FAMILY STUDY

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual - Volume Ten

TRAINING MANUAL

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

Cardiovascular Disease in American Indians (Phase IV)

Operations Manual

Volume Ten

TRAINING MANUAL

July 01, 2002

For copies, please contact

Strong Heart Study Coordinating Center

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STAFF TRAINING AND CERTIFICATION CHECKLIST

Trainee Name ________________________________

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<td>Weight</td>
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<td>Blood Pressures</td>
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<td>Diet - FFQ</td>
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<td>Doppler Blood Pressures</td>
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<td>ECG</td>
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<td>Personal Interview</td>
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SHS Phase IV Family Study

Quality Control Documentation

Trainee Name ________________________________

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INTERVIEWS
Interview Procedures

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

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

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

c. Read each question slowly.

d. Use correct intonation and emphasis.

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

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

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

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

i. Do not add apologies or explanations for questions unless they are printed in the questionnaire.

PROBING: Probes are additional questions asked or statements made by the interviewer when the answer given by a respondent is incomplete or irrelevant. Probing has two major functions: (1) To motivate the respondent to reply more fully; (2) to help the respondent focus on the specific content of the question. It must fulfill these functions without biasing the respondent's answers. However, probes, when they are used, MUST be neutral. Probing can introduce bias, such as by summarizing your understanding of the response to the subject when an unclear response has been given, or by offering some alternative interpretations from which the respondent can choose, and this must be guarded against.

The following are NON-DIRECTIVE methods of probing:

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

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

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

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

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

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

**Common Interviewer Errors**

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

The following are the common interviewer errors:

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

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

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

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

Training and Quality Assurance

PERSONAL INTERVIEWS

Training

Interviewers will be trained using a standardized procedure for administering each questionnaire. Training will include instructions in research interviewing techniques and in completing each form. Interviewer skill training will include:

a) adherence to the standardized protocol
b) use of non-judgmental attitudes
c) degree and nature of prompting
d) appropriate problem solving
e) proper handling of participants' comments and documenting relevant information on logs
f) post interview responsibilities

Quality Assurance

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

Checklist for Personal Interviews

The Study Coordinator will observe and tape one interview during the first exam month on interviews conducted by each interviewer and record the results below. As each procedure is carried out, indicate if it is correct by checking the "yes" or "no" column. Suggestions and comments can be written in the space provided. Quarterly observation will be followed after interviewers are certified and have demonstrated the standards of the study have been met.

<table>
<thead>
<tr>
<th>Interviewer code#</th>
<th>Date observed</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Observer code#</th>
<th></th>
</tr>
</thead>
</table>

- Establishes correct environment (for privacy and participant comfort).
  Yes____ No____
- Uses proper introduction of questionnaire and self (purpose of form/data).
  Yes____ No____
- Reassures participant: confidential_____ voluntary_____ can skip Q's_____  Yes____ No____
- Reads questions exactly as written, slowly, distinctly, in a neutral tone with no omissions or rewording.
  Yes____ No____
- Reads questions in correct order following skip patterns when required.
  Yes____ No____
- Conducts interview in understandable language for participant. If in native language, uses correct translations.
  Yes____ No____
- Repeats questions in full that are misheard or misunderstood.
  Yes____ No____
- Uses neutral probes non-directively and appropriately (using pauses, repeating answers, giving ranges, etc.)
  Yes____ No____
- Handles problem solving situations with proper interventions. (This includes participants’ questions.)
  Yes____ No____
- Remains nonjudgmental throughout interview.
  Yes____ No____
- Records answers correctly on forms. Edit forms before participant leaves clinic for any corrections.
  Yes____ No____
- Provides closure with participant (including expression of appreciation).
  Yes____ No____

Comments:________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
ANTHROPOMETRY
Procedure for Measuring Height, Weight, Waist and Hip Circumferences

1. Height and Weight

a) Standing Body Height

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

b) Body Weight

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

2. Supine Waist (Abdominal) Girth

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

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

4. Upper Arm Circumference

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

A Novel Products tension tape is used to measure both abdominal and hip girth and the upper arm circumference.
Figure 1. Frankfort Plane for Measuring Body Height

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

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

Supine waist girth at level of umbilicus
Figure 3. Location of Upper Arm, Hip, and Calf Circumference

Upper Arm Circumference

Hip Girth (at maximum protrusion of gluteal muscles)
SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

