FAMILY STUDY

Cardiovascular Disease in American Indians (Phase V)

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 V)

Operations Manual

Volume Ten

TRAINING MANUAL

July 01, 2006

For copies, please contact

Strong Heart Study Coordinating Center

Center for American Indian Health Research
College of Public Health

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## Staff Training and Certification Checklist

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## SHS Phase V 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
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 V 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 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 V 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.

**Interviewer code#** ____________  **Date observed** ________________

**Observer code#** ____________

- Establishes correct environment (for privacy and participant comfort).  
  Yes _____  No _____

- Uses proper introduction of questionnaire and self (purpose of form/data).  
  Yes _____  No _____

- Reassures participant: confidential_____ voluntary____ can skip Q's____  
  Yes _____  No _____

- Reads questions exactly as written, slowly, distinctly, in a neutral tone with no omissions or rewording.  
  Yes _____  No _____

- Reads questions in correct order following skip patterns when required.  
  Yes _____  No _____

- Conducts interview in understandable language for participant. If in native language, uses correct translations.  
  Yes _____  No _____

- Repeats questions in full that are misheard or misunderstood.  
  Yes _____  No _____

- Uses neutral probes non-directively and appropriately (using pauses, repeating answers, giving ranges, etc.)  
  Yes _____  No _____

- Handles problem solving situations with proper interventions.  
  (This includes participants' questions.)  
  Yes _____  No _____

- Remains nonjudgmental throughout interview.  
  Yes _____  No _____

- Records answers correctly on forms. Edit forms before participant leaves clinic for any corrections.  
  Yes _____  No _____

- Provides closure with participant (including expression of appreciation).  
  Yes _____  No _____

**Comments:**

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ANTHROPOMETRY
Procedures 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 footstool is used if the examiner is shorter than the participant so that the examiner's view is level with the point of measurement on the head of the participant. The participant's height is recorded to the nearest centimeter using the rounding method. The participant is instructed to stand as straight as possible but with feet flat on the floor. (A check is made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and the metal ruler is mounted perpendicular to the floor). A chart converting centimeters to inches is on the wall or available for use in informing the participant of his/her height in inches.

   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 acromion and olecranon (Figure 3). Record the measurement to the nearest centimeter using the rounding method. This measurement is used to select the proper size blood pressure cuff.

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

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

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

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 V 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.
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 ____________________

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<th>Observer</th>
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YES ( ) NO ( ) Tech instructs subject to remove shoes for height and weight.
YES ( ) NO ( ) Tech positions subject appropriately for height measurement.
YES ( ) NO ( ) Tech balances and zeroes the scale before subject is weighed.
YES ( ) NO ( ) Subject is weighed accurately to the nearest kg by the tech.
YES ( ) NO ( ) Hip girth is measured accurately with the tape measure placed horizontally around the maximal protrusion of the gluteal muscles.
YES ( ) NO ( ) Tech measures arm circumference accurately, rounding to the nearest cm.
YES ( ) NO ( ) Tech correctly positions subject for waist measurement.
YES ( ) NO ( ) Measure of waist taken correctly, tape position at umbilicus.
ECG
SHS PHASE V 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 instructions are found in the appendix of Volume VI of this 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 (see below).
SHS PHASE V 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 1200.

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 PRESSURE
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](image)

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<td>Large Adult</td>
<td>33 to 41 cm</td>
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<td>Thigh</td>
<td>&gt;41 cm</td>
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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 V 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 and cuff at heart level, 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 2nd and 3rd readings  
v) Average 2nd and 3rd 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 (see below). Also, quarterly, each tech should be part of a pair of techs who simultaneously measure blood pressure using a Y-tube stethoscope on a volunteer. Each tech should record their readings separately. A third tech should then transfer the readings to the Simultaneous BP Observation Form (see below) and should calculate the differences between the two sets of measurements. The standard of error is 4 mmHg for each individual measurement and 3 mmHg for the average of the three readings.
SHS PHASE V 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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Strong Heart Study V         07/01/06      X-24       Training Manual
SHS PHASE V 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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<th>Technician #2 Code # / Initials</th>
<th>Observer Code # / Initials</th>
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<td>Cuff size</td>
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<td>Pulse obliteration pressure</td>
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<td>SBP #1</td>
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<td>Average DBP</td>
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Comments: _____________________________________________________________

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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.
SHS PHASE V FAMILY STUDY

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 (see below).
SHS PHASE V 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 the RJL Equipment Company. This involves a small low frequency current that travels across the body through the extracellular fluids. The measurement of bioelectrical impedance is related to the volume of the conductor and, when expressed as impedance or conductance, is proportional to fat free mass. The participants do not feel anything when this measurement is obtained.

1. 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 (pins in bones will not affect the results). Jewelry should be removed from the side on which the electrodes are placed.

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

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

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 anklebones to bisect the medial malleolus; make sure that the cut edge of the electrode is toward the thigh.

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

Once the electrodes have been properly attached to the subject, depress the button for “resistance” and record the resistance value on the physical examination form (S6). Then depress the button for “reactance” and record the reactance value on the S6 form.
SHS PHASE V FAMILY STUDY

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 Volume III of the SHS Phase V 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 (see below). The measurement results should agree within 15 ohms.
SHS PHASE V 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.

Technician Code # / Initials ________________________
Observer Code # / Initials ________________________
Date Observed ____________________

YES ( ) NO ( ) Explains procedure to subject.
YES ( ) NO ( ) Questions subject about recent exercise and alcohol consumption.
YES ( ) NO ( ) Asks subject to remove right shoe and sock.
YES ( ) NO ( ) Positions subject supine, with right side nearest to analyzer.
YES ( ) NO ( ) Assures that there is no skin to skin contact at axillas, thighs, abdomen.
YES ( ) NO ( ) Assures that arms are placed to subject’s side without hands touching anything.
YES ( ) NO ( ) Electrodes placed correctly.
YES ( ) NO ( ) Leads connected correctly.
YES ( ) NO ( ) Records resistance and reactance.

Comments: __________________________________________

________________________________________________

________________________________________________
DOPPLER BP
Using Doppler to Measure the Ankle-Brachial Index (ABI)

1. Move the participant to the supine position

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

2. Procedure for Measuring Brachial (arm) Blood Pressure

   a) By consulting the participant's Data Form, the observer verifies that the same arm and the same cuff size are used as for the sitting blood pressure readings. If the participant had his/her sitting blood pressure taken on the right arm earlier in the clinic examination, the cuff is applied on the right arm at this time. The blood pressure cuff is applied over the brachial artery according to the instructions found in the Sitting Blood Pressure section of this manual.

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

3. Procedure for Measuring Ankle Blood Pressure

   a) Apply the blood pressure cuff.

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

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

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

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

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

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

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

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

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

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

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

calf
lower leg centered on
cuff
velcro "hocks"
medial malleolus
back of heel
posterior tibial artery
exam table
velcro "fabric on reverse"
hoses to
sphygmomanometer
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 V FAMILY STUDY

Training and Quality Assurance

DOPPLER BLOOD PRESSURE

Training

Technician instruction will include:

a) rationale for ankle systolic blood pressure and Ankle-Brachial Index measurement
b) explanation to subject
c) positioning of subject
d) blood pressure cuff size selection
e) application of cuff on right arm (if sitting BP was taken on the right arm), right ankle, left ankle
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 arm (if sitting BP was taken on the right arm), right ankle, and left ankle

Quality Assurance

Observation of technicians will be done quarterly by the Study Coordinator. Performance by the tech should include all of the criteria listed above, the evaluation should be recorded on the Checklist for Doppler Blood Pressures (see below). The tech's results should be within 4 mmHg of the coordinator's pressure results.
SHS PHASE V 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 arm (if sitting BP was taken on the right arm), right ankle, and left ankle.
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 arm (if sitting BP was taken on right arm), right ankle, and left ankle.

