CLINICAL MEASUREMENTS

INTRODUCTION

Participants have clinical measurements performed at many different visits. This section describes how each measurement should be done, regardless of the visit at which they're done. Some general guidelines include:

- Ensure Clinical Center (CC) staff are appropriately trained and certified to perform specific Women's Health Initiative (WHI) clinical measurements (required).
- Evaluate carefully CC staff's expertise, training, and state licensure guidelines to determine who should perform specific measurements (recommended).
- Cross-train and certify CC staff on several measurement procedures to allow maximum flexibility in CC operations (recommended).
- Record all measurements in metric units (required).
- Maintain measurement equipment in good working order (required).
- Make arrangements for appropriate back-up equipment either on-site or from equipment suppliers or service representatives (recommended).

The routine of the CC over time will encourage familiarity with clinical measurement procedures. These measurements are an important aspect of the study and the collection of this information must be done with a sense of care and excellence.

9.1 Resting Pulse (Required)

Clinical Trial (CT) and Observational Study (OS) participants have a resting pulse determination during screening and follow-up visits as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. Perform this procedure before (or at least 30 minutes after) other potentially stressful procedures (e.g., blood draw or weight measurement). The pulse should be measured in a quiet area away from other CC activities. Have a table next to the chair where the participant sits. Have the participant sit quietly with both feet flat on the floor without smoking or talking for a 5-minute rest period before taking the pulse measurement. A clock or watch with a second-hand or a stopwatch is required for this procedure. The pulse measurement can immediately precede the blood pressure (BP) measurement without a rest period in between if the arm circumference measurement for BP is done before this rest period [see *Section 9.2 Blood Pressure (Required)*].

9.1.1 Training and Certification

Women's Health Initiative (WHI) CC staff can perform the resting pulse measurement after completion of the WHI training and certification process.

9.1.2 Performing the Measurement

Instruct the participant to rest her elbow and forearm comfortably on the table. The resting pulse is usually measured at the radial artery. With the participant's palm turned upward, use the pads of your index and middle fingers to palpate the radial artery until a maximum pulsation is detected. Count the pulse for 30 seconds using the second-hand of a watch or clock or setting a stopwatch at 0. Record the number of beats in 30 seconds on *Form 80 - Physical Measurements*. Then, multiply the number by two and record that result also on Form 80 Inform the participant of her resting pulse measurement.

9.1.3 Alert Values for Resting Pulse

Refer participants with a markedly irregular pulse or a resting pulse rate of less than 40 beats/minute or greater than 130 beats/minute to your Clinic Practitioner (CP). Check your CC guidelines for any CC-specific alert actions for the resting pulse measurement.

9.2 Blood Pressure (Required)

Clinical Trial and OS participants have BP determinations during screening and follow-up visits as outlined in *Vol. 1 – Study Protocol and Policies, Table 1-A1.1 – Frequency of Data Collection*. A conventional mercury sphygmomanometer, appropriate-sized BP cuffs and stethoscope with a bell are required for this procedure. If you are using a non-mercury manometer due to institutional biohazard requirements, notify the CCC of the name/model number of the equipment being used and the exact date the equipment was implemented. The procedures documented below pertain to a mercury manometer. Also needed are a clock or watch with a second-hand or a stopwatch for this procedure. Perform this procedure before (or at least 30 minutes after) other potentially stressful procedures (e.g., blood draw or weight measurement). Although it is recommended that the BP be measured before the blood draw, if this is not possible, do the two procedures in opposite arms (e.g., left arm for blood draw, right arm for BP), allowing sufficient time (e.g., 30 minutes to one hour) to pass after the blood draw and before the BP measurement. If the BP is measured right after the pulse and a sufficient rest period precedes the pulse, it is not necessary to rest again between the pulse and BP measurements (as long as arm circumference is measured before the rest period). The BP measurement area should be free of excessive noise and the participant should not be interviewed at this time. Obtain two sitting systolic and diastolic BP measurements using a conventional mercury sphygmomanometer and record the results on *Form 80 – Physical Measurements*.

It is advisable to have an additional conventional mercury sphygmomanometer and standard stethoscope available in the CC in case of an equipment failure.

9.2.1 Training and Certification

Women's Health Initiative CC staff can perform the BP measurements after completion of the WHI training and certification process.

9.2.2 Blood Pressure Procedures

The BP measurement is based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and direct registration of pressure levels by a manometer. The observer inflates the appropriate-sized cuff placed on the participant's upper arm, listens for the first (systolic) and the last (diastolic) Korotkoff sounds, reads the level in the column, deflates the cuff, and records the readings.

9.2.2.1 Blinding

The CC staff person performing the BP measurement is automatically blinded at the baseline visit because the BP measurement is done before randomization to a treatment group. At each annual follow-up visit, the BP measurement should be performed without knowledge of the participant's treatment assignment or previous visit's BP measurements.

To keep the CC personnel blinded to the previous visit's BP measurements, clip a blank *Form 80 – Physical Measurements* to the outside of the participant's file. Leave the *Form 80* attached to the front of the file while you perform and record the BP measurements for the current visit. Once completed, you may then review the contents of the participant's file for BP information relating to the previous visit, if necessary.

9.2.2.2 Arm Circumference Measurement

Since participants have varying body builds, different-sized arm cuffs should be available. Proper cuff size must be used to avoid over- or under-estimation of the correct BP. Measure the participant's right arm to determine the appropriate cuff size before allowing the participant to rest (or the left arm if the right was used for the blood draw). Otherwise, an additional 5-minute rest will be needed before the BP measurement can be taken to ensure accurate readings. If the participant's right arm is injured or missing, use the left arm for the arm circumference and BP measurement.

Use the following procedures to measure the participant's arm circumference to determine the appropriate cuff size:

- Ask the participant to remove her upper garment if she is wearing heavy clothing that covers her arm. (Be sure that the participant is assured of privacy if she must remove clothing.)
- Request the participant to stand with her forearm horizontal to the floor (elbow should be bent slightly).
- Measure her arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax her arm along the side of her body.
- Draw the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin.
- Use the measurement to determine the correct cuff size and record the type of cuff and which arm is used on *Form 80*.

Do not use the markings on the BP cuff for reference. Instead, use the following criteria for determining the appropriate cuff size (i.e., size of the cuff's bladder width, not its length).

Arm Circumference (cm/in.)	Cuff's Bladder Size (cm)*
16.0 - 22.5 cm (6.4 - 9 in.)	small cuff (9.0 cm)
22.6 - 30.0 cm (9.1 - 12 in.)	regular cuff (12.0 cm)
30.1 - 37.5 cm (12.1 - 15 in.)	large cuff (15.0 cm)
37.6 - 43.7 cm (15.1 - 17.5 in.)	thigh cuff (17.5 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

9.2.2.3 Rest Period

If the BP is not measured immediately after the pulse measurement, ask the participant to sit with both feet flat on the floor and to rest without talking for five minutes before measuring her BP. Instruct the participant on correct posture with her back supported, both feet flat on the floor, and arm resting on a table next to the chair. The BP measurement area should be free of excessive noise and the participant should not be interviewed at this time.

9.2.2.4 Application of the Cuff

Use the following procedures when applying the BP cuff:

- Ensure that the participant is seated comfortably and both feet are flat on the floor with her sleeve rolled up or her upper garment removed, if necessary.
- Place the appropriate-sized cuff (see *Section 9.2.2.2 - Arm Circumference Measurement*) around the upper right arm (or left, if the right arm is injured or missing) approximately at heart level. Place the participant's palm facing upward (the participant may rest her forearm and elbow on a table). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of her elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body.

*The bladder widths shown are 40% or more of the corresponding arm circumferences.

Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it overlaps the cuff.

9.2.2.5 Determining the Maximal Inflation Level

Determine the pressure to which to inflate the cuff for the systolic BP measurement. This procedure ensures that the cuff pressure at the start of the reading exceeds the systolic BP and allows you to hear the first Korotkoff sound. The procedures for determining the maximal inflation level are as follows:

- Attach the cuff tubing to the conventional mercury sphygmomanometer.
- Palpate the radial pulse (if the radial pulse is difficult to palpate, the brachial pulse may be used).
- Inflate the cuff until the radial pulse is no longer felt (palpated systolic).
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mmHg above the palpated systolic pressure (maximal inflation level) for subsequent readings.

