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

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

Individual's Consent for Participation in a Research Project

I, ________________________________________, voluntarily agree to participate in the study entitled: CARDIOVASCULAR DISEASE IN AMERICAN INDIANS (The Strong Heart Study Phase III), which is sponsored by the National Heart, Lung, and Blood Institute, under the supervision of Dr. Elisa T. Lee.

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

2. DESCRIPTION OF STUDY: You will be given an examination to identify diseases of the heart or blood vessels. The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. Your exam will be completed in one or possibly 2 visits, will take a total of about 3 to 4 hours, and will include the following:

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

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

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

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

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

Strong Heart Study III 6/1/97 II A- 1 Sample of Consent Form
Blood Pressure: Blood pressure and stiffness of blood vessels will be measured over your wrist using an experimental machine and computer program that have not been approved by the Food and Drug Administration. There are no known risks to you from these measurements. The information from this stiffness measurement will not be used in your medical care. This recording will also be read at Cornell University in New York.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

YOU MAY STOP PARTICIPATING
This study is designed to examine cardiovascular health in both you and your community. You are free to refuse to answer any or all of the questions in the health interview without losing your right to health care or any other benefit to which you are entitled; however, we hope you will answer all.
You may also withdraw or refuse any part of the exam without losing your right to health care or any other benefit to which you are entitled. However, your cooperation in completing as many of the tests as possible is appreciated and important in learning as much as possible about cardiovascular disease in American Indians.

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

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

If you have any questions about your rights as a research subject, you may take them to the Director of Research Administration, University of Oklahoma Health Sciences Center, Room 121, Library Building, telephone number (405) 271-2090 or to Mr. Samuel M. Hope, Chairperson, Oklahoma City Area IHS Institutional Review Board, Indian Health Service, Five Corporate Plaza, 3625 NW 56th Street, Oklahoma City, OK, 73112, telephone number (405) 951-3829.

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

Check all that apply:

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

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

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

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

______ Date ___________________________ Signature of Research Subject

______ Date ___________________________ Signature of Witness

______ Date ___________________________ Signature of the Principal Investigator
UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

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I, ____________________________, voluntarily agree to participate in the study entitled: CARDIOVASCULAR DISEASE IN AMERICAN INDIANS (The Strong Heart Study Phase III), which is sponsored by the National Heart, Lung, and Blood Institute, under the supervision of Dr. Elisa T. Lee.

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

2. DESCRIPTION OF STUDY: You will be given an examination to identify diseases of the heart or blood vessels. The results of your exam and related information in your medical records (Indian Health Service or other relevant medical records) will be used for research purposes. Your exam will be completed in one or possibly 2 visits, will take a total of about 3 to 4 hours, and will include the following:

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

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

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

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

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

Date __________________ Signature of Research Subject

Date __________________ Signature of Witness

Date __________________ Signature of the Principal Investigator
<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. Medical Release Signed</td>
<td></td>
</tr>
<tr>
<td>3. One Touch blood test, Reading</td>
<td></td>
</tr>
<tr>
<td>4. ProAct/Reflotron (if done), Reading</td>
<td></td>
</tr>
<tr>
<td>5. Fasting blood sample</td>
<td></td>
</tr>
<tr>
<td>6. Glutol</td>
<td></td>
</tr>
<tr>
<td>7. Urine sample</td>
<td></td>
</tr>
<tr>
<td>8. Two-hour blood sample</td>
<td></td>
</tr>
<tr>
<td>9. Personal interview forms</td>
<td></td>
</tr>
<tr>
<td>10. Gambling</td>
<td></td>
</tr>
<tr>
<td>11. Medication</td>
<td></td>
</tr>
<tr>
<td>12. Medical history form</td>
<td></td>
</tr>
<tr>
<td>13. ECG</td>
<td></td>
</tr>
<tr>
<td>14. Impedance measurement</td>
<td></td>
</tr>
<tr>
<td>15. Height and Weight</td>
<td></td>
</tr>
<tr>
<td>16. Abdominal, hip and arm circumference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>17.</td>
<td>Sitting blood pressure</td>
</tr>
<tr>
<td>18.</td>
<td>Doppler blood pressure</td>
</tr>
<tr>
<td>19.</td>
<td>Neuropathy tests</td>
</tr>
<tr>
<td>20.</td>
<td>Carbon monoxide</td>
</tr>
<tr>
<td>21.</td>
<td>Carotid Ultrasound</td>
</tr>
<tr>
<td>22.</td>
<td>Dietary survey</td>
</tr>
<tr>
<td>23.</td>
<td>Quality of life questionnaire</td>
</tr>
<tr>
<td>24.</td>
<td>Sleep Habit (family members)</td>
</tr>
<tr>
<td>25.</td>
<td>Physical Activity (family members)</td>
</tr>
<tr>
<td>26.</td>
<td>Payment or payment form</td>
</tr>
</tbody>
</table>
Appendix A -- 2(b)
STRONG HEART STUDY III
Post Exam Activities

