FAMILY STUDY

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual - Volume Three

PERSONAL INTERVIEW AND GENERAL EXAMINATION

THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH
THE STRONG HEART STUDY

Cardiovascular Disease in American Indians
(Phase IV)

Operations Manual

Volume Three

PERSONAL INTERVIEW AND GENERAL EXAMINATION

June 1, 2001

For copies, please contact

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# VOLUME III

PERSONAL INTERVIEW AND GENERAL EXAM

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CHAPTER ONE

Clinical Examination - General

1.1 INTRODUCTION

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

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

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

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

The training of the registered nurses, nurse practitioners, health profession students, physician assistants and physicians on the Phase IV protocol occurred on January 29 to February 2, 2001 at the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma and was based on the written protocol. Each Study Center has designated a primary examiner and at least one other person who is available to perform examinations in the absence of this primary person.
Certification requires adequate performance of the components of the examination as validated during training. In case of loss of a center's staff member, a replacement may be trained locally by someone certified in the procedure(s). The same certification requirements as used in the initial training must be met. Quality control focuses on the potential for false positive examinations. Because most participants are healthy, the frequency of abnormal findings is relatively small. The presence of real abnormalities among those with normal examinations is also small (a low false negative rate), and this makes it inefficient to re-examine the many individuals with normal findings. The review of positive findings is part of the medical data review. After the initial training, continuing education includes regular review of the protocol.

1.2 COMPONENTS OF THE CLINICAL EXAMINATION, ENDPOINTS AND RISK FACTORS

1.2.1 Components of the Clinical Examination

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

1. Personal Interview

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

2. Physical Examination

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

1) Anthropometric measurements will be made with participants in loose clothing without shoes, and with heavy objects removed from pockets:
   i) Weight -- The scale will be balanced on a level and firm surface prior to weighing a participant. The participant will stand in the middle of the scale platform, head erect and looking straight ahead. Results will be rounded to the nearest kg.
ii) Height -- The participant will stand erect on the floor with his back against the vertical mounted ruler, heels together and looking straight ahead. The right angle will be brought down snugly but not tightly on the top of the head so that height can be accurately measured and rounded to the nearest centimeter.

iii) Waist and hip circumferences -- For the waist, anthropometric tape will be applied at the level of the navel with the patient supine and breathing quietly. Results will be rounded to the nearest cm. For the hip, the participant will stand erect but relaxed with weight distributed equally over both feet. The measure will be made at the level of maximum protrusion of the hips with the tape kept horizontal. These measurements are rounded to the nearest centimeter.

iv) Body fat measurement -- Using an RJL bioelectric impedance meter, resistance and reactance are recorded. Percent body fat will be estimated by the RJL formula based on total body water.

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

2) Examination of the following:

i) Pedal pulses – With the participant supine, the presence of posterior tibial (palpating inferior to the medial malleolus of each foot) and dorsalis pedis (palpating superior) pulses will be determined.

ii) Ankle edema -- With foot coverings removed, participant will be examined in the supine position. Gentle but firm pressure will be applied along the mid-tibia, anteriorly down to the ankle in each leg. The degree of edema (0-4) will be recorded.

3) Blood pressure measurements:

i) With the participant sitting with right arm on table, the cuff will be connected to a standard manometer and the pulse obliteration pressure will be established and recorded. After five minutes, the cuff will be reconnected and inflated to +30 mm above the obliteration pressure and held constant for 5 seconds. The cuff will be slowly deflated (2 mm/sec) while reading pressures for 1st and 5th phases. Before measurements 2 and 3 are taken, the participant will raise the arm for five seconds. After another 25 seconds with arm on the table, the measurement will be repeated a second and third time. The average of the last two measurements will be used for analysis.

ii) Using a Doppler, with the participant supine, right brachial and both ankle systolic pressures will be measured two times.
4) Twelve-lead resting ECG measurement -- Using a Marquette Mac-PC or MAC 1200 EKG machine, a 12-lead EKG will be obtained in a standard manner. EKGs will be electronically transmitted to Cornell University, and confirmed interpretations will be transmitted back to the field location to be filed in the participant’s medical record. Tracings will be Minnesota coded electronically.

5) Fasting blood samples for measurements of total triglyceride (TG) and cholesterol, LDL and HDL cholesterol, LDL size, apolipoproteins AI & B, Lp(a), apo E genotype, plasma fibrinogen, and PAI-1, and DNA isolation, glucose, creatinine, insulin, chemistry profile, and CBC will be obtained. As a point of clarification, **ALL tubes will be taken from patients who are on renal dialysis or have had a kidney transplant.**

6) Urine will be collected at the beginning of the physical examination for measurement of albumin and creatinine.


10) Pedometry will be used to assess physical activity of the participants at home for one week. Each participant will wear an Accusplit Activity meter for 7 days (from waking till going to bed each day), recording daily activity counts in a diary, and returning the diary to the clinic after recording 7 consecutive days of activity.

For those family members returning for reexamination, they will not be asked questions regarding things that do not change, such as Tribal enrollment and Indian heritage. In addition, Apolipoproteins B & AI, Lp(a), apo E genotype, chemistries, and CBC will not be reassessed.

The IHS medical records will also be reviewed to determine whether the participant was hospitalized or received out-patient treatment for ESRD, stroke, myocardial infarction, or other manifestation of CVD.

A checklist to be used for the physical examination and a reminder of post examination activities are given in Appendix A-2 (a) and (b).

The clinical examination will last approximately three hours. The participant will arrive at the clinic fasting in the morning. After registration, a study staff member will explain the study and procedures to the participant, answer questions, if any, and have the consent form signed. A consent form will be signed by parents of all participants under 18 years of age, and participants under 18 years of age will also sign the form indicating their willingness to participate. The participant will then be instructed to go to the laboratory for blood drawing and
to provide a urine specimen. The participant will then be offered a light snack. The nurse clinician and other staff will then conduct the personal interview, obtain anthropometric measurements, blood pressure, impedance measurement for body fat composition, and obtain an echocardiogram, an ultrasound assessment of the carotid artery, radial artery tonometry, and ECG measurements. After all the procedures are completed, the participant will receive payment or sign the payment form and be thanked for his/her participation.

If possible, all of the components, except for the FFQ, psychosocial questionnaire, and echo exams, should be completed in one visit. If an individual leaves before the examination is completed, it must be completed before the study is completed. The personal interview and consent may be completed up to two weeks prior to the physical examination if such arrangements are more convenient. The FFQ and psychosocial questionnaires may be given to the participant to complete before attending the clinic visit. If they are not complete, every effort should be made to have the participant complete them while in the clinic for the rest of the exam.
1.2.2 Endpoints and Risk Factors

A. MORBIDITY EVENT CRITERIA

1. Definite Myocardial Infarction (MI)

Minnesota codes 1.1.x or 1.2.x except 1.2.6 and 1.2.8 with no 7.1 or 7.4 or History of MI verified by chart review as definite MI

2. Possible Myocardial Infarction

Minnesota codes 1.3.x, 1.2.6, or 1.2.8 with no 7.1 or 7.4 or History of MI verified by chart review as possible MI

3. Definite Coronary Heart Disease (CHD)

Definite MI, or Definite CHD verified by chart review to include cardiac cath, proven coronary artery disease, PTCA, coronary artery bypass grafting, or abnormal stress ECG plus abnormal imaging (i.e., both must be abnormal), or Angina Pectoris plus LBBB (7.1.1) or ST changes (4.1) or T wave changes (5.1) or verified possible MI,

4. Possible Coronary Heart Disease

Possible ECG MI (1.3.x, 1.2.6, 1.2.8) or Angina Pectoris or Minnesota codes 7.1, 4.1, 4.2, 5.1, 5.2, 7.4 or Unconfirmed history of MI or Positive functional test of ischemia (such as treadmill) without invasive confirmation or Possible ECG or imaging in scintigraphic studies (not both).

5. Definite Cardiovascular Disease (CVD)

Definite CHD or Congestive Heart Failure or Cardiomyopathy or Valvular Heart Disease or Left ventricular Hypertrophy by Echocardiogram or Left ventricular Hypertrophy by ECG (3.1 or 3.3 plus 4.1-4.3 or 5.1-5.3) or Ankle Arm Index <= 0.8 or Atrial Fibrillation or Minnesota codes 4.1, 5.1, 6.1, 6.2, 6.8, 7.1, 7.2, 7.4 or Non-coronary heart surgery or carotid or other vascular surgery
or Pacemaker implantation
or Bruits by physical examination
or Intermittent Claudication by Rose Questionnaire
or Positive non-coronary angiography
1.3 RECRUITING

1.3.1 Recruitment Techniques

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

Recruiting participants to the Strong Heart Family Study is more than simply getting the person to come into the clinic for an exam. Their participation in the Study is the result of an ongoing effort of Strong Heart personnel to recognize, establish trust with, and care about the people who take time to participate in the Study. Without our participants, we have no Strong Heart Family Study.

Greet people wherever you see them. Call them by name and make the effort to greet them first.

Take time to be in places like the Tribal Office, Post Office, Hospital and any location where there is a large gathering of people. Talk gently with them about other subjects and then slowly talk with them about Strong Heart participation.

Don’t sit in the car and honk the horn when making home visits (unless you have safety concerns). Walk to the door and tell them why you are there. Take the initiative to visit with them first and see how they are.

People without a car often feel shut-in and frustrated. It is important to visit with them about a variety of things first before approaching them about participating in the Study.

Sometimes, when possible, it helps to offer a helping hand in things that need to be done, let people know that you recognize them as a person and not only a participant.

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

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

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

**PLEASE** always remember that the client is a volunteer. Treat them with courtesy and recognize that they have often gone to a great deal of effort in both time and energy in coming into the clinic to participate.

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

Set goals that are clear to all personnel and allow sufficient time for the recruiters to reach them. Everyone should contribute to the recruitment effort.
Recognize the daily rhythms of your community. Some participants are affected more by the community events, seasons and check days than others are. Try to be sensitive to the participant’s needs when scheduling.

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

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

Give people encouragement, even when they are doing well.

Research Clinic is not a “priority” to some people. Take your time - don’t reschedule them continuously.

When approached by people who express interest in the heart study, get names of the person, both parents and grandparents, and tell them you’ll see if they fit in one of the family pedigrees.

Be willing to let the participant take part in as much as possible. Although it is ideal to have the participant complete the entire exam at once, it is not always possible. Be willing to adjust your schedule to accommodate the participant.

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

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

1.3.2 Recruitment Instructions

For the Phase IV clinical examination, we will recruit selected individuals who participated in the Phase I exam, and members of their families. Our goal is to recruit large families in which many family members (fathers and mothers of Phase I participants, the participants’ children, and other relatives) are willing to participate. Eligible study participants who have large families are being identified through the Strong Heart Study database and a list will be provided to recruiters. Individuals will be contacted in an order convenient for each center. Local publicity campaigns and mailed information will alert participants before participation is requested.

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

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

1. That the volunteer should not eat breakfast the morning of the exam and should not eat or drink anything but water after 9:00 p.m. the previous evening;

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

3. That the volunteer should not take their morning diabetes medication until blood drawing is completed;

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

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

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

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

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

1.3.3 Recruitment Form

The recruitment form (see Appendix B of this volume) will be used to collect information on family members. A form should be completed for each person who is recruited into the Strong Heart Family Study. This means that a form is needed for every family member who participates. The form has several pages. The Strong Heart Family Study ID number should be entered in the upper right corner of each page. In the upper left corner of every page of the form, enter the family number and the household number. If the family is so large that the form does
not have enough spaces for entering information on all family members, please contact Dr. Jean MacCluer or Dr. Kari North in San Antonio. They will provide instructions for collecting the information on additional family members.

Page 1:

On the first row of page 1, enter information about the person being interviewed (the participant). On the following rows, enter information for the participant's mother and her parents and the participant's father and his parents.

Next, enter information about the participant's spouses or partners. You don't need to record information about a spouse or partner unless he/she is the parent of one or more of the participant's children. Enter the first spouse or partner in the row labeled 1, the second in the row labeled 2, and so on.

Next, enter information on the participant's sons and daughters. For each son or daughter, circle 1, 2, 3, or 4, to indicate who is the other parent of the son or daughter. The total number of sons and daughters refers to the total across all pages.

Page 2:

Page 2 provides space to list the participant's brothers and sisters. In the top section, enter information about full brothers and sisters (who share both parents with the participant). The total number of brothers and sisters refers to the total across all pages.

Next, enter information about the parents of the participant's half brothers and half sisters (who share only one parent with the participant). For example, if the participant and her half sister have the same mother but different fathers, enter information for the half sister's father. There is enough room for information on four different parents of half brothers and half sisters.

Next, enter information on the participant's half brothers and half sisters. For each half brother or half sister, circle 1, 2, 3, or 4, to indicate who is the other parent of the half brother or half sister (the parent not shared with the participant). The total number of half brothers and half sisters refers to the total across all pages. (If the spaces are not sufficient to enter information on the half siblings other parent, use an additional page?)

Page 3:

Page 3 is a supplement, which may be used to record additional children if there is not enough room on page 1. It is to be used if the participant has more sons and daughters by spouses/partners 1, 2, 3, and 4 than can be recorded on page 1.
Page 4 is a supplement, which may be used if the participant has more than four spouses/partners. The top section provides space to enter information on as many as four additional spouses/partners (numbers 5, 6, 7, or 8).

Next, enter information on the participant's additional sons and daughters by these spouses/partners. For each son or daughter, circle 5, 6, 7, or 8, to indicate who is the other parent of the son or daughter.

Page 5:

Page 5 is a supplement, which may be used to record additional brothers and sisters if there is not enough room on page 2. The total number of brothers and sisters refers to the total across all pages.

Page 6:

Page 6 is a page at the end of the Recruitment or Family Information Form provided for confidential comments. If used, it should be detached from the form and sent immediately to:

Dr. Kari North  
Department of Genetics  
Southwest Foundation for Biomedical Research  
7620 N.W. Loop 410  
San Antonio, TX  78227-5301.  
Phone:  (210) 258-9772  
Fax:   (210) 670-3317  
email:  knorth@darwin.sfbr.org
1.4 PERSONAL INTERVIEW

1.4.1 Components of the Personal Interview

The personal interview is designed to obtain demographic information, family history, medical history, health behavior, acculturation and stress data that are considered important in identifying risk factors for cardiovascular disease. The following questionnaires (see forms in Appendix D of this volume) will be administered during the clinical examination (note: diet (item #9) and psychosocial (item #10) forms are self-administered and may be given to the participant up to 2 weeks prior to the exam):

1. Pregnancy/lactation screen
2. Personal Interview Form (I and II)
3. Medical History Form
4. Reproduction and Hormone Use
5. Rose Questionnaire
6. Respiratory
7. Medication Use
8. Family Information Form (see Appendix B)
9. Dietary Form (Food Frequency Questionnaire - FFQ)
10. PSYCHOSOCIAL QUESTIONNAIRES
   - Cultural Factors
   - Quality of Life (SF-12)
   - CES-D
   - Locus of Control
   - Social Support
   - Anger/Hostility - optional
   - Psychosocial Checklist

Personal living habits such as dietary, cigarette smoking and alcohol consumption, and stress have been considered as important risk factors for cardiovascular disease. Data on these factors as well as demographic information will be collected by using the Personal Interview Forms (I and II) and the FFQ. Other pertinent forms are the Medical History Form (questions on medical conditions), the medications form, and the Rose Questionnaire for angina pectoris and intermittent claudication. These questionnaires are included in Appendix D.

1.4.2 Guidelines for Interviewers

1. Introduction

The personal interview is probably one of the most important procedures for data collection in epidemiologic research. The personal interview usually increases response over self-administered questionnaires. Most of the SHS questionnaires are interviewer administered with the exception of the diet (FFQ) and psychosocial forms, which are designed to be self-
administered. The interviewers will need to assist some participants in completely filling out those forms.

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

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

2. Types of Interviews

Structured versus Unstructured Interviews

In an unstructured interview the responses to questions are open-ended, and information given is to be recorded as given. In a structured interview the questions are usually closed, with a specific set of answers provided in the questionnaire.

For the Strong Heart Family Study, we are using both structured and unstructured interviews. The use of structured interviews is the best way to maintain consistency in the data being collected. Interviewer training is important in order to maintain as much consistency in the interviews between study centers as possible.

Because we are using structured and unstructured interviews, we can achieve even more consistency if all interviewers conduct the interviews in a similar way. Therefore, ask each question as it is written. Do not reword the question. Also, ask the questions in the order they are given in the interview form. Hopefully, by following these procedures we can achieve a high degree of consistency in the way the interviews are conducted.

3. Style of the Interview

The interview style is also important and some of the components that are generally considered to be acceptable interview style are listed below. In addition to the components of style listed below, the following interviewer characteristics are also very important: Politeness is very important since we will be asking sensitive questions to strangers, in a situation where they
may be uncomfortable. Sensitivity on the part of the interviewer is also important, in order to know how and when to be more or less assertive in asking for information. Besides these qualities, please develop your style in accordance with these guidelines:

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

b. Non-interpretive style. As above, the interviewer should not use a style that might be considered teaching or preaching. An interpretive response is one which indicates that the interviewer's intent is to teach. We are interested in the respondent's impression of what was happening, not in the interviewer's impression.

c. Allow for respondent to complete sentences. Do not try to help the respondent by answering the questions for him/her. No matter how slowly the respondent is speaking, putting words in the respondent's mouth or not allowing the respondent to finish thoughts will generally alter the information which the respondent is attempting to give. However, long hesitations may be bridged by asking appropriate questions.

d. Supportive remarks. Remarks which indicate that the intent of the interviewer is to reassure, to pacify, or to reduce the intensity of the respondent's feelings are appropriate. However, these should be in keeping with local terms and expressions, and should be short so as not to detract from the interview itself.

e. Probing. This is an important response style which will be discussed further. A probe is a response which indicates that the interviewer's intent is to seek further information, to provoke further discussion along a certain line, or to question the respondent. Direct probes will be specific questions about details of what the respondent said.

f. Non-directive, or understanding. A typical non-directive response might be "I see". This is the general idea of understanding murmuring. The interviewer might also repeat what the respondent just said. This may prompt the respondent to elaborate.
4. Gain Rapport with the Interviewee before Commencing Interview

The first step in gaining the confidence of the respondent is a straightforward, believable introduction of the interview and the reason for this contact. It may help in gaining rapport with the respondent if you tell him/her a little about yourself, such as where you are from, and your background, etc. If the respondent seems to hesitate or has some questions, the interviewer must be prepared with a more detailed explanation of why the information is needed. Also, if the respondent raises the issue of the confidentiality of the information collected, the interviewer must be prepared to reassure him/her of the precautions taken to respect their privacy.

5. Interviewer Error

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

The following are the common interviewer errors:

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

b. Probing errors. Failing to probe when necessary, biased probing, irrelevant probing, inadequate probing, preventing the respondent from saying all he or she wishes to say.

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

d. Flagrant cheating. Not asking a question but recording a response, recording a response when the respondent does not answer the question asked. These kinds of errors do occur and this has been amply documented by various studies. Cheating has been shown to be more common when the interviewer is in an uncomfortable situation with the interviewee, i.e., he/she is difficult. In such situations the question should still be asked and if the participant refuses to answer the question(s), the refusal should be documented on the form.
6. Circumstances for the Interview

We will not have very much control over the circumstances for the interviews. However, the following should be considered in arranging for conducting interviews:

a. Time. There will be little control over the time of the interviews, since we will have many different interviews to carry out over a short period of time. When possible, the interview should be conducted after the snack has been served, otherwise the interviewee may tend to be somewhat uncomfortable.

b. Place. The place for the interview should be chosen where there are as few distractions as possible. Try to select a place where the location is quiet, comfortable and private. If it is possible, it is ideal to sit at a table, with the interviewer facing the interviewee, so that the interviewer can organize the papers. Privacy is very important. If the respondent will need to refer to records during the interview, be sure that the records are available before the interview begins.

7. Asking Procedures

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

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

b. Read the questions exactly as they are worded in the questionnaire. If the question is misunderstood, then it may be repeated, interchanging local terms, if necessary for understanding.

c. Read each question slowly.

d. Use correct intonation and emphasis.

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

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

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

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

i. Do not add apologies or explanations for questions unless they are printed in the questionnaire.
PROBING: Probes are additional questions asked or statements made by the interviewer when the answer given by a respondent is incomplete or irrelevant. Probing has two major functions: (1) To motivate the respondent to reply more fully; (2) to help the respondent focus on the specific content of the question. It must fulfill these functions without biasing the respondent's answers. However, probes, when they are used, MUST be neutral. Probing can introduce bias, such as by summarizing your understanding of the response to the subject when an unclear response has been given, or by offering some alternative interpretations from which the respondent can choose, and this must be guarded against.

The following are NON-DIRECTIVE methods of probing:

a. Repeat the question (RQ). All that may be required to clear up a vague answer may be to repeat the question. You may begin by saying "I am not sure that I understood you, let me just repeat the question so that I can be sure to get your answer right."

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

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

d. Neutral questions or comments. Various neutral probes may be used for purposes such as clarification, specificity, or completeness: "What do you mean exactly?", "In what way?", "Could you be more specific about that?", "Anything else?", "Can you tell me more about it?"

e. Interpretation. Make sure that the question was understood, since that may be the reason for incomplete answers. You may need to ask the question again, perhaps substituting some local terms, if there is a problem in interpretation.

FEEDBACK: The provision of feedback by the interviewer to the respondent about his or her performance has been the subject of much research. Some studies have shown that the use of feedback in health-related surveys increased the amount of reporting of most events. Your decision about whether to provide feedback may depend upon the performance of the person you are interviewing and your experience in the benefits of providing feedback.

8. Specific Instructions for Telephone Interviewing

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

9. Instructions for Recording Responses

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

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

a. Make sure that you understand each response.

b. Make sure that the response is adequate.

c. Do not answer for the respondent (i.e., do not infer a response from an incomplete or inadequate reply).

d. Begin writing as soon as the respondent begins talking. (The respondent's interest may be held by repeating the response aloud as you are writing).

e. Use the respondent's own words and record the answers verbatim.

f. Include everything that pertains to the question's objectives.

g. Note in the questionnaire the nature and place of each probe used.

h. Do not erase anything. If a response is wrong, strike it out and enter the correct response above the previous response.

i. Write "refused/8" beside any question that the respondent refused to answer.

1.4.3 Training & Quality Control of Interviewers

1. Training

Central training for interviewers was conducted at the training session in Oklahoma City (January 29 – February 2, 2001) prior to the start of exams. Interviewers were trained in the use of a standardized procedure for administering each questionnaire. Training included instructions
in research interviewing techniques and in completing each form. Interviewer skill training includes:

(a) adherence to the standardized protocol
(b) use of non-judgmental attitudes
(c) degree and nature of prompting permitted
(d) dealing with problem interviewing situations
(e) handling participants’ comments and recording relevant information on the note logs
(f) post-interview responsibility for the data

2. Quality control of interviewers

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

1.5.1 Blood Pressure

As blood pressure rises, so does risk of ischemic heart disease and its complications. The range of normal blood pressures is wide. Even within the "normal range", risk increases as the upper limits are approached. Usually, blood pressures are expressed as systolic pressure/diastolic pressure; values. 140/90 mmHg or higher are considered to be hypertensive for adults. Middle-aged persons with a diastolic blood pressure of 90-104 mmHg (so called "mild" hypertension) have a risk of heart attack that is about 70 percent higher than that of persons with a diastolic pressure under 80 mmHg (normal value). Persons with a diastolic blood pressure exceeding 104 mmHg (moderately severe to severe hypertension) have a risk more than twice that of those with a normal value. Hypertension is an especially strong risk factor for stroke, renal disease, and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure.

1.5.2 Measurement of Body Fat

Although early records are not conclusive, all evidence indicates that obesity among American Indians was rare until the last century. Their farming and hunting lifestyles which were associated with high degrees of physical activity and the lack of consistently abundant food sources, probably assured the maintenance of a lean population. However, with the advent of "Westernization" and the reservation system, obesity has increased steadily among all Indian tribes and is now a major health problem. It is thus essential to evaluate the extent of obesity in the individuals in this study in order to ascertain its heritability, role in cardiovascular disease, and relationship to risk factors such as diabetes and hypertension.

In the past, assessment of obesity in population studies was invariably accomplished either by algorithms such as ratios of weight to height, or by measurements of skin folds using calipers. This was because assessment of body composition required either very expensive equipment or time consuming procedures, such as underwater weighing. Within the past few years, instrumentation has become available to allow estimates of body composition from measurements of tetrapolar impedance. This measurement of bioelectrical impedance is quick and easy to perform and has been extensively validated against densitometry. These validations were first performed by Lukaski et. al. and by Roche et. al., in a wide variety of individuals. The conductivity increases in individuals with low percent body fat and the instrumentation calculates the percent body fat utilizing a computerized algorithm.

1.5.3 Anthropometric Measurements

Among obese individuals, the distribution of body fat is related to certain patterns of morbidity. Vague and co-workers have observed that body fat distribution differs among obese individuals, and that obese subjects can be roughly divided into two groups depending on whether accumulation of body fat is subcutaneous and peripheral (referred to as gynecoid or female type obesity) or whether the fat accumulation is central and primarily in the omentum (referred to as central or android obesity). The latter distribution has been shown in a number of
studies to be consistently associated with dyslipidemia, hypertension, insulin resistance, and cardiovascular disease. Most studies have shown that central obesity is a risk factor for coronary artery disease.

No systematic studies of body fat distribution or its heritability have been made among the American Indians. However, visual observations suggest that central obesity is much more prevalent among this racial group.

The quantification of central vs. peripheral obesity is not well standardized. Original studies were done simply by photographs and visual evaluations. This was supplanted by body circumference measurements with investigators generally taking the ratio of the body circumference at the waist to the hip or the thigh as a measure of fat distribution. However, it is clear that the body fat of interest in central obesity is the non-subcutaneous, and therefore, whole body scanning devices are necessary for a precise evaluation of this depot. Nevertheless, it has been shown in a number of population studies that the comparative circumference measurements are an approximation of the body fat distribution and the only practical techniques usable in a field study.

1.5.4 Measurements of Peripheral Vascular Disease

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

A thorough evaluation of peripheral arterial occlusive disease usually entails both a history and a physical examination including measurements of pulses and segmental blood pressures and then more complex measures such as angiography or sonography. The latter two techniques are both expensive and difficult to apply in a field setting. On the other hand, both Criqui et al and Beach et al have used segmental blood pressures measured by a simple doppler instrument in studies involving hundreds of patients. In addition, the correlation between quantitative velocity measurements and segmental blood pressures with occlusion as measured directly by angiography has been established.

Because of time limitations and economic consideration for purchase of equipment, the following indices of peripheral vascular disease will be made in this study.

1. Rose Questionnaire for intermittent claudication.
2. Palpation of posterior tibial and dorsalis pedis pulses.
3. Measurement of the ratio between blood pressures taken at the antecubital fossa (brachial) and ankle (posterior tibial) using a doppler listening device (Imex Elite 100 Doppler).

1.5.5 Electrocardiograms

All participants will have a resting electrocardiogram so that evidence for ischemic changes and left ventricular hypertrophy can be determined. Heritability of ECG abnormalities can be evaluated and related to their ability to predict CVD.

1.5.6 Overview of Laboratory Measurements

Table 1.1: Definition of Lipoproteins

<table>
<thead>
<tr>
<th>Class</th>
<th>%Lipid</th>
<th>% Protein</th>
<th>Origin and Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chylomicrons</td>
<td>99</td>
<td>1</td>
<td>Intestine; transport of newly absorbed dietary fats; normally not detectable in plasma after a 12-hr fast; creamy layer on top of plasma tube after 12 hrs in the refrigerator.</td>
</tr>
<tr>
<td>VLDL, very low density</td>
<td>90</td>
<td>10</td>
<td>Liver; transport of newly synthesized triglycerides to peripheral tissue; lipoprotein approximately 80% of plasma TG is in this fraction</td>
</tr>
<tr>
<td>LDL, low density lipoproteins</td>
<td>75</td>
<td>25</td>
<td>Liver; derived from VLDL after the triglycerides have been metabolized; transport of cholesterol; approximately 75% of plasma cholesterol is in this fraction</td>
</tr>
<tr>
<td>HDL, high density lipoproteins</td>
<td>45</td>
<td>55</td>
<td>Liver and intestine; transport of cholesterol from peripheral tissues back to the liver</td>
</tr>
</tbody>
</table>

1. Lipoprotein Profile

Lipoprotein Physiology: Lipoproteins are basically spherical particles ranging widely in size and composed of two components: the lipids (or fats) in the core of the particle and the proteins on the surface of the particle. The two types of lipids, which we are interested in measuring as part of the present research, are triglyceride (TG) and cholesterol (CHOL). Depending on the relative amount of these two components and
various associated proteins, different classes of lipoproteins can be defined (Table 1.1 above).

The evidence is overwhelming from both cross-sectional and prospective studies in a wide variety of populations that total and LDL cholesterol are significantly associated with the occurrence of atherosclerotic coronary vascular disease (ASCVD), and the HDL cholesterol has a negative or "protective" effect. There are several lines of evidence that level of lipoprotein lipids and apoproteins are genetically determined.

The relationship of CVD with total triglycerides or VLDL triglycerides has been more controversial. Several population studies have now demonstrated an independent positive association between elevated triglycerides and ASCVD. Triglycerides are also closely linked to obesity, hyperglycemia and low HDL, and are therefore important to measure because of their reflection of these disorders. Some of the ambiguity concerning the associations between triglycerides and coronary vascular disease stems from the possibility that all elevations in triglycerides may not be equal. That is, elevated VLDL with a high proportion of protein, or cholesterol rich VLDL such as that observed in many diabetics may be more atherogenic than large, triglyceride-rich VLDL.

Measurements are made of total plasma cholesterol and triglyceride. HDL is measured after precipitation of LDL and VLDL. In SHS-IV, the LDL cholesterol concentration is estimated by the Friedewald formula for samples with triglycerides ≤ 400 mg/dl (variable name: LDL_EST) and directly measured when triglycerides > 400 mg/dl (variable name: LDL_DIRECT). For data analysis purposes, the two sets of data can be combined into a single LDL cholesterol variable, provided that the above protocol is mentioned in the methods section of potential publications.

**LDL Direct Measurement:** LDL cholesterol is directly measured by the precipitation of LDL cholesterol with buffered polyanionic reagent while leaving HDL and VLDL in the supernatant solution. The supernatant is then assayed using an enzymatic cholesterol reagent. The difference between the cholesterol value of the supernatant and the untreated specimen is equal to the amount of LDL cholesterol in the sample.

2. **Glucose**

Diabetes is a well-established, major risk factor for CVD and is very prevalent in the Strong Heart Study population. Impaired glucose tolerance, fasting hyperinsulinemia, and diabetes/obesity have strong genetic components, and the fasting plasma glucose test is a cost-effective test to detect these traits.

Glucose concentrations will be measured in fasting samples, and the diagnostic criteria developed by the ADA will be applied to define NGT, IFG and diabetes. Previous SHS data indicate prevalence rates of DM by ADA criteria are similar to those using OGTT, and that IFG and DM - ADA are similar to IGT and DM - WHO in predicting CVD. Blood for this assay is obtained in tubes containing fluoride to prevent consumption of glucose by WBCs. Previous studies have shown that tubes of blood containing fluoride
can be held on ice for up to four hours before isolating the plasma, and glucose values are stable. Glucose is measured on the Hitachi analyzer using a glucose oxidase technique.

3. Hemoglobin Alc

Hemoglobin Alc will be measured only in those individuals whose fasting plasma glucose ≥ 110 mg/dL. This is the same practice approved under Phase III, and it minimized the expense of measuring HbAlc in normoglycemic individuals. HbAlc may be a better marker of the entire symptom complex of diabetes than glucose values derived from the oral glucose tolerance test. Little et. al. reported that 68% of Pima Indians with impaired glucose tolerance and elevated HbAlc values went on to develop diabetes on follow-up testing 1/6 to 6.1 years later. Inclusion of HbAlc will give an integrated, longitudinal measure of glycemia and allow a better estimate of glucose control. It will also be of practical importance to both participants and field investigators.

4. Insulin

Insulin concentration in blood has been reported in several recent studies to be an independent risk factor for the development of CVD. Although the mechanism of this association has not been established, there are several intriguing possibilities involving its link with insulin resistance, hypertension, dyslipidemia, and thrombosis. The first three factors have been linked in several population studies in individuals with central obesity. However, some studies suggest that these factors are not universally associated. It will thus be of interest to measure fasting insulin concentrations in individuals at the three centers, to evaluate its heritability alone and in relation to blood pressure, triglycerides, body fat, waist/hip ratio and fibrinogen.

Insulin will be measured using an overnight radioimmunoassay developed as a modification of the method of Morgan and Lazarow. It utilizes a double antibody method; both antibodies and labeled insulin can be obtained efficiently from commercial sources. Although no absolute reference plasma pools are available for insulin, we have constructed our own control pools. The assay has proven to be stable over time with a coefficient of variation of 8-10%. One source of error in insulin measurements occurs in some individuals who have been previously treated with insulin, and thus have circulating insulin antibodies. Samples from insulin treated diabetics will be flagged at the time of drawing, so that their data can be separately evaluated.

5. LDL Size

Size of LDL particles can be estimated by gel exclusion electrophoresis. The smaller, faster-migrating LDL is termed the “B” type. It is atherogenic and strongly associated with coronary heart disease. The small dense LDL particle is associated with increased triglyceride and apoB levels, and decreased apoAI and HDL cholesterol. The small LDL particle is more susceptible to oxidation and this may contribute to its atherogenic potential. A significant proportion of the risk of carrying the type B particle is genetically endowed, and there are important differences between the sexes.
6. **Fibrinogen**

Fibrinogen is well established as an independent risk factor for prevalent and incident CVD in many populations, and fibrinogen has been shown to be an independent predictor of CVD morbidity in SHS. Fibrinogen was highest in the Arizona participants (and quite high compared to other US populations) and lowest in the Dakota participants, being closely associated with diabetes prevalence. An analysis of the correlates of fibrinogen revealed that the strongest correlate of fibrinogen, by a large margin, was the level of albuminuria, independent of diabetes status. Fibrinogen may be linked to CVD either through its thrombotic or inflammatory properties. Fibrinogen levels have been closely linked to other measures of vascular disease such as ankle-arm blood pressure index, in other populations.

7. **PAI-1**

Several reports have indicated that PAI-1 may be an independent risk factor for CVD. This is an attractive scenario, because acute increases in PAI-1 have been associated with hypofibrinolytic states, a clinically significant situation requiring anticoagulation. In the Phase II exam, we measured PAI-1 in the cohort, and in the Phase III Strong Heart Study examination, we measured PAI-1 in the family members only.

Concerning PAI-1 levels and their changes over time, the following additional factors may play a role:

1) The mechanism for the association of PAI-1 with diabetes is unclear, and might be through insulin levels, lipid changes, and/or inflammation associated with vascular disease (as described above for fibrinogen) because PAI-1, like fibrinogen, is an acute-phase reactant. The triglyceride mechanism is intriguing because the lipid levels in the Arizona group were not as abnormal as might be expected from the diabetes prevalence.

2) There is a relatively common genotype (4G---→ 5G change in PAI-1 promoter) that has been linked to the cytokine-mediated and insulin regulation of PAI-1. Measuring PAI-1 would allow us to test if changes in PAI-1 levels are modulated by 4G---→5G genotype, among other possible gene variations.

8. **Urinary Albumin/Creatinine**

Increased concentration of albumin in the urine of diabetic individuals is a strong and independent predictor of all-cause and coronary heart disease mortality. In a study of persons with type 1 diabetes, those who had microalbuminuria had nearly a 200-fold increased risk of cardiovascular disease in the decade following the initial observation compared to those whose urine had normal amounts of albumin. Furthermore, urinary
A/Cr is an independent predictor of CVD in SHS. These findings led to speculation the albumin “leak” in the glomeruli reflects a widespread capillary vasculopathy affecting the heart, eyes and, perhaps, other organs. The appearance of nephropathy may not be a simple consequence of diabetes. Family studies indicate that diabetic nephropathy is more likely to occur among children of parents with nephropathy, families with hypertension, or in siblings of patients with nephropathy. Furthermore, the presence of small, but abnormal amounts of albumin in the urine is predictive of progression to overt nephropathy. It is clear from studies of both types of diabetes that albuminuria clusters among families and several candidate genes have been proposed.

9. CBC and Chemistry Profile

The hematocrit and CBC will be determined locally at each center by standardized automated methods at no laboratory cost. A 12-analyte chemistry profile will be done at the Washington Hospital Center pathology laboratory. Total protein determinations will be used to estimate whole blood viscosity, and hematocrit is related to CVD risk. These relatively simple measurements accurately predict whole blood viscosity (multiple r=0.78 – 0.92, at several shear rates). Numerous studies document that increased hematocrit, plasma viscosity, or whole blood viscosity are associated with hypertension and diabetes, and predict subsequent cardiovascular events. One possible mechanism of these associations is the increased shear stress imposed on the arterial intima by more viscous blood flowing past it. The chemistry profile is a cost-efficient group of tests that will be used to assess rates of hepatocellular disease (transaminases, bilirubin), gall bladder/bile duct obstruction (alkaline phosphatase), hyperproteinemia, electrolyte imbalance and hyperuricemia.

