FAMILY STUDY

Cardiovascular Disease in American Indians
(Phase V)

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 V)

Operations Manual

Volume Three

PERSONAL INTERVIEW AND GENERAL EXAMINATION

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# VOLUME III

## PERSONAL INTERVIEW AND GENERAL EXAM

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CHAPTER ONE

Clinical Examination - General

1.1 INTRODUCTION

Participants of the Phase III pilot family study and/or the Phase IV family study are invited to enroll in the Phase V re-exam. This component of the study consists of a personal interview, a limited physical examination, and laboratory tests. The Phase V Strong Heart Family Study provides unique opportunities to examine the genetic basis of a wide spectrum of cardiovascular phenotypes to enable continued quantification of CVD, to assess secular trends in cardiovascular risk factors and CVD events, with a focus on diabetes, and to further evaluate the alarming prevalence of diabetes, diabetes-associated risk factors and preclinical CVD in young AI.

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. Appendix A below contains the consent forms for each of the 3 field centers. Persons who are institutionalized will be excluded. Pregnant women will not be examined until at least six weeks post partum, and lactating women must be at least six weeks post partum.

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

The training of the registered nurses, nurse practitioners, health profession students, physician assistants and physicians on the Phase IV protocol occurred on March 14 – 16, 2006 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) Personal information including health facility(ies) normally used. In Phase V, the data on this form are NOT transmitted to the CC, but are kept in secure files in the field for use as needed by authorized SHS personnel.

2) Demographic information, marital status, education, weight satisfaction, artificial sweetener use, income, tobacco use, passive smoking, alcohol intake, and perceived stress.

3) Medical history, including reproductive history, and Rose questionnaire for angina pectoris and intermittent claudication.

4) Dietary survey: The Block Food Frequency questionnaire as modified to add foods identified to be commonly eaten in SHS communities, will be self-administered following instruction by clinic staff.

5) Psychosocial information: MOS SF-12 (Quality of Life), CES-D (depression) scale, social support, posttraumatic stress screening scale, generalized anxiety screening scale, spirituality, and fatalism questionnaires.

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 (absent, mild, marked – 1 - 3) will be recorded.

3) Blood pressure measurements:

i) With the participant sitting with right arm on table, the brachial artery will be palpated (just medial to and above the ante-cubital fossa), and this location will be marked for stethoscope placement. The correct cuff size will be chosen and the cuff will be wrapped around the arm with the center of the bladder over the artery. After a 5-minute wait, the cuff will be connected to a standard manometer, and the pulse obliteration pressure will be established and recorded. The participant will be asked to raise the measurement arm for five seconds and then wait another 25 seconds with the arm on the table. The cuff will then be inflated to +30 mm above the obliteration pressure and held constant for 5 seconds. The cuff will be slowly deflated (2 mm/sec) while reading pressures for 1st and 5th phases. Before measurements 2 and 3 are taken, the participant will raise the arm for five seconds. After another 25 seconds with arm on the table, the measurement will be repeated 2 more times. The average of these 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 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 will be obtained for measurements of total triglyceride (TG), cholesterol, LDL and HDL cholesterol, plasma fibrinogen, leptin, CRP, serum FFA, glucose, HbA1c (when glucose > 100 mg/dl), creatinine, insulin, chemistry profile, CBC and DNA isolation. 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.


9) Pedometry will be used to assess physical activity of the participants at home for one week. Each participant will wear an Accusplit pedometer for 7 days (from waking till going to bed each day), recording daily activity counts on the 7-day pedometer record sheet, and returning the record to the clinic after recording 7 consecutive days of activity.

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

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

The clinical examination will last approximately three to four hours. The participant will arrive at the clinic fasting in the morning. After registration, a study staff member will explain the study and procedures to the participant, answer questions, if any, and have the consent form signed (see Appendix A – 1 below for consent forms used in the 3 centers). 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 and popliteal arteries, 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 questionnaires, 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** (see Volume 2 of this manual)

A. **MORBIDITY EVENT CRITERIA**

1. **Definite Myocardial Infarction (MI)**
   
   Minnesota codes 1.1.x or 1.2.x except 1.26. and 1.28 with no 7.1 or 7.4 or History of MI verified by chart review as definite MI

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

3. **Definite Coronary Heart Disease (CHD)**
   
   Definite MI, or Definite CHD verified by chart review to include cardiac cath, indicating coronary artery occlusion, 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 Definite stroke 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

6. Possible Cardiovascular Disease (CVD)

Possible CHD
or Possible stroke
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.

Eligible participants for the Phase V exam are the previous participants of the Phase III pilot family study and/or the Phase IV family study; only these previous participants are eligible for enrollment in Phase V, which is a re-exam of all surviving family study participants.

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 SHS participants are volunteers. Treat them with courtesy and recognize that they have often gone to a great deal of effort in both time and energy in 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 the 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.

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 V clinical examination, eligible participants are the previous participants of the Phase III pilot family study and/or the Phase IV family study; only these previous participants are eligible for enrollment in Phase V, which is a re-exam of all surviving family study participants. Some local publicity and mailed information will alert the eligible participants before their enrollment in Phase V is requested.

When contacting an eligible participant, the interviewer re-introduces the Strong Heart Family Study and once again 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 participant is not at
home at the time of the phone call or visit, call backs are made as necessary to meet the individual and schedule the clinic appointment. 100% participation is the goal.

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

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

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 any of his/her morning medications; he/she will take them later at the clinic after 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.
1.4 PERSONAL INTERVIEW

1.4.1 Components of the Personal Interview

The personal interview is designed to obtain demographic information, medical history, health behavior, and stress data that are considered important in identifying risk factors for cardiovascular disease. The following questionnaires (see forms in Appendix C of this volume) will be administered during the clinical examination (note: psychosocial forms (item #8) and diet questionnaire (item #11) are self-administered and may be given to the participant up to 2 weeks prior to the exam):

1. Personal Interview Forms (I and II)
2. Medical History Form
3. Reproduction and Hormone Use
4. Rose Questionnaire
5. Physical Exam Form
6. Sample Collection Checklist
7. CBC Results
8. PSYCHOSOCIAL QUESTIONNAIRES
   • Quality of Life (SF-12)
   • CES-D Scale (Depression)
   • Social Support
   • Other (posttraumatic stress screening scale, generalized anxiety screening scale, spirituality, and fatalism)
   • Psychosocial Checklist
9. Seven-Day Pedometer Record
10. Medication Checklist
11. Food Frequency Questionnaire – (FFQ) (Dietary Form)

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 C.

1.4.2 Guidelines for Interviewers

1. Introduction

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

The following are the common interviewer errors:

- 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 B 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
(March 14-16, 2006) 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 stroke. The range of normal blood pressures is wide. Even within the "normal range", risk increases as the upper limits are approached. Usually, blood pressures are expressed as systolic pressure/diastolic pressure; values. 140/90 mmHg or higher are considered to be hypertensive for nondiabetic adults and 130/80 for those with diabetes. Hypertension is an especially strong risk factor for stroke, renal disease, and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure.

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

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.

A thorough evaluation of peripheral arterial occlusive disease usually entails both a history and a physical examination including measurements of pulses and segmental blood pressures and then more complex measures such as angiography or sonography. The following indices of peripheral vascular disease will be made in this study.

1. 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 (Nicolet Imex Elite 100 Doppler).
4. To provide direct measures of peripheral arterial disease, the geometry and presence of atherosclerotic plaque in the popliteal arteries (PA) will be assessed by ultrasound.

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. 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>

1.5.6.1 Penn Medical Lab (SHS Core Lab) Assays The following are assays conducted at baseline that will be repeated on samples from the Phase V re-examination.

1. Lipoproteins

The relationship between cholesterol and coronary heart disease is well established. Lipoprotein measurements, especially LDL cholesterol and HDL cholesterol are important predictors of atherosclerosis. While somewhat more controversial, triglyceride concentrations, especially in relation to HDL cholesterol, are an important factor in assessing the risk of coronary heart disease in either populations or individuals. Although genetic regulation of lipoprotein metabolism is well-recognized and has been described in detail by SHS investigators and others, few studies have evaluated the genetic determinants of changes in lipoprotein concentrations and the relations among these changes and manifestations of preclinical disease, such as ECHO and carotid measures. We chose not to re-measure apoB and apoA1 in Phase V, because our analyses of the cohort data show they are not as effective predictors of CVD as LDL and HDL. Lipoprotein subfractions, measured in a subset late in Phase IV, will not be repeated unless important linkage signals for them are found.

Measurement of Lipoproteins. The beta estimate will be used to measure lipoprotein profile. Lipids are analyzed on plasma samples on the Johnson & Johnson Vitros 950 and 250 using dry,
multilayered, analytical elements coated on a polyester support. The final reaction for the cholesterol, triglyceride, and HDL cholesterol assays involves the oxidation of a leuco dye by hydrogen peroxide, catalyzed by peroxidase. The density of the dye formed is proportional to the lipid concentration present in the sample and is measured by reflectance spectrophotometry. The cholesterol analysis is based on an enzymatic method similar to that proposed by Allain et al. The CV is 1.1-2.0%. The triglyceride analysis is based on an enzymatic method as described by Spayd et al. The CV is 1.9-2.7%.

HDL is separated by the precipitation of the low density lipoprotein (LDL) and very low density lipoprotein (VLDL) using dextran sulfate (MW 50,000) and magnesium chloride. The reagent used contains iron particles that are coated with a polymer that enhances the capture of the non-HDL lipoproteins onto the particles. The supernate containing HDL cholesterol is prepared by removing the precipitated lipoproteins when a magnetic field is applied. The CV is 1.8-3.7%.

The difference between the cholesterol value of the supernate and that of the untreated specimen is equal to the amount of the LDL cholesterol in the sample. CV for calculated LDL is 1.8-3.7%. LDL Direct is a reflex test and is performed if triglycerides are > 400. In the SHS, approximately 10% of participants require LDL Direct measurements. The LipiDirect Magnetic LDL Cholesterol Test contains a buffered polyanionic reagent that precipitates LDL while leaving HDL and VLDL in the supernatant solution. Applying a magnetic field to the mixture pulls away precipitated LDL and the supernate is then assayed using an enzymatic cholesterol reagent. CV averages 2.0-2.6%.

2. Fasting Plasma Glucose and Fasting Insulin
Diabetes is a well-established risk factor for CVD, and this condition occurs with great frequency in the SHS population. Insulin resistance and obesity also occur frequently and are known risk factors for diabetes. Understanding the genetic and environmental determinants of these phenotypes is an important part of our genetic analyses of CVD; re-measuring key analytes in the family members will allow us to monitor the increasing prevalence of insulin resistance and diabetes that is apparent from our initial exam and permit examination of change over time. Because of time constraints in the exam, and the correlation between fasting glucose and OGTT for identifying diabetes in our population (particularly in the younger members), we will rely on fasting glucose and omit the glucose tolerance test.

Measurement of Glucose. The Vitros GLU slide is a multilayered, analytical element coated on a polyester support. It measures glucose concentration in serum and plasma. The inter-assay coefficient of variation is 1.2-1.8%.

Measurement of Insulin. Plasma insulin is measured on the Immulite 2000 analyzer using the Insulin reagent kit from Diagnostic Products. Immulite Insulin is a solid-phase, two-site chemiluminescent assay. Calibrators and controls are supplied by Diagnostic Products. Linearity for this assay is 0.2-400 IU/mL, and CV is < 10%.

3. Hemoglobin A1c
HbA1c will be measured in individuals whose fasting plasma glucose > 100 mg/dL. During Phase IV, we used 110 mg/dL as the cutoff; we have revised this downward to coincide with the
redefinition of impaired fasting glucose by the American Diabetes Association (ADA). This approach minimizes the expense of measuring A1c in normoglycemic individuals, a low-yield endeavor. Moreover, A1c provides an integrated measure of glycemia, allows a better estimate of glucose control, and may be a better marker of the entire symptom complex of diabetes than glucose values derived from the oral glucose tolerance test. Changes in A1c may be correlated with other genetic analyses focused on progression of diabetes and the relations among diabetes severity and cardiovascular abnormalities.

Measurement of Hemoglobin A1c. The assay will be performed on frozen whole blood samples using a Primus CLC385 automated HPLC system and reagents supplied by the manufacturer. The assay is directly standardized to DCCT values. The assays use a boron affinity column, and the values produced after freezing are indistinguishable from those obtained on fresh samples. Our method is certified traceable by the DCCT and the National Glycohemoglobin Standardization Program (NGSP). CV is 1.7-3.7%.

4. Fibrinogen
Fibrinogen, a marker of both coagulation and inflammation, is an established risk factor for prevalent and incident CVD. In the SHS, fibrinogen is an independent predictor of incident CVD. Fibrinogen also has been shown to be associated with markers of preclinical cardiovascular disease. Moreover, fibrinogen has been shown to be closely correlated with markers of inflammation, such as CRP and adiponectin (inverse). Our genetic analyses will focus on the interactions among genetic determinants for fibrinogen, PAI-1 and CRP, and whether there are determinants that predict changes in fibrinogen concentrations or its relations to measures of preclinical disease. PAI-1 will not be re-measured because its variance was high; and it is unlikely that we could detect change over time with sufficient precision.

Measurement of Fibrinogen. Fibrinogen is measured in an automated clot-rate assay based upon the original method of Clauss, using the STA-R Instrument (Diagnostica Stago), with standardization with the CAP reference material. Proficiency is checked with the CAP Coagulation Proficiency Testing Program. Inter- and intra-assay precision testing resulted in a CV of 3%. Both frozen and lyophilized controls are used.

5. Urinary Albumin/Creatinine
Increased concentration of albumin in the urine of diabetic individuals predicts all-cause and CVD mortality in the SHS and in other studies. It is hypothesized that the albumin "leak" in the glomeruli reflects a widespread capillary vasculopathy affecting the heart, eyes, and perhaps other organs. However, 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. It is clear from studies of both types of diabetes that albuminuria clusters among families, and several candidate genes have been proposed. The ability to monitor changes in albuminuria in the family members and relate these to changes in ECHO, carotid and popliteal parameters will add additional power to our genetic analyses.

Measurement of Urinary Albumin. Urine microalbumin is measured with the Hitachi 717 auto analyzer by using an immunoprecipitin assay (Microalbumin SPQ II Kit, DiaSorin). Albumin in
the sample reacts with a specific antibody to form insoluble antigen-antibody complexes. Calibrators and three levels of quality controls are used for each testing, and the reportable range of the assay is 5-240 mg/dL. CV averages 2.1-4.6%.

**Measurement of Urinary Creatinine.** Urine creatinine is measured with the Hitachi 717 auto analyzer using the standard kinetic picric alkaline method. Creatinine reacts with picric acid in an alkaline medium to produce a complex that absorbs light at 510 nm. Absorbance is directly proportional to concentration. Controls are purchased from Bio-Rad (Lyphocheck Quantitative Urine Controls Normal/Abnormal) and NIST(NERL) Standard 15. Three levels of quality control samples are used. CV averages 3.5-5.5%.

6. **CBC and Chemistry Profile**

The hemotocrit and CBC will be determined locally at each center by standardized automated methods. A 16-analyte chemistry profile will be done by the core laboratory. Total protein determinations will be used to estimate whole blood viscosity. 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 also will be used to assess comorbidities, such as hepatocellular disease (transaminases, bilirubin) and gall bladder/bile duct obstruction (alkaline phosphatase, bilirubin, hyperproteinemia, and electrolyte imbalance). Total serum protein concentration can be used for evaluation of nutritional status. Creatinine is a function of lean body mass and can be used to compute an estimated GFR.

**Measurement of Chemistry Profile.** A total of 16 analytes will be measured in this profile: glucose, BUN, creatinine, Tprot, Alb, Na, K, Cl, Alk Phos, AST, Tbili, B/C, A/G, ALT, and Cal., using the Johnson & Johnson Vitros 950 and 250. All reagents are tailored to the specific analyte to be measured. Two quality control samples are monitored for accuracy, precision, and stability. The following have a CV < 5%: Na, K, Cl, Alk Phos, AST, Tbili, B/C, A/G, and Cal. ALT has a CV < 10%.

7. **Free Fatty Acids**

Free fatty acid metabolism is central to several metabolic pathways that are implicated in the atherosclerotic process. The role of free fatty acids (FFAs) as regulators of lipoprotein metabolism has been understood for a number of years; elevations of FFA stimulate hepatic TG synthesis and drive VLDL production, and this has been postulated to be a major mechanism of the elevated VLDL observed in insulin resistance and diabetes. Fatty acids participate in several aspects of the metabolism of glucose and insulin. Elevated FFAs decrease cellular glucose metabolism and reduce insulin-mediated glucose disposal. In addition, fatty acids suppress insulin secretion and thus are postulated to be one of the mediators of the beta-cell failure that occur in type 2 diabetes. Finally, elevations of FFAs influence vascular function; they cause endothelial damage, leading to vasoconstriction, release of inflammatory cytokines, and enhanced thrombosis. For these reasons, it will be of interest to include FFA in the genetic analyses, both to search for linkage signals, and to examine potential interactions with regions that control lipoprotein metabolism, insulin action, and vascular function.
**Measurement of Free Fatty Acid.** Free fatty acids (FFA) are measured by using the Wako NEFA C test kit (Richmond, VA), an in vitro enzymatic colorimetric method for the quantitation of FFA in human serum. In brief, this method relies upon the acylation of coenzyme A (CoA) by the fatty acids in the presence of added acyl-CoA synthetase (ACS). The acyl-CoA thus produced is oxidized by added acyl-CoA oxidase (ACOD) with generation of hydrogen peroxide. Hydrogen peroxide, in the presence of peroxidase (POD), permits the oxidative condensation of 3-methyl-N-ethyl-N-(β-hydroxyethyl)-aniline (MEHA) with 4-aminoantipyrine to form a purple colored adduct, which can be measured colorimetrically at 550 nm. The sensitivity of the assay is 0.01 mEq/L. CV is < 5%.

8. C-reactive protein (CRP)
Numerous studies have shown that CRP levels predict CVD and cardiovascular events in apparently healthy individuals. A close association between CRP and type 2 diabetes is also becoming evident. To date, much in vitro data have emerged in support of a role for CRP in atherogenesis. The proinflammatory, proatherogenic effects of CRP that have been documented in endothelial cells include the following: decreased nitric oxide and prostacyclin and increased endothelin-1, cell adhesion molecules, monocyte chemoattractant protein-1 and IL-8, and increased plasminogen activator inhibitor-1. In monocyte-macrophages, CRP induces tissue factor secretion, increases reactive oxygen species and proinflammatory cytokine release, promotes monocyte chemotaxis and adhesion, and increases oxidized low-density lipoprotein uptake. Also, CRP has been shown in vascular smooth muscle cells to increase inducible nitric oxide production, increase NFkappa(b) and mitogen-activated protein kinase activities, and, most importantly, upregulate angiotensin type-1 receptor resulting in increased reactive oxygen species and vascular smooth muscle cell proliferation. In addition, a number of polymorphisms in the genes controlling CRP expression and other inflammatory cytokines have been identified. Thus, we will re-measure CRP to assess genetic determinants of changes and their relationship to atherosclerosis.

**Measurement of CRP.** High sensitivity CRP in human serum or plasma is measured using the BN II Systems. In brief, polystyrene particles coated with monoclonal antibodies specific to human CRP are aggregated when mixed with samples containing human CRP. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration. The sensitivity of the assay is 0.175 mg/L, and the CV is < 4.1%.

9. Leptin
Leptin is a plasma protein encoded by the ob gene, secreted by adipocytes and involved in the control of body weight. Plasma concentrations of leptin are increased in human obesity and positively correlated to the body fat mass in lean and obese subjects. In addition to long-term regulation of the body weight, hyperleptinemia has been considered a component of the metabolic syndrome and a role for leptin as a possible cause of vascular disease has been recently suggested. Recent studies found that, in patients with angiographically confirmed coronary atherosclerosis, leptin is a novel predictor of future cardiovascular events independent
of other risk factors, including lipid status and CRP. It has been shown that leptin might exert an atherogenic effect through the generation of oxidative stress in endothelial cells.

**Measurement of Leptin.** Serum levels of leptin will be measured using standardized radioimmunoassay (RIA) kits from Linco Research (St. Charles, Mo). For leptin, the kit uses human recombinant leptin for both standard and tracer, with anti-serum raised against human recombinant leptin. The limit of detection is 0.5-100 ng/ml (100 ul sample size). The intra- and inter-assay coefficients of variation are < 6% and < 9%, respectively.

1.5.6.2 Children’s National Medical Center (CNMC), Research Center for Genetic Medicine The following are candidate gene assays to be conducted on samples from the Phase V re-examination.

Candidate gene genotyping will be carried out at the Research Center for Genetic Medicine at Children’s National Medical Center (CNMC), in collaboration with Dr. Joe Devaney. This activity will be overseen by Dr. Lyle Best, PI of the Dakota Field Center.

The main emphasis of genetic investigation in the Strong Heart Family Study is linkage analysis and subsequent identification of positional candidate genes conducted by the SHS Genetics Center at the Southwest Foundation for Biomedical Research (SWF). Linkage analyses and fine mapping are being performed by SWF under its U01 funding. This section outlines plans by SHS investigators in collaboration with Dr. Devaney and the CNMC to analyze a few carefully selected candidate genes. Criteria for candidate gene selection, and the rationale for each are presented in this section.

This aspect of SHSV is an assessment of the relation of major vascular endpoints to a limited number of compelling polymorphisms in candidate genes not guided by the linkage study. In particular, this work is designed to test hypotheses regarding intermediate phenotypes and pathways that are less well represented in the SHS (and, therefore, candidate genes that are difficult to exclude on the basis of the linkage studies) but are of potential importance to vascular disease. Most important in this are novel vascular risk factors, including the innate immune system, cell adhesion, endothelial dysfunction, inflammation, and insulin sensitivity. Investigation will be limited to polymorphisms showing some evidence of functionality. Given the fall in costs of genotyping, where convincing functional variants exist, this potentially allows testing of novel hypotheses and areas of biology more cheaply than additional phenotyping. Importantly, it also allows examination of key polymorphisms (and contribution to meta-analysis) of data from American Indians--a group generally underrepresented in other large studies. Finally, it will allow assessment of associations of these genes with markers of preclinical disease obtained from echocardiographic, carotid and popliteal ultrasound results. In the course of our adiponectin studies in Phase IV, baseline DNA samples have been genotyped for this marker. The typing of DNA from baseline samples has been highly successful (almost 100% of tested samples) using approximately 5 ng of DNA -- less than 0.01% of existing DNA resources for participants. The following is a justification for our choices:

1. Mannose binding lectin (MBL)
This serum protein opsonizes a variety of pathogenic microorganisms by binding mannose moieties on their surface and activating complement via the lectin pathway prior to antibody formation. Major decreases in opsonization detected in 5-7% of Caucasians and commonly among other populations result from markedly decreased levels of MBL related to variations of both structural and promoter portions of this gene. In both children and adults, an increased risk of certain infections has been associated with low levels of MBL or genotypes predictive of low levels. There are two previous reports of an association between MBL genotypes and measures of CVD; and one study failing to find a relationship between MBL levels and a peripheral vascular disease. A recent paper described the association of C. pneumoniae infection and CAD, but only in the presence of variant MBL genotypes.

We examined DNA from 434 participants in the SHS. Genotypes for three common MBL coding variations and one promoter polymorphism were determined. The frequency of a composite genotype conferring low MBL levels was 20.7% in 217 cases and 11.1% in matched controls. After adjustment for demographic and CAD risk factors, including type 2 diabetes mellitus, fibrinogen, triglycerides, and hypertension, the OR was 3.2 (95% CI 1.5-7.0, p = 0.004). The high prevalence of variant MBL alleles and their relation to CAD in this population suggests potentially important public health implications.