Same Day:

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

Later:

Send carotid ultrasound tapes to reading centers
Make routine referrals
File confirmed ECG and ultrasound reports
Mail letters to patients
File laboratory findings in patients medical records
Mail laboratory specimens
Checklist for Quarterly Observation of BP Technicians

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

BP Technician Code # _______ Observer Code # _______

Date Observed / / (Month/Day/Year)

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

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

Special Comments: ____________________________________________________________
**Appendix A -- 4**  
**Recording Simultaneous Blood Pressure Observations On A Volunteer by Two Technicians**

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

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

<table>
<thead>
<tr>
<th>Technician IDs:</th>
<th>1st ID: ______</th>
<th>2nd ID: _______</th>
<th>Date: ______</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Technician</td>
<td></td>
<td>2nd Technician</td>
<td>Difference</td>
</tr>
<tr>
<td>a. Initial Arm Circumference (cm)</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>b. Initial Cuff Size Selected</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>c. Pulse Obliteration Pressure</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>d. First SBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>e. First DBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>f. Second SBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>g. Second DBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>h. Third SBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>i. Third DBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>j. Average SBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>k. Average DBP</td>
<td>______</td>
<td>______</td>
<td>______</td>
</tr>
</tbody>
</table>

Action taken if differences between technicians exceed limits specified:
Appendix A -- 5
Monthly Log for Sitting Blood Pressure Station

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

Monthly Check Procedures:

1. Sphygmomanometer:

   Date of Check

   Month

   1  2  3  4  5

   __________________________

   A. Check Tube for Oxide Dust

   B. Check Cap for Tightness

   C. Check that mercury is at zero with no pressure

List any problems found and corrective action taken:

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

Procedures performed only if there appear to be problems:
D. If mercury bounces even though the cap appears tight, remove cap, clean of any mercury beads, and check opening at top of tube for dust

Check Needed and Performed during weeks  
(Circle number of weeks applicable)

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

Needed and Performed during weeks

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

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

Month:

Date of check:

Point on height ruler where 30 cm on tape falls
Appendix A – 6

Maintenance Procedures for Standard Sphygmomanometer

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

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

2. The inflation system should then be reconnect, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:

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

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

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

Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.
Dear _____:

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

**Blood Pressure**

Your blood pressure was ______ (less than 140/90 and not taking medication for BP). This is within the normal range. It should be checked at least once a year.

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

Your blood pressure was ______ (less than 140/90, taking BP medication). This is within the normal range. Continue taking your blood pressure medication as directed by your medical care provider.

**Glucose Tolerance (Test for Diabetes)**

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

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

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

Your fasting blood sugar was ______ (known diabetic less than 200). On the day of the exam, your fasting blood sugar was under good control. Be sure to follow the advice of your medical care provider for control of your diabetes.

Your fasting blood sugar was ______ (known diabetic greater than 240). Your fasting blood sugar was higher than the usual target for diabetic patients. See your medical care provider for advice on how to attain better control.
Measurements of Blood Fats (Cholesterol and Triglycerides)

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

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

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

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

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

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

Electrocardiogram

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

Carotid Ultrasound

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

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

Body Fat

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

Carbon Monoxide in Your Breath

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

1) You were not exposed to carbon monoxide in the day prior to test (0-8 ppm).
2) You may have been exposed to tobacco smoke in the last day (9-14 ppm)

3) For smokers -- smoking may have caused you to have a high carbon monoxide level (15-50 ppm).