10. ApoE Genotype

Apolipoprotein E (ApoE) is a ligand for the LDL receptor. Three apoE genotypes occur in humans, and variations in cholesterol levels and coronary heart disease are associated with the phenotypic patterns. Data from elderly Finnish men showed that the apoE4 gene was a significant predictor of coronary heart disease death. The Framingham Study found that apoE phenotype 4 was significantly associated with coronary heart disease in both sexes, even after adjustment for hypertension, smoking, obesity, diabetes, HDL and LDL cholesterol. Among Strong Heart Study participants, the prevalence of ε2 was significantly lower than among White Americans. LDL cholesterol and apoB concentrations were highest among those with ε4 and lowest among those with ε2. Concentrations of HDL cholesterol and apoA1 were lowest among those with ε4 and highest in ε2. ApoE was significantly related to glucose control in women, but not in men; those with ε4 had higher glucose and HbA1c concentrations.

ApoE Genotype Method: The apoE gene is first amplified by PCR. The amplified product (268 bp) is then exposed to Hhal restriction enzyme and the digestion products separated by agarose or polyacrilamide gel electrophoresis. The DNA fragments are visualized by ethidium bromide staining. ApoE genotype and phenotype methods are in agreement >98% of the time. Blinded duplicates show near-perfect agreement. (Reference: van den Maagdenberg AM, de Knijff P, Stalenhoef AF, Gevers Leuven JA, Havekes LM, Frants RR Apolipoprotein E*3-Leiden allele results from a partial gene duplication in exon 4. Biochem Biophys Res Commun. 1989;165:851-7.)
11. ApoB

Apolipoprotein B (apoB) is the major protein component of LDL and is a constituent of chylomicrons, intermediate density lipoproteins and VLDL. Several studies suggest that concentrations of apoB correlate more closely with the risk of ASCVD than routine lipid measurements. ApoB concentrations are independent risk factors for carotid atherosclerosis and silent cerebral infarction in Japanese men. In some studies, multiple regression analysis shows that ApoB levels are significantly and independently associated with angiographically proven carotid atherosclerosis and with premature coronary heart disease.

There is strong evidence for the genetic contribution to the concentrations of apoB. For example, the Bogalusa Heart Study described low ratios of apoAl:apoB among offspring of parents who had coronary heart disease. Similar associations have been described among patients undergoing coronary arteriography at an early age in whom apoB levels show strong familial aggregation. Several studies found evidence that apoB concentrations are influenced by a single gene with large effect. This gene is unlinked to the apoB structural locus. It will be imperative to have reliable measurements of apoB among the Strong Heart Study offspring to perform linkage analyses.

12. ApoA1

Apolipoprotein Al (apoAl) is a central element in reverse cholesterol transport. Numerous cross-sectional population studies found an inverse relationship between apoA1 levels and coronary heart disease, and it is a regular predictor of CVD in SHS. Octogenarians who are free of coronary heart disease have significantly higher apoAl levels than age-matched controls with coronary heart disease. As with apoB, genetic factors affect the level of apoAl and presumably the risk of coronary heart disease. The concentrations of ApoAl are strongly influenced by the rates of catabolism and synthesis. Prenger et al. reported that a single dominant gene Mendelian model of transmission accounted for variation in apoA1 levels among siblings of patients undergoing cardiac catheterization. The singly locus accounted for 37-49% of variation in observed apoA levels.

13. Endothelin-1 and VCAM

The coronary arteries have an active role in the pathogenesis of atherosclerosis and coronary heart disease; they are not simply the passive repositories of injury caused by oxidative stress, dyslipidemia, thrombosis and sheer injury. Both genetic and environmental factors affect the vessel’s susceptibility to injury and its response in terms of tone and vascular wall proliferation. Since SHS began, a great deal has been learned about the molecular processes leading to vascular wall injury and its responses to damage.

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

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

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

SVCAM-1 will be measured using a VCAM-specific, commercially available monoclonal solid-phase ELISA kit (R&D Systems, Inc., Minneapolis, MN). Interassay CV is 8.5-10.2% and the sensitivity <2.0 ng/ml. Expected mean human values are ~550 ng/ml with a 2-SD range of 395-714 ng/dl.

Endothelin-1 will be measured using an endothelin-1 specific, commercially available, monoclonal solid-phase EIA kit (R&D Systems, Inc., Minneapolis, MN). Interassay CV is 5.1-6.5 and sensitivity <1.0 pg/ml. Expected mean human values are ~0.6 pg/mL with a 2-SD range of 0.3-0.9 pg/mL.
14. Thyroid-Stimulating Hormone (TSH)

Over the years, several studies have identified hypothyroidism as a stimulus to dyslipidemia and, potentially through that mechanism, coronary atherosclerosis. Since these studies have depended on use of coronary arteriography, an invasive technique with a measurable complication rate, little is known of the relation of thyroid metabolism to atherosclerosis in population-based samples. In addition, it is well known that skeletal muscle relaxation is slowed in the setting of hypothyroidism, but whether this phenomenon occurs in arterial and cardiac muscle is unknown. Preliminary data from SHS reveals that 553/4475 subjects in Phase I were receiving thyroid replacement therapy. This yields a prevalence of treated hypothyroidism of 3.4% vs. a pooled prevalence of 0.5-2% in nationally published studies. We will perform a third-generation TSH assay to be used in Phase IV is a solid-phase chemiluminescence immunometric assay (DPC Immulite Third Generation TSH). The assay is linear between 0.00s and 75 ulU/mL and thus should be useful in detecting hypo-, normal, and hyperthyroid patients.

1.5.7 Measurement of Physical Activity – Pedometry

Pedometer – Activity Monitor

The physical activity questionnaire, in general, is the most common measure of physical activity levels in research studies. However, an activity questionnaire alone may not be the best way to quantify lower intensity, variable frequency, lifestyle activities such as walking (Kriska, 1990; Sallis, 1985). An objective measure of activity will be used to supplement the information collected previously in SHS by an activity questionnaire. The objective measure that we plan to use is the Yamax Accusplit AE120 Activity Meter, a simple, inexpensive, pedometer.

Step monitors are now successfully being used to estimate levels of movement expressed as "daily steps taken throughout the day" and to document activity changes in intervention efforts (Yamanouchi, 1995). However, activity monitors also have their own set of limitations, such as the inability of capturing cycling, swimming and upper body movement. The Yamax Accusplit AE120 step counter will be given to each participant at the time of the clinic visit to wear at home for seven consecutive days. The Yamax Accusplit AE120 Activity Meter is a pocket-sized pedometer that displays the number of steps taken. Verbal/written instructions for the monitors will be presented to the participant with a diary that needs to be completed on the seven days that the monitor is worn (see forms in Appendix D of this volume). The participants will keep the pedometers and will be encouraged to use them to monitor and increase their physical activity levels.
1.6 PHYSICAL EXAMINATION

During the examination, participants wear a gown, or loose fitting clothes that do not impair accurate body measurements and the examination. It is helpful to have them wear large scrub pants to enable the pant legs to be rolled up for the ECG examinations. Shoes and socks are removed for the supine examination and weight and height measurements. The form to be used is given in Appendix D.

1.6.1 Anthropometry

Anthropometry is performed before the clinic snack with the participant's bladder empty. The subject may wear a scrub suit or clothing into the station. Measurements may be taken over the scrub suit or light clothing only. Make sure that the pockets are empty and the belt is removed. Height and weight measurements are not to be taken with the participant wearing shoes.

Measurements, if possible, are taken by a team of two persons (one acting as observer, the other as recorder). If two are available, the first observer takes the measurements, calling out the value of the measurement.

The first observer keeps the measuring instrument in place until the recorder repeats the number. The recorder also checks the examinee's position during the procedure. If a single observer performs the measurements, each should be recorded immediately after they are taken. Values taken are rounded to the nearest unit indicated for each measure. Fractions less than 0.5 will be omitted and fractions greater than or equal to 0.5 will be rounded up to the next higher unit.

1. Height and Weight

a) Standing Body Height

The participant stands erect on the floor or the horizontal platform with his/her back against the vertical mounted ruler, heels together and against the vertical ruler, looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane which includes the lower margin of the bony orbit and the bony socket containing the eye the most forward point in the supratragal notch just above the anterior cartilaginous projections of the external ear) (Figure 1). The right angle is brought down snugly but not tightly on the top of the head. A foot stool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method described above. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and
the metal ruler is mounted perpendicular to the floor). A chart converting centimeters to inches is on the wall or available for use in informing the participant of his/her height in inches.

b) Body Weight

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

2. Supine Waist (Abdominal) Girth

An anthropometric tape is applied at the level of the umbilicus (navel) with the patient supine (Figure 2) and the participant is instructed to "breathe quietly". The measurement is made and recorded to the nearest centimeter using the rounding method described above.

3. Erect Hip Girth

Instruct the participant to stand erect yet relaxed with weight distributed equally over both feet. The hip girth is measured at the level of maximal protrusion of the gluteal muscles (hips) (Figure 3). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest centimeter using the above rounding method. Only one measurement is made. The greatest source of error for this measurement is due to not having the tape horizontal. Technician(s) should check the position of the tape to assure its correct position from both the front and back.

4. Upper Arm Circumference

The participant sits on a table or stool so that the right arm hangs freely with the right hand resting on the right knee. The observer applies the tape measure horizontally at the midpoint between the acromium and olecranon (Figure 3). Record the measurement to the nearest centimeter using the rounding method described above. This measurement is used to select the proper size blood pressure cuff.

A Novel Products tension tape is used to measure both abdominal and hip girth and the upper arm circumference.
Figure 1 (a). General Description: The scapulae, or shoulder blades, are large, triangular, flat bones situated in the dorsal part of the thorax between the levels of the second and seventh ribs. A sharp ridge, the spine, runs diagonally across the posterior surface of the flattened, triangular body. The end of the spine projects as a flattened, expanded process called the acromion. This process articulates with the clavicle.

Figure 1 (b). the Frankfort Plane: The horizontal plane which includes the lower margin of the bony orbit, the bony socket containing the eye and the most forward point in the supratragal notch, the notch just above the small prominence of skin covered cartilage projecting over the meatus of the external ear.
Figure 2. Location of Waist Girth Measurement

Supine waist girth at level of umbilicus
Figure 3. Location of Upper Arm, Hip, and Calf Circumference
1.6.2 Training and Certification for Anthropometry

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

1. Training is conducted centrally by a staff experienced in anthropometry.

2. Each field center trains one or two individuals before the baseline examination. One individual from each center is designated the center's anthropometry supervisor.

3. If additional personnel are needed by a center to perform anthropometry, training is provided by the center's anthropometry supervisor.

4. Training includes:
   a. Introduction - rationale for body size measurements, overview of technique, expected limits of reproducibility, and pitfalls related to anthropometry.
   b. Demonstration of technique – the trainer demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as recording of data.
   c. Practice - technicians divide into groups of three, and two techs perform measurements on the third in a round-robin fashion. This is done under the observation of staff experienced in anthropometry. Differences in technique and clarification of problem areas are discussed.
   d. Testing - several subjects are assessed independently and blindly by each technician. Each technician's measurements are compared with the trainer's measurements and the results discussed in class. The four subjects examined have four distinctly different body types: lean, obese, athletic, and aged.
   e. Certification - technicians must measure one or more test subjects and be within certain standards of error:
      1) The waist and hip measurements must agree within 2 cm on each subject, and the arm and height measurements must agree within 1 cm.
      2) The weight must agree within 1 kg.

If these are met, the subject receives certification for field work. Trainees who have problems are identified, and they are allowed to practice and try again to be certified.
1.6.3 Sitting Blood Pressure

1. Introduction

In the Strong Heart Study, sitting blood pressure is measured in a resting state, using 3 measurements with a Baum mercury sphygmomanometer. Within any one individual, variation in blood pressure is substantial, even within a few minutes and particularly under conditions perceived as stressful. Use of three replicate readings tends to reduce this short-term variation.

2. Standardized Clinic Procedure

Correct measurement of blood pressure is of the utmost importance to the success of this study. It is essential that the procedure described below for measuring blood pressure be followed exactly. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

3. Description of the Equipment

a) Stethoscope

A standard stethoscope with a bell is used. Korotkoff sounds are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10-12 inches from the bell piece to "Y" branching. This length provides optimal acoustical properties and allows the observer to read the sphygmomanometer at eye level and in a comfortable position. Ear pieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

i) The earpiece should be directed downwards and forwards into the external ear canal.
ii) The earpieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.
iii) The valve between the bell and the diaphragm should be turned in the correct direction.
iv) The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery - immediately below the cuff and medial to the cubital fossa above the medial epicondyle of the radius and posterior to the biceps muscle. Light pressure accentuates the low-pitched sound and avoids compression murmurs. When pressing too heavily with the bell on the artery a murmur can be heard which may prolong the apparent duration of phase 4 and give inaccurate readings.

b) Sphygmomanometers
Standardized Baum mercury instruments are used for all clinic visits. The mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to the rubber tubing from the inflatable rubber bladder of the cuff. As the inflatable rubber bladder is filled with air, the air pressure in the bladder travels through the connecting rubber tubing. The pressure pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., rounded up to the nearest even number.

c) Cuffs and Bulbs

Proper size of the cuff is essential for accurate blood pressure measurement. Study Centers have four standardized Baum cuffs available – pediatric, adult, large adult, and thigh cuff.

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the Strong Heart Study, arm size is measured and the cuff size is selected as follows:

<table>
<thead>
<tr>
<th>Cuff Size</th>
<th>Arm Circumference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric</td>
<td>&lt; 24 cm</td>
</tr>
<tr>
<td>Adult</td>
<td>24 to 32 cm</td>
</tr>
<tr>
<td>Large Adult</td>
<td>33 to 41 cm</td>
</tr>
<tr>
<td>Thigh</td>
<td>&gt; 41 cm</td>
</tr>
</tbody>
</table>

4. Blood Pressure Measurement Instructions

Some of the many extraneous factors influencing blood pressure are controlled by standardizing the measurement technique and the environment in which the measurement is made. Uncontrolled factors, such as time of day, arm circumference, recent use of caffeine, and identity of the observer are recorded, so that they can be taken into account during analysis.
The Strong Heart Study participants are asked to avoid caffeine (tea, coffee, chocolate, and soft drinks), eating, heavy physical activity, smoking and alcohol intake for twelve hours and to refrain from smoking for at least one-half hour prior to the clinic visit. Current drug intake, including medications affecting blood pressure and non-prescription drugs, is recorded on the day of the examination. A detailed history of smoking and alcohol intake are also recorded.

5. Staff Preparation for Measuring Blood Pressure

In relating to the Strong Heart participants, remember that participation in the study is voluntary. Participants are given full explanation and instructions about the preparation for the blood pressure examination and an opportunity for questions. The setting in which blood pressure measurements are made is standardized.

6. Measurement Procedures

The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 minutes to make three blood pressure measurements including the initial five-minute rest. The blood pressure measurements are made early in the clinic visit sequence immediately following the reception and informed consent, and more than 15 minutes after phlebotomy. Once the participant is given instructions and explanations and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

a) If the participant indicates that there is a medical or postsurgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the data collection form that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.

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

c) Palpate the brachial artery (just medial to and above the ante-cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery.

d) Record the time. Allow a five-minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary.

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

f) Measurement 1: Connect the cuff to the manometer. Inflate rapidly to the pulse obliteration level + 30 mm. Holding the pressure constant with the bulb, wait 5 seconds. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. If the mercury column falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the higher number should be used.

g) Measurements 2 and 3: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement in step f above and disconnect cuff.

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

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

7. Reporting the Blood Pressure Results to the Participant

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

8. Procedure for changing the peak inflation level

Occasionally the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. The observer immediately deflates the cuff by releasing the thumbscrew and disconnecting the cuff tube. Then have the participant hold the cuff-wrapped arm vertically for five seconds. Proceed with blood pressure measurement, starting at a new peak inflation level, 10 mmHg above the previous level.
9. Sitting Blood Pressure Training and Certification

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

The first training session begins with a description and demonstration of the correct blood pressure measurement procedure. Trainees watch the American Heart Association blood pressure instruction videotape. A checklist is used for certifying all persons taking BPs (Appendix A – 3). Simultaneous BPs will be recorded using a Y stethoscope as described in Appendix A – 4.

It is the responsibility of each field center to conduct these procedures and report to the Coordinating Center when the procedures are completed.

Y tube stethoscope observations are made in conjunction with the blood pressure training video during initial training and for quarterly quality control. The trainer has the observer-trainee go through the entire blood pressure measurement procedure using a quality control checklist. The observer and trainer listen with the Y Tube and record the values on separate sheets. Two measurements on one subject are obtained. Measurements by the trainer and the trainee should agree within 4 mmHg on any one reading (systolic or diastolic) and averages should agree within 3 mmHg.

10. Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed centrally and applied at all field centers. These measures include:

a) recruitment of the most qualified personnel
b) standardized training and certification
c) retraining as necessary
d) observation of data collection by supervisors, using the checklist given in Appendix A – 3. One checklist is used for each technician and mailed to the Coordinating Center each month
e) frequent staff meetings to provide feedback
f) editing of data, both manual and by computer
g) a quality assurance program administered by the Coordinating Center
h) simultaneous Y Tube observation of each technician by the blood pressure supervisor
i) equipment maintenance program
11. Technician Training and Quality Control

Blood pressure technicians are trained centrally prior to participant recruitment. New technicians hired after the start of the study are trained locally by the Study Coordinator or a designated "Blood Pressure Supervisor".

The Coordinating Center directs a blood pressure quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure data every 3 months, comparing means for each technician with the values for all technicians, by center. These statistics are adjusted for weight, age and sex of the participants by the use of Z-scores. Arbitrary levels of Z-scores, (which can be modified according to performance) are used to detect possible systematic deviations in blood pressure measurement by individual technicians. Digit preference is also monitored for each technician. The Form for Recording Simultaneous Blood Pressure Observations in Appendix A – 4 will be used.

12. Equipment Maintenance

Each study center is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the nurse clinician, and all staff are instructed to report any real or suspected equipment problems to that person promptly.

All checks, inspections, cleanings and problems indicated are documented and recorded by date in a permanent log. Problems and solutions are also recorded. The local nurse clinician sends a copy of this log monthly to the Coordinating Center. A copy of this log is given in Appendix A – 5.

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

i) the zero level
ii) mercury leakage
iii) manometer column for dirt or mercury oxide deposit
iv) condition of all tubing and fittings

The equipment is cleaned if inspection indicates it is needed, or at least once a year. Specific maintenance instructions for the standard sphygmomanometer are provided in Appendix A – 6.

1.6.4 Ankle Systolic Blood Pressure

1. Move the participant to the supine position.

Assist the participant in moving to the supine position on the examination table.

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

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

The posterior tibial artery is usually palpated as it courses posteriorly to the medial malleolus. Even if the posterior tibial pulse is not palpable, the posterior tibial artery is used as the location for the marker line on the cuff for the "over the artery position". Any kinks in the tubing are removed, and any "tugging" of the tubing on the participant's leg is relieved.

3. Procedure for Measuring Ankle Blood Pressure

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

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

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

d) Take a second blood pressure using the same techniques, and record the second blood pressure on the Physical Examination Form.
e) Repeat this procedure to record the left ankle blood pressure.

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

If the participant had his/her sitting blood pressure taken on the right arm earlier in the clinic examination, the cuff is applied on the right arm at this time. The observer then uses the Doppler to record the brachial pressure. The pressure recorded in the right arm is used to calculate the brachial/ankle systolic pressure ratio for both lower extremities.

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

The observer now removes all conduction jelly. Socks and a robe or other garments are now replaced, and the participant is escorted to the next workstation.
Figure 4. Placement of the blood pressure cuff on the ankle. Step 1 - Positioning the lower leg on the cuff.
1.6.5 Electrocardiogram

1. Basic description

a) A Marquette Mac-PC (or Mac-1200) based system will be used (see Volume VI).

b) All ECGs will be transmitted centrally to the New York Hospital - Cornell Medical Center in New York electronically by modem.

c) All ECGs will be read in a standard manner at the ECG Reading Center by Board Certified or Board Eligible Staff Cardiologists and transmitted or mailed back to

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

Step 3. Wrap and secure cuff

"ears" about equal

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Figure 5. Placement of the blood cuff on the ankle. Step 2 and Step 3: Wrapping and securing the cuff
the site of origin for clinical correlation or other action, if required. In any case, all ECGs will be overread and promptly returned.

d) All ECGs will be Minnesota coded at Cornell by computer analysis.

e) The Strong Heart Study will itself maintain a permanent copy of all cardiograms in its possession to assure "perpetual" availability of the study data for study members.

f) A standard level of competence must be demanded of our personnel performing ECGs at each site. A "competency exam" will be conducted of all persons recording ECGs at individual sites by a physician (or other designated person) who will judge the ability of the person being examined to adhere to standard protocol.

2. Minimal Equipment Requirements

a) A Mac-PC with modem (see SHS Phase III Manual, Volume IV) or a Mac-1200 machine (see SHS Phase IV Manual, Volume VI) will be used at each clinic.

b) New York Hospital - Cornell Medical Center will provide free use of their mainframe MUSE (Marquette Universal System for Electrocardiology) system (except for study hook-up costs and paper costs) for the duration of the study. This system can be accessed 24hrs/day by modem and stores all study cardiograms together or by center. Also, floppy disc downloading can be accomplished to a Mac-1200 compatible format.

Transmission instructions and Standardized ECG are given in Volume VI of the manual.

Procedures will differ at each center concerning how ECG readings are supplied to local physicians and IHS health records. A copy of the ECG obtained at the time of performance, if marked "unconfirmed", can be included in the patients chart that day (if so indicated on the participant’s consent form). A clinical reading will be performed at Cornell and returned by reverse transmission procedure WITHIN one week. A hard copy of this clinical reading will also be sent to the Coordinating Center for storage.

All ECGs will be Minnesota coded at Cornell using computer analysis of the ECGs. The Minnesota codes will then be added to the ECG data set by the Coordinating Center for data analyses.
1.6.6 Impedance Measure

The measurement of body fat is accomplished using the Quantum II Impedance Meter made by RJL Equipment Company. This involves a small low frequency current that travels across the body through the extracellular fluids. The measurement of bioelectrical impedance is related to the volume of the conductor and, when expressed as impedance or conductance, is proportional to fat free mass. The participants do not feel anything when this measurement is obtained.

1. Procedure

a) Before beginning, explain to the participant why you are making the measurement, and check to see that the participant has not exercised vigorously for the past 12-hours and has not consumed alcohol in the past 24-hours. Make sure that the subject is not dehydrated. Record past vigorous exercise or alcohol consumption on the data form.

b) Before beginning the test, be sure that the subject cable is securely attached to the RJL spectrum, have the participant remove the right shoe and sock and lie down with the right side nearest to the analyzer;

c) If the examination table is metallic, it must have a foam pad - all of the body must be on the pad.

d) For best results:

i) Use electrodes only once.

ii) Legs should be far enough apart so that the thighs do not touch each other. A towel may be used to prevent the legs and thighs from touching.

iii) Hands and arms should be far enough apart so that the arms and hands do not touch the torso. A towel can be used to prevent the arms from touching the body.

iv) No body parts should be in contact with any external metal (jewelry and pins in bones will not affect the results).

v) Participant's skin should be clean, dry and warm to the touch. If the skin is oily, clean it with an alcohol swab before attaching the electrodes.

Prior to the attachment, cut the electrodes in half bisecting the foil tab. The cut edge of the electrode placed on the ankle and wrist should face toward the shoulder and thigh respectively. The cut edge of the other two may face in either direction.
e) Electrode Placement:

i) Attach the black wires to the foot with the red clip connected to the electrode at the ankle (F1). Attach the red wires to the hand with the red clip connected to electrode at the wrist (H1).

ii) Put H1 on an imaginary line from the protruding bone of the wrist to bisect the ulnar head; make sure that the cut edge of the electrode is toward the shoulder.

iii) Put H2 just above the knuckles of the right hand or on any finger; there should be at least 5 cm difference between H1 and H2.

iv) Put F1 on an imaginary line between the protruding ankle bones to bisect the medial malleolus; make sure that the cut edge of the electrode is toward the thigh.

v) Put F2 just above the toes of the right foot or on the great toe (there should be 5 cm difference between F1 and F2)

Once the electrodes have been properly attached to the subject, the values for resistance and reactance will appear on the screen. Record these on the results sheet. Make sure that the toggle switch is set on x1.

2. Instructions for Impedance Meter

Checking Instrument

Before testing the first patient, be sure that the cables are not crimped or damaged. Place the Resistance/Reactance switch in the resistance position. Place the switch labeled x1/x10 in the x1 position. Attach the 2 clips from one patient cable to one side of 500 ohm resistor provided.

Attach the two clips from the other cable to the other side of the resistor. Turn power on. Resistance displayed should be between 490 and 510 ohms. If resistance is in this range, proceed with patient testing.

Note: Patient cables are made of silver. Take care not to bend or abuse cables. They should be left plugged into instrument to minimize handling, except when relocating instrument.

3. Quality Control for Impedance Measure

Training for the measurement of body fat using the bioelectric impedance meter was accomplished by an experienced nurse to demonstrate the following steps:
a. Instructions concerning the use and verification of the machine.

b. Demonstration by instructor of the procedure.

c. Practice by the individual operators.

d. Certification of operators if instructor and operator achieve an impedance measure where resistance and reactance were each within 15 ohms.

For ongoing quality control in each center, one individual will be designated as supervisor of the impedance measures. This individual will assure that each of the other operators of the instruments is re-certified quarterly by having him/her perform an impedance measure on the same individual as the instructor. These should agree within 15 ohms.

In addition, the instructor is responsible for the monitoring of the impedance meter. The instructor should observe individual operators performing impedance measures at least quarterly to verify consistent and proper technique.

1.6.7 Examination of the Pulses

a) Ankle Edema

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

b) Posterior Tibial Pulse

The examiner palpates inferior to the medial malleolus of each foot. The presence or absence of arterial pulsation is recorded. If in doubt, the examiner compares with the radial pulsation.

c) Dorsalis Pedis Pulse

The superior aspect of each foot is palpated for the presence or absence of this pulse.
1.6.8 Physical Findings to be Confirmed by a Physician to Assure Presence of CHF

The participants should be referred for evaluation by a physician if these findings are noted so they can be confirmed and evaluated for the presence of congestive heart failure.

Bilateral ankle edema, orthopnea, or paroxysmal nocturnal dyspnea.

The standard IHS referral form should be used to refer patients with newly observed physical findings described above to an internist or cardiologist so that the diagnosis can be confirmed and the prevalence of congestive heart failure can be determined. In such cases, use the Physician Referral Form for Diagnosis of CHF in Appendix A – 10.
1.7 REFERRAL GUIDELINES

It is the intention of the Strong Heart Study that individuals who participate in the physical examination will be provided both with education and encouragement concerning a healthy lifestyle aimed at preventing cardiovascular disease. If significant medical conditions are uncovered during the course of the study, participants will receive assistance in arranging appointments for medical care. They will also receive assistance arranging transportation for emergent, immediate and urgent referrals.

1. Referral procedure:

a) All participants reporting for the medical exam will receive appropriate educational materials concerning a heart healthy lifestyle. In addition, the examining personnel, when possible, will endeavor to educate the participants during the exam concerning the importance of risk factor reduction and modifications that the individual might make to improve his/her risk for cardiovascular disease. At the end of the exam, the participant will receive a copy (see Appendix A – 7(a) of this volume) of their BP and glucometer readings, their BMI calculation, and their Acanthosis Nigricans evaluation. The importance of any abnormal findings from the exam and recommendations for referral will be communicated to the participant at this time. For referrals in the emergent, immediate or urgent categories, the participant will be assisted in arranging transportation and appointments. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant’s provider or clinic of choice. For routine referrals, the reason for the referral and information necessitating referral will be given to the participant and a referral letter will be sent to the provider of their choice.

b) When the clinically useful laboratory results and ECG report have returned, a follow-up letter will be mailed to each participant thanking him or her for participating and supplying him/her with basic medical information obtained during the exam. Any results requiring referral will be pointed out in this letter and a referral letter will also be sent to the provider designated by the participant at the time of their exam. (See example of letter and suggested interpretation in Appendices A – 7(b) and A – 8)

c) When the carotid ultrasound and echocardiogram reports have returned, a follow-up letter will also be mailed to each participant supplying him/her with basic medical information obtained during the exam. Any results requiring referral will be pointed out in this letter and a referral letter will also be sent to the provider designated by the participant at the time of their exam. (See example of letter and suggested interpretation in Appendices A – 7 and A – 8)

d) In order to ensure that the patient receives appropriate referral and treatment for significant medical conditions uncovered during the course of the study,
consistent referral levels have been established as described below which will be applied at each center. Communication with the participant will be initiated at the time results indicating Emergent, Urgent and Immediate referrals are made available to the field centers. Communications regarding results indicating routine referrals made be held for short periods of up to two weeks to allow batching of results and somewhat fewer letters.

e) Before exams begin, the local SHS director will discuss the referral process with the clinical director for the primary IHS clinic for the community. The proposed method of notifying patients regarding referral will be reviewed, and the clinical director’s input will be sought as to which individual or office will be receiving referral information. There needs to be a designated provider to accept referrals for participants who do not specify a particular provider at that facility; the provider handling emergency duty for that day would be the most reasonable for Emergent and Immediate referrals. The clinical director should also designate which provider(s) will be responsible for handling Routine and Urgent referrals, and who would assume that responsibility if a particular provider were on leave or otherwise unavailable. The basic plan should be documented in writing and signed by the clinical director and SHS representative.

It is understood that it is the responsibility of SHS to provide referral information to the participants and to the provider or clinic of their choice. Assistance will often be given in arranging an appointment or providing transportation, but further follow-up of missed appointments, secondary referrals to specialty care by the participant’s provider will not be the responsibility of SHS.

2. Referral Levels

The Strong Heart Study refers participants using established guidelines for referral. Uniform criteria for referral of participants are implemented at all centers. Emergency, immediate, urgent, and routine referrals are made. Methods for referring participants who have no physician are established with the participant. All referrals are documented on a separate log and copies of the referrals are kept in the Strong Heart Study folders. The following levels of referral are established:

a) Emergency Referral: The patient is immediately escorted to a physician, or an emergency squad or an ambulance is summoned.

In such situations study personnel will provide emergency care to the best of their ability and training as appropriate to the emergencies that arise. Findings and measurements indicating referral will also be communicated directly to the emergency staff.
b) Immediate Referral: The participant is urged to see his/her physician within one day.

The SHS staff notifies the participant's physician or nearest IHS facility and makes appropriate arrangements for the SHS participant to be seen within 24 hours. The participant is provided with an IHS referral form or other written summary to take to his/her physician and transportation is provided or arranged if needed. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant’s provider or clinic of choice.

c) Urgent Referral: The participant is urged to see his/her physician within one week.

SHS staff makes an appointment for needed follow-up whenever possible. An IHS referral form or other written summary is provided to the participant and transportation is arranged if needed. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant’s provider or clinic of choice.

d) Routine Referral: The participant is contacted, and it is suggested that they see their physician or provider within one month, or at the first convenient appointment.

An IHS referral form or other written summary is filled out and sent to the provider of choice. When a group of participants is referred for routine referral by sending a packet of referral materials to a provider or clinic, an individual who will take responsibility for distribution of this material to the proper providers must sign for receipt of the referrals; or alternatively, a certified letter could be sent to the provider or clinic. (Please see 1.d above)

e) No Referral: At the conclusion of the exam, if there are no findings requiring referral, the participant will be given the results of BP and glucometer readings, BMI calculation and Acanthosis Nigricans evaluation, and advised that they are within acceptable limits. They will also be advised that further results from laboratory tests will be sent to them in the mail, and that results of carotid ultrasound and echocardiograms will be sent to their provider (if so designated in the consent form).

3. Standing orders for nursing or staff referral:

Guidelines for referral are provided in the table below. The SHS nursing staff determines the acuteness of the findings, as well as whether or not the condition is being followed by a physician.
If the participant is aware of and being followed medically for a condition, judgment is exercised about whether to refer. The standard IHS referral form or other written summary is used to provide appropriate clinical information to the health care professional who will evaluate the patient. A copy of this referral will be retained with the research forms to document the referral that was made.

Referral at the time of examination

**Emergency Referral**

**Statement to Participant**

("Consult M.D. immediately")

- SBP $\geq 260$ mmHg
  
  Your BP is very high

- DBP $\geq 130$ mmHg
  
  Your BP is very high

- One Touch glucose <50
  
  Your blood sugar is very low. Give juice or sugar!

- Any finding or symptom suggestive of a life-threatening illness, including evidence of acute MI, unstable angina, or pulmonary edema

**Immediate Referral**

**Statement to Participant**

("Consult M.D. today")

- Fasting One Touch glucose > 400
  
  Your blood sugar is very high

- SBP 180-259 mmHg
  
  Your BP is very high

- DBP 110-129 mmHg
  
  Your BP is very high

- Diabetic foot ulcer
  
  Your foot must be seen by a physician

- Angina in last day
  
  Your chest pains may be important

- Neurologic symptoms in past week
  
  Your symptoms may be important

- Other severe symptoms or findings
  
  Your symptoms may be important

- Untreated asthma or worsening asthma
  
  You may have a serious problem in your lungs
### Urgent Referral

<table>
<thead>
<tr>
<th>Finding / Symptom</th>
<th>Statement to Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible &gt;75% neck vessel obstruction</td>
<td>Possible &gt;75% neck vessel obstruction</td>
</tr>
<tr>
<td>Cardiac Echocardiogram indicating significant pericardial effusion or an intracardiac mass</td>
<td>Cardiac Echocardiogram indicating significant pericardial effusion or an intracardiac mass</td>
</tr>
<tr>
<td>Angina over 24 hours ago</td>
<td>Your chest pains may be important</td>
</tr>
<tr>
<td>Neurologic symptoms, untreated, one week to six months ago</td>
<td>Your symptoms may be important</td>
</tr>
<tr>
<td>Suspected congestive heart failure</td>
<td>Your symptoms may be important</td>
</tr>
<tr>
<td>Other acute, but less severe symptoms</td>
<td>Your symptoms may be important</td>
</tr>
<tr>
<td>Inappropriate medication usage</td>
<td>Taking medication incorrectly may be dangerous</td>
</tr>
<tr>
<td>Non-diabetic with a fasting One Touch glucose of ≥ 200</td>
<td>Your blood sugar is high</td>
</tr>
<tr>
<td>Diabetic with fasting One Touch glucose &gt;300</td>
<td>Your blood sugar is high</td>
</tr>
<tr>
<td>Chronic cough, fever, weight loss, and other symptoms suggestive of active TB or valley fever</td>
<td>You may have a serious problem in your lungs</td>
</tr>
<tr>
<td>Carotid ultrasound findings indicate possible 50-75% neck vessel obstruction</td>
<td>You may have serious problem in your neck vessel(s)</td>
</tr>
</tbody>
</table>

### Routine Referral

<table>
<thead>
<tr>
<th>Blood Pressure Range</th>
<th>Statement to Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP 140-179 mmHg</td>
<td>Your BP is elevated into the borderline range. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
<tr>
<td>DBP 90-110 mmHg</td>
<td>Your BP is elevated into borderline range. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
</tbody>
</table>
Non-diabetic with a fasting One Touch glucose of \( > 130 \)
Diabetic with fasting One Touch glucose \( > 150 \)

Old MI (Rose Questionnaire), previously unrecognized

Neurologic problem (stroke, TIA symptoms) \( > 6 \) months ago, unrecognized

Claudication, previously unrecognized

Both pedal pulses are missing in one extremity and not previously referred

or the ratio of doppler pressure of ankle/arm \( < 0.8 \)

Your blood sugar is high

Your chest pain may be important

Your symptoms may be important

Your leg pain may be important

You may have poor blood circulation to your feet. You should check with your doctor

---

**Referral After Lab and Other Test Results Are Available**

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

Laboratory will call field center; or use an alternative system involving a verified receipt (e.g., certified Email, FAX with return message confirming). Follow-up will be considered either immediate or urgent as indicated in the list of critical values. For immediate referral, SHS staff should notify participants by phone, or home visit, and (if they can not be reached personally within 4-6 hours) by certified letter. Efforts should continue to contact the participant and discuss results in person. SHS staff should help arrange transportation if needed. An IHS referral form or other written summary is provided.

2) Routine report -- Copies of routine results are sent to each participant with an interpretation of results. If the participants have new findings that they have not previously been advised of, such as newly diagnosed diabetes, or cholesterol \( > 300 \), an IHS referral form or other written summary should be provided, and SHS staff should assist the participant in making an appointment and arranging transportation for follow-up (see letter in Appendix A – 7 and interpretation in Appendix A – 8).

3) Carotid Ultrasound -- The Cornell Reading Center will call the field center (or use an alternate system involving a verified receipt) if \( > 50\% \) obstruction is noted on the carotid artery. If the obstruction is \( \geq 75\% \), the participant should have an
immediate referral (within 24 hours) for follow up. If the obstruction is between 50 and 74%, the participant should have an urgent (within the week) referral. If non-obstructive plaque (< 50%) is detected, the participant should be referred for risk factor assessment and counseling by his/her primary health care provider.

4) Echocardiogram -- The Cornell Reading Center will call the field center if there is a significant pericardial effusion, intracardiac mass, or other finding of serious consequence to the participant. Level of referral will depend on the urgency of the condition, as assessed by the reading center and other medical consultants to the field centers.