9.2.2.6 Performing the Measurement

Wait 30 seconds after determining the maximal inflation level and follow the steps below for performing the BP measurement:

- Place the ear pieces of the stethoscope, with the tips turned forward, into your ears.
- Apply the bell of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. (Use of the bell is required because the Korotkoff sounds can be heard more easily.) Effective use of the bell requires careful palpation of the brachial artery to know exactly where to place the bell. Place the bell just below, but not touching, the cuff or tubing.
- Close the thumb valve and squeeze the bulb, inflating the cuff at a rapid but smooth and continuous rate to the maximal inflation level. *Note*: Your eyes should be level with the mid-range of the manometer scale and focused on the level to which you will raise the pressure.
- Open the thumb valve very slightly and maintain a constant rate of deflation of no more than 2-3 mm Hg per second, allowing the cuff to deflate. Listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) until 10 mmHg below the level of the diastolic reading (i.e., 10 mmHg below the level where you hear the last regular sound). (See *Section 9.2.3 - Criteria for Systolic and Diastolic Blood Pressure* and *Section 9.2.4 - Guidelines for Blood Pressure Readings*).
- Deflate the cuff fully by opening the thumb valve and remove the stethoscope ear pieces.
- Record the systolic and diastolic values from the first reading on *Form 80 - Physical Measurements*.
- Hold the participant's arm vertically above her head for a full five seconds to relieve blood pooling.
- Have the participant sit quietly for 30 seconds, then repeat the BP measurement and record the systolic and diastolic values from the second reading on *Form 80 - Physical Measurements*.
- Tell the participant her BP measurement.

9.2.3 Criteria for Systolic and Diastolic Blood Pressure

To identify correctly systolic (Phase I) and diastolic (Phase V) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the mercury column.

- The systolic value (Phase I) is the pressure level at which you hear the first of two or more knocking sounds in appropriate rhythm. *Note:* A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) does not alter the interpretation of the BP.

- The diastolic value (Phase V) is the pressure level at which you hear the last of these rhythmic sounds (usually muffled).
- Drop the mercury column at 2-3 mmHg per second, from the maximum inflation pressure until 10 mmHg below that of the last regular sound heard. The control of the deflation rate is essential for accurate readings and depends on proper handling of the bulb and its control valve.

9.2.4 Guidelines for Blood Pressure Readings

- Make all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between markings on the mercury column to the next higher even-numbered marking).
- Make readings at the top of the meniscus (rounded surface) of the mercury column.
- When the pressure is released too quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer or do a repeat measurement.

9.2.5 Maintenance of Sphygmomanometer

Check the sphygmomanometer with each use for correct zero. Place the instrument flat on the table and disconnect the inflation system. With eyes level with the zero line, ensure the top of the meniscus is on the zero line. Send the instrument for repair if the reading is either above or below the zero mark.

Check the sphygmomanometer annually to ensure that the cap of the manometer fits properly and tightly. Roll the cuff around a plastic bottle or tin can and secure in place. Close the valve on the air-flo system and inflate the instrument until the mercury rises to 240 mmHg. Close the valve. The mercury column should remain stable. If the column continues to fall, there is an air leak and the system should be re-inflated until the column rises to 200 mmHg. Pinch the tubing at various locations to localize the area of the leak, then replace the leaking tubing, cuff, or valve.

With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Do not attempt to clean the glass column with a pipe cleaner, as hazardous levels of mercury aerosol will be produced. Send the instrument to your local supplier annually for inspection and cleaning or as-needed in the interim.

Since mercury is a hazardous, toxic substance, all maintenance and disposal procedures must be performed carefully and properly (consult your local institution for guidelines). Do not perform any maintenance procedures that will expose the mercury to air. A manometer specialist with expertise in handling toxic substances should be contacted to add or withdraw mercury from the instrument.

With each use, check the BP cuffs to ensure they are in good condition, (i.e., they are not frayed or torn). Also, check the BP cuffs on a regular basis to ensure all sizes of cuffs are available. Document all BP equipment checks on a CC Equipment Log. (See *Volume 7, Section 4, Table 4.1 – CC Equipment Maintenance* for schedule.)

9.2.6 Alert Values

An abnormal BP reading may temporarily exclude a participant from further screening or may prompt referral to her physician. Follow these guidelines for BP alerts:

- Report to the participant's primary care provider (participant remains eligible):

  systolic BP > 160 and < 200, or
  diastolic BP > 95 and < 105

- Make an urgent referral to the participant's primary care provider (within the week) and temporarily exclude from the CT:

  systolic BP > 200 and ≤ 210, or

diastolic BP > 105 and ≤ 120

- Make an immediate referral to the participant's primary physician via telephone before the participant leaves the CC (with a follow-up letter documenting the information discussed by phone) and temporarily exclude from the CT:

systolic BP > 210, or
diastolic BP > 120

Participants may be eligible after starting treatment for hypertension, but repeat readings while on treatment must show systolic BP < 200 and diastolic BP < 105. If a participant seeks treatment after Screening Visit 1 (SV1) and wishes to continue in the study, she may return for Screening Visit 2 (SV2), and should have her BP rechecked at that time. Record the two new BP readings on a new *Form 80 - Physical Measurements*.

9.3 Height (Required)

Clinical Trial and OS participants have their height measured during screening and follow-up visits as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. Clinical Centers are required to use a wall-mounted stadiometer that measures in centimeters (see *Section 2.3.2 - Equipment and Supplies CCs Must Purchase*) for all height measurements. Bone density sites are required to use wall-mounted Harpenden stadiometers for height measurements. The loss of height associated with vertebral deformity is a secondary endpoint of the trial. This objective requires that we achieve the greatest possible precision for this measurement.

9.3.1 Training and Certification

Women's Health Initiative CC staff can perform the height measurement after completion of the WHI training and certification process.

9.3.2 Performing the Measurement

A participant's standing height is the distance from the soles of the feet to the top of the head with the participant standing erect and looking straight ahead. Use the following procedures in determining the participant's height:

- Mount the stadiometer so that the participant stands on a level, uncarpeted, hard surface (or on a piece of plywood on a flat carpet).
- Instruct the participant to remove her shoes.
- Ask her to stand erect with:
  1) her back to the wall-mounted stadiometer,
  2) the back of her head, back (scapulae), and buttocks touching the measuring board, and
  3) with her weight distributed evenly across both feet and her feet flat on the floor with both heels together.
- Check that the participant is in the correct position. (If she is obese or has a kyphotic posture, she may be positioned so that only the buttocks or the scapulae are in contact with the measuring board; in the case of extreme kyphosis, measure the height with the participant standing in a sideways position.)
- Instruct her to look straight ahead and keep her arms relaxed and hanging loosely at her sides.
- Bring the sliding headpiece down firmly, but not tightly, on the top of her head.
- Use a foot stool to adjust the sliding headpiece if the participant is tall, so that your eyes are level with the point of measurement.
- Instruct the participant to inhale deeply and record the reading on the stadiometer just before she exhales.
- Record the height on *Form 80 - Physical Measurements* in centimeters, rounding up to the nearest tenth of a centimeter.
- Tell the participant her height in inches (a chart converting centimeters to inches may be used).

9.3.3 Maintenance of Wall-Mounted Stadiometer

Ensure that the stadiometer is mounted on a straight wall that is at a true 90-degree angle to a level floor. There should be a foot of unoccupied wall space on either side of the stadiometer Whenever the stadiometer is moved, check to confirm that it is positioned properly.

Stadiometer at Non-Bone Density Sites

Check the wall-mounted measuring board annually with a measuring stick to ensure its accuracy. If the measuring board is inaccurate, check the manufacturer's information for instructions on re-mounting.

Regularly clean the surface of the measuring board with mild soap and a damp cloth. Remove the soap with a clean, damp cloth and dry the surface thoroughly. Preserve the board's finish by occasionally treating it with a light furniture wax. Clean the sliding headpiece with a mild glass cleaning solution and a paper towel or dry cloth.