4) For non-smokers > 20 ppm, smoker > 50 ppm -- you may have been exposed to carbon monoxide from a faulty heater or car exhaust. You should have your carbon monoxide level retested and if it is still high, you should request assistance from your local environmental health office to determine if you have a faulty heater or car exhaust.

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

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

Sincerely,

SHS
Appendix A -- 8
Interpretation of Examination Results and Suggestions

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

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

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

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

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

Lipids: These are the fats measured in your blood.

Total cholesterol measures both good and bad cholesterol.

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

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

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

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

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

Glucose is blood sugar. Patients with diabetes have high blood sugars.
   Fasting glucose 140 or higher = Diabetes
   Fasting glucose less than 140 = Normal
Two hour post 75gm glucose load

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

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

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

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

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

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

- Poor control - 9.6% and above
- Fair control - 7.6% - 9.5%
- Good control - 6.0% - 7.5%
- Normal Value - 5.9% and below
Human Immunodeficiency Virus (HIV) and Hepatitis B

INTRODUCTION:

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

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

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

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

PURPOSE:

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

PREVENTION:

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

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

3. Specimens leaking from their containers should be discarded after requesting a replacement. In those cases in which the specimen is not replaceable, the outside of the soiled container should be disinfected with either a 1:10 sodium hypochlorite solution (household bleach) or Lysol spray and left standing for at least ten minutes before performing any laboratory procedure(s).
4. Every laboratorian should wear gloves and be dressed in a laboratory gown or uniform when handling and processing specimens. This will minimize the risk of contamination to exposed body parts or street clothing. Gloves should be worn and disposed of in accordance with the "Gloves (Proper Use and Disposal)" policy. Hands and other skin surfaces should be washed thoroughly and immediately after coming into contact with blood or body fluids.

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

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

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

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

9. To prevent transmission of HIV or HBV, the platform on the finger prick device (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 bio-hazard bags and autoclaved prior to final disposition by either incineration or sanitary carting.

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

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

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

FIRST AID AFTER CONTAMINATION OR LIKELY CONTAMINATION

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

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

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

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

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

REFERENCES:


### THE STRONG HEART STUDY III

**PHYSICIAN REFERRAL FORM FOR DIAGNOSIS OF CONGESTIVE HEART FAILURE**

**ID Number:**

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

### I. Major Criteria

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

### II. Minor Criteria

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

III. Major/Minor Criteria

<table>
<thead>
<tr>
<th>Present</th>
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<th>Not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss 4.5 kg in 5 days in response to treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IV. Tests that were performed on this patient.

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echocardiogram</td>
<td></td>
</tr>
<tr>
<td>Chest x-ray</td>
<td></td>
</tr>
<tr>
<td>Measurements of vital capacity</td>
<td></td>
</tr>
<tr>
<td>Measurements of venous pressure</td>
<td></td>
</tr>
</tbody>
</table>

In your opinion, does Mr./Ms. __________________________ have congestive heart failure?  

[ ] YES  [ ] NO

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

[ ] Valvular heart disease

[ ] Atherosclerotic heart disease

[ ] Cardiomyopathy

[ ] Other. Please specify: ________________________________________________________

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

We thank you very much for your assistance.

______________________________  ________________________
Signature                       Date

Strong Heart Study III 3/31/97
APPENDIX  B

INSTRUCTIONS FOR QUESTIONNAIRES AND DATA FORMS
Appendix B - 1
Strong Heart Study III
Instructions for the Personal Interview Forms I and II

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

<table>
<thead>
<tr>
<th>ITEM #</th>
<th>DESCRIPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Personal Interview Form I**

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

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

Write in community code from list.

Write in social security number.

A. Demographic Information

1  Enter last name, left justified.
   Enter first name, left justified.
   Enter middle name, left justified. If no middle name, leave blank.

