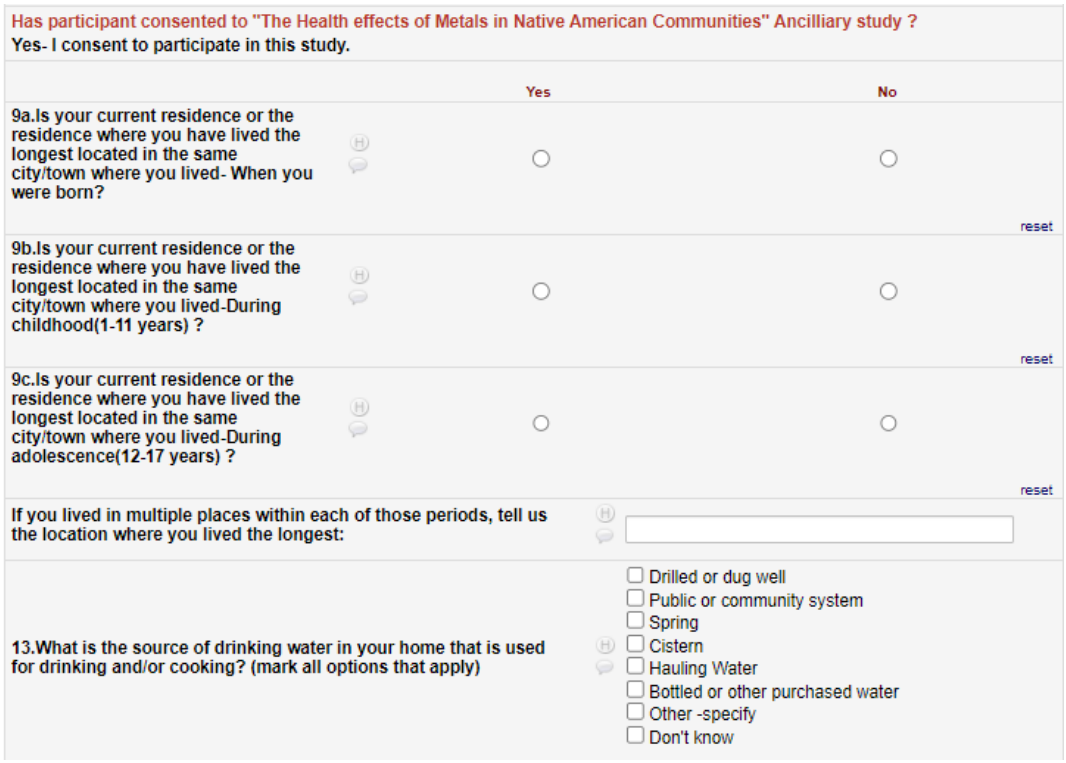


For more information this blood draw and processing the samples, refer to Psychosocial Questionnaires Manual of Operations (Volume V).

3.9.6.4 Additional Address Information and Drinking Water Questions

Additional address and drinking water questions will be administered to participants who consented to participate in the Health Effects of Metals in Native American communities: A Longitudinal Multi-omics Study.

These questions will be administered as part of the Personal Interview I form and will only appear in the REDCap system if the participant consented yes to this ancillary study and the answer is Yes on the Screening for COVID, pregnancy & Exit form on REDCap.



Has participant consented to "The Health effects of Metals in Native American Communities" Ancilliary study ?
Yes- I consent to participate in this study.

	Yes	No	
9a.Is your current residence or the residence where you have lived the longest located in the same city/town where you lived- When you were born?	○	○	reset
9b.Is your current residence or the residence where you have lived the longest located in the same city/town where you lived-During childhood(1-11 years) ?	○	○	reset
9c.Is your current residence or the residence where you have lived the longest located in the same city/town where you lived-During adolescence(12-17 years) ?	○	○	reset

If you lived in multiple places within each of those periods, tell us the location where you lived the longest:

13.What is the source of drinking water in your home that is used for drinking and/or cooking? (mark all options that apply)

- ☐ Drilled or dug well
- ☐ Public or community system
- ☐ Spring
- ☐ Cistern
- ☐ Hauling Water
- ☐ Bottled or other purchased water
- ☐ Other -specify
- ☐ Don't know

3.9.6.5 Bristol Stool Chart

The Bristol Stool Chart will be self-administered to participants who consented to participate in the Gut Microbiome, Aging, and Cardiometabolic Diseases in American Indians ancillary study.

This form will only appear in the REDCap system if the participant consented yes to this ancillary study and the answer is Yes on the Screening for COVID, pregnancy & Exit form on REDCap.

The participant will either bring or mail this questionnaire back to the Field Center. The FC staff will enter the information in REDCap.

	Date	Type of Stool
Day 1 (2 days BEFORE stool sample was collected)	M-D-Y	
Day 2 (1 day BEFORE stool sample was collected)	M-D-Y	
The day ON which stool sample was collected	M-D-Y	

Please note, if the participant did not have a bowel movement in the previous two days since the stool sample was collected, they can provide information about the type of stool for their previous 2 bowel movements.

4. Quality Control

Collection of duplicate physical examinations and laboratories will be done on every 10th participant at each center until 500 participants overall have been enrolled in Phase 7 (done approximately on 10% of the participants). After 500 participants have been enrolled, collection of duplicate laboratory samples will be done on every 20th participant at each center (done approximately on 5% of the participants)..

The CC will generate a list of QC IDs for the laboratory QC samples where the lab QC IDs start with the center ID in the first two digits followed by sequential numbers. For example, the Arizona QC sample will be given a QCID of 330001, followed by 330002. This QC ID will be recorded on the Sample Collection Checklist to link to the participant's SHS ID. Each site will also keep a log file to link the laboratory QC ID with the participant's SHS ID, which will be uploaded to REDCap.

Members of the quality control committee at the CC will be responsible for monitoring the data entered into REDCap. This includes checks for completeness, ambiguous or erroneous data entry errors. Data checks and logical checks will be built into the REDCap system to help mitigate data entry errors.

Quality control reports will be generated by the CC on a quarterly basis and distributed to each field center. These reports will include information on the following:

- Accrual overall and by each field center
- Number of participants who completed the Phase VII examination, Phase VII laboratories, and each ancillary study
- Summary statistics (including mean, median, range, maximum and minimum) for continuous measurements will be generated and any data not meeting consistency checks will be flagged and noted in the report.
- Summary statistics (including distributions) for categorical measurements will be generated and any data not meeting consistency checks will be flagged and noted in the report.
- Duplicate measurements for anthropometry, blood pressure and laboratory tests will be monitored and if differences between these duplicate measurements are seen beyond the acceptable differences will be flagged and noted in the report. If there are consistent issues with the duplicate measurements, this may lead to retraining of the staff.
- Laboratory results that need to be reviewed by the participant's physician will be flagged and sent to the appropriate field center for the field center to communicate to the participant.

Quality control reports will be provided to the Steering committee bi-annually and prior to the OSMB. A quality control report will also be generated to be included in the OSMB report and any time the OSMB requests a report.

The quality control data checks and contents of the quality control reports can be changed based on feedback from the Quality Control Committee, the Steering Committee, and/or the OSMB.

5. Field Staff ID Codes

Use your provided Field Staff ID in all fields that indicate entering this ID information. For questions about this IDs, contact the Field Site Coordinator.

6. If You Have Questions

REDCap issues	Pravina Kota, MBA, MS Pravina-Kota@ouhsc.edu
SHS Phase VII forms and other general SHS questions	Kimberly Malloy, MS Kimberly-Malloy@ouhsc.edu

Training

Manual of Operations Volume VIII

Strong Heart Study Phase VII

July 1, 2023

Version 2.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
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Tracking of Revisions to Manual of Operations Volume VIII: Training

Date of Revision	Revised Section	Revision	Approved by, Date
4/20/2023	Entire document	Fixed formatting issues	SHS CC, 11/1/2022

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VIII. Training

1. Staff Training Forms

Strong Heart Study Phase VII

Staff Training and Certification Checklist

Trainee Name _____

The order of Phase VII Exam protocol is:

- Administration of Consent
- Blood/urine sample collection
- Snack/drink provided to participant
- Questionnaires
- Administration MOCA
- Ancillary studies
- NIH Toolbox

Quality checks are to be certified by designated SHS QA personnel:

Task	Date of Certification	Initial
Anthropometry		
Hip		
Waist		
Arm		
Height		
Weight		
Blood Pressures		
Diet – FFQ		
Doppler Blood Pressures		
Edema		
LAB		
Morbidity & Mortality Surveillance		
Pedal Pulses		
Personal Interview		

Strong Heart Study Phase VII

Quality Control Documentation

Trainee Name _____

Activity	QC	QC	QC	QC	QC	QC	QC
Date							
Consent Form							
Personal Interviews							
Diet FFQ							
Anthropometry							
Sitting Blood Pressures							
Doppler Blood Pressures							
Edema and Pedal Pulses							
Laboratory							

2. Interview Procedures

In general, the rules for asking questions in structured interviews can be summarized as follows:

1. Questions must be asked according to the instructions for each form and question. Be sure to read and re-read the instructions for each questionnaire you are using, and to ask all the questions in the same way to each person interviewed.

2. 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.

3. Read each question slowly.

4. Use correct intonation and emphasis.

5. Ask the questions in the order that they are presented in the questionnaire.

6. Ask every question that applies to the respondent (all inapplicable questions will be identified as such by skip instructions in the questionnaire).

7. Repeat questions IN FULL that are misheard or misunderstood.

8. Read all linking or transitional statements exactly as they are printed.

9. Do not add apologies or explanations for questions unless they are printed in the questionnaire.

2.1 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:

1. 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."

2. The expectant pause. Waiting expectantly will tell the respondent that the interviewer is expecting more information than has been provided.

3. Repeat the reply. Repeating the reply aloud while recording it may stimulate the respondent to provide more details.

4. 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?"

5. 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.

2.2 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.

2.3 Common Interview Errors

We should try to minimize interviewer error during this study. The primary objectives of epidemiologic research are (1) to obtain measurements of exposure and disease variables relevant to the objectives of the study, and (2) to maximize completeness and minimize error in these measurements. The presence of an interviewer may both reduce error and increase error. It may reduce error by increasing the response rate, motivating the subject to respond well and probing to obtain complete data when the responses volunteered fall short of what is desired. The presence of an interviewer may increase error if, by his or her appearance, manner, method of administration of the questionnaire or method of recording of the responses, he or she exerts a qualitative influence on the subject's responses. Possible sources of error in the interview for data collection include (1) conditions of administration (privacy, heat, light, ventilation, freedom from distraction, lack of time, etc.); (2) interaction of the personality, sex or race of the interviewer with that of the subject; and, (3) performance by the interviewer (questioning, prompting and recording of responses).

The following are the common interviewer errors:

1. Asking errors. Omitting questions or changing the wording of questions. This may be particularly important if the interview is performed in Native language.

2. 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.

3. Recording errors. Recording something not said, not recording something said, incorrectly recording response.

4. 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.

3. Personal Interview Training and Quality Assurance

3.1 Training

Interviewers will be trained using a standardized procedure for administering each questionnaire. Training will include instructions in research interviewing techniques and in completing each form.