When the stadiometer is not in use, move the sliding headpiece to the bottom of the board so that it rests on the rubber spacers. This will guard against the headpiece sliding down the measuring board on its own and possibly breaking. Alternatively, you may choose to remove the sliding headpiece and place it out of reach. The following is a list of possible problems that may occur with the sliding headpiece and the appropriate adjustments to make:

- Sliding headpiece does not glide freely because it rubs against the wall: slightly loosen the screws from the wall.
- Sliding headpiece is difficult to slide because of pressure between the side of the measuring board and the spring on the inner curve of the sliding headpiece: remove the headpiece and slightly flatten the spring on its inner curve.
- Sliding headpiece is so loose that it falls down the measuring board: remove the headpiece and slightly bend the spring on its inner curve to increase the pressure between the headpiece and the measuring board.

Stadiometer at Bone Density Sites

The Harpenden stadiometer, used to measure height at the bone density sites, contains a direct-reading counter mounted on a counter-balanced carriage that rides on ball bearings. The counter is a self-contained unit and requires no maintenance. A spare counter is often provided for replacements. It is recommended that you place a weight of about 0.5 kg on the headboard to standardize pressure on the head and improve measurement performance.

Because the counter may break if the headboard is "raced" up or down the measuring board, move the Harpenden headboard to its top-most position when not in use. Lubricate any bearings or counter-weight pulleys semi-annually with one drop of light machine or instrument oil. Wash the formica or plastic covering with soap and water.

Daily calibration is required for the Harpenden stadiometer at bone density sites:

- Place a 600 mm metal rod between the headboard and the floor so that it stands vertically.
- If the counter does not record the correct length of the rod, loosen the counter by undoing the two metal retaining screws and pull it away from the main fiber cog of the carriage.
- In this position, turn the small metal cog of the counter until it records the true length of the metal rod.
- Press the counter against the back plate so that the teeth of the counter cog and the carriage cog engage and tighten the retaining screws.
- Move the headboard up and down the backboard a number of times to ensure the counter continues to give an accurate reading. If it does not, the counter must be replaced.

Document, as appropriate, annual or daily stadiometer checks on a CC Equipment Log. (See *Volume 7, Section 4, Table 4.1 – CC Equipment Maintenance* for schedule.)

9.3.4 Reliability Testing of Portable Stadiometer

Clinical Centers are required to use a wall-mounted stadiometer that measures in centimeters for all height measurements. Clinical Trial and OS participants may have height measurements made using a portable stadiometer during screening and follow-up visits at WHI off-site clinic visits. However, a CC must obtain approval from the CCC before using a portable stadiometer. To obtain approval, the CC must document the reliability testing and provide the CCC with a copy of the results.

Reliability testing will help to assure the quality of the height measurement using the portable stadiometer both study-wide and by individual clinic staff. Reliability testing will also serve to collect information on the reliability of height measurements using wall-mounted stadiometers compared to portable stadiometers.

The reliability testing requires two examiners at the CC to do height measurements using a wall-mounted stadiometer and a portable stadiometer. Height measurements must be done for six participants. To compare the effect between the examiner and the stadiometer, both examiners will take the participant's height measurement using the wall-mounted stadiometer. One examiner will assemble the portable stadiometer and perform the measurement procedure without reading the measurement. The other examiner will read and document the results of the height measurement using the portable stadiometer. The portable stadiometer must be disassembled and re-assembled between each reading, with each examiner assembing and taking the reading three times. Record the results on the Portable Stadiometer Reliability Testing log and forward to the CCC (see Figure 9.2). The CCC will notify the CC on results of the testing. Refer to Bulletin 86 text or WHI Directory for the recommended distributor.

Performing the Measurement

Two examiners (#A and #B) will validate the data for the portable stadiometer reliability testing using the procedure below. To minimize any possibility of bias, both examiners must be blinded to each other's measurements.

- Explain the procedure to the participant and why it's being done.
- Examiner #A will measure a participant's height using the wall-mounted stadiometer in accordance with the standard WHI procedure outlined in Section 9.3.2 - Performing the Measurement.
- Examiner #B will repeat this procedure 15-30 minutes later using the same wall-mounted stadiometer for the same participant.
- Examiner #A will disassemble and reassemble the portable stadiometer and perform the measurement procedure according to the manufacturer's recommendations.
- Examiner #B will read and record the height measurement results from the portable stadiometer.

  Note that each examiner must disassemble and re-assemble the portable stadiometer, prepare participants for the height measurement, and read and record the height measurement using the portable stadiometer for three participants (total of 6 participants at each CC).
- To preserve the integrity of the reliability testing, do not give the participant the measurements until after all three measurements (2 wall-mounted and 1 portable) are taken.

Completion of Reliability Testing Log

Record the data for the three measurements for each participant (two for the wall-mounted stadiometer reading and one for the portable stadiometer reading) on a CC copy of *Figure 9.2 – Portable Stadiometer Testing Log* along with the appropriate examiner IDs for each measurement. Once the six participant height measurements are completed, send the original log to your CM liaison at the CCC.

The CCC will review the completed Reliability Testing Log. Once approved, the CCC will forward approval for local use of the portable stadiometer to the CC.

Figure 9.2

Portable Stadiometer Reliability Testing Log

(not for key-entry)

Clinical Center:

Date	CC/Participant ID	Wall-Mounted Stadiometer				Portable Measuring Board	
		ID# of Examiner A	Height	ID# of Examiner B	Height	ID# (of examiner who reads and records portable measurement *)	Height
1. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm
2. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm
3. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm
4. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm
5. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm
6. __/__/__	__ __ - __ __ __ __ __ - __	__ __ __	_____.___cm	__ __ __	_____.___cm	__ __ __	_____.___cm

Complete and forward original log to your CCC CM Liaison (keep a copy at your CC).

*Note: Other examiner (A or B as appropriate) will disassemble and reassemble the portable stadiometer and perform measurement procedure (without reading the measurement).

9.4 Weight (Required)

Clinical Trial and OS participants have their weight measured during screening and follow-up visits as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. A balance beam scale that measures in kilograms is required for all weight measurements (see *Section 2.3.2 - Equipment and Supplies* CCs Must Purchase).

9.4.1 Training and Certification

A WHI staff person may measure body weight after completion of the WHI training and certification process.

9.4.2 Performing the Measurement

Use the following procedures to measure a participant's weight:

- Instruct the participant to remove her jacket, her shoes, other heavy clothing, and to empty her pockets.
- Lift both poises (weights) and position them at zero before asking the participant to step onto the scale. Ensure that the beam is balanced evenly at zero with no weight on the scale (see *Section 9.4.4 - Calibration Check* for recalibration guidelines).
  Ask the participant to step onto the scale, facing the measurement beam.
- Instruct her to stand in the middle of the platform on the scale with her head erect and eyes looking straight ahead.
- Ask the participant to distribute her weight evenly on both feet.
- Lift the counterweight (larger weight), and slide it to the right until the beam approaches balance with the participant standing in the proper position.
- Adjust the top poise until the beam is balanced evenly.
- Read the weight with your eyes level to the point of measurement on the scale.
- Ask the participant to step off the scale.
- Record the weight on *Form 80 - Physical Measurements*, rounding up to the nearest tenth of a kilogram.
- Return the counter poise to the 40-kg mark and the top poise to zero.
- Tell the participant her weight in pounds (a chart converting kilograms to pounds may be used).

9.4.3 Maintenance of Scale

With normal use, the scale should last for many years. In order to ensure long life, the following maintenance practices are recommended:

- The scale equipment should remain in a stationary position; it should not be moved from room to room, nor moved within the same room.
- The scale should not be tipped, and the platform should be kept free of objects.
- The scale should always remain standing on a level, uncarpeted, hard surface or on a piece of plywood on a flat carpet.
- While the top poise slides easily across the column, the counter poise must always be lifted carefully before it is moved across the column. This procedure prevents wear on the notches, which could cause incorrect readings.
- The top poise should rest on zero when the scale is not in use. The counter poise should rest on the 40-kg mark when the scale is not in use. If the counter poise is left at zero, the gear mechanisms may be subjected to unnecessary wear.