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

3  Write down the participant’s marital status.

4  Write down the name of participant's spouse.

5  Ask whether her/his spouse also participated in the Strong Heart Study.

6a  Enter left justified with blank separating number from street name and street name from unit number. If post office box, enter after street address.

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

   c  Enter left justified, county of residence.

   d  Enter state of residence as two digit postal abbreviation.

   AZ= Arizona   SD= South Dakota
   OK= Oklahoma   ND= North Dakota
If residential address is different from the mailing address, write in the residential address following the rules given in item 7a-d.

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

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

Ask the participant where does she/he want the Strong Heart Study results sent.

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

**Personal Interview Form II**

A. WEIGHT CONTROL: questions about efforts to lose weight

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

11-12 Ask participant whether she/he want to gain or lose weight, and how is she/he doing it.

B. PHYSICAL ACTIVITY

13-14 Ask if the participant had any difficulty getting in or out of a bed or chair in Q13. Then, ask if he/she had been confined to bed or chair since last SHS examination because of injury or illness. If the answer is YES, fill in the number of **weeks** confined to bed or chair in Q14a.

15 Ask what condition(s) limit the participant’s activities and record them.

16 Ask participant how often during a typical week that he/she involved in activities required *mild effort* such as walking, gardening, yardwork, fishing, softball, etc..

17 Ask participant how often during a typical week that he/she involved in activities required *relative strenuous effort* such as digging, chopping wood, heavy construction, hauling hay, fixing fence, running and other strenuous sports, etc..

C. DENTURE AND EATING PROBLEMS

18 Ask participant how many natural teeth he/she still have.

19 Ask participant to describe how he/she eat.

20 Ask participant to rate his/her ability to chew food.
FAMILY INCOME

Questions 21-26 assess the family income so that the subject's socioeconomic status can be determined. Ask the questions as stated in the questionnaire. Prepare a sheet of income levels to show the participant.

21 Ask participant whether his/her household income meets his/her family's needs?
22 Ask what is the participant's main daily activity(s). Check up to three main activities.
23 Ask participant where is his/her source of income. Check all applicable answers.
24 Ask participant which source provides the most income from the answers provided in Q23.
25 Ask participant, on the average, how many hours per week he/she works for paid job(s).
26 Ask participant what is his/her annual household income.

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

27 This will determine how common ceremonial uses of tobacco is. Ceremonial tobacco use is probably not associated with adverse health effects.
28 Determine whether participant currently smokes cigarettes.
29 Determine average cigarettes smoked per day, which may have a significant effect on heart diseases and other health problems.
30 Ask the participant on the occasions which he/she is most likely to smoke or increase smoking.
31 Ask the participant on the occasion he/she increase smoking, how many cigarettes does/did he/she smoke per day.
32 Ask the participant whether he/she want to change smoking habit and how.
33 Determine when non-smoking participants quit smoking or if they are "never smokers" (smoked less than 100 cigarettes per day)
34 Ask the participant whether he/she quit smoking since last SHS exam. If the answer is "YES", ask when and why.
35 This question tries to find second-hand smoking. Ask participant, regardless of his/her smoking status, on the average, how many hours does he/she exposed to the smoke of others.
ALCOHOL Questions related to alcohol consumption are frequently not answered accurately in surveys. Questions included in this questionnaire have been widely used and validated in several national studies.

35 Question 35 determines when the individual last had any alcoholic beverage. If the last drink has less than 30 days fill in the box labeled number of days. If the last drink was within the last year, but more than 30 days fill in the number of months. If the last drink was over one year ago fill in the number of years. If the last drink was one or more years ago, skip to Q42.

36 Question 36 assesses the average number of drinks consumed in a typical week. Frequently individuals with severe drinking problems especially binge drinkers do not consume alcoholic beverages by the can, glass or shot, but rather drink wine or hard liquor out of a bottle. Record the type and frequency of drinks in the table.

37 Question 37 will tell you the frequency of alcoholic consumption. Many individuals with severe alcohol problems will only drink on the weekends (i.e., 8 days per month) or at the time of the month when they receive income. Assume 30 days a month.