Interviewer skill training will include:

1. Adherence to the standardized protocol
2. Use of non-judgmental attitudes
3. Degree and nature of prompting
4. Appropriate problem solving
5. Proper handling of participants' comments and documenting relevant information on logs
6. post interview responsibilities

3.2 Quality Assurance

To assure consistency and accuracy and minimize interviewer variances, the study coordinator will monitor one interview during the first exam month on interviews conducted by each interviewer. For "new staff," this should be repeated each month until the Coordinator determines that the interviewer has met the standards of the study. Then, new staff members will be observed on a quarterly basis along with experienced interviewers. Should any interviewer fall short of the required standards, retraining will be required with special attention given to the problem areas. If the problem persists, the interviewer will be removed from the task of conducting interviews.

Strong Heart Study Phase VII

Checklist for Personal Interviews

The Study Coordinator will observe and tape one interview during the first exam month on interviews conducted by each interviewer and record the results below. As each procedure is carried out, indicate if it is correct by checking the "yes" or "no" column. Suggestions and comments can be written in the space provided. Quarterly observation will be followed after interviewers are certified and have demonstrated the standards of the study have been met.

Interviewer code# _____ **Date observed** _____

Observer code# _____

Establishes correct environment (for privacy and participant comfort).	Yes_____	No_____
Uses proper introduction of questionnaire and self (purpose of form/data).	Yes_____	No_____
Reassures participant: confidential_____ voluntary____ can skip Q's____	Yes_____	No_____
Reads questions exactly as written, slowly, distinctly, in a neutral tone with no omissions or rewording.	Yes_____	No_____
Reads questions in correct order following skip patterns when required.	Yes_____	No_____
Conducts interview in understandable language for participant. If in native language uses correct translations.	Yes_____	No_____
Repeats questions in full that are misheard or misunderstood.	Yes_____	No_____
Uses neutral probes non-directively and appropriately (using pauses, repeating answers, giving ranges, etc.)	Yes_____	No_____
Handles problem solving situations with proper interventions. (This includes participants' questions.)	Yes_____	No_____
Remains nonjudgmental throughout interview.	Yes_____	No_____
Records answers correctly on forms. Edit forms before participant leaves clinic for any corrections.	Yes_____	No_____
Provides closure with participant (including expression of appreciation).	Yes_____	No_____

Comments: _____

_____

_____

_____

4. Anthropometry

4.1 Procedures

1. 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 footstool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90-degree angle to the floor, the wall is straight, and the metal ruler is mounted perpendicular to the floor). A chart converting centimeters to inches is on the wall or available for use in informing the participant of his/her height in inches.

2. Body Weight
   Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Tanita BWB-8005 Adult Digital Scale) with head erect and eyes looking straight ahead. Record the results to the nearest kilogram using the rounding method. To maintain accuracy, the scale is zeroed daily and must be calibrated with a known weight (50-lb) every month or whenever the scale is moved. To calibrate the scale, check that the 50-lb weight weighs 50 lbs. after zeroing the scale. Furthermore, the operator should make sure that an adult must weigh 50 lbs. more when standing on the scale holding the weight.

3. 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.

4. Erect Hip Girth
   Instruct the participant to stand erect yet relaxed with weight distributed equally over both feet. The hip girth is measured at the level of maximal protrusion of the gluteal muscles (hips) (**Figure 3**). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest centimeter using the rounding method. Only one measurement is made. The greatest source of error for this measurement is due to not having the tape horizontal. Technician(s) should check the position of the tape to assure its correct position from both the front and back.

5. 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. This measurement is used to select the proper size blood pressure cuff.

   A Novel Products Figure Finder tape measure is used to measure both abdominal and hip girth and the upper arm circumference.

Figure 1. Frankfort Plane for Measuring Body Height

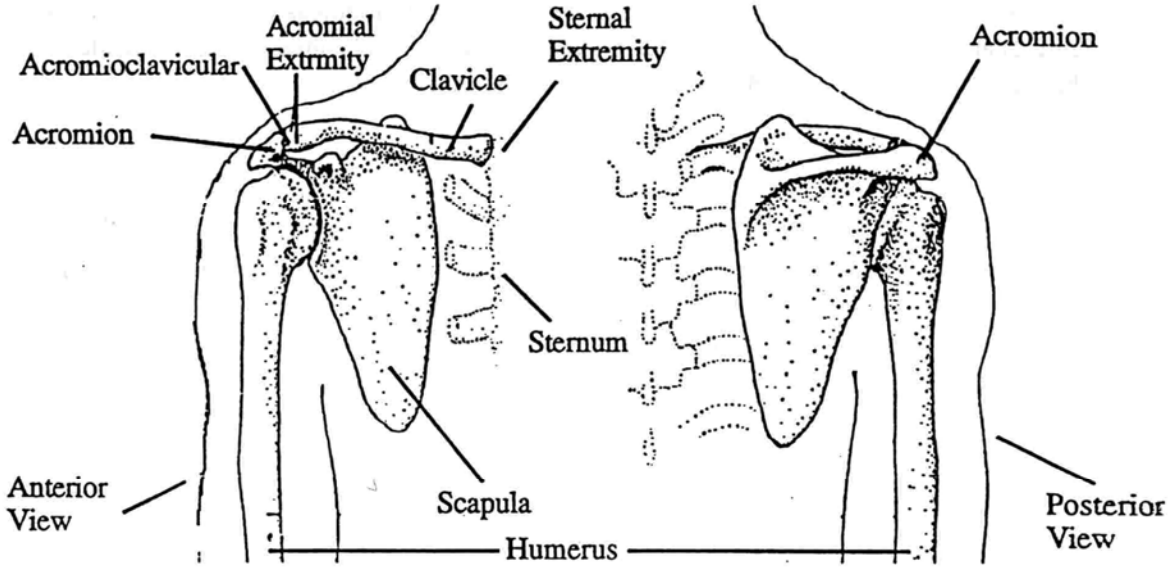


Figure 1 (a). General Description: The **scapulae**, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body.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

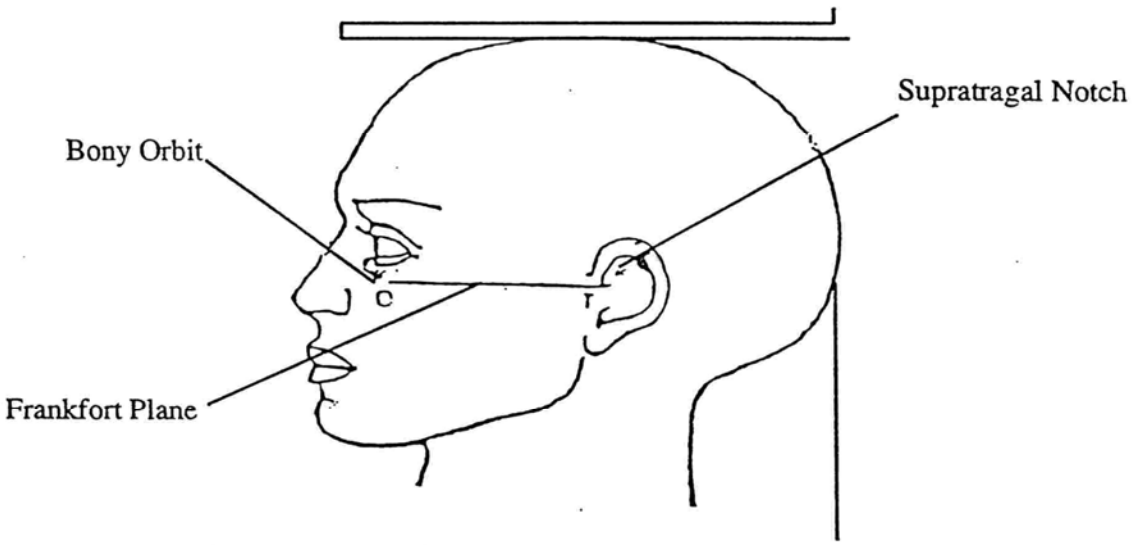


Figure 1 (b). the Frankfort Plane: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external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