ANTHROPOMETRY

Training

Technician skill training will include:

a) Introduction - rationale for body size measurements
   - overview of technique
   - expected limits of reproducibility
   - pitfalls related to anthropometry
b) Demonstration - an expert demonstrates the proper technique of each measurement on a volunteer subject. This includes a description of proper and improper techniques, as well as how to record the data.
c) Practice - techs perform measurements on each other or on a volunteer under the observation of an experienced anthropometrist. Differences in technique and clarification of problems are discussed.
d) Testing - several subjects are assessed independently and blindly by each technician. The subjects should be from four distinctly different body type groups: lean, obese, athletic, and aged. Each tech's measurements are compared with the expert's measurements and the results are discussed with the tech.
e) Certification - technicians must measure one or more test subjects and be within the standards of error:
   1) The waist and hip measurements must agree within two cm on each subject, and the arm and height measurements must agree within one cm.
   2) The weight must agree within one kg.

Quality Assurance.

To insure consistency and accuracy, study coordinators will monitor technicians quarterly. Observation should include proper technique and accuracy within the standards of error listed above.
SHS PHASE IV FAMILY STUDY

Checklist for Anthropometry

The Study Coordinator will observe each technician quarterly. If each procedure is carried out correctly, indicate so by checking the "YES" space. Results of measurements should be within standard of error:
- The waist and hip measurements must agree within two cm on each subject, and the arm and height measurements must agree within one cm.
- The weight must agree within 1 kg.

Technician Code # / Initials ______________________
Observer Code # / Initials ______________________
Date Observed ______________________

<table>
<thead>
<tr>
<th>YES ( ) NO ( )</th>
<th>Technician</th>
<th>Observer</th>
<th>Difference</th>
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<tbody>
<tr>
<td>Tech instructs subject to remove shoes for height and weight.</td>
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<tr>
<td>Tech positions subject appropriately for height measurement.</td>
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<tr>
<td>Tech balances and zeroes the scale before subject is weighed.</td>
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<tr>
<td>Subject is weighed accurately to the nearest kg by the tech.</td>
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</tr>
<tr>
<td>Hip girth is measured accurately with the tape measure placed horizontally around the maximal protrusion of the gluteal muscles.</td>
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</tr>
<tr>
<td>Tech measures arm circumference accurately, rounding to the nearest cm.</td>
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<td></td>
</tr>
<tr>
<td>Tech correctly positions subject for waist measurement.</td>
<td></td>
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<tr>
<td>Measure of waist taken correctly, tape position at umbilicus.</td>
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ECG
SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

STANDARD ECG

Training

Technician skill training will include:

a) procedure for recording baseline ECG
b) electrode position measuring and marking
c) chest lead placement
d) limb lead placement
e) skin preparation
f) application of electrodes
g) recording the 12 - lead ECG

Standard ECG instruction follows this section and is found in the SHS Phase IV MANUAL.

Quality Assurance.

The study coordinator will monitor the ECG technicians quarterly to insure accurate and consistent examinations. Observation should include evaluation of all the criteria listed above and should be recorded on the Checklist for ECGs.
SHS PHASE IV FAMILY STUDY

Checklist for ECGs

The study coordinator will monitor ECG technicians quarterly to assure consistent, accurate examinations. If each procedure is carried out correctly, indicate so by checking the "YES" space.

Technician Code # / Initials ________________

Observer Code # / Initials ________________

Date Observed ________________

YES ( ) NO ( ) Subject is instructed to disrobe to the waist, lay supine in a relaxed position and to avoid movement during recording.

YES ( ) NO ( ) Chest electrodes are positioned correctly.

YES ( ) NO ( ) Limb electrodes are positioned correctly.

YES ( ) NO ( ) Skin preparation is used for poor electrode adhesion

YES ( ) NO ( ) Electrodes left in place 2-3 minutes before recording.

YES ( ) NO ( ) Subject information correctly entered into MAC PC.

YES ( ) NO ( ) Appropriate recording of ECG performed.

YES ( ) NO ( ) Recording repeated if artifact on tracing, subject encouraged to relax.

Comments: ____________________________________________

_________________________________________________________________

_________________________________________________________________

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_________________________________________________________________
BLOOD PRESSURES
Procedures for Taking Blood Pressures

1. Determine Cuffs

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

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

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

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

2. Measurement Procedures

The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 minutes to make three blood pressure measurements including the initial five-minute rest. The blood pressure measurements are made early in the clinic visit sequence immediately following the reception and informed consent, and more than 15 minutes after phlebotomy.