38 Question 38 assess the quantity of average alcohol consumed in a day when participant drinks.

39 Ask the participant when he/she drinks more than the usual consumption, how much and how often.

40-41 Question 40-41 assess the frequency of binge drink in the past month and the past year, respectively.

42 Ask whether the participant use any of the substance for alcohol.

43 Question 43 assesses the reliability of the answers responded by the subject. Write down your personnel code number and the date of completion of interview.
<table>
<thead>
<tr>
<th>Tribe</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absentee-Shawnee tribe of Indians of Oklahoma</td>
<td>141</td>
</tr>
<tr>
<td>Agua-Caliente Band of Cahuilla Indians of the Agua-Caliente Indian Reservaton, Palm Springs, CA</td>
<td>263</td>
</tr>
<tr>
<td>Ak Chin Indian Comm. of Papago Indians of Maricopa, Ak Chin Reservation, Arizona</td>
<td>360</td>
</tr>
<tr>
<td>Alabama and Coushatta Tribes of Texas</td>
<td>223</td>
</tr>
<tr>
<td>Alabama-Quassarte Tribal Town of the Creek Nation of Ind. of Oklahoma</td>
<td>266</td>
</tr>
<tr>
<td>Alturas Indian Rancheria of Pit River Indians of California</td>
<td>385</td>
</tr>
<tr>
<td>Apache Tribe of Oklahoma</td>
<td>231</td>
</tr>
<tr>
<td>Arapahoe Tribe of the Wind River Reservation, Wyoming</td>
<td>011</td>
</tr>
<tr>
<td>Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana - Assiniboine</td>
<td>235</td>
</tr>
<tr>
<td>Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana - Sioux</td>
<td>276</td>
</tr>
<tr>
<td>Augustine Band of Cahuilla Mission Indians of the Augustine Reservation, California</td>
<td>255</td>
</tr>
<tr>
<td>Bad River Band of the Lake Superior Tribe of Chippewa Indian of the Bad River Res, WI</td>
<td>243</td>
</tr>
<tr>
<td>Barona Capitan Grande Band of Diegueno Mission Indians, Barona Reservation, California</td>
<td>330</td>
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<tr>
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Appendix B -- 3
The Strong Heart Study Phase III
Rationale and Instructions for Assessment of Physical Activity

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

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

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

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

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

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

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

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

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

The MAQ has been shown to be both reliable and valid (through comparisons with activity monitors, fitness (field) testing, and the doubly-labeled water technique) in adults and adolescents alike (Kriska, 1990; Schultz, 1994; Aaron, 1993). Test-retest reliability of the instrument was shown to be quite good with Spearman rank-order correlations ranging from 0.62 to 0.96 for individuals aged 10-60 yrs (Kriska, 1990). In addition, the past week section of the questionnaire was found to be related to the
Caltrac activity monitor (rho=0.62; p<0.05) to the same degree as that found in other similar studies comparing the two measures (Kriska, 1990). Finally, the cross-sectional relationship between reported physical activity levels as determined by this questionnaire and blood glucose, insulin, and obesity have been demonstrated in the Pima Indians as well as other populations (Pereira, 1995; Kriska, 1993; Kriska, Presented Abstract, 1994).

The versatility of the questionnaire is best demonstrated by the fact that modified versions of this questionnaire are being successfully used to estimate physical activity levels in a variety of populations:
- Pima Indian adults (Kriska, 1993, 1992, 1990);
- Pima children (Fontvieille, Kriska, and Ravussin; 1993);
- white and black adolescents (Aaron, Kriska, et al., 1993, 1995);
- populations in the South Pacific and Indian Oceans (Diabetes in the South Pacific: Environmental /Genetic Determinants; P. Zimmet, P.I.; A. Kriska, Co-Investigator);
- Nigerian civil servant workers (Epidemic Hypertension in Nigerian Workers. C. Bunker, P.I.; A. Kriska, Co-Investigator);
- Native Americans from across the country (Cardiovascular Disease in American Indians. B. Howard, E. Lee, and T. Welty, P.I.s);
- Virgin Islanders (E. Tull, P.I.; A. Kriska, Consultant);
- Canadian Indians (B. Zinman and S. Harris, P.I.s; A. Kriska, Collaborator);
- Cherokee Indians (E. Lee, P.I., A. Kriska, Collaborator);
- Natives Indians from Mexico (L. Schultz, PI).

