



BODY SIZE Protocol and QxQ

I. INTRODUCTION AND GENERAL INSTRUCTIONS

The PCaP “Body Size Questionnaire” is to be completed during the in-home visit before the snack and after offering the research subject the opportunity to empty his bladder. This form consists of three interviewer-administered questions regarding self-reported weight and height history, as well as locations to record body measurements (height, weight, waist and hips) obtained on each PCaP subject by the nurse to assess current physical frame and body fat distribution. All measurements are made with research subjects wearing light-weight non-constricting clothing. Weight and height are measured without shoes.

The research nurse verifies the accurate placement of the measuring instrument for each measurement and records each measurement immediately after it is taken. Values are **rounded down** to the unit indicated for each measurement (except weight). Anatomical landmarks for body measurements are identified in Figures 1-3.

The purpose of the detailed instructions below is to encourage consistency both within and between study centers in methods and training related to height, weight, waist and hip circumference. Study staff should adhere as closely as possible to the prescribed procedures so as to reduce measurement error.

II. PROCEDURE: DETAILED INSTRUCTIONS FOR RESEARCH NURSE INTERVIEWER-ADMINISTERED QUESTIONS

The script below should be read to the research subject prior to administering the body size questionnaire.

“Now I would like to ask you several questions about your past height and weight. If you don’t remember exactly, please make your best guess. In addition, I will also measure your height, weight, waist and hips. You may choose not to answer any of the questions I ask or decline any body measurement.”

Q1. “What was your usual weight 1 year ago?” Ask the question verbatim. “1 year ago” refers to 12 months prior to the in-home visit date. Record the appropriate response by circling response item “a, b or c”. If item “a” is circled, record the number of pounds reported by the research subject, rounding down if the subject provides increments of a whole pound (for example: 170 and ½ pound would be rounded down and recorded as

170 pounds). [In the event the subject provides weight in kilograms the nurse should carry a conversion chart from kilograms to pounds].

Q2. “Thinking back to when you were about 25 years old, what was your usual weight at age 25?” Ask the question verbatim. Record the appropriate response by circling response item “a, b or c”. If item “a” is circled, record the number of pounds reported by the research subject, rounding down if the subject provides increments of a whole pound (for example: 170 and ½ pound would be rounded down and recorded as 170 pounds). [In the event the subject provides weight in kilograms the nurse should carry a conversion chart from kilograms to pounds].

Q3. “How tall were you without shoes at about age 25?” Ask the question verbatim. Record the appropriate response by circling response item “a, b or c”. If item “a” is circled, record the number of feet and inches reported by the research subject. [In the event the subject provides height in centimeters the nurse should carry a conversion chart from centimeters to feet and inches.[1 inch =2.54 centimeters; 1 centimeter = .39 inches].

III. PRODECURE: DETAILED INSTRUCTIONS FOR BODY SIZE MEASUREMENTS

General Provisions

For the height and weight measurements, the subject should be asked to remove any excess clothing (sweatshirts, sweaters, or jackets) and should be barefoot or wearing socks. The subject should also be asked to remove any items from their pockets or on their body that may inappropriately increase the measurement of their body weight.

The scale should be placed on a firm (uncarpeted), level floor for accurate measurements.

If subject has been fasting, body measurements should be taken before he eats or drinks

Subject should empty his bladder before body measurements are taken

Standing Height

Equipment:

Tri Square

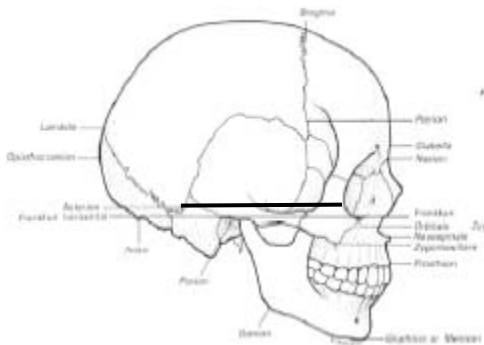
Tape rule

PCaP post-it note or erasable marking pencil

1. Assure the subjects is prepared for the measurements and that the procedure is explained
2. If the subject has a hair accessory or hairstyle which interferes with the measurement, he will be asked to remove the accessory or change his hairstyle.

If the subject refuses to comply with regard to hairstyle or accessory, then he will still be measured, and the measurer will make a note in the comment section of the Body Measurement Questionnaire form.