Once the participant is given instructions and explanations and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

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

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

c) Palpate the brachial artery (just medial to and above the ante-cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five-minute wait.
d) Record the time. Allow a five-minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary.

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

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

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

To assure accuracy, the second and third blood pressure readings are averaged using a calculator.

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

3. Procedure for changing the peak inflation level

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

Training and Quality Assurance

BLOOD PRESSURE MEASUREMENT

Training

Skill training will include:

a) Patient instruction, allowing opportunity for questions
b) Measure right arm for correct cuff size
c) Palpate brachial artery, medial to and above antecubital fossa
d) Mark pulse point
e) Wrap cuff, center of bladder over brachial pulse
f) Leave subject for five minutes of rest
g) Position subject, instruct subject on posture (sit upright with right arm bent at elbow, legs uncrossed)
h) Allow full five minutes for rest
i) Environment free of excessive noise
j) Find pulse obliteration point using standard manometer
k) Calculate peak inflation, 30 mmHg above pulse obliteration point
l) Place stethoscope in ears
m) Inflate cuff rapidly to calculated peak
n) Count full five seconds with pressure steady
o) Place bell on brachial pulse
p) Deflate cuff slowly, 2 mmHg per second
q) Deflate cuff rapidly after 2 absent sounds
r) Record reading
s) Disconnect tubes
t) Instruct subject to hold right arm vertical for full five seconds
u) Wait at least 30 seconds before proceeding to 2\textsuperscript{nd} and 3\textsuperscript{rd} readings
v) Average 2\textsuperscript{nd} and 3\textsuperscript{rd} readings, inform subject of average BP

Quality Assurance.

To insure consistent and accurate measurements, the study coordinator will observe technicians quarterly. They should demonstrate proper technique as listed above. The study coordinator should record his/her observations and comments on the BP checklist. Also, quarterly, each tech should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to the Simultaneous BP Observation Form and should calculate the differences between the two sets of measurements. The standard of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.
SHS PHASE IV FAMILY STUDY

Checklist for Blood Pressure

Technician Code # / Initials _______________________

Observer Code # / Initials _______________________

Date Observed _______________________

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

Comments: ______________________________________

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SHS PHASE IV FAMILY STUDY

Simultaneous Blood Pressure Observation Form

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

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Strong Heart Study IV   07/01/2002   X-25   Training Manual
PEDAL PULSES
AND EDEMA
Examination of Edema and Pedal Pulses

1. **Ankle Edema**

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

2. **Posterior Tibial Pulse**

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

3. **Dorsalis Pedis Pulse**

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

EXAMINATION OF PEDAL PULSES AND EDEMA

Training

Technician instruction will include:

a) rationale for exams
b) visualization and palpation of lower extremities for edema
c) palpation of posterior tibial pulses
d) palpation of dorsalis pedis pulses

Quality Assurance

Observation of technicians should be done quarterly. Evaluation should include all of the criteria listed above and should be recorded on the Q. A. Checklist.
SHS PHASE IV FAMILY STUDY

Checklist for Pedal Pulses and Edema

Observation of technicians should be performed quarterly. If each step in the list below is carried out correctly, mark the “YES” space.

Technician Code # / Initials _______________________

Observer Code # / Initials _______________________

Date Observed _______________________

YES ( ) NO ( ) Positions subject supine.

YES ( ) NO ( ) Examines and palpates lower extremities for edema.

YES ( ) NO ( ) Records status of edema.

YES ( ) NO ( ) Palpates posterior tibial pulses, bilaterally. (Posterior and inferior to the medial malleolus)

YES ( ) NO ( ) Palpates dorsalis pedis pulses, bilaterally. (Superior aspect of each foot)

YES ( ) NO ( ) Records presence or absence of pulses.

Comments: ________________________________

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IMPEDANCE
Procedure for Impedance Measure

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

1. Explain to the participant why you are making the measurement.

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

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

4. For best results:
   i) Use electrodes only once.

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

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

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

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

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

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

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

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

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

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

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

IMPEDANCE

Training

Technician instruction will include:

a) rationale for body composition estimate measurement
b) use of equipment and supplies needed
c) explanation to subject
d) positioning of subject
e) electrode placement
f) recording of resistance and reactance results

The complete, detailed procedure is located in the SHS PHASE IV MANUAL.