2. Interleukin 6 (IL6) -174 C to G
Interleukin 6 is a key stimulator of release of acute phase proteins, including fibrinogen and C-reactive protein. A -174 C to G polymorphism in the IL-6 promoter has been described. In vitro expression supports a functional role, with lower expression in the presence of the C allele. In non-disease states, the C allele is associated with lower concentration of IL-6 as well as lower glucose concentrations and relative insulin sensitivity and higher endothelium dependent vasodilatation. IL-6 -174 C to G also has been proposed as a candidate gene for vascular disease, and the C allele has been associated with reduced carotid intimal medial thickness and coronary heart disease in some but not all studies.

3. Thrombospondin 4 (A387P variant)
Thrombospondins are a family of extracellular matrix glycoproteins involved in cell adhesion. A large-scale screen of functional polymorphisms in the GeneQuest study highlighted the A387P variant as having the strongest association with vascular disease (Odds Ratio of myocardial infarction for P allele of 1.89). The A387P variant also appears to have functional consequences, affecting folding and secretion of the protein and also influencing adhesion of endothelial cells where the protein is expressed.

4. Lymphotoxin-α (G252A, A804C variants)
Variants in the lymphotoxin-α gene were found to have a significant association with myocardial infarction (OR 1.78) in a large Japanese case control study using genome-wide SNP analysis screening 92788 gene-based SNPs. The G252A variant lies in intron 1 and influences transcription of this key cytokine and in turn expression of a range of adhesion molecules and cytokines, while the A804C variant causes an amino acid change.

5. Toll-like receptor-4 (TLR-4)
Toll-like receptors, such as TLR-4, respond to microbial lipopolysaccharide by activating the NFκB signaling pathway, and induce a wide variety of cytokines and other inflammatory mediators. Many immunohistochemical, human cultured coronary artery cell, and model animal investigations have provided evidence for the influence of TLR-4 receptors on processes related to atherosclerosis. Genotypic variants of TLR-4 have been associated with CRP and WBC response to pulmonary LPS challenge in humans. Various lines of clinical evidence suggest a role for TLR-4 in the pathogenesis of CVD. The Asp299Gly polymorphism has been associated with incident CVD outcomes and IMT measurements. Additionally, the efficacy of pravastatin is modified by this same TLR-4 polymorphism.

6. Peroxisome Proliferator-Activated Receptorγ (PPARγ) Pro12Ala

PPARγ is an important candidate gene for insulin sensitivity and has previously been related to vascular disease. In addition to very rare loss of function mutations (PPARγ mutations, digenic mutations of PPARγ and PPP1R3), it is now clear that a common mutation (Pro12Ala) of PPARγ has both functional consequences in vitro and relates reliably to development of type 2 diabetes in large populations. Pro12Ala was calculated to contribute 25% of population-attributable risk of type 2 diabetes in a Scandinavian population with a protective effect of the rarer Alanine 12 allele. More recently, the Alanine 12 allele has been associated with protection against incident myocardial infarction (OR 0.71).

Methods for genotyping. Genotyping will be carried out at the Research Center for Genetic Medicine at Children’s National Medical Center (CNMC), in collaboration with Dr. Joe Devaney. The Research Center acts as a core facility for several large-scale studies and is well equipped for high-throughput genotyping. The CNMC facility contains the following equipment that will be useful in these studies: an ABI 7700 Sequence Detection System, two Transgenomic denaturing high performance liquid chromatography systems, six high-throughput sequencers (three ABI 16-capillary laser-induced fluorescence sequencing systems, an ABI 96-capillary laser-induced fluorescence sequencing system, and two Beckman CEQ 2000XL 8-capillary laser-induced fluorescence sequencing systems), an Hitachi Genespec II spectrophotometer, an Applied Biosystems Voyager matrix-assisted laser desorption ionization time of flight/time of flight mass spectrometer [MALDI TOF/TOF], and a Perseptive Biosystems cytoflour 96-well plate reader.

i. SNP Discovery by DHPLC. Genomic DNA is amplified using PCR with primers designed to each candidate gene promoter region. PCR will be performed in a final volume of 10 µl containing 50 ng genomic DNA, 10 pmol of each primer (Invitrogen, Carlsbad, CA), 250 µM of each dNTP (Invitrogen), 1 µl of GeneAmp 10x buffer II, 0.8 µl of 25 mM MgCl₂, and 0.5 units of AmpliTaQ Gold polymerase (Applied Biosystems, Foster City, CA). Thermal cycling is performed at 94°C for 12 min, 94°C for 0.5 min, 55°C for 0.5 min, and 72°C for 1 min for 35 cycles. The PCR reaction is performed in an MJ Research 96-well block Tetrad thermocycler (Waltham, MA).

PCR products then will be screened with DHPLC using liquid chromatography column temperatures selected based on sequence and base pair length of PCR product. The HPLC system used is the Wave DNA fragment analysis system (Transgenomic, Inc., San Jose, CA) with a DNASep column that has a stationary phase consisting of 2-µm nonporous alkylated (C₁₈)
poly (styrene-divinylbenzene) particles, a UV detector set at 260 nm, and an autosampler with the capacity to handle 192 samples (Transgenomic, Inc., San Jose, CA). The two eluents used for analysis on the HPLC system are A: 0.1 M triethylammoniumacetate (TEAA) and B: 0.1 M TEAA/25% acetonitrile.

PCR products from above (10 µl per sample) are eluted at a flow rate of 0.9 ml/min with a linear acetonitrile gradient. The elution gradient and melting temperature predictions were determined by WAVEMAKER software (Transgenomic). The separation gradient (% B per min) for analysis is adjusted to elute the amplicon between 1.0 and 2.5 min and is analyzed at multiple column temperatures to ensure heteroduplex detection. Optimal run temperatures are empirically determined on the basis of each fragment's characteristic melting profile. Data analysis is based on comparison with a normal control included in the analysis of each region. Heterozygote profiles are detected as distinct from homozygous wild-type elution profile.

Finally, amplicons that showed heteroduplexes, as compared with controls, will be sequenced to identify the base change. Prior to sequencing, enzymatic treatment is accomplished by mixing the PCR product (10 µl) with ExoSAP-IT (4 µl) incubating at 37 °C for 15 min followed by 80 °C for 15 min to inactivate the exonuclease and alkaline phosphatase enzymes prior to sequencing. Twenty ng of pure PCR product is sequenced in both directions using the identical primers used for the initial PCR with the BigDye™ Terminator 3.1 Kit (Applied Biosystems) according to the manufacturer’s instructions. After the sequencing reaction, the products are purifed using ethanol precipitation. Samples will be analyzed on an ABI PRISM® 3100 Genetic Analyzer (Applied Biosystems). Nucleotide changes will be identified by aligning sequence generated for comparison with corresponding Genbank sequence using SEQUENCHER 4.1.4 analysis software (Gene Codes, Ann Arbor, MI).


**iii. SNP Genotyping.** In allelic discrimination assays, the PCR assay includes a specific, fluorescent, dye-labeled probe for each allele. The probes contain different fluorescent reporter dyes (VIC and FAM) to differentiate the amplification of each allele. During PCR, each probe anneals specifically to complimentary sequences between the forward and reverse primer sites. AmpliTaq gold DNA polymerase cleaves probes that hybridize to the allele. Cleavage separates the reporter dye from the quencher dye, which results in increased fluorescence by the reporter dye. The signal generated by PCR amplification indicates the alleles that are present in the sample.

**1.5.6.3 Penn Medical Lab (PML) Sample Storage and Quality Control** The following describes receipt, storage, and quality control of samples received by PML.

An SOP for DNA and sample storage has been approved by the SHS Indian Communities. It is contained in the Volume 4 of this manual.
The SHS field centers notify PML at least one day in advance of shipments via the laboratory’s customer service e-mail account PennMedLab@medstar.net. Upon receipt of the specimens, the Specimen Processors at PML open the package and count the number of specimens. The SHS specimens are logged into the logbook and, based on the turn-around-time, the processing and assaying schedule is set. Samples for storage are treated upon arrival as "tests" (i.e., they are assigned lab sequence numbers and the "result" of the test is the site of storage by freezer, shelf, and box number). The computerized storage of this information allows timely inventory of stored material and quick retrieval when needed.

1. Storage Conditions
SHS samples are stored in gasketed Corning CryovialsTM at –80°C in Revco Freezers at MedStar Research Institute. The freezers are continually monitored for variations in temperature, and they also are connected to a robotic alarm system that telephones laboratory supervisors and technical personnel if a temperature deviation is sensed. Emergency backup power is supplied by a diesel generator tested according to JCAHO regulations.

2. Automated Inventory System
PML has recently re-inventoried all SHS samples in preparation for converting the existing inventory to a comprehensive database inventory system. The system upgrade, currently underway, enables researchers to learn about the specimens available for future research needs.

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

From this storage repository and inventory, we can easily access specific samples for analyses when needed. Although some case control studies have been done, ample amounts of samples remain, even for the key CVD endpoints.

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

4. Sample Retrieval, Processing, and Accounting
Upon receiving written authorization from the Sample Storage Committee to release specimens, PML generates a pull list from the inventory database. The Clinical Research Supervisor creates the pull list by querying the database on one or more database fields. A basic pull list will contain, but is not limited to, the following information: participant ID, lab sequence number, specimen type, volume, box number, freezer number, and freezer location.

The Clinical Research Supervisor compares the pull list to the authorization form, and depending upon the purpose for the samples, an epidemiologist or the Coordinating Center may be asked to review and verify the IDs on the list prior to PML staff retrieving the samples. The samples, as they are pulled from inventory by the Research Coordinators and/or Specimen Processors, are checked out of their designated permanent freezer location and their temporary location is logged via the “Sample Disposition” function so that there is an audit trail created for each specimen. Upon completion of the aliquot, the specimens are checked back into their designated permanent location in the inventory. During the check-in process, the database is updated with the new volume and a revised freeze/thaw count. Additionally, a batch database function enables the lab staff to quickly import a brief description of why the specimens were removed from inventory.

Every 6 months, the Coordinating Center and PML will reconcile datasets to ensure all laboratory results have been resulted and no discrepancies exist. Additionally, the two entities will reconcile storage rosters. The Coordinating Center will provide PML with a list of all SHSV participants who should have storage samples in the inventory. PML will compare the Coordinating Centers list to the inventory roster. All discrepancies will be researched, and unresolved issues will be properly documented and reported to the SHS Steering Committee.

Samples are released to investigators studying CVD, pulmonary disease, or their risk factors only by written authority of the SHS Steering committee according to guidelines approved by tribal councils and IRBs of participating institutions. Regulations concerning confidentiality, such as HIPAA, are strictly followed. In addition, because the samples in this study are ultimately the property of the participating Indian Communities, unused material is returned to PML so that community oversight can be maintained. PML maintains a computerized database of stored samples. The policies governing release of specimens are contained in Volume 1 of this manual.

5. Quality Control

i. Procedures
Penn Medical Laboratory and the SHS participate in extensive internal and external control programs to ensure stable, accurate, and precise measurements. Quantitative measurements are performed according to strict written guidelines conforming to those of the College of American Pathologists (CAP). Good Laboratory Practice rules are used throughout the laboratory. Instrumentation is maintained according to manufacturer’s standards, and performance is monitored according to CAP guidelines. Reagents are purchased from stable sources and purity is monitored according to CAP regulations. Assays are checked for linearity, sensitivity, parallelism, effects of freeze/thaw, recovery, and within-batch and between-batch coefficients of variation. All sample storage, short-term or long-term, is at -80°C to minimize degradation. Controls at several levels are run with every batch and plotted on Levy-Jennings plots. Whenever possible, lyophilized and frozen controls are used for long-term drift assessment.
PML technicians receive ongoing continuing education and rigorous periodic performance evaluations. Standard Westgard rules are applied to quantitative assays using at least two, and no more than three, quality control samples per run. Standard rules used for assay acceptance include Quality $2s$, $10s$, $1s$. Quality control rules are programmed into on-line software (BioRad DADE), and technicians are required to visually review Levy-Jennings plots to look for drift. All assay results are reviewed by a technical supervisor before final release into the data system.

Quality control pools are purchased from Bio-Rad. PML participates in all available CAP proficiency tests. In addition, PML takes part in CDC-NHLBI Lipid Standardization, CAP, and Northwest Lipid Research Laboratories (NWLRC) Standardization (ReLABS) programs to ensure external comparability and precision. When no formal proficiency tests are available, PML cross-exchanges samples with other reference labs not less than once each quarter. These laboratories include NWLRC (S. Marcovina) and the University of Vermont (R. Tracy). Additional internal controls include monthly linearity checks and 20-sample precision runs on all quantitative analytes. PML uses an internal blinded duplicate system, in which samples are introduced into the receiving area at least bi-monthly, and results are reviewed by the laboratory director. The entire laboratory staff participates in monthly quality control meetings, in which each analyte is reviewed and actions taken to address problems are critiqued. Laboratory errors and deviations from standard operating procedures are documented in quality assurance incident reports that undergo multiple levels of supervisory review. These reports are used to implement training or revise procedures to continually minimize variance and maximize adherence to standard procedures.

Data are downloaded electronically from the autoanalyzer and randomly audited for accuracy. Our data system has multiple levels of electronic redundancy, culminating in an off-site daily copy. Access to the LIS (Laboratory Information System) is double-password-secured, and SHS samples are only identifiable by their lab sequence number and numeric study ID. A clear trail of sample processing and handling is available to allow tracing of the pathway of any given sample through the laboratory. A random sample of 5% of all SHS data points is audited monthly. This audit examines sample processing, analytical procedures, and data consistency from bench-top to data output. The results of the audit are reviewed at the monthly lab meeting. All off-line data are entered into the laboratory information system by the bench technologist, who double-checks the entries before sending them to the Technical Supervisor. An additional 10% random quality check is performed by the Technical Supervisor before the results are verified and released. The data system is fully documented and maintained according to CAP regulations.

Emergency power sources maintain the system in case of blackout, and the network is backed-up every 24 hours. Weekly images of the database are kept off-site in fireproof safes. PML has been accepted by CAP as a specialty laboratory and was inspected in January 2006.

**ii. Field Training**

PML published a detailed lab manual for the field centers (see Volume 4 of this manual). Central training (group and individual) for the laboratory staffs and phlebotomists of the 3 centers was conducted at the training session in Oklahoma City (March 14-16, 2006) prior to the
start of exams. The training sessions emphasized uniform and optimal sample handling, as well as shipping procedures designed to ensure accountability and safe transfer of samples. Site technicians were trained or re-trained in the safe handling of biologic specimens, and considerable emphasis was placed on maintaining communication between the sites and the lab. To maximize uniform and optimal collection of samples across sites, the lab produced color, plastic laminated flip-charts. The flip-charts were designed to be used at the phlebotomy stations as quick reminders of SHS sample processing procedures. These were well received, and this methodology has been widely used by our colleagues in other studies.

The lab receives monthly reports of the variance from the Coordinating Center summarizing the data by site for the blinded duplicates for each analyte. These are reviewed by the lab director. If the data suggested a sample mix-up, the coordinator at that site is contacted and the local procedures are reviewed and corrected as necessary. The lab provides visits by the PML Laboratory supervisor, if necessary, to train new personnel.

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). 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, pedometers also have their own set of limitations, such as the inability of capturing cycling, swimming and upper body movement. The Accusplit pedometer will be given to each participant at the time of the clinic visit to wear at home for seven consecutive days. The Accusplit pedometer is a pocket-sized pedometer that displays the number of steps taken. Verbal and written instructions for the monitors will be presented to the participant with a record sheet that needs to be completed on the seven days that the monitor is worn (see form in Appendix C of this volume). The participants will keep the pedometers and will be encouraged to use them to monitor and increase their physical activity levels in their normal daily lives.

Central training on pedometry for the personnel of the 3 field centers was provided by Ms. Kristi Storti and Dr. Andrea Kriska during the training session in Oklahoma City (March 14-16, 2006) prior to the start of exams.
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 shorts or large scrub pants (to enable the pant legs to be rolled up) for the ECG and popliteal artery examinations. Shoes and socks are removed for the supine examination and weight and height measurements. The form to be used is given in Appendix C.

1.6.1 Anthropometry

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

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 measurement. 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 footstool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method described above. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and the 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 acromion and olecranon (Figure 3). Record the measurement to the nearest centimeter using the rounding method described above. This measurement is used to select the proper size blood pressure cuff.

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

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 anthropology. The training program for taking body size measurements consists of the following components.

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

2. Each field center trains one or two individuals before the start of the examinations. One individual from each center is designated the center's anthropology supervisor.

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

4. Training includes:

   a. Introduction - rationale for body size measurements, overview of technique, expected limits of reproducibility, and pitfalls related to anthropology.

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

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

   e. Certification - technicians must measure one or more test subjects and be within the standards of error:

      1) The waist and hip measurements must agree within 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 staff member receives certification for field work. Trainees who have problems are identified, and they are allowed to practice and try again to be certified.

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. Earpieces 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 SHS participants are asked to avoid caffeine (tea, coffee, chocolate, and soft drinks), eating, heavy physical activity, smoking and alcohol intake for twelve hours and to refrain from smoking for at least one-half hour prior to the clinic visit. Current drug intake, including medications affecting blood pressure and 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 a full explanation and instructions about the preparation for the blood pressure examination and an opportunity for questions. The setting in which blood pressure measurements are made is standardized.

6. Measurement Procedures

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

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

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

c) Palpate the brachial artery (just medial to and above the ante-cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five-minute wait.

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

e) Connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no longer felt. Deflate and record the pulse obliteration pressure. Have the participant raise measurement arm for 5 seconds and the wait another 25 seconds with the participant’s arm on the table.
f) Measurement 1: Connect the cuff to the manometer. Inflate rapidly to the pulse obliteration level + 30 mm. Holding the pressure constant with the bulb, wait 5 seconds. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. If the sounds do not cease completely, the fourth Korotkoff sound will be used. If the mercury column falls in between two scale marks at the time the first or fifth Korotkoff sound is heard, the higher number should be used.

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

Average blood pressure readings are calculated using 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
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(a).

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

i) the zero level
ii) air leakages
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-Brachial Index (ABI) Measurement

1. Move the participant to the supine position.

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

2. Procedure for Measuring Brachial (arm) Blood Pressure

   a) 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 blood
pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual.

b) The observer then uses the Doppler to record the brachial pressure. The pressure recorded in the arm is used to calculate the ankle-brachial systolic pressure ratio for both lower extremities (see below).

3. Procedure for Measuring Ankle Blood Pressure

a) 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.

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

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

d) 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.

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

f) Repeat this procedure to record the left ankle blood pressure.

If it appears impossible to obliterate the sounds, pump the cuff (with no break in pumping) to 250 mmHg to confirm lack of obliteration and then record 999 on the physical examination form.

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

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-1200 based system will be used (see Volume VI of this manual).

   b) All ECGs will be transmitted centrally to the New York Hospital - Cornell Medical Center in New York electronically by modem.
c) All ECGs will be read in a standard manner at the ECG Reading Center by Board Certified or Board Eligible Staff Cardiologists and transmitted or mailed back to the site of origin for clinical correlation or other action, if required. In any case, all ECGs will be overread and promptly returned.

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

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

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

2. Minimal Equipment Requirements

a) A Mac-1200 with modem (see Volume VI of this manual) 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 this 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 the 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 (pins in bones will not affect the results). Jewelry should be removed from the side on which the electrodes are placed.

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, depress the button for “resistance” and record the resistance value on the physical examination form (S6). Then depress the button for “reactance” and record the reactance value on the S6 form. See Appendix C below.

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.

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.
1.7 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 and their BMI calculation, as well as any significant physical findings that may have been noted. The importance of any abnormal findings from the exam and recommendations for referral will be communicated to the participant at this time. For referrals in the emergent, immediate or urgent categories, the participant will be assisted in arranging transportation and appointments. Whenever possible, findings and measurements indicating referral will also be communicated directly to the participant’s provider or clinic of choice (see Appendix A – 7b for a sample letter to be sent when an emergent, immediate, or urgent referral is needed but repeated efforts to contact the participant have failed). For routine referrals, the reason for the referral and information necessitating referral will be given to the participant and a referral letter will be sent to the provider of their choice.

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(c) and A – 8 below)

c) When the carotid and popliteal 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(c) 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 may 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 and 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, and BMI calculation, 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 and popliteal 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**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Statement to Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP ≥ 200 mmHg</td>
<td>Your BP is very high</td>
</tr>
<tr>
<td>DBP ≥ 120 mmHg</td>
<td>Your BP is very high</td>
</tr>
<tr>
<td>Sure Step Hospital Meter (SSHM) glucose &lt;50</td>
<td>Your blood sugar is very low.</td>
</tr>
<tr>
<td>Any finding or symptom suggestive of a life-threatening illness, including evidence of acute MI, unstable angina, or pulmonary edema</td>
<td>Describe rationale for referral to participant</td>
</tr>
</tbody>
</table>

**Immediate Referral**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Statement to Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHHM fasting glucose &gt; 400</td>
<td>Your blood sugar is very high</td>
</tr>
<tr>
<td>SBP 180-199 mmHg</td>
<td>Your BP is very high</td>
</tr>
<tr>
<td>DBP 110-119 mmHg</td>
<td>Your BP is very high</td>
</tr>
<tr>
<td>Diabetic foot ulcer</td>
<td>Your foot must be seen by a physician</td>
</tr>
<tr>
<td>Angina in last day</td>
<td>Your chest pains may be important</td>
</tr>
<tr>
<td>Neurologic symptoms in past week</td>
<td>Your symptoms may be important</td>
</tr>
<tr>
<td>Other severe symptoms or findings</td>
<td>Your symptoms may be important</td>
</tr>
<tr>
<td>Untreated asthma or worsening asthma</td>
<td>You may have a serious problem in your lungs</td>
</tr>
<tr>
<td>Carotid ultrasound findings indicate possible &gt;75% obstruction</td>
<td>You may have a serious problem in your neck vessel(s)</td>
</tr>
</tbody>
</table>
Popliteal ultrasound findings indicate possible >75% obstruction or deep vein thrombosis

You may have a serious problem in your leg vessel(s)

Cardiac Echocardiogram indicating significant pericardial effusion or an intracardiac mass

You may have a serious problem with your heart.

**Urgent Referral**

SBP 160-179 mmHg

Your BP is not in proper control. Recommend that participant confirm blood pressure reading within 1 week

DBP 100-109 mmHg

Your BP is not in proper control. Recommend that participant confirm blood pressure reading within 1 week

Angina over 24 hours ago

Your chest pains may be important

Neurologic symptoms, untreated, one week to six months ago

Your symptoms may be important

Suspected congestive heart failure

Your symptoms may be important

Other acute, but less severe symptoms

Your symptoms may be important

Inappropriate medication usage

Taking medication incorrectly may be dangerous

Non-diabetic with a fasting SHHM glucose of ≥ 200
Diabetic with fasting SHHM glucose >300

Your blood sugar is high

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

You may have a serious problem in your lungs

Carotid ultrasound findings indicate possible 50-75% obstruction

You may have serious problem in your neck vessel(s)

Popliteal ultrasound findings indicate

You may have serious problem in your
possible 50-75% obstruction leg vessel(s)

<table>
<thead>
<tr>
<th>Routine Referral</th>
<th>Statement to Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SBP 140-159 mmHg</strong></td>
<td>Your BP is not in proper control. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
<tr>
<td><strong>DBP 90-100 mmHg</strong></td>
<td>Your BP is not in proper control. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
<tr>
<td><strong>SBP 130-139 mmHg</strong></td>
<td>Diabetic: Your BP is not in proper control for someone with diabetes. Recommend that participant confirm blood pressure reading within 1 month Non-Diabetic: Your BP is in a range that puts you at risk for high blood pressure. There may be some things that you need to do to bring it into a better range. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
<tr>
<td><strong>DBP 80-89 mmHg</strong></td>
<td>Diabetic: Your BP is not in proper control for someone with diabetes. Recommend that participant confirm blood pressure reading within 1 month Non-Diabetic: Your BP is in a range that puts you at risk for high blood pressure. There may be some things that you need to do to bring it into a better range. Recommend that participant confirm blood pressure reading within 1 month</td>
</tr>
</tbody>
</table>

Non-diabetic with a fasting SHHM glucose of > 130
Diabetic with fasting SHHM glucose >150

Old MI (Rose Questionnaire), previously unrecognized

Your blood sugar is high
Your blood sugar is high
Your chest pain may be important
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 symptoms may be important

Your leg pain may be important

You may have a problem in 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 sample letters in Appendix A – 7 and interpretations in Appendix A – 8).