### Strong Heart Study Critical Values for Laboratory Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Critical Value</th>
<th>Immediate or Urgent Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Glucose</td>
<td>≤ 40 or ≥ 400 mg/dl</td>
<td>Immediate</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>≥ 300 mg/dl</td>
<td>Urgent</td>
</tr>
<tr>
<td>Total Triglyceride</td>
<td>≥ 1000 mg/dl</td>
<td>Urgent</td>
</tr>
<tr>
<td>Plasma Creatinine</td>
<td>≥ 3.0 mg/dl</td>
<td>Immediate***</td>
</tr>
<tr>
<td>Na</td>
<td>≤ 125 or ≥ 150 meq/dl</td>
<td>Immediate</td>
</tr>
<tr>
<td>K</td>
<td>≤ 3.0 or ≥ 6.5 meq/dl</td>
<td>Immediate</td>
</tr>
<tr>
<td>Ca</td>
<td>≤ 8.0 or ≥ 12.0 mg/dl</td>
<td>Immediate</td>
</tr>
<tr>
<td>PO₄</td>
<td>≥ 6.0 mg/dl</td>
<td>Urgent</td>
</tr>
<tr>
<td>Total Bilirubin</td>
<td>≥ 4.0 mg/dl</td>
<td>Urgent</td>
</tr>
<tr>
<td>ALK</td>
<td>≥ 400 IU/L</td>
<td>Urgent</td>
</tr>
<tr>
<td>BUN</td>
<td>&gt;40 mg/dl</td>
<td>Immediate***</td>
</tr>
<tr>
<td>Cl</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>CO₂</td>
<td>&lt;15 meq/L</td>
<td>Immediate</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Mg</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>AST</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>ALT</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>LDH</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Total Protein</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Albumin</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>CBC</td>
<td>Local IHS Laboratory critical values for CBC results will be followed</td>
<td></td>
</tr>
</tbody>
</table>

*** Note: When the field center is aware of End-Stage Renal Disease, or dialysis treatments for the participant, these values can be simply noted as abnormal on the summary sheet to the
participant, with the explanation that we expect these to be abnormal when an individual has ESRD or is on dialysis.

**ECG REFERRAL:**

a) *ECG findings requiring review by a physician before participant leaves SHS clinic or prompting phone call from ECG Core Lab for emergency referral:*

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

or SHS Dakota Center MDs:
- Dr. Lyle Best: 701-246-3884
- Dr. Jeff Henderson: 605-355-2401
- Dr. Tom Welty: 520-522-9005

or SHS Arizona Center MDs:
- Dr. James Galloway: 1-800-777-7522
- Dr. W. James Howard: 1-800-564-2536

**If unable to obtain consultation from above sources, initiate emergency referral.**

- ST segment elevation or depression consistent with acute myocardial infarction or subendocardial ischemia
- 3rd degree AV-block
- ventricular tachycardia
- sustained supraventricular tachycardia with heart rate >135
- any heart rate < 30

b) *ECG findings to be reviewed the same day or prompting phone call from ECG core lab for immediate referral:*

- any heart rate <35 or >135
- atrial fibrillation or atrial flutter with ventricular rate <50 or >110

c) *ECG findings where urgent referral is appropriate:*

- VPC couplets
- 2nd degree AV block
- New left bundle branch block
- New right bundle branch block
- Wolff-Parkinson-White
- Left ventricular hypertrophy
- T-wave inversion consistent with myocardial ischemia
- myocardial infarction of indeterminate age or age undetermined
- QT prolongation
d) **Examples of isolated abnormal ECG findings that do not require referral but can be sent to participant’s physician as part of routine report:**

- single ectopic beats of any frequency
- left axis deviation/left anterior hemiblock
- unusual p-wave axis (non-sinus atrial rhythm), wandering atrial pacemaker, av junctional rhythm
- old left or right bundle branch block
- incomplete right bundle branch block (right ventricular conduction delay)
- ST elevation consistent with early repolarization
- 1st degree AV block
1.8 QUALITY ASSURANCE (QC) PROGRAM

A quality control committee oversees the conduct and evaluation of QC procedures. Field center coordinators will be responsible for reviewing all QC data as they become available and following up on any problems that are detected. The QC committee will monitor efficacy of retraining and problem solving.

a. Data collection

Every data form will be checked for completeness at the field center. Ambiguous or erroneous items will be clarified and corrected. The data entry programs generated by the Coordinating Center will provide an additional quality control check by building in range and logic checks. The program will refuse to accept such data until the errors are corrected. During the first two months of examination, all forms will be double entered. After this initial period, 10% of the examinations will be randomly selected for double entry. The Coordinating Center will track the data entry error rates. If the data entry error rate of any field center is greater than 0.5%, that center will have to double enter all the examination data of that month. Computer printouts of inconsistent data items will be sent back to each field center for clarification or correction. Summary statistics such as mean, median, range, maximum and minimum for continuous variables and frequency distributions for categorical variables will be calculated monthly for each center, and data not meeting consistency checks will be flagged. Summary statistics will be generated quarterly to identify any peculiar or unreasonable values. Further verifications will be made and errors corrected.

b. Quality Control site visits

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

c. Quality Control -- Equipment

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

1) Anthropometry and blood pressure

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

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

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

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

2) Laboratory tests

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

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

4) Food Frequency Questionnaire (FFQ)

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

5) Certification of technicians

Each center will recruit the most qualified personnel. Clinical staff will be centrally trained and certified before the examination begins and newly hired personnel will be trained at each clinic. Re-certification will occur every six months to ensure accurate and consistent performance.

6) Monitoring of Study progress

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

f. Confidentiality and security of data

All personnel with access to the collected data are required to sign a confidentiality pledge. Completed data forms are placed in locked file cabinets at every center and are accessible by authorized staff members only. At the Coordinating Center, the data are stored on computers that are used exclusively by the Strong Heart Study and are safeguarded by passwords that are known only to authorized personnel. The data are stored on hard disk and four copies of floppy/optical diskettes. Two of the Zip disks/optical diskettes are stored in two different locations other than the Coordinating Center office. All of the disks and diskettes are updated daily.
APPENDIX A -- 1

Consent Forms for
the Arizona Field Center,
the North/South Dakota Field Center,
and
the Oklahoma Field Center

(Agent and Minor Consent/Assent Forms)
FAMILY STUDY

INFORMATION AND CONSENT FORM (1/17/01)

INSTITUTION: MedStar Research Institute

STUDY NUMBER: 88-8 PRINCIPAL INVESTIGATOR: Barbara V. Howard, Ph.D.

STUDY TITLE: Cardiovascular Disease in the Pima Indians. (Strong Heart Study)

INTRODUCTION: We invite you (or your child) to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study. Please read the following material to make sure that you understand this research study. If you have trouble reading this form, one of the staff will read it to you. You should know that: 1) taking part in the study is entirely your choice; 2) you (or your child) might, or might not be personally helped by joining this study, but knowledge will be gained that may help others; 3) you (or your child) may withdraw from the study at any time without losing any benefits which you (or your child) usually have. The kind of study, the benefits, risks, discomforts and other information are found below. If you (or your child) want to join the study, signing this form shows that you have read this Information and Consent Form (or had it read to you), understand what it says, and agree to take part in this research project. We will have an interpreter help you, if you want one. We want you to discuss any questions you have with the staff members before you sign this form.

PURPOSE: This research is to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

HOW YOU WERE PICKED: You (or your child) were asked to take part in the fourth phase of the Strong Heart Study (SHS), because you or one of your relatives joined the first phase of SHS.

PROCEDURE: By joining this study, you (or your child) agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:

1. Blood Tests. Twelve or more hours after you last ate anything, we will take a drop of blood from your (your child’s) finger and four ounces from your (your child’s) arm to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, D.C. for future tests, including gene testing, to learn about
cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. The blood will be stored until it has no more scientific value for studying these problems; then it will be gotten rid of like any other laboratory or clinic that tests your blood. Your blood cells will not be kept growing, cloned, and your blood will not be used for making a profit.

2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your (your child’s) arms, legs and chest and connected to an ECG machine. Heart specialists at Cornell University in New York will read this ECG test.

3. **Cardiac and Carotid Ultrasound Study.** These are "pictures" of your heart and of the arteries in your (your child’s) neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.

4. **Breathing Tests.** You (or your child) will be asked to blow into an instrument that measures the contents of the air in your lungs.

5. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.

6. **Body composition.** A machine will check how much muscle, fat, and water you (or your child) have in your body by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.

7. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using a machine and computer program that have not currently been approved by the Food and Drug Administration. We know of no risks to you (or your child) from this test of blood vessel stiffness.

8. **Health Questions.** Questions will be asked about many things that can change you (your child’s) general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, stress and gambling. Also questions about your family’s health, and well being will be asked.

**OTHER INFORMATION**

1. **POSSIBLE RISKS OF THIS STUDY**
Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You (or your child) may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your (your child’s) medical record, and if you (or your child) apply for insurance, the results may make it harder for you (your child) to get insurance. We will normally put your results of the tests done by Strong Heart...
Study in your (your child’s) IHS record, so that your clinic can use them, but we won’t do that, if you don’t want this done.

2. **BENEFITS**  
If we find a medical problem, you (or your child) will be asked to check with your (your child’s) clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You (or your child) will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check ups. You should go to your regular clinic for physical exams, and treatment of any health problems.

3. **WHY GENETIC TESTS ARE BEING DONE**  
The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won’t get cardiovascular disease; and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you (or your child) personally.

   In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5 year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say “for sure” that something new is discovered. For these reasons you will probably NOT be contacted about results of your genetic tests. If a gene is found that would be important to predict your risk for (or help you avoid) heart disease we will contact you and ask, whether you would like to have the results of this gene testing explained to you.

   Also, even though we try to be as exact as possible, early research tests like this may not be as dependable as the blood tests you have done at your regular clinic. For this reason, it might be necessary to have a particular gene test done again in a clinical laboratory. The Strong Heart Study would not be able to pay for this extra testing.

   If we learn something important from this study, further research may be done after Phase IV is over in 2005. The researchers may contact you then, if we discover something new that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas by Dr. Jean MacCluer and her staff.

4. **CONFIDENTIALITY**  
The results collected from this study will not be given to anyone else without your permission. Only study researchers and (by law) some people from the Food and Drug Administration, Indian Health Service Institutional Review Board, and/or the National Heart Lung and Blood Institute, which oversee this project, will be able to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of
the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your (your child’s) medical records will be used for statistics to learn about these diseases without letting anyone know your (your child’s) name. Names of people who join the study will never be reported in medical journals or at medical meetings. Medically important results will be put in your (your child’s) medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics.

5. **RESEARCH-RELATED INJURIES**
   It is very unlikely that you (your child) will be injured from joining in this research, but if that happens medical care will be provided by the Indian Health Service or the Gila River Health Care Corporation, if you are eligible for such services.

6. **PAYMENT**
   This exam will not cost you (your child) anything. You (your child) will be paid $40.00 for participating in the examination. If you need to have the exam in two visits, we will divide this into two $20 payments. The payments are to help with your travel expenses, and to give you something for your (or your child’s) time helping this study.

7. **PROBLEMS OR QUESTIONS**
   Should any problems or questions come up about this study or any research-related injury, including questions about your (your child’s) test results, you should contact the Principal Investigator(s): Dr. Barbara V. Howard (202) 877-6530 and Dr. James Galloway (520) 694-7000 or the Project Coordinator, Betty A. Jarvis, RN. Address: Strong Heart Study – Arizona Center, 1616 E. Indian School Rd. # 250, Phoenix, AZ. 85016 Phone: 602-277-0488

8. **RESEARCH PARTICIPANTS’ RIGHTS**
   You may contact Dorothy Meyer, CNM, MPH, Chair of the Phoenix Area IHS Institutional Review Board, Phoenix Area Indian Health Service, Two Renaissance Square, 40 N. Central Avenue, Phoenix, AZ 85004. Telephone: (602) 364-5175, about your (your child’s) rights as a research participant.

   You may also contact Daniel Herr, M.D., Chair, Institutional Review Board, (202)-877-7259.

9. **STOPPING THE STUDY**
   You (or your child) may stop at any time or refuse any part of the exam without losing your (your child’s) right to health care or any other benefit that you (or your child) normally have. However, we hope you (your child) will finish as many of the tests as possible. During the study, the researchers may ask you (your child) to drop out of the study, if the staff feels it is not in your (your child’s) best interest to go on.

10. **FOLLOW-UP**
    You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you (or your child) about these conditions. The parts of your exam that are
medically useful will be sent you (your child), when they are available. You (or your child) will also be sent Strong Heart Study newsletters now and then, to tell you (or your child) about results of the study. SHS researchers may contact you for more information about your (your child’s) health in the future, or to tell you about test results that are important for your (your child’s) health.

11. **CONSENT TO PARTICIPATE**
I have read, or had read to me, this Information and Consent Form, and I have been able to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risks and benefits that I learned about in this Information and Consent Form, I want to join in this research (or have my child join the study). A copy of this Information and Consent Form will be given to me to keep and look back on.

**I WANT TO JOIN THE STRONG HEART STUDY – PHASE IV RESEARCH STUDY.**

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my (my child’s) IHS chart.

I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my (my child’s) chart at a different health care provider. Please send to:

__________________________________  ____________________________________  
__________________________________  ____________________________________  
__________________________________  ____________________________________  

I would____ would not____ like important genetic test results reported to myself or my clinic providers.

If you need to contact me about results of tests that may be important to my (my child’s) health, please use this address (I will let you know if I have a change of address):

__________________________________  ____________________________________  
__________________________________  ____________________________________  
__________________________________  ____________________________________  

PRINTED NAME OF PARTICIPANT  __________________

SIGNATURE OF ADULT PARTICIPANT  DATE

SIGNATURE OF PARENT OR GUARDIAN IF PARTICIPANT IS LESS THAN 18 YEARS OLD.  DATE

In my opinion, the participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

SIGNATURE OF PERSON OBTAINING CONSENT  DATE
The Strong Heart Family Study is research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research. Here are some tests that will be done and some other things that you need to know.

1. **Blood Tests.** We will check how much sugar, cholesterol and other fats are in your blood 12 or more hours after you eat. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. It will be stored in laboratories in Washington, D.C. and San Antonio, Texas until it is no longer needed. Then we will get rid of it.

2. **Electrocardiogram or “ECG”**. This is a tracing of heart waves that will be sent to Cornell University in New York for reading.

3. **Carotid and Cardiac Echo study.** This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.

4. **Urine Test.** Some urine will be taken to find out how the kidneys are working.

5. **Body Composition.** A machine will find out how much muscle, fat, and water is in your body by passing a tiny charge from your hand to your foot. There is no known risk from this test and you won’t feel anything.

6. **Physical Examination.** We will check your blood pressure in the arms and legs, your height, weight, waist/hip, arm size and body fat. We know of no risk to you from these tests.

7. **Health interview.** There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, and where you get your health care. You are free to not answer any or all of the questions, but we hope that you will answer them all.

**Other information:**

1. **Possible risks of joining the study.** Drawing the blood may cause a little pain and sometimes a bruise. Tests that will be done are like in regular medical checkups, and have a low chance of causing problems. If your test results from the study are put in your medical record, and if you apply for insurance, the results may make it harder for you to get insurance.

2. **Benefits.** The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.
3. **Why genetic tests are being done.** This study does testing on the genes, or DNA in your blood cells. The reason is to find genes that may cause or protect people from heart and lung disease. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will probably NOT be contacted about your personal results.

If we learn something important from this study, more research may be done after Phase IV is over in 2005. The researchers may contact you then, if something new is discovered that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for BioMedical Research, San Antonio, Texas.

4. **Payment.** This exam will not cost you or your parents anything. You will be paid $40 for answering the questions having blood drawn, and completing the examination. This money is paid to help with your travel costs and to thank you for the time we have taken.

5. **Stopping the study.** We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam.

6. **Assent to participate.** I know the reason for these tests, which tests will be done, and the bad and good things that go with them. By signing this paper, I am saying that I want to be part of this research:

   PRINTED NAME OF PARTICIPANT ___________________________ DATE

   MINOR PARTICIPANT’S SIGNATURE ___________________________ DATE

   SIGNATURE OF PARENT OR GUARDIAN ___________________________ DATE

   In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed assent.

   SIGNATURE OF PERSON OBTAINING ASSENT ___________________________ DATE
INFORMATION AND CONSENT FORM

STUDY TITLE: Cardiovascular Disease in Sioux Indians. The Strong Heart Study-Phase IV

PRINCIPAL INVESTIGATOR: Lyle G. Best, M.D.

GRANT RECIPIENT: Missouri Breaks Industries Research, Inc.

INTRODUCTION: We invite you (or your child) to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study. Please read the following material to make sure that you understand this research study. If you have trouble reading this form, one of the staff will read it to you. You should know that: 1) taking part in the study is entirely your choice; 2) you (or your child) might, or might not be personally helped by joining this study, but knowledge will be gained that may help others; 3) you (or your child) may withdraw from the study at any time without losing any benefits which you (or your child) usually have. The kind of study, the benefits, risks, discomforts and other information are found below. If you (or your child) want to join the study, signing this form shows that you have read this Information and Consent Form (or had it read to you), understand what it says, and agree to take part in this research project. We will have an interpreter help you, if you want one. We want you to discuss any questions you have with the staff members before you sign this form.

PURPOSE: This research is to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

HOW YOU WERE PICKED: You (or your child) were asked to take part in the fourth phase of the Strong Heart Study (SHS), because you or one of your relatives joined the first phase of SHS. About 3600 people from the Dakotas, Oklahoma and Arizona will take part in Phase IV of SHS.

PROCEDURE: By joining this study, you (or your child) agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your (your child’s) finger and 8 tablespoons from your (your child’s) arm to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, D.C. for future tests, including gene testing, to learn about cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. The blood will be stored until it has no more scientific value for studying these problems; then it will be disposed of in the standard way. Your blood cells will not be kept growing, cloned, and your blood will not be used for making a profit.

2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your (your child’s) arms, legs and chest and connected to an ECG machine. Heart specialists at Cornell University in New York will read this ECG test.
3. **Cardiac and Carotid Ultrasound Study.** These are “pictures” of your heart and of the arteries in your (your child’s) neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.

4. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.

5. **Body fat.** A machine will check how much fat you (or your child) have by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.

6. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using a machine and computer program that have not currently been approved by the Food and Drug Administration. We know of no risks to you (or your child) from this test of blood vessel stiffness.

7. **Health and Family Questions.** Questions will be asked about many things that can change your (your child’s) general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, and stress. Also questions about who your family members are, how they are related to you, their health, and well being will be asked.

**OTHER INFORMATION**

1. **POSSIBLE RISKS OF THIS STUDY**
   Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You (or your child) may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your (your child’s) medical record, and if you (or your child) apply for insurance, the results may make it harder for you (your child) to get insurance. We will normally put your results of the tests done by Strong Heart Study in your (your child’s) IHS record, so that your clinic can use them, but we won’t do that, if you don’t want this done.

2. **BENEFITS**
   If we find a medical problem, you (or your child) will be asked to check with your (your child’s) clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You (or your child) will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check ups. You should go to your regular clinic for physical exams, and treatment of any health problems.

3. **WHY GENETIC TESTS ARE BEING DONE**
   The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won’t get cardiovascular disease; and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These
genetic tests are not likely to help you (or your child) personally.

In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5-year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say “for sure” that something new is discovered. For these reasons you will probably NOT be contacted about results of your genetic tests. If a gene is found that would be important to predict your risk for (or help you avoid) heart disease, we will contact you and ask whether you would like to have the results of this gene testing explained to you.

Also, even though we try to be as exact as possible, early research tests like this may not be as dependable as the blood tests you have done at your regular clinic. For this reason, it might be necessary to have a particular gene test done again in a clinical laboratory. The Strong Heart Study would not be able to pay for this extra testing.

If we learn something important from this study, further research may be done after Phase IV is over in 2005. The researchers may contact you then, if we discover something new that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas or at other laboratories with the approval of the Strong Heart Study researchers.

4. **CONFIDENTIALITY**

   Only study researchers and (by law) some people from the Food and Drug Administration, Indian Health Service Institutional Review Board, and/or the National Heart Lung and Blood Institute, which oversee this project, may need to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your (your child’s) medical records will be used for statistics to learn about these diseases without letting anyone know your (your child’s) name. These statistics will be reported in medical journals, at medical and research meetings and to your Tribe; but the names of people who join the study will never be reported. Medically important results will be put in your (your child’s) medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics. A “Certificate of Confidentiality” will be provided by the Department of Health and Human Services, this helps prevent courts and others from obtaining your confidential research information, but there is no way to guarantee that a court could not force our study to reveal some information.

5. **RESEARCH-RELATED INJURIES**

   It is very unlikely that you (your child) will be injured from joining in this research, but if that happens the Indian Health Service will provide medical care, if you are eligible for such services. Neither Missouri Breaks Industries Research, Inc., nor the Indian Health Service, nor any person involved with this research project has provisions for financial compensation in the event of such injury.

6. **PAYMENT**
This exam will not cost you (your child) anything. You (your child) will be paid $25.00 for answering the questions and having blood drawn, and $20 when you (your child) have the ultrasound tests done. This will probably take two visits. The payments are to help with your travel expenses, and to give you something for your (or your child’s) time helping this study. You (your child) will also be given a health promotion gift.

7. **PROBLEMS OR QUESTIONS** Should any problems or questions come up about this study or any research-related injury, including questions about your (your child’s) test results, you should contact the Principal Investigator, Dr. Lyle Best or the Project Coordinator, Marcia O’Leary, RN. Address: Strong Heart Study - Dakota Center, P.O. Box 9010, Rapid City, SD 57709. Telephone:(605) 355-2377 or 605-865-3418.

8. **RESEARCH PARTICIPANTS’ RIGHTS**
You may contact Dr. Elaine Miller, Chairperson of the Aberdeen Area IHS Institutional Review Board, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Ave SE, Aberdeen, SD 57401 Telephone: (605) 226-7544, about your (your child’s) rights as a research participant.

9. **STOPPING THE STUDY**
You (or your child) may stop at any time or refuse any part of the exam without losing your (your child’s) right to health care or any other benefit that you (or your child) normally have. However, we hope you (your child) will finish as many of the tests as possible. During the study, the researchers may ask you (your child) to drop out of the study, if the staff feels it is not in your (your child’s) best interest to go on.

10. **FOLLOW-UP**
You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you (or your child) about these conditions. The parts of your exam that we think are medically useful will be sent you (your child), when they are available. You (or your child) will also be sent Strong Heart Study newsletters now and then, to tell you (or your child) about results of the study. SHS researchers may contact you for more information about your (your child’s) health in the future, or to tell you about test results that are important for your (your child’s) health. You may also be contacted in the future by SHS researchers for information about new family members or to clarify family relationships.

11. **RESPONSIBILITY FOR THE STUDY**
The Aberdeen Area Indian Health Service was responsible for Phases I and II, and the Aberdeen Area Tribal Chairmen’s Health Board was responsible for Phase III. The Missouri Breaks Research, Inc has taken responsibility for the Strong Heart Family Study (Phase IV) including keeping the research records. Signing this consent form will let Missouri Breaks Research Inc. staff, with professional supervision of the principal investigator, look at the information collected in earlier phases of the study.

12. **CONSENT TO PARTICIPATE**
I have read, or had read to me, this Information and Consent Form, and I have been able to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risks and benefits that I learned about in this Information and Consent Form, I consent to participate in this study.
Form, I want to join in this research (or have my child join the study). A copy of this Information and Consent Form will be given to me to keep and look back on.

I WANT TO JOIN THE STRONG HEART STUDY-PHASE IV RESEARCH STUDY.

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my (my child’s) IHS chart.

I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my (my child’s) chart at a different health care provider. Please send to:

__________________________________
__________________________________
__________________________________
__________________________________

I would ____ would not ____ like important genetic test results reported to myself.

I would ____ would not ____ like important genetic test results reported to my clinic providers.

If you need to contact me about results of tests that may be important to my (my child’s) health, please use this address (I will let you know if I have a change of address):

__________________________________
__________________________________
__________________________________
__________________________________

PRINTED NAME OF PARTICIPANT     DATE
__________________________________
SIGNATURE OF ADULT PARTICIPANT   DATE
__________________________________
SIGNATURE OF PARENT OR GUARDIAN IF PARTICIPANT IS LESS THAN 18 YEARS OLD.   DATE

In my opinion, the participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

__________________________________
SIGNATURE OF PERSON OBTAINING CONSENT   DATE

PhIVHarmCons/DakCtr/Feb 1601
ASSENT FORM
STRONG HEART STUDY FAMILY STUDY

The Strong Heart Study is doing research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research. Here are some tests that will be done and some other things that you need to know.

1. **Blood Tests.** We will check how much sugar, cholesterol and other fats are in your blood 12 or more hours after you eat. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. It will be stored in laboratories in Washington, D.C. and San Antonio, Texas until it is no longer needed, then it will be disposed of in a standard way.

2. **Electrocardiogram or “ECG”**. This is a tracing of heart waves that will be sent to Cornell University in New York for reading.

3. **Carotid and Cardiac Echo study.** This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.

4. **Urine Test.** Some urine will be taken to find out how the kidneys are working.

5. **Body fat.** A machine will find out how much fat is in your body by seeing how a very tiny little bit of electricity flows through you. There is no known risk from this test and you won’t feel anything.

6. **Physical Examination.** We will check your blood pressure in the arms and legs (this can cause a mild squeezing feeling), measure your height, weight, waist/hip, arm size and body fat. We know of no risk to you from these tests.

7. **Health interview.** There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, and where you get your health care. You are free to not answer any or all of the questions, but we hope that you will answer them all.
Other information:

1. **Possible risks of joining the study.** Drawing the blood may cause a little pain and sometimes a bruise. Tests that will be done are like in regular medical checkups, and have a low chance of causing problems. If results that could be important to your health are found from your tests, we will need to tell both you and your parents because you are not yet of legal age.

2. **Benefits.** The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.

3. **Why genetic tests are being done.** This study does testing on the genes, or DNA in your blood cells. The reason is to find genes that may cause or protect people from heart, lung disease and stroke. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will probably NOT be contacted about your personal results.

If we learn something important from this study, more research may be done after Phase IV is over in 2005. The researchers may contact you then, if something new is discovered that would be important for you to know about. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas.

4. **Confidentiality.** Shortly after we get your samples, your name is replaced by a number, so that even most of the staff that run the tests will not have any name connected with your sample. The results of the exam and any information in your medical records will be used for statistics to learn about these diseases without letting anyone know your name. These statistics will be reported in medical journals, at medical and research meetings and to your Tribe; but the names of people who join the study will never be reported. A “Certificate of Confidentiality” will be provided by the Department of Health and Human Services, this helps prevent courts and others from obtaining your confidential research information, but there is no way to guarantee that a court could not force our study to reveal some information.

5. **Payment.** This exam will not cost you or your parents anything. You will be paid $25 for answering the questions and having blood drawn, and $20 when the echo tests are done. This will usually take two visits. This money is paid to help with your travel costs and to thank you for the time we have taken.

6. **Stopping the study.** We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam.
7. **Assent to participate.** I know the reason for these tests, which tests will be done, and the bad and good things that go with them. By signing this paper, I am saying that I want to be part of this research:

__________________________  
PRINTED NAME OF PARTICIPANT  
__________________________  
DATE

__________________________  
MINOR PARTICIPANT’S SIGNATURE  
__________________________  
DATE

__________________________  
SIGNATURE OF PARENT OR GUARDIAN  
__________________________  
DATE

In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed assent.

__________________________  
SIGNATURE OF PERSON OBTAINING ASSENT  
__________________________  
DATE

Ph_IVAssent\0akCtr\Feb1601
CONSENT FORM
University Of Oklahoma Health Sciences Center
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
(The Strong Heart Study Phase IV)
Elisa T. Lee, Ph.D., Principal Investigator

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. If you have trouble reading this consent form, one of the staff will read it to you. Discuss this with your family and friends.

You are being asked to take part in the Strong Heart Family Study because you or one of your relatives participated in the first phase of the Strong Heart Study and because your family is large and your family members are interested in participating.

Why Is This Study Is Being Done?
This research is being done to learn more about genetics, or things you inherit from your parents, to help explain why cardiovascular and lung diseases happen. This will be done by testing genetic material (DNA) in blood cells for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

How Many People Will Take Part in the Study?
About 3600 people will take part in this study nationwide. About 1200 of these individuals will participate at this location.

What Is Involved in the Study?
We invite you to take part in the Strong Heart Study, a research study of cardiovascular and lung diseases and their risk factors in American Indians. Cardiovascular disease includes heart disease, stroke, and diseases of the blood vessels. Known risk factors for cardiovascular disease include diabetes, unhealthy diet, fats in the blood, obesity, smoking, high blood pressure, alcohol misuse, and physical inactivity. New risk factors may be investigated by this study.

PROCEDURE:
By joining this study, you agree to have a physical examination to study cardiovascular and lung diseases and risk factors that go along with these diseases. The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits.

The physical examination will include:
1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your finger and four ounces (8 tablespoons) from your arm by a needle to find the level of sugar, cholesterol and other fatty substances. Some of your blood will be saved at Penn Medical Research Laboratories in Washington, DC and at the Southwest Foundation for Biomedical Research in San Antonio, TX for future tests, including gene testing, to learn about cardiovascular and lung diseases, and risk factors for those diseases. Other laboratories may do some of these tests. We will not test your blood for other things without your permission. Your blood will be stored until it has no more scientific value for studying heart,
lung, and blood disease; then it will be destroyed. Your blood cells will not be cloned or kept growing, and your blood will not be used for making a profit.

2. **Electrocardiogram (ECG).** An ECG is a test of whether your heart is working normally; 12 monitoring tabs will be placed on your arms, legs and chest and connected to an ECG machine. This ECG test will be read by heart specialists at Cornell University in New York.

3. **Cardiac and Carotid Ultrasound Study.** These are "pictures" of your heart and of the arteries in your neck using sound waves to find out how well your heart works and if fat deposits are in your arteries. These will also be read at Cornell University in New York.

4. **Breathing Tests.** You will be asked to blow into an instrument that measures carbon monoxide. Carbon monoxide levels are high in smokers, people who have to breathe smoke, and people who have bad furnaces.

5. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.

6. **Body fat.** A machine will check how much fat you have by passing a very tiny electrical current through your body. This current is too small to feel, and there is no known risk for this test.

7. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Blood pressures and stiffness of blood vessels will be tested over your wrist, using an experimental computer program that has not currently been approved by the Food and Drug Administration. We know of no risks to you from this test of blood vessel stiffness.

8. **Health and Family Questions.** Questions will be asked about many things that can change your general health, including exercise, alcohol and tobacco use, where you get health care, what you eat, stress and gambling. Also questions about who your family members are, how they are related to you, their health, and well being will be asked.

**OTHER INFORMATION**

The study does testing on your genes, or genetic material (DNA) in your white blood cells to find genes that may cause or protect people from cardiovascular and lung diseases, or their risk factors. Genes may determine who will and who won’t get cardiovascular disease, and how we might be able to prevent these diseases in people who are more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you personally.

In Phase IV we will be mainly looking for the location of genes that might cause cardiovascular and lung diseases. We think it is very unlikely that the actual genes themselves will be found during this 5-year period. Also, in a study like this, what we find usually needs to be repeated by other researchers before we can say “for sure” that something new is discovered. For these reasons you will NOT be contacted about results of your genetic tests. If we learn something important from this study, further research may be done after Phase IV is over in 2005. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas or at other laboratories with the approval of the Strong Heart Study researchers.

**How Long Will I Be in the Study?**
The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. You may withdraw from the study at any time without losing any benefits, which you usually have.
What Are the Risks of the Study?
Most of the tests are part of a standard medical check-up and have a very low risk of side effects. Taking blood from your arm and finger can be a little painful and may give you a bruise. You may have some discomfort in your arms and/or legs, when blood pressure is taken. If your test results from the study are put in your medical record, and if you apply for insurance, the results may make it harder for you to get insurance. We will normally put your results of the tests done by Strong Heart Study in your IHS record, so that your clinic can use them, but we won’t do that, if you don’t want this done.

Risks of genetic testing: If the genetic tests being done in this study determined that your disease is caused by genetic abnormalities, your family members could face problems in obtaining insurance coverage for this disease, even if they have no symptoms. However, in order to do everything possible to keep this from happening, the results of this test will NOT be given to anyone outside the study staff. This means that it will not be made available to you, your family members, your private physician, your employer, your insurance company, or any other party as allowed by law.

Are There Benefits to Taking Part in the Study?
If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check-ups. You should go to your regular clinic for physical exams and treatment of any health problems.

What Other Options Are There?
This is a research study. Research studies involve only individuals who choose to participate, and you are free to choose not to participate.

What About Confidentiality?
Only study researchers and (by law) some people from the Food and Drug Administration, the Institutional Review Boards, and/or the National Heart, Lung and Blood Institute, which oversee this project, may need to see results that could be connected with your name. Shortly after we get your samples, your name is replaced by a number, so that even most of the staff who run the tests will not have any name connected with your sample. The results of the exam and any information in your medical records will be used for statistics to learn about these diseases without letting anyone know your name. Names of people who join the study will never be reported in medical journals or at medical meetings. Medically important results will be put in your medical record, unless you tell us not to place them there. If you sign a release, we will send your medical results to other clinics.

What Are the Costs?
This exam will not cost you anything.

Will I Be Paid for Participating in This Study?
You will be paid $25.00 for answering the questions and having blood drawn, and $25 when you have the ultrasound tests done. This may take two visits. The payments are to help with your
travel expenses, and to give you something for your time helping this study. You will also be given a health promotion gift.

**What If I am Injured or Become Ill While Participating in This Study?**
It is very unlikely that you will be injured or become ill from joining in this research, but if that happens medical care will be provided by the Indian Health Service, if you are eligible for such services. Otherwise, emergency medical treatment is available, but you or your insurance company may be expected to pay the usual charge for this treatment. No funds have been set aside by the University of Oklahoma Health Sciences Center, the Indian Health Service, or the National Heart, Lung, and Blood Institute to compensate you in the event of injury. If you have questions about the availability of care, you may contact the Lawton Indian Health Service Hospital at (580) 353-0350 or the Anadarko Indian Health Service Clinics at (580) 247-2458.

**What Are My Rights as a Participant?**
Taking part in this study is voluntary. You may stop at any time or refuse any part of the exam without losing your right to health care or any other benefit that you normally have. During the study, the researchers may ask you to drop out of the study, if the staff feels it is not in your best interest to go on.

You will be told as soon as possible, if any life-threatening health problems are found. Your signed consent form will help the SHS staff to make appointments at the hospital or clinic for you about these conditions. The parts of your exam that we think are medically useful will be sent to you when they are available. You will also be sent Strong Heart Study newsletters periodically, to tell you about results of the study. SHS researchers may contact you for more information about your health in the future, or to tell you about test results that are important for your health. You may also be contacted in the future by SHS researchers for information about new family members or to clarify family relationships.

**Whom Do I Call If I Have Questions or Problems?**
If you have questions about the study, contact Dr. Elisa Lee or her colleagues at 405-271-3090. For questions about your rights as a research subject, contact Nancy Nisbett, the Director of the Office of Research Administration, at 405-271-2090, or Mr. Samuel M. Hope, Chairperson, Oklahoma City Area IHS Institutional Review Board, Indian Health Service, Five Corporate Plaza, 3625 NW 56th Street, Oklahoma City, OK, 73112, telephone number (405) 951-3829.

**Signature:**
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or institution from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I want to join the Strong Heart Study-Phase IV research study:

I do ____ do not ____ want the medical test results that may be important to my future health or the health of my family filed in my IHS chart.
I would ____ would not ____ like the medical test results that may be important to my future health or the health of my family filed in my chart at a different health care provider. Please send to:

__________________________________

__________________________________

__________________________________

__________________________________

If you need to contact me about results of tests that may be important to my health, please use this address (I will let you know if I have a change of address):

__________________________________

__________________________________

__________________________________

__________________________________

Research Subject:_________________________________________ Date:_________

Witness:_________________________________________ Date:_________

Person Obtaining Informed Consent:__________________________ Date:_________

Principal Investigator:____________________________________ Date:_________

SHS Phase IV Family Study, IRB No. 08473, Revised: November 10, 2000
This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. If you have trouble reading this consent form, one of the staff will read it to you. Discuss this with your family and friends.

**Why Is This Study Being Done?**
The Strong Heart Study is doing research to try to learn more about heart disease, lung disease and stroke among American Indians and their families. Your parent or guardian says it is ok for you to participate in this testing. You also need to know about these tests so you can tell if you want to be part of this research.

**What Is Involved in the Study?**
Here are some tests that will be done and some other things that you need to know.

1. **Blood Tests.** Twelve or more hours after you last ate anything, we will take a drop of blood from your finger and four ounces (8 tablespoons) from your arm by a needle. We will check how much sugar, cholesterol, and other fats are in your blood. The blood will also be used to look for genes that cause or protect against heart disease, lung disease and strokes. Your blood will be stored until it has no more scientific value for studying heart, lung, and blood disease; then it will be destroyed.

2. **Electrocardiogram or “ECG”**. This is a tracing of heart waves that will be sent to Cornell University in New York for reading.

3. **Carotid and Cardiac Ultrasound study**. This is a picture of the arteries in your neck and of your heart using sound waves to see if fat deposits are in the arteries and how well your heart works.

4. **Urine Test.** We will ask you for some urine to find out how your kidneys are working.

5. **Body fat.** A machine will find out how much fat is in your body by seeing how a very tiny little bit of electricity flows through you. There is no known risk from this test, and you won’t feel anything.

6. **Breathing Tests.** You will be asked to blow into a machine to check for carbon monoxide which is a special gas that can come from smoking or heaters that don’t work right.
7. **Physical Examination.** We will check your blood pressure in the arms and legs, measure your height, weight, waist, arm size and body fat. We know of no risk to you from these tests.