Comments:_____________________________________


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<thead>
<tr>
<th></th>
<th>Technician</th>
<th>Observer</th>
<th>Difference</th>
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</thead>
<tbody>
<tr>
<td>Right Arm (if sitting BP was taken on right arm)</td>
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<tr>
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<tr>
<td>Left Ankle</td>
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</table>
ACCUSPLIT
PEDOMETER
DIRECTIONS TO PARTICIPANTS FOR USING THE PEDOMETER

The ACCUSPLIT Pedometer measures movement. You are being asked to wear this pedometer EVERY DAY for a seven-day period from ______________ to ______________. The pedometer is worn on the hip and should be clipped to the waistband of your pants/skirt, underwear, or belt. Most importantly, the pedometer must be worn in an upright position. Please keep the pedometer firmly against your body so it does not move around freely. **DO NOT LET THE PEDOMETER GET WET** by wearing it in the rain or while bathing or swimming. Please remember to reset the pedometer to “0” (zero) when you put it on in the morning and to record the number of steps from the pedometer in your activity record when you take it off at night.

If you have any questions, please contact ______________________ at ______________________.

SPECIFIC INSTRUCTIONS

1. Every morning, just before you put the pedometer on, push the **YELLOW** reset button so that the pedometer resets to “0”.
2. Record the time that you attached the pedometer in your pedometer record. Make sure to indicate am or pm.
3. Wear the pedometer on your hip (please see pictures above), make sure to keep it upright, and make sure that it remains firmly in place against your body.
4. **Wear the pedometer ALL DAY except when bathing, swimming, or in the rain (unless the pedometer is protected by clothing and will not get wet).** If you take off the pedometer for longer than 30 minutes, record the length of time it was off (minutes or hours) in your pedometer record.
5. At bedtime, take off the pedometer. Record in your pedometer record (a) the number of steps taken on the pedometer, and (b) the time you removed your pedometer. Make sure to indicate am or pm.
6. Please do not touch the **YELLOW** reset button during the day or you will erase your activity numbers.
7. **Keep the cover closed or the pedometer will not record your activity.**
8. Do not wear the pedometer in a pants, coat, or shirt pocket. The pedometer will not work correctly.
9. Please bring back or mail to us, in the self-addressed stamped envelope, the pedometer record after you have completed your week.
10. Please keep the pedometer as a token of our appreciation for your participation in the Strong Heart Family Study.

Thank you very much for your time and effort.
## SEVEN-DAY PEDOMETER RECORD

**SHS Family I.D.:** ________________  |  **SHS I.D.:** ________________

**Name:** __________________________  |  **SHS I.D.:** ________________

### REMINDER: RESET THE PEDOMETER TO “0” EVERY MORNING

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<th>Date</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
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<td>Did you take off the pedometer for any reason for longer than 30 minutes? Please circle “Y” for yes or “N” for no.</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>If yes, for how long (indicate minutes or hours)?</td>
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</table>

Complete this question after completing the pedometer record.

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

Yes_____  No_____
SHS PHASE V FAMILY STUDY

Checklist for Accusplit 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 bring back the record.

Comments: ____________________________________________________________

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LAB
1.0 Safety Precautions, Universal Precautions and Personal Protective Equipment for the Handling of Blood and Working in a Laboratory Setting:

Lab testing in research is important. Your work brings new and important information to the scientific and medical community. The special equipment and skills such as attention to detail, organization and phlebotomy are critical to the success of this project. Your work on this project will probably expose you to a variety of potentially hazardous situations. The following learning modules are designed to help you keep safe on the job.

Each site should have at least one staff member who will be actively involved in this process attend the initial training session. This person, in turn will be responsible for training additional personnel at his/her facility. The training session will cover all procedures related to supplies, equipment, and preparation of log sheets, labeling, collection, processing, storage, packing and shipping of specimens.

Throughout the study, a qualified observer should regularly monitor and evaluate the work of those involved in the collection and processing of blood samples. Specific plans should be made to train new staff members at each facility. Training should include a detailed review of the Strong Heart Study laboratory manual as well as supervised practice in the application of the techniques required by the protocol.

This section will provide knowledge to protect you and others. In addition to these instructions, use commonsense on the job every day.

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don’t take chances
- Don’t operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
- Avoid direct contact with blood, sera or plasma. Cover any scratches or cuts on fingers and hands very carefully and use gloves in the handling of specimens.
- All tubes, containers and other materials exposed to blood must be disposed of in appropriately labeled waste receptacles for biohazardous materials.
- When removing stoppers from vacutainers, use a splash shield to prevent
droplets from spraying onto your skin or eyes.

- All samples should be stored in sealed containers or tubes.
- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.
- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.
- Avoid working alone
- Post important phone numbers and emergency numbers prominently
- Know before an accident where to go and what to do
- Know the location of safety showers, eyewashes and fire extinguishers

Module I: Safety Precautions

This module will include the following:

- Provide knowledge to protect you and others.
- Demonstrate common procedures that will be used on the job every day.

Here are some guidelines:

- Be cautious and follow procedures.
- Take your time and concentrate on what you are doing.
- Avoid contact with hazardous chemicals
- Treat unknown substances as hazardous
- Follow all equipment operating instructions
- Don’t take chances
- Don’t operate anything if you have not been trained on that equipment
- Follow all instructions
- Report any malfunctioning or suspicious-appearing equipment immediately
- Never pipette samples by mouth.
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- All site personnel should be informed of and guided by current OSHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.
• Immunization against Hepatitis B is highly recommended for persons
drawing blood and handling biological specimens.

Emergencies can happen, so be prepared:

• Avoid working alone
• Post important phone numbers and emergency numbers prominently
• Know before an accident where to go and what to do
• Know the location of safety showers, eyewashes and fire
  extinguishers

Some of the equipment in the areas you will be working is reviewed
below:

• **Glassware** like vacutainers can break, causing chemical and cut
  hazards. Some of the chemicals contained in the vacutainers are
  EDTA and heparin. Although serious hazards are unlikely if exposed,
  still follow procedures if an accident occurs. To avoid contact, use the
  right type of glassware for each job, and discard chipped or cracked
  vacutainers in an approved receptacle. Don’t force anything made of
  glass.

• **Electrical equipment** always carries the potential of shock or fire.
  Don’t touch it with wet hands or while standing on a wet floor. Report
  any shocks, and don’t attempt to do repairs if you haven’t been trained.

• **Centrifuges** and other equipment with moving parts can catch your
  clothing or open up suddenly, showering you with dangerous material.
  Keep clothing or long hair away from them. Make sure the load is
  balanced, the top is locked down, and the equipment has stopped
  before you open it.

**Module II: Personal Protective Equipment**

This module will include the following:

° Proper use of protective clothing.
° First-aid instructions

Let protective equipment work for you.

For this aspect of the study, always use assigned protective clothing and
equipment. Always check that it is in good condition before putting it on. For this
study the following are required:

• **Goggles or side shield safety glasses** to protect against splashes or
  flying objects are required any time you are working with specimens or
performing phlebotomy.

- **Gloves** must be worn to protect against any chemicals or exposure to samples
- **Long sleeves** are required to the length of your wrist and meet the glove.
- **Lab coats** must be full length and fully buttoned down the front.
- **Sturdy closed toed shoes** are required to cover your feet in case of spills or accidents

If you are exposed to a hazardous substance or samples, take the following actions:

For first-aid instructions, here are some general instructions. You should check with your supervisor for specific instructions at your institution prior to an accident.

- **Eyes**: Flush with water for 15 minutes.
- **Ingestion**: Follow labels and MSDS instructions. MSDS is an abbreviation for Materials Safety Data Sheet and is available from the manufacturer for every chemical produced.
- **Skin Contact**: If limited to a small area of the body such as the hands, remove any contaminated gloves or clothing and wash with copious amounts of water. If there is greater exposure, stand under emergency shower and remove contaminated clothing immediately.
- **Inhalation**: Get to fresh air and get prompt medical attention.

Module III: Preventing Exposure to Blood Borne Pathogens:

This module will include the following:

- Universal precautions
- Work practices, including the use of protective clothing that eliminates or minimizes exposure to staff and subjects
- Housekeeping procedures to ensure cleanliness and possible spread of infection
- Hepatitis B vaccinations for employees at risk
- Exposure evaluation and follow-up for exposure incidents
- Hazardous material container warnings such as biohazard labels
- Confidential, accurate employee medical records

Your chance of being directly exposed to bloodborne pathogens on the job is small. But keeping exposure minimal can only succeed if staff members use the tools to protect themselves on the job.
• **Universal Precautions** are your best protection against any risk to exposure. This means all staff must treat all blood, urine, and other potentially infectious body fluids as if they are infected.