Quality Assurance

An individual at each study center will be designated as the supervisor of the impedance measures. The supervisor will assure that each of the other operators of the instruments is re-certified quarterly by having him/her perform an impedance measure on the same subject as the supervisor. The observation of the operators should include evaluation of all criteria listed above and should be recorded on the Checklist for Impedance. The measurement results should agree within 15 ohms.
**SHS PHASE IV FAMILY STUDY**

**Checklist for Impedance**

The Impedance supervisor will monitor each of the other operators of the instrument quarterly. The observation of the operators should include the following criteria. If performed accurately, mark the "YES" space.

<table>
<thead>
<tr>
<th>Technician Code # / Initials</th>
<th>Observer Code # / Initials</th>
<th>Date Observed</th>
<th>YES (   )  NO (   )</th>
<th>Explains procedure to subject.</th>
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<td>YES (   )  NO (   )</td>
<td>Questions subject about recent exercise and alcohol consumption.</td>
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<td>YES (   )  NO (   )</td>
<td>Asks subject to remove right shoe and sock.</td>
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<td>YES (   )  NO (   )</td>
<td>Positions subject supine, with right side nearest to analyzer.</td>
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<td>YES (   )  NO (   )</td>
<td>Assures that there is no skin to skin contact at axillas, thighs, abdomen.</td>
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<td>YES (   )  NO (   )</td>
<td>Assures that arms are placed to subject’s side without hands touching anything.</td>
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<td>YES (   )  NO (   )</td>
<td>Electrodes placed correctly.</td>
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<td>YES (   )  NO (   )</td>
<td>Leads connected correctly.</td>
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<td></td>
<td>YES (   )  NO (   )</td>
<td>Records resistance and reactance.</td>
</tr>
</tbody>
</table>

**Comments:** __________________________________________________________

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DOPPLER BP
Using Doppler to Measure Ankle Systolic Blood Pressure

1. Move the Participant to the Supine Position

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

2. Applying the Blood Pressure Cuff

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

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

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

3. Procedure for Measuring Ankle Blood Pressure

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

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

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

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

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

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

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

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

The observer now removes all conduction jelly. Socks and a robe or other garments are now
replaced, and the participant is escorted to the next workstation.
Figure 4. Placement of the Blood Pressure Cuff on the Ankle
Step I. Positioning the Lower Leg on the Cuff

- velcro "fabric on reverse"
- lower leg centered on cuff
- velcro "hocks"
- medial malleolus
- hoses to sphygmomanometer
- back of heel
- posterior tibial artery
- exam table
- calf
Figure 5  Placement of the Blood Pressure Cuff on the Ankle

Steps II and III: Wrapping and Securing the Cuff

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

Step 3. Wrap and secure cuff

"ears" about equal
SHS PHASE IV FAMILY STUDY

Training and Quality Assurance

DOPPLER BLOOD PRESSURE

Training

Technician instruction will include:

a) rationale for ankle systolic blood pressure
b) explanation to subject
c) positioning of subject
d) blood pressure cuff size selection
e) application of cuff - right ankle, left ankle, right arm
f) palpation of pulse, marking location, application of ultrasound gel
g) listening for pulse using IMEX Elite 100 DOPPLER
h) cuff inflation to peak pressure (50 mmHg higher than pulse obliteration pressure of sitting right arm measurement)
i) recording of the first pulse sound
j) repeat for a second pressure
k) perform on right ankle, left ankle, and right arm (if sitting BP was taken on the right arm)

Quality Assurance

Observation of technicians will be done quarterly by the Study Coordinator. Performance by the tech should include all of the criteria listed above, the evaluation should be recorded on the checklist for Doppler Blood Pressures. The tech's results should be within 4 mmHg of the coordinator's pressure results.
SHS PHASE IV FAMILY STUDY

Checklist for Doppler Blood Pressures

The Study Coordinator will observe technicians quarterly. Performance by the technician should include the following steps. If each step is completed correctly, mark the "YES" space.

Technician Code # / Initials ____________________________

Observer Code # / Initials ____________________________

Date Observed ____________________________

YES ( ) NO ( ) Explains procedure to subject.
YES ( ) NO ( ) Positions subject, supine.
YES ( ) NO ( ) Selects appropriate cuff size.
YES ( ) NO ( ) Applies cuff correctly, right ankle, left ankle, right arm.
YES ( ) NO ( ) Palpates pulse, marks location, and applies ultrasound gel.
YES ( ) NO ( ) Listens for pulse using IMEX Elite 100 DOPPLER.
YES ( ) NO ( ) Inflates cuff to calculated peak pressure.
YES ( ) NO ( ) Records the first pulse sound.
YES ( ) NO ( ) Repeats for second pressure.
YES ( ) NO ( ) Performs on right ankle, left ankle, and right arm (if sitting BP was taken on right arm).