3) Carotid and Popliteal Ultrasound -- The Cornell Reading Center will call the field center if > 50% obstruction is noted in the carotid or popliteal artery. If the obstruction is ≥ 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>≤ 60 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>Immediate</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 PHOS</td>
<td>≥ 400 IU/L</td>
<td>Urgent</td>
</tr>
<tr>
<td>BUN</td>
<td>≥ 40 mg/dl</td>
<td>Immediate**</td>
</tr>
<tr>
<td>Cl</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Uric Acid</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Mg</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>AST (SGOT)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>ALT (SGPT)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Total Protein</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Albumin</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td>≤ 0.4 or ≥ 4.0 microunits/ml</td>
<td>Urgent</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: Since these involve lab values determined at MedStar labs and thus a minimum of 24 hours old, due to shipping and other considerations, immediate referral (within 24 hours) seems appropriate, even though some extreme values represent very serious conditions.

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

**ECG REFERRAL:**

a) **ECG findings requiring review by a physician before participant leaves SHS clinic or before SHS staff leave participant’s home 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: 605-348-6100
If unable to obtain consultation from above sources, initiate emergency referral for the following:

- 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
- QT prolongation

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

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 refuses to accept such data until the errors are corrected. The field centers will double-enter 10% of the forms each month (or at least one double entry per transmission). 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% for any transmission, that center will be asked to re-enter (as second entry) the data of all the forms in that transmission. 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 quarterly. Duplicate measures of anthropometry (height, weight, waist, and electrical impedance measurements) will be performed by a second observer on a quarterly basis. These data will be sent to the Coordinating Center for analysis. Results of the analysis will be provided to the field centers and the Steering Committee. Differences between duplicate measures exceeding the following values will be considered unacceptable:

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

In addition, distributions of measurements and digit preference for each staff member will be compiled and repeated quarterly.

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 quarterly by the Coordinating Center for accuracy and consistency. The percent of pairs with differences within 5% and 10% will be computed. Correlation coefficients and technical error rates will be calculated. Poor correlation or unreasonably high technical error will be reported to the Laboratory and the Steering Committee.

3) Personal interview

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

4) Food Frequency Questionnaire (FFQ)

The Block FFQ is self-administered; participants receive guidance from SHS staff in how to fill out the questionnaire. The developer, Block Dietary Data Systems (BDDS), has provided documentation (see Volume 9 of this manual) that describes each question. During the March 2006 training sessions in OK, Jean Norris, MS, RD, DrPH (BDDS) provided training for the field staffs in how to instruct participants and how to check the FFQs for completeness, for
proper pencil entries on the FFQ bubble forms, and for correction of the bubble forms if improperly filled in (e.g., pen instead of pencil). Trained staff members will assist any participants having difficulty with the FFQ.

5) Certification of technicians

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

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 was generated, and the Coordinating Center will monitor the progress of each field center according to these projected numbers and provide monthly progress reports to the Steering Committee. If the percentage of projected recruitment in a certain field center falls below 80%, the PI and the field coordinator will be informed, so that the efforts can be focused on recruitment. This program proved to be an efficient tool for monitoring the progress of SHS- in previous phases and will be continued in Phase V 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 quarterly.

e. 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 optical diskettes. Two of the Zip disks/optical diskettes are stored in two different locations other than the Coordinating Center office.
APPENDIX A
APPENDIX A -- 1

Consent Forms for
the Arizona Field Center,
the North/South Dakota Field Center,
and
the Oklahoma Field Center
MedStar Research Institute Informed Consent for Clinical Research

INTRODUCTION
We invite you to continue to take part in a research study called the Strong Heart Study (SHS). You were asked to take part in the fifth phase of the SHS, because you joined during an earlier phase of SHS. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s). If you have trouble reading this form, one of the staff will read it to you.

WHAT IS THE PURPOSE OF THIS STUDY?
This purpose of this study is to learn how heart disease and its risk factors change over time. We also want 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 comparing the results of this exam to your previous one and by continuing to test the genetic material (DNA) in the blood sample you gave previously for genes that may cause or protect against cardiovascular, or lung diseases or their risk factors.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?
It is important that you read and understand several points that apply to all who take part in our studies:
• Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
• You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
  • You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?
The investigator is Barbara V. Howard, PhD. The research is being sponsored by The National Heart Lung and Blood Institutes (NHLBI). MedStar Research Institute is being paid by NHLBI to conduct this study with Dr. Howard as the primary investigator.

WHO CANNOT PARTICIPATE IN THIS STUDY?
You cannot be in this study if you did not join an earlier phase of SHS.

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?
Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study(ies)_______________________________________

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 8200 people will take part in this study, at three sites, 1251 people will be recruited at this site.

**WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?**

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 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 from your arm to find the level of sugar, cholesterol and other fatty substances. Some of the 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 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 to develop products that will be sold. You will retain the right to have the sample material destroyed at any time by contacting the Principal Investigator.

2. **Electrocardiogram (ECG).** An ECG is a test of the electrical activity of your heart.; 12 monitoring tabs will be placed on your 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, Carotid and Popliteal Ultrasound Study.** These are “pictures” of your heart and of the arteries in your neck and legs 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 composition.** A machine will check how much muscle, fat, and water you 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.

6. **Physical Examination.** Blood pressures in your arms and legs, pulses in your ankles and feet, your height, weight, waist and arm size will be measured.

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

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.
You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study, we may not be able to use any of the information gathered from your participation.

**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 about these conditions. The parts of your exam that are medically useful will be sent to you, when they are available. You will also be sent Strong Heart Study newsletters now and then, 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.

**WHAT ARE THE RISKS AND SIDE EFFECTS 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 may feel some pressure in your 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 the results of the tests done during the exam and the results of the blood tests in your Indian Health Service record so that our clinic can use them, but we wont do that if you don’t want this done. Results from genetic tests will not be placed in your medical record.

Please tell the investigator about all medications including over the counter drugs or herbal supplement you are taking, even if you don’t think they are important.

**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 personally.

In Phase V 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 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 on cardiovascular and/or lung disease may be done after Phase V is over. 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.

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

There are not expected to be any immediate benefits to you for taking part in this study. We expect the findings to be helpful to people in the future. If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical check-ups. You should go to your regular clinic for physical exams, and treatment of any health problems.

**WHAT OTHER OPTIONS ARE THERE?**

You always have the option to not be in this study.

**WHAT ABOUT CONFIDENTIALITY?**

Efforts will be made to protect your personal information to the extent allowed by law. Medical records of research study participants are securely stored and maintained according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request, inspect, and/or copy your research and medical records for quality assurance and data analysis include groups such as the NHLBI which oversees this project, Indian Health Service Institutional Review Board, and the MedStar Research Institute Institutional Review Board (IRB).

Only these institutions 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 who run the tests will not connect your name with your sample. The results of the exam and any information in your medical record 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.

An Observational Data Safety and Monitoring Board, which is a group of experts not connected to the study, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

This exam will not cost you anything. You 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 you time helping this study.

**WHAT ARE THE COSTS?**

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for the tests and procedures that are part of this research study.
WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

It is very unlikely that you will be injured or harmed 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.

NHLBI, the sponsor of this study, does not intend to provide reimbursement for costs of medical treatment for injury or illness if such costs are not covered by the Indian Health Service, the Gila River Health Care Corporation or by your medical insurance. No funds have been set aside, by the NHLBI, the MedStar Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of the exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Dr. Barbara V. Howard (301) 560-7302 or the Project Coordinator, Marie Russell, MD. Address: Strong Heart Study – Arizona Center, 1616 E. Indian School Rd. #250, Phoenix, AZ 85016 Phone: 602-277-0488.

If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

You may contact Kenneth Simpson, DBA, RN, Chair of the Phoenix Area INDIAN HEALTH SERVICE Institutional Review Board, Phoenix Area Indian Health Service, Two Renaissance Square, 40 N. Central Avenue, Phoenix, AZ 85004. Telephone: (602) 364-5045, about your rights as a research participant.

For questions about your rights as a research participant, you may also contact the MedStar Research Institute. Direct your questions to the Office of Regulatory Integrity at:

Address: MedStar Research Institute
6495 New Hampshire Avenue
Suite 201
Hyattsville, MD 20783

Telephone: (301) 560-7339
Toll Free: (800) 793-7175
Fax: (301) 560-7336
SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual’s satisfaction.

Signature of Person Obtaining Consent

Date of Signature

I, the undersigned have been informed about this study’s purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Barbara V. Howard, PhD and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant’s Signature

Date of Signature

Signature of Witness

Date of Signature
INFORMATION AND CONSENT FORM

STUDY TITLE: Cardiovascular Disease in Sioux Indians. The Strong Heart Study – Phase V

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

GRANT RECIPIENT: Missouri Breaks Industries Research, Inc.

INTRODUCTION: We invite you to take part in the Strong Heart Study (SHS), 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 might, or might not be personally helped by joining this study, but knowledge will be gained that may help others; 3) you may withdraw from the study at any time without losing any benefits which you usually have. The kind of study, the benefits, risks, discomforts and other information are found below. If you 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 heart/blood vessel diseases, risk factors for these conditions and how they change over time. We will also continue to study 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 were asked to take part in the fifth phase of the Strong Heart Study, because you agreed to be part of the fourth phase of SHS. About 3600 people from the Dakotas, Oklahoma and Arizona will take part in Phase V of SHS.

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 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 8 tablespoons from your 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. and Southwest Foundation of Biomedical Research in San Antonio, Texas 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 or 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 arms, legs and chest and connected to an ECG machine. Heart specialists at Cornell University in New York will read this ECG test.

3. **Heart, neck and leg artery ultrasound study.** These are “pictures” of your heart and of the arteries in your neck and legs 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 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.

5. **Physical Examination.** Blood pressures in your arms and legs, your height, weight, waist and arm size will be measured. Measurements of your height, weight and waist will be made. The pulses and condition of the skin on your legs will be checked. 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.

6. **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, and stress. Also questions about who your family members are, how they are related to you, their health, and well being will be asked. You will also be asked to carry a pedometer around with you for a few days. This is a small machine, about the size of a watch, which can count the number of steps that you take each day.

**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 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.

2. **BENEFITS**
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.

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. Someday genes may help determine who is at extra risk for 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 V we will be looking for the location of genes that might cause cardiovascular and lung diseases; and beginning to test particular genes to see if they have changes that seem to be important for predicting cardiovascular disease. What we find will usually need 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 V is over in 2011. 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 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. 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. 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 will be injured by joining in this research, but if that should happen 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 anything. You will be paid $25 for answering the questions and having blood drawn, and $20 when you 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 time helping this study. You 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 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 605.964.3418.

8. **RESEARCH PARTICIPANTS’ RIGHTS**
   You may contact Dr. Elaine Miller (605.226.7341) or Dr. Dewey Ertz (605.341.8647) co-chairs of the Aberdeen Area IHS Institutional Review Board, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Ave SE, Aberdeen, SD 57401, Toll Free# 866.331.5794, about your rights as a research participant.

9. **STOPPING THE STUDY**
   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. However, we hope you will finish as many of the tests as possible. 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.

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 about these conditions. The results of your exam that we think are medically useful will be sent you, when they are available. You will also be sent Strong Heart Study newsletters now and then, 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.

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 and the current Phase V) including keeping the research records. Signing this consent form will let Missouri Breaks Research Inc. staff, with professional supervision of the principal investigator, look at the information collected in earlier phases of the study.

12. CONSENT TO PARTICIPATE
I have read, or had read to me, this Information and Consent Form, and I have been able to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risks and benefits that I learned about in this Information and Consent Form, I want to join in this research. 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 V 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:

__________________________________
__________________________________
__________________________________
__________________________________

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 health, please use this address (I will let you know if I have a change of address):

__________________________________
__________________________________
__________________________________
__________________________________

PRINTED NAME OF PARTICIPANT  ____________________  DATE

Strong Heart Study V  07/01/06  III A-12  Appendix A -- 1
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
This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

**Why Have I Been Asked To Participate In This Study?**
You are being asked to take part in this study because you participated previously in the family study part of the Strong Heart Study (SHS) (pilot family study portion of SHS Phase III and/or in SHS Phase IV).

**Why Is This Study Being Done?**
This research is being done to learn how heart disease and its risk factors change over time. We also want 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 comparing the results of this exam to your previous one and by continuing to test the genetic material (DNA) in the blood sample you gave previously 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 3800 people will take part in this study nationwide. About 1300 of these individuals will participate at this location.

**What Is Involved In The Study?**
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.

**PROCEDURES:**

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. Your blood will be stored by SHS until Phase V ends in 2010; then all Study samples will be returned to the tribes or given to the National
Heart, Lung, and Blood Institute (the Study sponsor) depending on the wishes of the tribes at that time. Your blood cells will not be cloned or kept growing, and your blood will not be used to develop commercial products. You will retain the right to have the sample material destroyed at any time by contacting the Principal Investigator.

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, Carotid, and Popliteal Ultrasound Study.** These are "pictures" of your heart and of the arteries in your neck and legs 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 have by passing a very tiny electrical current through your body.

7. **Physical Examination.** Blood pressures in your arms and legs, pulses in your ankles and feet, your height, weight, waist and arm size will be measured.

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 your family’s health and well being will be asked.

**FOLLOW-UP:** You will be told immediately, 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. After your exam, SHS researchers will contact you as soon as medically useful results become available (e.g., results of your blood tests and your cardiovascular tests such as the ECG) in order to tell you about these results and any implications for your health care needs. You may obtain a copy of any of your other results by asking the Study staff or phoning the Principal Investigator at 405-271-3090. You will also be sent Strong Heart Study newsletters now and then to tell you about results of the study. We will contact you annually (until the Study ends in 2010) to ask you about the current state of your health. This contact will likely be by phone, letter, or home visit and will be brief (about 10 minutes or less) in order to find out if you have had any sort of cardiovascular test (e.g., a treadmill test) or a cardiovascular episode (e.g., a heart attack or stroke).

**OTHER INFORMATION:** This 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. 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
V is over. The DNA studies will be done at the Southwest Foundation for Biomedical Research, San Antonio, TX 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 will be in the Study for an additional 5 years (until the end of the Study in 2010). 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, may give you a bruise, cause you to feel faint, and has a slight risk of infection. You may have some discomfort in your arms and/or legs, when blood pressure is taken. The machine that measures body fat passes a tiny current through your body, but it is too small to feel, and there is no known risk for this test. 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?
There are not expected to be any immediate benefits to you for taking part in this study. We expect the findings to be helpful to people in the future. If we find a medical problem, you will be asked to check with your clinic or doctor for the tests and treatment they feel you need. The Strong Heart Study can help you make appointments, but will not pay for tests or treatment. You will be told how to cut down your chances of cardiovascular and lung diseases. This study should not take the place of regular medical 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 will be 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. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

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

**Will I Be Paid For Participating in This Study?**
You will be given a $25 Wal-Mart gift card for answering the questions and having blood drawn, and another $25 Wal-Mart gift card 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 Are My Rights As a Participant?**
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Leaving the study will not result in any penalty or loss of benefits that you would otherwise receive. We will tell you about any new information that may affect your health, welfare or willingness to stay in this study.

You understand that you have the right to access the medical information that has been collected about you as a part of this research study. However, you agree that you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

**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 participant, contact the OUHSC Director, Human Research Participant Protection Program at 405-271-2045 or the 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 agree to participate in the Strong Heart Study-Phase V 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.
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):

__________________________________
__________________________________
__________________________________
__________________________________

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 Participant: _________________________ Date: ________________

Subject's Printed Name ________________________________

Person Obtaining Informed Consent: __________________ Date: ________________

IRB Office Version Date: 08/11/05
## THE STRONG HEART STUDY V
### Clinical Examination – Checklist

Participant’s name: ________________________________

<table>
<thead>
<tr>
<th>ID Number: __________________</th>
<th>Date: __________________</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Items</th>
<th>If done, date and initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Consent Form Signed</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>2. HIPAA Form Signed</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>3. Personal interview forms</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>4. Medical history form</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>5. Reproduction and hormone use (women)</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>6. Rose questionnaire</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>7. Physical examination</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>8. Sample collection checklist</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>9. CBC Results (when results returned from local lab)</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>10. Quality of Life form</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>11. CES-D Scale form</td>
<td>_________________   ___</td>
</tr>
<tr>
<td>12. Social Support form</td>
<td>_________________   ___</td>
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<tr>
<td>13. Other Questions About Your Life form</td>
<td>_________________   ___</td>
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<tr>
<td>14. Psychosocial questionnaires checklist</td>
<td>_________________   ___</td>
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<tr>
<td>15. Seven-Day Pedometer Record form</td>
<td>_________________   ___</td>
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<tr>
<td>16. Medication checklist</td>
<td>_________________   ___</td>
</tr>
<tr>
<td></td>
<td>Procedure</td>
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<tr>
<td>17</td>
<td>ECG</td>
</tr>
<tr>
<td>18</td>
<td>Impedance measurement</td>
</tr>
<tr>
<td>19</td>
<td>Height and weight</td>
</tr>
<tr>
<td>20</td>
<td>Abdominal, hip, and arm circumference</td>
</tr>
<tr>
<td>21</td>
<td>Sitting blood pressure</td>
</tr>
<tr>
<td>22</td>
<td>Doppler blood pressure</td>
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<tr>
<td>23</td>
<td>Physical examination QC (if appropriate)</td>
</tr>
<tr>
<td>24</td>
<td>Food Frequency Questionnaire</td>
</tr>
<tr>
<td>25</td>
<td>Carotid ultrasound</td>
</tr>
<tr>
<td>26</td>
<td>Popliteal ultrasound</td>
</tr>
<tr>
<td>27</td>
<td>Echocardiogram</td>
</tr>
<tr>
<td>28</td>
<td>Payment or payment form</td>
</tr>
</tbody>
</table>
Appendix A – 2(b)

THE STRONG HEART STUDY V
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 carotid and popliteal ultrasound and echocardiography measurements

Later:

Send ultrasound tapes to reading center
Make routine referrals
File confirmed ECG and ultrasound/echo reports
Mail letters to participants
File laboratory findings in participant’s medical records (if so indicated on consent form)
Mail laboratory specimens
THE STRONG HEART STUDY V
Checklist for Blood Pressure

Technician Code # / Initials _______________________

Observer Code # / Initials _______________________

Date Observed ________ / _______ / _______ (Month/Day/Year)

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

Comments: ____________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________
Appendix A – 4
THE STRONG HEART STUDY V
Simultaneous Blood Pressure Observation Form

Quarterly, each technician should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to this form and should calculate the differences between the two sets of measurements. The acceptable margin of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.

<table>
<thead>
<tr>
<th>Technician #1 Code # / Initials</th>
<th>Technician #2 Code # / Initials</th>
<th>Observer Code # / Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tech #1</td>
<td>Tech #2</td>
<td>Difference</td>
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<tr>
<td>Arm circumference</td>
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<tr>
<td>Cuff size</td>
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<tr>
<td>Pulse obliteration pressure</td>
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<tr>
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<tr>
<td>DBP #3</td>
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<tr>
<td>Average SBP</td>
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<tr>
<td>Average DBP</td>
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</table>

Comments: ________________________________________________________________

Strong Heart Study V 07/01/06 III A-23 Appendix A – 4
# Appendix A – 5(a)
## THE STRONG HEART STUDY V
### Quality Control

**SPHYGMOMANOMETERS**

<table>
<thead>
<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)
## THE STRONG HEART STUDY V
### Quality Control

**SCALE & MEASUREMENT TAPES**

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<th>MONTH</th>
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<th>CALIBRATED WEIGHTS</th>
<th>MEASURING TAPE, to 30 cm METAL TAPE</th>
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</table>
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. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted. If the reading is either above or below the zero mark, the system should be returned to the manufacturer or replaced.

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

3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the system should be returned to the manufacturer or replaced.

4. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Check with the manufacturer to determine where the system should be sent for maintenance.

5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry. All clinics should have a mercury spill kit available, and staff should be trained in how to use the kit.
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 V
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 130/80 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 130/80). This is in a range that may be high enough to cause complications if you are a diabetic, or may indicate that you need to do some things that will reduce your chances of developing high blood pressure. You should make an appointment for follow-up with your medical care provider, since this level may cause trouble in the future.

Your blood pressure was _____ (equal to or 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 usually considered acceptable; but especially if you are diabetic and your blood pressure is equal to or greater than 130/80 you may wish to discuss this with your doctor at your next visit. 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 100 mg/dl). This is within the desirable range.

Your fasting blood sugar was _____ (equal to or more than 100 but less than 126). This is within a range that doctors now diagnose as “pre-diabetes”. There are good studies now proving that people with blood sugars at this level can prevent the development of diabetes by increasing their daily exercise and decreasing their weight (if overweight). We suggest that you contact your medical provider in the coming month to have this result checked and get further advice.

Your fasting blood sugar was _____ (known diabetic, less than 150). On the day of the exam, your fasting blood sugar was probably under adequate control. Be sure to follow the advice of your medical care provider for control of your diabetes.

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

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

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

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

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

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

**Smoking**

One of the areas that we have asked some questions about today is smoking. While occasionally smoking tobacco as a religious practice probably causes no harm; smoking cigarettes or using other tobacco as a daily habit carries many health risks. Most people think of the risk of lung and other cancers, which is very important; but actually the risk of death and
illness from heart disease is a much greater risk from smoking. If you currently smoke, 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 and leg 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)

TO BE USED FOR EMERGENT, IMMEDIATE, AND URGENT REFERRALS

THE STRONG HEART STUDY V

Sample Letter

Date: ______________

Dear Clinic staff and Strong Heart Study participant ______________________________ (name),

Normally we would have contacted you in person about this problem; but we were just not able to reach you, and so have needed to send this in the mail. If we had been able to talk with you in person, there would have been other details we would have told you about; we hope you will bring this with you to your clinic so they will be able to help you better.

If you would like help making an appointment with your clinic, please contact us at the SHS office in [Eagle Butte at 605-964-1260, or Pine Ridge at 605-455-1395]. If this problem involves an EKG or ultrasound test we can get copies of the actual pictures for your clinic to use or send to their consultants, if they wish.

We are suggesting that you contact your regular medical care provider because of the following abnormalities that we have found during your testing:

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

We think it is best for you to talk with your doctor or clinic about this problem: right now or within the next: 24 hours week.

Thank you again for participating in the Strong Heart Study, and we hope that this information has helped you and your doctors improve your health.

Sincerely,

[LYLE BEST, MD
701-246-3884
MARCIA O’LEARY, RN
605-865-3327]
NOTE: THIS LETTER IS TO BE USED ONLY FOR NORMAL RESULTS OR ROUTINE REFERRALS FOLLOWING THE RETURN OF LAB, ECG OR ULTRASOUND RESULTS.