Figure 2. Location of Waist Girth Measurement

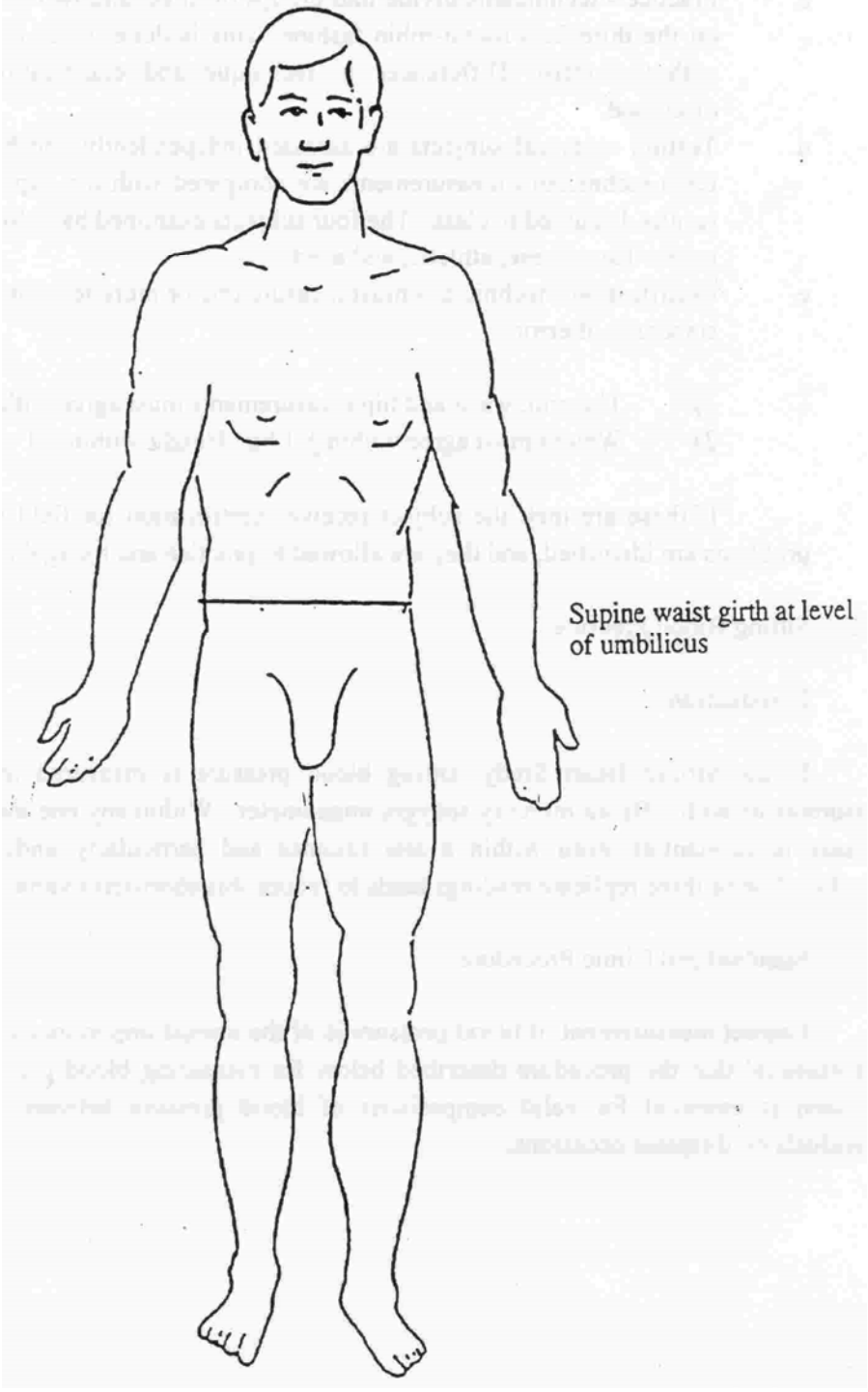
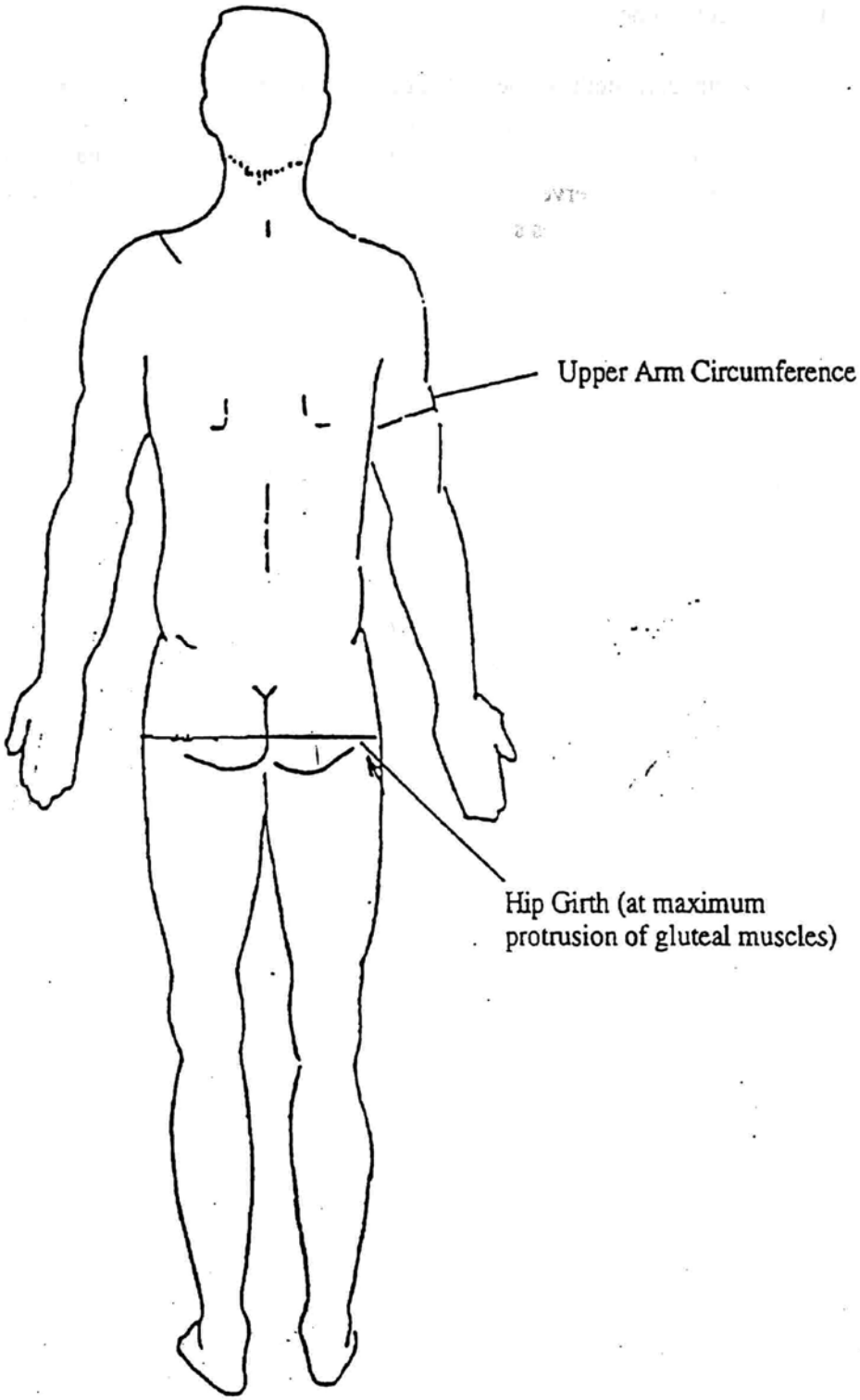


Figure 3. Location of Upper Arm, Hip, and Calf Circumference



4.2 Training

Technician skill training will include:

1. Introduction
   a. Rationale for body size measurements
   b. Overview of technique
   c. Expected limits of reproducibility
   d. Pitfalls related to anthropometry

2. Demonstration
   An expert demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as how to record the data.

3. Practice
   Techs perform measurements on each other or on a volunteer under the observation of an experienced anthropometrist. Differences in technique and clarification of problems are discussed.

4. Testing
   Several subjects are assessed independently and blindly by each technician. The subjects should be from four distinctly different body type groups: lean, obese, athletic, and aged. Each tech's measurements are compared with the expert's measurements and the results are discussed with the tech.

5. Certification
   Technicians must measure one or more test subjects and be within the standards of error:
   a. The waist and hip measurements must agree within two cm on each subject
   b. The arm and height measurements must agree within one cm.
   c. The weight must agree within one kg.

4.3 Quality Assurance

To ensure consistency and accuracy, study coordinators will monitor technicians quarterly. Observation should include proper technique and accuracy within the standards of error listed above.

Strong Heart Study Phase VII

Checklist for Anthropometry

The Study Coordinator will observe each technician quarterly. If each procedure is carried out correctly, indicate so by checking the "YES" space. Results of measurements should be within standard of error:

- The waist and hip measurements must agree within two cm on each subject, and the arm and height measurements must agree within one cm.
- The weight must agree within 1 kg.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

YES ( ) NO ( )	Tech instructs subject to remove shoes for height and weight.
YES ( ) NO ( )	Tech positions subject appropriately for height measurement.
YES ( ) NO ( )	Tech balances and zeroes the scale before subject is weighed.
YES ( ) NO ( )	Subject is weighed accurately to the nearest kg by the tech.
YES ( ) NO ( )	Hip girth is measured accurately with the tape measure placed horizontally around the maximal protrusion of the gluteal muscles.
YES ( ) NO ( )	Tech measures arm circumference accurately, rounding to the nearest cm.
YES ( ) NO ( )	Tech correctly positions subject for waist measurement.
YES ( ) NO ( )	Measure of waist taken correctly, tape position at umbilicus.

Technician	Observer	Difference	
Height	_____	_____	_____
Weight	_____	_____	_____
Hip	_____	_____	_____
Arm	_____	_____	_____
Waist	_____	_____	_____

5. Blood Pressure

5.1 Procedures

1. Determine Cuffs

   Proper size of the cuff is essential for accurate blood pressure measurement. Study Centers have four standardized Baum cuffs available - pediatric, adult, large adult, and thigh cuff.

   The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the Strong Heart Study, arm size is measured and the cuff size is selected as follows:

   Table 1: Determination of cuff size based on arm circumference (Mid humeral)

Cuff	Arm circumference (cm)
Small adult	< 24 CM
Adult	24-32cm
Large adult	33-41cm
Adult thigh	>41 cm

2. Measurement Procedures

   The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 minutes to make three blood pressure measurements including the initial five-minute rest. The blood pressure measurements are made early in the clinic visit sequence immediately following the reception and informed consent, and more than 15 minutes after phlebotomy.

   Once the participant is given instructions and explanations and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

   a. If the participant indicates that there is a medical or postsurgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the data collection form that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.

   b. Seat the participant with the right arm on the table. The bend at the elbow (ante-cubital fossa) should be at heart level. Legs should be uncrossed and head support comfortable. The participant should be able to relax the neck and shoulder muscles as much as possible.

   c. Palpate the brachial artery (just medial to and above the ante-cubital fossa) and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five-minute wait.

d. Record the time. Allow a five-minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary.

e. Connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no longer felt. Deflate and record the pulse obliteration pressure. Have the participant raise measurement arm for five seconds and then wait another 25 seconds with the participant's arm on the table.

f. Measurement 1: Connect the cuff to the manometer. Inflate rapidly to the pulse obliteration level + 30 mm. Holding the pressure constant with the bulb, wait 5 seconds. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. If the column falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the **higher number** should be used.

g. Measurements 2 and 3: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement in step f above and disconnect cuff. To assure accuracy, the second and third blood pressure readings are averaged using a calculator.

If for any reason the observer is unable to complete or has forgotten to complete any portion of the examination (and the participant is gone), draw two horizontal lines through the space(s) on the form. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure workstation, completely deflate the cuff and start over with a replacement reading.

5.2 Training

Skill training will include:

1. Patient instruction, allowing opportunity for questions
2. Measure right arm for correct cuff size
3. Palpate brachial artery, medial to and above antecubital fossa
4. Mark pulse point
5. Wrap cuff, center of bladder over brachial pulse
6. Leave subject for five minutes of rest
7. Position subject, instruct subject on posture (sit upright with right arm bent and cuff at heart level, legs uncrossed)
8. Allow full five minutes for rest
9. Environment free of excessive noise
10. Find pulse obliteration point using standard manometer

11. Calculate peak inflation, 30 mmHg above pulse obliteration point
12. Place stethoscope in ears
13. Inflate cuff rapidly to calculated peak
14. Count full five seconds with pressure steady
15. Place bell on brachial pulse
16. Deflate cuff slowly, 2 mmHg per second
17. Deflate cuff rapidly after 2 absent sounds
18. Record reading
19. Disconnect tubes
20. Instruct subject to hold right arm vertical for full five seconds
21. Wait at least 30 seconds before proceeding to 2nd and 3rd readings
22. Average 2nd and 3rd readings, inform subject of average BP

5.3 Quality Assurance

To insure consistent and accurate measurements, the study coordinator will observe technicians quarterly. They should demonstrate proper technique as listed above. The study coordinator should record his/her observations and comments on the BP checklist (see below). Also, quarterly, each tech should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to the Simultaneous BP Observation Form (see below) and should calculate the differences between the two sets of measurements. The standard of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

Strong Heart Study Phase VII

Checklist for Blood Pressure

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

YES ( ) NO ( )	Provide subject instruction, allowing opportunity for questions.
YES ( ) NO ( )	Measure right arm for correct cuff size.
YES ( ) NO ( )	Palpates brachial artery, medial to and above antecubital fossa.
YES ( ) NO ( )	Marks pulse point.
YES ( ) NO ( )	Places cuff correctly.
YES ( ) NO ( )	Leaves subject for 5 minutes rest.
YES ( ) NO ( )	Subject positioned correctly.
YES ( ) NO ( )	Provides environment free of excessive noise.
YES ( ) NO ( )	Finds pulse obliteration point.
YES ( ) NO ( )	Calculates peak inflation.
YES ( ) NO ( )	Places stethoscope in ears.
YES ( ) NO ( )	Inflates cuff rapidly to calculated peak.
YES ( ) NO ( )	Holds pressure steady for full 5 seconds.
YES ( ) NO ( )	Places bell on brachial pulse
YES ( ) NO ( )	Deflates cuff slowly, 2 mmHg per second.
YES ( ) NO ( )	Deflates cuff rapidly after 2 absent sounds.
YES ( ) NO ( )	Records readings.
YES ( ) NO ( )	Disconnects tubes.
YES ( ) NO ( )	Instructs subject to hold right arm vertical for full five seconds.
YES ( ) NO ( )	Waits at least 30 seconds before proceeding to 2nd and 3rd readings.
YES ( ) NO ( )	Average 2nd and 3rd readings, informs subject of average BP.