9.4.4 Calibration Check

Before you begin using the balance beam scale and annually thereafter, have the scale certified by a local department of weights and measures or a certified scale technician. If this certification is not possible, inform the Clinical Coordinating Center (CCC).

Check the scale against known weights on a semi-annual basis and whenever the scale is moved, using the procedure below. Each CC should have a 50-kg weight (or two 25-kg weights) for this purpose. If these weights are not certified (e.g., body-building weights), have their exact weight determined by the local department of weights and measures or a certified scale technician. Perform the calibration check as follows:

- Put both the top and counter poises in the zero position. With no weight on the platform, the beam should "float."
- If the beam is not balanced when both poises are in the zero position, turn the balance screw to the right or left until the scale is balanced.
- Put the known weights on the scale, and adjust the poises until the beam "floats" and verify that the scale is measuring the weights accurately.
- If the scale is outside a 0.2 kg range of accuracy, call an independent service technician to recalibrate it.

Document semi-annual scale checks and annual certifications on a CC Equipment Log. (See *Volume 7, Section 4, Table 4.1 – CC Equipment Maintenance* for schedule.)

9.4.5 Portable Scales

Often times a CC will use a portable scale (not a balance beam scale) to measure weight if clinic operations are performed at a remote site. If the CC plans to use a portable scale, the CC must send the CCC specifications of the name, model number, and the local calibration services available. The CCC must approve any non-WHI equipment changes.

Criteria for a portable scale include the following:

- Scale is well-made and sturdy
- Scale must be able to be calibrated
- Scale weighs in kilograms
- Scale can measure weights up to at least 160-180 kilograms (350-400 pounds)
- Allowable scale error is within 1 kg of certified weights
- An independent certified technician certifies portable scale annually

Equipment checks and procedures include the following:

- Calibrate the scale with two 25 kg weights and one 150 kg weight semi-annually.
- Document annual and semi-annual certifications and calibrations, respectively, in an equipment log.
- Set the scale to zero before weighing participants.
- If scale operates on batteries, use a power cord in lieu batteries.

9.5 Waist and Hip Circumference (Required)

Clinical Trial and OS participants have their waist and hip circumference measured during screening and at specified follow-up visits (CT in year 1 and a subsample of CT in years 3, 6, and 9; OS in year 3) and at close-out as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. A measuring tape that measures in centimeters is required for this procedure and the CCC provides tape measures in two lengths: 152 cm (5 ft.) and 183 cm (6 ft).

9.5.1 Training and Certification

Women's Health Initiative CC staff can perform waist and hip circumference measurements after completing the WHI training and certification process.

9.5.2 Performing the Measurement (Waist Circumference)

- Instruct the participant to remove any extra layers of clothing, belts, girdles, or binding pantyhose (only non-binding undergarments can be worn).
- Instruct the participant to stand with her weight distributed evenly on both feet, abdomen relaxed, arms at her sides, and feet together.
- Facing the participant, place the tape measure in a horizontal plane at the level of the natural waist, which is the narrowest part of the torso. An assistant may be needed to help position the tape in a horizontal plane. Alternatively, a wall-mounted mirror can be used to assist with positioning the tape in the horizontal position. If it is difficult to identify a waist narrowing, measure the smallest horizontal circumference in the area between the participant's ribs and iliac crest.
- Ensure that the zero end of the tape is below the measurement value.
- Verify that the participant is standing erect and that the tape measure is horizontal.
- Take the waist measurement at the end of a normal expiration, without the tape measure compressing the skin.
- Record the waist measurement on *Form 80 - Physical Measurements*, rounding up to the nearest half centimeter.

9.5.3 Performing the Measurement (Hip Circumference)

- Measure the hip circumference after the waist circumference.
- Place the tape measure around the participant's hips in a horizontal plane at the site of maximum extension of the buttocks.
- Ensure that the zero end of the tape is below the measurement value.
- Ensure that the tape measure is in contact with, but does not compress, the participant's skin.
- Verify that the participant is standing erect and that the tape measure is horizontal. An assistant may be needed to help position the tape in a horizontal plane. Alternatively, a wall-mounted mirror may be used to ensure that the tape is positioned in a horizontal plane if an assistant is unavailable.
- Record the hip circumference measurement on *Form 80 - Physical Measurements*, rounding up to the nearest half centimeter.

9.5.4 Maintenance of Measurement Tool

Inspect the tape measure monthly, as needed, for damage or wear and tear. Document tape measure checks on an Equipment Log (See *Volume 7, Section 4, Table 4.1 – CC Equipment Maintenance* for schedule.) Contact the CCC for a replacement, as needed.

9.6 Functional Measurement (Subsample Only) Status

A subsample of CT participants (identified by WHILMA) who are 65 to 79 years old at baseline will have functional status measurements performed during screening and follow-up visits, as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. These measurements will include grip strength, timed chair stands, and a timed walk.

Experience from other studies has suggested that participants have enjoyed the functional status measures and the challenges they present. The value of the physical performance data will be of benefit in understanding the relationship between physical functioning, institutionalization, service utilization, health status, and mortality.

9.6.1 Functional Status Measurement Procedures for Older Women

The following guidelines describe considerations for performing functional status measurements in older women. Refer to *Section 20.2.1 – Older Women* for more guidelines on working with older women.

9.6.1.1 Footwear

Measures of physical functioning should be performed with the participant wearing tennis shoes or shoes with very low or no heels. Some of the tests are much harder to perform with higher heels on. Ask the participant if the footwear she is wearing is what she wears most of the time around the house. Soft-soled, non-heeled slippers should not be worn; they may cause the participant to slip.

9.6.1.2 Physical Limitations and Safety Precautions (Required)

If the participant indicates she has a physical problem, discuss with her whether she should attempt each test, given the physical problem. You might say, "With me standing here beside you, do you think it would be unsafe for you to try to do it?"

Occasionally the participant will be so unsteady that the staff member will be concerned for her safety. If you are uncertain about the safety of performing a particular test, refer the participant to the CP or other appropriate clinician for guidance. The staff member may decide not to perform the test if the participant appears in imminent danger of falling. If a test is not conducted for safety reasons, mark the appropriate response on the form. In all instances, stay close to the participant to offer support. Stay to the side of the participant, rather than in front, to steady her if necessary. After reading the verbal instructions and demonstrating each maneuver for the participant, ask, "*Do you feel it would be safe to try?*"

If there is any reason that either the WHI staff person or the participant feels a particular performance measure would be unsafe, the measure should not be attempted. Emphasize this without alarming the participant.

9.6.1.3 Refused/Unable

If a test is not attempted because the participant refuses or prefers not to complete it, record the reason on *Form 90 - Functional Status*. If a test is attempted but the interviewer or the participant decides that the test cannot be completed, record that the test was not completed.

9.6.1.4 Falls

In the unlikely event that a participant should begin to fall, do not attempt to pull her up, rather help to lower her down gently in order to reduce the impact of the fall. Do not hold the participant by the hand; hold her around the torso under the shoulders. If the participant falls and is not injured, help her up by having her get on her knees or on all fours, place a chair next to her and have her support herself on the chair as you lift under the shoulders. Do not try to lift the participant alone from the floor. It may be helpful to have the stopwatch around your neck or wrist so that you can immediately let go of the stopwatch and have both hands free to help the participant. In the event that the participant requires assistance, simply drop the stopwatch and

disregard the timing. Local incident reports and appropriate medical referrals should be made based on the severity of the fall.

9.6.1.5 Improving Data Quality

Three techniques are recommended to improve data quality:

- *Commitment* – motivate the participant. Getting the participant to state her willingness to try to do the functional status measures and agreeing to work hard is an important first step.
- *Instructions* – should be directive and motivational and should make clear what is to be accomplished and the criteria for a good performance. Instructions include detailed verbal instructions, careful demonstration of each maneuver (with concurrent verbal instructions), asking if the participant understands, and answering any questions she might have. You may need to provide verbal instructions or a demonstration of the maneuver more than once. For some participants, detailed verbal instructions may seem tiresome or unnecessary. It may help to say to each participant that you are going to explain each test in detail because this is the best way to make sure that everyone does the test in the same way. It is up to you to determine whether the participant understands what is required and to provide the appropriate level of instruction.
- *Feedback* – provide cues to the participant about the adequacy of her performance. The feedback should reinforce the instructions and need for commitment. Feedback may include repeating relevant parts of the instructions as well as giving such encouragement as "*Keep going*", "*Good*", "*Steady*", or "*We appreciate your effort*".