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

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

MAQ-Inactivity Section: This activity questionnaire also assesses physical activity at the lower end of the activity curve, i.e., extreme inactivity, since it is possible that the effect of physical activity on glucose intolerance may only be observed at this level in some populations. In addition, the best way to compare subjectively determined physical activity levels between populations may be to examine the percent inactive (or completely sedentary) for each population. The specific questions used to investigate inactivity are provided in the general section of the MAQ (Kriska, 1992, 1990). As an example, the average number of HOURS per DAY usually spent watching television may be a potentially useful index of inactivity (Fontvieille, 1993). Finally, it may be necessary to identify those
individuals who reported that they had been confined to a bed or chair for more than one week over the past year as a result of an illness or injury in order to separate them from the individuals who were physically able to be physically active but chose to be sedentary.

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

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

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

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

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

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

**Past Year Leisure Activity Calculations**

\[
\text{Past Year hours/week} = (\# \text{ of mos checked}) \times (\text{times/mos}) \times (\text{minutes/time}) \div 52 \div 60.
\]

The hours/week of all activities are summed to determine the total hours/week over the past year. (Results can also be expressed in kcal · kg⁻¹ · wk⁻¹ by multiplying hours/week spent in each activity by the estimated MET value as was discussed above.)
Note: Because reported time spent walking for exercise has been found to be unreliable in many populations, it is recommended that the data are analyzed with and without inclusion of this leisure activity.

Past Year Occupational Activity Calculations

1. Past-year moderate activity (calculate only for job entries in which Column "B" is checked):
(mos/yr) x (4 weeks/mo) x (days/week) x (hours/day of moderate activity) ÷ 52 = hours/week averaged over the past year
   where hours/day of moderate activity = (hours/day - hours sitting) + (min/day of walking or pedaling a bike to work ÷ 60).

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

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

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

Total Physical Activity Calculations

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

REFERENCES:


Special Tips for Administration of the Modifiable Activity Questionnaire.

**Leisure Section:**

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

1. All activities identified from this list by the participant are written by the interviewer in the "Activity" column provided.

2. For each activity identified, the interviewer
   - checks off the months of the past year that the activity was performed.
   - enters the "Average # of Times per Month" and the "Average Number of Minutes" the activity was usually performed.

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

**Occupational Activity:**

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

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

1. Enter the names of all jobs in the "JOB NAME" column. The "occupations" homemaker, disabled, retired or unemployed should only be used if another job was not identified during that month.

2. Enter the number of months the participant performed each job over the past 12 months in the "MOS/YR" column. Account for all months of the year.

For each entry in the JOB NAME column, the interviewer will determine the following information:
3. Enter the "JOB CODE" that best describes the job using the list that appears below the matrix.

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

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

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

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

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

Modifiable Activity Questionnaire

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

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

Strong Heart Study III 3/31/97

Physical Assessment
Walking for exercise (outdoor, indoor at mall or fitness center, treadmill) ................................................................. 40

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>J</th>
<th>F</th>
<th>M</th>
<th>A</th>
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</table>

2. In general, how many HOURS per DAY do you usually spend watching television?  __________ hrs

3. Over this past year, have you spent more than one week confined to a bed or chair as a result of an injury, illness or surgery?
   Yes _______ No _______
   If yes, how many weeks over this past year were you confined to a bed or chair?  ______ weeks

4. Do you have difficulty doing any of the following activities?
   a. getting in or out of a bed or chair?  Yes ______ No ______
   b. walking across a small room without resting?  Yes ______ No ______
   c. walking for 10 minutes without resting?  Yes ______ No ______

5. Did you ever compete in an individual or team sport (not including any time spent in sports performed during school physical education classes)?
   If yes, how many total years did you participate in competitive sports?  ______