  All specimens should be regarded as potentially hazardous.

**DO:**

- Wash hands and exposed skin with soap and water immediately after exposure to infectious materials or after taking off gloves or other personal protective equipment.
- Use antiseptic or cleansers or towelettes only if washing facilities aren’t available.
- Minimize splashing, spraying, or spattering of blood or other potentially infectious materials.
- Place contaminated sharps in assigned labeled, puncture-resistant, leak-proof containers.

**DON’T:**

- Don’t shear or break contaminated needles or other sharps, and don’t bend, recap, or remove unless specifically instructed.
- Don’t keep food, drink, medication or makeup in work areas with exposure potential.
- Don’t eat, drink, smoke apply cosmetics or lip balm, or handle contact lenses in work areas with exposure potential.
- Don’t pipette or suction anything by mouth.

• **Protective Clothing:**

  **BEFORE you** put on protective clothing, make sure it’s in good condition. Don’t wear anything that’s damaged or does not fit properly.

  **AFTER tasks** in the area are completed, remove all protective clothing before leaving that area. Remove protective clothing in such a manner as to minimize exposure and avoid contamination. Place protective clothing in a specially assigned area or container for decontamination, washing, storage or disposal.

• **Housekeeping:**

  Written procedures and a cleaning schedule help keep the workplace free of infection.
• **Cover** equipment and surfaces with plastic wrap, aluminum foil, or impervious absorbent paper. Remove and replace covering that is, or may be, contaminated.

**Module IV: Proper Labeling**

This module will include the following:

- Correct identification and labeling of containers with biohazardous labels
- Instructions in case of exposure

Proper labeling of containers for regulated waste must be labeled with fluorescent orange or orange-red biohazard warning labels.

Examples in the clinical area or lab are: refrigerators and freezers containing blood and other potentially infectious materials and other containers used to store, transport or ship blood and other potentially infectious materials.

Biohazard labels **ARE** required for the following:

- waste containers used for disposal of contaminated needles
- refrigerator or freezer holding blood or other potentially infectious material
- individual specimen containers for storage or shipment zip-loc biohazard bags

Biohazard labels **ARE NOT** required for the following:

- when red bags or red containers are used
- on individual containers or blood of other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal

The risk of exposure is very small and most encounters with an HIV or HBV carrier pose no risk. AIDS and Hepatitis B can be transmitted through:

- Sexual contact
- Shared needles
- Needlestick injuries from infected needles or sharps
- Direct contact between broken or chaffed skin and infected body fluids.
- Hepatitis B can also be transmitted through dried blood and contaminated surfaces.

Neither AIDS (HIV) nor Hepatitis B are transmitted by:
- Coughing or sneezing
- Touching an infected person
- By using the same equipment, materials, toilets, showers, or water fountains.

**Be safe!!!** Your employer must make available, free of charge or at a reasonable time and place, the hepatitis B vaccine and vaccination series to all employees at risk. Any booster doses recommended by the US Public Health Service also must be provided. You are not required to participate in a prescreening program to receive the vaccine series. Also, the vaccine can be available at a later time if initially declined. If you choose to not receive the vaccine, your facility will ask you to complete and sign a form stating your refusal. This is required by law.

**If you are directly exposed, REPORT IT IMMEDIATELY!!!**

An exposure incident is specific to eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee’s duties. A common example of exposure would be a puncture from a used needle.

If exposed, you should contact your supervisor immediately. This allows for timely medical evaluation and follow up as well as for timely testing of the source. Your facility will provide immediate, confidential assistance and medical evaluation, including a blood test. All information will be treated with the strictest of confidence.

**2.0 Sample Collection Instructions:**

Personnel involved in sample collection should be highly experienced with vacutainer and butterfly blood collections, and be prepared to handle common problems, such as difficult blood collection and situations such as fainting. The phlebotomist should also be familiar with precautions to avoid exposing themselves to blood and be trained in the following:

- Ideally staff will have cardiopulmonary resuscitation (CPR) certification.
- It is suggested that they read "Collection and Handling of Laboratory Specimens: A Practical Guide"\textsuperscript{1} or a similar phlebotomy manual.
- Personnel should wear clean white lab coats (with no blood stains) and

maintain a neat appearance. Lab coats will be full length, with long sleeves. Lab coats will be buttoned closed down the full length of the coat.

• Personnel will wear protective eyewear. Safety glasses are required when performing phlebotomy, processing specimens and preparing samples for storage and/or shipment.
• Staff should wear nametags and introduce themselves (if necessary) before a blood draw.
• Long hair and bangs should be pulled back.
• Phlebotomists and assistants should not chew gum or have any food in their mouths during blood draws. Food and drink must never be brought into areas used for blood drawing or processing.
• Staff will attempt no more than three venipunctures on the same subject. After three failed attempts, another person will be asked to try.

Module I: Sample Collection Facilities

This module will include the following:

° Room requirements for sample collection
° Supplies for sample collection

The area in which phlebotomy will occur should be clean and tidy with no evidence of previous blood draws such as used needles, blood stains, etc. A phlebotomy chair should be available for 15-20 minute periods to allow subjects to be seated for 10 minutes prior to a blood draw. If not available within the room, there should be quick access to a bed or examining table and ammonia capsules in case a subject feels faint. Also, there should be easy access to emergency equipment in case of cardiac arrest. Ideally, only the participant and phlebotomist (and assistant when needed) are in the room during the procedure.

The room should be set up in advance with basic supplies for blood collection:

° Vacutainer holders/hub
° Vacutainer needles
° Disposable graduated transfer pipettes
° alcohol wipes or swabs
° 2x2 sterile gauze pads
° band aids
° adhesive tape
° urine collection cups
° disposable latex gloves
° ammonia inhalants
° paper cups
° emesis basin
Module II: Sample Collection and Processing

This module will include the following:

- Completion of clinical logs
- Completion of laboratory requisitions
- Demonstration of One-Touch Sure Step Flexx procedure
- Proper labeling of vacutainers and transport tubes
- Venipuncture Instructions
- Posture during blood collection
- Difficult Venipuncture Techniques
- Vacutainers for Sample Collection and Processing Instructions

Sample Collection Logs and Laboratory Requisition Forms

Clinic personnel should carefully review the description of collection requirements to ensure that specimens are collected in the proper order and use the proper technique. Each clinic should set up a blood collection and blood processing notebook or a laboratory logbook in advance. It should be located in the blood collection/processing area. This should be a hardbound notebook from which pages cannot be easily removed. Pages should have columns headed for date, visit number, participant name and ID, barcode labels, redraw labels and room to write "comments" about any problems with blood draws or processing, including hemolysis of samples, etc.

In addition to the logs for the clinical area, it will be necessary to complete a laboratory requisition form for each subject (see example of this PARTICIPANT SAMPLE FORM in Appendix C below). The completed requisition form should include the following:

- Exam ID
- Date of Collection
- Under left column marked “write the number of samples sent” record the actual number of samples sent.

After proper completion of requisition form, affix barcode label to both copies of the form and one label in the laboratory log book.
Redraw
If sample collection is a redraw, indicate “yes” on new requisition form and take the following steps:

- Affix original barcode label to both copies of the requisition form
- Also affix redraw barcode label to both copies of the requisition form
- Place redraw label by the appropriate participant ID in laboratory log book

One-Touch Sure Step Flexx Procedure

1) One-Touch Sure Step Flexx glucose reading from a drop of blood obtained by finger stick. Using the blood from the venipuncture procedure below will not provide comparable results since there is a difference between capillary blood (fingerstick) and venous blood values.

2) See One-Touch Sure Step Flexx procedure for calibrating the glucometer and steps to follow in obtaining a glucose reading. (Consult with the operations manual, which can be obtained from Lifescan, Inc. 1-800-227-8862) A video and training will be provided at the initial training session. Thereafter, training will be provided on-site. See Appendix A of this volume (p. IV-A-1 below) for additional instructions.

Labeling Collection Tubes and Samples:

Prior to venipuncture, a label showing the date and time of collection and participant ID number should be written by the phlebotomist.