9.6.2 Training and Certification

Women's Health Initiative CC staff can perform functional status measurements after completion of the WHI training and certification process.

9.6.3 Grip Strength (Required)

Grip strength is a measure of upper-body strength and has been used as a general indicator of frailty. Measure the grip strength in the dominant arm using an adjustable, hydraulic hand grip dynamometer that measures in kilograms (see *Section 2.3.2 - Equipment and Supplies CCs Must Purchase*).

9.6.3.1 Grip Strength Procedure

Measure the grip strength twice in the dominant arm unless the participant has had a recent flare-up of extreme arthritis, recent surgery, or residual weakness from an injury or stroke. If both arms are affected, do not measure the participant's grip strength.

- Determine whether to test grip strength, and which side to test, by doing the following:
  1. Hand dominance: determine whether the participant is right- or left-handed. In ambidextrous participants, take the measurement on the right side.
  2. Determine if the participant has had a stroke or injury with residual weakness on one or both sides. You could ask, "*Have you had a stroke or injury that has made one arm weaker than the other?*" In participants with a history of injury or stroke with residual arm weakness on the dominant side, take the measurement on the other side. If both sides are affected, do not measure participant's grip strength.
  3. Determine if the participant has had an acute flare-up of arthritis in the hand or surgery on the hand or wrist in the past three months (12 weeks). You could ask*, "Has any pain or arthritis in your hands gotten worse recently? Have you had any operations on your hands or wrists in the past three months?*" If she has had an acute flare-up of arthritis or is less than 13 weeks post-fusion, arthroplasty, tendon repair, or synovectomy (or other related surgeries), then do <u>not</u> test grip

strength on the affected side. If both sides are affected or the participant refuses the procedure, do not test grip strength and document this on *Form 90 - Functional Status*.

- Demonstrate how to do the procedure by placing the dynamometer in your dominant hand with the dial facing away from the palm. It is recommended that you say, "*In this exercise I'm going to use this instrument to measure the strength in your arms. First, let me show you how it's done*." Your arm should be flexed 90 degrees at the elbow with the forearm parallel to the floor. As you demonstrate, instruct the participant to squeeze the handle maximally while simultaneously lowering the arm on a 3-second count. Release the grip when your arm is extended completely, hanging straight at your side. Your arm should not touch your body and the gripping action should be a slow, sustained squeeze rather than an explosive jerk.

- Have the participant practice the maneuver by doing one sub-maximal trial, using her dominant arm, to determine if she understands the procedure. You could say, *"I'd like you to hold the dynamometer in your (right/left) hand and just slightly squeeze the handle like I showed you.*" Make sure the participant understands the entire procedure. The hand grip should be at the second setting and the participant should use the wrist safety strap on the dynamometer to minimize any chance of dropping the instrument.

- Reset the dial to zero.

- Have the participant perform two trials on the same side, coaching her to squeeze as hard as she can. You could say, "*Now, when I say 'squeeze,' squeeze as hard as you can while I count to three. The two pieces of metal will not move, but I will be able to read your grip strength on the dial. If you feel any pain, tell me and we will stop.*"

- Reset the dial to zero after each trial. If the participant has trouble completing two trials with her dominant hand, attempt to get two readings with her non-dominant hand. If the participant can only complete one trial, document that measurement on *Form 90 - Functional Status*.

- Record the measurement on the dial to the nearest kilogram (rounding up) for both trials on *Form 90 - Functional Status.*

- Record which hand was used to measure the grip strength.

9.6.3.2 Maintenance of Hand Grip Dynamometer

For routine maintenance, follow the instructions in the dynamometer owner's manual for checking the posts, hydraulics, handle, and peak-hold needle on a semi-annual basis. Be careful not to drop the dynamometer.

Check the zero position of the gauge needle with each use. To adjust it back to zero, unscrew the gauge cover. Using a screwdriver, turn the slot in the gauge needle shaft in the opposite direction that you want the needle to rotate. Restrain the needle from turning by holding it as near the center as possible while turning the shaft. The adjustment is a trial-and-error procedure, so if the needle does not end up at zero after the first try, repeat the procedure. Once the adjustment has been completed, replace the gauge cover.

Check the calibration of the hand grip dynamometer on a semi-annual basis. Hang individual 5-kg and 20-kg (5-kg and 15-kg may be used instead of 20-kg) weights across the handle, using one large (or two smaller) Velcro straps on each side of the dynamometer handle. Lift the weights slowly and just slightly off the floor while they are strapped to the dynamometer handle. To avoid potential for injury, several CC staff people should help with this calibration check. The lifting motion should be very slow and smooth and the weight should remain distributed evenly between the two sides of the handle. Record the maximum kilograms registered on an Equipment Log. Repeat the procedure three times and average the three calibration trials.

The dynamometer should be accurate within ± 2 kg for the average of the three calibration trials. If the calibration check is not within these limits, it may be necessary to send the dynamometer to the manufacturer for repair and recalibration. DO NOT attempt to recalibrate the dynamometer yourself. Calibration errors can be caused by dropping the dynamometer or by leaks in the hydraulic system. The manufacturer may have a

lending program so that CCs will not be without a dynamometer; if not contact the CCC. Note: Clinical Centers are no longer required to send the dynamometer to the manufacturer for routine calibration, only on an as-needed basis.

Document semi-annual hand grip checks and calibrations on a CC Equipment Log. (*See Volume 7, Section 4, Table 4.1 – CC Equipment Maintenance* for schedule.)

9.6.4 Chair Stand (Required)

A participant's performance on the chair stand offers information about her lower body strength and mobility and is a general indicator of frailty. A stopwatch and a standard, straight-backed, flat-seated (non-padded), armless chair is required for this procedure. A thin strip of masking tape should be placed across the seat of the chair half-way between the front and the back of the seat.

9.6.4.1 Chair Stand Procedure

The chair stand performance involves determining the participant's ability to stand up from a standard chair and counting the number of times she arises from the chair in 15 seconds, both without using her arms. The participant should be wearing comfortable shoes (heels less than 1½") or stockings. Perform the chair stand as follows:

- Place the back of the chair against a wall to steady it. Stand next to the participant to provide assistance if she loses her balance.
- Single chair stand:
  1. Have the participant sit in the chair, assuming the position from which she would normally stand up from a chair (but no more than half-way forward on the seat of the chair) with her feet resting on the floor and her arms folded across her chest. Ask her to stand up without using her arms. You could say, "This test measures the strength of your legs. *Fold your arms across your chest. Now please try to stand up without using your arms. If it's painful, you can stop*." If she is unable to rise without using her arms, ask her to stand up using her arms to push off. If she is unable to stand up on her own or refuses to complete the test, thank her for her efforts and do not continue the test. Document this information on *Form 90 - Functional Status*.
  2. Have the participant sit down again.
- If the participant was able to complete one chair stand without using her arms, have her perform the timed chair stand:
  1. Ask her to repeat the chair stand starting from the sitting position and to continue repeating stands for a total of 15 seconds. You could say, "*Please keep your arms folded across your chest. When I say 'Ready, stand!,' Stand up straight and sit down, stand up and sit down, and keep on standing and sitting as fast as you can without stopping in between or using your arms to push off. I want to see how many times you can stand, then sit, stand, then sit in 15 seconds. If you start having pain or discomfort, you can stop the procedure. Now watch while I demonstrate*." Demonstrate two to three rapid chair stands.
  2. Tell the participant to stand ("*Okay, start*!") and start the stopwatch. Count out loud each time she arises. When 15 seconds have passed, immediately stop the stopwatch while you say, "*Okay, stop*."
  3. Record the number of completed chair stands (i.e., the number of times the participant arises before time is called). If she tires before completing 15 seconds, confirm that she cannot continue anymore. If she says she can continue, keep timing; otherwise stop.
  4. Allow the participant to rest quietly for 1 to 2 minutes (or longer, if needed), and repeat the timed procedure.
  5. Record the results of the chair stand on *Form 90 - Functional Status*.