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

<table>
<thead>
<tr>
<th>Job Name</th>
<th>Job Code</th>
<th>Min/Day</th>
<th>Mos/Yr</th>
<th>Day/Wk</th>
<th>Hrs/Day</th>
<th>Hrs Sitting</th>
<th>Check the category that best describes job activities when not sitting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Category A</td>
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<td>Sitting</td>
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<td></td>
<td>Standing still w/o heavy lifting</td>
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<td></td>
<td></td>
<td>Light cleaning - ironing, cooking, washing, dusting</td>
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<td>Driving a bus, taxi, tractor</td>
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<td></td>
<td>Jewelry making/weaving</td>
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<td>General office work</td>
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<td></td>
<td></td>
<td>Occasional/short distance walking</td>
</tr>
</tbody>
</table>

|          |          |         |        |        |         |            | Category B                          |
|          |          |         |        |        |         |            | (includes most indoor activities)       |
|          |          |         |        |        |         |            | Carrying light loads                  |
|          |          |         |        |        |         |            | Continuous walking                    |
|          |          |         |        |        |         |            | Heavy cleaning - mopping, sweeping, scrubbing, vacuuming |
|          |          |         |        |        |         |            | Gardening - planting, weeding          |
|          |          |         |        |        |         |            | Painting/Plastering                    |
|          |          |         |        |        |         |            | Plumbing/Welding                       |
|          |          |         |        |        |         |            | Electrical work                        |
|          |          |         |        |        |         |            | Sheep herding                          |

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

**JOB CODES**

Not employed outside of the home:

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

Employed (or volunteer):

6. Armed Services
7. Office worker
8. Non-office Worker
Appendix B -- 4
THE STRONG HEART STUDY PHASE III
Instructions for Phase III Gambling Questionnaire

(Page 8 of the Personal Interview Form 2)

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

Question 1

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

Question 2

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

Question 3

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

Question 4

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

Question 5

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

Question 6

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

Question 7

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

Question 8
This question inquires about the largest amount bet in any single day. It means the total amount wagered that day in any one gambling session.
Appendix B -- 5
THE STRONG HEART STUDY PHASE III
Instructions for Medical History Interview

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

A. Current Medications

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

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

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

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

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

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

Strong Heart Study III 3/31/97 II B - 31 Instruction for Medical History
4. Rheumatic heart disease is a sequellae of rheumatic fever and typically stenosis or insufficiency (tightness or leakiness) of the valves of the heart.

5. Gallstones. If participants say they have had gall bladder removed check "yes" because almost all cholecystectomies are done for gallstones. All participants in Phase II had gall bladder ultrasound tests done. If gallstones were detected they should have been informed.

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

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

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

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

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

12. Lung problems. When inquiring about emphysema, the interviewer should also ask about difficulty in breathing. Participants with a chronic cough should be considered to have chronic bronchitis. If they have asthma, ask if they still have it.

13. Heart catheterization. Ask if patient had any kind of heart catheterization. If "yes," determine whether they had an angioplasty or other procedure, the date of the procedure and also the hospital where it was done. Using the Procedures and Tests Photocopy Check List, obtain the medical record of this procedure (the catheterization report and pictures) and the narrative hospital summary for review by the SHS Morbidity Review Panel. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center. This should not include use of a treadmill for exercise purposes. Show participant a picture of a diagnostic treadmill exercise test.

14. Treadmill test or exercise test to examine the heart. If "yes," determine the date of the procedure and the hospital where it was done. Using the Procedures and Tests Photocopy Check List, obtain the medical record of this procedure (the ECG paper from the test and the report) and the narrative hospital summary for review by the SHS Morbidity Review Panel. If the test included use of thallium, also obtain a copy of the nuclear medicine report. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS
occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center.

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

16. Heart Attack. When inquiring about heart attack, this would usually have involved hospitalization, but in some instances, the patient could have been told they had a heart attack in the past on the basis of an electrocardiogram. If the patient indicates that he/she had a heart attack, ask if there were more than one. Obtain information about each hospitalization and record in (o) below so that medical records can be reviewed for morbid event. Be sure to have participants sign the release forms for non-IHS hospitals, if hospitalizations occurred in the last ten years.