Pre-numbered and bar-coded labels will be provided to the study sites. Take care to select the correct number depending on whether the samples are being collected from the participant as a QA sample or for a Courtesy visit.

To properly label vacutainers and shipping vials, the white section of the label must be applied (first) to the tube laterally with the clear end wrapped over the white section of the label after the label is wrapped around the tube.

Module III: Venipuncture Procedure

This module will include the following:

- Correct Venipuncture procedures

Posture During Blood Draws:

A participant should be seated during blood draws. However, if the participant is clearly uncomfortable with the blood drawing situation, because of a previous fainting episode or a fear of fainting, have the participant lie down provided the
blood draw can proceed within 10 minutes. This is to ensure that blood is collected before body fluid shifts occur, which could alter plasma concentrations of outcome variables. Therefore, it is desirable that less than 10 minutes elapse between the participant's lying down and completion of the blood draw.

Difficult Venipunctures:

There will be several common situations in which vascular access may be difficult. These will include but are not limited to the following:

- Palpated vein feels small or rolls.
- Excess subcutaneous tissue and fat lies over veins.
- Participant complains of being stuck more than once on a previous visit (no single staff person will attempt more than three venipunctures on a single participant at a single clinic visit) or has had a bad experience elsewhere.
- Participant has been stuck once already and none of the usual veins are palpable.

All reasonable efforts should be made to collect a blood sample, including use of a 23 gauge needle if that is the only means available to obtain a sample, e.g., in the case of a child or elderly person. If the participant experiences any of the above problems, and is agreeable to a repeat attempt, you may try the following procedure:

- Check back of hand and forearm for venipuncture sites with larger veins.
- Attempt one or more vein dilation methods:

  1. Hot pack venipuncture site with a warm, wet towel or apply heating pad for 3-5 minutes.
  2. Have participant hold hand in warm water for 3-5 minutes.
  3. Have participant dangle arm at side with tourniquet in place for one minute.
  4. Use blood pressure cuff as a tourniquet by pumping pressure to 60-80 mm Hg.
  5. Be sure room is not too cool.

1) Position the participant in comfortable chair in an environment free from distraction.

2) Query the participant about their fasting state. Example: "When was the last time you ate or drank anything except water?" The participant should be fasting for about 12 hours. Record the time since the last food or beverage was consumed. If subject is not fasting, record time and note in comment section what foods or beverages were consumed that morning. Be sure to include any
additives like cream, sugar, or artificial sweeteners if a beverage was consumed. Regardless of fasting state, proceed with drawing procedure.

3) Inform the participant about the procedure. Explain the procedure to the participant, e.g., "I will be drawing a blood sample from your arm today. You will probably feel a small prick when I insert the needle."

4) Assemble all materials; have extra tubes within reach.

5) Blood samples will be collected from Strong Heart Study participants using conventional vascular access with a multi-draw Vacutainer (butterfly) needle and collection of the blood sample into Vacutainer tubes.

6) The antecubital site of the left arm will be used as the first choice for venipuncture. The median cubital vein is the one most frequently used. If the venipuncture of this vein is unsuccessful, the cephalic and basilic may be the next appropriate choice, followed by veins on the back of the hand. For known mastectomy participants, avoid use of an arm where there was axillary lymph node dissection.

7) Be sure all necessary supplies and equipment are available and set up in advance. Note visit type and type of Vacutainer tubes required. Label tubes with participant ID# and date and time of collection. Complete all lab forms before specimen collection. Ensure that all necessary equipment is functioning properly.

8) Be sure a full length lab coat is worn and buttoned. Wash hands and put on protective gloves.

9) Fit luer adapter needle at end of collection set into Vacutainer sleeve and place the first collection tube into sleeve/hub.

10) Position participant’s arm on the drawing table. Extend the arm toward you, palm up.

11) Apply tourniquet 3 inches above a venipuncture site. If it is necessary to apply a tourniquet for preliminary vein selection, release it for two minutes and reapply immediately before entering the vein.

12) Pull skin taut 2 inches below site to keep vein from rolling.

13) Palpate vein. (A vein feels like an elastic tube and returns when pressure is applied). If the presence of a vein is questionable, remove or loosen the

If no radial pulse can be felt, the tourniquet is too tight. Tourniquet must not be in place more than two minutes.
tourniquet. If the structure remains, it probably was not a vein; if it
disappears assume it was a vein. Another technique to assist in locating a
vein is to moisten the skin with alcohol as it will decrease the friction and
may aid in the palpation of a vein. If no vein is felt, try other arm or another
site (See section on "Difficult Venipunctures").

14) Cleanse skin over vein thoroughly using a circular motion from center to
periphery. Wipe alcohol with new 2x2 gauze to dry the area.

DO NOT TOUCH SKIN AFTER CLEANSING.

15) With the bevel of the needle in upright position, enter vein. Hold needle in
the same direction as vein and at a 15-degree angle to vein. Insert the
multidraw needle bevel up, parallel to vein. Use a straight smooth
movement through the skin; do not poke around. The needle is sterile; do
not touch it while performing venipuncture. If vein rolls, withdraw needle
slightly without coming completely out of the arm and try a second
attempt. If the vein collapses, remove the needle and tourniquet. Apply
slight pressure to the puncture site. Try another site and/or call another
staff person to assist. After a new location has been determined, usually
the other arm, begin the procedure again. Reapply the tourniquet,
possibly have participant open and close the fist, swab areas with alcohol
and dry, then reinsert the tube. If there is still no blood, stop the
procedure and use techniques in section on "Difficult Venipunctures."

16) If the phlebotomy is successful, draw required blood tubes. After blood begins to
flow, secure butterfly with a piece of tape and loosen the tourniquet. Place tubes
in conditions as specified in the instructions.

If blood does not begin to flow, try the following:

a) Move the needle slightly in or out.
b) Rotate needle slightly or lift needle to move bevel away from the wall of
the vein.
c) Try another tube.
d) Loosen tourniquet; blood flow may be impeded if tourniquet is too tight.
e) Be sure to watch for signs of hematoma or swelling from the vein. If there
is any indication of hematoma or swelling, immediately remove tourniquet
and needle. Place 2x2 gauze over the site, and apply pressure and/or ice
pack on site for 5 minutes. If the first attempt to obtain blood is
unsuccessful (with the subject's permission) try again on the opposite arm.
The same technician should not attempt a venipuncture more than
three times.

17) When first tube is filled, remove tube and replace with the next tube. Invert all
filled tubes except SST tubes 8-10 times and place on ice. DO NOT place SST
tube on ice.
18) Proceed with collection of tubes in this order. Label all tubes:

Fasting:
1. (3) Red top (SST) tubes
2. (1) or (2) Light Blue top (Citrate) tubes
3. (1) Gray top (Sodium fluoride) tubes
4. (4) Lavender top (EDTA) tubes

19) After drawing the last tube, remove the tourniquet. Use clean gauze to apply slight pressure to arm and withdraw needle, then immediately apply pressure to site. Apply gentle pressure to the site.

20) Request participant apply pressure at site for 3-5 minutes while leaving the arm straight at the elbow. This is more important than elevating the arm or bending the elbow, which some participants might do automatically.

21) Confirm that bleeding has stopped, and apply a pressure bandage at venipuncture site. If bleeding has not stopped, elevate arm and continue to apply pressure until it stops.

22) Check preprinted labels and tubes, making sure the ID# and tube designation are correct.

23) Dispose of entire needle set-up into a proper biohazard disposal container. *Never try to re-cap a needle since this puts you at risk for a needle puncture.*

24) Check site. If blood oozes from the site, have the participant apply pressure to the site 1-2 minutes longer or as long as is necessary, elevating arm above head. Apply Band-Aid.

25) Give the participant labeled urine specimen cup and instruct him to void into the container. Inform him/her where to leave the container.

26) Remove gloves, wash hands, and proceed to next participant.
Realize that the participant might be disoriented, embarrassed, or irritable and may need additional attention. Recognize also that this incident will have an impact on future blood drawing, and possible adherence through the study, and must be handled with reassurance. Make a note in the participant's file so that clinic staff will be aware of the situation in the future.

Finish venipuncture following procedures outlined above, if possible. If multiple attempts at venipuncture are unsuccessful, do not reschedule the participant unless both the technician and the participant agree that this is an unusual situation and that there is a high probability of obtaining a sample on the first try at another visit.