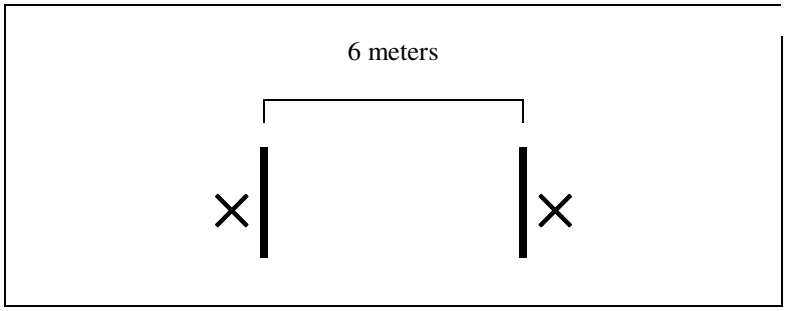
9.6.5 Timed Walk (Required)

The timed walk functional status test measures a participant's functional ability and fitness. A stopwatch and 6-meter gait course (see below) are required for this measurement.

9.6.5.1 Gait Course

Set up a gait course on an uncarpeted or flat-carpeted floor 6 meters in length. Mark the course by lines at either end and by a large, black "X" ½-meter beyond the line at either end (see *Figure 9.1 - Gait Course*).

Figure 9.1
Gait Course



9.6.5.2 Timed Walk Procedure

This performance test measures a participant's ability to perform a 6-meter walk and the time required (in seconds) to complete the walk. Perform this test twice. The participant may use walking aids (such as canes or walkers) during this test. The participant should be wearing comfortable walking shoes. In all instances, the examiner should walk beside and just behind the participant and be ready to support her if she should trip or lose her balance. Occasionally, a participant will be so unsteady on her feet that the examiner will be concerned for her safety. The examiner may decide not to perform the test if the participant appears to be in imminent danger of falling (e.g., someone who arrives in a wheelchair but wants to try every test). (See *Section 9.6.1.2 - Physical Limitations and Safety Precautions*.) As a general rule, each participant should be encouraged to attempt the test. If the participant is too unsteady to perform the test, but tries, indicate this on *Form 90 - Functional Status*.

- Tell the participant that she should walk normally down the length of the course. If she usually uses a cane or other walking aid and would feel more comfortable with it, then she should use it during this test.
- Have the participant stand just behind and in the center of the starting line on the gait course. Explain that this is the walking course and she should walk to the other end of the course at her usual speed, just as if she were walking down the street to go to the store. Instruct her to walk all the way to the "X"-mark at the other end before she stops. Let her know that you will walk with her and keep track of the time it takes her to complete the course. Advise her that if she has pain or feels like she might fall, she can stop at any time.
- When the participant is positioned properly at the start line, instruct her to begin and start the stopwatch at the word, "*Begin*."
- Walk beside and just behind the participant for the entire course.
- Stop the stopwatch when <u>one</u> of the participant's feet is <u>all the way across</u> the end line.
- Have the participant turn around and repeat the test in the opposite direction.
- Record the participant's ability to complete the test, her use of any assistive devices, and the two completion times on *Form 90 - Functional Status*.

9.7 Clinical Breast Exam (Required)

Clinical Trial participants will have a Clinical Breast Exam (CBE) during screening and annual follow-up visits as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection* and at non-routine visits if clinically indicated. The CBE is optional for Dietary Modification (DM) participants who have signed the appropriate consent form (i.e., that indicates a CBE may be done).

If a participant refuses to have the CBE done at the CC, a written report of an outside provider exam should be obtained and abstracted onto *Form 84 – Clinical Breast Exam*. If the written report cannot be obtained, a verbal report from a clinician (i.e., LPN, RN, PA, NP, or MD) is acceptable. A report of normal is acceptable. Any abnormal reports need to be thoroughly investigated and documented.

9.7.1 Training and Certification

A WHI physician, licensed practical nurse (LPN; trained and supervised in accordance with state practice regulations), registered nurse (RN), nurse practitioner (NP), or physician assistant (PA) may perform a CBE after completion of the WHI training and certification process.

9.7.2 Performing the CBE

Perform the CBE in a private examining room with good lighting (the CBE can be performed just before the pelvic exam for HRT participants or in conjunction with the electrocardiogram (ECG) if done at a different screening visit). For this exam, have the participant remove her upper clothing, including her bra, and have her put on a front-opening gown.

- Inspect the breasts first with the participant in a relaxed sitting position, then with arms overhead, then with her hands pressed against her hips, and finally, leaning forward.
- Inspect each breast for asymmetry, skin dimpling, or nipple retraction.
- Palpate the axillae for lymph nodes.
- Have the participant lie in a supine position and ask her to place her left hand under her head while a small pillow is placed under her back on the same side.
- Palpate the left breast systematically from the outer to inner edge of each quadrant so as to cover all quadrants, or in decreasing concentric circles.
- With her arm by her side, again palpate the axilla for lymph nodes.
- Repeat the procedure on the right side.
- Enter the findings of the CBE on *Form 84 - Clinical Breast Exam*.
- Document any abnormalities that require follow-up evaluation and record follow-up results on *Form 84*.
- See *Section 5.1.2.1 - Exclusions Based on Baseline Clinical Breast Exam Findings for CT* eligibility guidelines.

9.8 Breast Self-Exam Instruction (Required)

Clinical Trial participants have breast self-examination (BSE) teaching during one of their screening visits. The BSE teaching can be done during the CBE and should take no more than 10 minutes. Breast self-examination practice may be reinforced with a shower card or video during subsequent follow-up visits (if needed) and re-instruction may be offered (if needed).

9.8.1 Training and Certification

A WHI physician, LPN (trained and supervised in accordance with state practice regulations), RN, NP, or PA may teach BSE after completion of the WHI training and certification process.

9.8.2 Performing Breast Self-Exam (BSE) Instruction

Ask the participant if she knows how to do BSE and, if so, ask her to demonstrate her BSE method.

If she is uncomfortable demonstrating BSE, or if further instruction is necessary, begin with a brief review of the anatomy of the breast, using the breast model (supplied by the CCC) as a visual aid. Include explanations of topography, general appearance and shape, and normal variability of breast tissue consistency. Describe the different types of breast tissue and how they may feel to palpation. This review may be done by showing a BSE video (an annotated listing of available videos can be obtained from the CCC). Help the participant identify a date and time each month when it is convenient for her to perform the BSE.

Using the breast models or the participant's own breasts, demonstrate a decreasing concentric circular or quadrant palpation technique starting at the upper outer edge of the breast. A teaching model that has soft, nodular background tissue with variably-sized simulated tumors can also be used. Throughout this demonstration, emphasize the importance of proper palpation technique using your finger pads in a massaging motion with firm pressure. You can ask the participant to palpate the practice model.

Describe to the participant how to inspect her breasts in a relaxed sitting or standing position in front of a mirror. Show her how to perform BSE on herself by having her lie supine in the same position as for the CBE. Tell her that she should do these maneuvers while lying down or standing in the shower. Holding your fingers over hers, move her hand in a circular motion over her breast to teach her the appropriate palpation technique. Watch her palpate her entire breast. Watch her abduct one arm completely and palpate her axilla with her opposite hand. Teach and watch the examination of both breasts and axillae.

Mark on *Form 84 - CBE* when the BSE is completed.

Note: The BSE may be streamlined for participants who demonstrate correct BSE (e.g., it may not be necessary to watch the video or use the breast models). BSE teaching is not a WHI intervention, but is an ethical consideration that should be available as part of the overall baseline breast health evaluation for CT participants.

9.9 Pelvic Exam and Pap Smear

All HRT participants have a pelvic exam during screening. Pap smears should also be done at the time of the screening pelvic exam, unless the participant has had a Pap smear in the last 12 months, in which case a report of the findings can be requested. Hormone Replacement Therapy participants with intact uteri will have follow-up pelvic exams, and HRT participants with intact cervices will have Pap smears, as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*.