8. **Health interview.** There will be questions about your general health and also diet, exercise, alcohol and tobacco use, stress, where you get your health care, and gambling. You are free to not answer any or all of the questions.

**How Long Will I Be in the Study?**
The examination and questions will take about 3 to 4 hours and will be done in 1 or 2 visits. We hope that you will finish all the tests and answer all the questions, but you may stop or refuse any part of the exam without losing any benefits that you usually have.

**What Are the Risks of the Study?**
Drawing the blood may cause a little pain and sometimes a bruise. The tests in the exam are similar to those in a regular medical checkup, and have a low chance of causing problems.

**Are There Benefits to Taking Part in the Study?**
The tests done in this study may find problems that need medical help. The people working on the study will help you see a doctor or go to the clinic for any problems that are found.

**Other Information**

**Why genetic tests are being done.** This study does testing on the genes, or DNA, in your blood cells. The reason is to find genes that may cause or protect people from heart and lung disease. It might be possible to prevent these diseases in people, if a test can tell who is more likely to get them. This research will mostly help future generations. These genetic tests are not likely to help you yourself. Since this kind of research takes a long time, and often needs to be repeated to be sure about the results, you will NOT be contacted about your personal results. If we learn something important from this study, more research may be done after Phase IV is over in 2005. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, Texas.

**What Other Options Are There?**
You are free to choose not to participate.

**What Are the Costs?**
This exam will not cost you or your parents anything.

**Will I Be Paid for Participating in This Study?**
You will be paid $25 for answering the questions and having blood drawn, and $25 when the ultrasound tests are done. This may take two visits. This money is paid to help with your travel
costs and to thank you for the time we have taken. You will also be given a health promotion gift.

**Signature:**

**Consent to participate.** I know the reason for these tests, which tests will be done, and the risks and benefits that go with them. By signing this paper, I am saying that I want to be part of this research:

Minor Participant’s Signature: _______________________________ Date: ________

Signature of Parent or Guardian: _______________________________ Date: ________

Witness: _______________________________ Date: ________

In my opinion, the minor participant understands what is involved in the Strong Heart Study exam and is able to give informed consent.

Person Obtaining Consent: _______________________________ Date: ________

Principal Investigator: _______________________________ Date: ________

SHS Phase IV Family Study, IRB No. 08473, Revised: November 10, 2000
### Clinical Examination – Checklist

<table>
<thead>
<tr>
<th>Items</th>
<th>If done, date and initial</th>
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<tbody>
<tr>
<td>1. Consent Form Signed</td>
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<td>2. Pregnancy/lactation screen (if appropriate)</td>
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<td>3. Medical Release Signed</td>
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<td>4. Sample collection checklist</td>
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<td>5. Family information form</td>
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<td>6. Personal interview forms</td>
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<td>7. Medical history form</td>
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<td>8. Reproduction and hormone use (women)</td>
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<td>9. Rose questionnaire</td>
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<td>10. Respiratory questionnaire</td>
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<td>11. Medication checklist</td>
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<td>12. Psychosocial questionnaires checklist</td>
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<td>13. ECG</td>
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<td>14. Impedance measurement</td>
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<td>15. Height and weight</td>
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<tr>
<td>16. Abdominal, hip, and arm circumference</td>
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</tbody>
</table>

Participant’s name: ____________________________________________________________

ID Number: ______________________ Date: ____________________________

mo  day  yr
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<thead>
<tr>
<th></th>
<th>Procedure</th>
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<tbody>
<tr>
<td>17.</td>
<td>Sitting blood pressure</td>
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<tr>
<td>18.</td>
<td>Doppler blood pressure</td>
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<tr>
<td>19.</td>
<td>Food Frequency Questionnaire</td>
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<tr>
<td>20.</td>
<td>Carotid ultrasound</td>
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<tr>
<td>21.</td>
<td>Echocardiogram</td>
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<tr>
<td>22.</td>
<td>Radial tonometry</td>
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<tr>
<td>23.</td>
<td>Pedometer diary</td>
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<tr>
<td>24.</td>
<td>Payment or payment form</td>
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Appendix A – 2(b)

THE STRONG HEART STUDY IV
Post Exam Activities

Same Day:

- Process blood specimens
- Review morbidity (chart review at clinic site)
- Stamp participant’s clinic chart with SHS exam information (if so indicated on consent form)
- Add codes: Community, Tribe, clinic/hospital, medicines
- Edit for missing data
- Transmit ECGs to New York
- Make all but routine referrals
- Complete ultrasound and tonometry measurements

Later:

- Send ultrasound tapes to reading center
- Make routine referrals
- File confirmed ECG and ultrasound/tonometry reports
- Mail letters to participants
- File laboratory findings in participant’s medical records (if so indicated on consent form)
- Mail laboratory specimens
Appendix A – 3

SHS PHASE IV FAMILY STUDY
Checklist for Blood Pressure

Technician Code # / Initials ________________________

Observer Code # / Initials ________________________

Date Observed _____ / _____ / _____ (Month/Day/Year)

YES ( ) NO ( ) Provide subject instruction, allowing opportunity for questions.
YES ( ) NO ( ) Measure right arm for correct cuff size.
YES ( ) NO ( ) Palpates brachial artery, medial to and above antecubital fossa.
YES ( ) NO ( ) Marks pulse point.
YES ( ) NO ( ) Places cuff correctly.
YES ( ) NO ( ) Leaves subject for 5 minutes rest.
YES ( ) NO ( ) Subject positioned correctly.
YES ( ) NO ( ) Provides environment free of excessive noise.
YES ( ) NO ( ) Finds pulse obliteration point.
YES ( ) NO ( ) Calculates peak inflation.
YES ( ) NO ( ) Places stethoscope in ears.
YES ( ) NO ( ) Inflates cuff rapidly to calculated peak.
YES ( ) NO ( ) Holds pressure steady for full 5 seconds.
YES ( ) NO ( ) Places bell on brachial pulse
YES ( ) NO ( ) Deflates cuff slowly, 2 mmHg per second.
YES ( ) NO ( ) Deflates cuff rapidly after 2 absent sounds.
YES ( ) NO ( ) Records readings.
YES ( ) NO ( ) Disconnects tubes.
YES ( ) NO ( ) Instructs subject to hold right arm vertical for full five seconds.
YES ( ) NO ( ) Waits at least 30 seconds before proceeding to 2nd and 3rd readings.
YES ( ) NO ( ) Average 2nd and 3rd readings, informs subject of average BP.

Comments: ______________________________________

_________________________________________________

_________________________________________________

_________________________________________________
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.

<table>
<thead>
<tr>
<th>Technician #1 Code # / Initials</th>
<th>Technician #2 Code # / Initials</th>
<th>Observer Code # / Initials</th>
<th>Date Observed</th>
<th>Tech #1</th>
<th>Tech #2</th>
<th>Difference</th>
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<tbody>
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<td>Arm circumference</td>
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<td>Cuff size</td>
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<td>Pulse obliteration pressure</td>
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# Appendix A – 5(a)
## SHS Phase IV Family Study
### Quality Control

**SPHYGMOMANOMETERS**

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<tr>
<th>MONTH</th>
<th>DATE</th>
<th>INIT.</th>
<th>MERCURY LEVEL IS AT ZERO WITH NO PRESSURE</th>
<th>CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHG</th>
<th>CHECK CAP FOR TIGHTNESS</th>
<th>CHECK TUBE FOR OXIDE DUST</th>
<th>COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.</th>
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## Appendix A – 5(b)
### SHS Phase IV Family Study
#### Quality Control

**SCALE & MEASUREMENT TAPES**

<table>
<thead>
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<th>MONTH</th>
<th>DATE</th>
<th>INIT.</th>
<th>PORTABLE SCALE</th>
<th>CALIBRATED WEIGHTS</th>
<th>HEIGHT METAL TAPE 50 cm, 60 cm</th>
<th>MEASURING TAPE, to 30 cm METAL TAPE</th>
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MAINTENANCE PROCEDURES FOR STANDARD SPHYGMOMANOMETERS

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting.

1. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, mercury should be added or withdrawn until it does read zero. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.

2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:
   a) The system should be re-inflated until the column rises to 200 mmHg.
   b) The tubing should be pinched at various locations to localize the area of the leak.
   c) Appropriate replacement of the tubing, cuff, or valve should be performed.

3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the silicone rubber, which provides a seat for both ends of the glass tube, should be replaced.

4. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with this instrument. The tube should then be replaced and the zero level rechecked.

5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.
NOTE: THIS LETTER IS TO BE USED ONLY FOR NORMAL RESULTS OR ROUTINE REFERRALS. EMERGENT, IMMEDIATE AND URGENT REFERRALS SHOULD FOLLOW THE GUIDELINES IN SECTION 1.8.

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

Dear ____________:

Thank you very much for taking part in the Strong Heart Study today.

Blood Pressure

When your blood pressure is too high it causes extra “wear and tear” on your heart and blood vessels. Over the years this can lead to hardening of the arteries and then stroke, heart attacks and kidney damage. Doctors have known for many years now that properly controlling blood pressure helps to prevent these medical problems.

Your blood pressure was _____ (less than 140/90 and you do not take medication for your blood pressure). This is within the normal range. It should be checked at least once a year.

Your blood pressure was _____ (greater than 140/90). This is above the normal range. You should make an appointment for follow-up with your medical care provider, since high blood pressure may cause heart problems and stroke.

Your blood pressure was _____ (less than 140/90, and you take blood pressure medicine). This is within the normal range. Continue taking your blood pressure medicine as directed by your medical care provider.

Glucometer test for Diabetes.

Diabetes causes the blood sugar to be too high. Over a long period of time this seems to cause damage to the blood vessels, eyes, kidneys and nerves. We are now quite sure that lowering the blood sugar into the normal range helps to prevent these problems. This glucometer test is very accurate but not as exact as the laboratory test that will be done on the blood sample from your arm. The results from that test will be sent to you later.

Your fasting blood sugar was _____ (less than 130 mg/dl). This is within the desirable range.

Your fasting blood sugar was _____ (more than 130 but less than 200) These values are higher than normal and raise the possibility that you may have diabetes. These results will need to be checked by the sample taken from your arm, but we suggest that you contact your medical provider in the coming week or so to have this result checked sooner than that.
Your fasting blood sugar was _____ (known diabetic, less than 150). On the day of the exam, your fasting blood sugar was probably under adequate control. Be sure to follow the advice of your medical care provider for control of your diabetes.

Your fasting blood sugar was_____ (known diabetic greater than 150 but less than 300). Your fasting blood sugar was not as good as it should be for diabetic patients. We suggest that you see your medical care provider in the coming week or so for advice on how to get better control.

**Body Weight and “Body Mass Index” or “BMI”**

We have measured your body weight and height. We have done a calculation from these two numbers that give us another number called the “BMI”. This can be compared to the BMI of other people and gives you information about your health risk from obesity.

Your BMI was_____ (less than 25) which is considered normal. We hope you will continue to balance your diet and exercise to maintain this healthy level.

Your BMI was_____ (more than 25 but less than 30) which is higher than normal. We suggest that you think carefully about ways that you can reduce the foods that have alot of calories and increase the amount of exercise that you do each day. If you want help with planning these changes, we can assist you.

Your BMI was_____ (more than 30 which is definitely higher than normal. We suggest that you let us help you make an appointment to see a dietician that can advise you about ways to change you eating habits. We would also suggest that you discuss with your medical provider ways to increase your exercise.

**Acanthosis Nigricans**

This is a condition that causes thickening and a slightly darker look to the skin, especially at the back of the neck. This is usually seen in people above their recommended weight and may show that they are becoming resistant to the effects of insulin. People with this condition often go on to develop type II diabetes. If you are able to reduce the calories in your diet, get more exercise and reduce your weight, these changes will often get better or disappear.

During your exam, our staff found NO______, SOME______, or DEFINITE______ acanthosis nigricans.

**Smoking**

One of the areas that we have asked some questions about today is smoking. While occasionally smoking tobacco as a religious practice probably causes no harm; smoking cigarettes or using other tobacco as a daily habit has 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, we would like to tell you about some methods that could help you quit.

We hope this information has been helpful. There will be results from your blood tests, ultrasound of the neck blood vessels and ultrasound heart pictures coming back in the next days and weeks. You will be contacted and advised if these tests are normal or abnormal. If there are problems with your results, we will tell you how to get help from your medical providers to take care of your health.

In the meantime, remember these 7 important ways to keep your heart healthy:
1) Eat sensibly, keep your weight normal, watch the amount of fat in your diet
2) Exercise sensibly, and regularly
3) Know that your blood pressure is normal, or work with your provider to control it
4) Know that your blood sugar is normal, or work to control it
5) If you use tobacco as a habit, please stop
6) Abstain from alcohol, or drink in moderation with only one or two drinks per day
7) Try to get the rest and relaxation that you need, and enjoy life!

We look forward to working with you to learn more about your health.

Sincerely,

The Strong Heart Staff
Appendix A – 7(b)

NOTE: THIS LETTER (or its ALTERNATE form) IS TO BE USED ONLY FOR NORMAL RESULTS OR ROUTINE REFERRALS. EMERGENT, IMMEDIATE AND URGENT REFERRALS SHOULD FOLLOW THE GUIDELINES IN SECTION 1.8.

THE STRONG HEART STUDY IV
Sample Letter to Participant Concerning Test Results

Dear Strong Heart Study participant:

Attached are results of your [blood tests, or carotid artery ultrasound, or echocardiogram, etc] study that were done as part of the Strong Heart Study. These results have also been sent to _________________as you requested when you came in for your exam.

ON THE NEXT PAGE YOU WILL FIND A SUMMARY OF THE ABNORMAL RESULTS FROM YOUR TESTS, AND RECOMMENDATIONS ABOUT WHAT SHOULD BE DONE.

If we have suggested that you see your medical provider in the coming week or sooner, we will have also tried to reach you by phone. We would like to help you make arrangements for an appointment or for a ride to the clinic, if that is needed.

If you have any questions about these results, contact your health care provider or the staff at the SHS office in [Eagle Butte, or Pine Ridge..... at (605) 964-1177etc]. The attached sheet describes the purpose of each test.

Thank you for your participation in the Strong Heart Study and for helping us learn more about heart disease and strokes in Indian people.

Sincerely,

Principal Investigator
Strong Heart Study

substitute the following paragraph for the first paragraph of the above form letter:

“Attached are results of your [blood tests, or carotid artery ultrasound, or echocardiogram, etc] study that were done as part of the Strong Heart Study. Honoring your request as stated in your consent form, the attached lab results were NOT sent to the IHS or any other medical facility or healthcare provider. However, it may be in your best interests for you to show your healthcare provider these results during your next visit.”
SUMMARY OF ABNORMAL RESULTS

FOR EXAMPLE:

Cholesterol 229 mg/dl

This is a fatty substance in your blood that may clog arteries if it is too high. Everyone should know his/her cholesterol level. It is best to have your cholesterol below 200 mg/dl. Levels 200-239 mg/dl are moderate risk. Levels 240 mg/dl or higher are high risk. Persons with high levels should eat fewer fatty foods and more foods high in fiber such as cereals, fruits, and vegetables. They may also need medicine to lower their cholesterol.

LDL Cholesterol 166 mg/dl

This is the bad cholesterol that clogs the arteries. It is best to have levels below 130 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. People who have had a heart attack are usually advised to get their levels below 100 mg/dl so that further clogging of arteries is prevented.

CAROTID ULTRASOUND RESULTS

Narrowing less than 50%

These results show that you have a certain amount of hardening of the arteries in the large blood vessels in your neck. These blood vessels supply circulation to the brain. Sometimes clots that form in the neck can travel up into the head to cause stroke. Usually surgery is NOT recommended for people with your level of narrowing, but we do suggest that you are careful to do things that will prevent this hardening from getting worse. We recommend that you talk with your medical provider about this at your next appointment in the coming month.
THE STRONG HEART STUDY IV
INTERPRETATION OF BLOOD TESTS

Cholesterol
This is a fatty substance in your blood that may clog arteries if it is too high. Everyone should know his/her cholesterol level. It is best to have your cholesterol below 200 mg/dl. Levels 200-239 mg/dl are moderate risk. Levels 240 mg/dl or higher are high risk. Persons with high levels should eat fewer fatty foods and more foods high in fiber such as cereals, fruits and vegetables. They may also need medicine to lower their cholesterol.

Triglycerides
This is another type of fat in the blood that may cause problems in the pancreas if it is too high. Levels should be below 250 mg/dl. Levels above 1,000 mg/dl are high risk for pancreas problems. Triglyceride levels may be higher in people with diabetes and if they are, improving the control of blood sugar and avoiding alcohol often can lower the level.

HDL Cholesterol
This form of cholesterol is good in that it may prevent clogging of arteries. Levels below 35 mg/dl are high risk and can be increased by exercise.

LDL Cholesterol
This is the bad cholesterol that clogs the arteries. It is best to have levels below 130 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. People who have diabetes or have had a heart attack are usually advised to get their levels below 100 mg/dl so that further clogging of arteries is prevented.

Calcium
High values (above 10.5 mg/dl) or low values (below 9.1 mg/dl) may indicate problems with diet or how your body handles calcium.

Phosphorus
High values (above 3.7 mg/dl) or low values (below 2.3 mg/dl) may indicate problems with how your body handles phosphorus.

Uric Acid
High levels (above 7.2 mg/dl) are seen in people with gout, a form of arthritis, or other medical problems.

Fasting Glucose
Levels of 126 mg/dl or higher may indicate that you have diabetes and further follow up is needed if you do.

Total Protein
High levels (above 8.0 mg/dl) or low levels (below 6.0 mg/dl) may indicate problems that need further follow up.
BUN  
High levels (above 20 mg/dl) may indicate kidney problems or dehydration and should be followed up.

Albumin  
This is a protein in the blood. Low levels (below 3.5 mg/dl) may occur when people have health problems that affect the production of protein in the liver.

Total Bilirubin  
High levels (above 1.2 mg/dl) occur in people with liver problems and cause people to turn yellow and itch.

Liver Function Tests  
High values:
- ALK Phos above 100 U/L
- LDH above 180 U/L
- AST above 42 U/L
- ALT above 42 U/L

These test values are high when people have liver disease or other health problems. Sometimes they can go up just by having three or more alcoholic drinks in a day.

Electrolytes  

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<tr>
<th>Electrolyte</th>
<th>Low Values</th>
<th>High Values</th>
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<tbody>
<tr>
<td>Sodium</td>
<td>below 135 meq/dl</td>
<td>above 147 meq/L</td>
</tr>
<tr>
<td>Potassium</td>
<td>below 3.3 meq/L</td>
<td>above 5.5 meq/L</td>
</tr>
<tr>
<td>Chloride</td>
<td>below 95 meq/L</td>
<td>above 110 meq/L</td>
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<tr>
<td>CO2</td>
<td>below 22 meq/L</td>
<td>above 29 meq/L</td>
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These tests measure how well your body is handling salt. Sometimes blood pressure medicines cause electrolytes to become too high or too low, especially potassium.

Creatinine  
High levels (above 1.2 mg/dl) indicate kidney problems and should be followed up.

CBC  
Complete Blood Count. This test measures the types of cells you have in your blood. If hemoglobin is less than 14.0 grams (gm) for men or 12.0 grams for women or hematocrit is less than 42% for men or 37% for women, it indicates you are anemic and may need further tests to find out why. If your white blood cells are less than 4.8 thousand or more than 10.8 thousand, you may have an infection or other health problem that affects the white blood cells. If your platelets are below 130 thousand or above 424 thousand, you may need further tests to find out why.
URINE ALBUMIN/CREATININE RESULTS

Less than 30 mg/g  When you have less than 30 mg/g (milligrams per gram) of albumin/creatinine in your urine, this indicates that your kidneys are not leaking protein.

30 to 299 mg/g  When you have greater than 29 mg/g, but less than 300 mg/g of albumin/creatinine in your urine, your kidneys are leaking small amounts of protein. During your next visit to a medical provider, inform them of this lab value. Taking the appropriate medication, changing your diet, exercising on a regular basis, or changing your lifestyle to reduce stress can help maintain normal blood pressure and blood sugar, which in turn protect the kidneys from further damage.

Equal to or greater than 300 mg/g  When you have equal to or greater than 300 mg/g of albumin/creatinine in your urine, this indicates your kidneys are leaking large amounts of protein. If you have not already done so, you should receive a medical evaluation for this problem. Strict adherence to your medical provider's orders concerning the use of medication, change in diet, amount of exercise and/or changes in lifestyle to maintain normal blood pressure and blood sugar values can help protect the kidneys from further damage.

CAROTID ULTRASOUND RESULTS

Narrowing less than 50%  These results show that you have a certain amount of hardening of the arteries in the large blood vessels in your neck. These blood vessels supply circulation to the brain. Sometimes clots that form in the neck can travel up into the head to cause stroke. Usually surgery is NOT recommended for people with your level of narrowing; but we do suggest that you are careful to do the things that make hardening of the arteries less likely. We recommend that you talk with your medical provider about this at your next appointment in the coming month.
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 place intact into puncture-resistant containers. The same criteria should be applied to used scalpel blades and any other sharp device that may be contaminated by a patient.

9. To prevent transmission of HIV or HBV, the platform on the finger prick device (Autoclik, etc.) should be changed between patients.

10. Reusable devices, such as tissue grinders, pipettes, etc, should be placed into vesicles containing an appropriate germicide prior to being autoclaved and cleaned.

11. Mouth pipetting of blood or serum or plasma is forbidden for any clinical laboratory procedure. Mechanical pipetting devices are available and must be routinely used.

12. All laboratory specimens and disposables should be discarded in bio-hazard bags and autoclaved prior to final disposition by either incineration or sanitary carting.

13. Accidental spillage of a specimen should be promptly cleaned up with any of the previously mentioned disinfectants. This solution should be freshly prepared and kept in its diluted form no longer than one week.

14. If accidental contamination occurs to an exposed area of the skin, wash first with a good liquid antimicrobial detergent soap (i.e., hibiclens, chlorhexidine gluconate, etc.). Rinse well with water, then apply a 1:10 dilution of household bleach or 50% isopropyl or ethyl alcohol. Leave preparation on skin surface for at least one minute before final washing with the liquid soap and water.
15. All work bench areas should be cleaned and sanitized with an appropriate germicidal agent at the end of each work shift.

16. Before workers leave the laboratory, all protective clothing should be removed. In addition, all laboratory personnel should wash their hands and arms with an appropriate germicidal detergent soap (i.e., chlorhexidine gluconate with alcohol).

FIRST AID AFTER CONTAMINATION OR LIKELY CONTAMINATION

1. SKIN: Wash the skin well with soap and water.

2. EYES: Flush eyes with water by using the safety eye wash.

3. NEEDLE STICK: Squeeze the affected part gently to somewhat cleanse the wound by bleeding. Cleanse with soap and water.

4. MOUTH: Immediately rinse out the mouth with large amounts of clean water. Do not swallow the water. (mouth pipetting is strictly forbidden)

5. For all incidents:

   a. Notify the supervisor and report to the Employee Health Unit, or in the event Employee Health is closed, go to the Emergency Room.

   b. An incident report form must be filed.

   c. The decision to administer hepatitis immune globulin is made by the Employee Health Unit.

   d. The hepatitis B surface antigen (HBsag) vaccine HAS BEEN AND IS AVAILABLE to high risk personnel (laboratory, ICU, etc.) All Strong Heart Study personnel who handled blood should receive three dose of hepatitis B vaccine.

REFERENCES:


Appendix A – 10

THE STRONG HEART STUDY IV
PHYSICIAN REFERRAL FORM FOR DIAGNOSIS
OF CONGESTIVE HEART FAILURE

ID Number: ______________

While Mr./Mrs. ___________________________ was participating in our examination, it appeared to us that he/she might have congestive heart failure. He/She thus has been referred to you for care. Listed below are the criteria that we are using for the identification of congestive heart failure in our study. We would very much appreciate it if you could complete the form below and send it to us, so that it may assist us in making the diagnosis. Please record all that are present when you evaluate the patient. Thank you.

I. Major Criteria

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<tr>
<th>Present</th>
<th>Absent</th>
<th>Not Evaluated</th>
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<tr>
<td>Paroxysmal nocturnal dyspnea or orthopnea</td>
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<tr>
<td>Neck vein distention</td>
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<td></td>
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<tr>
<td>Rales</td>
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<td></td>
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<tr>
<td>Cardiomegaly</td>
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<tr>
<td>Acute pulmonary edema</td>
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<tr>
<td>S3 gallop</td>
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<tr>
<td>Increased venous pressure &gt; 16 cm of water</td>
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<tr>
<td>Circulation time ≥ 25 seconds</td>
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<tr>
<td>Hepatojugular reflux</td>
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II. Minor Criteria

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<tr>
<th>Present</th>
<th>Absent</th>
<th>Not Evaluated</th>
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</thead>
<tbody>
<tr>
<td>Ankle edema</td>
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<tr>
<td>Night cough</td>
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<tr>
<td>Dyspnea on exertion</td>
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<tr>
<td>Hepatomegaly</td>
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</tbody>
</table>
Pleural effusion  
Vital capacity decrease 1/3 from maximum  
Tachycardia (rate of ≥ 120/min)  

III. Major/Minor Criteria  

<table>
<thead>
<tr>
<th>Weight loss 4.5 kg in 5 days in response to treatment</th>
<th>Present</th>
<th>Absent</th>
<th>Not Evaluated</th>
</tr>
</thead>
</table>

IV. Tests that were performed on this patient  

<table>
<thead>
<tr>
<th>Echocardiogram</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest X-ray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurements of vital capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurements of venous pressure</td>
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<td></td>
</tr>
</tbody>
</table>

In your opinion, does Mr./Mrs. ____________________________________________ have congestive heart failure?  

<table>
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<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If YES, what is the underlying cause? (Please check the appropriate cause described below)  

<table>
<thead>
<tr>
<th>Valvular heart disease</th>
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<tbody>
<tr>
<td>Atherosclerotic heart disease</td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy</td>
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</tr>
<tr>
<td>Other. Please specify: ____________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

What is your specialty/sub-specialty of medical practice?  

We thank you very much for your assistance.
APPENDIX B

Instructions for Recruitment

and

Recruitment Forms
The purpose of the Strong Heart Family Study is to find genes that influence heart disease risk factors in American Indians. We already have recruited more than 300 people in large families from each of three field centers, in Oklahoma, the Dakotas, and Arizona. In Phase IV our goal for each field center is to recruit an additional 900 people in large families (an average of 30 or more members each).

**Describing the Strong Heart Family Study**

The success of the Family Study will depend in part on our ability to explain the study to participants in a way that will make its value clear. The following paragraphs may help:

Heart disease and diabetes are serious health problems for American Indians and for other Americans as well. Medical research has established that both heart disease and diabetes tend to run in families; if you have close relatives with heart disease or diabetes, then you are more likely to develop these diseases yourself.

The reasons why heart disease and diabetes run in families are not well understood. Family members usually live in the same household for at least a part of their lives, and as a result they tend to have similar diets, similar exercise patterns, and similar exposure to smoking. Family members also share the same genes, and we think that some of these genes increase the risk of heart disease and diabetes. Family patterns of heart disease and diabetes probably result from a combination of environment and genes.

The goal of the Strong Heart Family Study is to study the family patterns of heart disease and diabetes in American Indians. We hope to recruit a few large families in your community, including parents, children, and grandchildren. For each participating family, we will draw a family tree. We will give each family member a physical examination and we will ask questions about diet and about other lifestyle factors that we believe are important for heart disease and diabetes. For each person, we will measure traits that are related to risk of heart disease and diabetes (such as cholesterol levels in the blood). All of the information on family members will be coded so that individuals and families can't be identified by name, and confidentiality will be strictly maintained.

We will analyze the family patterns of traits related to heart disease and diabetes, and we will try to determine whether genes influence each trait. If the effects of a gene can be detected, then we will try to pinpoint the location of the gene by studying the DNA obtained from white blood cells. In the long term, we hope to find the genes and determine how they contribute to heart disease and diabetes.

Discovering the genes that contribute to heart disease and diabetes is very important for reducing the burden of these diseases on families and communities. If these genes can
be identified, then new treatments can be developed and new ways of preventing disease can be found. We will also be able to help people to modify their environments so that the effects of harmful genes are lessened. This will lead to a longer life and a better quality of life.

Choosing Families for the Study

Preliminary family trees have been constructed by computer using information from the family history forms that were completed for each participant in Strong Heart Study Phase I, and information gathered by each field center during the pilot family study in Phase III. For each center, families have been identified for which:

(1) there is a "core sibship" of at least five full siblings, of whom at least three are Strong Heart Study participants; and

(2) the SHS participants in the core sibship have a total of at least 12 offspring who are at least 18 years old.

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

Because we wish to assure that there will be enough large families to meet our recruitment goals in Phase IV, we also have identified numerous large families in each field center that do not quite meet recruitment criteria, for example, families in which the core sibship contains only two Strong Heart Study participants, but in which those participants have at least 12 offspring.

In choosing families for the Family Study, an additional important criterion will be the family's interest in participating. However, as we recruit families, it is important to avoid "ascertainment bias". We want the families in the Family Study to be representative of their communities, and not selected specifically because they have health problems (nor do we want to exclude families simply because they have members with heart disease or diabetes). Sometimes families of patients with heart disease or diabetes are more willing to participate in family studies than are members of the community in general. To minimize possible problems with ascertainment bias, you will be provided with a list of families that meet our criteria. The families that are recruited should be chosen from this list, and recruitment should continue until at least 900 members of large families have been recruited. If the list does not provide you with a sufficient number of interested families or family members, a supplementary list of eligible families will be provided to you by the Southwest Foundation.

Family Tree Construction

Understanding the Family Tree Diagrams

An example of a small family tree is shown at the top of the next page. In a family tree diagram, males are represented by squares □ and females by circles ○. Solid squares ■ or circles ● represent members of the original Strong Heart Study cohort. Individuals who are
no longer living are represented by a diagonal line through a square or circle. The parents of one or more children are represented by a horizontal line joining a square and a circle. (For the Family Study we need to know the natural parents of each person, but we do not need to know whether those parents are married.)

A sibship, which is a group of brothers and sisters who share the same two parents, is represented by another horizontal line, the sibship line, with vertical lines dropping from it to the squares and circles that represent each of the sibs. A vertical line dropping from the marriage line to the sibship line joins the parents and their children together. The diagram below represents a woman who is a Strong Heart Study participant, her husband who is no longer living, and their four children, two daughters and two sons.

Family tree diagrams can be extended to include additional relatives. The family tree below shows a three generation family with the grandparents in the top generation. They have four children, three of whom are Strong Heart Study cohort members. Each of the children is (or was) married. The daughter on the left, a Strong Heart Study cohort member, has four children. One of her brothers has three children and the other, a Strong Heart Study cohort member, has four. Her sister has been married twice. She has three children by her first husband and one by her second.

Additional information also can be included on the family tree: names, dates of birth, etc. are often written below the symbol representing each family member.

Family Trees Constructed from the Family History Forms

The family trees created from the Family History forms provide some basic information for eligible families. However, some important information is missing because it was not included on the Family History forms. For example,
• We know the names and dates of birth (and death) for the offspring of SHS cohort members, but the Family History Forms do not list the other parent of each of these offspring, and therefore we don't know whether the offspring are full sibs or half sibs.

• The Family History Forms have no information about the spouses and offspring of the non-SHS sibs of SHS cohort members.

The non-SHS members of the families are known only by their names (they have no SHS numbers) and the initial family trees were created by matching names between records. Therefore, we anticipate some mistakes in the family trees created from the Family History Forms. For example,

• If names were misspelled or not clearly written on the Family History Forms, then branches of the family tree may be missed (i.e., some of the relatives are not shown). In some cases, first and last names appear to have been interchanged. In these cases, relatives also are missed.

• In cases in which both a husband and wife are SHS cohort members, the wife (for example) may list six offspring and the husband, only five. We do not know whether the husband's list is incomplete or whether the wife had a child in another marriage.

As discussed below, during the recruitment and interview process, any inaccuracies in the initial family trees should be corrected and missing information should be added.

The Family Informant

We do not know which of the large families that we have identified will be most interested in participating in the Family Study and which family members are living. Before lengthy interviews are conducted with individual family members, the degree to which the families are interested in participating in the Family Study must be determined, and we must begin the process of verifying the accuracy of the family trees. For example, some individuals whom we believe to be full siblings may in fact share only one parent, and thus may be half siblings. An interview with an elder who is knowledgeable about the family (a "family informant") will be the first step in determining which families are likely to be interested and whether the family relationships as we have recorded them are correct.

If the family informant (1) verifies the accuracy of the family tree, and/or provides new information to indicate that the family meets the criteria listed above, and (2) expresses his/her belief that a large number of members of the core sibship and their relatives (at least 30 family members in all) will be interested in participating, then the family will be chosen for the Family Study.
Informed Consent

The first step in interviewing any potential participant is to obtain formal permission to be asked questions about the person and his or her relatives. This is done by giving the person the Informed Consent document (see forms in Appendix A – 1). Each potential participant is asked to read this document, which describes the Strong Heart Study, and then to decide whether or not to take part in the study and a subsequent examination. Each sheet must bear the signature of the interviewer and the participant.

Interviewing the Family Informant

The interview with the family informant will have to be unstructured. The first step is to describe the Family Study briefly to the informant. The next step will be to discuss the computer-generated family tree, describing the meaning of the symbols, and to ask the informant to verify the correctness and completeness of all of the information on it: each name and birth date, family relationships (e.g., whether individuals are full or half siblings), which individuals are no longer living, names of other individuals not included in the family tree (e.g., additional children, parents whose names aren't recorded), etc. As the informant corrects faulty information on the family tree or provides new information, the interviewer should clearly mark the changes directly on the family tree. New symbols should be added for family members who need to be added to the family tree, and if any persons need to be deleted, their symbols and names should be crossed out on the family tree. Any information provided by the informant that should not be shared with other family members (and therefore should not be displayed on revised versions of the family tree) should be clearly marked confidential.

If the information provided by the family informant indicates that the family is not suitable for the Family Study, either because of inappropriate size or structure or because of likely lack of interest, the interviewer should thank the informant for his/her time and terminate the interview.

If, on the basis of the interview, the family remains a good candidate for the Family Study, then the interviewer should ask the informant for addresses of as many family members as possible. This information can set the stage for the recruitment of family members.

Faxing the Revised Family Tree to San Antonio

Immediately after the completion of the family informant interview, the family tree with its hand-entered corrections should be faxed to the Southwest Foundation in San Antonio (Dr. Kari North, fax number: 210-670-3317). Hand-written entries on the family tree must be clearly written so that the fax copies will be readable. A corrected family tree will be generated and immediately faxed back to the center for use in interviews with subsequent family members.

Recruiting Family Members

Please see the Recruiting section of this manual for helpful suggestions on recruiting participants into the Strong Heart Family Study. Most of the families targeted as possible candidates for the Family Study have been identified because (a) they contain a core sibship of at
At least size five, of whom at least three are Strong Heart Study participants, and (b) the members of the core sibship have a total of at least 12 offspring. To assure that there will be enough large families to meet our recruitment goals in Phase IV, we also have identified large families in each field center that do not quite meet recruitment criteria, for example, families in which the core sibship contains only two Strong Heart Study participants, but in which those participants have at least 12 offspring.

For families enrolled in the Family Study, every effort should be made to recruit and interview the following family members:

1. All members of the core sibship, whether or not they are Strong Heart Study cohort members.
2. All age-eligible (at least 15 years of age) offspring of core sibship members.
3. All current and (if possible) previous spouses of core sibship members, if these spouses are parents of the offspring listed in (2).
4. The parents of the core sibship.
5. The parents of spouses of core sibship members, if the spouses are parents of the offspring listed in (2).
6. Any age-eligible grandchildren of core sibship members.
7. Any spouses of individuals listed in (2), if they are parents of age-eligible offspring.

In other words, the family members to be recruited include the core sibship members, their parents, children, and grandchildren, and any spouses who are parents of these family members. Note that for any person recruited, it is important to get information on both of their parents. Our goal is to recruit at least 30 members per family. It is likely that in order to maintain good rapport with the families, some individuals will have to be enrolled who do not qualify under categories (1) - (7). For example, some family members may want their spouses to participate even though they have no children. These extra family members should be enrolled if the recruiter feels that it is necessary to maintain the good will and cooperation of the family, but such enrollments should not be encouraged.

**Interviewing Family Members**

For each enrolled family member, the SHS Family Information Form should be administered. A copy of this form is below (Participant Interview forms following p. III B-10). The complete interview should be conducted for the first few family members examined and for any family members who are found to be particularly knowledgeable about their family. As more and more members of the family are interviewed, it will become apparent that some of the information being obtained is repetitive. For example, there is no need to ask each member of a large sibship for the full names of all of their siblings. However it is important that this information be complete and
accurate for every family member, and that it be verified by more than one person. Therefore the interviewer must use judgment in deciding which family members should be given the complete interview and which ones should simply be asked to verify information provided by others and to fill in missing information.

The SHS Family Information Form

The SHS Family Information Form requests information about the participant and his/her family:

Page 1: Information is recorded about the participant, his/her mother and father, all four grandparents, sons and daughters, and the other parent of each son or daughter. There is space for up to four “other parents”.

Page 2: Information is recorded about the participant’s brothers and sisters, half brothers and half sisters (who share only one parent with the participant), and the other (unshared) parent of each half brother and half sister.

Page 3: Information is recorded about additional sons and daughters. This page is used only if there are more sons and daughters than can be recorded on the first page.

Page 4: Information is recorded about additional sons and daughters and the other parent of each son or daughter. This page is used only if there are more than four “other parents”.