**Note:** If sample is not collected, try to reschedule the visit especially if the technician and participant agree that this is an unusual situation and that is not likely to occur again. If participant does not wish to reschedule, indicate in the comment section on the visit form that the samples were not collected.

If Fainting Episodes Are Experienced:

If participant shows signs of becoming faint (loss of color in the face, unusual sweating on the forehead) or reports feeling dizzy:

- Finish drawing blood if possible but do not proceed if participant is clearly in trouble.
- Remain calm and call for help.
- Have participant lay head on table or move participant into a fully reclined position, if possible.
- Have participant prop feet up on pillow or cushion and elevate participant's legs above her head.
- Continue talking to participant to assess level of consciousness.
- Prevent injuries from possible fall or seizure.
- Have participant lie down for 5-10 minutes after removing the needle; apply pressure on vein.
- Apply cool compress to forehead.
- Use ammonia capsule if needed.
- Keep participant in a reclined position until the subject feels better.
- Taking blood pressure readings to assess recovery may be worthwhile.
- Offer participant water, juice and food after they have recovered.

**Urine Sample Collection:**

1. Containers for routine collection should be clean and hold about 50 ml in volume and
must have a tight-fitting lid.

2 The participant’s privacy should be assured and a clean bathroom available.

3 Instruct the participant to perform the following steps:

∗ Remove cap from the labeled container before beginning urination
∗ Void directly into toilet and after stream is steady, pause.
∗ Begin stream again and fill approximately half of the cup.
∗ Finish urinating, firmly place cap on container and return sample to the study person.

Flow charts summarizing processing procedures are in Appendix B-1A through B-1C of the SHS Phase V Manual, Volume 4.
General Sample Collection:

**Table I: General Instructions for Sample Processing of Blood & Urine Samples**

<table>
<thead>
<tr>
<th>Collection Tube</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serum Storage</strong></td>
<td>1. Let stand at room temperature for 20 minutes so blood can clot. If samples cannot be processed within the hour, refrigerate sample or place on ice. 2. Centrifuge at 3000 rpm (1000xG) for 10 minutes. 3. Place approximately 1 ml of serum sample in each of the appropriate 2ml-cryovials and label.</td>
</tr>
<tr>
<td><strong>Plasma Storage</strong></td>
<td>1. <em>This vacutainer must be allowed to fill completely with blood at the time of collection.</em> 2. After collection gently invert 8-10 times. Place on ice or refrigerate immediately. 3. Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. 4. Place approximately 1 ml of plasma sample in each of the appropriate 2ml-cryovials and label.</td>
</tr>
<tr>
<td><strong>EDTA Plasma Storage</strong></td>
<td>1. After collection, gently invert 8-10 times. Place on ice or refrigerate immediately. 2. Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. 3. Place approximately 1 ml of plasma sample in each of the appropriate 2ml-cryovials and label.</td>
</tr>
</tbody>
</table>
| **Leptin** | 1. After collection, gently invert 8-10 times, place on ice or refrigerate immediately. 2. Tube #1: Prior to centrifuging, mix well and pipette approximately 1 ml of whole blood and place in each appropriate 2-ml cryovial and label. Re-cap tube #1. 3. All three tubes: Centrifuge at 3000 rpm (1000xG) for 10 minutes at 4°C. First, place approximately 1 ml of plasma sample in each of the appropriate 2-ml cryovials and label. Then, remove the buffy coat using the **Purple top tube buffy coat isolation protocol** as follows: 

  **Buffy Coat:**
  1. After plasma has been removed, there should be about 1/8th inch of plasma remaining on top of the buffy coat.
  2. With either a glass or plastic pipette, place the tip of the pipette at the bottom of the small plasma layer just slightly above the buffy coat. Also, rest the pipette against the glass inside edge of the vacutainer tube.
  3. Slowly draw up the buffy coat by moving the pipette in a circular motion around the inside of the vacutainer.
  4. Remove all of the buffy coat from one tube and place in a 2.0 ml cryovial (orange cap).
  5. Cap cryovial firmly, apply label.
  6. With each tube repeat steps 1-4 using a different pipette for each tube. Use a new clean pipet for each tube. Do not mix the buffy coats between cryovials, ie only one buffy coat from one tube per cryovial. |
| **Urine Storage** | 1. Do not centrifuge. 2. After collection, place on ice or refrigerate immediately. 3. Place 1 ml of urine sample in each of the appropriate 2-ml cryovials and label. |
### Table II: Participant Collection Instructions

<table>
<thead>
<tr>
<th>Collection Tube Type</th>
<th>Tests</th>
<th>Sample Type</th>
<th>Storage/Shipping Requirement</th>
<th>Cryovial Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 10 ml SST (red/gray tiger top)</td>
<td>Chem Profile, Lipids, Insulin, CRP, FFA Storage</td>
<td>Serum</td>
<td>Frozen</td>
<td>4 2 ml-red cap vial</td>
</tr>
<tr>
<td>1 4.5 ml Lt blue or 2 2.7ml Lt blue</td>
<td>Fibrinogen Storage</td>
<td>Na Citrate Plasma</td>
<td>Frozen</td>
<td>1 2ml-blue cap vial</td>
</tr>
<tr>
<td>1 4.0 ml Gray</td>
<td>0 hour (fasting) glucose</td>
<td>NaFl Plasma</td>
<td>Frozen</td>
<td>2 2 ml-black cap vial</td>
</tr>
<tr>
<td>3 10 ml Purple</td>
<td>HemoglobinA1c DNA Isolation Leptin EDTA Storage</td>
<td>Whole Blood Buffy coat EDTA Plasma EDTA Plasma</td>
<td>Frozen</td>
<td>3 2 ml-neutral cap vial 3 2 ml-orange cap vial 2 2 ml-purple cap vial 8 2 ml-purple cap vial</td>
</tr>
<tr>
<td>1 cup Random Urine</td>
<td>Albumin/Creatinine Storage</td>
<td>Urine</td>
<td>Frozen</td>
<td>2 2 ml-yellow cap vial 4 2 ml-yellow cap vial</td>
</tr>
</tbody>
</table>
**Table III:** QA Collection Instructions:

<table>
<thead>
<tr>
<th>Collection Tube Type</th>
<th>Tests</th>
<th>Sample Type</th>
<th>Storage/Shipping Requirement</th>
<th>Cryovial Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 ml SST</td>
<td>Serum</td>
<td>Frozen</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Chem Profile, Lipids Insulin, CRP FFA</td>
<td></td>
<td></td>
<td>2 ml-red cap vial</td>
</tr>
<tr>
<td></td>
<td>Insulin, CRP FFA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4.5 ml Lt blue or 2.7 ml Lt blue</td>
<td></td>
<td>Frozen</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>Fibrinogen</td>
<td>Na Citrate Plasma</td>
<td>Frozen</td>
<td>2 ml-blue vial</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4 ml Gray</td>
<td>NaF1 Plasma</td>
<td>Frozen</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>0 hour (fasting) glucose</td>
<td></td>
<td></td>
<td>2 ml-black cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10 ml Purple</td>
<td>Whole Blood</td>
<td>Frozen</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>HemoglobinA1c</td>
<td>EDTA Plasma</td>
<td>Frozen</td>
<td>2 ml-neutral cap vial</td>
</tr>
<tr>
<td></td>
<td>Leptin</td>
<td></td>
<td></td>
<td>2 ml-purple cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 cup Random Urine</td>
<td>Albumin/Creatinine</td>
<td>Urine</td>
<td>Frozen</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 ml-yellow cap vial</td>
</tr>
</tbody>
</table>
### Table IV: Courtesy Collection Instructions