Comments: ______________________________________________________________________________________
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<tr>
<th></th>
<th>Technician</th>
<th>Observer</th>
<th>Difference</th>
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<td>Left Ankle</td>
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<td>Right Arm</td>
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DIGIWALKER
PEDOMETER
DIRECTIONS TO PARTICIPANTS FOR USING THE Pedometer

The Accusplit Activity Meter (pedometer) counts the number of steps taken while walking. You have been requested to wear this meter EVERY DAY for a seven day period from

( the day after exam ) to ( the seventh days of wearing ). The pedometer is to be clipped at the waist to your clothes, underwear, or on a belt and worn on the ________ hip and must be kept in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. You can use a belt or elastic strap to keep it in place on your hip. Please DO NOT LET THE Pedometer GET WET by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in the morning and to record the pedometer number in your activity record when you take it off at night.

If you have any questions, please contact:

_____________________________________ at ____________________________________.

Specific Instructions

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

Thank you very much for your time and effort!
SHS PHASE IV FAMILY STUDY

Checklist for Digiwalker Pedometer

Technicians should be observed quarterly administering the pedometer instructions. If each item below is carried out correctly, mark the "YES" space.

Technician Code # / Initials _______________________

Observer Code # / Initials _______________________

Date Observed _______________________

Instructs participant with the following information:

YES ( ) NO ( ) Explains purpose of pedometer measurement.
YES ( ) NO ( ) Must wear for seven days.
YES ( ) NO ( ) Push the reset button every AM to read “0”.
YES ( ) NO ( ) Record the current time on the activity record page.
YES ( ) NO ( ) Keep the pedometer on all day. Record length of time if taken off.
YES ( ) NO ( ) Do not get the pedometer wet.
YES ( ) NO ( ) Remove pedometer and record meter number on activity record page.
YES ( ) NO ( ) Record the time removed on activity page record.
YES ( ) NO ( ) Do not touch the button during the day.
YES ( ) NO ( ) Wear the pedometer firmly on dominant hip.
YES ( ) NO ( ) Keep the cover closed.
YES ( ) NO ( ) Do not wear in pocket or sideways.
YES ( ) NO ( ) Mail the record or arrange for pick up.

Comments: __________________________________________

_____________________________________________________

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### Equipment – Quality Assurance Checklist

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*SHS Phase IV Family Study*

*ARIZONA FIELD CENTER*

*DAKOTA FIELD CENTER*

*OKLAHOMA FIELD CENTER*
IMPEDANCE
# SHS Phase IV Family Study

## IMPEDANCE QUALITY CONTROL

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ONE TOUCH
SHS Phase IV Family Study

QUALITY CONTROL LOG

Glucose Controls will remain stable until manufacturer’s date or “opened” expiration date, whichever comes first.

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<tr>
<th>Test Strip</th>
<th>Low Level Control</th>
<th>Normal Level Control</th>
<th>High Level Control</th>
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<th>Date</th>
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<th>Init.</th>
<th>Lot #</th>
<th>Code #</th>
<th>Exp.</th>
<th>Accep Range</th>
<th>Actual Value</th>
<th>Mean +/-</th>
<th>W/in Range Y/N</th>
<th>Accep Range</th>
<th>Actual Value</th>
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<th>W/in Range Y/N</th>
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X-50

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

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

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

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

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

5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.
# SHS Phase IV Family Study

## Quality Control

### SPHYGMOMANOMETERS

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<th>MONTH</th>
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<th>MERCURY LEVEL IS AT ZERO WITH NO PRESSURE</th>
<th>CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHg</th>
<th>CHECK CAP FOR TIGHTNESS</th>
<th>CHECK TUBE FOR OXIDE DUST</th>
<th>COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.</th>
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*Strong Heart Study IV  07/01/2002*  
*X-53*  
*Training Manual*
SCALE/TAPE
SHS Phase IV Family Study

Quality Control

SCALE & MEASUREMENT TAPES

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<th>MEASURING TAPE, to 30 cm METAL TAPE</th>
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