EMERGENT, IMMEDIATE AND URGENT REFERRALS SHOULD FOLLOW THE GUIDELINES IN SECTION 1.8.

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

Dear Strong Heart Study participant:

Attached are results of your blood tests, or carotid/popliteal 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. It would be a good idea to talk about any abnormal results with your doctor within the next month or at your next visit. Bringing this letter to the clinic will help them answer your questions.

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

XXXXXXXXXXXXXX OR XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX substituting the following for the first paragraph above:
“Honoring your request as stated in your consent form, the attached lab results were not sent to the IHS or any other medical facility or healthcare provider. It may be in your best interest for you to show your healthcare provider these results during your next visit.”
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 100 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. For people who have had a heart attack (or are diabetic), it is especially important to get their LDL level well 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, and 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 V
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 150 mg/dl. Triglyceride levels tend to 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 100 mg/dl. Levels of 130-159 mg/dl are moderate risk. Levels 160 mg/dl or higher are high risk. For people who have had a heart attack (or are diabetic), it is especially important to get their levels well below 100 mg/dl, so that further clogging of arteries is prevented.

Calcium (Ca)
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 (PO$_4$)
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. A level of 100-125 mg/dl indicates that you probably have “pre-diabetes” and should discuss with your medical provider ways of preventing or delaying the development of diabetes.

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

<table>
<thead>
<tr>
<th>Test</th>
<th>High Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK Phos</td>
<td>above 100 U/L</td>
</tr>
<tr>
<td>AST (SGOT)</td>
<td>above 42 U/L</td>
</tr>
<tr>
<td>ALT (SGPT)</td>
<td>above 42 U/L</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Electrolyte</th>
<th>Low Values</th>
<th>High Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (Na)</td>
<td>below 135 meq/dl</td>
<td>above 147 meq/L</td>
</tr>
<tr>
<td>Potassium (K)</td>
<td>below 3.3 meq/L</td>
<td>above 5.5 meq/L</td>
</tr>
<tr>
<td>Chloride (Cl)</td>
<td>below 95 meq/L</td>
<td>above 110 meq/L</td>
</tr>
<tr>
<td>CO₂</td>
<td>below 22 meq/L</td>
<td>above 29 meq/L</td>
</tr>
</tbody>
</table>

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.
Hemoglobin A1C  This shows what level your blood sugar has been at for the past 6 weeks or so. It is not as changeable as your blood sugar, and it is handier for your doctor and you to use to figure out how well your diabetes is controlled. The normal range is between 4.4 and 6.4%, and people with diabetes should try to get their level as close to normal as possible.

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/POPLITEAL ULTRASOUND RESULTS

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. The carotid arteries supply circulation to the brain. Sometimes clots that form in these neck blood vessels can travel up into the head to cause stroke. Usually surgery is NOT recommended for people with your level of narrowing of the neck arteries, 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.
Narrowing more than 50% This can cause slowing of the circulation to your brain and sometimes strokes. Occasionally surgery is needed to improve this situation. We strongly suggest that you see your medical provider sometime soon, preferably in the coming week.

Narrowing more than 75% This can cause a serious slowing of the circulation to your brain and sometimes strokes. Not always, but sometimes surgery is needed to improve this situation. We strongly suggest that you see your medical provider in the next 24 hours.

Only your Doctor can make the determination of what you need for follow up care. It is important for you to follow up with your physician so that he/she can consider your history and determine what, if any, follow-up care is needed.

Popliteal Ultrasound Results:

Narrowing less than 50% These results show that you have a certain amount of hardening of the arteries in large blood vessels in your legs (popliteal arteries), which supply blood to your legs. This narrowing found during the ultrasound exams indicates some hardening of your arteries. Usually surgery is NOT recommended for people with your level of narrowing of these leg arteries; 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.

Narrowing more than 50% This can cause some slowing of the circulation to your legs and sometimes pain during walking or sores or gangrene. Occasionally surgery is needed to improve this situation. We strongly suggest that you see your medical provider sometime soon, preferably in the coming week.

Narrowing more than 75% This can cause a serious slowing of the circulation to your legs and sometimes pain during walking or sores or gangrene. Not always, but sometimes surgery is needed to improve this situation. We strongly suggest that you see your medical provider in the next 24 hours.

Only your Doctor can make the determination of what you need for follow up care. It is important for you to follow up with your physician so that he/she can consider your history and determine what, if any, follow-up care is needed.
ECHOCARDIOGRAM RESULTS

Abnormal valve conditions

Sometimes one or more of the valves in your heart becomes too narrowed, or starts to leak. When this happens, the heart has to work harder to circulate the blood. Blood clots and infections can also form in the heart and cause problems in other parts of the body. Many of these problems can be corrected by surgery or helped by proper medicines. We suggest that you see your medical provider sometime in the next week to discuss this problem and talk about ways to deal with it.

Only your Doctor can make the determination of what you need for follow up care. It is important for you to follow up with your physician so that he/she can consider your history and determine what, if any, follow-up care is needed.
INTRODUCTION:

The virus that causes AIDS is a human retro virus that has been named HIV (human immuno-deficiency virus). The virus primarily infects cells of the T-lymphocyte system, but is also able to infect other cells such as macrophages and those of the central nervous system. The virus destroys the cellular immunity of infected people, leaving them susceptible to a variety of opportunistic diseases.

It has been established that the virus can be transmitted: (1) through sexual contact; (2) through parenteral exposure, including sharing needles and syringes when injecting illicit drugs, transfusion of blood or its components, and infusion of clotting factors concentrates; and (3) through perinatal exposure, probably both transplacental and intra-partum transmission and postpartum transmission.

To date, there is no evidence that the HIV virus can be transmitted by casual social contact, not even among people living in the same household. Recent reports by the CDC suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known.

Hepatitis B virus (HBV) is transmitted in ways similar to HIV.

PURPOSE:

To stress the importance of following recommended precautions to prevent exposure to the AIDS and HBV virus.

PREVENTION:

1. Before initiating work, all bench areas should be cleaned and sanitized daily with an appropriate disinfectant.

2. All laboratory specimens should be treated as if they were contaminated with either HIV or HBV. Any specimens specifically taken from known AIDS or hepatitis patients should be clearly marked as requiring isolation and transported in a leak proof container.

3. Specimens leaking from their containers should be discarded after requesting a replacement. In those cases in which the specimen is not replaceable, the outside of the soiled container should be disinfected with either a 1:10 sodium hypochlorite solution (household bleach) or
Lysol spray and left standing for at least ten minutes before performing any laboratory procedures).

4. Every laboratorian should wear gloves and be dressed in a laboratory gown or uniform when handling and processing specimens. This will minimize the risk of contamination to exposed body parts or street clothing. Gloves should be worn and disposed of in accordance with the "Gloves (Proper Use and Disposal)" policy. Hands and other skin surfaces should be washed thoroughly and immediately after coming into contact with blood or body fluids.

5. Wear masks, gowns (or aprons), and goggles (or glasses) when there is a possibility that blood or body fluids may splash or splatter on you.

6. All laboratory specimens that must be manipulated before processing (i.e., body fluids to be diluted, caps on tubes of blood to be opened, specimens to be split or transferred, etc.) should be handled cautiously.

7. Centrifuge carriages should be sanitized daily (or after each use if possible HBVs or AIDS specimen is being centrifuged) with a germicide. After weekly use, centrifuge interiors should be sprayed with an appropriate disinfectant.

8. To prevent needle stick injuries, needles should never be recapped, separated from syringes, or otherwise manipulated. Instead, used needles should be placed intact into puncture-resistant containers. The same criteria should be applied to used scalpel blades and any other sharp device that may be contaminated by a patient.

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

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

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

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

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

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

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

FIRST AID AFTER CONTAMINATION OR LIKELY CONTAMINATION

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

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

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

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

5. For all incidents:
   a. Notify the supervisor and report to the Employee Health Unit, or in the event Employee Health is closed, go to the Emergency Room.
   b. An incident report form must be filed.
   c. The decision to administer hepatitis immune globulin is made by the Employee Health Unit.
   d. The hepatitis B surface antigen (HBsag) vaccine HAS BEEN AND IS AVAILABLE to high risk personnel (laboratory, ICU, etc.) All Strong Heart Study personnel who handle blood should receive three dose of hepatitis B vaccine.

REFERENCES:


APPENDIX  B

Instructions for Questionnaires

and

Data Forms
Appendix B -- 1

THE STRONG HEART STUDY V
Instructions for the Personal Interview Forms I and II

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

ITEM # DESCRIPTIONS

---

Personal Interview Form I (NO DATA ENTRY for this form - to be filed in the field center folder only)

Study Identification Number (previously assigned in Phase III or Phase IV) and SHS Family ID should be completely filled in after the consent form is completed and subject is enrolled in Phase V.

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

Write in social security number.

Write in community name and 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 If a female participant has ever married, write down her maiden name.

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

4 Write down the name of IHS and the non-IHS hospital usually used by the participant. Write in facility number is associated.

5a Current mailing address. Enter left justified with blank separating number from street name and street name from unit number. If post office box, enter after street address.

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

c Enter left justified, county of residence.

d Enter state of residence as two digit postal abbreviation and 5-digit postal zip code.

AZ= Arizona          SD= South Dakota
OK= Oklahoma         ND= North Dakota
6. If residential address is different from the mailing address, write in the residential address following the rules given in item 5a-d.

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

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

**Personal Interview Form II**

**A. BASIC INFORMATION:**

1. Check the gender of the participant.

2. Fill in the birthday of the participant.

3. Write down the participant's current marital status.

4. Enter number of years of education the participant has received.

**B. WEIGHT SATISFACTION: questions about efforts to lose weight**

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

6-7. Ask participant whether she/he want to gain or lose weight, and how is she/he doing it.

**C. ARTIFICIAL SWEETENERS**

8. Number of diet drinks ingested in last 7 days.

9. Use of artificial sweeteners.

10. If used, type of artificial sweeteners used.

**D. FAMILY INCOME**

Questions 11-14 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.

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

12. Ask whether the participant is attending a school.

13. Ask participant, on the average, how many hours per week he/she work in a paid job(s).

14. Ask participant to choose the correct annual household income level for her/his household.
E. **TOBACCO:** These questions are very important to assess accurately because smoking is a major risk factor for cardiovascular disease.

15. This question will determine whether 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.

16. Determine when participant started smoking regularly. Record age in years.

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

17a-b If participant reported she/he quit smoking, ask when and why.

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

19. Ask the participant about the occasions when she/he is most likely to smoke or increase smoking. Check ALL the appropriate boxes.

20. Ask the participant, regarding occasions she/he increased smoking, how many cigarettes she/he smoked per day.

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

22. Ask the participant, if currently smoking, whether she/he wants to change her/his smoking habit and how.

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

24. If yes, how often per day does the participant use chewing tobacco or snuff.

F. **PASSIVE SMOKING:** This section asks about second-hand smoke exposure.

25. Ask participant, regardless of her/his smoking status, on the average, how many hours is she/he exposed to the smoke of others.

G. **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.

26. Question 26 determines when the individual last had an 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 Q33.

27. Question 27 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.

28. Question 28 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 in a month.

29. Question 29 assesses the quantity of alcohol consumed in a day when participant drinks.

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

31-32. Questions 31 & 32 assess the frequency of binge drinking in the past month and the past year, respectively.

H. PERCEIVED STRESS:

33-39. Stress has been associated with the occurrence of CVD in many population studies. Questions 33-39 assess the participant’s personal feelings about the degree of stress the SHS participant had in a general sense during the PAST MONTH.

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

41-44. Question 41 assesses the reliability of the answers given by the participant. Question 42 asks if the participant completed all or only part of the interview. Write down your personnel code number and the date of completion of the interview.
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<td>Skull Valley Band of Goshute Indians of Utah</td>
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<td>California</td>
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<td>and South Dakota</td>
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<tr>
<td>Stockbridge-Munsee Community of Mohican Indians of Wisconsin</td>
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<td>Summit Lake Paiute Tribe of the Summit Lake Reservation, Nevada</td>
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<td>Utu Utu Gwaiti Paiute Tribe of the Benton Paiute Reservation, California</td>
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<tr>
<td>Viejas Baron Long Captain Grande Band of Diegueno Mission Indians,</td>
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<td>Akutan, Native Village of Akutan</td>
<td>504</td>
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<tr>
<td>Alakanuk, Village of Alakanuk</td>
<td>505</td>
</tr>
<tr>
<td>Alatna Village</td>
<td>506</td>
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<tr>
<td>Alegnagik, Village of Alegnagik</td>
<td>507</td>
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Appendix B  --  3
THE STRONG HEART STUDY V
Instructions for Medical History Interview

Before beginning, make certain that the correct study identification number of the participant is entered at the top of the form. Explain to the participant that some questions need to be asked about her/his medical history so that we can better evaluate whether or not she/he has heart disease or a tendency for heart disease. Stress that the information will be confidential and that his/her name will never be used in any publication.

A. 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 fracture 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 their 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 his/her 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, exercise test, or Chemical Stress 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.

20. Ask if participant is taking aspirin everyday to prevent a heart attack or stroke.
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).

6. Ask if hypertension developed during first pregnancy.

7. Ask if told she had Preeclampsia during that pregnancy.

8. Ask about number of cigarettes smoked while pregnant.

9. Ask if participant had Preeclampsia in one or more subsequent pregnancies (if any).

10. Ask if participant had ever had eclampsia during a pregnancy.

11. Ask if the participant’s mother or a sister ever had Preeclampsia.

12. 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.

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

14. 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.

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

16. Ask the participant whether her menstrual cycles have stopped. If "Yes", 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 ask 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 participant is currently taking estrogen pills other than birth control pills, be sure they are recorded on the medication history.
17-22. Use questionnaire as written to obtain information about estrogen use. Record when the participant started to use estrogen, for how long altogether, reason(s) for using estrogen, and if progesterone was also used in combination with or in addition to estrogen.

23-24. Ask the participant whether she is still using estrogen at the time of interview. If not, why?

25-28. Ask the participant whether she ever has ever used progesterone alone. If yes, when started and for how long and whether still taking progesterone.
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.
DIRECTIONS TO PARTICIPANTS FOR USING THE Pedometer

The ACCUSPLIT Pedometer measures movement. You are being asked to wear this pedometer EVERY DAY for a seven-day period from ______________ to ______________. The pedometer is worn on the hip and should be clipped to the waistband of your pants/skirt, underwear, or belt. Most importantly, the pedometer must be worn in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. **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 number of steps from the pedometer 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 **YELLOW** reset button so that the pedometer resets to “0”.
2. Record the time that you attached the pedometer in your pedometer record. Make sure to indicate am or pm.
3. Wear the pedometer on your hip (please see pictures above), make sure to keep it upright, and make sure that it remains firmly in place against your body.
4. **Wear the pedometer ALL DAY except when bathing, swimming, or in the rain (unless the pedometer is protected by clothing and will not get wet). If you take off the pedometer for longer than 30 minutes, record the length of time it was off (minutes or hours) in your pedometer record.**
5. At bedtime, take off the pedometer. Record in your pedometer record (a) the number of steps taken on the pedometer, and (b) the time you removed your pedometer. Make sure to indicate am or pm.
6. Please do not touch the **YELLOW** reset button during the day or you will erase your activity numbers.
7. **Keep the cover closed or the pedometer will not record your activity.**
8. Do not wear the pedometer in a pants, coat, or shirt pocket. The pedometer will not work correctly.
9. Please bring back or mail to us, in the self-addressed stamped envelope, the pedometer record after you have completed your week.
10. Please keep the pedometer as a token of our appreciation for your participation in the Strong Heart Family Study.

Thank you very much for your time and effort.
APPENDIX  C

STRONG HEART STUDY

PHASE V

Questionnaires and Data Forms
DEMOGRAPHIC INFORMATION:

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

2. If ever married, what was your maiden name?
   ____________________________________________________________

3. If married, what is your spouse’s name? (if not married, go to Q4)

4. To which IHS and non-IHS Hospital/Clinic do you usually go? List the one they go to most often first. Give names and codes.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Chart number</th>
<th>IHS 1=yes, 2=no</th>
<th>Hospital Code</th>
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</thead>
<tbody>
<tr>
<td>a.</td>
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<tr>
<td>b.</td>
<td></td>
<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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</tbody>
</table>
5. What is your current mailing address?

   a. _____________________________________________
      Street/P.O. Box

   b. _____________________________________________
      City/town

   c. _____________________________________________
      County

   d. State and zip code: ___________________________

6. Is your residential address the same as above?

   Yes |___| 1   No |___|2   If no, what is your current residential address?

   a. _____________________________________________
      Street

   b. _____________________________________________
      City/town

   c. _____________________________________________
      County

   d. State and zip code: ___________________________

7. What is your home telephone number or at what telephone number can we reach you or leave a message?
   0 = If unlisted
   9 = If no phone

8. What is your work or other contact telephone number?
   0 = If same as home phone
   9 = If not applicable or unknown
BASIC INFORMATION:

1. Gender: Male |___| 1  Female |___| 2

2. Date of Birth: [___]/[___]/[___]

3. What is your marital status? |___|
   1 = Never married  5 = Widowed
   2 = Currently married  6 = Adult roommate/partner/significant other
   3 = Divorced  
   4 = Separated

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

4. How many years of education have you completed? |___|___|___|
   0-12 = Vo-tech or years of school (Vo-tech/GED = 12)
   14 = Junior college
   16 = Bachelors
   18 = Masters
   19 = Law Degree
   20 = Doctorate
   999 = Unknown

WEIGHT SATISFACTION:

5. Are you satisfied with your present weight?
   Yes |___| 1  (go to Q8)  No |___| 2  Unknown/unsure |___| 9

6. Do you want to lose or gain weight: Lose |___| 1  Gain |___| 2

7. 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
8. How often did you drink diet drinks, like diet Coke, diet Pepsi, diet Dr. Pepper, diet lemonade or diet iced tea, etc., in the PAST WEEK? (Please check only one.)

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<th></th>
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<tbody>
<tr>
<td>0 = Never</td>
<td>3 = Three to four times a week</td>
<td>6 = More than once a day</td>
<td></td>
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</tr>
<tr>
<td>1 = Once a week</td>
<td>4 = Five to six times a week</td>
<td>9 = Don’t know or can’t remember</td>
<td></td>
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</tr>
<tr>
<td>2 = Twice a week</td>
<td>5 = Everyday</td>
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</table>

9. How often do you use artificial sweeteners to sweeten your drinks, such as coffee or tea? (Please check only one.)

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</thead>
<tbody>
<tr>
<td>0 = Never (go to Q11)</td>
<td>1 = Occasionally</td>
<td>2 = Often</td>
<td>3 = Always</td>
<td></td>
</tr>
</tbody>
</table>

10. If you ever use artificial sweeteners, what type do you use? If uncertain of type, ask for packet color. (Please check all that apply.)

a) Saccharin, such as Sweet ‘N Low (usually in a pink packet)  
   Yes [___] 1  No [___] 2

b) Sucralose, such as Splenda (usually in a yellow packet)  
   Yes [___] 1  No [___] 2

c) Aspartame, such as Equal or NutraSweet (usually in a blue packet)  
   Yes [___] 1  No [___] 2

d) Other, such as Cyclamate, Weight Watchers or Acesulfame Potassium, like Sunett  
   Yes [___] 1  No [___] 2

e) Don’t know, don’t care  
   Yes [___] 1  No [___] 2

FAMILY INCOME:

11. Does your household income meet your family’s needs?  
    Yes [___] 1  No [___] 2  Unsure [___] 9

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

13. 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)

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

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</thead>
<tbody>
<tr>
<td>Less than 5,000</td>
<td>20,000 to 25,000</td>
<td>25,000 to 35,000</td>
<td>35,000 to 50,000</td>
<td>Over 50,000</td>
</tr>
<tr>
<td>[___] 1</td>
<td>[___] 5</td>
<td>[___] 6</td>
<td>[___] 7</td>
<td>[___] 8</td>
</tr>
<tr>
<td>5,000 to 10,000</td>
<td>10,000 to 15,000</td>
<td>15,000 to 20,000</td>
<td>Don’t know/not sure</td>
<td>Refused</td>
</tr>
<tr>
<td>[___] 2</td>
<td>[___] 3</td>
<td>[___] 4</td>
<td>[___] 9</td>
<td>[___] 0</td>
</tr>
</tbody>
</table>
TOBACCO:

15. During your lifetime have you smoked 100 cigarettes or more total?
   Yes [ ] 1  No [ ] 2  (go to Q23)

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

17. Did you quit smoking?  Yes [ ] 1  No [ ] 2  (go to Q18)
   a) If you quit, when did you last smoke?
      (Just the year, please)  ____________
   b) What reason(s) did you have for quitting?
      Please check all that apply:
      Yes  No
      i) Doctor’s advice  [ ] 1  [ ] 2
      ii) Health concerns  [ ] 1  [ ] 2
      iii) Expenses  [ ] 1  [ ] 2
      iv) Family pressure  [ ] 1  [ ] 2
      v) Peer pressure  [ ] 1  [ ] 2
      vi) Other  [ ] 1  [ ] 2
      specify: ______________________________________

18. On the average, how many cigarettes do/did you usually smoke per day?  ____________
   (Please give an average for a typical week)
   0 = Less than one cigarette per day
   a) If the average is less than one cigarette per day,  ____________
      number of cigarettes per month?  ____________

19. On which occasions are/were you most likely to smoke or increase your smoking?
   Please read the list and check the appropriate response.
   Yes  No
   a) stressful times  [ ] 1  [ ] 2
   b) casinos  [ ] 1  [ ] 2
   c) wakes/funerals  [ ] 1  [ ] 2
   d) when drinking alcohol  [ ] 1  [ ] 2
   e) social meetings  [ ] 1  [ ] 2
   f) when you have extra money  [ ] 1  [ ] 2
   g) bingo  [ ] 1  [ ] 2
   h) school  [ ] 1  [ ] 2
   i) other, specify: _____________________________________  [ ] 1  [ ] 2
20. On the occasions that your smoking increased, how many total cigarettes do/did you smoke per day? __|__|__

21. Do you smoke cigarettes now? Yes [___] 1 No [___] 2 (If No, go to Q23)

22. If you currently smoke, would you like to change your smoking habit?

Yes [___] 1 No [___] 2 (If No, go to Q23)

a) If yes, would you prefer to…

   Yes No
   i) Reduce the number of cigarettes per day [___] 1 [___] 2
   ii) Switch to lower “tar” or “nicotine” cigarettes [___] 1 [___] 2
   iii) Use nicotine patch/chewing gum/medications [___] 1 [___] 2
   iv) Quit [___] 1 [___] 2
   v) Other, specify: ________________________________ [___] 1 [___] 2

23. Do you use chewing tobacco/snuff now? Yes [___] 1 No [___] 2 (If No, go to Q25)

24. If yes, how many times a day do you use it? _________ times/day. (Enter 0 if less than once a day or used sporadically.)

PASSIVE SMOKING:

25. 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.)
ALCOHOL:

PLEASE READ THE FOLLOWING TO THE PARTICIPANT:
ALCOHOL QUESTIONS

The next few questions are about the use of wine, beer or liquor, including all kinds of alcoholic beverages. We are asking these questions about alcohol because we think alcohol consumption may be related to heart disease. We assure you that this information is strictly confidential and that we are not judging your drinking habits and do not intend to report them to anyone. GIVE DRINKS CHART TO PARTICIPANT. Sometimes it’s hard to count drinks, so here is a chart to show you what we mean. REVIEW CHART WITH PARTICIPANT: READ IF NECESSARY.