Page 5: Information is recorded about additional brothers and sisters. If necessary, add information about additional half brothers and half sisters, and record the other (unshared) parent of each.

Page 6: Information is recorded on the page at the end of the Recruitment or Family Information Form that is provided for confidential comments. If used, it should be detached from the form and sent immediately to Dr. Kari North (see contact information below).

Recruiters should keep a separate record identifying one or more family contact persons who can be asked for additional information.

The following conventions should be used for this interview:

**Coding unknown information:** If information is unknown, draw two horizontal lines in the space. This indicates that the question has been dealt with.

**Names:** Whenever full names are requested, the interviewer should enter last, first, and middle names; Jr. or Sr. (if relevant); maiden name for married women; and nickname.

**Dates:** All dates should be recorded as month/day/year, with year coded as four digits, e.g., December 1, 1996 should be coded as 12/01/1996. The four-digit year is important because birth dates for members of multi-generation families can span more than a century.
**Sex:** Enter 'M' or 'm' for males. 'F' or 'f' for females.

**Date of birth/Current age:** If birth date is known, enter month/day/year (separated by /). If only year of birth is known, enter the four-digit year. (Entering all four digits is important!) If only current age is known, enter the age in years.

**Birthplace:** Birthplace of family members is a useful source of identification, particularly for relatives who are not resident in the area being surveyed, or who are deceased.

**Alive:** Indicate whether each family member is alive by entering Y for yes (living) and N for no longer living.

**Date of death/Age at death:** If the death date is known, enter month/day/year (separated by /). If only year of death is known, enter the four-digit year. (Entering all four digits is important!) If only age at death is known, enter the age in years.

**Tribal affiliation:** Questions are included about the tribal affiliation of the participant and his/her relatives. This information is requested because people of different backgrounds can have different genes, and we want to be certain to take this into account as we look for genes that increase the risk of heart disease. We will not use this information to analyze an individual participant’s degree of Indian ancestry.

**Household:** It is important to know which family members live in the same household because these family members may share certain environmental risk factors. When you interview the first member of a family, assign household number 1 to that person and write 1 next to the symbol for that person on the family tree. Ask which other family members live in the same household and write 1 next to each of their symbols as well. When you interview the next family member who is not in household 1, write 2 next to the symbols for that person and everyone else in his/her household. Continue with additional family members, using 3, 4, and as many additional household numbers as are needed to specify all households in the family. Write the household number of the participant (the person indicated as "self") in the appropriate place on each page of the Family Information Form.

**Information on relatives:** For recording information on offspring and siblings of the participant, interviewers should use as many sheets labeled "Your Sons and Daughters" and "Your Brothers and Sisters" as needed. The extra sheets, which are color coded, will be available separately and won't be provided in the Family Information Form itself. They should be stapled to the back of the Interview Form after the completion of the interview.

Information is requested for some relatives of family members even though these relatives will not be enrolled in the Family Study at this time. This information will be of value in linking families together, and perhaps in the future, in extending the study to more remote relatives. Thus it is important to record the names of (1) parents and grandparents of members of the top generation
(i.e., of the parents of the core sibship); (2) spouses and offspring of members of the bottom generation (i.e., of the offspring of core sibship members); and (3) parents and siblings of spouses of the core sibship members. This information should be sought even for relatives who are no longer living.

**Defining relationships:** For a family study, it is important to distinguish between full and half siblings, and between biological and adoptive relationships. Therefore when you ask for information about a participant's brothers and sisters, it is important to ask whether the participant and the sibling have the same mother and the same father. If one parent is different, the name of that parent should be recorded in the space provided (Your Half Brothers and Half Sisters Other Parent). On the lines where you have listed the half siblings who have Other Parent #1, circle 1 in the first column. For half siblings who have Other Parent #2, circle 2, etc.

In recording information about a participant's children, you should ask for the name of the other parent of each offspring and record it under Your Children’s Other Parent(s). On the lines where you have listed the children of Other Parent #1, circle 1 in the first column. For the children of Other Parent #2, circle 2, etc.

In recording information about a participant's spouse, please allow for the possibility that the participant may have a partner to whom he/she is not married. For the Family Study we need to know the natural parents of each person, but we do not need to know whether those parents are married.

**Using the Family Tree as a Visual Aid**

As the interviewer is questioning each family member, he/she probably will find it helpful to show the family tree to the participant. An up to date family tree serves as a useful visual aid for both the interviewer and the participant. As in the initial interview with the family informant, any corrections or additional information should be written by hand directly on the family tree and faxed to San Antonio, where the family tree will be redrawn by computer and faxed back to the center.

**A Note of Caution**

Questions about family relationships should be asked with sensitivity to each family member's background. For example, if a family member is known to be adopted, special care must be taken in phrasing questions about the identity of the person's natural father and mother and about brothers and sisters who are blood relatives. Caution also must be used if the interviewer has information of which the family member is unaware. It is important that the interviewer **review the Family Information Form before the interview** and note any questions that need to be asked with special care (or not asked at all, if that information can be obtained elsewhere).

If there are any sensitive issues (questions that couldn't be asked or information of which family members are unaware) or if there are any uncertainties concerning family relationships, please describe on the last page of the SHS Family Information Form, detach the page, and send it directly to Dr. North at the address shown below. These pages also can be faxed, but please call or email first to be certain that the fax can be retrieved immediately.
Assigning a Permanent ID

Strong Heart Study IDs are assigned to each participant in the Strong Heart Family Study by the SHS field staff in the SHS clinic, when they first enter the study (i.e., when they sign the consent form). The format for the Strong Heart Study IDs is described elsewhere.

Each family member, whether or not they are a participant, also is assigned a permanent Family Study ID number (PID). These codes consist of two capital letters, followed by a two-digit family number and a three-digit sequential number. Thus, AZ01001 is the first person in family 01 in the Arizona field center. Leading zeros are used to keep all codes the same length. Examples of PIDs are as follows:

AZ01001  DA01001  OK01001
AZ01002  DA01002  OK01002
AZ01003  DA01003  OK01003  Etc.

Note that

1. All Permanent ID Codes must be unique.
2. Each individual may be assigned only one Permanent ID Code.
3. PIDs are needed even for family members who are not examined – even for family members who are not living – because we need to be able to link individuals into families by computer.
4. An individual’s PID may not be reassigned when he or she leaves the study, moves to another place, dies, etc.

Addresses

Addresses of participants are requested on the Personal Interview Form for two reasons: (1) to enable recruiters to contact the family members, and (2) to help us to verify which family members now live in the same household and thus share certain environmental risk factors.
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Family Study ID number: __________________________

SHS ID number: __________________________

Participant's name: __________________________

**Notes for Drs. MacCluer and North:**

Please detach from form and send immediately to:
Dr. Kari North, Department of Genetics, Southwest Foundation for Biomedical Research, 7620 N.W. Loop 410, San Antonio, TX 78227-5301.
Phone (210) 258-9772, Fax (210) 670-3317, Email knorth@darwin.sfbr.org

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APPENDIX C

Instructions for Questionnaires

and

Data Forms
**Appendix C -- 1**

**Strong Heart Study IV**

**Instructions for the Personal Interview Forms I and II**

Subject should be seated comfortably and made to feel welcome during this interview because it is the first form collected and will set the scene for later data collection.

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**Personal Interview Form I**

Study Identification Number should be completely filled in with the number assigned at the time the consent form is completed and subject is registered.

1st digit represents the center number (1=SD, 2=OK, 3=AZ).  
2nd digit should be "0" for all interviewees.  
3-6 digits will be the consecutive number of the subject interviewed within the center.

Write in social security number.

Write in community code from list.

A. Demographic Information

1 Enter last name, left justified.  
Enter first name, left justified.  
Enter middle name, left justified. If no middle name, leave blank.  
Enter nickname or other name being used by friends.

2 Check the gender of the participant.

3. Fill in the birthday of the participant.

4 Write down the participant's current marital status.

5 If a female participant has ever married, write down her maiden name.

6 Write down the name of a married participant's spouse.

7 Write down the name of IHS and the non-IHS hospital which participant usually goes. Write in facility with which number is associated.

8a Enter left justified with blank separating number from street name and street name from unit number. If post office box, enter after street address.

b Enter left justified, city/town or reservation of residence.

c Enter left justified, county of residence.
Enter state of residence as two digit postal abbreviation and postal zip code.

AZ= Arizona  SD= South Dakota
OK= Oklahoma  ND= North Dakota

If residential address is different from the mailing address, write in the residential address following the rules given in item 9a-d.

Enter complete telephone number of home phone or phone at which participant can be reached during the evenings.

Enter complete telephone number of work phone or phone at which participant can be reached during the day.

Enter number of years of education the participant has received.

Ask participant, whether she/he is an American Indian by heritage. Fill in the appropriate answer.

If answer to Q13 is a "Yes", ask the participant what is her/his estimated total amount of Indian heritage. Using fractions, such as 4/4, 3/8, 3/32, etc., to record the response. If participant refuses to answer, record 99/00. If participant does not know the amount, record 88/00.

Next, ask the participant which tribe she/he is enrolled in. Use the tribal code list to find the appropriate code. If the participant does not know the tribe of enrollment, record 999. If the tribe reported is NOT on the list, record 998.

If participant is NOT an American Indian, ask which ethnic group she/he belongs to. Check the appropriate box.

**Personal Interview Form II**

**A. WEIGHT CONTROL: questions about efforts to lose weight**

1. Ask whether the participant is satisfied with her/his current weight?

2-3. Ask participant whether she/he want to gain or lose weight, and how is she/he doing it.

**B. FAMILY INCOME**

Questions 4-7 assess the family income so that the subject's socioeconomic status can be determined. Ask the questions as stated in the questionnaire. Prepare a sheet of income levels to show the participant.

4. Ask participant whether her/his household income meets her/his family's needs?

5. Ask whether the participant is attending a school.
6 Ask participant, on the average, how many hours per week her/his works for paid job(s).

7 Ask participant what is her/his annual household income.

C. TOBACCO: These questions are very important to assess accurately because smoking is a major risk factor for cardiovascular disease.

8 This question will determine the participant is a smoker or not. A person who has smoked less than 100 cigarettes in her/his lifetime is not considered a smoker since the damage caused by smoking is negligible.

9 Determine when participant started smoke regularly. Record age in years.

10 Ask participant whether she/he quit smoking in the past.

10a-b If participant reported she/he quitted smoking, ask when and why.

11 Determine average cigarettes smoked per day, which may have a significant effect on heart diseases and other health problems.

12 Ask the participant on the occasions which she/he is most likely to smoke or increase smoking. Check ALL the appropriate boxes.

13 Ask the participant on the occasion she/he increase smoking, how many cigarettes does/did she/he smoke per day.

14 Ask the participant whether she/he is smoking currently.

15 Ask the participant whether she/he wants to change smoking habit and how.

16 Ask the participant whether she/he uses chewing tobacco or snuff now.

17 How often per day does the participant use chewing tobacco or snuff.

D. PASSIVE SMOKING: This section tries to assess second-hand smoking.

18 Ask the participant when she/he was growing up, did her/his father or male guardian smoke cigarettes regularly.

19 Ask the participant when she/he was growing up, did her/his mother or female guardian smoke cigarettes regularly.

20 Ask the participant when she/he was growing up, did she/he spend a lot of time with someone smoke cigarettes regularly.

21 Ask participant, regardless of her/his smoking status, on the average, how many hours is she/he exposed to the smoke of others.
E. **ALCOHOL:** Questions related to alcohol consumption are frequently not answered accurately in surveys. Questions included in this questionnaire have been widely used and validated in several national studies.

22 Question 22 determines when the individual last had any alcoholic beverage. If the last drink was less than 30 days ago, fill in the box labeled number of days. If the last drink was within the last year, but more than 30 days ago, fill in the number of months. If the last drink was over one year ago, fill in the number of years. If the last drink was one or more years ago, skip to Q29.

23 Question 23 assesses the average number of drinks consumed in a typical week. Frequently individuals with severe drinking problems, especially binge drinkers, do not consume alcoholic beverages by the can, glass or shot, but rather drink wine or hard liquor out of a bottle. Remind the participant to use the drinks chart to estimate the number of drinks in a typical week.

24 Question 24 will tell you the frequency of alcoholic consumption. Many individuals with severe alcohol problems will only drink on the weekends (i.e., 8 days per month) or at the time of the month when they receive income. Assume 30 days a month.

25 Question 25 assesses the quantity of alcohol consumed in a day when participant drinks.

26 Ask the participant when she/he drinks more than the usual consumption, how much and how often in a month.

27-28 Questions 27 & 28 assess the frequency of binge drinking in the past month and the past year, respectively.

F. **PERCEIVED STRESS:**

29-35 Stress has been associated with the occurrence of CVD in many population studies. Questions 29-35 assess the participant’s personal feelings about the degree of stress the SHS participant had in a general sense during the **PAST MONTH.**

36 Ask the participant, on the average, how much time she/he watches TV per day.

37 Question 37 assesses the reliability of the answers given by the participant. Write down your personnel code number and the date of completion of the interview.
### TRIBAL CODES

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White Mountain Apache Tribe of the Fort Apache Indian Reservation, Arizona

Wichita Indian Tribe of Oklahoma

Winnebago Tribe of the Winnebago Reservation of Nebraska

Winnemucca Indian Colony of Nevada

Wisconsin Winnebago Indian Tribe of Wisconsin

Wyandotte Tribe of Oklahoma

Yankton Sioux Tribe of South Dakota

Yavapai-Apache Indian Community of the Camp Verde Reservation, Arizona

Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona

Yerington Paiute Tribe of the Yerington Colony and Campbell Ranch, Nevada

Yomba Shoshone Tribe of the Yomba Reservation, Nevada

Yurok Tribe of the Hoopa Valley Reservation, California

Zuni Tribe of the Zuni Reservation, New Mexico

Alaska Villages
  Ahtna, Inc.
  Akhiok, Native Village of Akhiok
  Akiachak, Native Village of Akiachak
  Akiak Native Community
  Akutan, Native Village of Akutan
  Alakanuk, Village of Alakanuk
  Alatna Village
  Alegnaqik, Village of Alegnaqik
  Aleut Corporation
  Allakaket Village

Strong Heart Study IV  06/01/01  III C-17  Tribal Code
Before beginning, make certain that the correct study identification number or the participant is entered at the top of the form. Explain to the participant that some questions need to be asked about her/his medical history so that we can better evaluate whether or not she/he has heart disease or a tendency for heart disease. Stress that the information will be confidential and that their name will never be used in any data analysis.

A. Current Medications

"It is important that we are able to identify all of the pills and medicines that you are now taking. We will talk about each one of the medicines that you brought with you. For each one, we would like to know whether you take it regularly. Don't worry if you forgot to take it when you were supposed to; just tell us as accurately as you can how often you have taken." The interviewer then proceeds to ask about each medicine that the patient brought with him/her, and records for each, the name on the bottle. If the bottle is unlabeled, record the color and shape of the pill and save one of them so that it can be identified in the PDR later. After you have gone through all of the medicines that the patient brought with him/her, then ask "Are there any medicines that you are taking that you forgot to bring", if the answer is yes, record them also in Section A.

B. We would appreciate it if you can give us information about your past medical history.

I am going to ask about a number of medical conditions. Did you ever see a doctor or other health care professional for any of the problems that I am going to mention. (Note to Interviewer: When inquiring about how many years ago, if the patient has trouble remembering, try to ask in what year or how old they were when they had the condition; we can then calculate from their current age or from the current year, the number of years ago and enter it in the appropriate box).

1. High Blood Pressure. For high blood pressure, the interviewer should be alert for those individuals who answer no, who might in fact have been prescribed or taking medication for hypertension. If the patient does not know when the hypertension first began, ask when they first began taking medication for high blood pressure and record that date.

2. Arthritis. The interviewer should also inquire about arthritis.

3. Fractures associated with osteoporosis should be explained as fractures caused by bones getting weak. Such fractures often occur in older people with minor trauma or sometimes with no history of trauma. Back bones (vertebrae) can sometimes collapse (compression fractures) and such fractures are usually caused by osteoporosis when they occur in older people. Record the location of each fractures that you feel is related to osteoporosis.

4. Rheumatic heart disease is a sequela of rheumatic fever and typically stenosis or insufficiency (tightness or leakiness) of the valves of the heart.
5. Gallstones. If participants say they have had gall bladder removed check “yes” because almost all cholecystectomies are done for gallstones.

6. Cancer. The interviewer, when inquiring about cancer should ask about cancer and diseases such as leukemia, lymphoma and tumors of the skin. If they answer yes, record the type of cancer.

7. Diabetes and type of treatment. The interviewer should be alert to individuals who reply no, who are in fact taking oral hypoglycemic agents or insulin. If they have diabetes, ask if they still have it and when they were first told they had diabetes. Also record the type of treatment they are taking. Check “yes” for “do nothing” if they are not taking any medication nor exercising, nor controlling their diet for their diabetes.

8. Kidney Failure. The interviewer should describe this as kidney failure if she/he has been told that their kidneys are not working.

9-10. Renal dialysis and transplantation. When inquiring about renal dialysis, the interviewer should also ask if the patient must go two or three times a week to have a machine cleanse their blood. If they have not had a transplant, ask them if they are on the waiting list for a transplant.

11. Cirrhosis of the Liver or Yellow Jaundice. The interviewer should stress that this can occur both because of alcohol and for other reasons as well.

HEART PROBLEMS:

12. Heart catheterization. Ask if patient had any kind of heart catheterization. If “yes”, determine whether they had an angioplasty or other procedure, the date of the procedure and also the hospital where it was done. This should not include use of a treadmill for exercise purposes. Show the participant a picture of a diagnostic treadmill exercise test.

13. Angioplasty (balloon, PCTA, or stent procedure). Ask if the participant ever had an angioplasty procedure. If yes, record when and where.

14. Treadmill test or exercise test to examine the heart. If “yes”, determine the date of the procedure and the hospital where it was done.

15. Heart failure. "That is, did the doctor or health care provider ever tell you that your heart was not working properly?" The necessity to sleep with several pillows (orthopnea) suggests heart failure.

16. Heart Attack. When inquiring about heart attack, this would usually have involved hospitalization, but in some instances, the patient could have been told they had a heart attack in the past on the basis of an electrocardiogram. If the patient indicates that she/he had a heart attack, ask if there were more than one. Obtain information for the most recent ones.

17. If the patient indicates that she/he has had other heart trouble, the interviewer should ask about the symptoms.
18. Stroke. If the participant indicates that she/he has not had a stroke, ask also whether she/he has had any episode where she/he suddenly could not move a part of her/his body for a prolonged period of time.

19. Surgery on chest. Question 19a is designed to ensure that we get accurate information on cardiac surgery so that medical records can be obtained. Use anatomical diagrams if available to help the participants recall the type of surgery they had.
Appendix C -- 4
The Strong Heart Study Phase IV
Instructions for Reproduction and Hormone Use: Women Only

If the patient is a female, explain that we know that in many cases, women appear to be protected from heart disease. Therefore it is necessary for us to ask some questions about their reproductive history, because we are trying to better understand why women appear to have less heart disease.

1-4. After inquiring about the number of times pregnant and the number of live births and abortions, the number of live births plus the number of pregnancies lost, should equal the number of times pregnant. (Unless one or more births of twins, etc. occurred).

5. Ask about use of birth control pills and be sure they are recorded on the medication history if they are currently taking them. Ask the participant when she first used birth control pills and for how long.

6. Ask about use of birth control implant. Ask the participant when she first used a birth control implant and for how long.

7. Ask about use of birth control shots, such as Depo Provera. Ask the participant when she first used birth control shots and for how long.

8. Ask when the participant started to have regular menstrual cycles (periods). Record the age in years.

9. Ask the participant whether her menstrual cycles have stopped.

10. If "Yes" go to Q10 and ask her whether the periods stopped more than 12 months.

If "Yes", ask participant her age when her periods stopped completely and the reason menstruation stopped. The interviewer should answer whether the menopause or the cessation of periods occurred naturally or whether it occurred after an operation to remove the womb or uterus.

ESTROGEN AND PROGESTERONE

Use the questionnaire as written. If participants are currently taking estrogen pills other than birth control pills, be sure they are recorded on the medication history.

11-15. Use questionnaire as written to obtain information about estrogen use. Record when the participant started to use estrogen, for how long all together, reason(s) for using estrogen, and if progesterone is also being added for use.

16-18. Ask the participant whether she is still using estrogen at the time of interview. If not, why?

19-22. Ask the participant whether she ever has ever used progesterone alone. If yes, when started and for how long.
This questionnaire, originally developed by Rose & Blackburn, has been the mainstay of cardiovascular disease surveys for a number of years. The primary feature of this questionnaire is to have a standardized assessment for the pain associated with angina and intermittent claudication. Since it is well recognized that there can be many other causes for both chest and leg pain, the main objective of the questionnaire is to ask a series of questions so that certain patterns of pain will be assigned positively and others will not be assigned. For this reason, it is important that the questions be asked in the order stated. In addition, during several points of the questionnaire, there is an asterisk if a certain answer is received. The purpose of this asterisk is to assure that the questioner then proceeds to the next section. If an answer is received that has an asterisk, it has been determined that this answer indicates that the pain is not characteristic of either angina or intermittent claudication and thus, it is not necessary to proceed with that section.

The questions are essentially self-explanatory. It is permissible, and in fact advisable, when referring to pain or discomfort in the chest to elaborate to describe this pain as a tightening or crushing feeling that may or may not radiate onto the left arm.

In addition, since this is a standardized questionnaire developed in Britain, phrases such as "carry-on" can also be described as "keep on going" or "continue to walk or climb".

Note that participants who are unable to walk should skip from Question 2 (section A) to Section B. Non-ambulatory participants also can skip to section C.
Appendix C -- 6

The Strong Heart Study Phase IV
Instructions for Use of the Respiratory Questionnaire

1-11. These questions are self-explanatory and are part of standard respiratory questionnaires.

12. Lung problems: When inquiring about emphysema, the interviewer should also ask about difficulty in breathing. Participants with a chronic cough should be considered to have chronic bronchitis. If they have asthma, ask if they still have it.
Appendix C -- 7
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

DIRECTIONS TO PARTICIPANTS FOR USING THE ACTIVITY METER
(PEDOMETER)

The Accusplit Activity Meter (pedometer) counts the number of steps taken while walking. You have been requested to wear this meter EVERY DAY for a seven day period from _______ to _______. The pedometer is to be clipped at the waist to your clothes, underwear, or on a belt and worn on the _______ hip and must be kept in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. You can use a belt or elastic strap to keep it in place on your hip. Please DO NOT LET THE PEDOMETER GET WET by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in the morning and to record the pedometer number in your activity record when you take it off at night.

If you have any questions, please contact:

__________________________________________________________________________ at

__________________________________________________________________________.

Specific Instructions
1. Every morning, just before you put the pedometer on, push the reset button to read “0”.
2. Record the time you reset the pedometer on the activity record page.
3. Wear the pedometer all day except for bathing, swimming or in the rain (unless you can keep it dry). If you take it off, record the length of time it was off (minutes or hours) on your activity record page.
4. At bedtime, take off the pedometer. Record on your activity record page (a) the pedometer number (the number of steps taken), and (b) the time you removed the pedometer.
5. Please do not touch the reset button during the day or you will erase your activity numbers.
6. Wear the pedometer on your dominant hip (right hip for right handed people and left hip for left handed people), keep it upright, and make sure it fits firmly against your body so it does not move around.
7. Keep the cover closed or it will not record your steps.
8. The pedometer will not work correctly if it is in a pants, coat, or shirt pocket. It will not work correctly if it is sideways either.
9. Please mail the activity record to us in the self-addressed stamped envelope after you complete your week.
10. Please keep the pedometer as a token of our appreciation of your participation in the Strong Heart Family Study.

Thank you very much for your time and effort!
THE STRONG HEART—FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Screening for Pregnancy and Lactation
WOMEN ONLY

SHS Family Study ID: ___________  SHS ID number: ___________

Administered to women < 50 years of age at time consent is obtained. It can be self-administered.

1. Are you pregnant?
   Yes [__]  No [__]  Not sure [__]

2. When was your last menstrual period?
   If unknown, leave the boxes blank
   [__] / [__] / [__] yr

3. When did your last pregnancy end?
   Never pregnant = 01-01-1001
   Currently pregnant = 01-01-1900
   [__] / [__] / [__] yr

4. Are you now breast-feeding?
   Yes [__]  No [__]

5. If "yes", how long you have been breast-feeding (in months)?
   [__] month(s)

Women who think they may be pregnant should not be examined or have blood drawn, because pregnancy changes the blood lipids. Women who think they may be pregnant should be referred for prenatal care. Women can participate in the Family Study six weeks postpartum even if they are lactating.

6. Code number of person completing this form
   [__] / [__] / [__] yr

7. Date of data collection
   [__] / [__] / [__] yr
THE STRONG HEART—FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PERSONAL INTERVIEW FORM I

SHS Family I.D.: ________________ SHS. I.D.: ________________
Social Security Number: ________________
Community name: ______________________ Community Code: ________________

A. DEMOGRAPHIC INFORMATION:

1. Your Name:
   a. Last: ________________
   b. First: ________________
   c. Middle: ________________
   d. Nickname/Other Name: ________________

2. Gender: Male [ ] Female [ ]

3. Date of Birth: [____][____][____][____]

4. What is your marital status?
   1 = Never married (Skip to Q. 7)  4 = Separated
   2 = Currently married          5 = Widowed
   3 = Divorced                 6 = Adult roommate/partner/significant other

5. If ever married, what was your maiden name?
   ________________

6. If married, what is your spouse's name? (if not married, skip to Q7)
   Last: ________________ First: ________________ Middle: ________________
7. 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.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Chart number</th>
<th>IHS 1=Yes, 2=No</th>
<th>Hospital Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td></td>
<td></td>
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<tr>
<td>b.</td>
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<td></td>
<td></td>
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<tr>
<td>c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td></td>
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</tr>
</tbody>
</table>

8. What is your current mailing address?

a. ____________________________
   Street/P.O. Box
b. ____________________________
   City/town

c. ____________________________
   County
d. State and zip code:
   ____________________________

9. Is your residential address the same as above?
   Yes [ ] 1  No [ ] 2 if no, what is your current address?

a. ____________________________
   Street/P.O. Box
b. ____________________________
   City/town:
c. ____________________________
   County:
d. State and Zip code:
   ____________________________

10. What is your home telephone number? Or at what telephone number can we reach you or leave a message? 0= If unlisted

    ____________________________
    area code
    9= If no phone

11. What is your work or other contact telephone number?
    0= If same as home phone
    ____________________________
    area code
    9= If not applicable or unknown
Since we know that years of education may be a risk factor for some diseases, we need to ask about the years of education you have completed.

12. How many years of education have you completed?  
   0-12 = Vo-tech or years of school (Vo-tech/GED = 12)  
   14 = Junior college  
   18 = Masters  
   20 = Doctorate  
   999 = Unknown

We are studying heart disease in American Indians. Often, heart disease is more common in some families and tribal groups than others. For that reason, we need to ask you about your Indian heritage.

13. Are you an American Indian by heritage/blood? Yes [ ] 1  
   If YES, answer Q14, Q15  
   No [ ] 2  
   If NO, answer Q16

14. What do you estimate to be your total amount of Indian heritage/blood?  
   (non-Indian=00/00, refused=99/00)  
   [ ] [ ]

15. What is your tribe of enrollment?  
   Enter name and IHS tribal code: ___________________________  
   [ ] [ ]

16. If you are not American Indian, what ethnicity are you?  
   White, non-Hispanic [ ] 1  
   White, Hispanic [ ] 2  
   Black, not Hispanic Origin [ ] 3  
   Asian or Pacific Islander [ ] 4  
   Other, please specify: ___________________________ [ ] 5
A. WEIGHT SATISFACTION
1. Are you satisfied with your present weight?
   Yes [ ] 1 (skip to B)  No [ ] 2  Unknown/unsure [ ] 9

2. Do you want to lose or gain weight?  Lose [ ] 1  Gain [ ] 2

3. How do you plan to do this?
   Less  More  No change
   a) Eating
      [ ] 1  [ ] 2  [ ] 3
   b) Physical activity
      [ ] 1  [ ] 2  [ ] 3
   c) Medication
      Yes [ ] 1  No [ ] 2
   d) Other, specify: ____________________________  Yes [ ] 1  No [ ] 2

B. FAMILY INCOME:
4. Does your household income meet your family's needs?
   Yes [ ] 1  No [ ] 2  Unsure [ ] 9

5. Are you going to school?  Yes [ ] 1  No [ ] 2

6. How many hours per week do you work at a job or jobs that pay you a salary or wage? (Fill in number of hours)
   ___________

7. Which of the following categories best describes your annual household income from all sources? Please show a list.
   Less than 5,000 [ ] 1  20,000 to 25,000 [ ] 5  Don't know/not sure [ ] 9
   5,000 to 10,000 [ ] 2  25,000 to 35,000 [ ] 6  Refused [ ] 0
   10,000 to 15,000 [ ] 3  35,000 to 50,000 [ ] 7
   15,000 to 20,000 [ ] 4  Over 50,000 [ ] 8
C. TOBACCO:

8. During your lifetime have you smoked 100 cigarettes or more total?  
   Yes [___]1  No [___]2  (skip to Q16)

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

10. Did you quit smoking?  Yes [___]1  No [___]2  (skip to Q11)
    a) If you quit, when did you last smoke?  
       (Just the year, please)
    b) What reason(s) did you have for quitting?  Please check all that apply:
       i) Doctor's advice
       ii) Health concerns
       iii) Expenses
       iv) Family pressure
       v) Peer pressure
       vi) Other
       specify: ____________________________

11. On the average, how many cigarettes do/did you usually smoke per day?  
    0 = Less than one cigarette per day

   a) If less than one cigarette per day, number of cigarettes per month?
12. On which occasions are/were you most likely to smoke, or increase your smoking?  
Please read the list and check the appropriate response. 

a) stressful times  Yes |   | No |   
   1 |  2 
b) casinos  Yes |   | No |   
   1 |  2 
c) wakes/funerals  Yes |   | No |   
   1 |  2 
d) when drinking alcohol  Yes |   | No |   
   1 |  2 
e) social meetings  Yes |   | No |   
   1 |  2 
f) when you have extra money  Yes |   | No |   
   1 |  2 
g) bingo  Yes |   | No |   
   1 |  2 
h) school  Yes |   | No |   
   1 |  2 
i) other, specify: _______________________________  Yes |   | No |   
   1 |  2 

13. On the occasions that your smoking increased, how many total cigarettes do/did you smoke per day?  

14. Do you smoke cigarettes now?  
Yes |   | No |   
   1 |  2  
(if No, skip to Q16) 

15. If you currently smoke, would you like to change your smoking habit?  
Yes |   | No |   
   1 |  2  
(if No, skip to Q16) 

a) If yes, would you prefer to...  

i) Reduce number of cigarettes per day  Yes |   | No |   
   1 |  2 

ii) Switch to lower "tar" or "nicotine" cigarettes  Yes |   | No |   
   1 |  2 

iii) Use nicotine patch/chewing gum/medications  Yes |   | No |   
   1 |  2 

iv) Quit  Yes |   | No |   
   1 |  2 

v) Other, specify: _______________________________  Yes |   | No |   
   1 |  2 

16. Do you use chewing tobacco/snuff now?  
Yes |   | No |   
   1 |  2 
17. If yes, how many times a day do you use it? _________ times/day (Enter 0 if less than once a day or use sporadically)

D. PASSIVE SMOKING:

18. When you were growing up, did your father or male guardian ever smoke cigarettes regularly?
   Yes [____]1  No father/male guardian [____]3
   No [____]2  Unknown [____]9

19. When you were growing up, did your mother or female guardian ever smoke cigarettes regularly?
   Yes [____]1  No mother/female guardian [____]3
   No [____]2  Unknown [____]9

20. When you were growing up, did someone you spent a lot of time with smoke cigarettes regularly?
   Yes [____]1  No such person [____]3
   No [____]2  Unknown [____]9

21. 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. 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 whisky = 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 everclear in punch = 1 drink
22. Have you ever consumed alcoholic beverages?

   Yes [ ] No [ ] (this section of the interview is finished, go to Question 29)

   a) If yes, when was your last drink? (Choose only one)

      [ ] 1 Within the last week
      [ ] 2 Within the last month
      [ ] 3 Within the last year. Number of months
      [ ] 4 More than a year ago

      (If over a year, this section of the interview is finished, please go to Question 29)

23. How many alcoholic drinks do you have in a typical week?

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

   (Indicate the number of days per month)

25. On the days you drink any liquor, beer or wine, about how many drinks do you have, on average? (Indicate number of drinks per day)

26. When you drink more than your usual amount, how many total drinks do you have?

   a) How many times in a month?

27. How many times during the PAST MONTH did you have 5 or more drinks on an occasion? Indicate times per month. (Enter zero if subject has quit drinking more than one month ago.)

28. How many times during the PAST YEAR did you have 5 or more drinks on an occasion?

F. PERCEIVED STRESS:

In the past month, how often have you (Q29-35):

   Not at all Rarely Sometimes Often Most of the time Not sure

29. been upset because of something that happened unexpectedly?  [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 9

30. felt nervous or "stressed"?  [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 9
31. dealt with irritating life hassles?
   Not at all    Rarely    Sometimes    Often    Most of the time    Not sure
   1          2          3          4          5          9

32. felt that things were going your way?
   1          2          3          4          5          9

33. felt unable to control irritations in your life?
   1          2          3          4          5          9

34. felt that you were on the top of things?
   1          2          3          4          5          9

35. felt difficulties or problems were piling up so high that you could not handle them?
   1          2          3          4          5          9

36. On the average, how much time per day do you watch TV?
   hours  minutes

G. ADMINISTRATIVE INFORMATION:

37. How reliable was the participant in completing the questionnaire?
   Very reliable   Reliable   Unreliable
   1          2          3
   Very unreliable   Uncertain
   4          5

38. Did the participant complete the interview?
   Yes, completed the interview
   1
   No, refused all questions
   2

39. Interviewer:
   

40. Date of interview:
   

THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MEDICAL HISTORY FORM

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

B. MEDICAL CONDITIONS:

"Now I’d like to ask you some questions about medical problems. Has a medical person EVER told you that you had any of the following conditions?"