17. If the patient indicates that he/she has had other heart trouble, the interviewer should ask about the symptoms, because of the possibility that it may in fact fit in a, b or c above. If any of these procedures were done since Phase I exam, use the Procedures and Tests Photocopy Check List and obtain a copy of the test or operative report and the narrative hospital summary for review by the SHS Morbidity Review Panel. Be sure to have PARTICIPANTS sign the release forms for non-IHS HOSPITAL, if HOSPITALIZATIONS occurred since the Phase I examination. Attach the Photocopy Checklist to medical records materials and forward the packet to the Coordinating Center.

18. Stroke. Ask if the patient indicates that he/she has not had a stroke, ask also whether he/she has had any episode where he/she suddenly could not move a part of his/her body for a prolonged period of time. Obtain information about each hospitalization and record in (Question 20) below so that medical records can be reviewed for morbid event. Be sure to have participants sign the release forms for non-IHS hospitals, if hospitalizations occurred in the last ten years.

19. Surgery on chest. Question 19a is designed to ensure that we get accurate information on cardiac surgery so that medical records can be obtained. Use anatomical diagrams if available to help the participants recall the type of surgery they had.

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

20. First part: Check all sources of medical care that participant received in the last five years. Read all the items on the list. If the participant has not received any care in the last five years, check "nowhere". In the right hand column just check USUAL source of care.

21. Check all sources of health insurance coverage. Check "none" if the participant has no other coverage.

22. Just check the most frequent means that the participant gets to health care.
23. Record the dollar cost (nearest dollar) paid by the participant out of pocket to get to health care. If they drive their own vehicle, use $0.31/mile is a reasonable amount to calculate the cost for a round trip to the usual health care provider. Record "yes" if the CHR or family member provides transportation at no cost to the participant.

24. Record travel time (one way) to their usual source of care using the categories provided.

25. Record if the participant’s usual source of medical care needs an appointment for care.

26. Check the appropriate box for waiting time to see the health care provider.

27. If participant can be seen as walk-ins before a scheduled appointment record the time usually required to be seen by a physician or physician’s assistant (28a). If participant cannot be seen as a walk-in, record how long it takes to get an appointment (28b).

28. Record the usual cost they have to pay for an office visit out of pocket. For patients receiving care at an IHS or Tribal facility, this would usually be 0.
Appendix B -- 6(a)
The Strong Heart Study Phase III
Instructions for Reproduction and Hormone Use: Women Only
for SHS-I Cohort

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

1. Ask if the participant’s menstrual cycles have stopped.

2. When inquiring about menstrual cycles stopping permanently, this means for more than one year.

3-4. If the patient does not know how old she was when they stopped, ask if she remembers what year was the last year that she had a menstrual period. The interviewee should answer whether the menopause or the cessation of periods occurred naturally or whether it occurred after an operation to remove the womb or uterus. By referring to the patients' age and the year in which the periods stopped, then the interviewer can compute the age when they stopped completely.

5-7. Use questionnaire as written. If patients are currently taking estrogen pills or birth control pills, be sure they are recorded on the medication history.
Appendix B -- 6(b)
The Strong Heart Study Phase III
Instructions for Reproduction and Hormone Use: Women Only
SHS Family Study -- for SHS Family Members

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

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

5-7. Ask about use of birth control pills and be sure they are recorded on the medication history if they are currently taking them.

8. When inquiring about menstrual cycles stopping permanently, this means for more than one year.

9. If the patient does not know how old she was when they stopped, ask if she remembers what year was the last year that she had a menstrual period. By referring to the patients' age and the year in which the periods stopped, then the interviewer can compute the age when they stopped completely.

10-11. The interviewer should answer whether the menopause or the cessation of periods occurred naturally or whether it occurred after an operation to remove the womb or uterus.

12-14. Use questionnaire as written to obtain information about estrogen use. Be sure to record estrogen as part of the medication history if they are currently taking it.
Appendix B -- 7
The Strong Heart Study Phase III
Instructions for Use of the Rose Questionnaire
for Angina and Intermittent Claudication

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

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

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

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