One whole 12 ounces can of beer = 1 drink
A whole six-pack of beer = 6 drinks
One case of beer = 24 drinks
One quart of beer = 2.5 drinks
One pint of beer = 1.3 drinks
One 40 ounces of beer = 3.3 drinks
A glass (4 ounces) of wine = 1 drink
One pint (16 ounces) of wine = 4 drinks
One quart (32 ounces) of wine = 8 drinks
A shot or gulp of straight hard liquor, like whiskey = 1 drink
One pint (16 ounces) of hard liquor = 12 drinks
One quart (32 ounces) of hard liquor = 24 drinks
A full glass of a mixed drink, like everclear in punch = 1 drink

26. Have you ever consumed alcoholic beverages?

   Yes [____] 1   No [____] 2 (go to Q33)

   a) If “YES,” when was your last drink? (Choose only one)

      [____] 1 Within the last week

      [____] 2 Within the last month

      [____] 3 Within the last year. Number of months [____] [____] [____]

      [____] 4 More than a year ago (go to Q33)

27. How many alcoholic drinks do you have in a typical week?

28. How many days in a typical month do you have at least one drink? (Indicate the number of days per month.)

29. On the days when you drink any liquor, beer or wine, about how many drinks do you have, on average? (Indicate number of drinks per day.) (# of Drinks)

30. When you drink more than your usual amount, how many total drinks do you have?

   a) How many times in a month? (# Times/Month)
31. 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.)

32. How many times during the PAST YEAR did you have 5 or more drinks on an occasion?

PERCEIVED STRESS

In the past month, how often have you (Q33-39):

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Most of the time</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
</tbody>
</table>

33. been upset because of something that happened unexpectedly?

34. felt nervous or “stressed”?

35. dealt with irritating life hassles?

36. felt that things were going your way?

37. felt unable to control irritations in your life?

38. felt that you were on the top of things?

39. felt difficulties or problems were piling up so high that you could not handle them?

40. On the average, how much time per day do you watch TV?

ADMINISTRATIVE INFORMATION:

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

<table>
<thead>
<tr>
<th>Very reliable</th>
<th>Reliable</th>
<th>Unreliable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Unreliable</td>
</tr>
</tbody>
</table>

42. Did the participant complete ALL or PART of the interview?

<table>
<thead>
<tr>
<th>Yes, completed ALL or PART of the interview</th>
<th>No, refused ALL questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

43. Interviewer code:

44. Interview date:

month/day/year
MEDICAL HISTORY

IS THE PARTICIPANT FEMALE?  Yes |___| 1  No |___| 2

MEDICAL CONDITIONS:

"Now I’d like to ask you some questions about medical problems. Has a medical person EVER told you that you had any of the following conditions?"

1. a) High blood pressure?
   Yes |___| 1  No |___| 2  Only during pregnancy |___| 3  Unknown |___| 9

b) If "YES," how old were you when you were first told by a medical person that you had high blood pressure (for women, not during pregnancy)? Indicate the actual age. Don't know = 999 |___|___|___|

c) If "YES," are you taking any medication to control your blood pressure?
   Yes |___| 1  No |___| 2  Unknown |___| 9

   YES  NO  UNKNOWN

2. Arthritis? |___| 1  |___| 2  |___| 9

3. Any fractures associated with brittle bone disease or osteoporosis? |___| 1  |___| 2  |___| 9

   a) If "YES," where? ____________________________________________________

4. Rheumatic heart disease? |___| 1  |___| 2  |___| 9

5. Gallstones? |___| 1  |___| 2  |___| 9

6. Cancer, including leukemia and lymphoma? |___| 1  |___| 2  |___| 9

   a) If "YES," specify type of cancer: ______________________________________
7. Diabetes? Yes [ ] 1 No [ ] 2 Only during pregnancy [ ] 3 Unknown [ ] 9
(If No or Unknown, go to Q8)

a) How old were you when you were first told by a medical person that you had diabetes? *Indicate the actual age.* Don't know = 999

b) What type of treatment are you taking for your diabetes? *(Check appropriate answer.)*

YES NO
i) insulin [ ] 1 [ ] 2
ii) oral hypoglycemic agent [ ] 1 [ ] 2
iii) by dietary control [ ] 1 [ ] 2
iv) by exercise [ ] 1 [ ] 2
v) do nothing [ ] 1 [ ] 2
vi) other: ________________________________ [ ] 1 [ ] 2

8. Has a medical person ever told you that you had kidney failure? [ ] 1 [ ] 2 [ ] 9
(If No or Unknown, go to Q11)

a) If “YES,” are one or both working well now? [ ] 1 [ ] 2 [ ] 9

b) How old were you when you were first told by a medical person that you had kidney failure? *Indicate the actual age.* Don't know = 999

YES NO UNKNOWN

9. Are you currently on renal dialysis? [ ] 1 [ ] 2 [ ] 9

10. Have you ever had a kidney transplant? [ ] 1 [ ] 2 [ ] 9

a) If “YES,” is the new kidney working well? [ ] 1 [ ] 2 [ ] 9

b) If “NO,” are you waiting for a kidney transplant? [ ] 1 [ ] 2 [ ] 9

11. Cirrhosis of the liver? [ ] 1 [ ] 2 [ ] 9
HEART PROBLEMS:

12. Have you had a heart catheterization?  Yes ___ 1  No ___ 2  Unknown ___ 9

   (A heart catheterization is a study in which a tube is inserted into the heart through the groin or arm to see how the heart works.)

   a) If “YES,” when and where (most recent)?  _____/_____/_____
       month    day    year

   i) hospital/clinic: ________________________________

13. Have you ever had an angioplasty (balloon, PCTA or Stent procedure)?

   Yes ___ 1  No ___ 2  Unknown ___ 9

   a) If “YES,” when and where (most recent)?  _____/_____/_____
       month    day    year

   i) hospital/clinic: ________________________________

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

   Yes ___ 1  No ___ 2  Unknown ___ 9

   a) If “YES,” when and where?  _____/_____/_____
       month    day    year

   i) hospital/clinic: ________________________________

Has a doctor ever told you that you had any of the following conditions?
(If more than one episode, enter information for the MOST RECENT.)

15. Congestive heart failure?  Yes ___ 1  No ___ 2  Unknown ___ 9

   a) If “YES,” when and where?  _____/_____/_____
       month    day    year

   i) hospital/clinic: ________________________________

   b) If “YES,” do you still have heart failure now?  Yes ___ 1  No ___ 2  Unknown ___ 9
16. Heart attack?  
   Yes [ ] 1  No [ ] 2  Unknown [ ] 9
   a) If “YES,” when and where?  
      _______ / _______ / _______  
      month  day  year
   i) hospital/clinic: ________________________________

17. Any other heart trouble?  
   Yes [ ] 1  No [ ] 2  Unknown [ ] 9
   a) If “YES,” please specify type: ________________________________
   b) If “YES,” when and where?  
      _______ / _______ / _______  
      month  day  year
   i) hospital/clinic: ________________________________

18. Stroke?  
   Yes [ ] 1  No [ ] 2  Unknown [ ] 9
   a) If “YES,” when and where?  
      _______ / _______ / _______  
      month  day  year
   i) hospital/clinic: ________________________________

19. Have you ever had surgery on your chest?  
   Yes [ ] 1  No [ ] 2  (go to Q20)
   a) Was it heart surgery?  
      Yes [ ] 1  No [ ] 2  (go to Q20)
      If “YES,” which surgery have you had?
      i) Bypass?  
         Yes [ ] 1  No [ ] 2  Unknown [ ] 9
         If “YES,” when and where (most recent)?  
         _______ / _______ / _______  
         month  day  year
         hospital/clinic: ________________________________
      ii) Valvular repair/ replacement?  
          Yes [ ] 1  No [ ] 2  Unknown [ ] 9
          If “YES,” when and where (most recent)?  
          _______ / _______ / _______  
          month  day  year
          hospital/clinic: ________________________________
iii) Pacemaker?  Yes [ ] 1  No [ ] 2  Unknown [ ] 9

If “YES,” when and where (most recent)?  _______/_______/_______

hospital/clinic: ________________________________________________________

iv) Other?  Yes [ ] 1  No [ ] 2

If “YES,” when and where (most recent)?  _______/_______/_______

Please specify: _______________________________________________________

hospital/clinic: ________________________________________________________

20. Are you taking aspirin daily to prevent a heart attack or a stroke?

   Yes [ ] 1  No [ ] 2  Unknown [ ] 9

ADMINISTRATIVE INFORMATION:

21. Did the participant complete ALL or PART of the interview?

   Yes, completed ALL or PART of the interview [ ] 1

   No, refused ALL questions [ ] 2

22. Interviewer code:  [ ] [ ] [ ]

23. Interview date:  _______/_______/_______

IF THE PARTICIPANT IS FEMALE GO TO REPRODUCTION AND HORMONE USE.

IF THE PARTICIPANT IS MALE GO TO ROSE QUESTIONNAIRE.
“The following questions are related to your childbearing history and childbearing organs.”

(For Q1 – Q4, use 999 for Unknown.)

1. How many times have you been pregnant (gravidity)?

2. How many of your pregnancies resulted in a live birth (parity)?

3. How many living children do you have?

4. How many pregnancies did you lose (including miscarriage or stillbirth)?

Preeclampsia (pree-i-CLAMP-see-ah), also called toxemia, is a condition that typically starts after the 20th week of pregnancy and is related to increased blood pressure and protein in the mother’s urine.

5. Did you develop hypertension during your first pregnancy?

6. During that (first) pregnancy, were you told you had preeclampsia, toxemia or protein in your urine? (If BOTH Q5 and Q6 are NO go to Q8.)

7. How many weeks pregnant were you when you were first diagnosed with hypertension or preeclampsia (full term pregnancy is about 40 weeks, use 999 for unknown)?

8. Approximately how many cigarettes/day did you smoke during your pregnancy (enter “0” if you did not smoke, use 999 for unknown)?

9. Did you have preeclampsia, toxemia, or both hypertension and protein in your urine in one or more subsequent pregnancies?

10. Did you ever have eclampsia, i.e. a seizure (convulsion or “fit”) along with hypertension during a pregnancy or around the time of delivery?

11. Did your mother or sister ever have preeclampsia?

12. Have you ever used birth control pills? (If NO or NOT SURE, go to Q13.)
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

[ ] [ ] [ ]

Specify the duration in years. 0 = less than 6 months, 1 = 6–12 months, 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.

13. 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 Q14.)

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.

14. 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 Q15.)

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.

15. How old were you when you started to have regular menstrual cycles (periods)? Indicate the age in years. 999 = unknown

[ ] [ ] [ ]

16. Have your menstrual cycles (periods) stopped? Yes [ ] 1 No [ ] 2 (go to Q17)

a) If “YES,” have they stopped for 12 months or more? Yes [ ] 1 No [ ] 2 (go to Q17)

i) How old were you when your periods stopped completely? Indicate the age in years. 999 = unknown, can’t remember

[ ] [ ] [ ]
ii) Did your periods stop naturally, or because of surgery or hormone use, or for some other reason?

Natural |___| 1 (go to Q17)
Surgery |___| 2
Hormonal |___| 3 (go to Q17)
Other, specify: ___________________________________ |___| 4 (go to Q17)

iii) If SURGERY, were both of your ovaries removed?

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

“ESTROGEN and PROGESTERONE are types of female hormones that may be taken for many reasons, including after a hysterectomy or menopause, to regulate your periods or for any other reasons.”

17. 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 Q25.)

18. How old were you when you started using estrogen? Indicate age in years. |___| |___| |___|

19. 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.)

20. Do/Did you use estrogen for (answer all applicable) YES NO NOT SURE

a) post surgery (hysterectomy and removal of ovaries) |___| 1 |___| 2 |___| 3
b) relief of menopause symptoms |___| 1 |___| 2 |___| 3
c) prevent bone loss |___| 1 |___| 2 |___| 3
d) protect against heart disease |___| 1 |___| 2 |___| 3
e) doctor’s advice |___| 1 |___| 2 |___| 3
f) other: ___________________________________________ |___| 1 |___| 2 |___| 3

21. Do/Did you take progesterone in addition to, or in combination with, your estrogen treatment?

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

22. What form of estrogen are you taking? Is it a pill, patch, shot or other type?

pills |___| 1 patch |___| 2 shot |___| 3 other |___| 4 Not sure |___| 5
23. Are you still taking estrogen? Yes [__] 1 (go to Q25) No [__] 2 (go to Q24)

24. Why did you stop taking estrogen?

   a) Caused bleeding [__] 1 [__] 2 [__] 9
   b) Made breasts tender [__] 1 [__] 2 [__] 9
   c) Made you feel bloated [__] 1 [__] 2 [__] 9
   d) Made you feel “funny,” didn’t like the way you felt [__] 1 [__] 2 [__] 9
   e) Do not like taking any medicines [__] 1 [__] 2 [__] 9
   f) Too expensive [__] 1 [__] 2 [__] 9
   g) Doctor’s advice [__] 1 [__] 2 [__] 9
   h) Concerned about long-term side effects [__] 1 [__] 2 [__] 9
   i) Other: __________________________________ [__] 1 [__] 2 [__] 9

25. 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 Q29.)

26. How old were you when you started using progesterone? Indicate age in years. _______ _______

27. 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.)

28. Are you still taking progesterone? Yes [__] 1 No [__] 2

ADMINISTRATIVE INFORMATION:

29. Did the participant complete ALL or PART of the interview?

   Yes, completed ALL or PART of the interview [__] 1
   No, refused ALL questions [__] 2

30. Interviewer Code: [____] _______

31. Interview date: [____] [____]/[____]/[____] _______
   month day year
Chest Pain on Effort

1. Have you ever had any pain or discomfort in your chest?  
   Yes |___|1  
   No |___|2  (go to Q10)

2. Do you get it when you walk uphill, upstairs or hurry?  
   Yes |___|1  
   No |___|2  (go to Q9)  
   Never hurries or walks uphill or upstairs |___|3  
   Unable to walk |___|4  (go to Q9)

3. Do you get it when you walk at an ordinary pace on the level?  
   Yes |___|1  
   No |___|2

4. What do you do if you get it while you are walking?  
   Stop or slow down |___|1  
   Carry on |___|2  (go to Q9)  
   (Record “stop or slow down” if subject carries on after taking nitroglycerine.)

5. If you stand still, what happens to it?  
   Relieved |___|1  
   Not relieved |___|2  (go to Q9)

6. How soon?  
   10 minutes or less |___|1  
   More than 10 minutes |___|2  (go to Q9)

7. Will you show me where it was?  
   (Record all areas mentioned. Use the diagram below to show the location if participant cannot tell exactly.)  
   YES  NO
   Upper  
   Sternum (upper or middle) |___|1  |___|2  
   Sternum (lower) |___|1  |___|2
   Middle  
   Left anterior chest |___|1  |___|2  
   Left arm |___|1  |___|2
   Lower  
   Other: ___________________ |___|1  |___|2

8. Do you feel it anywhere else?  
   Yes |___|1  
   No |___|2  
   a) If “YES,” record additional information: ____________________________

The Strong Heart Study V – 05/23/2006  Page 1 of 2  Rose Questionnaire
Possible Infarction

9. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?
   Yes ___ | No ___

Intermittent Claudication

10. Do you get pain in either leg on walking?
    Yes ___ | No ___ (go to Q19)
    Unable to walk ___ (go to Q19)

11. Does this pain ever begin when you are standing still or sitting?
    Yes ___ (go to Q19)
    No ___

12. In what part of your leg did you feel it?
    Pain includes calf/calves ___
    Pain does not include calf/calves ___
    a) If calves not mentioned, ask: “Anywhere else?” Please specify: ____________________________
    (go to Q19)

13. Do you get it if you walk uphill or hurry?
    Yes ___ (go to Q19)
    No ___
    Never hurries or walks uphill ___

14. Do you get it if you walk at an ordinary pace on the level?
    Yes ___ | No ___

15. Does the pain ever disappear while you are walking?
    Yes ___ (go to Q19)
    No ___

16. What do you do if you get it when you are walking?
    Stop or slow down ___
    Carry on ___ (go to Q19)

17. What happens to it if you stand still?
    Relieved ___
    Not Relieved ___ (go to Q19)

18. How soon? 10 minutes or less ___ | More than 10 minutes ___

ADMINISTRATIVE INFORMATION:

19. Did the participant complete ALL or PART of the interview?
    Yes, completed ALL or PART of the interview ___
    No, refused ALL questions ___

20. Interviewer code: ___ ___ ___ ___

21. Interview date: ___/___/___
EXAMINATION OF EXTREMITIES FOR AMPUTATIONS

1. Are any extremities missing?  Yes [ ] 1  No [ ] 2  (go to Q2)

If “YES” to amputation, please code the cause of amputation:

1 = Diabetes  
2 = Trauma  
3 = Congenital  
4 = Other, please specify  
9 = Unknown

<table>
<thead>
<tr>
<th>Extremities</th>
<th>Check if Missing</th>
<th>Cause</th>
<th>If Other, please specify</th>
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<tbody>
<tr>
<td>a) Right arm</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>b) Right hand</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>c) Right finger(s)</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>d) Left arm</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>e) Left hand</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>f) Left finger(s)</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>g) Right leg above knee</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>h) Right leg below knee</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>i) Right foot</td>
<td>[ ]</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>j) Right toe(s)</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
</tr>
<tr>
<td>k) Left leg above knee</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
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<td>l) Left leg below knee</td>
<td>[ ]</td>
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<tr>
<td>m) Left foot</td>
<td>[ ]</td>
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<td>__________________________</td>
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<tr>
<td>n) Left toe(s)</td>
<td>[ ] # missing</td>
<td>[ ]</td>
<td>__________________________</td>
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</table>

BLOOD PRESSURE

2. Right arm circumference, measured in centimeters (cm) [ ] [ ] [ ] [ ]

Midway between acromion and olecranon.
3. Cuff size (arm circumference in brackets)  
   Pediatric (under 24cm) | 1  
   Regular arm (24 – 32cm) | 2  
   Large arm (33 – 41cm) | 3  
   Thigh (>41cm) | 4  

4. Pulse obliteration pressure  

5. Seated Blood Pressure:  
   \[ \text{Systolic BP} \quad \text{Diastolic BP} \]  
   a) First Blood Pressure Measurement  
   b) Second Blood Pressure Measurement  
   c) Third Blood Pressure Measurement  

6. Were the above blood pressures taken from RIGHT arm?  
   Yes | 1  
   No | 2  
   Specify: ____________________________  

7. Recorder ID (For the SHS staff who took BP):  

ANTHROPOMETRIC MEASUREMENTS:  
(Take off shoes and remove heavy objects from pockets.)  

<table>
<thead>
<tr>
<th>METRIC SYSTEM (centimeters/kilograms)</th>
<th>ENGLISH SYSTEM (inches/pounds)</th>
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<tr>
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<td></td>
</tr>
<tr>
<td>Weight (Standing) ........................</td>
<td></td>
</tr>
<tr>
<td>Hip circumference (Standing) ..........</td>
<td></td>
</tr>
<tr>
<td>Waist measurement at umbilicus (Supine)...</td>
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</table>

PEDAL PULSES AND EDEMA  

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<th>ABSENT</th>
<th>MISSING LIMBS</th>
<th>UNABLE TO ASSESS</th>
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</thead>
<tbody>
<tr>
<td>12. Right posterior tibial pulse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Right dorsalis pedis pulse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Left posterior tibial pulse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Left dorsalis pedis pulse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Pedal edema Absent</td>
<td></td>
<td>Mild</td>
<td>Marked</td>
</tr>
</tbody>
</table>

The Strong Heart Study V – 05/23/2006  Page 2 of 3  Physical Examination
**IMPEDANCE MEASUREMENT**

17. a) Was impedance taken? Yes [ ] 1 (go to b) No [ ] 2

   If No, due to:
   - Amputation [ ] 1
   - Wound/dressing [ ] 2
   - Cast [ ] 3
   - Dialysis shunt [ ] 4
   - Refusal [ ] 8

b) Taken on right side? Yes [ ] 1 (go to c) No [ ] 2

   If No, due to:
   - Amputation [ ] 1
   - Wound/dressing [ ] 2
   - Cast [ ] 3
   - Dialysis shunt [ ] 4
   - Refusal [ ] 8

c) Resistance ................................................................. [ ] [ ] [ ]
d) Reactance ................................................................. [ ] [ ] [ ]

**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).

<table>
<thead>
<tr>
<th></th>
<th>Right arm</th>
<th>Right ankle</th>
<th>Left ankle</th>
</tr>
</thead>
<tbody>
<tr>
<td>18. a) First systolic B.P.</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>18. b) Second systolic B.P.</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>18. c) Location</td>
<td>Posterior tibial [ ] 1</td>
<td>Posterior tibial [ ] 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dorsalis pedis [ ] 2</td>
<td>Dorsalis pedis [ ] 2</td>
<td></td>
</tr>
</tbody>
</table>

**ADMINISTRATIVE INFORMATION**

19. Did the participant complete ALL or PART of this examination?

   Yes, completed ALL or PART of the interview [ ] 1
   No, refused ALL questions [ ] 2

20. Examiner code: [ ] [ ] [ ] [ ]

21. Examination date: [ ] [ ] [ ]/ [ ] [ ] [ ]
   month day year
1. **Fasting SureStep Flex System glucose result.** 999 = not done

2. **Is FASTING blood sample taken?**
   - Yes, and participant has been fasting ................................................................. |___|1
   - Yes, but participant has NOT been fasting ......................................................... |___|2
   - No, participant has not been fasting ................................................................. |___|3
   - Other, specify: ____________________________________________________________ |___|4
   - No, participant refused .................................................................................... |___|8

3. **When was the last time you ate? (use military time)**

4. **Time of collection of fasting samples. (use military time)**

5. **Is urine sample taken?**
   - Yes |___| 1 *(go to Q7)*
   - No |___| 2

6. **If no, why?**
   - On dialysis .......................................................................................................... |___|1
   - Cannot urinate ...................................................................................................... |___|2
   - Other, specify: ____________________________________________________________ |___|3

7. **Time of collection of urine sample (use military time)**
8. **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>a) Three 10 ml SST</td>
<td>Chem Profile Lipids, Insulin, CRP, FFA</td>
<td>Serum</td>
<td>[ ]</td>
</tr>
<tr>
<td>b) Two 2.7 ml Lt Blue (or one 4.5 ml Lt Blue)</td>
<td>Fibrinogen</td>
<td>Plasma</td>
<td>[ ]</td>
</tr>
<tr>
<td>c) One 4 ml Gray</td>
<td>Fasting glucose</td>
<td>Plasma</td>
<td>[ ]</td>
</tr>
<tr>
<td>d) Three 10 ml Purple</td>
<td>HbA1c, Leptin, DNA</td>
<td>Whole blood/Plasma/Buffy coat</td>
<td>[ ]</td>
</tr>
<tr>
<td>e) One Purple (size site specific)</td>
<td>CBC</td>
<td>Whole blood</td>
<td>[ ]</td>
</tr>
<tr>
<td>f) Urine (One cup)</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 [ ] *(go 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>
<tr>
<td>a) One 10 ml SST</td>
<td>Chem Profile Lipids, Insulin, CRP, FFA</td>
<td>Serum</td>
<td>[ ]</td>
</tr>
<tr>
<td>b) Two 2.7 ml Lt Blue (or one 4.5 ml Lt Blue)</td>
<td>Fibrinogen</td>
<td>Plasma</td>
<td>[ ]</td>
</tr>
<tr>
<td>c) One 4 ml Gray</td>
<td>Fasting glucose</td>
<td>Plasma</td>
<td>[ ]</td>
</tr>
<tr>
<td>d) One 10 ml Purple</td>
<td>HbA1c/Leptin</td>
<td>Whole blood/Plasma</td>
<td>[ ]</td>
</tr>
<tr>
<td>e) Urine (One cup)</td>
<td>Albumin/Creatinine</td>
<td>Urine</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

12. **Instructions:** “We ask you not to use any tobacco, caffeine or alcohol until you have completed your visit with us today. We do this so that your test results are not affected by use of these substances.”
If you did, when and what: ______________________________________________________

---

**ADMINISTRATIVE INFORMATION:**

13. **SHS Code of person completing this form:** [ ] [ ] [ ] [ ] [ ] [ ]

14. **Today’s Date:** [ ] [ ] [ ] [ ] [ ] [ ] [ ]
   month day year
### CBC Results

<table>
<thead>
<tr>
<th>SHS I.D.:</th>
<th>SHS Family I.D.:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each center’s results may appear in different order. Please be careful when entering the results.