1. High blood pressure?  Yes [ ] 1 No [ ] 2 Only during pregnancy [ ] 3 Unknown [ ] 9
If "YES," how old were you when you were first told by a medical person that you had high blood pressure (for women, not during pregnancy)? Indicate the actual age. Don’t know = 999

2. Arthritis? YES [ ] 1 NO [ ] 2 UNKNOWN [ ] 9

3. Any fractures associated with brittle bone disease or osteoporosis? YES [ ] 1 NO [ ] 2 UNKNOWN [ ] 9
If "YES," where?

4. Rheumatic heart disease? YES [ ] 1 NO [ ] 2 UNKNOWN [ ] 9

5. Gallstones? YES [ ] 1 NO [ ] 2 UNKNOWN [ ] 9

6. Cancer, including leukemia and lymphoma? YES [ ] 1 NO [ ] 2 UNKNOWN [ ] 9
If "YES," specify type of cancer:

7. Diabetes? YES [ ] 1 NO [ ] 2 Only during pregnancy [ ] 3 Unknown [ ] 9
(if No or Unknown, skip to Q8)

a) How old were you when you were first told by a medical person that you had diabetes? Indicate the actual age. Don’t know = 999

b) What type of treatment are you taking for your diabetes? (Check appropriate answer)

 i) insulin YES [ ] 1 NO [ ] 2

 ii) oral hypoglycemic agent [ ] 1 [ ] 2

 iii) by dietary control [ ] 1 [ ] 2
iv) by exercise

v) do nothing

vi) other

8. Has a medical person ever told you that you had kidney failure?  
   (if No or Unknown, skip to Q11)
   YES     NO     UNKNOWN
   __I1__ __I2__ __I9__

   a) If Yes, are one or both working well now?
      YES     NO     UNKNOWN
      __I1__ __I2__ __I9__

   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
      __________

9. Are you currently on renal dialysis?  
   YES     NO     UNKNOWN
   __I1__ __I2__ __I9__

10. Have you ever had kidney transplant?  
    YES     NO     UNKNOWN
    __I1__ __I2__ __I9__

    a) If Yes, is the new kidney working well?
       YES     NO     UNKNOWN
       __I1__ __I2__ __I9__

    b) If No, are you waiting for a kidney transplant?
       YES     NO     UNKNOWN
       __I1__ __I2__ __I9__

11. Cirrhosis of the liver?  
    YES     NO     UNKNOWN
    __I1__ __I2__ __I9__

   HEART PROBLEMS:

12. Have you had a heart catheterization?  Yes __I1__  No __I2__  Unknown __I9__
    (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)?
       __________

        hospital/clinic: ________________________________
13. Have you ever had an angioplasty (balloon, PCTA, or Stent procedure)?
   Yes [ ] 1   No [ ] 2   Unknown [ ] 9

   a) If “YES,” when and where (most recent)?
      [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]
      mo  day yr
   hospital/clinic: ____________________________

14. Have you ever had a diagnostic exercise test or Chemical Stress test to check your heart?
   Yes [ ] 1   No [ ] 2   Unknown [ ] 9

   a) If “YES,” when and where?
      [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]
      mo  day yr
   hospital/clinic: ____________________________

Has a doctor ever told you that you had any of the following conditions?
(If more than one episode, enter information for the MOST RECENT)

15. Congestive heart failure?
   Yes [ ] 1   No [ ] 2   Unknown [ ] 9

   a) If YES,” when and where?
      [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]
      mo  day yr
   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?
      [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]
      mo  day yr
   hospital/clinic: ____________________________

17. Any other heart trouble?
   Yes [ ] 1   No [ ] 2   Unknown [ ] 9

   If “YES,” please specify type: ____________________________

   a) If YES,” when and where
      [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]
      mo  day yr
   hospital/clinic: ____________________________
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
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<tbody>
<tr>
<td>18. Stroke?</td>
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<tr>
<td>a) If YES, when and where?</td>
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<td></td>
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<tr>
<td>hospital/clinic:</td>
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<tr>
<td>19. Have you ever had surgery on your chest?</td>
<td>Yes</td>
<td>No</td>
<td><em>(skip to Q20)</em></td>
</tr>
<tr>
<td>a) Was it heart surgery?</td>
<td>Yes</td>
<td>No</td>
<td><em>(skip to Q20)</em></td>
</tr>
<tr>
<td>i) Bypass?</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>If “Yes,” when and where (most recent)?</td>
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<tr>
<td>hospital/clinic:</td>
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<tr>
<td>ii) Valvular repair/replacement?</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>If “Yes,” when and where (most recent)?</td>
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<td>hospital/clinic:</td>
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<tr>
<td>iii) Pacemaker?</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<td>If “Yes,” when and where (most recent)?</td>
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<td>hospital/clinic:</td>
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<tr>
<td>iv) Other?</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>If “Yes,” when and where (most recent)?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Please specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hospital/clinic:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
20. Did the participant complete the interview?
   Yes, completed the interview [ ]
   No, some questions refused [ ]
   No, refused all questions [ ]

IS THE PARTICIPANT FEMALE?
   Yes [ ] (go to next page)
   No [ ]

IF THE PARTICIPANT IS MALE, GO TO ROSE QUESTIONNAIRE

21. Interviewer:

22. Date of interview: [ ]
"The following questions are related to your childbearing history and childbearing organs."
(For Q1 - Q4, use 999 for Unknown)
1. How many times have you been pregnant? (gravidity)
   (If never pregnant, skip to Q5)
2. How many of your pregnancies resulted in a live birth (parity)?
3. How many living children do you have?
4. How many pregnancies did you lose (including miscarriage or stillbirth)?
5. Have you ever used birth control pills? Yes [ ] 1 No [ ] 2 Not sure [ ] 3
   (if NO or NOT SURE, go to Q6)
   a) Are you still using birth control pills? Yes [ ] 1 No [ ] 2
   b) How old were you when you started to use birth control pills?
      Indicate the age in years. 999=unknown
   c) How many years altogether did you use them?
      Specify the duration in years. 0=less than 6 months, 1=6-12 months, 999=unknown.
6. Have you ever had a birth control implant (such as Norplant)?
   Yes [ ] 1 No [ ] 2 Not sure [ ] 3
   (if NO or NOT SURE, go to Q7)
   a) Are you still using a birth control implant? Yes [ ] 1 No [ ] 2
   b) How old were you when you started to use a birth control implant?
      Indicate the age in years. 999=unknown, can’t remember
   c) How many years altogether did you use it?
      Specify the duration in years. 0=less than 6 months, 1=6-12 months, 999=unknown.
7. Have you ever used birth control shots (such as Depo Provera)?
   Yes [ ] 1 No [ ] 2 Not sure [ ] 3
   (if NO or NOT SURE, go to Q8)
a) Are you still using birth control shots?  
   Yes [ ] 1  
   No [ ] 2

b) How old were you when you started to use birth control shots?  
   Indicate the age in years.  999=unknown, can’t remember

   [ ] [ ]

c) How many years altogether did you use them?  
   Specify the duration in years.  0=less than 6 months, 1=6-12 months, 999=unknown

   [ ] [ ] [ ]

8. How old were you when you started to have regular menstrual cycles (periods)?  
   Indicate the age in years.  999=unknown

   [ ] [ ] [ ]

9. Have your menstrual cycles (periods) stopped?  
   Yes [ ] 1  
   No [ ] 2  (go to Q11)

10. If ‘YES’, have they stopped for 12 months or more?  
    Yes [ ] 1  
    No [ ] 2  (go to Q11)

   a) How old were you when your periods stopped completely?  
      Indicate the age in years.  999=unknown, can’t remember

      [ ] [ ] [ ]

   b) Did your periods stop naturally, or because of surgery or hormone use, or for some other reason?  
      Natural [ ] 1  (go to Q11)
      Surgery [ ] 2
      Hormonal [ ] 3  (go to Q11)

      Other, specify:  [ ] [ ]

      (go to Q11)

   c) If SURGERY, were both of your ovaries removed?  
      Yes [ ] 1  
      No [ ] 2  
      Unknown [ ] 3

   "ESTROGEN and PROGESTERONE are types of female hormones that may be taken for many reasons, including after a hysterectomy or the menopause, to regulate your periods or for other reasons."

11. Except for birth control pills, have you ever taken estrogen - either pills, as a patch or by shot - for any reason?  
    Yes [ ] 1  
    No [ ] 2  
    Not sure [ ] 3

    (if NO or NOT SURE, go to Q19)

12. How old were you when you started using estrogen?  
    Indicate age in years.  

   [ ] [ ] [ ] [ ]

13. How many years altogether did you take estrogen?  
    Specify duration in years.  
    (if less than 3 months, record 0. If more than 3 months but less than 1 year, record 1)
14. Do/Did you use estrogen for (answer all applicable)  
   a) post surgery (hysterectomy and removal of ovaries)  
      | YES | NO | NOT SURE |
      | 1   | 2  | 3        |
   b) relief of menopause symptoms  
      | 1   | 2  | 3        |
   c) prevent bone loss  
      | 1   | 2  | 3        |
   d) protect against heart disease  
      | 1   | 2  | 3        |
   e) doctor's advice  
      | 1   | 2  | 3        |
   f) other: ___________________________  
      | 1   | 2  | 3        |

15. Do/Did you take progesterone in addition to, or in combination with, your estrogen treatment?  
   Yes [ ] 1  No [ ] 2  Not sure [ ] 3  
   (If NO or NOT SURE, go to Q19)

16. What form of estrogen are you taking? Is it a pill, patch, shot or other type?  
   pill [ ] 1  patch [ ] 2  shot [ ] 3  other [ ] 4  Not sure [ ] 5

17. Are you still taking estrogen?  
   Yes [ ] 1 (go to Q19)  No [ ] 2 (go to Q18)

18. Why did you stop taking estrogen?  
   YES  NO  UNKNOWN
   a) Caused Bleeding  
      | YES | NO | UNKNOWN |
      | 1   | 2  | 3       |
   b) Made breasts tender  
      | 1   | 2  | 3       |
   c) Made you feel bloated  
      | 1   | 2  | 3       |
   d) Made you feel "funny," didn't like the way you felt  
      | 1   | 2  | 3       |
   e) Do not like taking any medicines  
      | 1   | 2  | 3       |
f) Too expensive
  YES | NO | UNKNOWN
  | 1  | 2  | 9

g) Doctor’s advice
  YES | NO | UNKNOWN
  | 1  | 2  | 9

h) Concerned about long-term side effects
  YES | NO | UNKNOWN
  | 1  | 2  | 9

i) Other: __________________________
  YES | NO | UNKNOWN
  | 1  | 2  | 9

19. Other than in combination with estrogens, have you ever taken progesterone by itself for any reason?
   Yes [ ] 1   No [ ] 2   Not sure [ ] 3
   (If NO or NOT SURE, go to Q23)

20. How old were you when you started using progesterone?
   Indicate age in years.
   [ ] [ ] [ ]

21. How many years altogether did you take progesterone? Specify duration in years.
   [ ] [ ] [ ]
   (If less than 3 months, record 0. If more than 3 months but less than 1 year, record 1)

22. Are you still taking progesterone?
   Yes [ ] 1   No [ ] 2

23. Did the participant complete the interview?
   Yes, completed the interview [ ] 1
   No, refused all questions [ ] 2

24. Interviewer:
   [ ] [ ] [ ] [ ] [ ] [ ]

25. Date of interview:
   [ ] [ ] [ ] [ ] [ ] [ ] [ ]
Section A: Chest Pain on Effort

1. Have you ever had any pain or discomfort in your chest?  
   Yes [ ] 1  No [ ] 2  
   (go to Section C)

2. Do you get it when you walk uphill, upstairs or hurry?  
   Yes [ ] 1  No [ ] 2  (go to Section B)  
   Never hurries or walks uphill or upstairs [ ] 3  
   Unable to walk [ ] 4  (go to Section B)

3. Do you get it when you walk at an ordinary pace on the level?  
   Yes [ ] 1  No [ ] 2

4. What do you do if you get it while you are walking?  
   Stop or slow down [ ] 1  
   (Record "stop or slow down" if subject carries on after taking nitroglycerine.)  
   Carry on [ ] 2  (go to Section B)

5. If you stand still, what happens to it?  
   Relieved [ ] 1  Not relieved [ ] 2  
   (go to Section B)

6. How soon?  
   10 minutes or less [ ] 1  More than 10 minutes [ ] 2  
   (go to Section B)

7. Will you show me where it was?  
   (Record all areas mentioned. Use the diagram below to show the location if participant cannot tell exactly.)  
   YES  NO  
   Upper:  
   Sternum (upper or middle) [ ] 1  [ ] 2  
   Sternum (lower) [ ] 1  [ ] 2  
   Middle:  
   Left anterior chest [ ] 1  [ ] 2  
   Left arm [ ] 1  [ ] 2  
   Lower:  
   Other:  
   [ ] [ ]

8. Do you feel it anywhere else?  
   Yes [ ] 1  No [ ] 2  
   If "YES," record additional information: 

---

Image of the diagram:

- Upper chest
- Middle chest
- Lower chest
- Left anterior chest
- Left arm
- Other areas

---

Strong Heart Study IV   06/01/01

III D-20

Rose Questionnaire
Section B: Possible Infarction

9. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?  
   Yes [ ] [1]  No [ ] [2]

Section C: Intermittent Claudication

10. Do you get pain in either leg on walking?  
    Yes [ ] [1]  No [ ] [2] (go to Q19)  
    Unable to walk [ ] [3] (go to Q19)

11. Does this pain ever begin when you are standing still or sitting?  
    Yes [ ] [1] (go to Q19)  
    No [ ] [2]

12. In what part of your leg did you feel it?  
    Pain includes calf/calves [ ] [1]  
    Pain does not include calf/calves [ ] [2] (go to Q19)  
    If calves not mentioned, ask: "Anywhere else?" Please specify: ____________________________

13. Do you get it if you walk uphill or hurry?  
    Yes [ ] [1]  No [ ] [2] (go to Q19)  
    Never hurries or walks uphill [ ] [3]

14. Do you get it if you walk at an ordinary pace on the level?  
    Yes [ ] [1]  No [ ] [2]

15. Does the pain ever disappear while you are walking?  
    Yes [ ] [1] (go to Q19)  
    No [ ] [2]

16. What do you do if you get it when you are walking?  
    Stop or slow down [ ] [1]  
    Carry on [ ] [2] (go to Q19)

17. What happens to it if you stand still?  
    Relieved [ ] [1]  
    Not Relieved [ ] [2] (go to Q19)

18. How soon?  
    10 minutes or less [ ] [1]  
    More than 10 minutes [ ] [2]

END OF ROSE QUESTIONNAIRE

19. Did the participant complete the interview?  
    Yes, completed the interview [ ] [1]  
    No, refused all questions [ ] [2]

20. Interviewer:

21. Date of interview: ____________________________
### Respiratory Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Skip Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. a) Do you usually have a cough?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. b) Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week?</td>
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<tr>
<td>1. c) Do you usually cough at all on getting up, or first thing in the morning?</td>
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<tr>
<td>1. d) Do you usually cough like this on most days for 3 consecutive months or more during the year?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1. e) How long have you had this cough?</td>
<td></td>
<td></td>
<td>(in years and months)</td>
</tr>
<tr>
<td>2. Do you usually bring up phlegm from your chest when you cough?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Does your chest ever sound wheezy or whistling:</td>
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<tr>
<td>3. a) when you have a cold?</td>
<td></td>
<td></td>
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<tr>
<td>3. b) occasionally apart from colds?</td>
<td></td>
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</tr>
<tr>
<td>3. c) most days?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3. d) most nights?</td>
<td></td>
<td></td>
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<tr>
<td>4. Have you ever had an attack of wheezing that has made you feel short of breath?</td>
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<tr>
<td>5. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill</td>
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<tr>
<td>6. Do you have to walk slower on level ground than people of your age due to breathlessness?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>7. Do you ever have to stop for breath when walking at your own pace on level ground?</td>
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<td></td>
</tr>
</tbody>
</table>
8. Do you ever have to stop for breath after walking 100 yards (the length of a football field) or after a few minutes on level ground?  
   Yes [ ] 1  No [ ] 2

9. Are you too breathless to leave the house or breathless after dressing or undressing?  
   Yes [ ] 1  No [ ] 2

10. Did you have any lung trouble before the age of 16?  
    Yes [ ] 1  No [ ] 2

11. Have you ever been told you snore?  
    Yes [ ] 1  No [ ] 2

12. LUNG PROBLEMS
    Has a medical person ever told you that you had any of the following conditions?  
    YES  NO  UNKNOWN

   a. Emphysema?  
      [ ] 1  [ ] 2  [ ] 9

   b. Hay fever?  
      [ ] 1  [ ] 2  [ ] 9

   c. Chronic bronchitis?  
      [ ] 1  [ ] 2  [ ] 9

   d. Asthma?  
      [ ] 1  [ ] 2  [ ] 9

      If "YES" for asthma, do you still have it now?  
      [ ] 1  [ ] 2  [ ] 9

   e. At any time during the last 12 months, have you had wheezing or whistling in your chest?  
      [ ] 1  [ ] 2  [ ] 9

13. Did the participant complete the interview?  
    Yes, completed the interview [ ] 1  
    No, refused all questions [ ] 2

14. Interviewer:  
   [ ] [ ] [ ] [ ] [ ]

15. Date of interview:  
   [ ] [ ] [ ] [ ] [ ] [ ] [ ]
I. EXAMINATION OF EXTREMITIES FOR AMPUTATIONS

1. Are any extremities missing?  Yes [ ]  No [ ] (Skip to next Section)

If "YES" to amputation, Please code the cause of amputation:
1 = Diabetes  4 = Other, please specify
2 = Trauma  9 = Unknown
3 = Congenital

<table>
<thead>
<tr>
<th>Extremities</th>
<th>Check if Missing</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Right arm</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>b. Right hand</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>c. Right finger(s)</td>
<td>[ ]</td>
<td># missing</td>
</tr>
<tr>
<td>d. Left arm</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>e. Left hand</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>f. Left fingers</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>g. Right leg above knee</td>
<td>[ ]</td>
<td># missing</td>
</tr>
<tr>
<td>h. Right leg below knee</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>i. Right foot</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>j. Right toe(s)</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>k. Left leg above knee</td>
<td>[ ]</td>
<td># Missing</td>
</tr>
<tr>
<td>l. Left leg below knee</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>m. Left foot</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>n. Left toe(s)</td>
<td>[ ]</td>
<td># Missing</td>
</tr>
</tbody>
</table>

II. 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) [ ]
   Regular arm (24-32cm) [ ]
   Large arm (33-41cm) [ ]
   Thigh (>41cm) [ ]
4. Pulse obliteration pressure

5. Seated Blood Pressure:
   a) **First** Blood Pressure Measurement
   b) **Second** Blood Pressure Measurement
   c) **Third** Blood Pressure Measurement

6. Were the above blood pressures taken from RIGHT arm?
   Yes [____] 1
   No [____] 2
   Specify: __________________________

7. Recorder ID (For the SHS staff who took BP):

III. **ANTHROPOMETRIC MEASUREMENTS:**
    (Take off shoes and remove heavy objects from pockets.)

   **METRIC SYSTEM**
   (centimeters/cm/kg)

8. Height (Standing) .............................................. [____] [____] cm

9. Weight (Standing) .............................................. [____] [____] kg

10. Hip circumference (Standing) .................................. [____] [____] cm

11. Waist measurement at umbilicus (Supine) .................... [____] [____] cm

IV. **PEDAL PULSES AND EDEMA**

12. Right posterior tibial pulse  [____] 1  [____] 2  [____] 3  [____] 4

13. Right dorsalis pedis pulse  [____] 1  [____] 2  [____] 3  [____] 4

14. Left posterior tibial pulse  [____] 1  [____] 2  [____] 3  [____] 4

15. Left dorsalis pedis pulse  [____] 1  [____] 2  [____] 3  [____] 4

16. Pedal edema  Absent [____] 1  Mild [____] 2  Marked [____] 3
V. IMPEDANCE MEASUREMENT

17. a) Was impedance taken?    Yes [ ] 1    No [ ] 2  
   (go to b)  
   if No, due to:  
   Amputation [ ] 1  
   Wound/dressing [ ] 2  
   Cast [ ] 3  
   Dialysis shunt [ ] 4  
   Refusal [ ] 5  

   (go to Q18)  

b) Taken on right side?  
   Yes [ ] 1    No [ ] 2  
   (go to c)  
   if No, due to:  
   Amputation [ ] 1  
   Wound/dressing [ ] 2  
   Cast [ ] 3  
   Dialysis shunt [ ] 4  
   Refusal [ ] 5  

c) Resistance  
   d) Reactance  

VI. 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).  

18. a) First systolic B.P.  
   Right arm [ ]  
   Right ankle [ ]  
   Left ankle [ ]  

b) Second systolic B.P.  

| Location | Posterior tibial [ ] 1 | Posterior tibial [ ] 1 | Dorsalis pedis [ ] 2 | Dorsalis pedis [ ] 2 |
VII. ACANTHOSIS NIGRICANS

19. Acanthosis Nigricans in the back of neck:

Not Present [__] 0
Grade 1 [__] 1
Grade 2 [__] 2
Grade 3 [__] 3
Grade 4 [__] 4

VIII. ADMINISTRATIVE INFORMATION

20. Did the participant complete this examination?

Yes, completed the examination [__] 1
No, refused all questions [__] 2

21. SHS Code of person completing this form

22. Date of Examination:

[ ___ ] [ ___ ] [ ___ ] [ ___ ] [ ___ ] [ ___ ]
THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SAMPLE COLLECTION CHECKLIST

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS I.D.:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Fasting One Touch glucose result. 999 = not done

2. Is Fasting blood sample taken?
   Yes, and participant has been fasting
   Yes, but participant has NOT been fasting
   No, participant has not been fasting
   Other, specify: ____________________________
   No, participant refused

3. When was the last time you ate (use military time)

4. Time of collection of fasting samples

5. Is urine sample taken?
   Yes [ ] 1 (go to Q7)  No [ ] 2

6. If no, why?
   On dialysis
   Cannot urinate
   Other, specify: ____________________________

7. Time of collection of urine sample
### Blood Samples/Urine Checklist

Check the box(es) if samples were collected.

<table>
<thead>
<tr>
<th>Item</th>
<th>Purpose</th>
<th>Type</th>
<th>Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>One 10 ml SST</td>
<td>Chem Profile, Lipids, Insulin</td>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>One 4.5 ml Lt Blue</td>
<td>PAI-1, Fibrinogen</td>
<td>Plasma</td>
<td></td>
</tr>
<tr>
<td>One 7 ml Gray</td>
<td>Fasting glucose</td>
<td>Plasma</td>
<td></td>
</tr>
<tr>
<td>One 10 ml Green</td>
<td>Heparin storage</td>
<td>Plasma/Buffy coat</td>
<td></td>
</tr>
<tr>
<td>One 10 ml Purple</td>
<td>HbA1c</td>
<td>Whole blood</td>
<td></td>
</tr>
<tr>
<td>One 10 ml Purple</td>
<td>DNA</td>
<td>Buffy coat</td>
<td></td>
</tr>
<tr>
<td>One 10 ml Purple</td>
<td>LDL size, ApoE</td>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>Albumin/creatinine</td>
<td>Urine</td>
<td></td>
</tr>
</tbody>
</table>

---

9. Is this participant also a volunteer for blood/urine QC?  
   Yes [ ]  No [ ]

If the participant is NOT a QC volunteer, skip to Q12.

10. QC ID (second digit is "3"):
   [ ] [ ] [ ] [ ] [ ] [ ] [ ]

11. QC samples checklist. Check the box(es) if samples were collected.

<table>
<thead>
<tr>
<th>Item</th>
<th>Purpose</th>
<th>Type</th>
<th>Check</th>
</tr>
</thead>
<tbody>
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<td></td>
</tr>
<tr>
<td>One 10 ml Purple</td>
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<td></td>
</tr>
<tr>
<td>Urine</td>
<td>Albumin/creatinine</td>
<td>Urine</td>
<td></td>
</tr>
</tbody>
</table>

### Instructions:

"We ask you not to use any tobacco, caffeine or alcohol until you have completed your visit with us today. We do this so that your test results are not affected by use of these substances."

12. If you did, when and what:
   [ ] [ ] [ ] [ ] [ ] [ ] [ ]

13. SHS Code of person completing this form:  
   [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

14. Today’s Date:  
   [ ] [ ] [ ] [ ] [ ] [ ] [ ]
**THE STRONG HEART—FAMILY STUDY**  
**GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS**  
**CBC Results**

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS. I.D.:</th>
</tr>
</thead>
</table>

*Each Center’s Results May Appear in Different Order, Please Be Careful When Entering the Results*

1. WBC (10^9/L)  
2. RBC (10^12/L)  
3. HGB (g/dL)  
4. HCT (%)  
5. MCV (fL)  
6. MCH (pg)  
7. MCHC (g/dL)  
8. RDW (%)  
9. Platelet count (PLT .. 10^9/L)  
10. MPV (fL)

**DIFFERENTIAL**

*Each Center’s Results May Appear in Different Order, Please Be Careful When Entering the Results*

11. NEUT (%)  
12. LYMPH (%)  
13. MONO (%)  
14. EOS (%)  
15. BASO (%)  
16. Code number of person completing this form  
17. Date of data collection

**III D-30**  
CBC Results
STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CULTURAL FACTORS QUESTIONNAIRE

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

How is this questionnaire administered?  By interviewer [____]  By self [____]  Refused [____]
(If you are not an American Indian, check refused.)

Traditional Values/Culture:
1. How well do you understand your Indian language? Read responses (check one).
   Not at all [____]  A little bit [____]  Almost everything [____]  Everything [____]
   (If NOT AT ALL, skip to Q4)

2. Can you speak your native language (interviewer should specify the language)?
   Yes, fluently [____]  Yes, but not fluently [____]  No [____] (Skip to Q4)

3. How often do you speak your native language? (Please read options.)
   Always [____]  Almost always [____]  Often [____]  Seldom [____]  Never [____]  Not applicable [____]

The next several questions are about your own native lifestyle.

4. How much do you identify yourself with your own tribal tradition?
   Not At All [____]  A Little [____]  Some [____]  A Lot [____]

5. How much do you identify yourself with non-Indian culture?
   Not At All [____]  A Little [____]  Some [____]  A Lot [____]

6. How comfortable do you feel in your own tribal tradition?
   Not At All [____]  A Little [____]  Some [____]  A Lot [____]

7. How comfortable do you feel in the non-Indian culture?
   Not At All [____]  A Little [____]  Some [____]  A Lot [____]

8. Interviewer/Reviewer: ____________________________

9. Date of interview: ____________

   mo  day  yr
THE STRONG HEART — FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

QUALITY OF LIFE 1

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

SHS. I.D.: _______ _______ _______ _______ _______ _______ _______ _______ _______

How is this questionnaire administered? By interviewer [ ] [ ] [ ] By self [ ] [ ] [ ] Refused [ ] [ ] [ ]

1. In general, would you say your health is: (Please Check Only One)
   - Excellent: [ ] [ ] [ ]
   - Very good: [ ] [ ] [ ]
   - Good: [ ] [ ] [ ]
   - Fair: [ ] [ ] [ ]
   - Poor: [ ] [ ] [ ]

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Please Check One Number Per Line)

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf: [ ] [ ] [ ]

3. Climbing several flights of stairs: [ ] [ ] [ ]

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

(Please Check One Answer Per Line)

4. Accomplish less than you would like: [ ] [ ]

5. Were limited in the kind of work or other activities: [ ] [ ]

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

(Please Check One Answer Per Line)

6. Accomplish less than you would like: [ ] [ ]

7. Didn’t do work or other activities as carefully as usual: [ ] [ ]
8. During the PAST 4 WEEKS, how much did pain interfere with your normal work, (including both work outside the home and housework)?
(Please Check One Answer)
Not at all ........................................... |__| 1
Slightly ............................................. |__| 2
Moderately ........................................... |__| 3
Quite a bit .......................................... |__| 4
Extremely .......................................... |__| 5

These questions are about how you feel and how things have been with you during the PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling

How much of the time during the PAST 4 WEEKS....
(Please Check One Number Per Line)

<table>
<thead>
<tr>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>a Good Bit of the Time</th>
<th>Some of the Time</th>
<th>a Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.  Have you felt calm and peaceful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Did you have a lot of energy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Did you feel downhearted and blue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Please Circle One Number)

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A Little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. Interviewer/Reviewer:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Date of interview:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CES-D SCALE

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS I.D.:</th>
</tr>
</thead>
</table>

How is this questionnaire administered? 1=By interviewer | 2=By self | 8=Refused

Here are some questions (Q2-Q22) about your feelings during the past week. For each of the following statements, please respond as to whether you felt that way: Rarely or Not At All, Some of the time, Often, or Most of the time.

During the past week...

<table>
<thead>
<tr>
<th>Question</th>
<th>Rarely or Not at ALL (&lt; 1 day)</th>
<th>Some 1-2 days</th>
<th>Often 3-4 days</th>
<th>Most of the Time 5-7 days</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I was bothered by things that don't usually bother me.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>2. I did not feel like eating; my appetite was poor.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>3. I felt that I could not shake the blues even with help from my family or friends.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>4. I felt that I was just as good as other people.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>5. I had trouble keeping my mind on what I was doing.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>6. I felt depressed</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>7. I felt that everything I did was an effort.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>8. I felt hopeful about the future.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>9. I thought my life had been a failure.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>10. I felt fearful.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>11. My sleep was restless.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
<tr>
<td>12. I was happy.</td>
<td>___1</td>
<td>___2</td>
<td>___3</td>
<td>___4</td>
<td>___9</td>
</tr>
</tbody>
</table>
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 . . .

<table>
<thead>
<tr>
<th></th>
<th>Rarely or Not at All</th>
<th>Some 1-2 days</th>
<th>Often 3-4 days</th>
<th>Most of the Time 5-7 days</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>I talked less than usual.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>14.</td>
<td>I felt lonely.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>15.</td>
<td>People were unfriendly.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>16.</td>
<td>I enjoyed life.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>17.</td>
<td>I had crying spells.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>18.</td>
<td>I felt sad.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>19.</td>
<td>I felt that people disliked me.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>20.</td>
<td>I felt like I couldn't do what I needed to do.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
</tbody>
</table>

For Question 21, please use the following scale: Rarely or Not at All, Some 1-2 days, Often 3-4 days, Most of the Time 5-7 days, Not Applicable.

<table>
<thead>
<tr>
<th></th>
<th>Rarely or Not at ALL</th>
<th>Some 1-2 days</th>
<th>Often 3-4 days</th>
<th>Most of the Time 5-7 days</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.</td>
<td>I have felt depressed or sad in this past year.</td>
<td><em><strong>1</strong></em></td>
<td><em><strong>2</strong></em></td>
<td><em><strong>3</strong></em></td>
<td><em><strong>4</strong></em></td>
</tr>
<tr>
<td>22.</td>
<td>Interviewer/Reviewer:</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>23.</td>
<td>Date of interview:</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

---

**Strong Heart Study IV 06/01/01**

**III D-35 CES-D Scale**
## MHLCC Scale

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS. I.D.</th>
</tr>
</thead>
</table>

**How was the questionnaire administered?**

- 1 = By interviewer
- 2 = By self
- 8 = Refused

Each item below is a belief statement about your medical condition with which you may agree or disagree. Each statement is a scale which ranges from strongly disagree (0) to strongly agree (3). For each item we would like you to write the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you write. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

<table>
<thead>
<tr>
<th>Strongly Disagree 0</th>
<th>Disagree 1</th>
<th>Agree 2</th>
<th>Strongly Agree 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If I become sick, I have the power to make myself well again.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>2. Often I feel that no matter what I do, if I am going to get sick, I will get sick.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>3. If I see an excellent doctor regularly, I am less likely to have health problems.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>4. Most things that affect my health happen by accidental happenings.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>5. I can only maintain my health by consulting health professionals.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>6. I am directly responsible for my health.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>7. Other people play a big part in whether I stay healthy or become sick.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>8. Whatever goes wrong with my health is my own fault.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>9. When I am sick, I just have to let nature run its course.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>10. Health professionals keep me healthy.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>11. When I stay healthy, I'm just plain lucky.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td></td>
<td>Strongly Disagree</td>
<td>Disagree</td>
<td>Agree</td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>12. My physical well-being depends on how well I take care of myself.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>13. When I feel ill, I know it is because I have not been taking care of myself properly.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>14. The type of care I receive from other people is what is responsible for how well I recover from an illness.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>15. Even when I take care of myself, it's easy to get sick.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>16. When I become ill, it's a matter of fate.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>17. I can pretty much stay healthy by taking good care of myself.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
<tr>
<td>18. Following doctor's orders to the letter is the best way for me to stay healthy.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
</tr>
</tbody>
</table>

19. Interviewer/ Reviewer: 

20. Date of interview: [ ] [ ] [ ] [ ] [ ] [ ]
The Strong Heart-Family Study
Genetics of Cardiovascular Disease in American Indians

Social Support

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

How was the questionnaire administered? 1=By interviewer 2=By self 8=Refused

This scale is an assessment of social support, and is made up of a list of statements, which may or may not be true about you. For each statement, check the response that best describes you.

1. How often do you talk on the phone or get together with friends or relatives who do not live with you?...
   - Every day ........................................... ..........................
   - A few times a week ........................................... ..........................
   - A few times a month ........................................... ..........................
   - Once a month ........................................... ..........................
   - Less than once a month, or ........................................... ..........................
   - Never (IF VOL.) ........................................... ..........................

   NOT MUCH AT ALL 1  SOME 2  A LOT 3

2. How much do your friends or relatives really care about you—a lot, some, or not much at all?
   ........................................... ..........................

3. How much do they understand the way you feel about things?
   ........................................... ..........................

4. How much do they appreciate you?
   ........................................... ..........................

5. How much can you rely on them for help if you have a serious problem?
   ........................................... ..........................

6. How much can you talk to them about your worries?
   ........................................... ..........................

7. How much can you relax and be yourself around them?
   ........................................... ..........................

Strong Heart Study IV  06/01/01  III D-38  Social Support
8. How often do your friends or relatives make too many demands on you—often, sometimes, rarely or never?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

9. How often do they argue with you?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

10. How often do they criticize you?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

11. How often do they let you down when you are counting on them?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

12. How often do they get on your nerves?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

13. How often do they drink or use drugs too much?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Among the people you know, is there someone . . .  

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

14. you can go with to play cards, or go to bingo, a powwow, or a community meeting?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

15. who would lend you money if you needed it in an emergency?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

16. who would lend you a car or drive you somewhere else if you really needed it?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

17. you could call who would bail you out if you were arrested and put in jail?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

18. you could count on to check in on you regularly?  

<table>
<thead>
<tr>
<th>RARELY</th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>


- Very isolated:  
  | 3 |
- Somewhat isolated:  
  | 2 |
- Not very isolated at all:  
  | 1 |
20. How often do you purposefully avoid family gatherings?...
   A lot .....................................................  [ ] 3
   Sometimes, or .............................................  [ ] 2
   Not very much at all ......................................  [ ] 1

21. Of those family gatherings you go to, how likely are you to leave early?...
   Very likely ..................................................  [ ] 3
   Somewhat likely, or ..........................................  [ ] 2
   Not at all likely ................................................  [ ] 1

22. Interviewer/Reviewer: ____________________________

23. Date of interview: ____________ _______ _______
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SPIELBERGER - AX/COOK MEDLEY SCALE

How was the questionnaire administered?  
1=By interviewer  
2=By self  
8=Refused

A number of statements which people have used to describe themselves when they feel angry or furious are given below (Q1-Q20). Please read each statement and then indicate how often you feel or act in the manner described when you are angry. This is a measure of your feelings; so there are no right or wrong answers.

<table>
<thead>
<tr>
<th>When I feel angry.....</th>
<th>Rarely Or Never</th>
<th>Sometimes</th>
<th>Often or Always</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I control my temper.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>2. I express my anger.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>3. I keep my feelings to myself.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>4. I make threats I don't really mean to carry out.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>5. I withdraw from people when I'm angry.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>6. I give people &quot;the silent treatment&quot; when I'm angry.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>7. I make hurtful remarks to others.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>8. I keep my cool.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>9. I do things like slam doors when I'm angry.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>10. I boil inside, but don't show it.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>11. I argue with others.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>12. I hold grudges that I don't tell anyone about.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
<tr>
<td>13. I strike out (emotionally or physically) at whatever makes me angry.</td>
<td>[ ] 0</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
</tr>
</tbody>
</table>
| Question                                                                 | Rarely Or Never | Sometimes | Often or Always | S15  
|-------------------------------------------------------------------------|----------------|-----------|----------------|------
| 14. I am more critical of (judge or find fault with) others than I let people know. | 0              | 1         | 2              | 3    |
| 15. I get angrier than I usually admit.                                  | 0              | 1         | 2              | 3    |
| 16. I calm down faster than most people.                                | 0              | 1         | 2              | 3    |
| 17. I say mean things.                                                  | 0              | 1         | 2              | 3    |
| 18. I am irritated (frustrated, annoyed) much more than people are aware of. | 0              | 1         | 2              | 3    |
| 19. I lose my temper.                                                   | 0              | 1         | 2              | 3    |
| 20. If someone bothers (frustrates, irritates) me, I am likely to tell him/her. | 0              | 1         | 2              | 3    |

These next questions (Q21- Q28) are about how you think about other people. Although we cannot really know what people would think or do unless they tell us, we would like to know your opinion as to whether you think each of the following statements is “True or False”. Once again, this is your opinion, so there is no right or wrong answer.

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. No one cares much about what happens to me.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>22. It is safer to trust nobody.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>23. Most people would lie to get ahead.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>24. Most people inwardly dislike putting themselves out to help other people.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>25. Most people will use unfair means to gain an advantage rather than lose it.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>26. Most people are honest mainly through fear of being caught.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>27. I often wonder what hidden reason another person may have for doing something nice for me.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>28. Most people make friends because friends are likely to be useful to them.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>29. Interviewer/Reviewer:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. Date of interview:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Strong Heart Study IV    06/01/01     III D-42    Spielberger –Ax/Cook Medley Scale
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PSYCHOSOCIAL CHECKLIST

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS I.D.</th>
</tr>
</thead>
</table>

Psychosocial questionnaires:

1. Did the participant finish all of the psychosocial questionnaires?  
   Yes [ ] 1  No [ ] 2  
   (go to Q3)  (if no, go to Q2)

2. Why were the psychosocial questionnaires not completed? (check all that apply)
   - Did not understand the questions  [ ]
   - Did not have time to complete  [ ]
   - Questions are inappropriate  [ ]
   - Unable to answer  [ ]
   - Other  [ ]
   List: ________________________

3. Interviewer’s code  [ ]

4. Date completed  [ ]
   mo  /  day  /  yr
THE STRONG HEART – FAMILY STUDY
GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

DIRECTIONS TO PARTICIPANTS FOR USING THE ACTIVITY METER
(PEDOMETER)

The Accusplit Activity Meter (pedometer) counts the number of steps taken while
walking. You have been requested to wear this meter EVERY DAY for a seven day period
from _______ to _______. The pedometer is to be clipped at the waist to your clothes,
underwear, or on a belt and worn on the _______ hip and must be kept in an upright
position. Please keep the pedometer firmly against your body so it does not move
around freely. You can use a belt or elastic strap to keep it in place on your hip. Please
DO NOT LET THE Pedometer GET WET by wearing it in the rain or while bathing or
swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in
the morning and to record the pedometer number in your activity record when you take
it off at night.

If you have any questions, please contact:

___________________________________________________________________________ at

___________________________________________________________________________.

Specific Instructions
1. Every morning, just before you put the pedometer on, push the reset button to read “0”.
2. Record the time you reset the pedometer on the activity record page.
3. Wear the pedometer all day except for bathing, swimming or in the rain (unless you
can keep it dry). If you take it off, record the length of time it was off (minutes or
hours) on your activity record page.
4. At bedtime, take off the pedometer. Record on your activity record page (a) the pedometer
number (the number of steps taken), and (b) the time you removed the pedometer.
5. Please do not touch the reset button during the day or you will erase your activity numbers.
6. Wear the pedometer on your dominant hip (right hip for right handed people and left hip for
left handed people), keep it upright, and make sure it fits firmly against your body so it does
not move around.
7. Keep the cover closed or it will not record your steps.
8. The pedometer will not work correctly if it is in a pants, coat, or shirt pocket. It will not work
correctly if it is sideways either.
9. Please mail the activity record to us in the self-addressed stamped envelope after you
complete your week.
10. Please keep the pedometer as a token of our appreciation of your participation in the Strong
Heart Family Study.