As of July 9, 2002, E-plus-P participants are no longer required to have annual pelvic exams and pap smears every three years. It is recommended that CCs consider this change on an individual basis with these participants, since some participants may still desire an examination, particularly if they do not have a current outside care provider. If the participant elects to have her examinations with her outside provider, clinics are no longer required to obtain documentation for these exams. It is recommended that if an exam is completed in the clinic, the appropriate form be completed (*Form 81 – Pelvic Exam* and/or *Form 92 – Pap Smear*).

E-Alone participants are still required to have a pap smear every three years if their cervix is still intact and a *Form 92 – Pap Smear* should be completed. If the participant refuses to have the pap smear in the clinic, a written or verbal report from the outside provider is required.

9.9.1 Training and Certification

A WHI CC physician, RN (trained in accordance with state regulations), NP, or PA may perform the pelvic exam and Pap smear after completion of the WHI training and certification process. Clinical Center staff performing these procedures must also be licensed appropriately in the state where the CC is located and comply with all state and federal regulations regarding physician supervision of their clinical practice, if appropriate.

9.9.2 Performing the Pelvic Exam and the Pap Smear

Perform the pelvic exam in a private examination room with good lighting. A female assistant may remain in the room if appropriate. Proper hand washing and clean technique must be used. Ask the participant to empty her bladder before the exam and be sure that she is gowned and draped appropriately during the exam.

Assist the participant into the lithotomy position, placing her feet in the stirrups at a comfortable length to prevent excessive abduction of the hips. The participant's hands should be either at her sides or over her chest to enhance abdominal muscle relaxation. With gloved hands, inspect the external vulva and perineum. Ask the participant to perform a valsalva maneuver (forcible exhalation against a closed glottis) to evaluate the pelvic structures for prolapse and relaxation. Then, insert a speculum that is lubricated with warm water and/or a small amount of water-soluble lubricant. Choose the appropriate-sized speculum; many older participants will require small specula. Inspect the vaginal mucosa and cervix. In participants with an intact cervix, obtain a cervical scraping from the exocervix using a wooden spatula first and then obtain an endocervical sample with the cytobrush. Two slides or one slide with two smears should be prepared—one smear marked "endocervical" and the other marked "exocervical." It is necessary that vaginal or cervical cells be collected and that an attempt be made to collect endocervical cells if the cervix is present. For the baseline exam, participants without a cervix should have a Pap smear scraping taken from the apex of the vagina. Only one slide need be prepared for such participants, marked "vaginal cuff." Immediately spray smeared slides with a fixative or place in a fixative jar to prevent air-drying artifact. Finally, remove the speculum and with lubricated gloved hands (e.g., K-Y jelly), perform a bimanual exam. Palpate for uterine size, consistency, position, mobility, and tenderness, as well as the presence of uterine or adnexal masses and uterine fibroids. Ask the participant to perform a valsalva maneuver to evaluate the presence of cystocele, rectocele, or uterine prolapse. A recto-vaginal exam should be done to assess a posterior uterus. Indicate results of the pelvic exam on *Form 81 - Pelvic Exam*.

Label the Pap smear slides with the participant's barcode labels and send to the local laboratory within two days of the procedure. Record the results on *Form 92 - Pap Smear*.

It is possible for a participant to have a cervix and not a uterus. These participants will have undergone a subtotal hysterectomy. Some participants may know that they had a "partial" hysterectomy, or they may not be aware that the cervix remains. If you see a cervix in a participant who gives a history of hysterectomy, request a copy of the operation records. If only a cervix is present, the participant should have baseline and follow-up Pap smears as for participants who have not had a hysterectomy. *See Sections 5.1.2.2 - Exclusions Based on Baseline Pelvic Exam Findings* and *5.1.2.3 - Exclusions Based on Baseline Pap Smear Findings* for further guidelines.

In the rare event that a uterus or uterine tissue is "discovered" in a participant who previously reported having a hysterectomy, contact your CCC Data Coordinator Liaison before dispensing any HRT study pills. The participant will be switched in WHILMA to the appropriate HRT study pills (either PERT or PERT placebo). Present the case to the CC consulting gynecologist, who will decide if an endometrial biopsy is necessary. Manage the participant accordingly.

9.9.3 Pelvic Exam and Pap Smear Findings

Follow usual clinical practice related to pelvic exams and Pap smear findings.

If endometrial cells or AGCUS (atypical glandular cells of undetermined significance) are found on Pap, the participant must have an EA and be referred to her primary care provider for cervical evaluation (e.g., colposcopy). The EA may be done at either the CC or by her primary care provider. If an EA is necessary, continue or discontinue study pills based on the algorithms in *Volume 2, Section 5.4.3.2 – Management According to Endometrial Histology.*

A participant with ASCUS (atypical squamous cells of undetermined significance) on Pap must have a repeat Pap. The repeat Pap may be done at the CC or by the participant's primary care provider. The participant's primary care provider may choose to do some other cervical evaluation (e.g., colposcoy) rather than a repeat Pap. Refer any participant with an abnormal repeat Pap to her primary care provider for further cervical evaluation (e.g., colposcopy).

Document the cervical follow-up to the initial Pap smear (e.g., 2nd Pap, colposcopy, biopsy) in the follow-up section of *Form 92 – Pap Smear*. Document any endometrial evaluation on *Form 82 – Endometrial Evaluation* or *Form 83 – Transvaginal Uterine Ultrasound* as appropriate.

(AGCUS and ASCUS categories as well as place to record results of second Pap will be included in *Form 92 – Pap Smear*, Ver. 2, scheduled for release with WHILMA V.43 upgrade in January 2001.)

9.10 Endometrial Aspiration

As of July 9, 2002, Endometrial Aspirations are no longer required for the subsample group.

Hormone Replacement Therapy participants with uteri will have endometrial aspirations during screening (before randomization) and, depending on subsampling and symptoms at routine visits and unscheduled follow-up contacts (see *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Collection*). A pathology report of an outside endometrial aspiration can be requested to document a baseline (if performed in the previous 12 months), routine or non-routine follow-up endometrial aspiration. Provide the participant with the HRT Handbook (see *Vol. 2, Appendix F, Figure F.3.2*), point out the relevant sections, and answer any questions she might have about the procedure and post-procedure care. Although it is possible for a participant to have a cervix and not a uterus, only those participants with uteri will have endometrial aspirations. If the practitioner cannot palpate a uterus, but the participant says she has not had a hysterectomy and a cervix is present, then it is safe to proceed with the endometrial aspiration. Occasionally, a short segment of lower uterine segment with functional endometrial tissue will be inadvertently left in situ during a subtotal hysterectomy. This should be suspected if the participant has had a subtotal hysterectomy and reports intermittent vaginal bleeding after the hysterectomy. Consult the CC Consulting Gynecologist in this case to determine if endometrial sampling should be attempted.

9.10.1 Training and Certification

A WHI CC physician, NP, or PA may perform the endometrial aspiration after completion of the WHI training and certification process. Clinical Center staff performing this procedure must be licensed appropriately to practice primary care in the state where the CC is located and comply with all state and federal regulations regarding physician supervision of their clinical practice, if appropriate. This procedure is reviewed in the training video, “Endometrial Aspiration”, available from the CCC.

9.10.2 Antibiotic Prophylaxis

Antibiotic prophylaxis may be needed for select participants before the aspiration. Policy and drug selection is left to the discretion of each CC. Often, asking the participants’ private physician whether prophylaxis is necessary (and the drug of choice) is the easiest and most consistent policy. In general, however, antibiotic prophylaxis before the endometrial aspiration should not be given unless:

- the participant or her physician indicates she has been given antibiotics in the past before surgical procedures and requests them for this procedure; or
- she has a prosthetic heart valve, previous history of endocarditis, rheumatic heart disease, or surgically-constructed systemic pulmonary shunt or conduit.

Antibiotic prophylaxis can be used in conjunction with artificial joints at CC discretion. *Figure E.5.8 in Appendix E shows* a model *Antibiotic and Medication Allergies Questionnaire (HRT Participants with Uteri*) assessment form for evaluating a participant’s need for antibiotic prophylaxis and allergies to medications.