1. WBC \((10^9/L \text{ or } K/\text{cmm or } K/\text{uL})\) .................................................. |___|___|_|___|___|
2. RBC \((10^{12}/L \text{ or } M/\text{cmm or } M/\text{uL})\) .................................................. |___|___|_|___|___|
3. HGB \((\text{g/dL})\) ........................................................................................................ |___|___|_|___|___|
4. HCT (%) ..................................................................................................... |___|___|___|_|___|___|
5. MCV (fL) ..................................................................................................... |___|___|___|_|___|___|
6. MCH (pg) ........................................................................................................... |___|___|_|___|___|
7. MCHC (g/dL) ..................................................................................................... |___|___|_|___|___|
8. RDW (%) ........................................................................................................... |___|___|_|___|___|
9. Platelet count \((\text{PLT. } 10^9/L \text{ or } K/\text{cmm or } K/\text{uL})\)...................... |___|___|___|_|___|___|
10. MPV (fL) ............................................................................................................ |___|___|_|___|___|

### Differential

Each center’s results may appear in different order. Please be careful when entering the results.

11. NEUT (%).......................................................................................................... |___|___|_|___|___|
12. LYMPH (%) ....................................................................................................... |___|___|_|___|___|
13. MONO (%)......................................................................................................... |___|___|_|___|___|
14. EOS (%) ............................................................................................................ |___|___|_|___|___|
15. BASO (%).......................................................................................................... |___|___|_|___|___|

### Administrative Information:

16. Did the participant have a CBC? Yes |___|1 No |___|2
17. Completer code: |___|___|___|
18. Completion date: |___|___|/|___|___|/|___|___|___|___|
    month day year
How is this questionnaire administered?   By interviewer [___1]   By self [___2]   Refused [___8]

These next questions ask how you feel about your own health.

1. In general, would you say your health is?  **(Please check only one.)**
   - Excellent ................................................................. [___1]
   - Very good ............................................................... [___2]
   - Good ........................................................................ [___3]
   - Fair .......................................................................... [___4]
   - Poor .......................................................................... [___5]

The following items are about activities you might do during a typical day.

**Does your health now limit you in these activities?** If so, how much?

| (Please check one number per line.) |
|-------------------------------------|----------------|---------------|
| Yes, Limited a Lot                  | Yes, Limited a Little | No, Not Limited at All |

2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ........................................... [___1] [___2] [___3]

3. Climbing **several** flights of stairs (or climbing a hill).... [___1] [___2] [___3]

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities **AS A RESULT OF YOUR PHYSICAL HEALTH?**

| (Please check one answer per line.) |
|-------------------------------------|----------------|---------------|
| Yes                                 | No             |

4. **Accomplished less** than you would like .............................. [___1] [___2]

5. Were limited in the kind of work or other activities ................... [___1] [___2]

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities **AS A RESULT OF ANY EMOTIONAL PROBLEMS** (such as feeling depressed or anxious)?  **(Please check one answer per line.)**

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

6. **Accomplished less** than you would like .............................. [___1] [___2]

7. Didn't do work or other activities as carefully as usual............ [___1] [___2]
8. During the **PAST 4 WEEKS**, how much did pain interfere with your normal work, (including both work outside the home and housework)?

(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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Have you felt calm and peaceful?...

(Please check one number.)

| 1 | 2 | 3 | 4 | 5 | 6 |

10. Did you have a lot of energy?........

(Please check one number.)

| 1 | 2 | 3 | 4 | 5 | 6 |

11. Did you feel downhearted and blue? .......................................... 

(Please check one number.)

| 1 | 2 | 3 | 4 | 5 | 6 |

12. During the **PAST 4 WEEKS**, how much of the time has your PHYSICAL HEALTH or EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

(Please check one number.)

<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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ADMINISTRATIVE INFORMATION:**

13. Interviewer/reviewer code: 

14. Interview/review date: 

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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</thead>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

month | day | year
THE STRONG HEART STUDY V  
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CES-D SCALE

| SHS I.D.: |___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

How is this questionnaire administered?  By interviewer [ ] 1  By self [ ] 2  Refused [ ] 8

Here are some questions (Q1-Q20) 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.

<table>
<thead>
<tr>
<th>During the past week...</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 9</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>Statement</th>
<th>Rarely or Not at ALL</th>
<th>Some</th>
<th>Often</th>
<th>Most of the Time</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. I talked less than usual.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>14. I felt lonely.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>15. People were unfriendly.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>16. I enjoyed life.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>17. I had crying spells.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>18. I felt sad.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>19. I felt that people disliked me.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
<tr>
<td>20. I felt like I couldn't do what I needed to do.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
</tbody>
</table>

### During the past year . . .

<table>
<thead>
<tr>
<th>Statement</th>
<th>Rarely or Not at ALL</th>
<th>Some</th>
<th>Often</th>
<th>Most of the Time</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. I have felt depressed or sad.</td>
<td>[ ] 1</td>
<td>[ ] 2</td>
<td>[ ] 3</td>
<td>[ ] 4</td>
<td>[ ] 9</td>
</tr>
</tbody>
</table>

---

**ADMINISTRATIVE INFORMATION:**

22. Interviewer/reviewer code: [ ] [ ] [ ]

23. Interview/review date: [ ] [ ] [ ]

Month | Day | Year

Next, we ask about how much support you get from your family and friends. Here is a list of statements, which may or may not be true about you. For each statement, check the response that best describes you.

1. How often do you talk on the phone or get together with friends or relatives who do not live with you?
   - Every day ................................................................. [5]
   - A few times a week .................................................. [4]
   - A few times a month ................................................. [3]
   - Once a month ......................................................... [2]
   - Less than once a month, or ...................................... [1]
   - Never .......................................................................... [0]

   NOT MUCH AT ALL  SOME  A LOT
   1  2  3

2. How much do your friends or relatives really care about you—\textbf{a lot}, \textbf{some}, or \textbf{not much at all}?
   [1] [2] [3]

3. How much do they understand the way you feel about things?
   [1] [2] [3]

4. How much do they appreciate you?
   [1] [2] [3]

5. How much can you rely on them for help if you have a serious problem?
   [1] [2] [3]

6. How much can you talk to them about your worries?
   [1] [2] [3]

7. How much can you relax and be yourself around them?
   [1] [2] [3]
8. How often do your friends or relatives make too many demands on you—often, sometimes, or rarely/never?

|___|0 |___| 1 |___| 2

9. How often do they argue with you?

|___|1 |___| 2

10. How often do they criticize you?

|___|0 |___| 1 |___| 2

11. How often do they let you down when you are counting on them?

|___|0 |___| 1 |___| 2

12. How often do they get on your nerves?

|___|0 |___| 1 |___| 2

13. How often do they drink or use drugs too much?

|___|0 |___| 1 |___| 2

14. Among the people you know, is there someone . . .

|___|0 |___| 1

15. you can go with to play cards, or go to bingo, a powwow, or a community meeting?

|___|0 |___| 1

16. who would lend you money if you needed it in an emergency?

|___|0 |___| 1

17. who would lend you a car or drive you somewhere else if you really needed it?

|___|0 |___| 1

18. you could call who would bail you out if you were arrested and put in jail?

|___|0 |___| 1

19. you could count on to check in on you regularly?

|___|0 |___| 1

19. How isolated do you feel?

- 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 al..................................................................................... |   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

ADMINISTRATIVE INFORMATION:

22. Interviewer/reviewer code: |   |

23. Interview/review date: |   |/   |   |   |   |
   month day year
A. Many people experience very frightening events sometime during their lives. Sometimes these experiences can upset them so much that their health suffers. The following six questions ask whether you have experienced such an event, and, if so, whether it has led to lasting problems. If you prefer not to answer a question, you can skip it.

1. Have you ever had an extremely frightening, traumatic or horrible experience like being a victim of a violent crime, seriously injured in an accident, being assaulted, seeing someone seriously injured or killed, or being a victim of a natural disaster?

   Yes |___|1
   No |___|2

   (If you answered “NO,” go to section B.)

   During the past month:

2. Did you relive the traumatic experience through recurrent dreams, preoccupation or flashbacks?

   Yes |___|1
   No |___|2

3. Did you seem less interested than usual in important things, feel “out of it,” or did you have a hard time with your feelings or emotions?

   Yes |___|1
   No |___|2

4. Did you have problems sleeping, concentrating, or having a short temper?

   Yes |___|1
   No |___|2

5. Did you avoid any place or anything that reminded you of the original horrible event?

   Yes |___|1
   No |___|2

6. Did you have some of the above problems for more than one month?

   Yes |___|1
   No |___|2
B. Sometimes people have worries they cannot control that affect their lives. The next three questions ask about such worries. If you prefer not to answer a question you can skip it.

**During the past month:**

7. Have you persistently worried about several different things, such as: work, school, family, money, and others?
   
   Yes [___] 1   No [___] 2

8. Did you find it difficult to control your worrying?
   
   Yes [___] 1   No [___] 2

9. Did your persistent worrying or nervousness cause problems with your work or your dealings with other people?
   
   Yes [___] 1   No [___] 2

C. Many people find that spirituality or some form of religious practice is important to their health and well-being. Others are less concerned with such things. Next are some general questions about spirituality. If you ever feel that you would prefer not to answer a question, you can skip the question. Please check one answer.

10. How important is spirituality in your life?
    
    Very [___] 1  Somewhat [___] 2  Not very [___] 3  Not at all [___] 4

11. How often do you spend time on religious or spiritual practices?
    
    Every day [___] 1  Several times [___] 2  From time to time, occasionally [___] 3  Not at all [___] 4

Do you have children?

   Yes [___] 1   No [___] 2
(If “YES,” go to Q12)   (If “NO,” go to Q13)

12. How important is it to you that your children participate in some kind of religious or spiritual practices? **After answering, go to Q14.**
    
    Very [___] 1  Somewhat [___] 2  Not very [___] 3  Not at all [___] 4

13. If you had children, how important would it be to you that they participate in some kind of religious or spiritual practices?
    
    Very [___] 1  Somewhat [___] 2  Not very [___] 3  Not at all [___] 4

14. How often do you seek comfort or guidance through religious or spiritual means?
    
    Often [___] 1  Sometimes [___] 2  Rarely [___] 3  Never [___] 4
D. These next questions are about getting and controlling diabetes. If you prefer not to answer a question, you can skip it.

Please note: answer 15a and 15b if you do not have diabetes; answer 16a and 16b if you have diabetes.

Please answer if you DO NOT have diabetes:

15. a) I will probably get diabetes at some time in my life.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Somewhat agree</th>
<th>Somewhat disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

b) There is nothing I can do to prevent getting diabetes. After answering, go to Q17.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Somewhat agree</th>
<th>Somewhat disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

Please answer if you DO have diabetes:

16. a) I was destined to get diabetes at some time in my life.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Somewhat agree</th>
<th>Somewhat disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

b) There was nothing I could do to prevent getting diabetes.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Somewhat agree</th>
<th>Somewhat disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

Everyone, please answer:

17. Once someone develops diabetes, there is nothing that can be done to prevent it from getting worse.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Somewhat agree</th>
<th>Somewhat disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

ADMINISTRATIVE INFORMATION:

18. Interviewer code: |___|___|___|

19. Interview date: |___|___|/|___|___|/|___|___|___|___|

month day year
THE STRONG HEART STUDY V
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

PSYCHOSOCIAL CHECKLIST

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

Psychosocial questionnaires:

1. Did the participant finish **All** or **PART** of the psychosocial questionnaires?
   - Yes | |1 | *(go to Q3)*
   - No | |2 | *(go to Q2)*

2. Why were the psychosocial questionnaires not completed? *(check all that apply)*
   - Did not understand the questions ........................................................................................................... | |1 |
   - Did not have time to complete ............................................................................................................... | |2 |
   - Questions are inappropriate .................................................................................................................. | |3 |
   - Unable to answer ..................................................................................................................................... | |4 |
   - Other ........................................................................................................................................................ | |5 |

List:  ______________________________________________________________

**ADMINISTRATIVE INFORMATION:**

3. Interviewer code:  | | | | | |

4. Interview date:  | | | | | |
   - month
   - day
   - year
DIRECTIONS TO PARTICIPANTS FOR USING THE Pedometer

The ACCUSPLIT Pedometer measures movement. You are being asked to wear this pedometer EVERY DAY for a seven-day period from ______________ to ______________. The pedometer is worn on the hip and should be clipped to the waistband of your pants/skirt, underwear, or belt. Most importantly, the pedometer must be worn in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. **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 number of steps from the pedometer 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 **YELLOW** reset button so that the pedometer resets to “0”.
2. Record the time that you attached the pedometer in your pedometer record. Make sure to indicate am or pm.
3. Wear the pedometer on your hip (please see pictures above), make sure to keep it upright, and make sure that it remains firmly in place against your body.
4. **Wear the pedometer ALL DAY except when bathing, swimming, or in the rain (unless the pedometer is protected by clothing and will not get wet).** If you take off the pedometer for longer than 30 minutes, record the length of time it was off (minutes or hours) in your pedometer record.
5. At bedtime, take off the pedometer. Record in your pedometer record (a) the number of steps taken on the pedometer, and (b) the time you removed your pedometer. Make sure to indicate am or pm.
6. Please do not touch the **YELLOW** reset button during the day or you will erase your activity numbers.
7. **Keep the cover closed or the pedometer will not record your activity.**
8. Do not wear the pedometer in a pants, coat, or shirt pocket. The pedometer will not work correctly.
9. Please bring back or mail to us, in the self-addressed stamped envelope, the pedometer record after you have completed your week.
10. Please keep the pedometer as a token of our appreciation for your participation in the Strong Heart Family Study.

Thank you very much for your time and effort.
### The Strong Heart Study V
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

**SEVEN-DAY Pedometer Record**

<table>
<thead>
<tr>
<th>SHS I.D.:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: _______________________________________</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SHS Family I.D.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reminder:** Reset the pedometer to “0” every morning.

<table>
<thead>
<tr>
<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><strong>Date</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Day of week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Write time attached</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
</tr>
<tr>
<td>Please circle either am or pm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pedometer steps at bedtime</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Write time removed</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
<td><strong>pm</strong></td>
<td><strong>am</strong></td>
</tr>
<tr>
<td>Please circle either am or pm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you take off the pedometer for any reason for longer than 30 minutes?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please circle “Y” for yes or “N” for no.</td>
<td><strong>Y</strong></td>
<td><strong>N</strong></td>
<td><strong>Y</strong></td>
<td><strong>N</strong></td>
<td><strong>Y</strong></td>
<td><strong>N</strong></td>
</tr>
<tr>
<td>If yes, for how long (indicate minutes or hours)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Complete this question after completing the pedometer record.

Have your physical activity levels in the past seven (7) days been typical for you compared to your regular activity level?
Yes_____ No_____

If no, |___| more active than usual |___| less active than usual

Comments: ____________________________________________________________
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 Q3)  Refused |___|4 (Cite reasons for refusal in the space below)

Reasons for refusal: ____________________________________________________  Go to Q3

PRESCRIPTION MEDICATIONS

1. Copy the name of the medication, the strength in milligrams (mg), and the total number of doses prescribed per day, week or month. (Include pills, dermal patches, eye drops, creams, salves and injections.)

2. On the average during the last two weeks, how many of these pills did you take a day/week/month?

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Prescribed Number</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></td>
<td></td>
</tr>
</tbody>
</table>

| 1. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 2. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 3. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 4. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 5. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 6. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 7. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
| 8. _____________________________  ________________  ____ | ___ D W M | Y N___ D W M |
### PRESCRIPTION MEDICATIONS (cont.)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Number Prescribed</th>
<th>PRN Medicine?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<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>
</tr>
</tbody>
</table>

| 9. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 10. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 11. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 12. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 13. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 14. | ____________________________ | ________________ | _____ D W M Y N___ D W M |
| 15. | ____________________________ | ________________ | _____ D W M Y N___ D W M |

Number unable to transcribe: __________________________

### 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.)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Circle: day week, month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Print the first 20 letters. Please print clearly.</td>
<td>Write the decimal as one of the digits.</td>
</tr>
</tbody>
</table>

| 1. | ____________________________ | ________________ | _____ D W M |
| 2. | ____________________________ | ________________ | _____ D W M |
| 3. | ____________________________ | ________________ | _____ D W M |
| 4. | ____________________________ | ________________ | _____ D W M |
| 5. | ____________________________ | ________________ | _____ D W M |
| 6. | ____________________________ | ________________ | _____ D W M |
| 7. | ____________________________ | ________________ | _____ D W M |
| 8. | ____________________________ | ________________ | _____ D W M |
| 9. | ____________________________ | ________________ | _____ D W M |

4. On the average during the last two weeks, how many of these pills did you take a day/week/month?
OVER-THE-COUNTER MEDICATIONS (cont.)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Strength (mg)</th>
<th>Circle: day week, month</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments: _______________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

ADMINISTRATIVE INFORMATION:

5. Interviewer code: |___|___|___|

6. Interview date: |___|___|/|___|___|/|___|___|___|___| month day year
BLOOD PRESSURE:

1. Right arm circumference, measured in CENTIMETERS (cm) |___|___|___|___|___|___|
   *Midway between acromion and olecranon*

2. Cuff size (arm circumference in brackets)
   - Pediatric (under 24cm) |___|1
   - Large arm (33-41cm) |___|3
   - Regular arm (24-32cm) |___|2
   - Thigh (>41cm) |___|4

3. Pulse obliteration pressure |___|___|___|

4. Seated Blood Pressure
   - Systolic BP |___|___|___|___|___|___|
   - Diastolic BP |___|___|___|___|___|___|
   a) First Blood Pressure Measurement |___|___|___|
   b) Second Blood Pressure Measurement |___|___|___|
   c) Third Blood Pressure Measurement |___|___|___|

5. Were the above blood pressures taken from RIGHT arm? Yes |___|1
   - No |___|2
   a) If no, why?
      - Amputation |___|1
      - Wound/dressing |___|2
      - Cast |___|3
      - Refusal |___|8

6. Recorder ID: |___|___|___|
ANTHROPOMETRIC MEASUREMENTS:

<table>
<thead>
<tr>
<th>ENGLISH SYSTEM (inches/pounds)</th>
<th>METRIC SYSTEM (centimeters/kilograms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Weight (Standing) ...............</td>
<td>[___</td>
</tr>
<tr>
<td></td>
<td>[___</td>
</tr>
<tr>
<td>8. Height (Standing) ...............</td>
<td>[___</td>
</tr>
<tr>
<td></td>
<td>[___</td>
</tr>
<tr>
<td>9. Waist (Supine)...................</td>
<td>[___</td>
</tr>
<tr>
<td></td>
<td>[___</td>
</tr>
<tr>
<td>10. Hip circumference (Standing)...</td>
<td>[___</td>
</tr>
<tr>
<td></td>
<td>[___</td>
</tr>
</tbody>
</table>

IMPEDANCE MEASUREMENT:

11. a) Was impedance taken? Yes [___] (go to b) No [___]

   i) If “NO,” due to: Amputation [___] Wound/dressing [___] Cast [___] Refusal [___]

b) Taken on RIGHT side? Yes [___] No [___]

   i) If “NO,” due to: Amputation [___] Wound/dressing [___] Cast [___] Refusal [___]

c) Resistance [___|___|___]

d) Reactance [___|___|___]

ADMINISTRATIVE INFORMATION:

12. Interviewer code: [___|___|___]

13. Interviewer date: [___|___|___] [___|___|___] [___|___|___]
FOOD QUESTIONNAIRE

RESPONDENT ID #

TODAY'S DATE

Jan 2006
Feb 2007
Mar 2008
Apr 2009
May 2010
Jun 2011
Jul 2012
Aug 2013
Sep 2014
Oct 2015

ABOUT THIS SURVEY
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 write your name in this box.

INSTRUCTIONS
There are usually two kinds of questions to answer for each food:

1. 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 any of the food in the question.

2. 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 most like the serving size you usually eat. (If you don’t have pictures, A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.)

3. 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).

ABOUT YOU
SEX
- Male
- Female

AGE

WEIGHT
pounds

HEIGHT
feet

If female, are you pregnant or breastfeeding?
- No
- Yes
- Not female

HOW OFTEN IN THE PAST YEAR

HOW MUCH ON THOSE DAYS
SEE PORTION SIZE PICTURES FOR A-B-C-D

Apple juice

Rice

PLEASE DO NOT WRITE IN THIS AREA
This 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. We will ask you about different TYPES (low-fat, low-carb) at the end of the survey. Include all types (like low-fat, sugar-free). Later you can tell us which type you usually eat.