Comments: _____

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Strong Heart Study Phase VII

Simultaneous Blood Pressure Observation Form

Quarterly, each technician should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to this form and should calculate the differences between the two sets of measurements. The acceptable margin of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

Technician #1 Code # / Initials _____

Technician #2 Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

	Tech #1	Tech #2	Difference
Arm circumference			
Cuff size			
Pulse obliteration pressure			
SBP #1			
DBP #1			
SBP #2			
DBP #2			
SBP #3			
DBP #3			
Average SBP			
Average DBP			

Comments: _____

_____

5.4 Testing Accuracy Aneroid Sphygmomanometer

You will need a Baumanometer instrument (mercury-gravity standard) and a "Y" connector with an inflation bulb and valve attached. Connect the Baumanometer instrument and the other instrument to be tested as shown below. Cuffs and bags are not used in this test.

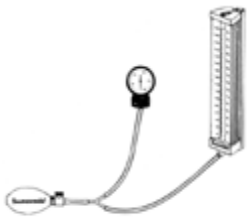

Diagram of a Wall Unit 33 connected to an aneroid with a "Y" connector

1. The Pressure Standard
   A Baumanometer® instrument is to be used as the pressure standard if:
   a. The mercury meniscus is at zero with no pressure applied to the instrument.
   b. The instrument is in a vertical position.
   c. The instrument responds promptly to pressure changes. Any two Baumanometer® instruments, regardless of age, will provide accurate, linear pressure readings at every pressure level if they meet the stated criteria for a correctly functioning manometer.

2. Test Procedure
   Check each instrument to be sure that it is at zero. Slowly inflate the instruments to 250 mm Hg and compare the readings. They should be the same, however, a deviation of ± 3 mm Hg is acceptable. Repeat this procedure at 200 mm Hg, 150 mm Hg, 100 mm Hg, 50 mm Hg, 10 mm Hg and 0 mm Hg. If the deviation is greater than ± 3 mm Hg at any of these points, the instrument being tested is inaccurate and needs adjustment or repair.

Test Kit (2941) needed for testing instrument accuracy

6. Pedal Pulses and Edema

6.1 Procedures

1. Ankle Edema
   The socks or other foot covering are removed. The participant is examined in the supine position. Gentle but firm pressure is applied along the mid-tibia, anteriorly down to the ankle in each leg. Pitting or indentation remaining after pressure is removed constitutes definite edema. The examiner identifies the mid-point between the prominence of the medial malleolus and the inferior border of the patella. Pitting at or above that mid-point is recorded as "marked" edema. Pitting only below that point is recorded as "mild" edema. The degree of edema is based on the extent.

2. Posterior Tibial Pulse
   The examiner palpates inferior to the medial malleolus of each foot. The presence or absence of arterial pulsation is recorded. If in doubt, the examiner compares with the radial pulsation.

3. Dorsalis Pedis Pulse
   The superior aspect of each foot is palpated for the presence or absence of this pulse.

6.2 Training

Technician instruction will include:

1. Rationale for exams

2. Visualization and palpation of lower extremities for edema

3. Palpation of posterior tibial pulses

4. Palpation of dorsalis pedis pulses

6.3 Quality Assurance

Observation of technicians should be done quarterly. Evaluation should include all the criteria listed above and should be recorded on the QA Checklist (see below).

Strong Heart Study Phase VII

Checklist for Pedal Pulses and Edema

Observation of technicians should be performed quarterly. If each step in the list below is carried out correctly, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

YES ( ) NO ( ) Positions subject supine.

YES ( ) NO ( ) Examines and palpates lower extremities for edema.

YES ( ) NO ( ) Records status of edema.

YES ( ) NO ( ) Palpates posterior tibial pulses, bilaterally.
(Posterior and inferior to the medial malleolus)

YES ( ) NO ( ) Palpates dorsalis pedis pulses, bilaterally.
(Superior aspect of each foot)

YES ( ) NO ( ) Records presence or absence of pulses.

Comments: _____

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_____

_____

7. Doppler Blood Pressures

7.1 Procedures

1. Move the participant to the supine position. If needed, assist the participant in moving to the supine position on the examination table.

2. Apply the Blood Pressure Cuff
   The appropriate ankle blood pressure cuff is applied on the right calf. The same size cuff should be used on the lower leg (calf) as the one used on the arm. In special instances, different cuff size may be used.

   At this point, a blood pressure cuff is applied above the ankle of the right leg, as shown in **Figure 4.** Place the cuff flat on the table (the surface marked "side to the patient" face up) with the appropriate ankle centered on the cuff. At this time disregard the "over the artery" marker. The lower edge of the cuff (from which the hoses extend) should be approximately 2 to 2.5 inches above the medial malleolus. Following the contour of the lower leg, wrap the end of the cuff with the velcro "fabric" over the ankle, as shown in **Figure 5**. Note that depending on the degree of tapering in this area, the cuff corner will be offset from parallel toward the knee. Holding the cuff from sliding, wrap the other end over the ankle (step III in **Figure 5**), again following the contour of the ankle, and secure the velcro. Check to be sure that the corners of the cuff extending above the upper edge of the cuff are about equal: if one end extends more than the other, loosen the Velcro and adjust the wrap. Next, locate the "over the artery" marker of the cuff, and rotate the cuff so that this line is directly over the posterior tibial artery. The cuff may be rotated more easily by sliding it toward the malleolus, and after alignment, the cuff can be made snug by pulling it up toward the calf. The cuff should conform closely to the shape of the ankle, with the lower edge 2 to 2.5 inches above the malleolus.

   The posterior tibial artery is usually palpated as it courses posteriorly to the medial malleolus. Even if the posterior tibial pulse is not palpable, the posterior tibial artery is used as the location for the marker line on the cuff for the "over the artery position". Any kinks in the tubing are removed, and any "tugging" of the tubing on the participant's leg is relieved.

3. Measure Ankle Blood Pressure
   a. Palpate both posterior tibial pulses and mark these locations. Apply ultrasound gel to the posterior tibial area over the pulse or in the area shown in **Figure 4**.

   b. Listen for the pulse using the Nicolet IMEX Elite 100 Doppler. If no pulse is audible or palpable, then try to use the dorsalis pedis pulse for the determination of blood pressure. If no pulse is audible, record zero for ankle blood pressure after the absence of pulse is verified by a second observer.

   c. Inflate cuff to a pressure reading 20 mm higher than the "Peak Pressure" used for the sitting arm pressure (i.e., obliteration plus 50 mmHg) and utilize identical deflation

techniques while listening with the Doppler. Record the first sound heard as systolic blood pressure on the physical exam form.

d. Take a second blood pressure using the same techniques and record the second blood pressure on the Physical Examination Form.

e. Repeat this procedure to record the left ankle blood pressure.

f. Repeat this procedure to record the right brachial blood pressure using the Doppler. The blood pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual. By consulting the participant's Data Form, the observer verifies that the same arm and the same cuff size are used as for the sitting blood pressure readings.

4. If the participant had his/her sitting blood pressure taken on the right arm earlier in the clinic examination, the cuff is applied on the right arm at this time. The observer then uses the Doppler to record the brachial pressure. The pressure recorded in the right arm is used to calculate the ankle/brachial systolic pressure ratio for both lower extremities.

5. To determine the right ankle arm index, add the 2 right ankle measurements and divide by 2 to obtain the average right ankle reading. Then add the 2 right arm measurements and divide by 2. Now divide the average of the right ankle by the average of the right arm to obtain the right ankle arm index. For the left ankle index, obtain the left ankle arm average by dividing the 2 left ankle readings by 2. Then divide this left ankle average by the right arm average to obtain the left ankle arm index. If the ratio of the ankle/arm pressure is less than 0.8 in either leg, the participant should be referred to his/her health care provider.

6. If it is impossible to obliterate the sounds after increasing the pressure to above 250 mmHg, record 999 on the physical examination form.

7. The observer now removes all conduction jelly. Socks and a robe or other garments are now replaced, and the participant is escorted to the next workstation.

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

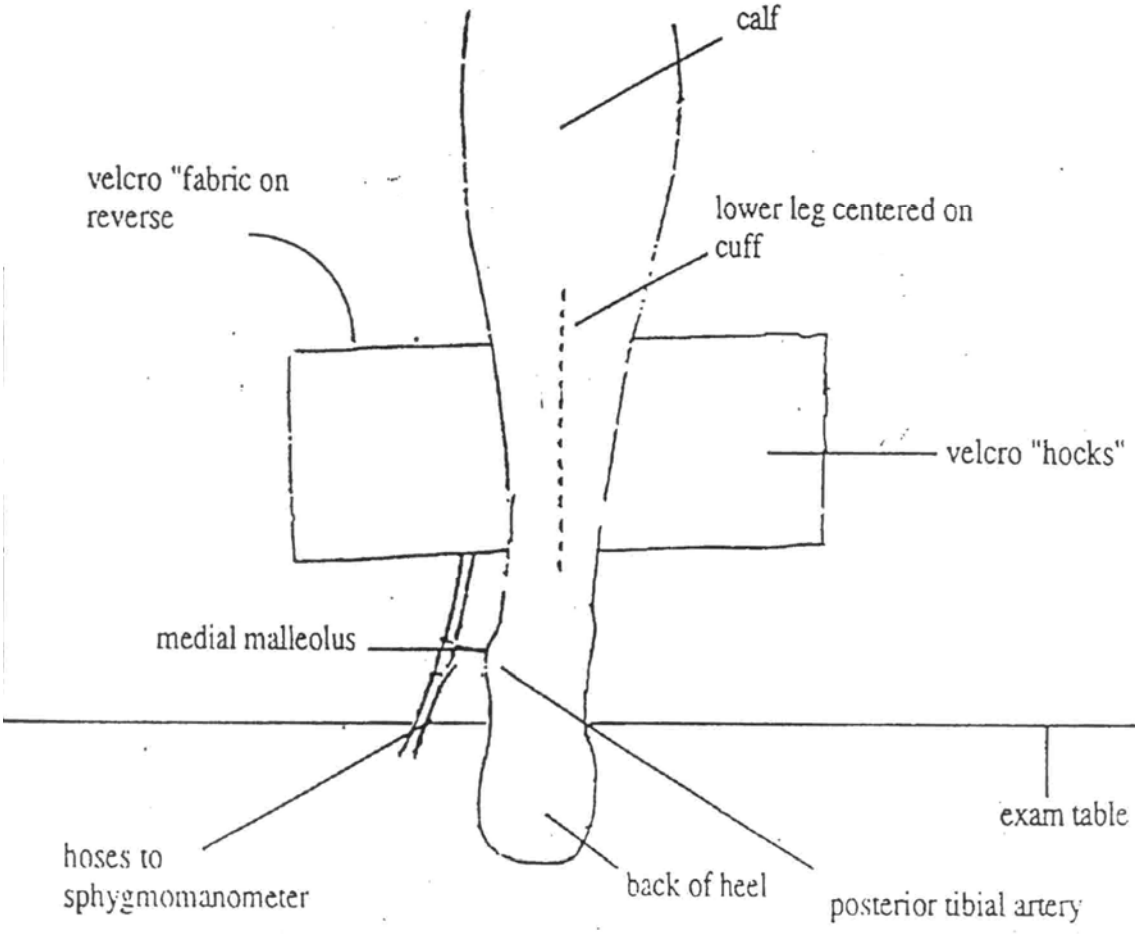
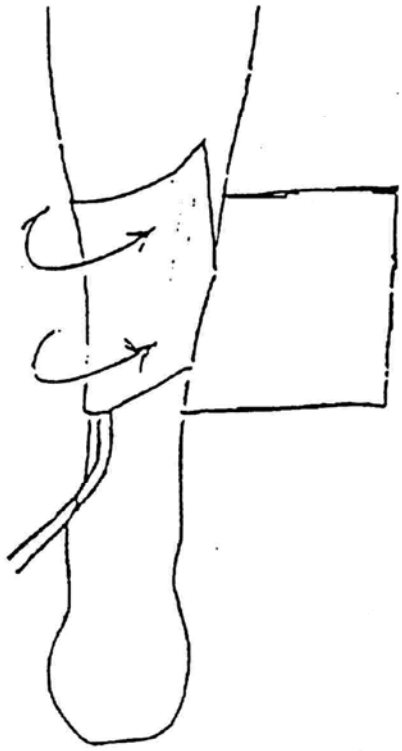