<table>
<thead>
<tr>
<th>Collection Tube Type</th>
<th>Tests</th>
<th>Sample Type</th>
<th>Storage/Shipping Requirement</th>
<th>Cryovial Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>10 ml SST</td>
<td>Serum</td>
<td>Frozen</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Chem Profile, Lipids, Insulin, CRP, FFA</td>
<td>Serum</td>
<td>Frozen</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4.5 ml Lt blue or 2.7 ml Lt blue</td>
<td>Fibrinogen</td>
<td>Frozen</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td>Na Citrate Plasma</td>
<td>Frozen</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Na Citrate Plasma</td>
<td>Frozen</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4 ml Gray</td>
<td>0 hour (fasting) glucose</td>
<td>NaFl Plasma</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Frozen</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>10 ml Purple</td>
<td>HemoglobinA1c</td>
<td>Whole Blood</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>DNA Isolation</td>
<td>Buffy Coat</td>
<td>Frozen</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EDTA Plasma</td>
<td>Frozen</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Leptin</td>
<td>EDTA Plasma</td>
<td>Frozen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EDTA Storage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 cup Random Urine</td>
<td>Albumin/Creatinine</td>
<td>Urine</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td>Urine</td>
<td>Frozen</td>
<td></td>
</tr>
</tbody>
</table>

### Module IV: Quality Assurance Sample Collection:

As part of the Quality Assurance process of this study, there is a need to assure that all the steps from the time that blood is collected to the time that results are reported are correct. To accomplish this, replication of unknown samples will be necessary by performing blind duplicate testing of samples. Blind duplicate samples, otherwise known as quality assurance (QA) samples, will be obtained from participants as follows:

1. Collect blind duplicate samples at a frequency of every 20th participant.
2. Collect blind duplicate samples only for the tests listed in Table III above.
3. In order to label the blind duplicate samples, the numbering system for these QA samples is similar to the Study ID and consists of 6 digits with the first digit corresponding to the center (1-SD, 2-OK, 3-AZ), the second digit will be a "3" to
indicate that the sample is a QA and the 4-digit participant ID number. The Coordinating Center should receive at monthly intervals the matching participant ID and corresponding QA for analysis. This list should not be made available to the Core Laboratory.

Processing and Shipping QA samples

These samples should be treated the same as the regular participant samples and be included in regular shipments with the participant and courtesy samples. DO NOT note the corresponding (regular) participant number anywhere on the form to go to the lab.

3.0 Sample Storage and Shipment

Module I: Equipment Maintenance

This module will include the following:

° Proper maintenance of equipment

The proper care of equipment promotes the life of any piece of equipment and will reduce the possibility of downtime while waiting for repair. Included in the proper maintenance of equipment is the requirement of taking temperatures of refrigerators and freezers.

• Refrigerators and Freezers

Storage requirements for samples include keeping samples at the proper temperature until samples are shipped. Never store samples in a self-defrost freezer. At each site, there should be a temperature log to record the temperatures of the room, all refrigerators and all freezers that hold samples. By recording and evaluating temperatures each day, you will see temperature fluctuation that is a signal that some part is not working properly and downtime is inevitable. It is also advisable to locate a maintenance/repair company that services your unit in the area before a problem is experienced. If temperatures begin to fluctuate, the repair service should be called in to evaluate the problem. It may be a simple repair like a door seal or it may require ordering a part. In any case, detecting the problem early will give you time to have the repair done while still maintaining samples at proper temperatures. In addition to recording temperatures, all refrigerators and freezers require routine maintenance. Follow manufacturer guidelines.

• Centrifuges

Like refrigerators and freezers, there are many makes and models of centrifuges. Follow manufacturer guidelines for the care of your centrifuge. In addition, locate a service company that can do maintenance and repairs. Find
this company before a problem occurs. In addition, once a month the inside bowl of the centrifuge should be cleaned with a disinfectant. Always wear gloves, safety glasses and a lab coat when performing this task.

**Module II: Storage Requirements**

This module will include the following:

- Proper storage
- Shipping instructions
- Proper packaging of samples
- Proper completion of FedEx airbill
- Notification of shipment to the lab

One important precaution which should always be kept in mind when handling samples is that all blood, except for the SST tube, should be cooled (either in the refrigerator or on ice) as soon as the samples are collected. They should be kept cold until processing is complete and samples are properly stored. After the SST tube is completely clotted (20-30 minutes) it should also be kept cool if it cannot be processed within the hour. Plasma should be separated from the cells within the hour. Plasma samples should not be allowed to freeze and thaw during any of the handling steps.
**Module III: Shipping Instructions**

**Table V: Shipping Instructions for All Visit Types (Participant, QA & Courtesy)**

PML = Penn Medical Laboratory
SFBR = Southwest Foundation for Biomedical Research

<table>
<thead>
<tr>
<th>Collection Tube Type</th>
<th>Tests</th>
<th>Sample Type</th>
<th>Storage/Shipping Requirement</th>
<th>Lab to Ship to:</th>
<th>Cryovial Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 10 ml SST</td>
<td>Chem Profile, Lipids, Insulin, CRP, FFA</td>
<td>Serum</td>
<td>Frozen</td>
<td>PML</td>
<td>4 2 ml-red cap vial</td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td>Serum</td>
<td>Frozen</td>
<td>PML</td>
<td>8 2 ml-red cap vial</td>
</tr>
<tr>
<td>1 4.5 ml Lt blue or</td>
<td>Fibrinogen</td>
<td>Na Citrate Plasma Na Citrate Plasma</td>
<td>Frozen</td>
<td>PML</td>
<td>1 2 ml-blue cap vial</td>
</tr>
<tr>
<td>2 2.7 ml Lt blue</td>
<td>Storage</td>
<td>Na Citrate Plasma Na Citrate Plasma</td>
<td>Frozen</td>
<td>PML</td>
<td>1 2 ml-blue cap vial</td>
</tr>
<tr>
<td>1 4 ml gray</td>
<td>0 hour (fasting) glucose</td>
<td>NaFl Plasmap</td>
<td>Frozen</td>
<td>PML</td>
<td>2 2 ml-black cap vial</td>
</tr>
<tr>
<td>3 10 ml Purple</td>
<td>HemoglobinA1c DNA Isolation Leptin EDTA Storage</td>
<td>Whole Blood Buffy Coat EDTA Plasma EDTA Plasma</td>
<td>Frozen</td>
<td>PML</td>
<td>3 2 ml-neutral cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SFBR</td>
<td>3 2 ml-orange cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 2 ml-purple cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8 2 ml-purple cap vial</td>
</tr>
<tr>
<td>1 cup Random Urine</td>
<td>Albumin/Creatinine Storage</td>
<td>Urine</td>
<td>Frozen</td>
<td>PML</td>
<td>2 2 ml-yellow cap vial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 2 ml-yellow cap vial</td>
</tr>
</tbody>
</table>
Supplies Required for Shipping

Frozen Samples:

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- FedEx Shipping Labels
- Biohazard bags
- Dry Ice
- Paper Towels for wrapping Storage Boxes
- Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
- 3/4" Scotch Brand Filament Tape

Note: 20 lbs of dry ice gives some insurance against thawing if the package is delayed a few hours.

Preparation of Samples for Shipment to Penn Medical Lab:

- Study laboratory requisitions stapled to extra unused labels for each set of samples must accompany each shipment.
- Each is printed on two-part carbonless form.
- Keep the last copy for your records and send the original with the samples. When your shipment is received, lab technicians at each laboratory will perform an inventory to be certain that all samples in the box correspond to those indicated on the shipping log. If the lab finds any discrepancies, they will call you to ask for your assistance in identifying extra samples or find lost samples.

Packing Shipping Containers

- All samples are to be packed according to DOT regulations and in compliance with shipper's requirements. This includes the following:
- Label the exterior of all shipping boxes according to the shipper's requirements. Boxes must have dry ice labels with the amount of dry ice marked on the label and orange-red labels with “Perishable” printed.
- Sort specimens to be sent to Penn Medical Lab or Southwest Foundation for Biomedical Research (See Table V above).
- Place approximately 20 pounds of dry ice at the bottom of the shipping box.
- Place packing material (i.e., chux, Styrofoam “peanuts” or newspaper) on top of dry ice.
Place samples in biohazard bags with forms in pocket of bag on top of packing.

Check all of the specimens in the box against the Shipping Log Form to be sure there are no transcription errors or missing specimens.

Add more packing material if there is additional space so samples cannot bounce around the box while in shipment.

Place "Class 9" (dry ice) labels on the outside of the cardboard shipping carton and record the amount enclosed.

Place polyfoam lid on box.

Close cardboard lids.

With ¾" tape secure the cardboard lid closed.

Prepare FedEx air bill.