Thank you very much for your time and effort!
ACTIVITY METER SEVEN-DAY RECORD

Name: ____________________________ Strong Heart Study ID No: __________

Family Study ID No: __________

Reminder: Reset the Activity Meter (pedometer) to "0" every morning

<table>
<thead>
<tr>
<th>Date</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day of week</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time attached</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meter number at bedtime</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time removed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you take off the meter for any reason?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, for how long?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Complete this question after completing this journal.

Has your physical activity in the past seven (7) days been typical for you compared to your regular activity level? Yes [ ] No [ ]
THE STRONG HEART STUDY III
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS
MEDICATION CHECKLIST

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

A. MEDICATION RECEPTION:

As you know, the Strong Heart Study will be describing prescription medications that its participants are using. We are particularly interested in medications your doctor prescribed for you that were filled by a pharmacist. These include pills, dermal patches, eye drops, creams, salves, and injections. The letter you received about this appointment included a plastic medications bag for all your current medications and asked you to bring them to the clinic.

Have you brought that bag with you?

Yes [ ] 1  No [ ] 2  (Make arrangements to obtain)

Took no meds [ ] 3  (Go to Section C)  Refused [ ] 4  (Cite reasons for refusal in the space below)

Reasons for refusal: ____________________________________________  : Go to Section C

B. PRESCRIPTION MEDICATIONS

1. Copy the name of the medication, the strength in milligrams (mg), and the total number of doses prescribed per day, week or month. (Include pills, dermal patches, eye drops, creams, salves, and injections)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Number Prescribed</th>
<th>PRN Medicine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print the first 20 letters only.</td>
<td>Write the decimal as one of the digits.</td>
<td>Circle: day, week, month</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
</tbody>
</table>
## PRESCRIPTION MEDICATIONS (cont.)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Prescribed</th>
<th>PRN Medicine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print the first 20 letters only. Please print clearly.</td>
<td>Write the decimal as one of the digits.</td>
<td>Circle: day, week, month</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>D W M</td>
<td>Y N D W M</td>
</tr>
</tbody>
</table>

Number unable to transcribe: ________________

### OVER-THE-COUNTER MEDICATIONS

3. Copy the name of the medication, the strength in milligrams (mg), and the total number of doses prescribed per day, week or month. (Include pills, dermal patches, eye drops, creams, salves, and injections)

4. On the average during the last two weeks, how many of these pills did you take a day/week/month?

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print the first 20 letters. Please print clearly.</td>
<td>Write the decimal as one of the digits.</td>
<td>Circle: day, week, month</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>Medication Name</td>
<td>Strength (mg)</td>
<td>Circle: day</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>week, month</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>D W M</td>
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<tr>
<td>13</td>
<td></td>
<td>D W M</td>
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<tr>
<td>14</td>
<td></td>
<td>D W M</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>D W M</td>
</tr>
</tbody>
</table>

Comments:

5. Interviewer:

6. Date of interview:
## THE STRONG HEART – FAMILY STUDY
### GENETICS OF CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

### PHYSICAL EXAMINATION – QC DUPLICATE MEASUREMENT

<table>
<thead>
<tr>
<th>SHS Family I.D.</th>
<th>SHS I.D.:</th>
</tr>
</thead>
</table>

### 1. BLOOD PRESSURE

1. Right arm circumference, measured in CENTIMETERS (cm)
   *Midway between acromion and olecranon*

2. Cuff size (arm circumference in brackets)
   - Pediatric (under 24 cm) □□□□
   - Large arm (33-41 cm) □□□□
   - Regular arm (24-32 cm) □□□□
   - Thigh (>41 cm) □□□□

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 □□□□
   - No □□□□

   If no, Why?
   - Amputation □□□□
   - Wound/dressing □□□□
   - Cast □□□□
   - Refusal □□□□

6. Recorder ID:
II. ANTHROPOMETRIC MEASUREMENTS

7. Height (Standing) _______ cm
8. Weight (Standing) _______ kg

9. a) Was impedance taken?
   Yes _____1 (Go to b)
   No _____2

   If NO, due to: Amputation _____1 Wound/dressing _____2 Cast _____3 Refusal _____8

   b) Taken on RIGHT side?
   Yes _____1
   No _____2

   If NO, due to: Amputation _____1 Wound/dressing _____2 Cast _____3 Refusal _____8

   c) Resistance ______
   d) Reactance ______

III. IMPEDANCE MEASUREMENT

10. Waist (Supine) _______ cm

IV. Acanthosis Nigricans

10. Acanthosis Nigricans in the back of neck:
   Not Present _____10
   Grade 1 _____1
   Grade 2 _____2
   Grade 3 _____3
   Grade 4 _____4

V. ADMINISTRATIVE INFORMATION

11. Code number of person completing this form _______

12. Date of data collection _____mo/_____day/_____/____ yr
This form is about the foods you usually eat. It will take about 30 - 40 minutes to complete.

- Please answer each question as best you can. Estimate if you aren't sure.
- Use only a No. 2 pencil.
- Fill in the circles completely, and erase completely if you make any changes.

Please print your name in this box.

### AVERAGE USE IN THE PAST YEAR

<table>
<thead>
<tr>
<th></th>
<th>LESS THAN ONCE per WEEK</th>
<th>1-2 per WEEK</th>
<th>3-4 per WEEK</th>
<th>5-6 per WEEK</th>
<th>1 per DAY</th>
<th>1 1/2 per DAY</th>
<th>2 per DAY</th>
<th>3 per DAY</th>
<th>4+ per DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>About how many servings of vegetables do you eat, per day or per week, not counting salad or potatoes?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>About how many servings of fruit do you eat, not counting juices?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often do you eat cold cereal?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often do you use fat or oil in cooking?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO

- Don't know, or Pam
- Butter/margarine blend
- Lard, fatback, bacon fat
- Stick margarine
- Low-fat margarine
- Soft tub margarine
- Corn oil, vegetable oil
- Butter
- Olive oil or canola oil

Please do not write in this area

---

95713
During the past year, have you taken any vitamins or minerals regularly, at least once a month?
- [ ] No, not regularly
- [ ] Yes, fairly regularly

(IF YES) WHAT DID YOU TAKE FAIRLY REGULARLY?

<table>
<thead>
<tr>
<th>VITAMIN TYPE</th>
<th>HOW OFTEN</th>
<th>FOR HOW MANY YEARS?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A FEW DAYS per MTH</td>
<td>1-3 DAYS per WEEK</td>
</tr>
<tr>
<td></td>
<td>per WEEK</td>
<td>16-44 DAYS per WEEK</td>
</tr>
<tr>
<td></td>
<td>16-44 DAYS per WEEK</td>
<td>1-5 YEARS</td>
</tr>
<tr>
<td>Multiple Vitamins. Did you take...</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Regular Once-A-Day, Centrum, or Thera type</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Stress-tabs or B-Complex type</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Antioxidant combination type</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Single Vitamins (not part of multiple vitamins)</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Vitamin A (not beta-carotene)</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Beta-carotene</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Folic acid, folate</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Calcium, alone or combined with something else</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Zinc, alone or combined with something else</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Iron</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Selenium</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

If you took Once-a-day, Centrum or Thera-type multiple vitamins, did you usually take types that

- [ ] contain minerals, iron, zinc, etc.
- [ ] do not contain minerals
- [ ] don’t know

If you took vitamin C or vitamin E:
- [ ] 100
- [ ] 250
- [ ] 500
- [ ] 750
- [ ] 1000
- [ ] 1500
- [ ] 2000
- [ ] 3000+
- [ ] Don’t know

How many milligrams of vitamin C did you usually take, on the days you took it?
- [ ] 100
- [ ] 200
- [ ] 300
- [ ] 400
- [ ] 600
- [ ] 800
- [ ] 1000
- [ ] 2000+
- [ ] Don’t know

How many IU’s of vitamin E did you usually take, on the days you took it?
- [ ] 100
- [ ] 200
- [ ] 300
- [ ] 400
- [ ] 600
- [ ] 800
- [ ] 1000
- [ ] 2000+
- [ ] Don’t know

Did you take any of these supplements at least once a month?
- [ ] Ginkgo
- [ ] Ginseng
- [ ] St. John’s Wort
- [ ] Kava Kava
- [ ] Echinacea
- [ ] Melatonin
- [ ] DHEA
- [ ] Glucosamine/Chondroitin
- [ ] Something else
- [ ] Didn’t take these

The next section is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions to answer for each food:

HOW OFTEN, on average, did you eat the food during the past year?
- [ ] Please DO NOT SKIP any foods. Mark “Never” if you didn’t eat it.

HOW MUCH did you usually eat of the food?

- [ ] Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., on the days you eat it.
- [ ] Sometimes we ask how much as A, B, C, or D. LOOK AT THE ENCLOSED PICTURES. For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat.
- [ ] Sometimes we made the “D” column a darker color. This is just to remind you to make sure you really eat that large a serving.

EXAMPLE: This person drank apple juice twice a week, and had one glass each time. Once a week he ate a “C” sized serving of rice (about 1 cup).

<table>
<thead>
<tr>
<th>HOW OFTEN</th>
<th>NEVER</th>
<th>A FEW TIMES per YEAR</th>
<th>ONCE per MON.</th>
<th>2-3 TIMES per WEEK</th>
<th>ONCE per WEEK</th>
<th>TWICE per WEEK</th>
<th>3-4 TIMES per WEEK</th>
<th>5-6 TIMES per WEEK</th>
<th>EVERY DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple juice</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Rice</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many glasses each time</td>
</tr>
<tr>
<td>How much each time</td>
</tr>
<tr>
<td>Beverages</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>V-8 juice or tomato juice</td>
</tr>
<tr>
<td>Real 100% orange juice or grapefruit juice, including fresh, frozen or</td>
</tr>
<tr>
<td>bottled</td>
</tr>
<tr>
<td>When you drink orange juice, how often do you drink a calcium-fortified</td>
</tr>
<tr>
<td>brand?</td>
</tr>
<tr>
<td>Other real fruit juices like apple juice, prune juice, lemonade</td>
</tr>
<tr>
<td>Kool-Aid, Hi-C, or other drinks with added vitamin C</td>
</tr>
<tr>
<td>Drinks with some juice in them, like Sunny Delight, Juice Squeeze</td>
</tr>
<tr>
<td>Instant breakfast milk shakes like Carnation, diet shakes like SlimFast,</td>
</tr>
<tr>
<td>or liquid supplements like Ensure</td>
</tr>
<tr>
<td>Glasses of milk (any kind)</td>
</tr>
<tr>
<td>When you drink glasses of milk, what kind do you usually drink?</td>
</tr>
<tr>
<td>MARK ONLY ONE:</td>
</tr>
<tr>
<td>Whole milk</td>
</tr>
<tr>
<td>Reduced-fat 2% milk</td>
</tr>
<tr>
<td>Low-fat 1% milk</td>
</tr>
<tr>
<td>Non-fat milk</td>
</tr>
<tr>
<td>Rice milk</td>
</tr>
<tr>
<td>Soy milk</td>
</tr>
<tr>
<td>I don't drink milk or soy milk</td>
</tr>
<tr>
<td>Regular soft drinks, or bottled drinks like Snapple (not diet drinks)</td>
</tr>
<tr>
<td>Beer or non-alcoholic beer</td>
</tr>
<tr>
<td>What kind? MARK ONLY ONE:</td>
</tr>
<tr>
<td>Regular beer</td>
</tr>
<tr>
<td>Light beer</td>
</tr>
<tr>
<td>Non-alcoholic beer</td>
</tr>
<tr>
<td>I don't drink beer</td>
</tr>
<tr>
<td>Wine or wine coolers</td>
</tr>
<tr>
<td>Liquor or mixed drinks</td>
</tr>
<tr>
<td>Glasses of water, tap or bottled</td>
</tr>
<tr>
<td>Coffee, regular or decaf</td>
</tr>
<tr>
<td>Tea or iced tea (not herb teas)</td>
</tr>
<tr>
<td>What do you usually add to coffee? MARK ONLY ONE:</td>
</tr>
<tr>
<td>Cream or half &amp; half</td>
</tr>
<tr>
<td>Nondairy creamer</td>
</tr>
<tr>
<td>Milk</td>
</tr>
<tr>
<td>None of these</td>
</tr>
<tr>
<td>What do you usually add to tea? MARK ONLY ONE:</td>
</tr>
<tr>
<td>Cream or half &amp; half</td>
</tr>
<tr>
<td>Nondairy creamer</td>
</tr>
<tr>
<td>Milk</td>
</tr>
<tr>
<td>None of these</td>
</tr>
</tbody>
</table>

**Do you usually add sugar (or honey) to coffee?**
- No
- Yes

**Do you usually add sugar (or honey) to tea?**
- No
- Yes
### How Often

**How often do you eat each of the following fruits, just during the 2-3 months when they are in season?**

<table>
<thead>
<tr>
<th>Fruit</th>
<th>Never</th>
<th>A Few Times</th>
<th>Once</th>
<th>2-3 Times</th>
<th>Once</th>
<th>2-4 Times</th>
<th>Once</th>
<th>5-6 Times</th>
<th>Once</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw peaches, apricots, nectarines, while they are in season</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cantaloupe, in season</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strawberries, in season</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watermelon, in season</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other fruit, in season; like grapes, honeydew, pineapple, kiwi</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**How often do you eat the following foods all year round? Estimate your average for the whole year.**

<table>
<thead>
<tr>
<th>Food</th>
<th>Never</th>
<th>A Few Times</th>
<th>Once</th>
<th>2-3 Times</th>
<th>Once</th>
<th>2-4 Times</th>
<th>Once</th>
<th>5-6 Times</th>
<th>Once</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bananas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apples or pears</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oranges or tangerines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grapefruit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### How Often

<table>
<thead>
<tr>
<th>Food</th>
<th>Never</th>
<th>A Few Times</th>
<th>Once</th>
<th>2-3 Times</th>
<th>Once</th>
<th>2-4 Times</th>
<th>Once</th>
<th>5-6 Times</th>
<th>Once</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast sausage, including sausage biscuits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancakes, waffles, French toast, Pop Tarts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Breakfast bars, granola bars, Power bars</td>
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<tr>
<td>Cooked cereals like oatmeal, cream of wheat or grits</td>
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<tr>
<td>High-fiber cereals like All Bran, Raisin Bran, Fruit-n-Fiber</td>
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</tr>
</tbody>
</table>

**Which high-fiber cereal do you eat most often? MARK ONLY ONE:**

- Fiber One, Fruit-n-Fiber, etc.
- Something else
- I don’t know
- I don’t eat it

<table>
<thead>
<tr>
<th>Product 9, Just Right or Total cereal</th>
<th>Never</th>
<th>A Few Times</th>
<th>Once</th>
<th>2-3 Times</th>
<th>Once</th>
<th>2-4 Times</th>
<th>Once</th>
<th>5-6 Times</th>
<th>Once</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any other cold cereal, like Corn Flakes, Cheerios, Special K</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Milk or milk substitutes on cereal</td>
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<tr>
<td>Yogurt or frozen yogurt</td>
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<tr>
<td>Cheese, sliced cheese or cheese</td>
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</tr>
<tr>
<td>Mayonnaise, salad dressing, adding on sandwiches</td>
<td></td>
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</tr>
</tbody>
</table>

When you eat cheese, is it

- Usually low-fat
- Sometimes low-fat
- Hardly ever low-fat
- Don’t know/don’t eat
### How Often

<table>
<thead>
<tr>
<th>Food Item</th>
<th>Never</th>
<th>1-2 Times per Year</th>
<th>1-3 Times per Month</th>
<th>1-2 Times per Week</th>
<th>3-4 Times per Week</th>
<th>5+ Times per Week</th>
<th>Every Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broccoli</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Carrots, or mixed vegetables or stews containing carrots</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Corn</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Green beans or green peas</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Spinach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mustard greens, turnip greens, collards</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>French fries, fried potatoes or hash browns</td>
<td></td>
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</tr>
<tr>
<td>White potatoes not fried, incl. boiled, baked, mashed &amp; potato salad</td>
<td></td>
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<tr>
<td>Sweet potatoes, yams (Not in pie)</td>
<td></td>
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</tr>
<tr>
<td>Cole slaw, cabbage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Green salad</td>
<td></td>
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<td></td>
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<tr>
<td>w tomatoes, including in salad</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Salad dressing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much you eat it</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Is your salad dressing
- Usually low-fat
- Sometimes low-fat
- Hardly ever low-fat
- Don’t know/don’t use

### How Much Each Time

<table>
<thead>
<tr>
<th>Food Item</th>
<th>How Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any other vegetable, like okra, squash, cooked green peppers</td>
<td></td>
</tr>
<tr>
<td>Refried beans or bean burritos</td>
<td></td>
</tr>
<tr>
<td>Chili with beans (with or without meat)</td>
<td></td>
</tr>
<tr>
<td>Baked beans, black-eye peas, pintos, any other dried beans</td>
<td></td>
</tr>
<tr>
<td>Vegetable stew</td>
<td></td>
</tr>
<tr>
<td>Vegetable soup, vegetable beef, chicken vegetable, or tomato soup</td>
<td></td>
</tr>
<tr>
<td>Split pea, bean or lentil soup</td>
<td></td>
</tr>
<tr>
<td>Any other soup, like chicken noodle, chowder, mushroom, instant soups</td>
<td></td>
</tr>
<tr>
<td>Spaghetti, lasagna or other pasta with tomato sauce</td>
<td></td>
</tr>
<tr>
<td>Cheese dishes with tomato sauce, like macaroni and cheese</td>
<td></td>
</tr>
<tr>
<td>Pizza, including carry-out</td>
<td></td>
</tr>
<tr>
<td>How much you eat it</td>
<td>A</td>
</tr>
</tbody>
</table>

---

*Note: The table continues with more food items and their frequency and quantity details.*
## How Often

<table>
<thead>
<tr>
<th>Food Description</th>
<th>Never</th>
<th>A Few Times a Year</th>
<th>Once a Month</th>
<th>Once a Week</th>
<th>2-3 Times a Week</th>
<th>3-4 Times a Week</th>
<th>5-6 Times a Week</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Tacos, burritos, enchiladas, tamales, etc. with meat or chicken</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How do you like beef cooked?</td>
<td>○ Rare</td>
<td>○ Medium</td>
<td>○ Well done</td>
<td>○ I don't eat beef</td>
<td></td>
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</tr>
<tr>
<td>Pork chops, pork roasts, or dinner ham</td>
<td>○</td>
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<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Veal, lamb or deer meat</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Ribs, spareribs</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<td>○</td>
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</tr>
<tr>
<td>Liver, including chicken livers or liverwurst</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>Gizzard, pork neckbones, chillins, pigs feet, etc.</td>
<td>○</td>
<td>○</td>
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<td>○</td>
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</tr>
<tr>
<td>Mixed dishes with beef or pork, like stew, combed beef hash, stuffed cabbage, meat dish with noodles</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Mixed dishes with chicken, like chicken casserole, chicken &amp; noodles, pot pie or in stir-fry</td>
<td>○</td>
<td>○</td>
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<td>○</td>
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<tr>
<td>Fried chicken, at home or in a restaurant</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Chicken or turkey not fried, such as baked, grilled, or on sandwiches</td>
<td>○</td>
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</tr>
<tr>
<td>Fried fish or fish sandwich, at home or in a restaurant</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Other fish, not fried</td>
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<tr>
<td>Hot dogs, or sausage like Polish, Italian or chorizos</td>
<td>○</td>
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<td>○</td>
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<td>○</td>
</tr>
<tr>
<td>Are your hot dogs</td>
<td>○ Usually low-fat</td>
<td>○ Sometimes low-fat</td>
<td>○ Hardly ever low-fat</td>
<td>○ Don't know/don't eat them</td>
<td></td>
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</tr>
<tr>
<td>Boloney, sliced ham, turkey, lunch meat, other lunch meat</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Are your lunch meats</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How Often</td>
<td>Never</td>
<td>A Few Times Per Year</td>
<td>Once/ Month</td>
<td>Once/ Week</td>
<td>Twice/ Week</td>
<td>Three-4 Times/ Week</td>
<td>Five-6 Times/ Week</td>
<td>Everyday</td>
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<tr>
<td>Odles, macaroni, pasta salad</td>
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<tr>
<td>Tofu, bean curd</td>
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<tr>
<td>Meat substitutes, such as veggie burgers, Gardenburgers</td>
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<tr>
<td>Chinese food, Thai or other Asian food, not counted above</td>
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<tr>
<td>Snacks like potato chips, corn chips, popcorn (not pretzels)</td>
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<tr>
<td>Are these snacks</td>
<td></td>
<td>Usually low-fat</td>
<td>Sometimes low-fat</td>
<td>Hardly ever low-fat</td>
<td>Don't know/don't eat</td>
<td></td>
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</tr>
<tr>
<td>How often</td>
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<tr>
<td>Peanuts, other nuts or seeds</td>
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<td></td>
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<tr>
<td>Crackers</td>
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<tr>
<td>Doughnuts, Danish pastry</td>
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<td></td>
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<tr>
<td>Cake, sweet rolls, coffee cake</td>
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<tr>
<td>Are they</td>
<td></td>
<td>Usually low-fat</td>
<td>Sometimes low-fat</td>
<td>Hardly ever low-fat</td>
<td>Don't know/don't eat</td>
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<tr>
<td>Cookies</td>
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<td></td>
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<tr>
<td>Are your cookies</td>
<td></td>
<td>Usually low-fat</td>
<td>Sometimes low-fat</td>
<td>Hardly ever low-fat</td>
<td>Don't know/don't eat</td>
<td></td>
<td></td>
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<tr>
<td>Ice cream, ice milk, ice cream bars</td>
<td></td>
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<tr>
<td>Are your ice cream</td>
<td></td>
<td>Usually low-fat</td>
<td>Sometimes low-fat</td>
<td>Hardly ever low-fat</td>
<td>Don't know/don't eat</td>
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<tr>
<td>Pumpkin pie, sweet potato pie</td>
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<td></td>
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<tr>
<td>Any other pie or cobbler</td>
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<td></td>
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<tr>
<td>Chocolate candy, candy bars</td>
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<td></td>
</tr>
<tr>
<td>Other candy, not chocolate, like hard candy, caramel, jelly beans</td>
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</tr>
</tbody>
</table>

Please do not write in this area.
### How Often

<table>
<thead>
<tr>
<th>Item</th>
<th>Never or a Few Times per Year</th>
<th>Once per Month</th>
<th>Once per Week</th>
<th>Twice or Three Times per Week</th>
<th>Four or More Times per Week</th>
<th>Every Day</th>
<th>More than Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biscuits or muffins</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Jils, hamburger buns, English muffins, bagels</td>
<td></td>
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<tr>
<td>Dark bread like rye or whole wheat, including in sandwiches</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>White bread or toast, including French, Italian, or in sandwiches</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Corn bread, corn muffins</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tortillas</td>
<td></td>
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</tr>
<tr>
<td>Rice, or dishes made with rice</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Margarine (not butter) on bread or on potatoes or vegetables, etc.</td>
<td></td>
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</tr>
<tr>
<td>Gravy</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Peanut butter</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Jelly, jam, or syrup</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Mayonnaise, sandwich spreads</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>teal, salsa or chile peppers</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Mustard, soy sauce, steak sauce, barbecue sauce, other sauces</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Did you use the pictures to choose your serving size on this form?   ○ Yes ○ No ○ I didn't have any pictures.

Would you say your health is ○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

How many times have you gone on a diet? ○ Never ○ 1-2 ○ 3-5 ○ 6-8 ○ 9 or more

Did you ever drink more beer, wine or liquor than you do now? ○ Yes ○ No

How many hours do you watch television or video, per day or per week on average? ○ None ○ 1-6 hours/week ○ 1 hour/day ○ 2 hours/day ○ 3 hours/day ○ 4+ hours/day

Do you smoke cigarettes now? ○ No ○ Yes

IF YES, On the average about how many cigarettes a day do you smoke now? ○ 1-5 ○ 6-14 ○ 15-24 ○ 25-34 ○ 35 or more

What language do you usually speak at home or with friends? ○ English ○ Spanish ○ Something else ○ English & something else equally

What is your ethnic group? (MARK ONE OR MORE)

○ Hispanic or Latino ○ Black or African American ○ American Indian or Alaska Native

○ White, not Hispanic ○ Asian ○ Native Hawaiian or Other Pacific Islander

Thank you very much for filling out this questionnaire. Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA

95713
<table>
<thead>
<tr>
<th></th>
<th>HOW OFTEN IN THE PAST YEAR</th>
<th>HOW MUCH EACH TIME</th>
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<tr>
<td></td>
<td>NEVER</td>
<td>A FEW TIMES PER YEAR</td>
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<tr>
<td>How often do you eat each of the following foods?</td>
<td>How often do you eat each of the following foods?</td>
<td>How often do you eat each of the following foods?</td>
</tr>
<tr>
<td>Spam</td>
<td></td>
<td></td>
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<tr>
<td>Menudo</td>
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<tr>
<td>Pazoie</td>
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<td>Juyasa</td>
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</tr>
<tr>
<td>Red chili stew or green chili stew</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indian taco</td>
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<tr>
<td>Frybread</td>
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<td></td>
</tr>
<tr>
<td>Corn tortilla</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flour tortilla</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Keep this in front of you while you are filling out the Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D: 
A = 1/4 Cup of Food  
B = 1/2 Cup of Food  
C = 1 Cup of Food  
D = 2 Cups of Food
APPENDIX E

STRONG HEART STUDY

PHASE IV

Derived Variables
DEFINITION OF STUDY VARIABLES
DEFINITION OF AGE, INDIAN HERITAGE, AND INELIGIBILITY

(All the variable names shown here were the SHS-I variables. To derive the same variables for the later phases of examinations, the original variable names may be different, but the algorithm remain the SAME).

1. SEX: PERSONAL INTERVIEW FORM II, Q12
   2 (FEMALE) INT2_1='2'
   1 (MALE) INT2_1='1'
   0/1 (Female/Male) when use numerical 0/1 for modeling.

2. AGE (IN YEARS), Q14 AND DOC IN PERSONAL INTERVIEW FORM II
   AGE = (DATE OF EXAM/INTERVIEW) - (DATE OF BIRTH)
   = (DOC - INT2_3) / 365.25

3. INDIAN BLOOD QUANTUM (BLOODALL), Q16 AND Q17 IN PERSONAL INTERVIEW II
   BLOODALL = (INT2_5 / INT2_6)
   = (INT2_8/INT2_9) + (INT2_11/INT2_12) + (INT2_14/INT2_15) +
   (INT2_17/INT2_18) + (INT2_20/INT2_21)

4. TRIBE OF ENROLLMENT, Q18 IN PERSONAL INTERVIEW II, INT2_28

5. RESIDENCE, PERSONAL INTERVIEW FORM II
   Q39, YEARS LIVING IN INDIAN COUNTRY/RESERVATION: INT2_49
   Q41a, YEARS LIVING OUTSIDE INDIAN COUNTRY/RESERVATION:
   INT2_51 = AGE - INT2_49

6. INELIGIBILITY:
   AGE: < 44.5 YEARS OR > 75.5 YEARS
   TRIBE: IF TRIBE OF ENROLLMENT (INT2_28) IS NOT ONE OF THE FOLLOWING
   OKLAHOMA: 231 - APACHE
   016 - CADDO
   039 - COMANCHE
   046 - DELAWARE
   005 - FT SILL APACHE
   062 - KIOWA
   170 - WICHITA
   DAKOTAS: 282 - OGLALA SIOUX
   277 - CHEYENNE RIVER SIOUX
   272 - DEVIL'S LAKE SIOUX
   OR ANY OTHER SIOUX (276, 279, 280, 281, 283, 284, 274, 285, 286, 287, 275,
   278 OR 045) LIVED IN PINE RIDGE, EAGLE BUTTE, AND FT. TOTTEN
   AREA.
   ARIZONA: 293 - PIMA/MARICOPA IN GILA RIVER INDIAN COMMUNITY
   377 - PIMA/MARICOPA IN SALT RIVER INDIAN COMMUNITY
   888 - MARICOPA
   360 - PAPAGO INDIAN OF MARICOPA IN AK CHIN (OLD CODE = '096')
RESIDENCE: Steering Committee decided not to use this criteria (1-10-92).
IF LIVED LESS THAN 6 MONTHS IN INDIAN COUNTRY/RESERVATION IN THE PAST YEAR, Q40 AND Q41b

Define Tribal Affiliation (TRIBE, VALUE 1-13)

OKLAHOMA: TRIBE OF ENROLLMENT
ARIZONA & DAKOTAS: TRIBE AND THE COMMUNITY (COMMUNITY CODE, CC) WHERE THE PARTICIPANT RESIDES

TRIBE WILL BE CLASSIFIED AS MISSING IF TRIBE AND COMMUNITY DO NOT MATCH.

ARIZONA:

CC IN ('126', '132', '133', '377') TRIBE='13' 'SALT RIVER'
CC IN ('096', '96 ', '211', '209', '360') TRIBE='11' 'AK CHIN-PAPAGO'
The rest of AZ participants: TRIBE='12' 'GILA RIVER'

EXCEPT FOR:
IF IDNO=302017 THEN TRIBE=11' /* AK CHIN BUT EXAM IN GRIC */
IF IDNO IN ('303335', '303337', '303338', '303341', '303342', '303346', '303369', '303375', '303379', '303389', '303401', '303413', '303415', '303426', '303429', '303362', '303378', '303406', '303351', '303527', '303433', '303350') THEN TRIBE=13;
IF IDNO IN ('303258', '303388', '303403') THEN TRIBE=12;
(these were instructed by the AZ PI)

DAKOTAS:

CC IN ('607', '612', '613', '614', '619', '623', '867', '868', '872') TRIBE='01' 'CHEYENNE RIVER'
CC IN ('358', '361', '362', '363', '477') TRIBE='02' 'SPIRIT LAKE'
CC IN ('526', '528', '849', '772', '778', '781', '782', '783', '784', '790') TRIBE='03' 'OGALALA SIOUX'

OKLAHOMA (by tribal enrolment, INT2_28):

INT2_28='231' TRIBE='04' 'APACHE'
INT2_28='016' TRIBE='05' 'CADDIO'
INT2_28='039' TRIBE='06' 'COMANCHE'
INT2_28='046' TRIBE='07' 'DELAWARE'
INT2_28='005' TRIBE='08' 'FT SILL APACHE'
INT2_28='062' TRIBE='09' 'KIOWA'
INT2_28='170' TRIBE='10' 'WICHITA'
DEFINITION OF DIABETIC STATUS:

I. DIABETES STATUS ACCORDING TO 1985 WHO CRITERIA:


A. KNOWN DIABETES (DM='4'):
   1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:
      a. ON INSULIN TREATMENT (class code: 682008);
      b. ON HYPOGLYCEMIC AGENT (class code: 682020);
      c. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');
   OR
   2. EITHER FASTING BLOOD SUGAR (GLUC_0) > 140 OR TWO-HOUR BLOOD SUGAR (GLUC_2) > 200 AND WITH MENTIONING ANY HISTORY OF DIABETES IN MEDICAL HISTORY (Q3f, MED25='1' OR '3').

B. NEW DIABETES (DM='3'):
   EITHER FASTING BLOOD SUGAR (GLUC_0) > 140 OR TWO-HOUR BLOOD SUGAR (GLUC_2) > 200 AND WITHOUT MENTIONING ANY HISTORY OF DIABETES IN MEDICAL HISTORY (Q3f, MED25='2' OR '9').

C. IMPAIRED GLUCOSE TOLERANCE (IGT) (DM='2'):
   GLUC_0 < 140 AND GLUC_2 BETWEEN 140 AND 199.

D. NORMAL GLUCOSE TOLERANCE:
   1. NGT WITH HISTORY OF DM (DM='1'):
      GLUC_0 < 140 AND GLUC_2 < 140 AND WITH A HISTORY OF DIABETES (MED25='1').
   2. TRUE NGT (DM='0'):
      GLUC_0 < 140 AND GLUC_2 < 140 AND WITHOUT A HISTORY OF DIABETES (MED25='2').

E. DIABETIC STATUS UNDETERMINED (DM=' '):
   1. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANT WITHOUT MENTIONING OF DIABETES IN THE MEDICAL HISTORY (MED25='2')
   2. RESULTS OF GTT WAS NOT RECEIVED, OR
   3. PARTICIPANT REFUSED GTT AND GLUC_0 WAS NOT SUFFICIENT TO DECIDE THE DIABETIC STATUS.

FOR SHS-I to SHS-III: sXdmwho, value ‘NGT’, ‘IGT’, ‘DM’, and ‘ ’, where NGT are DM='0' or '1'. IGT is DM='2', and DM are DM='3' or '4'.
II. DIABETES STATUS ACCORDING TO 1997 ADA CRITERIA:

$sXdmada=('DM', 'IFG', AND 'NFG')$

A. DIABETES:
   1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:
      a. ON INSULIN TREATMENT;
      b. ON HYPOGLYCEMIC AGENT;
      c. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');
      
       OR
   
   2. IF FASTING BLOOD SUGAR ($GLUC_0$) $\geq$ 126

B. IMPAIRED FASTING GLUCOSE TOLERANCE (IFG):
   $110 \leq GLUC_0 < 126$

C. NORMAL FASTING GLUCOSE TOLERANCE (NFG):
   1. NGT WITH HISTORY OF DM: NOT IN (I) AND (II), $GLUC_0 < 110$ AND NO DM TREATMENT.

D. DIABETIC STATUS UNDETERMINED:
   $GLUC_0$ WAS MISSING.
III. DIABETES STATUS ACCORDING TO 1998 WHO CRITERIA:

A. DIABETES:
1. IF THE PARTICIPANT WAS NOT GIVEN GTT, GTT CHECKLIST:
   a. ON INSULIN TREATMENT;
   b. ON HYPOGLYCEMIC AGENT;
   d. ON RENAL DIALYSIS OR HAD KIDNEY TRANSPLANTATION AND MENTIONED HISTORY OF DIABETES IN MEDICAL HISTORY QUESTIONNAIRE (Q3f, MED25='1');

   OR

2. IF FASTING BLOOD SUGAR (GLUC_0) ≥ 126

   OR

3. 2-HOUR BLOOD SUGAR (GLUC_2) ≥ 200

B. IMPAIRED FASTING GLUCOSE TOLERANCE (IFG):
   110 ≤ GLUC_0 < 126

C. IMPAIRED GLUCOSE TOLERANCE (IGT):
   GLUC_0 < 126 AND GLUC_2 BETWEEN 140 AND 199.

D. NORMAL FASTING GLUCOSE TOLERANCE (NFG):
   GLUC_0 < 110 AND NO DM TREATMENT

E. DIABETIC STATUS UNDETERMINED:
   GLUC_0 WAS MISSING.
IV. DURATION OF DIABETES, FOR DIABETIC PATIENTS ONLY:

DURATION OF DM VARIES DEPEND ON WHICH DM CRITERIA WAS USING.

IF AGE OF DIABETES WAS DIAGNOSED (Q3f, MED27) WAS KNOWN,
DURATION OF DM = AGE AT EXAM - MED27

IV. DIABETES CONTROL, FOR DIABETIC PATIENTS ONLY:

POOR CONTROL --- HbA1c ≥ 9.6%
FAIR CONTROL --- HbA1c: 7.6-9.5%
GOOD CONTROL --- HbA1c: 6.0-7.5%
NON-DIABETIC --- HbA1c < 6.0%

V. DIABETES TREATMENT, FOR DIABETIC PATIENTS ONLY, MEDICAL HISTORY:
(B, I, O, N)

A. BOTH INSULIN AND ORAL AGENT:
TAKING BOTH INSULIN (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008') AND HYPOGLYCEMIC AGENT (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682020') AT THE SAME TIME.

B. INSULIN TREATMENT:
TAKING INSULIN CURRENTLY (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008')

C. ORAL AGENT:
TAKING HYPOGLYCEMIC AGENT CURRENTLY (ANY OF THE MEDICATION CODE, MED2, MED4, MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682020')
DEFINITION OF CORONARY HEART DISEASE:

I. ANGINA PECTORIS - DEFINED BY THE ROSE QUESTIONNAIRE:

ROSEAP=1 (YES): ROSE1='1' AND (ROSE2='1' OR ROSE2='3') AND ROSE4='1' AND ROSE5='1' AND ROSE6='1' AND (ROSE7A='1' OR ROSE7B='1' OR (ROSE7C='1' AND ROSE7D='1'))), ELSE

ROSEAP=0 (NO)

II. MYOCARDIAL INFARCTION

A. MEDICAL HISTORY
1. HISTORY OF MI: Q3I IN MEDICAL HISTORY QUESTIONNAIRE MED37='1';
2. POSSIBLE MI FROM ROSE QUESTIONNAIRE: Q9 ROSE9='1'.

B. CLINICAL ABNORMAL ECG: (DR. OOPIK)
1. CLINICAL EVIDENCE OF ECG MI --- PANEL DECISION.
2. UNCODEABLE ECG
   a. MISSING LEADS
   b. BASELINE DRIFT (1 IN 20) IF IT OBSCURES ST-T SEGMENT.
   c. MUSCLE TREMOR GIVING 2 MM. PEAK-TO-PEAK OSCILLATION.
   d. OTHER TECHNICAL ERRORS MAKING Q WAVE MEASUREMENTS IMPOSSIBLE.
   e. MAJOR ABNORMAL QRS CONDUCTION PATTERNS(BBB, PACER, ETC.)
C. ECG CRITERIA BY MINNESOTA CODE

1. MAJOR ISCHEMIC ABNORMALITIES -
   a. MAJOR Q-WAVE ABNORMALITIES: 1.1.1 THROUGH 1.1.7.
   b. STRICT CRITERIA (e.g., THE TECUMSEH STUDY): 1.1.1-1.2.X, 4.1.X, 5.1-5.2, 6.1 OR 7.1.X.
   c. MINNESOTA DEFINITE MI: 1.1.X OR 1.2.X EXCEPT (1.2.6 OR 1.2.8)
   d. MINNESOTA POSSIBLE MI: 1.1.X, 1.2.X, OR 1.3.X

2. MINOR ECG ABNORMALITIES - MINOR ST AND T-WAVE CHANGES.
   b. WHITEHALL STUDY: 1.1.X, 1.3.X, 4.1.X-4.4, 5.1-5.3, OR 7.X.