Figure 5 Placement of the Blood Pressure Cuff on the Ankle
Steps II and III: Wrapping and Securing the Cuff

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



"ears" about equal

Step 3. Wrap and secure cuff

7.2 Training

Technician instruction will include:

1. Rationale for ankle systolic blood pressure
2. Explanation to subject
3. Positioning of subject
4. Blood pressure cuff size selection
5. Application of cuff - right ankle, left ankle, right arm
6. Palpation of pulse, marking location, application of ultrasound gel
7. Listening for pulse using IMEX Elite 100 DOPPLER
8. Cuff inflation to peak pressure (50 mmHg higher than pulse obliteration pressure of sitting right arm measurement)
9. Recording of the first pulse sound
10. Repeat for a second pressure
11. Perform on right ankle, left ankle, and right arm (if sitting BP was taken on the right arm)

7.3 Quality Assurance

Observation of technicians will be done quarterly by the Study Coordinator. Performance by the tech should include all of the criteria listed above, the evaluation should be recorded on the Checklist for Doppler Blood Pressures (see below). The tech's results should be within 4 mmHg of the coordinator's pressure results.

Strong Heart Study Phase VII

Checklist for Doppler Blood Pressures

The Study Coordinator will observe technicians quarterly. Performance by the technician should include the following steps. If each step is completed correctly, mark the "YES" space.

Technician Code # / Initials _____

Observer Code # / Initials _____

Date Observed _____

YES ( ) NO ( )	Explains procedure to subject.
YES ( ) NO ( )	Positions subject, supine.
YES ( ) NO ( )	Selects appropriate cuff size.
YES ( ) NO ( )	Applies cuff correctly, right ankle, left ankle, right arm.
YES ( ) NO ( )	Palpates pulse, marks location, and applies ultrasound gel.
YES ( ) NO ( )	Listens for pulse using IMEX Elite 100 DOPPLER.
YES ( ) NO ( )	Inflates cuff to calculated peak pressure.
YES ( ) NO ( )	Records the first pulse sound.
YES ( ) NO ( )	Repeats for second pressure.
YES ( ) NO ( )	Performs on right ankle, left ankle, and right arm (if sitting BP was taken on right arm).

Comments: _____

_____

_____

	Technician	Observer	Difference
Right Ankle	_____	_____	_____
Left Ankle	_____	_____	_____
Right Arm	_____	_____	_____

8. Laboratory

Refer to the Strong Heart Study Laboratory Manual of Operations (Volume IV) for details on laboratory procedures, training, and quality assurance.

8.1 Laboratory Holiday Schedule

Penn Medical Laboratory is closed on the following holidays:

Holiday	2022	2023	2024	2025	2026
New Years Day	Jan 3, 2022	Jan 2, 2023	Jan 1, 2024	Jan 1, 2025	Jan 1, 2026
ML King Day	Jan 17, 2022	Jan 16, 2023	Jan 19, 2024	Jan 17, 2025	Jan 16, 2026
President's Day	Feb 21, 2022	Feb 20, 2023	Feb19, 2024	Feb 17, 2025	Feb 15, 2026
Memorial Day	May 30, 2022	May 29, 2023	May 27, 2024	May 26, 2025	May 25, 2026
Independence Day	July 4, 2022	July 4, 2023	July 4, 2024	July 4, 2025	July 3, 2026
Labor Day	Sept 5, 2022	Sept 4, 2023	Sept 2, 2024	Sept 1, 2025	Sept 7, 2026
Thanksgiving	Nov 24, 2022	Nov 23, 2023	Nov 28, 2024	Nov 27, 2025	Nov 26, 2026
Christmas Day	Dec 26, 2022	Dec 25, 2023	Dec 25, 2024	Dec 25, 2025	Dec 25, 2026

SFBR Laboratories are closed on the following holidays:

Holiday	2022	2023	2024	2025	2026
New Years Day	Jan 3, 2022	Jan 2, 2023	Jan 1, 2024	Jan 1, 2025	Jan 1, 2026
Fiesta Friday	April 29, 2022	April 28,2023	April 26,2024	April 25, 2025	April 24, 2026
Memorial Day	May 30, 2022	May 29, 2023	May 27, 2024	May 26, 2025	May 25, 2026
Independence Day	July 4, 2022	July 4, 2023	July 4, 2024	July 4, 2025	July 3, 2026
Labor Day	Sept 5, 2022	Sept 4, 2023	Sept 2, 2024	Sept 1, 2025	Sept 7, 2026
Thanksgiving	Nov 24, 2022	Nov 23, 2023	Nov 28, 2024	Nov 27, 2025	Nov 26, 2026
Christmas Day	Dec 26, 2022	Dec 25, 2023	Dec 25, 2024	Dec 25, 2025	Dec 25, 2026

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Lab Safety and Protection Precautions Checklist

Technician Code # / Initials:		
Observer Code # / Initials:		
Date Observed:		
	Yes	**No**
Avoids direct contact with blood, sera, plasma or urine.		
Wears protective clothing, gloves, surgical mask, goggles or safety glasses when handling specimens or performing phlebotomy.		
Wears long-sleeved full-length lab coat buttoned down front or apron over scrubs.		
Wears close-toed shoes.		
Immunized against Hepatitis B.		
Disposes of tubes, containers and other material exposed to blood in appropriately labeled waste receptacles for biohazardous material.		
Places contaminated sharps in labeled, puncture-resistant, leak-proof containers.		
Processes blood where first aid instructions can be followed (i.e., wash off skin contact, eye wash, needle-stick instructions).		
Follows universal precautions and treats every specimen as potentially hazardous.		
Removes protective clothing before leaving processing area.		
Uses biohazard labels on refrigerator or freezer holding blood and on specimen containers for storage (including zip-lock bags).		
Comments:		

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Checklist for Sample Collection

Technician Code # / Initials:		
Observer Code # / Initials:		
Date Observed:		
	Yes	**No**
Room set-up with basic supplies for blood collection.		
Follows safety/universal precautions as outlined in checklist.		
Labels collection tubes with ID number and date of draw.		
Introduces self and wears nametag.		
Positions participant in comfortable chair in quiet environment.		
Explains blood drawing procedures and purpose.		
Conducts glucometer procedure as required.		
Completes forms related to blood collection accurately. Assesses fasting state of participant.		
Applies tourniquet. Palpates vein. Cleanses skin over vein using circular motion from center to periphery. Wipes with dry gauze following cleansing. Does not touch skin after cleansing.		
Conducts venipuncture using vascular access with a multi-draw vacutainer (butterfly) needle into vacutainer tubes.		
Draws tubes in order recommended by SHS Core Lab.		
Loosens tourniquet after blood flow starts.		
Does not attempt a venipuncture more than three (3) times.		
Inverts all tubes (except SST) 8-10 times and places on ice. SST tube is to remain upright at room temperature for 20 min.		
After the last tube is drawn, removes tourniquet and uses clean gauze to apply slight pressure to vein (has arm extended) and after 3-5 minutes, applies a pressure bandage.		
Disposes of entire needle set-up into biohazard container. Does not attempt to recap a needle.		
Obtains a urine sample from participant in a pre-labeled container and places it on ice immediately. Records time of voiding.		
Thanks participant and instructs them on next activity.		
Removes gloves, washes hand, proceeds to next participant.		
Comments:		

9. Equipment Quality Control

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Equipment Quality Control Checklist

Device	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
SPHYGMO-MANOMETER												
MEASURING TAPES												
SCALE												

9.1 Sphygmomanometer

9.1.1 Maintenance Procedures

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. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted. If the reading is either above or below the zero mark, the system should be returned to the manufacturer or replaced.

2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:
   a. The system should be re-inflated until the column rises to 200 mmHg.
   b. The tubing should be pinched at various locations to localize the area of the leak.
   c. Appropriate replacement of the tubing, cuff, or valve should be performed.

3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the system should be returned to the manufacturer or replaced.

4. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Check with the manufacturer to determine where the system should be sent for maintenance.

5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry. All clinics should have a mercury spill kit available, and staff should be trained in how to use the kit

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Sphygmomanometers Quality Control

Month	Date	Init.	Mercury Level is at Zero with No Pressure	Check for Air Leaks with Mercury at 200 mmHg	Check for Cap Tightness	Check Tube for Oxide Dust	Comment on Any Problems Found and Corrective Action Taken
JAN							
FEB							
MAR							
APR							
MAY							
JUN							
JUL							
AUG							
SEP							
OCT							
NOV							
DEC							

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Scale and Measurement Tape Quality Control

MONTH	DATE	INIT.	PORTABLE SCALE	CALIBRATED WEIGHTS
JAN				
FEB				
MAR				
APR				
MAY				
JUN				
JUL				
AUG				
SEP				
OCT				
NOV				
DEC				

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Monthly Tape Measure Quality Control Log

Each month tape measures will be calibrated against the stadiometer to check for signs of wear and stretching. One person will hold the zero mark of the tape against the height ruler at the 5 feet (60 inch) level. The second person will flatten the tape against the height ruler without stretching and record the stadiometer heights that correspond to the 12-inch and 42-inch marks on the tape measure (to the nearest 0.25 inch). If the measurers fall outside the 3’ 11 ¾” - 4’ ¼” (47 ¾” – 48 ¼”) or 1’ 5 ¾” – 1’ 6 ¼” (17 ¾” - 18 ¼”) ranges respectively, the tape is replaced.