Samples will be shipped by priority air so that they arrive at the laboratory **WITHIN 24 HOURS.** ONLY SHIP SAMPLES MONDAY though WEDNESDAY.

Retain a copy of the air bill as a receipt for tracking and auditing purposes.

The day of shipment, fax (202-877-7342), call 202-877-5040 or email the laboratory to inform them that a package is being sent.

Please give the following information:

- Date samples will be shipped
- The name of the person responsible for shipping the package and a phone number where the call can be returned if needed
- Number of shipping boxes sent
- FedEx tracking number
This information will allow the lab to track the package quickly if it does not arrive as planned.

If you have any question regarding samples or shipment to Penn Medical Lab:

Sophia Rushton-Reid: Phone: 202-877-8379
Fax: 202-877-7342
Email: Sophia rushton-reid@medstar.net
Shipping/Receiving Dept: Phone: 202-877-5040 or 202-877-5055
Technical Area: Phone: 202-877-5630

If you have any question regarding samples or shipment to Southwest Foundation for Biomedical Research Lab:

Shelly Cole: Phone: 210-258-9688
Fax: 210-670-3334
Email: scole@darwin.sfbr.org

• Holiday Schedule:

Penn Medical Laboratory is closed on the following holidays:

<table>
<thead>
<tr>
<th>Holiday</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>President’s Day</td>
<td>February 20, 2006</td>
<td>February 19, 2007</td>
<td>February 18, 2008</td>
<td>February 16, 2009</td>
<td>February 15, 2010</td>
</tr>
</tbody>
</table>
SFBR Laboratories are closed on the following holidays:

<table>
<thead>
<tr>
<th>Holiday</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiesta Friday</td>
<td>April 28, 2006</td>
<td>April 27, 2007</td>
<td>April 25, 2008</td>
<td>April 24, 2009</td>
<td>April 23, 2010</td>
</tr>
</tbody>
</table>

APPENDIX A

THE STRONG HEART STUDY, PHASE V
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

The following recommendations are made regarding maintenance and operation of the One-Touch Sure Step Flexx meter in order to ensure accurate readings of blood glucose.

There are 2 types of One Touch equipment (for Home use and for Hospital use). Hospital equipment requires daily QC checks, and this is also required by SHS. Please record the QC in your daily log. Be sure to use only Hospital products including the hospital test strips.

Excerpts taken from Sure Step Flexx meter operator's guide:

**General Care**

To keep the meter in good operating condition, you must keep it clean and handle it with care. Follow these simple rules:

- Keep the test strip holder and lens area clean.
- Keep the meter dry and avoid exposing it to extremes in temperature and humidity.
- Do not take apart the meter.
- If you drop the meter, inspect it for obvious damage.
- Perform a quality control test prior to running a patient blood glucose test.

**Cleaning**

When to Clean the Meter

- If dirt, blood, or lint is present.
- When an error message appears and the troubleshooting solution indicates cleaning the meter.
- As defined by your institution’s infection control policies.

Cleaning the Outside of the Meter

Clean the outside of the meter with a cloth dampened with a 10% bleach solution. Follow with a cloth moistened with water to remove residual bleach. Dry the meter thoroughly. Refer to “Cleaning Agents” on page 100 for other solutions that can be used to clean the outside of the meter.

▲ CAUTION: Do not get water inside the meter. Never immerse the meter or hold it under running water because it will damage the meter.

Cleaning the Test Strip Holder and Lens

To clean the test strip holder (cover and base), lens area, and contact points, use a 10% bleach solution followed by water. Dry thoroughly.

▲ CAUTION: Do not use alcohol, glass cleaners, or any cleansers containing
abrasives, phenol, or ammonia to clean the test strip holder or lens area because it will damage the meter parts.

1 Press down on the left side of the test strip holder. This releases the holder, allowing you to slide it from the meter.
2 Wipe the test strip holder cover and base with a cotton swab or soft cloth dampened with a 10% bleach solution. Be sure to thoroughly wipe the gray area on the inside cover. Clean both sides of the base. Follow with a cotton swab dampened with water to remove residual bleach.
   ▲ CAUTION: Bleach residue left on the test strip holder may lead to an error message or an inaccurate, high result.
3 Dry the test strip holder with a soft cloth or lint-free tissue. Close the holder and set it aside.
4 Using a cotton swab or soft cloth dampened with a 10% bleach solution, wipe the lens area and contact points. Wipe this area even if it doesn’t appear to be dirty. Use a cloth moistened with water to remove residual bleach.
   Be careful not to scratch the lens area or get water inside the meter, contact points, lens area
5 Dry the lens area gently with a clean, soft, lint-free cloth or tissue. Remove any lint.
6 Slide the closed test strip holder into the meter. Push the holder until it clicks into place.
7 Turn on the meter. If an error appears, check to make sure you installed the test strip holder correctly.
8 If necessary, wipe the scanner lens with a soft cloth dampened with water.
9 Perform a quality control test to verify that the result is within the expected range.

Changing the Batteries
The meter is powered by three size AA alkaline batteries. The LOW BATTERY message appears when the battery power is too low to perform a test. Change the batteries when the message appears. You may want to change the batteries if the battery bar on the status screen is low. Although the meter will continue to accurately perform glucose tests until the LOW BATTERY message appears, barcode scanning and data transfer may be affected before the message appears.
   ▲ CAUTION: Do not use rechargeable batteries.
   ■ NOTE: Neither the LOW BATTERY message nor the removal of batteries affects the test results stored in meter memory.
1 Turn off the meter.
2 Turn the meter over. Press down on the battery door latch and lift open the door.
3 Remove the batteries from the battery compartment and dispose of them according to your institution’s guidelines.
4 Insert three new size AA batteries, matching the positive + end of each battery with the + signs inside the battery compartment.
   ■ NOTE: The battery life depends on how quickly the meter is powered off after each test. Under optimal conditions—using the barcode scanner to enter information and turning off the meter immediately after test results are displayed and recorded—you can expect approximately 1000 tests.
5 Replace the battery compartment door.
6 Turn on the meter to verify power.

Adjusting the Screen Contrast
You can increase or decrease the meter’s LCD screen contrast.
1 Select Setup from the Main Menu.
2 Select LCD Contrast from the Setup Menu.
The options available at the Setup Menu are different for stand-alone meters and meters configured by a DataLink workstation.
3 Press the arrows to increase or decrease the LCD contrast.
A change occurs each time you press the arrow. The gauge within the bar gives you an approximate indication of the current setting.
4 When you are satisfied with the setting, press OK to save the setting and return to the Setup Menu, OR, press the back or menu key to ignore any changes and return to the Setup Menu.

Setting the Date and Time
You can set the date and time for meters operating in stand-alone mode.
1 Select Setup from the Main Menu.
2 Select Date/Time Entry from the Setup Menu.
The Date/Time Entry option is available for stand-alone meters only.
3 Enter the time using the 24-hour format (hours:minutes). Press OK to save the setting and advance to the date screen.
To exit the screen without changing the time, press back or menu key.
4 Enter the date using the mm/dd/yy (month/day/year) format. Press OK to save the setting and return to the Setup Menu.
To exit the screen without changing the date, press back or menu.

Performing a Patient Test
Setting Up the Meter
1 Press the power button to turn on the meter.
2 The status screen appears. Press Cont to continue.
3 Select Patient Test from the Main Menu.
4 Enter your operator ID and press OK.
If the meter is equipped with the optional barcode scanner, you may scan the barcode on your ID badge.
5 Enter the patient’s ID and press OK.
If the meter is equipped with the optional barcode scanner, you may scan the patient’s barcode.
■ NOTE: Carefully enter the ID. An accurate patient ID is imperative for transferring the correct results to the medical record.
❑ Operator ID required for all tests
❑ Maintain ID for ___ min. after power off
If your ID appears at the operator ID screen, press OK to confirm it is correct. If the ID is not correct or does not appear, enter your ID.
❑ Patient ID required
6 Select the test strip lot number (and code) from the list displayed.
The last test strip lot number selected appears at the top of the list. Use the arrow(s) to scroll through the list, if necessary. If the meter is equipped with the optional barcode scanner, you may scan the barcode on the test strip bottle label.