9.10.3 Performing the Endometrial Aspiration

Perform the endometrial aspiration in a private examination room with good lighting. This procedure should be carried out, if possible, following the pelvic exam and Pap smear. A female assistant may remain in the room if appropriate. Ask the participant to empty her bladder before the procedure. Assist the participant into the lithotomy position and be sure she is comfortable, gowned, and draped during the procedure. Always perform a bimanual examination of the uterus and adnexae just before the aspiration to verify the position and size of the uterus.

A flexible aspirator is the equipment of choice for WHI endometrial aspirations. Perform the endometrial aspiration as follows:

- Insert a speculum lubricated with warm water. Swab the cervix with betadine.

- It is recommended that you perform local paracervical and uterine anesthesia by infiltration of up to 1 cc of 1% lidocaine at each of the 4- and 8-o'clock positions of the cervical mucosa. Local anesthesia should be used particularly if the participant experiences discomfort during the procedure. If, after infiltration, she still experiences discomfort, lidocaine may also be infiltrated at the 2- and 11-o'clock positions. Alternatively, "Hurricaine gel" (benzocaine 20% gel), may be applied topically to the cervix as an anesthetic. If a participant has had problems with uterine cramping previously, she may be given a non-steroidal anti-inflammatory drug (NSAID), such as ibuprofen 400 mg by mouth, one-half hour before the endometrial aspiration, as long as she does not have any contraindication to the use of NSAIDs.
- The use of a tenaculum may be necessary to stabilize the cervix and provide counter-tension. Since many participants find the tenaculum uncomfortable, it is recommended that you use a local anesthetic (see above) if you must use the tenaculum. A small, lacrimal duct probe can be used to dilate a stenotic cervical os.
- Insert the flexible aspirator through the cervix into the uterus.
- Attempt to place the biopsy instrument at the apex of the uterus to maximize the probability of obtaining an adequate sample. Record on *Form 82 - Endometrial Aspiration* the depth (in centimeters) of the uterine cavity based on the markings on the aspirator. This measurement will be a reference to aid in instrument placement for subsequent endometrial procedures.
- Obtain endometrial tissue from all uterine surfaces by inserting, withdrawing slightly (not completely), and rotating the aspirator within the uterus. Cut the tip off the aspirator with scissors and allow the tip to fall into a formalin bottle that has been labeled with the participant's barcode label. Using the aspirator, push the specimen immediately into the same bottle.
- Forward the endometrial aspiration tissue to a local pathologist for review. Any material, no matter how scant, should be sent to the local pathologist for pathologic examination. Do not store the formalined tissue in your CC for more than two days.

Procurement of an endometrial specimen may not always be possible after entry into the uterine cavity due to atrophy.

If entry into the uterine cavity is not possible due to cervical stenosis, even after a paracervical block (and, if appropriate, an attempt by the consulting gynecologist has been made), a transvaginal uterine ultrasound can be performed. However, continue to make subsequent attempts at endometrial biopsy at the scheduled times during the follow-up exams and for vaginal bleeding (see *Section 5 - Hormone Replacement Therapy*).

Document pathology results on *Form 82 - Endometrial Aspiration*. Refer to *Volume 2, Section 5.1.2.5 – Exclusions Based on Baseline Endometrial Evaluation* for findings that would make a participant ineligible for HRT or, on follow-up, would require further work-up or treatment.

9.10.4 Performing Transvaginal Uterine Ultrasound

Schedule a transvaginal uterine ultrasound during screening or follow-up visits for a participant if an endometrial aspiration cannot be performed because of cervical stenosis. An endometrial thickness of * 5 mm will be accepted as normal (see *Section 5 - HRT*). Findings of pelvic pathology or other pathology would make the participant ineligible for HRT unless follow-up evaluation of these findings rules out malignancy. Document findings on *Form 83 - Transvaginal Uterine Ultrasound.*

9.11 Cognitive Assessment (Required)

9.11.1 Overview

Cognitive assessment is performed at baseline and follow-up visits for all HRT participants age 65 and older at baseline as outlined in *Vol. 1 - Study Protocol and Policies, Table 1-A1.1 - Frequency of Data Collection*. *Form 39 - Cognitive Assessment* is based on the NHLBI-funded Cardiovascular Health Study (CHS), an observational study of older women and men. This procedure uses the Modified Mini-Mental Status Examination (3MSE), a widely-used test of cognitive function among older people. It includes tests of orientation, registration, attention, calculation, recall, language, and visual-spatial skills. The interview-administered form does not require unusual skills or technology at the CC.

The hypothesis guiding this activity is that HRT may prevent age-related decrements in cognitive functioning (the ability to process different types of information).

The cognitive assessment procedure involves several activities:

- Training and certification.
- Preparing and assembling appropriate materials.
- Conducting the cognitive assessment interview with the participant. Note that the Benton Visual Retention Test (Benton) and Digit Symbol Substitution Tests (DSST) on the form are no longer administered.
- Scanning the completed *Form 39 - Cognitive Assessment*.

9.11.2 Training and Certification

Women's Health Initiative CC staff can perform cognitive assessment procedures after completion of the WHI training and certification process. Appropriate cognitive assessment interviewers should have good skills in probing and interpersonal communications. Clinical Centers should train and certify only two interviewers for this task, because the procedure will not be performed frequently and more than two interviewers will have difficulty staying in practice. However, this guideline is a recommendation; you may train and certify as many interviewers as needed for your CC.

The required training and certification procedures for conducting the cognitive assessment include:

- Reading the materials provided. Read through the form and form instructions. This will help you become familiar with the procedures. Try reading the interview out loud or in front of a mirror. Hearing yourself read the questions will help you to conduct the interview more smoothly. Make sure you have all necessary materials with you when you practice the interview.
- Practicing with friends, family, or other CC staff. Practice the interview twice with another person. Go through the form slowly at first, making sure that you have all the materials and that you find all the transitions from one type of question to another. The purpose of this type of practice is to familiarize yourself with the logistics of administering the form to another person. Mock participants should be asked to "stage" difficult or unusual situations for interviewers. Write questions directly onto the form for discussion with local training staff or CCC resource staff.
- Discussing problems and procedures with local training staff (or CCC resource staff). You should feel free to raise questions or concerns you might have after reading the materials and practicing the interviews. More than one discussion session interspersed throughout the training process may be beneficial.
- Conducting a formal interview session while being observed. This session will be the final step in the training and certification process. The interview should be conducted all the way through with a mock participant(s).

9.11.3 Prepare for the Interview

Before performing interviews with participants, re-familiarize yourself with the interview form, forms instructions, required materials, and procedures, particularly if you have not conducted the interview recently.

Interviewers should have the following materials available before beginning a cognitive assessment interview:

- *Form 39 - Cognitive Assessment* (with participant barcode label applied).
- One sheet of blank 8½" by 11" paper for the 3MSE with a participant barcode label applied in the top right-hand corner.
- Stopwatch and/or watch with a second hand for accurate timing on appropriate items.
- Two standard lead pencils with erasers.
- Laminated cards for 3MSE portion of the form (Card 39-1: "Close your eyes" statement and Card 39-2: overlapping pentagons), available from the CCC.
- Form instructions for reference.

9.11.4 Conducting the Cognitive Assessment Interview

Conduct the interview in a private area away from other participants, CC staff, or other distractions and at a desk or table the participant can use as a writing surface. Ask the participant if she is comfortable. Reassure her that this is a routine test of concentration and memory that will be done several times during the course of the study. It is not an intelligence test. Her responses will not be compared with other participants' responses and no individual information or participant identifiers will be reported in WHI publications. Tell the participant that some questions are more difficult than others and some questions will be asked more than once (see scripts on Form 39).

Ask each question on *Form 39 - Cognitive Assessment* in order, using the strategies and probes as described in the form instructions. Refer to *Section 2.1.4 - Interviewer Guidelines* for basic interviewing techniques such as staying neutral and probing carefully.

When the interview is completed, thank the participant and tell her she did well, without offering her specific feedback on her performance (the WHILMA database will score her responses). You might say, "*Thank you for doing this interview. You did just fine.*" Scan the completed form (note that the Benton and DSST sections of *Form 39 - Cognitive Assessment* will be blank).

Section 9
Clinical Measurements

Table of Contents