Date	**Initials**	**Tape**	**Stadiometer Measure (inches)**	**Acceptable Range (Y/N)**
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	
			Tape 12”: _____ Tape 42”: _____	

ECG Reading

Manual of Operations Volume IX

Strong Heart Study Phase VII

July 1, 2023

Version 1.0

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

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Tracking of Revisions to Manual of Operations Volume IX: ECG Reading

Date of Revision	Revised Section	Revision	Approved by, Date

Table of Contents

IX. Data Entry and Quality Control

1. Introduction

This manual of operation (MOP) provides guidelines for technicians at the Clinical Centers (sites) of Strong Heart Study regarding standard ECG recording and data management procedures. A brief description of processing the ECGs within the ECG Reading Center is also provided. The Epidemiological Cardiology Research Center (EPICARE) serves as the ECG reading center for the Strong Heart Study. It is situated at Wake Forest School of Medicine in Winston Salem, NC. The contact information for the EPICARE Center is provided in **Appendix 1.**

2. Background and Purpose

The standard 12-lead ECG plays a crucial role in cardiac evaluation within clinical practice and medical research. In alignment with previous phases of the Strong Heart Study, the Minnesota ECG Classification standards will be employed to classify various ECG abnormalities, including myocardial infarction/ischemia, cardiac chamber enlargement (including left ventricular hypertrophy), arrhythmias (including atrial fibrillation), conduction abnormalities, repolarization abnormalities, and others. Additionally, several ECG waveform measurements with prognostic significance will be incorporated.

3. Clinical Center Procedures

The procedures followed at the Clinical Centers encompass three key aspects: ECG acquisition (section 3.1), local screening for ECG alert findings (section 3.2), and transmission of the collected ECGs to the EPICARE Center (section 3.3).

In section 3.1, the process of ECG acquisition is outlined. This involves the steps and guidelines to be followed by technicians when conducting the standard 12-lead ECG recordings. It encompasses positioning the patient, attaching the electrodes, ensuring proper skin preparation, and recording the ECG using approved equipment and techniques.

Section 3.2 emphasizes the importance of local screening for ECG alert findings. This stage involves the preliminary examination of the recorded ECGs by trained personnel at the Clinical Centers. They will review the ECGs for any indications of significant abnormalities or alert findings as defined by the study protocols. These findings will be promptly identified and communicated to the appropriate medical personnel for further evaluation and necessary actions.

Section 3.3 focuses on transmitting the collected ECGs from the Clinical Centers to the EPICARE Center. Detailed instructions and protocols will be provided regarding the secure transfer of the ECG data, ensuring patient privacy and data integrity. The specific methods, such as electronic transmission or physical shipment, will be outlined to facilitate the efficient and reliable delivery of the ECGs to the EPICARE Center for centralized reading and analysis.

3.1 ECG Acquisition Procedures

3.1.1 Electrocardiograph

The GE MAC 5 electrocardiograph (**Figure 1**) will be used for ECG recording in the Strong Heart Study. The MAC 5 is a portable device and can easily be moved from one location to another. It can store data on a removable storage device (USB flash drive) for later web-based transmission. The ECG machine will be configured specifically for SHS by the ECG Center staff. The MAC 5 should be used for resting ECG recording only. It is not intended for use as a physiological monitor for vital signs.

The Strong Heart Study ECG technicians should become familiar with the GE MAC 5 Operator's Manual. The educational materials provided with the ECG machine have a tutorial on how to operate the machine. The MAC 5 Operator's Manual is available for review.

Figure 1: GE MAC 5 Electrocardiograph

3.1.2 Supplies

Order supplies in advance. The following equipment/supplies are needed for ECG recording and transmitting of the ECGs to the ECG center:

- GE MAC 5 Electrocardiograph with its 10-lead acquisition module
- USB flash drive
- MAC 5 ECG paper
- Felt tip non-toxic washable markers.
- Measuring tape
- Alcohol swabs and gauze pads
- Disposable silver chloride electrodes
- The EPICARE contact list (**Appendix 1**)
- Reference guides for "Patient Data Entry" (**Table 1**)
- GE MAC 5 operation manual

3.1.3 Preparation for ECG recording

- The participant should be relaxed/comfortable in a supine or semi-recumbent position.
- The examination bed should be adequately wide to accommodate the participant comfortably.
- Supply a drape for the exposed upper torso.
- Provide a cover as needed to prevent the participant from becoming chilled.
- Make sure ankles and wrists are accessible for electrode application.
- "Participant Data Entry" instructions should be available to ensure accuracy.
- Supplies needed for ECG acquisition should be assembled and arranged efficiently.

3.1.4 Location of the ECG electrodes

Location of limb electrodes (Figure 2)

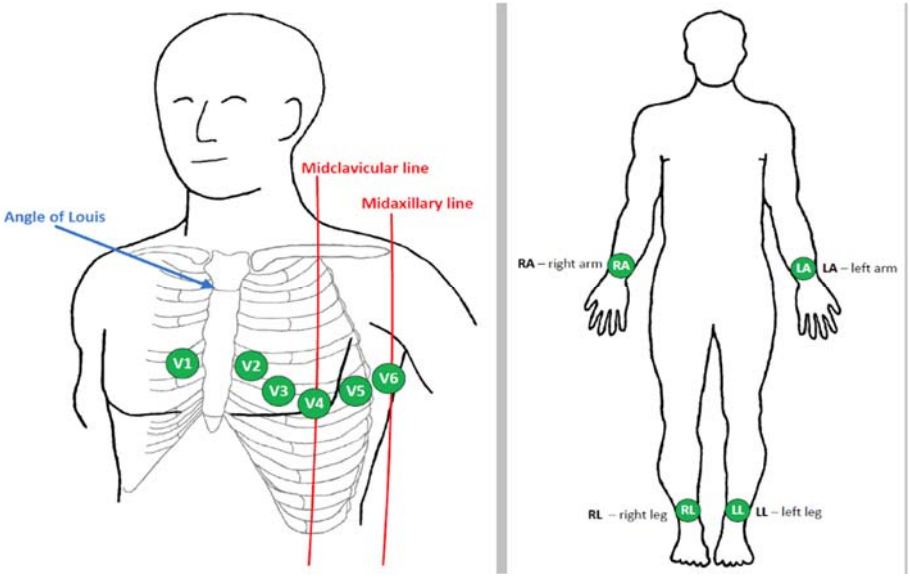
- Right Leg (RL) and Left Leg (LL)
  - On the inner side of the right leg (RL), above the ankle, rub an area about 1-2 inches in diameter with an alcohol swab using firm, circular motions.
  - Repeat this procedure for the left leg (LL).
  - Apply the electrodes, or mark the location for later application of the electrodes
  - In amputees, leg electrodes may be placed on the torso.

- Right Arm (RA) and Left Arm (LA)
  - Rub the inner side of the right arm (RA) above the wrist, as you did with the right and left legs.
  - Repeat the process for the left arm (LA).
  - Apply the electrodes, or mark the location for later application of the electrodes.
  - In amputees, arm electrodes may be placed on the shoulder, below the clavicle.

Location of chest electrodes (Figure 2)

- **Location of V1 and V2**
  - To accurately locate the chest electrodes, it is important to identify the "angle of Louis" or "sternal angle."
  - To find the sternal angle, gently place your fingers at the base of the throat in a central position and move them downward until you feel the top of the sternum or rib cage. Continue moving downward until you feel a bony lump - this is the "sternal angle."
  - The sternal angle is easiest to locate when the patient is lying down, as the surrounding tissue is tighter against the rib cage.
  - From the sternal angle, move your fingers to the left, and you will feel a gap between the ribs. This gap corresponds to the 2nd intercostal space. Run your fingers downward across the next rib and the following one. The space you are in is the 4th intercostal space. The junction of this space with the sternum is the position for V2.
  - Locate electrode V1 in the fourth intercostal space at the right sternal border. It should be at the same level as V2 and immediately to the right of the sternum.
  - Mark the locations of V1 and V2 for later electrode application.

Figure 2: Electrode Location



- **Location of V4 and V6**
  - From the position of V2, slide your fingers downward over the next rib to reach the 5th intercostal space. To locate V4, look at the chest and identify the left clavicle, which runs from the left shoulder to the top of the sternum. Position V4 in the 5th intercostal space, in line with the middle of the clavicle (mid-clavicular).
  - Follow the line of the 5th intercostal space a little further until you are immediately below the center point of the axilla (mid-axilla). This is where V6 should be placed.
  - Mark the locations of V1 and V2 for later electrode application

- **Location of V3 and V5**
  - Mark V3 exactly halfway between V2 and V4.
  - Mark V5 exactly halfway between V4 and V6.
  - You may use a measuring tape to get accurate locations.

Attaching the electrodes

- After marking the electrodes' positions and rubbing them with alcohol swabs, you may apply the electrodes.
- Lower limb electrodes should be facing up, but upper limb electrodes could be facing up or down
- Avoid placing electrodes directly over bones.
- Follow the same order every time to establish a routine and eliminate lead swaps.
- Position the multi-link on the participant's abdomen.
- Grasp each lead at the multi-link attachment point.
- Follow the lead wire to the electrode attachment end.
- Attach the wire to the electrode, making sure the clip is not in contact with electrode adhesive.
- Make sure lead wires have some slack and are hanging loosely.
- You may secure the lead wire to the skin by applying paper tape 1-inch below the clip, especially if the ECG shows baseline noise despite careful preparation.

3.1.5 ECG Recording

To record an ECG using the MAC 5, please review the MAC 5 Operator's Manual for detailed instructions. Here are some general steps:

1. Start by turning on the MAC 5. Press the "Power" button to power it on.
2. Press the "Patient Data" button. This will bring up another screen where you can enter the participant's data as specified in Table 2.
3. Once the participant's information is entered, check the display screen to verify the quality of the ECG signal. The Hookup Advisor, located at the top right of the screen, not only indicates the quality of the displayed ECG signal but also provides clear indications of any issues or problems.
4. If you are satisfied with the quality of the ECG signal, press the "ECG" key to print the ECG recording.

Table 1: Participant Data Entry into the MAC 5 for the Strong Heart Study

Category Listed on Mac 5	Entry to Machine by ECG Technician
LAST NAME	Do not enter the participant's last name. Enter **SHS**.
FIRST NAME	Enter Strong Heart Study exam visit number: 7
YEAR OF BIRTH	Due to PHI concerns, Enter 01/01/XXXX where XXXX is the year of the birth.
PARTICIPANT ID	Enter the ID number given by the SHS Coordinating Center
SECONDARY ID	Enter same as the Participant ID
TECHNICIAN	Select technician

3.2 Local ECG Screening and Referral

The ECG Reading Center does not provide diagnostic statements except as monthly research reading results to the Strong Heart Study CC. Therefore, screening of the ECGs will be conducted at the local level. This step is necessary to ensure the safety of the participants during the exam visit, and also to report the exam findings. Screening the ECGs at the local level does not require the study staff to possess specialized skills in reading ECGs. The screening and referral process involves reviewing the automated interpretation displayed on top of the ECG to identify the presence of certain ECG conditions, then act accordingly.