▲ CAUTION: To obtain accurate results, you must enter the correct test strip lot number (and code) for each new test.

The Patient Test screen appears with messages prompting you to apply blood to the strip and insert the strip.

❑ New reagent entry at workstation only

The meter may be set to allow you to enter new reagent information. If the test strip lot number does not appear in the list, press the Entr Lot# button and enter the test strip lot number, control code, and control ranges.

Applying Blood Sample to the Test Strip
The puncture site must be cleaned and thoroughly dried before obtaining the sample. Thus, the participant will be asked to wash his/her hands with soap and water and dry them. Then the staff will apply alcohol to the puncture site and wait for the alcohol to dry. A drop of capillary blood will be obtained by puncturing the finger using a lancing device. Follow your institution’s policy and procedure guidelines for blood collection.

7 Apply the blood to the center of the pink test square as follows:

Finger Stick
Carefully touch the center of the pink test square to the drop of blood on the patient’s finger. The test area will quickly absorb the blood.

8 Check the white pad on the front of the test strip and the confirmation dot on the back of the test strip.

• If the white pad becomes completely saturated, you have applied too much blood for an accurate result. Repeat the application with a new test strip.
• The confirmation dot should be completely blue. If white patches or streaks are visible, you have not applied enough blood for an accurate result. Repeat the application with a new test strip.

▲ CAUTION: Do not apply additional blood to the test strip or you may get an inaccurate result.

If white patches or streaks continue to appear after you have repeated the test and used a larger volume of blood, call the LifeScan Healthcare Professional Line at 1 800 524-7226.

Inserting the Test Strip
9 Firmly insert the test strip all the way into the test strip holder until it stops (the confirmation dot should be facing down).

▲ CAUTION: If you fail to completely insert the test strip, the test may start; however, you may receive an inaccurate, low result.

▲ CAUTION: You have up to 2 minutes to insert the test strip after the blood is applied. If you insert the test strip after 2 minutes, you may get an inaccurate result or an error message. Discard the test strip and repeat the test with a new test strip.

Patient Results
The patient test result appears in approximately 30 seconds.
◆ IMPORTANT: Do not remove the test strip until the countdown is complete.
If an error message appears, refer to Chapter 7, Troubleshooting, for information.
A glucose range may be defined by your system administrator. Results that fall above or below the limits of this range appear as follows:
• CRITICAL HIGH indicates a result above the range.
• CRITICAL LOW indicates a result below the range.
• HIGH indicates a result greater than 500 mg/dL.

◆ IMPORTANT: When the result is greater than 500 mg/dL and proper procedures are followed, the meter will display HIGH in virtually all cases. Additionally, the confirmation dot will be darker than the 350-mg/dL sample color dot on the test strip bottle Color Chart. This indicates hyperglycemia. Follow your institution’s policies for treatment.

10 Remove the test strip and dispose of it according to your institution’s policies and procedures.
11 You may press Entr Note and choose 1 to 3 comments that correspond to the patient’s current situation. Press OK, Or, press menu and continue testing.

■ NOTE: Results tagged with the comment “Procedure Err” are not included in any patient reports.

If you have problems using the meter to test patient samples, or if the meter malfunctions, call the LifeScan Healthcare Professional Line at 1 800 524-7226.

 REQUIRE message entry for patient tests outside the critical limits. You may be required to select a comment when a patient test result falls outside the limits of the range.

Record the glucose reading (from the Sure Step Flexx screen) on form S7, Sample Collection Checklist, item #1 (Fasting One-Touch Sure Step Flexx glucose result.)

Complete the rest of the sample collection checklist (form S7)
## Safety and Protection Precautions Checklist

- **Technician Code # / Initials:**
- **Observer Code # / Initials:**
- **Date Observed:**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoids direct contact with blood, sera, plasma or urine.</td>
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<td>Wears protective clothing, gloves, goggles or safety glasses when handling specimens or performing phlebotomy.</td>
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<tr>
<td>Wears long-sleeved full-length lab coat buttoned down front or apron over scrubs.</td>
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<td>Wears close-toed shoes.</td>
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<tr>
<td>Immunized against Hepatitis B.</td>
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<tr>
<td>Disposes of tubes, containers and other material exposed to blood in appropriately labeled waste receptacles for biohazardous material.</td>
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<tr>
<td>Places contaminated sharps in labeled, puncture-resistant, leak-proof containers.</td>
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<tr>
<td>Processes blood where first aid instructions can be followed (i.e., wash off skin contact, eye wash, needle-stick instructions).</td>
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<tr>
<td>Follows universal precautions and treats every specimen as potentially hazardous.</td>
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<td>Removes protective clothing before leaving processing area.</td>
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<tr>
<td>Uses biohazard labels on refrigerator or freezer holding blood and on specimen containers for storage (including zip-lok bags).</td>
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**Comments:**
## Checklist for Sample Collection

| Technician Code # / Initials: | | | | | | | |
| Observer Code # / Initials: | | | | | | | |
| Date Observed: | Yes | No | | | | | |
| Room set-up with basic supplies for blood collection. | | | | | | | |
| Follows safety/universal precautions as outlined in checklist. | | | | | | | |
| Labels collection tubes with ID number and date of draw. | | | | | | | |
| Introduces self and wears nametag. | | | | | | | |
| Positions participant in comfortable chair in quiet environment. | | | | | | | |
| Explains blood drawing procedures and purpose. | | | | | | | |
| Conducts glucometer procedure as required. | | | | | | | |
| Completes forms related to blood collection accurately. | | | | | | | |
| Assesses fasting state of participant. | | | | | | | |
| Conducts venipuncture using vascular access with a multi-draw vacutainer (butterfly) needle into vacutainer tubes. | | | | | | | |
| Draws tubes in order recommended by SHS Core Lab. | | | | | | | |
| Loosens tourniquet after blood flow starts. | | | | | | | |
| Does not attempt a venipuncture more than three (3) times. | | | | | | | |
| Inverts all tubes (except SST) 8-10 times and places on ice. SST tube is to remain upright at room temperature for 20 min. | | | | | | | |
| After the last tube is drawn, removes tourniquet and uses clean gauze to apply slight pressure to vein (has arm extended) and after 3-5 minutes, applies a pressure bandage. | | | | | | | |
| Disposes of entire needle set-up into biohazard container. Does not attempt to recap a needle. | | | | | | | |
| Obtains a urine sample from participant in a pre-labeled container and places it on ice immediately. Records time of voiding. | | | | | | | |
| Thanks participant and instructs them on next activity. | | | | | | | |
| Removes gloves, washes hands, proceeds to next participant. | | | | | | | |
| Comments: | | | | | | | |
STRONG HEART STUDY

PHASE V

FAMILY STUDY

Quality Control - Equipment
## Equipment – Quality Assurance Checklist

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SHS Phase V Family Study

QUALITY CONTROL LOG

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

<table>
<thead>
<tr>
<th>Test Strip</th>
<th>Low Level Control Solution</th>
<th>Normal Level Control Solution</th>
<th>High Level Control Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lot#</td>
<td>Date Opened</td>
<td>Opened Exp.</td>
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<table>
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<tr>
<th>Test Strip</th>
<th>Lot #</th>
<th>Code #</th>
<th>Exp.</th>
<th>Accep Range</th>
<th>Actual Value</th>
<th>Mean +/- Mean</th>
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<th>Accep Range</th>
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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. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted. If the reading is either above or below the zero mark, the system should be returned to the manufacturer or replaced.

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

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

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

5. Since mercury is a toxic substance, all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry. All clinics should have a mercury spill kit available, and staff should be trained in how to use the kit.
<table>
<thead>
<tr>
<th>MONTH</th>
<th>DATE</th>
<th>INIT.</th>
<th>MERCURY LEVEL IS AT ZERO WITH NO PRESSURE</th>
<th>CHECK FOR AIR LEAKS WITH MERCURY AT 200 mmHg</th>
<th>CHECK CAP FOR TIGHTNESS</th>
<th>CHECK TUBE FOR OXIDE DUST</th>
<th>COMMENT ON ANY PROBLEMS FOUND AND CORRECTIVE ACTION TAKEN.</th>
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SCALE/TAPE
## SHS Phase V Family Study

### Quality Control

**SCALE & MEASUREMENT TAPES**

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