<table>
<thead>
<tr>
<th>Breakfast sandwiches with eggs, like Egg McMuffins</th>
<th>A FEW TIMES per YEAR</th>
<th>ONCE per MONTH</th>
<th>2-3 TIMES per MONTH</th>
<th>2-4 TIMES per WEEK</th>
<th>5-6 TIMES per WEEK</th>
<th>EVERY DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other eggs like scrambled, boiled or omelets (not egg substitutes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast sausage, including in sausage biscuits, or in breakfast sandwiches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancakes, waffles, French toast or Pop Tarts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooked cereals like oatmeal, grits or cream of wheat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cold cereals, ANY KIND, like corn flakes, fiber cereals, or sweetened cereals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk or milk substitutes on cereal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yogurt or frozen yogurt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese, sliced cheese or cheese spread, including on sandwiches</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>Bananas</th>
<th>How many each time</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apples or pears</td>
<td>How many each time</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Oranges or tangerines</td>
<td>How many each time</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Peaches or nectarines, fresh</td>
<td>How many</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Other fresh fruits like grapes, plums, honeydew, mango</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Canned fruit like applesauce, fruit cocktail, canned peaches or canned pineapple</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

**How often do you eat each of the following 3 fruits, just during the summer months when they are in season?**

<table>
<thead>
<tr>
<th>Cantaloupe, in season</th>
<th>How much</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strawberries or other berries, in season</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Watermelon, in season</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

**How often do you eat each of the following vegetables all year round, including fresh, frozen, canned or in stir-fry, at home or in a restaurant?**

<table>
<thead>
<tr>
<th>Broccoli</th>
<th>How much</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carrots, or mixed vegetables with carrots</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Corn</td>
<td>How much</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Food Item</td>
<td>A Few Times per Year</td>
<td>Once per Month</td>
<td>2-3 Times per Month</td>
<td>Once per Week</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
<td>-----------------------</td>
<td>----------------</td>
<td>---------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Green beans or green peas</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinach (cooked)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greens like collards, turnip greens, mustard greens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweet potatoes, yams</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>French fries, home fries, hash browns</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes not fried, including mashed, boiled, baked, or potato salad</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cole slaw, cabbage, Chinese cabbage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Green salad, lettuce salad</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw tomatoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salad dressing, any kind, regular or low-fat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other vegetable, like squash, cauliflower, okra, cooked peppers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refried beans or bean burritos</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pinto beans, black beans, chili with beans, baked beans</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetable stew (without meat)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetable soup, vegetable-beef soup, or tomato soup</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Split pea, bean or lentil soup</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other soup including chicken noodle, cream soups, Cup-A-Soup, ramen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pizza</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spaghetti, lasagna or other pasta with tomato sauce</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macaroni and cheese</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other noodles like egg noodles, paella, sopa seca</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tofu or tempeh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat substitutes like veggie burgers, veggie chicken, vegetarian hot dogs or vegetarian lunch meats</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Do you ever eat chicken, meat or fish?**
- Yes
- No

IF NO, SKIP TO BREADS ON NEXT PAGE

<table>
<thead>
<tr>
<th>Food Item</th>
<th>How much</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamburgers, cheeseburgers, at home or in a restaurant</td>
<td>A</td>
</tr>
<tr>
<td>Hot dogs, or sausage like Polish, Italian or chorizo</td>
<td></td>
</tr>
<tr>
<td>Food Description</td>
<td>FFQ Frequency</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Lunch meat like bologna, sliced ham, turkey bologna, or any other lunch meat</td>
<td>NEVER</td>
</tr>
<tr>
<td>Meat loaf, meat balls</td>
<td>NEVER</td>
</tr>
<tr>
<td>Steak, roast beef, or beef in frozen dinners or sandwiches</td>
<td>NEVER</td>
</tr>
<tr>
<td>Tacos, burritos, enchiladas, tamales, with meat or chicken</td>
<td>NEVER</td>
</tr>
<tr>
<td>Ribs, spare ribs</td>
<td>NEVER</td>
</tr>
<tr>
<td>Pork chops, pork roasts, cooked ham (including for breakfast)</td>
<td>NEVER</td>
</tr>
<tr>
<td>Veal, lamb, deer meat</td>
<td>NEVER</td>
</tr>
<tr>
<td>Liver, including chicken livers or liverwurst</td>
<td>NEVER</td>
</tr>
<tr>
<td>Pigs feet, neck bones, oxtails, tongue</td>
<td>NEVER</td>
</tr>
<tr>
<td>Menudo, pozole, caldo de res, sancocho, ajiaco</td>
<td>NEVER</td>
</tr>
<tr>
<td>Any other beef or pork dish, like beef stew, beef pot pie, corned beef hash,</td>
<td>NEVER</td>
</tr>
<tr>
<td>Hamburger Helper</td>
<td>NEVER</td>
</tr>
<tr>
<td>Fried chicken, including chicken nuggets, wings, chicken patty</td>
<td>NEVER</td>
</tr>
<tr>
<td>Roasted or broiled chicken or turkey</td>
<td>NEVER</td>
</tr>
<tr>
<td>Any other chicken dish, like chicken stew, chicken with noodles, chicken salad,</td>
<td>NEVER</td>
</tr>
<tr>
<td>Chinese chicken dishes</td>
<td>NEVER</td>
</tr>
<tr>
<td>Oysters</td>
<td>NEVER</td>
</tr>
<tr>
<td>Shellfish like shrimp, scallops, crabs</td>
<td>NEVER</td>
</tr>
<tr>
<td>Tuna, tuna salad, tuna casserole</td>
<td>NEVER</td>
</tr>
<tr>
<td>Fried fish or fish sandwich</td>
<td>NEVER</td>
</tr>
<tr>
<td>Other fish, not fried</td>
<td>NEVER</td>
</tr>
<tr>
<td><strong>BREADS</strong></td>
<td></td>
</tr>
<tr>
<td>Biscuits, muffins, croissants (not counting breakfast sandwiches with egg)</td>
<td>NEVER</td>
</tr>
<tr>
<td>Hamburger buns, hotdog buns, hoagie buns, submarine</td>
<td>NEVER</td>
</tr>
<tr>
<td>Bagels, English muffins, dinner rolls</td>
<td>NEVER</td>
</tr>
<tr>
<td>Tortillas (not counting those eaten in tacos or burritos)</td>
<td>NEVER</td>
</tr>
<tr>
<td>Corn bread, corn muffins, hush puppies</td>
<td>NEVER</td>
</tr>
<tr>
<td>Any other bread or toast, including white, dark, whole wheat, and what you have</td>
<td>NEVER</td>
</tr>
<tr>
<td>in sandwiches</td>
<td>NEVER</td>
</tr>
<tr>
<td>Rice, or dishes made with rice</td>
<td>NEVER</td>
</tr>
<tr>
<td>Food Description</td>
<td>A Few Times a Year</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Margarine (not butter) on bread or on vegetables</td>
<td></td>
</tr>
<tr>
<td>Butter (not margarine) on bread or on vegetables</td>
<td></td>
</tr>
<tr>
<td>Energy bars, like Power Bars, Clif bars, Balance, Luna, Atkins bars</td>
<td></td>
</tr>
<tr>
<td>Breakfast bars, cereal bars, granola bars (not energy bars)</td>
<td></td>
</tr>
<tr>
<td>Peanuts, sunflower seeds, other nuts or seeds</td>
<td></td>
</tr>
<tr>
<td>Peanut butter</td>
<td></td>
</tr>
<tr>
<td>Snack chips like potato chips, tortilla chips, Fritos, Doritos, popcorn (not pretzels)</td>
<td></td>
</tr>
<tr>
<td>Crackers, like Saltines, Cheez-Its, or any other snack cracker</td>
<td></td>
</tr>
<tr>
<td>Jelly, jam</td>
<td></td>
</tr>
<tr>
<td>Mayonnaise, sandwich spreads</td>
<td></td>
</tr>
<tr>
<td>Catsup, salsa or chile peppers</td>
<td></td>
</tr>
<tr>
<td>Mustard, barbecue sauce, soy sauce, gravy, other sauces</td>
<td></td>
</tr>
<tr>
<td>Donuts</td>
<td></td>
</tr>
<tr>
<td>Cake, or snack cakes like cupcakes, Ho-Hos, Entenmann’s, or any other pastry</td>
<td></td>
</tr>
<tr>
<td>Cookies</td>
<td></td>
</tr>
<tr>
<td>Ice cream, ice cream bars</td>
<td></td>
</tr>
<tr>
<td>Chocolate syrup or sauce (like in milk or on ice cream)</td>
<td></td>
</tr>
<tr>
<td>Pumpkin pie, sweet potato pie</td>
<td></td>
</tr>
<tr>
<td>Any other pie including fast food pies or snack pies</td>
<td></td>
</tr>
<tr>
<td>Chocolate candy like candy bars, M&amp;Ms, Reeses</td>
<td></td>
</tr>
<tr>
<td>Any other candy, not chocolate, like hard candy, Lifesavers, Skittles, Starburst</td>
<td></td>
</tr>
<tr>
<td>Glasses of milk (any kind, including soy), not counting on cereal or coffee</td>
<td></td>
</tr>
<tr>
<td>Drinks like Slim Fast, Seg, Slender, Ensure or Atkins</td>
<td></td>
</tr>
<tr>
<td>Tomato juice or V-8 juice</td>
<td></td>
</tr>
<tr>
<td>Real 100% orange juice or grapefruit juice. Don’t count orange soda or Sunny Delight</td>
<td></td>
</tr>
<tr>
<td>Apple juice, grape juice, pineapple juice or fruit smoothies</td>
<td></td>
</tr>
</tbody>
</table>

**How Much on Those Days**

See portion size pictures for A-B-C-D.

- How many pats (top): 0, 1, 2, 3, 4
- How many tablespoons: 0, 1/2, 1, 2, 3
- How much: A, B, C
- How many pieces: 1, 2, 3
- How many in a day: 0, 1-2, 3-4, 5+
### HOW MUCH on the days you drink it?

<table>
<thead>
<tr>
<th>Beverage Description</th>
<th>A Few Times Per Year</th>
<th>Once Per Month</th>
<th>2-3 Times Per Week</th>
<th>Once Per Week</th>
<th>2-3 Times Per Week</th>
<th>3-4 Times Per Week</th>
<th>5-6 Times Per Week</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hi-C, Cranberry Juice Cocktail, Hawaiian Punch, Tang, Kool-Aid, lemonade, sports</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>drinks like Gatorade, or fruit flavored drinks (not including iced teas)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any kind of soft drink, like cola, Sprite, orange soda, regular or diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beer or non-alcoholic beer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wine or wine coolers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquor or mixed drinks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasses of water, tap or bottled</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coffee, regular or decaf</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hot tea (not including herbal teas)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**What do you usually add to coffee?** MARK ONLY ONE:
- Cream or half & half
- Non-dairy creamer
- Milk
- None of these
- Don't drink it

**What do you usually add to tea?** MARK ONLY ONE:
- Cream or half & half
- Non-dairy creamer
- Milk
- None of these
- Don't drink it

**Do you usually add sugar (or honey) to coffee?**
- No
- Yes IF YES, how many teaspoons each cup?

**Do you usually add sugar (or honey) to tea?**
- No
- Yes IF YES, how many teaspoons each cup?

**About how many servings of vegetables do you eat, per day or per week, not counting salad or potatoes?**

**About how many servings of fruit do you eat, not counting juices?**

**How often do you use fat or oil in cooking?**

**PLEASE DO NOT WRITE IN THIS AREA**

**SERIAL #**

PAGE 6
### If you eat the following foods, what type do you usually eat? MARK ONLY ONE ANSWER FOR EACH QUESTION

<table>
<thead>
<tr>
<th>Food Type</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk</td>
<td>Whole milk</td>
</tr>
<tr>
<td></td>
<td>Reduced-fat 2% milk</td>
</tr>
<tr>
<td>Slim Fast, Sego, Slender or Ensure</td>
<td>Low-Carb like Atkins</td>
</tr>
<tr>
<td>Orange juice</td>
<td>Calcium-fortified</td>
</tr>
<tr>
<td>Soda or pop</td>
<td>Diet soda, low-calorie</td>
</tr>
<tr>
<td>Iced tea</td>
<td>Homemade, no sugar</td>
</tr>
<tr>
<td>Beer</td>
<td>Regular beer</td>
</tr>
<tr>
<td>Hamburgers or cheeseburgers</td>
<td>Hamburgers</td>
</tr>
<tr>
<td>Hot dogs</td>
<td>Low fat or turkey dogs</td>
</tr>
<tr>
<td>Lunch meats</td>
<td>Low-fat or turkey lunch meats</td>
</tr>
<tr>
<td>Spaghetti or lasagna</td>
<td>Meatless</td>
</tr>
<tr>
<td>Cheese</td>
<td>Low Fat</td>
</tr>
<tr>
<td>Salad dressing</td>
<td>Low-Carb</td>
</tr>
<tr>
<td>Energy bars like Power Bar, Clif, Atkins</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Breakfast bars, cereal bars, or granola bars</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Bread</td>
<td>100% whole wheat</td>
</tr>
<tr>
<td>Tortillas</td>
<td>Corn</td>
</tr>
<tr>
<td>Chocolate candy or chocolate candy bars</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Cookies</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Cake, snack cakes, and other pastries</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Ice cream</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Jelly or jam</td>
<td>Low-Carb, low sugar</td>
</tr>
<tr>
<td>Beef or pork</td>
<td>Avoid eating the fat</td>
</tr>
<tr>
<td>Chicken or Turkey</td>
<td>Avoid eating the skin</td>
</tr>
</tbody>
</table>

### What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO

<table>
<thead>
<tr>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don't know, or Pam</td>
</tr>
<tr>
<td>Butter</td>
</tr>
<tr>
<td>Butter/margarine blend</td>
</tr>
<tr>
<td>Stick margarine</td>
</tr>
<tr>
<td>Soft tub margarine</td>
</tr>
<tr>
<td>Low-fat margarine</td>
</tr>
<tr>
<td>Corn oil, vegetable oil</td>
</tr>
<tr>
<td>Olive oil or canola oil</td>
</tr>
<tr>
<td>Lard, fatback, bacon fat</td>
</tr>
<tr>
<td>Crisco</td>
</tr>
</tbody>
</table>

### If you eat cold cereals, what do you eat? Choose one or two that you eat most often. (If you usually just eat one kind, just choose one.)

<table>
<thead>
<tr>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-carb cereals like Atkins, Total</td>
</tr>
<tr>
<td>Low-Carb Special K</td>
</tr>
<tr>
<td>Fiber One</td>
</tr>
<tr>
<td>Other fiber cereals like Raisin Bran, Fruit-n-Fiber</td>
</tr>
<tr>
<td>Cheerios, Grape Nuts, Shredded</td>
</tr>
<tr>
<td>Product 10, Complete</td>
</tr>
<tr>
<td>Other cold cereals, like Corn Flakes, Rice Krispies, Special K</td>
</tr>
<tr>
<td>Wheat, Wheatsies, Wheat Chex</td>
</tr>
<tr>
<td>All Bran, Bran Buds</td>
</tr>
<tr>
<td>Other cold cereals, like Frosted Flakes, Froot Loops</td>
</tr>
<tr>
<td>Sweetened cereals, like Frosted Flakes, Frosted Flakes</td>
</tr>
</tbody>
</table>

---

The Strong Heart Study V - 05/23/2006  
Page 7 of 8  
FFQ
### What vitamin supplements do you take fairly regularly?

**Multiple Vitamins. Did you take...**

- Prenatal vitamins
- Regular Once-A-Day, Centrum, Thera-Gran, “senior” vitamins or house brands of multiple vitamins
- Stress-tablets or B-Complex type

**Single Vitamins, not part of multiple vitamins**

- Vitamin A (not beta-carotene)
- Beta-carotene
- Vitamin C
- Vitamin E
- Folic Acid, Folate
- Calcium or Tums
- Vitamin D, alone or combined with calcium
- Zinc
- Iron
- Selenium
- Omega-3, fish oil, flax seed oil

---

**HOW OFTEN**

<table>
<thead>
<tr>
<th>A FEW TIMES</th>
<th>1-3 TIMES</th>
<th>4-6 TIMES</th>
<th>EVERY DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>PER MONTH</td>
<td>PER WEEK</td>
<td>PER WEEK</td>
<td>PER WEEK</td>
</tr>
</tbody>
</table>

**FOR HOW MANY YEARS?**

- LESS THAN 1 YEAR
- 1 YEAR
- 2 YEARS
- 3-5 YEARS
- 5-9 YEARS
- 10+ YEARS

---

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, how many milligrams of vitamin C did you usually take, on the days you took it:

- [ ] 100
- [ ] 250
- [ ] 500
- [ ] 750
- [ ] 1000
- [ ] 1500
- [ ] 2000
- [ ] 3000
- [ ] 4000
- [ ] 6000
- [ ] 8000
- [ ] 10000
- [ ] 20000
- [ ] Don't know

If you took vitamin E, 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
- [ ] 4000
- [ ] 6000
- [ ] 8000
- [ ] 10000
- [ ] 20000
- [ ] Don't know

Did you take any of these supplements at least once a week?

- [ ] Ginkgo
- [ ] St. John’s Wort
- [ ] Echinacea
- [ ] Oatmeal
- [ ] Melatonin
- [ ] Glucosamine/Chondroitin
- [ ] Didn’t take these

---

### How often do you eat each of the following foods?

<table>
<thead>
<tr>
<th>A FEW TIMES</th>
<th>1-3 TIMES</th>
<th>4-6 TIMES</th>
<th>EVERY DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>PER YEAR</td>
<td>PER MONTH</td>
<td>PER WEEK</td>
</tr>
</tbody>
</table>

**How much each time**

See portion size pictures for A-B-C-D

- [ ] How much A
- [ ] How much B
- [ ] How much C
- [ ] How much D

---

**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]

**SERIAL #**
FOOD QUESTIONNAIRE

Serving Size Choices

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D:

A = 1/4 Cup of Food  B = 1/2 Cup of Food  C = 1 Cup of Food  D = 2 Cups of Food
APPENDIX  D

STRONG HEART STUDY

PHASE V

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 - CADD0
              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', '303352', '303354', '303355') 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' 'CADDO'
INT2_28='039' TRIBE='06' 'COMANCHE'
INT2_28='046' TRIBE='07' 'DELWARE'
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) ≥ 126

B. IMPAIRED FASTING GLUCOSE TOLERANCE (IFG):
   110 ≤ 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.
DEFINITION OF DIABETIC STATUS -- CONT'D

IV. DURATION OF DIABETES, FOR DIABETIC PATIENTS ONLY:

DURATION OF DM VARIES DEPEND ON WHICH DM CRITERIA WAS USING.

IF AGE OF DIABETES WAS DIAGNOSED (Q3f, MED27) WAS KNOWN,
DURATION OF DM = AGE AT EXAM - MED27

IV. DIABETES CONTROL, FOR DIABETIC PATIENTS ONLY:
POOR CONTROL --- HbA1c ≥ 9.6%  FAIR CONTROL --- HbA1c: 7.6-9.5%
GOOD CONTROL --- HbA1c: 6.0-7.5%  NON-DIABETIC --- HbA1c < 6.0%

V. DIABETES TREATMENT, FOR DIABETIC PATIENTS ONLY, MEDICAL HISTORY:
(B, I, O, N)

A. BOTH INSULIN AND ORAL AGENT:
TAKING BOTH INSULIN (ANY OF THE MEDICATION CODE, MED2, MED4
MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008') AND
HYPOGLYCEMIC AGENT (ANY OF THE MEDICATION CODE, MED2, MED4
MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682020') AT THE SAME
TIME.

B. INSULIN TREATMENT:
TAKING INSULIN CURRENTLY (ANY OF THE MEDICATION CODE, MED2,
MED4 MED6, MED8, MED10, MED12, MED14, OR MED16, IS '682008')

C. ORAL AGENT:
TAKING HYPOGLYCEMIC AGENT CURRENTLY (ANY OF THE MEDICATION
CODE, MED2, MED4 MED6, MED8, MED10, MED12, MED14, OR MED16, IS
'682020')
DEFINITION OF CORONARY HEART DISEASE:

I. ANGINA PECTORIS - DEFINED BY THE ROSE QUESTIONNAIRE:

ROSEAP=1 (YES): ROSE1='1' AND (ROSE2='1' OR ROSE2='3') AND ROSE4='1' AND ROSE5='1' AND ROSE6='1' AND (ROSE7A='1' OR ROSE7B='1' OR (ROSE7C='1' AND ROSE7D='1'))), ELSE

ROSEAP=0 (NO)

II. MYOCARDIAL INFARCTION

A. MEDICAL HISTORY
   1. HISTORY OF MI: Q31 IN MEDICAL HISTORY QUESTIONNAIRE MED37='1';
   2. POSSIBLE MI FROM ROSE QUESTIONNAIRE: Q9 ROSE9='1'.

B. CLINICAL ABNORMAL ECG: (DR. 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.X-1.2.X, 4.1.X, 5.1-5.2, 6.1 OR 7.1.X.
   c. MINNESOTA DEFINITE MI: 1.1.X OR 1.2.X EXCEPT (1.2.6 OR 1.2.8)
   d. MINNESOTA POSSIBLE MI: 1.1.X, 1.2.X, OR 1.3.X

2. MINOR ECG ABNORMALITIES - MINOR ST AND T-WAVE CHANGES.
   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>
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</tr>
<tr>
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<td>1, 2</td>
<td>1, 2</td>
<td>Q AND QS</td>
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<td>QRS AXIS</td>
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<td>HIGH R</td>
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<td>4-1-X</td>
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<td>1, 2</td>
<td>ST JUNCTION (J)</td>
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<td>2, 3, 4</td>
<td>STJ</td>
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<tr>
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<td>1, 2, 3, 4</td>
<td>1, 2, 3, 4</td>
<td>T-WAVE</td>
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<tr>
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<td></td>
<td>A-V CONDUCTION</td>
</tr>
<tr>
<td>7-X-X</td>
<td>1-1, 1-2, 2-1, 2-2, 3, 4, 5, 6, 7, 8</td>
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<td></td>
<td>VENTRICULAR CONDUCTION DEF</td>
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<td>8-X-X</td>
<td>1-1, 1-2, 1-3, 1-4, 1-5, 2-1, 2-2, 2-3, 2-4, 3-1, 3-2, 3-3, 3-4, 4-1, 4-2, 5-1, 5-2, 6-1, 6-2, 6-3, 6-4, 7, 8, 9</td>
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<td></td>
<td>ARRHYTHMIAS</td>
</tr>
<tr>
<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**
  ** VCDETECT: 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 1.2.6. and 1.2.8 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
Bruitis 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>
<th>Variable name</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Definite fatal MI</td>
<td>defmi and defmidt</td>
</tr>
<tr>
<td>02</td>
<td>Definite sudden death due to CHD</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Definite fatal CHD</td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>Possible fatal CHD</td>
<td></td>
</tr>
<tr>
<td>05</td>
<td>Definite fatal stroke</td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Possible fatal stroke</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Definite fatal CHF</td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Possible fatal CHF</td>
<td></td>
</tr>
<tr>
<td>09</td>
<td>Other fatal CVD</td>
<td></td>
</tr>
<tr>
<td>10 and after</td>
<td>non-CVD death</td>
<td></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>
</tr>
<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>
</tr>
<tr>
<td>07</td>
<td>Possible CHD</td>
<td>poschd and poschddt</td>
</tr>
<tr>
<td>08</td>
<td>TIA</td>
<td>shstia and shstiad</td>
</tr>
<tr>
<td>09</td>
<td>Other CVD</td>
<td>othcvd and othcvddt</td>
</tr>
</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)
(SxPMI_S, values: Y/N)

SHS-I ECG date: ecgdate
SHS-II ECG date: ecgdate2
SHS-III ECG date: ecgdate3 (to be added)

**NOTE:** In Dr. Howard's Rising Tide paper (Circulation, 1999; 99:2389-2395):

- **Non-fatal CVD:** defmi, defchd, defstk (morbidity decision: 1, 3, 6), and definite ECG MI (s2dmi_s='Y').
- **Fatal CVD:** mortality final decision (01-09).
- **ALL CVD:** combined fatal and non-fatal CVD.
DEFINITION OF HYPERTENSION

I. BLOOD PRESSURE: AVERAGE OF THE LAST TWO SITTING BLOOD PRESSURES FROM PHYSICAL EXAM, Q17, Q18, Q19, AND Q20

SYSTOLIC BLOOD PRESSURE - SBP = (EXAM27 + EXAM29) / 2
DIASTOLIC BLOOD PRESSURE - DBP = (EXAM28 + EXAM30) / 2
MEAN BLOOD PRESSURE - MBP = (2/3 SBP) + (1/3 DBP)

SXsbp, sXdbp

II. HYPERTENSION

A. WHO CRITERIA

SXwhohtn=('B', ‘N’, ‘Y’).

HYPERTENSION (‘Y’):
1. TAKING ANTIHYPERTENSIVE DRUG (MEDICATION CODE=‘2408’)
   OR
2. TAKING (DIURETICS ('4028'), OR BETA-BLOCKERS ('1216') OR CARDIAC ('2404') OR VASODILATOR ('2412')) AND HISTORY OF HYPERTENSION (MED19='1')
   OR
3. SYSTOLIC BLOOD PRESSURE > 160 mmHg
   OR
4. DIASTOLIC BLOOD PRESSURE > 95 mmHg

BORDERLINE HYPERTENSION (‘B’):
140 mmHg < SBP < 160 mmHg OR
90 mmHg < DBP < 95 mmHg

NORMOTENSIVE (‘N’):
SBP < 140 AND DBP < 90 AND NO ANTIHYPERTENSIVE TREATMENT.