3.2.1 Emergency Referral (Immediate)

Initiate emergency referral for the following findings:

- ST-segment elevation or depression consistent with acute myocardial infarction or subendocardial ischemia
- 3rd-degree AV-block
- Ventricular tachycardia
- Sustained supraventricular tachycardia with heart rate >135
- Any heart rate < 30 beats/minute

3.2.2 Immediate Referral (Same Day)

Initiate immediate referral for the following ECG findings:

- Any heart rate <35 or >135 beats/minute
- Atrial fibrillation or atrial flutter with ventricular rate <50 or >110 beats/minute
- QT prolongation

3.2.3 Urgent Referral (Within 7 Days)

Initiate urgent referral for the following ECG findings:

- Ventricular premature contractions (VPCs) couplets
- 2nd degree AV block
- New left bundle branch block
- New right bundle branch block
- Wolff-Parkinson-White
- Left ventricular hypertrophy.
- T-wave inversion consistent with myocardial ischemia
- Myocardial infarction of indeterminate age or age undetermined
-

3.2.4 Routine Reporting (Within 30 Days or at First Convenience)

Examples of isolated abnormal ECG findings that do not require referral but can be sent to the participant's physician as part of routine reporting:

- Single ectopic beats of any frequency
- Left axis deviation/left anterior hemiblock
- Unusual p-wave axis (non-sinus atrial rhythm), wandering atrial pacemaker, av junctional rhythm
- Old left or right bundle branch block
- Incomplete right bundle branch block (right ventricular conduction delay)
- ST elevation consistent with early repolarization
- 1st degree AV block

3.3 ECG Data Management

3.3.1 Transmitting ECG to the Reading Center

- The MAC 5 electrocardiograph has the capability to store ECG digital signals as binary data files on a USB flash drive. These binary digital ECG data files can only be opened using the GE proprietary software.
- For the Strong Heart Study, the collected ECG data stored on the USB flash drive will be transmitted to the ECG Reading Center through a secure web-based tool utilizing a secured FTP server.
- MAC5 devices will be preconfigured by the ECG reading Center so that the machines can send the binary ECG files automatically to the Reading Center. Detailed instructions will be provided separately to each clinical site.

3.3.2 MAC 5 Directory Management and Data Storage

Keep your MAC 5 directory correct and current by doing the following:

- Before transmission, delete all unwanted ECGs, e.g., ECGs with flat lines, poor quality, or duplicates.
- Correct any errors in participant data entry, like ID numbers.
- Check the MAC 5 Operator's Manual for details.

4. Quality Control (QC) Procedures at the Clinical Center

The quality control plan for ECG acquisition in the Strong Heart Study involves activities that will occur prior to data collection (quality assurance) and efforts during the study to monitor and correct errors during data collection and processing (quality control). Since quality assurance and quality control can overlap, they are collectively referred to as quality control (QC). Three areas require attention for QC of ECG data collection and processing procedures: QC at the Clinical Center, QC of processing the study ECGs at the ECG Reading Center level, and QC of ECG machines. However, as the QC of processing study ECGs at the Reading Center level is highly technical and may not align with the purpose of this manual, only a brief description is provided under Section 5.1 Reading Center Technical Details.

4.1 Quality Control of ECG Recording Process

The quality assurance process at the Clinical Center level in the Strong Heart Study begins with training and certification of the ECG technicians. This includes standard ECG recording techniques and proper electrode placement. ECG machine operation and programming are also covered in the training program. To account for personnel turnover, new technicians will undergo certification before recording study ECGs. Materials such as videos, PowerPoint presentations, and the ECG Manual of Procedures will be provided to aid in training. The ECG Reading Center will monitor ECG quality and identify any acquisition errors. A monthly quality report, along with ECG data results, will be sent to the Strong Heart Study CC and discussed in the relevant committee.

4.1.1 Certification/Recertification Procedures

- All ECG technicians will undergo a certification process before acquiring study ECGs.
- Each technician must acquire and successfully transmit one good-quality ECG.
- The certification ECG could be recorded on a volunteer or another ECG technician at the same site.
- After evaluating the certification ECGs by EPICARE staff, the technicians will be notified of their certification status.
- The recertification process is the same as the certification process and will be requested if quality deterioration is observed at one of the Clinical Centers.
- The participant data entry on the MAC 5 should be done according to the instructions in **Table 2**.

Table 2: Entry into the MAC 5 for certification of technicians ONLY

Category	Entry
Patient ID	Enter 99999
Last name	Enter technician’s last name
First name	Enter technician's first name
Date of birth	Enter 01/01/XXXX where XXXX is the volunteer’s birth year
Technician	Add technician's name

4.1.2 Quality Grades

At the ECG Reading Center, the evaluation and ranking of ECG quality are carried out using an automated system with visual confirmation. The system assigns one of four quality grades: 0, 1, 2 (assigned automatically by the GE-MUSE system), and 5 (manually determined by EPICARE staff for the poorest quality). Notably, there are no quality grades 3 or 4 used in this evaluation.

The quality grades are defined as follows:

- Grade 0: Excellent quality, indicating that the ECG recording meets the highest standards.
- Grades 1 and 2: These grades indicate minor quality issues that do not significantly impact the accuracy of the automatic reading. The ECGs in these categories are still suitable for appropriate interpretation and analysis.
- Grade 5: This grade signifies significant quality issues that can interfere with the accurate automatic reading of the ECG. Grade 5 is manually assigned by EPICARE staff and denotes the poorest quality ECG recordings.

In studies like the Strong Heart Study, a poor quality alarm is triggered when more than 5% of the ECGs receive a quality grade of 5. This serves as an indicator that there may be a notable proportion of ECG recordings with significant quality issues, requiring attention and potential reevaluation.
The combination of automated grading and visual confirmation allows for the efficient and reliable evaluation of ECG quality at the ECG Reading Center, ensuring that high-quality recordings are used for accurate interpretation and analysis in the Strong Heart Study.

4.1.3 Examples of Common ECG Quality Problems and Possible Solutions

- EXCESSIVE BASELINE DRIFT (**Figure 3**): This occurs if the participant moves around or there is tension on the lead wires. Ask the participant to lie still for a few seconds. A drift of more than 1 mm between baseline points (QRS onset) of any two successive complexes is a sign of significant drift.

- EXCESSIVE MUSCLE NOISE (**Figure 4**): The participant is tense due to a lack of body support or feeling cold. Use a wide bed and a blanket to cover the participant.

- BASELINE DRIFT DUE TO TANGLED WIRES (**Figure 5**): Ensure that the wires are not pulling. Be sure to establish a good electrode connection. Lay a towel across the wires, if necessary. Adjusting the angle of the clip at the electrode often helps. You may need to tape down the chest leads; use only hypoallergenic medical tape to prevent allergic reactions. Use a U loop (not a cross loop) with the electrode wires.

- LOOSE ELECTRODE CONNECTION (**Figure 6**): Loose electrode connection may cause a wavy baseline in some ECG leads. Check each electrode to ensure that it is secure.

- SIXTY HZ NOISE (**Figure 7**): Periodic 60 HZ noise is sometimes visible in the record. This may be caused by AC interference from a nearby machine. Make a visual check of this before recording the ECG. Unplug any unnecessary surrounding electric equipment *Note:* Jewelry does not cause 60 HZ noise.

- MISSING LEADS AND LEAD REVERSAL (**Figure 8** - **Figure 10**): To minimize the chances of lead reversal and missing leads, check for flat lines and that QRS in aVR lead is mainly negative. Before recording, it is recommended to double-check the connections to ensure accuracy.