<table>
<thead>
<tr>
<th>MN CODES</th>
<th>ANTERO-LATERAL</th>
<th>POSTERIOR (INFERIOR)</th>
<th>ANTERIOR</th>
<th>PATTERN</th>
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<td>1, 2, 6, 7</td>
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<td>1, 2, 3, 4, 5, 6</td>
<td>1, 2, 7, 8</td>
<td>Q AND QS</td>
</tr>
<tr>
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<td>1, 3</td>
<td>1, 4, 5, 6</td>
<td>1, 2</td>
<td>Q AND QS</td>
</tr>
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<td></td>
<td>QRS AXIS</td>
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<td></td>
<td>HIGH R</td>
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<tr>
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<td>1, 2</td>
<td>ST JUNCTION (J)</td>
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<td>2, 3, 4</td>
<td>2, 3, 4</td>
<td>STJ</td>
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<tr>
<td>5-X</td>
<td>1, 2, 3, 4</td>
<td>1, 2, 3, 4</td>
<td>1, 2, 3, 4</td>
<td>T-WAVE</td>
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<td>A-V CONDUCTION</td>
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<td>7-X-X</td>
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<td>VENTRICULAR CONDUCTION DEF</td>
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<td></td>
<td>ARRHYTHMIAS</td>
<td></td>
</tr>
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<td>9-X</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>ST ELEVATION</td>
</tr>
</tbody>
</table>
ECG ABNORMALITIES
Program: ARVOEKG2.PGM

/*
   *********************************************************************
   ** NEXT SECTION DEFINES ECG ENDPOINTS USED BY DR. OOPIK: **
   ** DMI_E: DEFINITE MN MI, 111, 112, 121-125 OR 127 **
   ** PMI_E: POSSIBLE MN MI, 13X, 126, 128 **
   ** VENTRICULAR DEFECT: **
   ** LBBB: LT BUNDLE BRANCH BLOCK, 71X **
   ** RBBB: RT BUNDLE BRANCH BLOCK, 72X **
   ** IVCD: INTRAVENTRICULAR BLOCK, 74 **
   ** VCDEFECT: ANY VC DEFECT, ANY OF ABOVE, 71, 72, 74 **
   ** LEFT VENTRICULAR HYPERTROPHY: **
   ** LVH_NOST: LVH VOLTAGE WITHOUT ST, 31, 33 **
   ** LVH_MN: LVH VOLTAGE WITH ST, 31, 33, AND (51 OR 52) **
   ** LVH_CHS: LVH WITH ST-T, 31, 33 AND (51,52,41X,42 OR 43) **
   ** ISOLATED ST-T: **
   ** MAJORSTT: ISOLATED MAJOR ST-T, 41X-42, 51, 52 **
   ** WITHOUT 11-13 3-1, 3-3 **
   ** MINORST: ISOLATED MINOR ST, 43, 44 **
   ** WITHOUT 11-13 3-1, 3-3 **
   ** MINOR_T: ISOLATED MINOR T WAVE, 53, 54 **
   ** WITHOUT 11-13 3-1, 3-3 **
   ** ISO_STT: ISOLATED ST-T, ANY OF ABOVE, 41X-44, 51-54, **
   ** WITHOUT 11-13 3-1, 3-3 **
   ** STJ_L: LARGE STJ DEPRESSION, >2.0mm, 41X **
   ** STJ_S: SMALL STJ DEPRESSION, 1 TO 2.0mm, 42 **
   ** T-WAVE ITEMS: **
   ** T_NEGL: LARGE NEGATIVE T, < -5mm, 51 **
   ** T_NEGS: SMALL NEGATIVE T, -1 TO -5mm, 52 **
   ** A-V BLOCK: **
   ** FIRSTAVB: 1ST DEGREE AV BLOCK, 63 **
   ** SECONDAV: 2ND DEGREE AV BLOCK, 62X **
   ** AVBLOCK: AV BLOCK, 61, 62X, 63 **
   ** HEARTRAT: HEART RATE, CONTINUOUS VARIABLE **
   ** QRSAXIS: QRS VECTOR, CONTINUOUS VARIABLE **
   ** SHS DEF ECG MI (DMI_S): **
   ** 11X, 12X EXCEPT (126, 128, 71, OR 74) **
   ** SHS POS ECG MI (PMI_S): **
   ** 13X, 126, 128 EXCEPT (71, OR 74) **
********************************************************************* */
D. MORBIDITY EVENT CRITERIA

1. **Definite Myocardial Infarction (MI)**

   Minnesota codes 1.1.x or 1.2.x except 1.26. and 1.28 with no 7.1 or 7.4
   History of MI verified by chart review as definite MI

2. **Possible Myocardial Infarction**

   Minnesota codes 1.3.x, 1.2.6, or 1.2.8 with no 7.1 or 7.4
   History of MI verified by chart review as possible MI

3. **Definite Coronary Heart Disease (CHD)**

   Definite MI,
   Definite CHD verified by chart review to include cardiac cath, proven coronary artery disease, 
   PTCA, coronary artery bypass grafting, or abnormal stress ECG plus abnormal imaging (i.e., both must be abnormal),
   Angina Pectoris plus LBBB (7.1.1) or
   ST changes (4.1) or
   T wave changes (5.1) or
   verified possible MI,

4. **Possible Coronary Heart Disease**

   Possible ECG MI (1.3.x, 1.2.6, 1.2.8)
   Angina Pectoris
   Minnesota codes 7.1, 4.1, 4.2, 5.1, 5.2, 7.4
   Unconfirmed history of MI
   Positive functional test of ischemia (such as treadmill) without invasive confirmation
   Possible ECG or imaging in scintigraphic studies (not both).

5. **Definite Cardiovascular Disease (CVD)**

   Definite CHD
   Congestive Heart Failure
   Cardiomyopathy
   Valvular Heart Disease
   Left ventricular Hypertrophy by Echocardiogram
   Left ventricular Hypertrophy by ECG (3.1 or 3.3 plus 4.1-4.3 or 5.1-5.3)
   Ankle Arm Index <= 0.8
   Atrial Fibrillation
   Minnesota codes 4.1, 5.1, 6.1, 6.2, 6.8, 7.1, 7.2, 7.4
   Noncoronary heart surgery or carotid or other vascular surgery
   Pacemaker implantation
   Bruits by physical examination
   Intermittent Claudication by Rose Questionnaire
   Positive non-coronary angiography
DEFINE COMPOSITE CVD BY USING M&M SURVEILLANCE AND SHS ECG RESULTS

For fatal event, "deadcode" indicate cause of death. User needs to refer to the Mortality Survey Final Decision Form for the meaning and the definition of each of the causes (numerical code). This form, along with other M&M forms can be found in SHS-III Manual Volume I, Appendix C. It is also in the SHS-4 Manual Volume II, Appendix C. This form has not been changed since SHS-III. The variable "deaddate" refers to the date of death. The "deadcode" are:

<table>
<thead>
<tr>
<th>Cause of Death Code</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Definite fatal MI</td>
</tr>
<tr>
<td>02</td>
<td>Definite sudden death due to CHD</td>
</tr>
<tr>
<td>03</td>
<td>Definite fatal CHD</td>
</tr>
<tr>
<td>04</td>
<td>Possible fatal CHD</td>
</tr>
<tr>
<td>05</td>
<td>Definite fatal stroke</td>
</tr>
<tr>
<td>06</td>
<td>Possible fatal stroke</td>
</tr>
<tr>
<td>07</td>
<td>Definite fatal CHF</td>
</tr>
<tr>
<td>08</td>
<td>Possible fatal CHF</td>
</tr>
<tr>
<td>09</td>
<td>Other fatal CVD</td>
</tr>
<tr>
<td>10 and after</td>
<td>non-CVD death</td>
</tr>
</tbody>
</table>

For nonfatal events, the user needs to refer to the Morbidity Survey Decision Form for definition of each single cause. Since morbid events can reoccur, in this data set, I pulled all the events files together for each single event and selected the earliest one to represent the incident case as well as its date of occurrence. Thus, for nonfatal events, I separated the 9 CVD events in the Decision Form into 8 variables and the date of that specific event. They are:

<table>
<thead>
<tr>
<th>Decision Diagnosis Code</th>
<th>Event</th>
<th>Variable name</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Definite non-fatal MI</td>
<td>defmi and defmidt</td>
</tr>
<tr>
<td>02</td>
<td>Possible nonfatal MI</td>
<td>posmi and posmidt</td>
</tr>
<tr>
<td>03</td>
<td>Definite non-fatal stroke</td>
<td>defstk and defstkdtd</td>
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<tr>
<td>04</td>
<td>Possible non-fatal stroke</td>
<td>posstk and posstkdtd</td>
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<tr>
<td>06</td>
<td>Definite CHD</td>
<td>defchd and defchddt</td>
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<tr>
<td>07</td>
<td>Possible CHD</td>
<td>poschd and poschddt</td>
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<tr>
<td>08</td>
<td>TIA</td>
<td>shstia and shstiatd</td>
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<tr>
<td>09</td>
<td>Other CVD</td>
<td>othc and othcvddt</td>
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</tbody>
</table>
For SHS ECG MI, we were using MN Codes as:

**SHS DEFINITE ECG MI:** 11X, 12X EXCEPT (126, 128, 71, OR 74)
(SxDMI_S: x indicate phase, values: Y/N, ECGDATE)

**SHS POSSIBLE ECG MI:** 13X, 126, 128 EXCEPT (71, OR 74)
(SxPML_S, values: Y/N)

SHS-I ECG date: ecgdate
SHS-II ECG date: ecgdate2
SHS-III ECG date: ecgdate3 (to be added)

**NOTE:** In Dr. Howard's Rising Tide paper (Circulation, 1999; 99:2389-2395):

Non-fatal CVD: defmi, defchd, defstk (morbidity decision: 1, 3, 6), and definite ECG MI (s2dmi_s='Y').

Fatal CVD: mortality final decision (01-09).

ALL CVD: combined fatal and non-fatal CVD.
DEFINITION OF HYPERTENSION

I. BLOOD PRESSURE: AVERAGE OF THE LAST TWO SITTING BLOOD PRESSURES FROM PHYSICAL EXAM, Q17, Q18, Q19, AND Q20

SYSTOLIC BLOOD PRESSURE - \( SBP = \frac{(EXAM27 + EXAM29)}{2} \)
DIASTOLIC BLOOD PRESSURE - \( DBP = \frac{(EXAM28 + EXAM30)}{2} \)
MEAN BLOOD PRESSURE - \( MBP = \frac{2}{3} SBP + \frac{1}{3} DBP \)

\( Sx_{sbp}, sX_{dbp} \)

II. HYPERTENSION

A. WHO CRITERIA

HYPERTENSION ('Y'):
1. TAKING ANTIHYPERTENSIVE DRUG (MEDICATION CODE='2408')
   OR
2. TAKING (DIURETICS ('4028'), OR BETA-BLOCKERS ('1216') OR CARDIAC ('2404') OR VASODILATOR ('2412')) AND HISTORY OF HYPERTENSION (MED19='1')
   OR
3. SYSTOLIC BLOOD PRESSURE \( \geq 160 \text{ mmHg} \)
   OR
4. DIASTOLIC BLOOD PRESSURE \( \geq 95 \text{ mmHg} \)

BORDERLINE HYPERTENSION ('B'):
140 mmHg \( \leq \) SBP \( < 160 \text{ mmHg} \) OR
90 mmHg \( \leq \) DBP \( < 95 \text{ mmHg} \)

NORMOTENSIVE ('N'):
SBP < 140 AND DBP < 90 AND NO ANTIHYPERTENSIVE TREATMENT.

B. US CRITERIA: \( sx_{ushtn}=('N', 'Y'). \)

HYPERTENSION: WHO HYPERTENSION OR BORDERLINE HYPERTENSION
NORMOTENSIVE: SAME AS WHO NORMOTENSIVE.

DEFINITION OF ISOLATED HYPERTENSION:
1. HYPERTENSION: DBP \( \geq 90 \) AND SBP \( \geq 140 \)
2. DIASTOLIC HYPERTENSION: DBP \( \geq 90 \) AND SBP \( < 140 \)
3. ISOLATED SYSTOLIC HYPERTENSION: SBP \( \geq 140 \) AND DBP \( < 90 \)
4. NORMOTENSIVE: SBP < 140 AND DBP < 90

HYPERTENSION CONTROL, FOR HYPERTENSIVE PARTICIPANTS ONLY:
1. UNCONTROLLED HYPERTENSION: DBP \( \geq 90 \) OR SBP \( \geq 140 \)
DEFINITION OF RENAL DISEASE:

I. RENAL FUNCTION, PLASMA CREATININE:
A. CATEGORICAL VARIABLE:
   1 (RENAL INSUFFICIENCY)  PLASMA CREATININE ≥ 2.0 mg/dl
   0 (NORMAL)  PLASMA CREATININE < 2.0 mg/dl
B. CONTINUOUS VARIABLE, ADJUSTED FOR BMI

II. ALBUMINURIA: sxacr=('1', '2', '3')

ESTIMATED BY URINARY ALBUMIN - URINARY CREATININE RATIO
   3 (MACROALBUMINURIA)  ACRATIO ≥ 300 mg/g
   2 (MICROALBUMINURIA)  ACRATIO 30 - 299 mg/g
   1 (NORMAL)  ACRATIO < 30 mg/g

III. END STAGE RENAL DISEASE (ESRD)
   1 (YES)= ON RENAL DIALYSIS, MEDICAL HISTORY FORM, Q4a, MED42='1', OR
     HAD KIDNEY TRANSPLANT, MEDICAL HISTORY, Q4b, MED43='1', OR
     KIDNEY FAILURE, MEDICAL HISTORY, Q3g, MED29='1'
   0 (NO)= NONE OF ABOVE
DEFINITION OF PERIPHERAL VASCULAR DISEASE (PVD)

I. ANKLE-BRACHIAL RATIO (PVD_ABR), PHYSICAL EXAM, Q44, Q45, AND Q46

sXrt_aar and sXlt_aar

RIGHT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ANKLE.
RANKBP=(EXAM66 + EXAM68) / 2

LEFT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF LT ANKLE.
LANKBP=(EXAM70 + EXAM72) / 2

RIGHT ARM BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ARM.
RARMBP=(EXAM74 + EXAM75) / 2

RPVD_ABR = RANKBP / RARMBP
LPVD_ABR = LANKBP / RARMBP

PVD_ABR: (cut-off value may vary depending on investigator)
1 (YES): IF (RPVD_ABR < 0.8) OR (LPVD_ABR < 0.8) OR THE ANKLE DOPPLER
BPs WERE NOT AUDIBLE (EXAM70, EXAM72, EXAM74, OR EXAM75
WAS '0')
0 (NO): IF PVD_ABR ≥ 0.8.

(Cut-off point, such as 0.85 or 0.9, may vary according to the investigator).

II. PERIPHERAL OCCLUSION (PERIOCC):
ABSENCE OF DORSALIS PEDIS PULSE AND POSTERIOR TIBIAL PULSE ON EITHER
FOOT.
(PHYSICAL EXAM Q36-Q39),
PERIOCC=1 (YES): (EXAM58='2' AND EXAM60='2') OR (EXAM59='2' AND EXAM61='2')
PERIOCC=0 (NO): EXAM58='1' AND EXAM59='1' AND EXAM60='1' AND EXAM61='1'

III. PRESENCE OF FEMORAL BRUIT (BRUIT)
(PHYSICAL EXAM Q40-Q41)
BRUIT=1 (YES): EXAM62='1' OR EXAM63='1'
BRUIT=0 (NO): EXAM62='2' AND EXAM63='2'

IV. INTERMITTENT CLAUDICATION (MEDICAL HISTORY - ROSE QUESTIONNAIRE)
ROSEIC=1 (YES): ROSE10='1' AND ROSE11='1' AND ROSE12='1' AND (ROSE13='1' OR
ROSE13='3') AND ROSE15='2' AND ROSE16='1' AND ROSE17='1'
AND ROSE18='1', ELSE
ROSEIC=0 (NO):

V. COMPOSITE PVD (PVD_COMP)
PVD_COMP 1 (YES): PVD_ABR=1 OR PERIOCC=1 OR BRUIT=1 OR ROSEIC=1
PVD_COMP 0 (NO): PVD_ABR=0 AND PERIOCC=0 AND BRUIT=0 AND ROSEIC=0
DEFINITION OF OBESITY INDICES, PHYSICAL EXAM:

A. BODY MASS INDEX, Q1 AND Q2, (WEIGHT IN KILOGRAM) / (HEIGHT IN METER)²

\[ sXBMI = \frac{\text{EXAM94}}{(\text{EXAM03}/100)^2} \]

B. WAIST-HIP RATIO, Q33 AND Q9:

\[ sXWHR = \frac{\text{EXAM51}}{\text{EXAM13}} \]

C. PERCENT BODY FAT (sXPCTFAT):

(i) PCTFAT is calculated by using Rising’s underwater equation as following:

fat-free mass:

\[ \text{FFT} = 13.74 + 0.25 \times (\text{height}^2 / \text{resistance}) + 0.30 \times \text{(weight)} - 0.14 \times \text{(age)} + 6.18 \times \text{(sex)} \]

where: height in cm, weight in kg, age in years, sex (0=female, 1=male)

fat mass (FM) = weight - FFT

\[ \text{PCTFAT} = \left( \frac{\text{FM}}{\text{weight}} \right) \times 100\% \]

RESISTANCE: Q35a IN PHYSICAL EXAM

(ii) following equation was developed by Segal and used by IRAS

IF SEX='1' THEN FFM2 = 0.00108*HT*HT - 0.0209*RESIST + 0.23199*WT
- 0.1676*AGE + 22.66827; ELSE
IF SEX='0' THEN FFM2 = 0.00132*HT*HT - 0.04394*RESIST + 0.30520*WT
- 0.1676*AGE + 22.66827

where FFM2 is fat-free mass

\[ \text{PFAT}_\text{SG} = \text{ROUND}(100*(1-(\text{FFM2}/\text{WT})),.1) ; \]

(iii) the following equation was revised RJL for general population

IF SEX='1' THEN BODYH2O = EXP(1.1782*LOG(HT) - 0.5968*LOG(RESIST)
+ 0.3226*LOG(WT)); ELSE
IF SEX='0' THEN BODYH2O = EXP(1.2004*LOG(HT) - 0.5529*LOG(RESIST)
+ 0.2164*LOG(WT));

\[ \text{FFM3} = \frac{\text{BODYH2O}}{0.732} ; \]

\[ \text{FM3} = \text{WT} - \text{FFM3} ; \]

\[ \text{PFAT}_\text{RJL} = \text{ROUND}(((\text{FM3}/\text{WT})*100),.1) ; \]
DEFINITION OF RISK FACTORS
1. CIGARETTE SMOKING (PERSONAL INTERVIEW II, Q24-Q29):

A. SMOKING (NEVER, EX-SMOKER, CURRENT)

\[ SXsmoke = ('E', 'N', 'Y') \]

- N (NEVER) IF INT2_34='2' OR INT2_35=0
- E (EX) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='2'
- Y (CURRENT) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='1'
- ' ' (UNKNOWN) NONE OF ABOVE

IF GROUP INTO SMOKER VS NONSMOKER, (SMOKING=0 OR SMOKING=1) CAN BE COMBINED AS NON-CURRENT SMOKER;

OR

(SMOKING=1 OR SMOKING=2) CAN BE COMBINED AS EVER SMOKED.

B. SMOKING AMOUNT (FOR SMOKER ONLY):
1. DURATION OF SMOKING: Q29 (INT2_39)

2. AGE STARTED SMOKING:
   - CURRENT SMOKER: AGE AT EXAM - DURATION OF SMOKING
   - EX-SMOKER: AGE STOPPED SMOKING (Q27) - DURATION OF SMOKING

3. DAILY SMOKING AMOUNT (Q28): INT2_38

4. TOTAL SMOKING AMOUNT (\( \text{PPY} \), PER PACK YEAR):
   \[ \text{PPY} = \frac{(\text{DAILY SMOKING AMOUNT} \times \text{DURATION OF SMOKING})}{20} \]
   \[ = \frac{(\text{INT2_38} \times \text{INT2_39})}{20} \]

C. OTHER TYPE OF SMOKING: INTERVIEW II, Q30-Q32

0 (NO) IF (INT2_40='2' AND INT2_41='2' AND INT2_42='2')
1 (YES) IF (INT2_40='1' OR INT2_41='1' OR INT2_42='1')

D. PASSIVE SMOKING

0 (NO) IF INT2_33=0
1 (YES) IF INT2_33 > 0

DAILY EXPOSURE TIME (IN HOURS): INT2_33.

E. PARENTAL SMOKING:

0 (NONE) (INT2_31=2 OR INT2_31=3) AND (INT2_32=2 OR INT2_32=3)
1 (ONE) INT2_31=1 OR INT2_32=1
2 (BOTH) INT2_31=1 AND INT2_32=1
2. **EDUCATION: PERSONAL INTERVIEW FORM II, Q15 - INT2_4**
   A. CONTINUOUS:  \( s1edu = INT2_4 \) (YEARS)
   B. CATEGORICAL:
      i. **THREE CATEGORIES (EDUCAT1):**
         1. (LESS THAN HIGH SCHOOL) \( 0 \leq INT2_4 < 12 \)
         2. (HIGH SCHOOL GRADUATE AND/OR SOME COLLEGE) \( 12 \leq INT2_4 < 16 \)
         3. (COLLEGE GRADUATE) \( INT2_4 \geq 16 \)
      ii. **FOUR CATEGORIES (EDUCAT2):**
         1. (LESS THAN NINE YEARS) \( 0 \leq INT2_4 < 9 \)
         2. (SOME HIGH SCHOOL) \( 10 \leq INT2_4 < 12 \)
         3. (SOME COLLEGE) \( 13 \leq INT2_4 < 16 \)
         4. (COLLEGE GRADUATE) \( INT2_4 \geq 16 \)

3. **TOTAL DEGREE OF INDIAN BLOOD: INTERVIEW II, Q16**
   A. CONTINUOUS:  \( BLOODALL = (INT2_5 / INT2_6) \times 100\%
   B. CATEGORICAL:
      0. (LESS THAN 25%) \( 0 < BLOODALL < 25\%
      1. (LESS THAN 50%) \( 25 \leq BLOODALL < 50\%
      2. (50-74.9%) \( 50 \leq BLOODALL < 75\%
      3. (75-99.9%) \( 75 \leq BLOODALL < 100\%
      4. (FULL BLOODED) \( BLOODALL = 100\%

4. **INDIAN TRADITION: INTERVIEW II, Q35-Q38**
   A. SPEAK NATIVE LANGUAGE, INDYLANG
      0. (NO) \( INT2_45='3' \) OR \( INT2_46='5' \)
      1. (YES) \( INT2_45='1' \) OR \( INT2_46='1' \) OR \( INT2_46='2' \) OR \( INT2_46='3' \) OR \( INT2_46='4' \)
   B. USE TRADITIONAL MEDICINE/HERBS, INDYMED
      0. (NO) \( INT2_47='5' \) OR '9'
      1. (YES) \( INT2_47='1' \) OR '2' OR '3' OR '4'
   C. TRADITIONAL CEREMONIES, INDYCERE
      0. (NO) \( INT2_48='5' \) OR '9'
      1. (YES) \( INT2_48='1' \) OR '2' OR '3' OR '4'

5. **STRESS: INTERVIEW II, Q42-Q46**
   A. SLEEP LOSS, Q42, SLEPLOSS
      0. (NO) \( INT2_52='1' \)
      1. (YES) \( INT2_52='2' \) OR '3'
   B. STRAIN OR STRESS, Q43, STRAIN
      0. (NO) \( INT2_53='1' \)
      1. (YES) \( INT2_53='2' \) OR '3'
C. OPEN ARGUMENTS, Q44, QUARREL
0 (NO) \ INT2_54='1' OR '2'
1 (YES) \ INT2_54='3' OR '4' OR '5'

D. ALCOHOL PROBLEM OF HOUSEHOLD, Q45, HOUSETOH
0 (NO) \ INT2_53='1'
1 (YES) \ INT2_53='2'

E. SIZE OF HOUSEHOLD, Q46, HOUSSIZE
1 (SMALL) \ INT2_54 < 4
2 (MEDIUM) \ 4 < INT2_54 < 10
3 (LARGE) \ INT2_54 ≥ 10

6. ALCOHOL USE
A. ALCOHOL DRINKING STATUS, sXETOH=('0', '1', '2'), Q47-Q48
0 (NEVER) \ INT2_57='2'
1 (EX-DRINKER) \ INT2_57='1' AND (INT2_59 > 12 OR INT2_60 > 1)
2 (CURRENT) \ INT2_57='1' AND INT2_60 = 0

B. BINGE DRINK
1. DURING THE PAST MONTH, Q52
0 (NO) \ 0 < INT2_64 < 5
1 (YES) \ INT2_64 ≥ 5

2. DURING THE PAST YEAR, Q53
0 (NO) \ 0 < INT2_65 < 5
1 (YES) \ INT2_65 ≥ 5

C. AMOUNT OF ALCOHOL INTAKE
Average weekly drinking amount: INT2_61 (preferred ETOH variable)
Average daily drinking amount: INT2_63
7. SOCIOECONOMIC STATUS (SES)
   A. RECEIVING FEDERAL ASSISTANCE:
      1. FOOD STAMPS / WIC, Q56
         0 (NO)  INT2_68 = 0
         1 (YES) INT2_68 > 0
      2. COMMODITY FOOD, Q57
         0 (NO)  INT2_69 = 0
         1 (YES) INT2_69 > 0
      3. FEDERAL ASSISTANCE, FEDHELP
         0 (NO)  INT2_68 = 0 AND INT2_69 = 0
         1 (YES) INT2_68 > 0 OR INT2_69 > 0
   B. SES (EDUCATION, FAMILY INCOME, ...) 
      1. HOUSEHOLD INCOME, Q58: USE THE CATEGORIES LISTED IN THE QUESTIONNAIRE.

8. FAMILY HISTORY OF DISEASES - PERSONAL INTERVIEW II, FAMILY HISTORY
   A. CLASSIFICATION:
      1. PARENTAL, FOR RELATIONSHIP CODE 1 AND 2 (FH1 AND FH14)
      2. FIRST DEGREE FULL-BLOOD RELATIVES:
         RELATIONSHIP CODE: 1 (MOTHER), 2 (FATHER), 3 (SISTER), 5 (BROTHER), 7 (DAUGHTER), AND 8 (SON).
      3. ALL FIRST DEGREE RELATIVES, ALL CODES.
   B. DISEASE HISTORY
      1. HEART DISEASE: MI AND HD
      2. CARDIOVASCULAR DISEASE: MI, HD, HBP, CVA
      3. DIABETES: DM
      4. KIDNEY FAILURE: KF
      5. ARTHRITIS: AT
      6. CANCER
9. MEDICAL HISTORY, MEDICAL HISTORY FORM

A. PRESCRIBED MEDICATIONS: USE CATEGORIES IN THE MANUAL (p. 282)

<table>
<thead>
<tr>
<th>No.</th>
<th>Medication</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>ANTIHISTAMINE (400)</td>
<td>9. ANTIHISTAMINE (400)</td>
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<td>2</td>
<td>ANTI-INFECTIVE (612)</td>
<td>10. ANTIBIOTICS (812)</td>
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<td>ANTI-INFECTIVE (1000)</td>
<td>4. BETA-BLOCKERS (1216)</td>
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<td>ANTICOAGULANTS (2000)</td>
<td>6. CARDIAC DRUGS (2404)</td>
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<td>5</td>
<td>HYPOLIPIDEMIC (2406)</td>
<td>8. HYPOTENSIVE (2408)</td>
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<td>ANALGESIC (2808)</td>
<td>10. ASPIRIN (280892)</td>
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<td>ANTICONVULSANTS (2812)</td>
<td>12. PSYCHOTHERAPY (2816)</td>
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<td>ADRENALS (6804)</td>
<td>14. Oral Contraceptives (6812)</td>
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<td>9</td>
<td>DIURETICS (4028)</td>
<td>16. GI DRUGS (5600)</td>
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<td>10</td>
<td>DIURETICS (6816)</td>
<td>18. INSULIN (682008)</td>
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<td>SULFONYLUREAS (682020)</td>
<td>20. THYROID AGENTS (6836)</td>
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<td>12</td>
<td>OINTMENTS (8400)</td>
<td>22. VITAMINS (8800)</td>
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<td>13</td>
<td>UNCLASSIFIED (9200)</td>
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</tr>
</tbody>
</table>

B. HISTORY OF:

1. GALLSTONE, Q3c
   - 0 (NO) MED22='2'
   - 1 (YES) MED22='1'

2. ARTHRITIS, Q3d
   - 0 (NO) MED23='2'
   - 1 (YES) MED23='1'

3. CANCER, Q3e
   - 0 (NO) MED24='2'
   - 1 (YES) MED24='1'

4. KIDNEY FAILURE, Q3g
   - 0 (NO) MED28='2'
   - 1 (YES) MED28='1'

5. EMPHYSEMA, Q3h
   - 0 (NO) MED31='2'
   - 1 (YES) MED31='1'

6. LIVER CIRRHOSIS, Q3i
   - 0 (NO) MED32='2'
   - 1 (YES) MED32='1'

7. RENAL DIALYSIS, Q4a
   - 0 (NO) MED42='2'
   - 1 (YES) MED42='1'

8. KIDNEY TRANSPLANT, Q4b
   - 0 (NO) MED43='2'
   - 1 (YES) MED43='1'
10. REPRODUCTION AND HORMONE USE (FEMALE ONLY), MEDICAL HISTORY

A. REPRODUCTION:
1. TIMES PREGNANT, Q7-1, REPRO1
2. NUMBER OF LIVE BIRTH, Q7-2, REPRO2
3. NUMBER OF LOST PREGNANCIES, Q7-3, REPRO3
4. NUMBER OF LIVING CHILDREN, Q7-4, REPRO4
5. MENOPAUSAL, Q8
   0 (NO) REPRO5='2'
   1 (YES) REPRO5='1'
6. AGE AT MENOPAUSE, Q9, REPRO6

B. HORMONE USE
1. ORAL CONTRACEPTIVE, Q11
   0 (NO) REPRO9='2'
   1 (YES) REPRO9='1'
2. AGE STARTED TO USE OC PILLS, Q12, REPRO10
3. TOTAL DURATION OF USING OC PILLS, Q13, REPRO11
4. EVER USE OF ESTROGEN OTHER THAN OC PILLS, Q14
   0 (NO) REPRO12='2'
   1 (YES) REPRO12='1' OR MEDICATION CODE (Q1a-Q1h) CONTAINS '6816' (POST MENOPAUSAL ESTROGEN)
5. AGE STARTED TO USE ESTROGEN, Q15, REPRO13
6. TOTAL DURATION OF USING ESTROGEN, Q16, REPRO14
11. PHYSICAL ACTIVITY

WILL CONSULT WITH DR. ANDREA KRISKA

12. LAB DATA
A. LIPID - CONTINUOUS VARIABLE
   1. TOTAL TRIGLYCERIDE, ln(TRIG)
   2. TOTAL CHOLESTEROL, CHOLEST
   3. HDL CHOLESTEROL, HDL_CHOL
   4. LDL CHOLESTEROL, LDL_CHOL
   5. VLDL TRIGLYCERIDE, VTRIG
   6. VLDL CHOLESTEROL, VCHOL
   7. RATIOS:
      i. VCHOL/VTRIG
      ii. HDL_CHOL/CHOLEST
      iii. HDL_CHOL/LDL_CHOL
      iv. APOB/(CHOLEST-HDL_CHOL)
      v. APOA1/HDL_CHOL
      vi. APOB/LDL_CHOL

B. APOLIPOPROTEINS: APOA1, APOB

C. GLUCOSE:
   1. FASTING BLOOD GLUCOSE, GLUC_0
   2. 2-HR BLOOD GLUCOSE, GLUC_2

D. FIBRINOGEN

E. PLASMA INSULIN

F. FIBRINOGEN

G. APO E PHENOTYPE

H. PLASMA CREATININE

I. URINARY ALBUMIN AND CREATININE

J. GLYCATED LDL
CUT POINTS FOR CONTINUOUS VARIABLES:

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>LOW (0)</th>
<th>MEDIUM (1)</th>
<th>HIGH (2)</th>
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<tbody>
<tr>
<td>AGEGP</td>
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<tr>
<td>45-54</td>
<td>55-64</td>
<td>65-74</td>
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</tbody>
</table>

OBESITY: USING NHANES-II CRITERIA

In SHS-I: OBESE FEMALE: BMI > 32.3
MALE: BMI ≥ 31.3
OVERWT FEMALE: 32.3 > BMI > 27.8
MALE: 31.1 > BMI ≥ 27.3

SHS-II and later: Overweight: BMI 25-29.9
Obesity, level 1: BMI 30-34.9
Obesity, level 2: BMI 35-39.9
Obesity, level 3: BMI 40-44.9
Obesity, level 4: BMI 45 and above

OBES_FAT FEMALE: PCTFAT < 41%  PCTFAT > 41%
MALE: PCTFAT < 29%  PCTFAT > 29%

OBES_WHR FEMALE: WHR ≤ 0.98  WHR > 0.98
MALE: WHR ≤ 0.96  WHR > 0.96

TOTAL CHOLESTEROL (NCEP GUIDELINE)
CHOLEST < 200  CHOLEST 200-239  CHOLEST ≥ 240
(mg/dl)

TOTAL TRIGLYCERIDES 2001 Guideline
TRIG < 250 (mg/dl)  TRIG ≥ 250
TRIG < 200 mg/dl  TRIG ≥ 200

HDL CHOLESTEROL (NCEP GUIDELINE)
2001 Guideline
HDL_CHOL < 35  HDL_CHOL > 35
(mg/dl)
HDL_CHOL < 40  HDL_CHOL > 40

LDL CHOLESTEROL (NCEP GUIDELINE)
LDL_CHOL < 130  LDL_CHOL 130-159  LDL_CHOL ≥ 160
(mg/dl)

THE CONTINUOUS VARIABLES MAY ALSO BE ANALYZED BY QUARTILES.
Nested Case-Control Design:

For the Adiponectin and Thyroid case-control studies

Design: Nested case-control (case-control within an existing longitudinal study) Frequency matching is recommended.

Cases and controls are identified at the same point in time and previous exposure is examined for association with disease. After applying exclusion criteria, cases are selected. From the remaining pool of susceptibles, controls are selected. Controls are matched to cases based on the distribution of diabetes, study center, and gender among randomly selected cases. For instance, if 8% of the cases are women with diabetes from Arizona, then 8% of the controls will also be women with diabetes from Arizona.

Exclusion Criteria:
- prevalent and incident CVD occurring from baseline to phase 2 and CVD cases identified at the phase 2 exam (ECGMI) will be excluded.
  - Prevalent and incident CVD, Fatal and Non-Fatal variables:
    - Deadcodes 1, 2, 3, 4, 7 & 8 (Definite MI, Definite Sudden death due to CHD, Definite and Possible CHD, Definite and Possible CHF)
    - ECG MI identified at phase 1 or phase 2 exam
    - Non-fatal CVD events between phases 1 and 2. (DEFMI and DEFCHD).
- Anyone with renal disease - plasma creatinine level >1.2 mg/dL (from phase 2 lab data)
- Anyone taking thyroid medication (at phase 2)
- Anyone taking glucocorticoid (at phase 2)
- Anyone taking troglitazone (at phase 2)
- Prevalent and incident definite stroke, Fatal and Non-Fatal variables: Deadcodes 05 and 06, and DEFSTK

Matching criteria:
- Gender
- Study site
- Diabetes status (2 groups, diabetes and no diabetes), diabetes defined using ADA criteria: self report or taking oral diabetes medication or taking insulin or FG >= 126 (at phase 1 or phase 2 exams)

Selection Process:

1. Apply exclusion criteria to phase 2 participants: (Deadcodes 1, 2, 3, 4, 5, 6, 7 & 8, DEFMI, DEFCHD, ECGMI, DEFSTK, plasma creatinine >1.2, taking thyroid meds, glucocorticoid and/or troglitazone). Remove any participant who meets any exclusion criterion.

2. Identify incident CVD cases occurring after phase 2 exam through ALLCVD99: (Deadcodes 1, 2, 3, 4, 7 & 8, not 5 & 6; DEFMI, DEFCHD, and ECGMI-from-phase 3 exam)
3. Remove all incident cases identified in step 2 from the pool of susceptibles at phase 2.

4. Divide the cases into the following 12 categories:

   1) Women from AZ with DM
   2) Women from OK with DM
   3) Women from SD with DM
   4) Women from AZ no DM
   5) Women from OK no DM
   6) Women from SD no DM
   7) Men from AZ with DM
   8) Men from OK with DM
   9) Men from SD with DM
   10) Men from AZ no DM
   11) Men from OK no DM
   12) Men from SD no DM

5. Randomly select 162 cases in as even a distribution as is possible from each of the 12 categories.

6. Select 162 controls from phase 2 participants who remain after the identified cases are removed

7. The distribution of controls should mirror that of the cases.

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