B. US CRITERIA: sXushtn=('N', ‘Y’).

HYPERTENSION: WHO HYPERTENSION OR BORDERLINE HYPERTENSION
NORMOTENSIVE: SAME AS WHO NORMOTENSIVE.

============================================================================

1. HYPERTENSION:    DBP > 90 OR SBP > 140

2. DIASTOLIC HYPERTENSION:  DBP > 90 AND SBP < 140

3. ISOLATED SYSTOLIC HYPERTENSION: SBP > 140 AND DBP < 90

4. NORMOTENSIVE    SBP < 140 AND DBP < 90

============================================================================

DEFINITION OF ISOLATED HYPERTENSION:
1. HYPERTENSION: DBP ≥ 90 AND SBP ≥ 140
2. DIASTOLIC HYPERTENSION: DBP ≥ 90 AND SBP < 140
3. ISOLATED SYSTOLIC HYPERTENSION: SBP ≥ 140 AND DBP < 90
4. NORMOTENSIVE DBP < 140 AND SBP < 90

============================================================================

HYPERTENSION CONTROL, FOR HYPERTENSIVE PARTICIPANTS ONLY:
1. UNCONTROLLED HYPERTENSION: DPB ≥ 90 OR SBP ≥ 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

\[ sXrt_{aar} \text{ and } sXlt_{aar} \]

RIGHT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ANKLE.
\[ RANKBP = \frac{EXAM66 + EXAM68}{2} \]
LEFT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF LT ANKLE.
\[ LANKBP = \frac{EXAM70 + EXAM72}{2} \]
RIGHT ARMBP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT ARM.
\[ RARMBP = \frac{EXAM74 + EXAM75}{2} \]
\[ RPVD_{ABR} = \frac{RANKBP}{RARMBP} \]
\[ LPVD_{ABR} = \frac{LANKBP}{RARMBP} \]

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 \textbf{AND} POSTERIOR TIBIAL PULSE ON EITHER FOOT.
(PHYSICAL EXAM Q36-Q39),
\[ \text{PERIOCC}=1 \text{ (YES): } (\text{EXAM58}='2' \text{ AND EXAM60}='2') \text{ OR } (\text{EXAM59}='2' \text{ AND EXAM61}='2') \]
\[ \text{PERIOCC}=0 \text{ (NO): } \text{EXAM58}='1' \text{ AND EXAM59}='1' \text{ AND EXAM60}='1' \text{ AND EXAM61}='1' \]

III. PRESENCE OF FEMORAL BRUITS (BRUIT)
(PHYSICAL EXAM Q40-Q41)
\[ \text{BRUIT}=1 \text{ (YES): } \text{EXAM62}='1' \text{ OR EXAM63}='1' \]
\[ \text{BRUIT}=0 \text{ (NO): } \text{EXAM62}='2' \text{ AND EXAM63}='2' \]

IV. INTERMITTENT CLAUDICATION (MEDICAL HISTORY - ROSE QUESTIONNAIRE)
\[ \text{ROSEIC}=1 \text{ (YES): } \text{ROSE10}='1' \text{ AND ROSE11}='1' \text{ AND ROSE12}='1' \text{ AND (ROSE13='1' OR ROSE13='3') AND ROSE15='2' AND ROSE16='1' AND ROSE17='1' AND ROSE18='1', ELSE} \]
\[ \text{ROSEIC}=0 \text{ (NO): } \]

V. COMPOSITE PVD (PVD_COMP)
\[ \text{PVD_COMP 1 (YES): } \text{PVD_ABR}='1' \text{ OR PERIOCC}='1' \text{ OR BRUIT}='1' \text{ OR ROSEIC}='1' \]
\[ \text{PVD_COMP 0 (NO): } \text{PVD_ABR}='0' \text{ AND PERIOCC}='0' \text{ AND BRUIT}='0' \text{ AND ROSEIC}='0' \]
DEFINITION OF OBESITY INDICES, PHYSICAL EXAM:

A. BODY MASS INDEX, Q1 AND Q2, (WEIGHT IN KILOGRAM) / (HEIGHT IN METER)^2

\[ sXBMI = \frac{(EXAM94)}{(EXAM03/100)^2} \]

B. WAIST-HIP RATIO, Q33 AND Q9:

\[ sXWHR = \frac{EXAM51}{EXAM13} \]

C. PERCENT BODY FAT (sXPCTFAT):

(i) PCTFAT is calculated by using Rising's underwater equation as following:

\[ FFT = 13.74 + 0.25 \times (\text{height}^2 / \text{resistance}) + 0.30 \times \text{weight} - 0.14 \times \text{age} + 6.18 \times \text{sex} \]

where: height in cm, weight in kg, age in years, sex (0=female, 1=male)

\[ \text{fat mass (FM)} = \text{weight} - \text{FFT} \]

\[ \text{PCTFAT} = \left( \frac{\text{FM}}{\text{weight}} \right) \times 100\% \]

RESISTANCE: Q35a IN PHYSICAL EXAM

(ii) following equation was developed by Segal and used by IRAS

IF SEX='1' THEN \[ \text{FFM2} = 0.00132 \times \text{HT} \times \text{HT} - 0.04394 \times \text{RESIST} + 0.30520 \times \text{WT} - 0.1676 \times \text{AGE} + 22.66827; \]
ELSE
IF SEX='0' THEN \[ \text{FFM2} = 0.00108 \times \text{HT} \times \text{HT} - 0.0209 \times \text{RESIST} + 0.23199 \times \text{WT} - 0.06777 \times \text{AGE} + 14.59453; \]

where FFM2 is fat-free mass

\[ \text{PFAT}_SG = \text{ROUND}(100*(1-(\text{FFM2}/\text{WT})),.1); \]

(iii) the following equation was revised RJL for general population

IF SEX='1' THEN \[ \text{BODYH2O} = \exp(1.1782 \times \log(\text{HT}) - 0.5968 \times \log(\text{RESIST}) + 0.3226 \times \log(\text{WT})); \]
ELSE
IF SEX='0' THEN \[ \text{BODYH2O} = \exp(1.2004 \times \log(\text{HT}) - 0.5529 \times \log(\text{RESIST}) + 0.2164 \times \log(\text{WT})); \]

\[ \text{FFM3} = \text{BODYH2O} / 0.732; \]
\[ \text{FM3} = \text{WT} - \text{FFM3}; \]
\[ \text{PFAT}_RJL = \text{ROUND}((\text{FM3}/\text{WT})^{*}100),.1); \]
1. CIGARETTE SMOKING (PERSONAL INTERVIEW II, Q24-Q29):

A. SMOKING (NEVER, EX-SMOKER, CURRENT)

\[ SXsmoke = \{'E', 'N', 'Y'\} \]

- **N** (NEVER) IF INT2_34='2' OR INT2_35=0
- **E** (EX) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='2'
- **Y** (CURRENT) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='1'

\‘\‘ (UNKNOWN) NONE OF ABOVE

IF GROUP INTO SMOKER VS NONSMOKER, (SMOKING=0 OR SMOKING=1) CAN BE COMBINED AS NON-CURRENT SMOKER;

OR

(SMOKING=1 OR SMOKING=2) CAN BE COMBINED AS EVER SMOKED.

B. SMOKING AMOUNT (FOR SMOKER ONLY):

1. DURATION OF SMOKING: Q29 (INT2_39)

2. AGE STARTED SMOKING:
   - CURRENT SMOKER: AGE AT EXAM - DURATION OF SMOKING
   - EX-SMOKER: AGE STOPPED SMOKING (Q27) - DURATION OF SMOKING

3. DAILY SMOKING AMOUNT (Q28): INT2_38

4. TOTAL SMOKING AMOUNT (\(sXppy\), PER PACK YEAR):

   \[ PPy = \frac{(DAILY\ SMOKING\ AMOUNT \times DURATION\ OF\ SMOKING)}{20} = \frac{(INT2_38 \times INT2_39)}{20} \]

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:  \( s1edu = \text{INT2}_4 \) (YEARS)
   B. CATEGORICAL:
      i. THREE CATEGORIES (EDUCAT1):
         1 (LESS THAN HIGH SCHOOL)  \( 0 \leq \text{INT2}_4 < 12 \)
         2 (HIGH SCHOOL GRADUATE AND/OR SOME COLLEGE)  \( 12 \leq \text{INT2}_4 < 16 \)
         3 (COLLEGE GRADUATE)  \( \text{INT2}_4 \geq 16 \)
      ii. FOUR CATEGORIES (EDUCAT2):
         1 (LESS THAN NINE YEARS)  \( 0 \leq \text{INT2}_4 \leq 9 \)
         2 (SOME HIGH SCHOOL)  \( 10 \leq \text{INT2}_4 \leq 12 \)
         3 (SOME COLLEGE)  \( 13 \leq \text{INT2}_4 \leq 16 \)
         4 (COLLEGE GRADUATE)  \( \text{INT2}_4 \geq 16 \)

3. TOTAL DEGREE OF INDIAN BLOOD: INTERVIEW II, Q16
   A. CONTINUOUS:  \( \text{BLOODALL} = (\text{INT2}_5 / \text{INT2}_6) \times 100\% \)
   B. CATEGORICAL:
      0 (LESS THAN 25%)  \( 0 < \text{BLOODALL} < 25\% \)
      1 (LESS THAN 50%)  \( 25 \leq \text{BLOODALL} < 50\% \)
      2 (50-74.9%)  \( 50 \leq \text{BLOODALL} < 75\% \)
      3 (75-99.9%)  \( 75 \leq \text{BLOODALL} < 100\% \)
      4 (FULL BLOODED)  \( \text{BLOODALL} = 100\% \)

4. INDIAN TRADITION: INTERVIEW II, Q35-Q38
   A. SPEAK NATIVE LANGUAGE, INDYLANG
      0 (NO)  \( \text{INT2}_45 = '3' \) OR \( \text{INT2}_46 = '5' \)
      1 (YES) \( \text{INT2}_45 = '1' \) OR \( '2' \) AND \( \text{INT2}_46 = '1' \) OR \( '2' \) OR \( '3' \) OR \( '4' \)
   B. USE TRADITIONAL MEDICINE/HERBS, INDMED
      0 (NO)  \( \text{INT2}_47 = '5' \) OR \( '9' \)
      1 (YES) \( \text{INT2}_47 = '1' \) OR \( '2' \) OR \( '3' \) OR \( '4' \)
   C. TRADITIONAL CEREMONIES, INDYCERE
      0 (NO)  \( \text{INT2}_48 = '5' \) OR \( '9' \)
      1 (YES) \( \text{INT2}_48 = '1' \) OR \( '2' \) OR \( '3' \) OR \( '4' \)

5. STRESS: INTERVIEW II, Q42-Q46
   A. SLEEP LOSS, Q42, SLEPLOSS
      0 (NO)  \( \text{INT2}_52 = '1' \)
      1 (YES) \( \text{INT2}_52 = '2' \) OR \( '3' \)
   B. STRAIN OR STRESS, Q43, STRAIN
      0 (NO)  \( \text{INT2}_53 = '1' \)
      1 (YES) \( \text{INT2}_53 = '2' \) OR \( '3' \)
C. OPEN ARGUMENTS, Q44, QUARREL
0 (NO) \hspace{1cm} \text{INT2}_54='1' \hspace{0.5cm} \text{OR} \hspace{0.5cm} '2' \\
1 (YES) \hspace{1cm} \text{INT2}_54='3' \hspace{0.5cm} \text{OR} \hspace{0.5cm} '4' \hspace{0.5cm} \text{OR} \hspace{0.5cm} '5'

D. ALCOHOL PROBLEM OF HOUSEHOLD, Q45, HOUSETOH
0 (NO) \hspace{1cm} \text{INT2}_53='1' \\
1 (YES) \hspace{1cm} \text{INT2}_53='2'

E. SIZE OF HOUSEHOLD, Q46, HOUSSIZE
1 (SMALL) \hspace{1cm} \text{INT2}_54 \leq 4 \\
2 (MEDIUM) \hspace{0.5cm} 4 < \text{INT2}_54 < 10 \\
3 (LARGE) \hspace{0.5cm} \text{INT2}_54 \geq 10

6. ALCOHOL USE
A. ALCOHOL DRINKING STATUS, s\textsc{Xetoh}=('0', '1', '2'), Q47-Q48
0 (NEVER) \hspace{1cm} \text{INT2}_57='2' \\
1 (EX-DRINKER) \hspace{0.5cm} \text{INT2}_57='1' \hspace{0.5cm} \text{AND} \hspace{0.5cm} (\text{INT2}_59 \geq 12 \hspace{0.5cm} \text{OR} \hspace{0.5cm} \text{INT2}_60 \geq 1) \\
2 (CURRENT) \hspace{0.5cm} \text{INT2}_57='1' \hspace{0.5cm} \text{AND} \hspace{0.5cm} \text{INT2}_60 = 0

B. BINGE DRINK
1. DURING THE PAST MONTH, Q52
0 (NO) \hspace{1cm} \text{INT2}_64 < 5 \\
1 (YES) \hspace{1cm} \text{INT2}_64 \geq 5 \\

2. DURING THE PAST YEAR, Q53
0 (NO) \hspace{1cm} \text{INT2}_65 < 5 \\
1 (YES) \hspace{1cm} \text{INT2}_65 \geq 5

C. AMOUNT OF ALCOHOL INTAKE

Average weekly drinking amount: \hspace{1cm} \text{INT2}_61 \hspace{0.5cm} (\text{preferred \textsc{Etoh} variable}) \\

Average daily drinking amount: \hspace{1cm} \text{INT2}_63
7. **SOCIOECONOMIC STATUS (SES)**
   A. RECEIVING FEDERAL ASSISTANCE:
      1. FOOD STAMPS / WIC, Q56
         0 (NO) \( \text{INT2}_{68} = 0 \)
         1 (YES) \( \text{INT2}_{68} > 0 \)
      2. COMMODITY FOOD, Q57
         0 (NO) \( \text{INT2}_{69} = 0 \)
         1 (YES) \( \text{INT2}_{69} > 0 \)
      3. FEDERAL ASSISTANCE, FEDHELP
         0 (NO) \( \text{INT2}_{68} = 0 \) AND \( \text{INT2}_{69} = 0 \)
         1 (YES) \( \text{INT2}_{68} > 0 \) OR \( \text{INT2}_{69} > 0 \)
   B. SES (EDUCATION, FAMILY INCOME, ...)
9. MEDICAL HISTORY, MEDICAL HISTORY FORM

A. PRESCRIBED MEDICATIONS: USE CATEGORIES IN THE MANUAL (p. 282)

1- ANTIHISTAMINE (400)  
2- ANTIBIOTICS (812)  
3- ANTINEOPLASTIC RX (1000)  
4- BETA-BLOCKERS (1216)  
5- ANTICOAGULANTS (2000)  
6- CARDIAC DRUGS (2404)  
7- HYPOLIPIDEMIC (2406)  
8- HYPOTENSIVE (2408)  
9- ANALGESIC (2808)  
10- ASPIRIN (280892)  
11- ANTICONVULSANTS (2812)  
12- PSYCHOTHERAPY (2816)  
13- ADRENALS (6804)  
14- Oral Contraceptives (6812)  
15- DIURETICS (4028)  
16- GI DRUGS (5600)  
17- MENOPAUSAL ESTROGEN (6816)  
18- INSULIN (682008)  
19- SULFONYLUREAS (682020)  
20- THYROID AGENTS (6836)  
21- OINTMENTS (8400)  
22- VITAMINS (8800)  
23- UNCLASSIFIED (9200)

B. HISTORY OF:

1. GALLSTONE, Q3c
   0 (NO) MED22='2'  
   1 (YES) MED22='1'

2. ARTHRITIS, Q3d
   0 (NO) MED23='2'  
   1 (YES) MED23='1'

3. CANCER, Q3e
   0 (NO) MED24='2'  
   1 (YES) MED24='1'

4. KIDNEY FAILURE, Q3g
   0 (NO) MED28='2'  
   1 (YES) MED28='1'

5. EMPHYSEMA, Q3h
   0 (NO) MED31='2'  
   1 (YES) MED31='1'

6. LIVER CIRRHOSIS, Q3i
   0 (NO) MED32='2'  
   1 (YES) MED32='1'

7. RENAL DIALYSIS, Q4a
   0 (NO) MED42='2'  
   1 (YES) MED42='1'

8. KIDNEY TRANSPLANT, Q4b
   0 (NO) MED43='2'  
   1 (YES) MED43='1'
10. REPRODUCTION AND HORMONE USE (FEMALE ONLY), MEDICAL HISTORY

A. REPRODUCTION:
1. TIMES PREGNANT, Q7-1, REPRO1
2. NUMBER OF LIVE BIRTH, Q7-2, REPRO2
3. NUMBER OF LOST PREGNANCIES, Q7-3, REPRO3
4. NUMBER OF LIVING CHILDREN, Q7-4, REPRO4
5. MENOPAUSAL, Q8
   0 (NO)  REPRO5='2'
   1 (YES) REPRO5='1'
6. AGE AT MENOPAUSE, Q9, REPRO6

B. HORMONE USE
1. ORAL CONTRACEPTIVE, Q11
   0 (NO)  REPRO9='2'
   1 (YES) REPRO9='1'
2. AGE STARTED TO USE OC PILLS, Q12, REPRO10
3. TOTAL DURATION OF USING OC PILLS, Q13, REPRO11
4. EVER USE OF ESTROGEN OTHER THAN OC PILLS, Q14
   0 (NO)  REPRO12='2'
   1 (YES) REPRO12='1' OR MEDICATION CODE (Q1a-Q1h) CONTAINS '6816' (POST MENOPAUSAL ESTROGEN)
5. AGE STARTED TO USE ESTROGEN, Q15, REPRO13
6. TOTAL DURATION OF USING ESTROGEN, Q16, REPRO14
11. PHYSICAL ACTIVITY

WILL CONSULT WITH DR. ANDREA KRISKA

12. LAB DATA
A. LIPID - CONTINUOUS VARIABLE
   1. TOTAL TRIGLYCERIDE, ln(TRIG)
   2. TOTAL CHOLESTEROL, CHOLEST
   3. HDL CHOLESTEROL, HDL_CHOL
   4. LDL CHOLESTEROL, LDL_CHOL
   5. VLDL TRIGLYCERIDE, VTRIG
   6. VLDL CHOLESTEROL, VCHOL
   7. RATIOS:
      i. VCHOL/VTRIG
      ii. HDL_CHOL/CHOLEST
      iii. HDL_CHOL/LDL_CHOL
      iv. APOB/(CHOLEST-HDL_CHOL)
      v. APOA1/HDL_CHOL
      vi. APOB/LDL_CHOL

B. APOLIPOPROTEINS: APOA1, APOB

C. GLUCOSE:
   1. FASTING BLOOD GLUCOSE, GLUC_0
   2. 2-HR BLOOD GLUCOSE, GLUC_2

D. FIBRINOGEN

E. PLASMA INSULIN

F. FIBRINOGEN

G. APO E PHENOTYPE

H. PLASMA CREATININE

I. URINARY ALBUMIN AND CREATININE

J. GLYCATED LDL
### CUT POINTS FOR CONTINUOUS VARIABLES:

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>LOW (0)</th>
<th>MEDIUM (1)</th>
<th>HIGH (2)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>NO</td>
<td>YES</td>
<td></td>
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<tr>
<td>AGE/GP</td>
<td>45-54</td>
<td>55-64</td>
<td>65-74</td>
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<tr>
<td><strong>OBESITY: USING NHANES-II CRITERIA</strong></td>
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<td>In SHS-I:</td>
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<tr>
<td>OBESE FEMALE: BMI &gt; 32.3</td>
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<td>(95%)</td>
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<td>OVERWT FEMALE: BMI &gt; 27.8</td>
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<td>(85%)</td>
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<td>SHS-II and later:</td>
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<tr>
<td>Overweight: BMI 25-29.9</td>
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<tr>
<td>Obesity, level 1: BMI 30-34.9</td>
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<td>Obesity, level 2: BMI 35-39.9</td>
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<td>Obesity, level 3: BMI 40-44.9</td>
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<tr>
<td>Obesity, level 4: BMI 45 and above</td>
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<tr>
<td>**OBES_FAT FEMALE: PCTFAT &lt; 41%</td>
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<td>PCTFAT &gt; 41%</td>
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<tr>
<td>MALE: PCTFAT &lt; 29%</td>
<td></td>
<td>PCTFAT &gt; 29%</td>
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<tr>
<td>**OBES_WHR FEMALE: WHR &lt; 0.98</td>
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<td>WHR &gt; 0.98</td>
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<tr>
<td>MALE: WHR &lt; 0.96</td>
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<td>WHR &gt; 0.96</td>
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</tr>
<tr>
<td><strong>TOTAL CHOLESTEROL (NCEP GUIDELINE)</strong></td>
<td>CHOLES &lt; 200</td>
<td>CHOLES 200-239</td>
<td>CHOLES &gt; 240</td>
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<td>(mg/dl)</td>
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<tr>
<td><strong>TOTAL TRIGLYCERIDES 2001 Guideline</strong></td>
<td>TRIG &lt; 250 (mg/dl)</td>
<td>TRIG &gt; 250</td>
<td>TRIG &gt; 200</td>
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<td>TRIG &lt; 200 mg/dl</td>
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<tr>
<td><strong>HDL CHOLESTEROL (NCEP GUIDELINE)</strong></td>
<td>HDL_CHOL &lt; 35 (mg/dl)</td>
<td>HDL_CHOL &gt; 35</td>
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<td>(mg/dl)</td>
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<tr>
<td><strong>LDL CHOLESTEROL (NCEP GUIDELINE)</strong></td>
<td>LDL_CHOL &lt; 130 (mg/dl)</td>
<td>LDL_CHOL 130-159</td>
<td>LDL_CHOL &gt; 160</td>
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<td>(mg/dl)</td>
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The continuous variables may also be analyzed by quartiles.
APPENDIX E

STRONG HEART STUDY

PHASE V

Special Designs and Methods
Nested Case-Control Design:

For the Adiponectin and Thyroid case-control studies

**Design:** Nested case-control (case-control within an existing longitudinal study) Frequency matching is recommended.

Cases and controls are identified at the same point in time and previous exposure is examined for association with disease. After applying exclusion criteria, cases are selected. From the remaining pool of susceptibles, controls are selected. Controls are matched to cases based on the distribution of diabetes, study center, and gender among randomly selected cases. For instance, if 8% of the cases are women with diabetes from Arizona, then 8% of the controls will also be women with diabetes from Arizona.

**Exclusion Criteria:**
- Prevalent and incident CVD occurring from baseline to phase 2 and CVD cases identified at the phase 2 exam (ECGMI) will be excluded.
  - Prevalent and incident CVD, Fatal and Non-Fatal variables:
    - Deadcodes 1, 2, 3, 4, 7 & 8 (Definite MI, Definite Sudden death due to CHD, Definite and Possible CHD, Definite and Possible CHF)
    - ECG MI identified at phase 1 or phase 2 exam
    - Non-fatal CVD events between phases 1 and 2. (DEFMI and DEFCHD).
  - Anyone with renal disease - plasma creatinine level >1.2 mg/dL (from phase 2 lab data)
  - Anyone taking thyroid medication (at phase 2)
  - Anyone taking glucocorticoid (at phase 2)
  - Anyone taking troglitazone (at phase 2)
  - Prevalent and incident definite stroke, Fatal and Non-Fatal variables: Deadcodes 05 and 06, and DEFSTK

**Matching criteria:**
- Gender
- Study site
- Diabetes status (2 groups, diabetes and no diabetes), diabetes defined using ADA criteria: self report or taking oral diabetes medication or taking insulin or FG >= 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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