Figure 3: Excessive baseline drift due to sudden movement of the participant

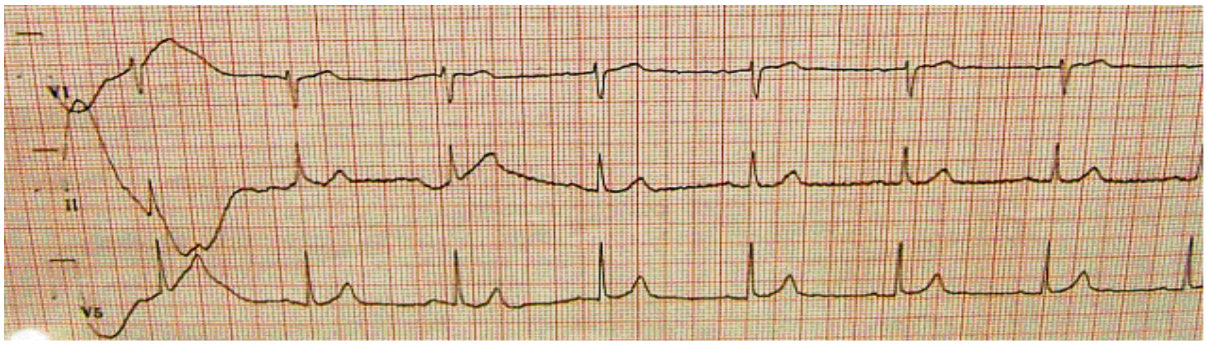


Figure 4: Excessive muscle noise

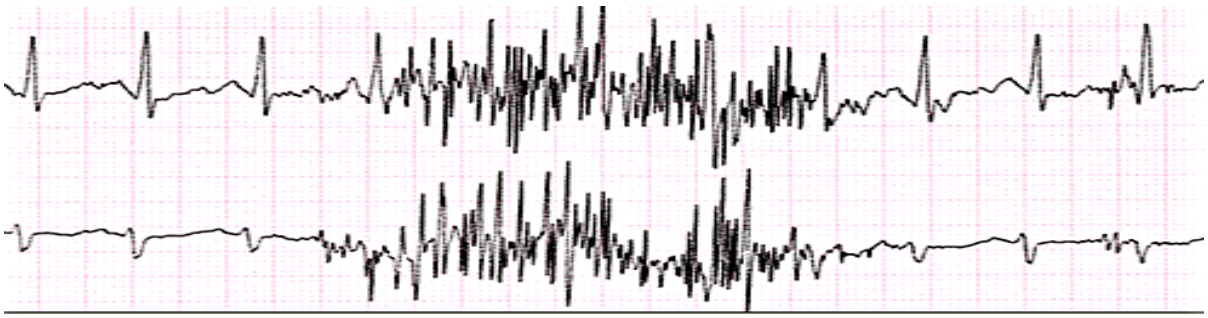


Figure 5: Baseline drift due to tangled wires

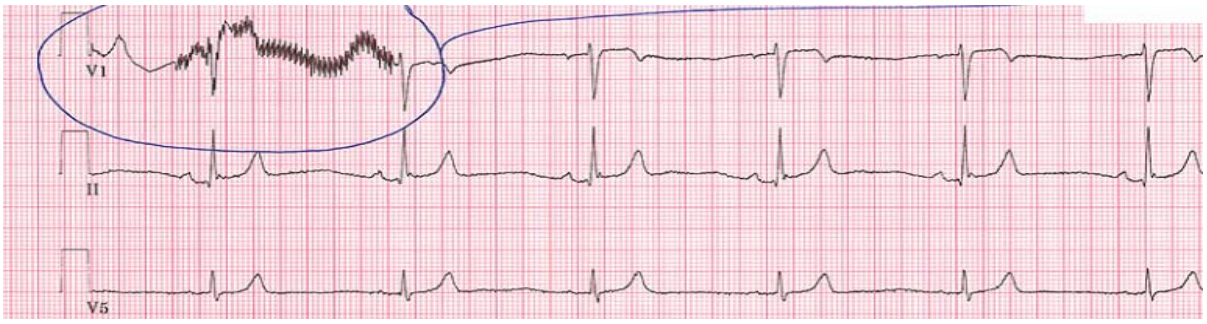


Figure 6: Wavy V1 baseline due to a loose electrode

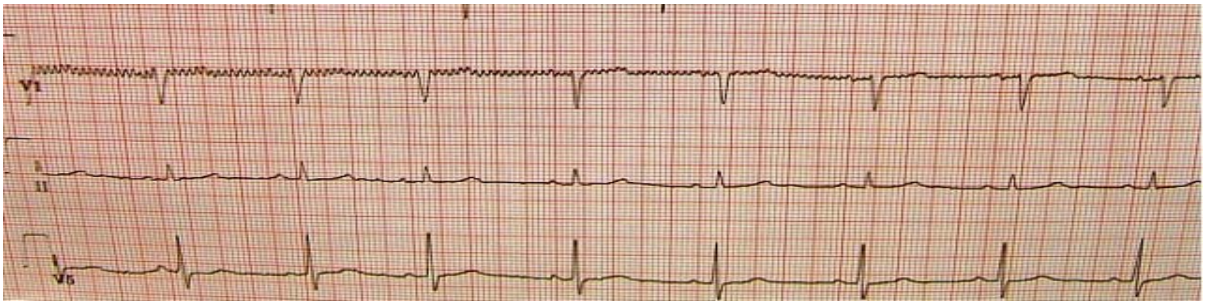


Figure 7: Wavy V1 baseline due to loose electrodes

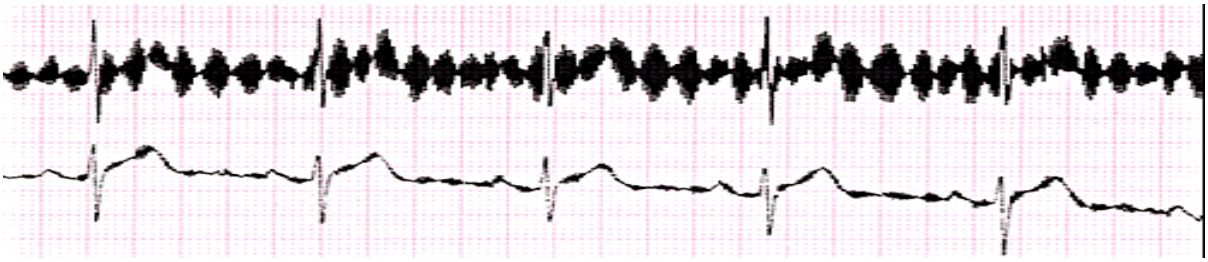


Figure 8: Flat line due to missing V1 lead

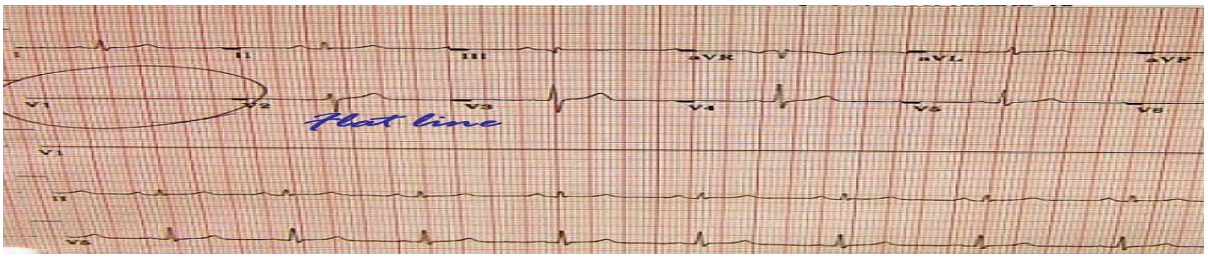


Figure 9: Lead reversal denoted by positive aVR compared to the normal

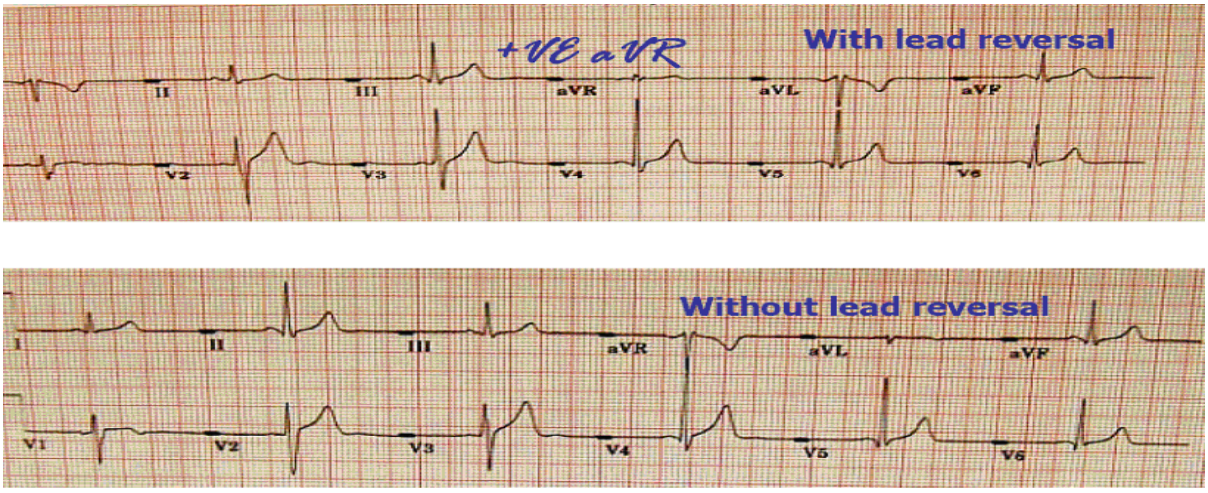
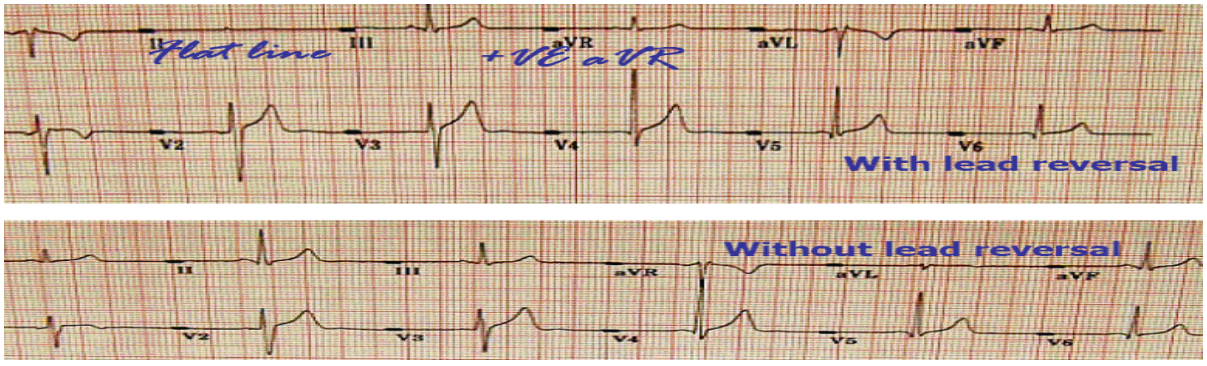


Figure 10: Lead reversal denoted by flat line in one of the limb leads (upper panel) **compared to the normal** (lower panel)



5. Reading Center Technical Details

Set-up of the machines should be done at the Reading Center or with the assistance of one of the Reading Center staff if it must be done at the Clinical Center. It may be necessary to re-program the machine after starting the study if a malfunction occurs, or the battery has been allowed to become dead.

5.1 Data Processing

Strong Heart Study ECGs will be electronically transmitted to Reading Center via secured FTP. ECGs will then be uploaded by the ECG Center staff to the GE- MUSE ECG management server. The digital ECGs are stored in an electronic database at the Strong Heart Study Reading Center, in a Marquette measurement matrix, separated by participant ID. This database will remain unaltered. Additional databases are created after conducting the QC. These databases are then transformed into Minnesota Code and Novacode categories by the EPICARE ECG coding program**.**

5.2 Data Reporting

Monthly reports with the reading results will be sent from the EPICARE to the Strong Heart Study Data Coordinating Center (DCC) using secured FTP. All electronic ECGs will be processed and reported within 30 days from receipt. Note: Reporting results of the participants are not under the scope of the Reading Center and are not discussed here. Instead, what is referred to here is sharing the research reading results with the DCC.

5.3 Quality Control of the ECG Center Procedures

The ECG Reading Center maintains a comprehensive internal quality control protocol to ensure the accuracy and consistency of ECG coding and measurement performance. This protocol includes several monitoring processes:

- Inter- and intra-reader variability: Regular monitoring is conducted to assess the consistency and agreement among different readers in interpreting and coding visual ECGs on paper. This helps identify any variations or discrepancies that may occur and allows for necessary corrective actions. This would not apply to the Strong Heart Study, given the digital nature of the ECGs

- Procedures against software changes: Safeguards are in place to protect against software changes that could lead to secular time trends in ECG measurements. The ECG Reading Center continuously monitors the "raw" measurements of PR, QT, and QRS intervals using the Marquette ECG processing program. Sudden and unexplained departures in these parameters are investigated to identify and rectify any procedural or software alterations.

- Visual checks for ECG abnormalities: Each electronically received ECG is visually inspected for specific abnormalities, including arrhythmias (such as atrial fibrillation and ectopic beats), major conduction defects, and pacemakers. This visual supervision is performed by an ECG coder and verified by a senior ECG coder to ensure accurate identification and classification of abnormalities.

- Review by ECG Reading Center PI: Major ECG abnormalities, such as new myocardial infarction, significant QSTT serial changes, and major arrhythmias and conduction defects, are reviewed by the Principal Investigator (PI) of the ECG Reading Center during the monthly report and the final quality control check at the end of the study. This additional review by the PI ensures the highest level of accuracy and reliability in the interpretation of critical ECG findings.

By implementing these rigorous quality control measures, the ECG Reading Center maintains the accuracy and consistency of ECG coding and measurement performance, ensuring the reliability of data generated for the Strong Heart Study. Also, the ECG acquisition procedures will be similar to the prior visits. This is crucial to compare ECG findings among participants within the same visit (and future visits).

Appendices

Appendix 1 Strong Heart Study ECG Reading Center Contact List

Staff	Role	Contact
Soliman, Elsayed, MD, MSc, MS	EPICARE Director	esoliman@wakehealth.edu
Oguz Akbilgic, Ph.D.	EPICARE Associate Director	oakbilgi@wakehealth.edu
Keasler, Lisa	Associate Project Manager	lkeasler@wakehealth.edu Tel: (336)-716-0387
Semseddin Moldibi, MS	Data Manager, SAS Programmer	smoldibi@wakehealth.edu

Contact Lisa Keasler with questions about ECG recording, transmission, or hardware malfunction. Contact Oguz Akbilgic and Semseddin Moldibi with questions about data management. Contact Elsayed Soliman with any other questions.