3. The subject stands erect on the floor with his back against the wall.
4. The heels are placed together and positioned against the wall.
5. The subject is instructed to stand as straight as possible, but with feet flat on the floor.
6. The weight of the subject is distributed evenly on both feet. The arms hang freely by the sides of the body, with the palms facing the thighs.
7. The subject is asked to place the ankles or knees together, whichever come together first (often they will come together simultaneously). If the subject has knock-knees, the feet are separated so that the medial borders of the knees are in contact but not overlapping.
8. The scapulae and buttocks are in contact with the wall if possible, or whichever part of the body touches the wall first.
9. The subject will be standing erect with the mid-axillary line perpendicular to the floor. Verify on the right side of the body.
10. The heels, buttocks, scapulae, and the posterior aspect of the cranium (head) of some subjects cannot be placed in one vertical plane while maintaining a reasonable natural stance. These subjects are positioned so that only the buttocks and the heels or the cranium are in contact with the wall.
11. The subject looks straight ahead with his head positioned in the Frankfurt Horizontal plane (Figure 1 below). Draw an imaginary line that passes through the bottom of the orbit (eye socket) and through the top of the auditory aperture (ear opening). This line defines the Frankfurt Plane, the plane in which the head is normally carried during life.
12. Figure 1. Frankfurt Plane



13. The subject is asked to inhale deeply and maintain a fully erect position without altering the load on the heels.
14. Reposition the head in the Frankfurt plane if necessary, to assure accurate positioning.
15. The moveable tri-square is placed on the most superior point on the head with sufficient pressure to compress the hair. The right angle is brought down snugly, but not tightly, on the top of the head, with the vertical rod against the wall.

(Holding a deep breath makes the subject stand up straighter and taller, and allows for a more stable and reliable reading).

16. Using either a post it note or erasable pencil, mark the point on the wall in which the inferior aspect of the tri-square meets the wall
17. After the point is marked, the tri-square may be removed and the subject may step away
18. Using the tape measure, measure the exact height from the floor to the inferior tri-square point.
19. Record the measurement, to the nearest centimeter – rounding down, on the body measurement questionnaire.
20. If an erasable pencil is used to create the inferior tri square point, assure it is erased after the measurement is taken.

Body weight

Equipment

Tenita HD-351 weight scale with 4 x AA batteries

NOTE: Scale should be labeled with ID # and calibration weight (5 kg)

5 kg calibration weight

- 1) Assure the subjects is prepared for the measurements and that the procedure is explained
- 2) The scale must be level and on a firm surface (not a carpet).
- 3) Body weight will be measured using a Tenita HD-351 scale.
- 4) Before a subject is weighed, the scale, when placed on a firm surface, should indicate zero when no weight is on the scale. If not, by using the Personal Key each scale must be zeroed to 0.0 kg prior to use (by gently tapping the Personal Key with the nurses toe).
- 5) The subject is instructed to stand in the middle of the platform of the scale with head erect and eyes looking straight ahead. The subject stands still over the center of the scale with the body weight evenly distributed over feet, feet next to one another, and the arms hanging freely by the sides of the body. The subject should be barefoot or wearing socks. The subject should hold the head up and face forward. Make sure the subject is not leaning to one side and that the head is stationary.
- 6) If the measurement fluctuates while the subject is standing on the scale, he may not be standing in the exact middle of the scale base with his feet beside each other. The further the center of weight is from the exact center of the base, the more likely the scale reading will fluctuate. This is more likely to happen with heavier and/or taller men. Reposition the subject until the measurement is constant.
- 7) When the digital readout is stable, record the weight on Body Size Questionnaire to the nearest 0.1 kg rounding down.
- 8) Each scale must be calibrated after 25 measurements or every 30 days, which ever is more frequent, using the calibration weight provided (a known 5 kg weight).
 - a) The 5 kg weight should be placed in the center of the scale.
 - b) If the scale reads 5 kg, the scale may continue to be used in the field for subject body measurements.

- c) If the scale does not measure 5 kg, every effort must be made to correct the problem including but not limited to
 - (1) change batteries
 - (2) check position of scale
 - (3) check position of weight
- d) Calibrations are to be recorded in the equipment log sheet for the particular piece of equipment
- e) If the calibration is not accurate, and corrective action is not successful, the scale should be removed from use in the field
 - i) The inability to calibrate the specific scale should be noted on the in the equipment log notebook for the particular piece of equipment
 - ii) The project manager should contact the appropriate supply to either have the piece of equipment repaired or replace.
 - iii) All actions, including contacts, dates of contacts, discussions during contacts should be noted on the in the equipment log notebook for the particular piece of equipment.

Girth

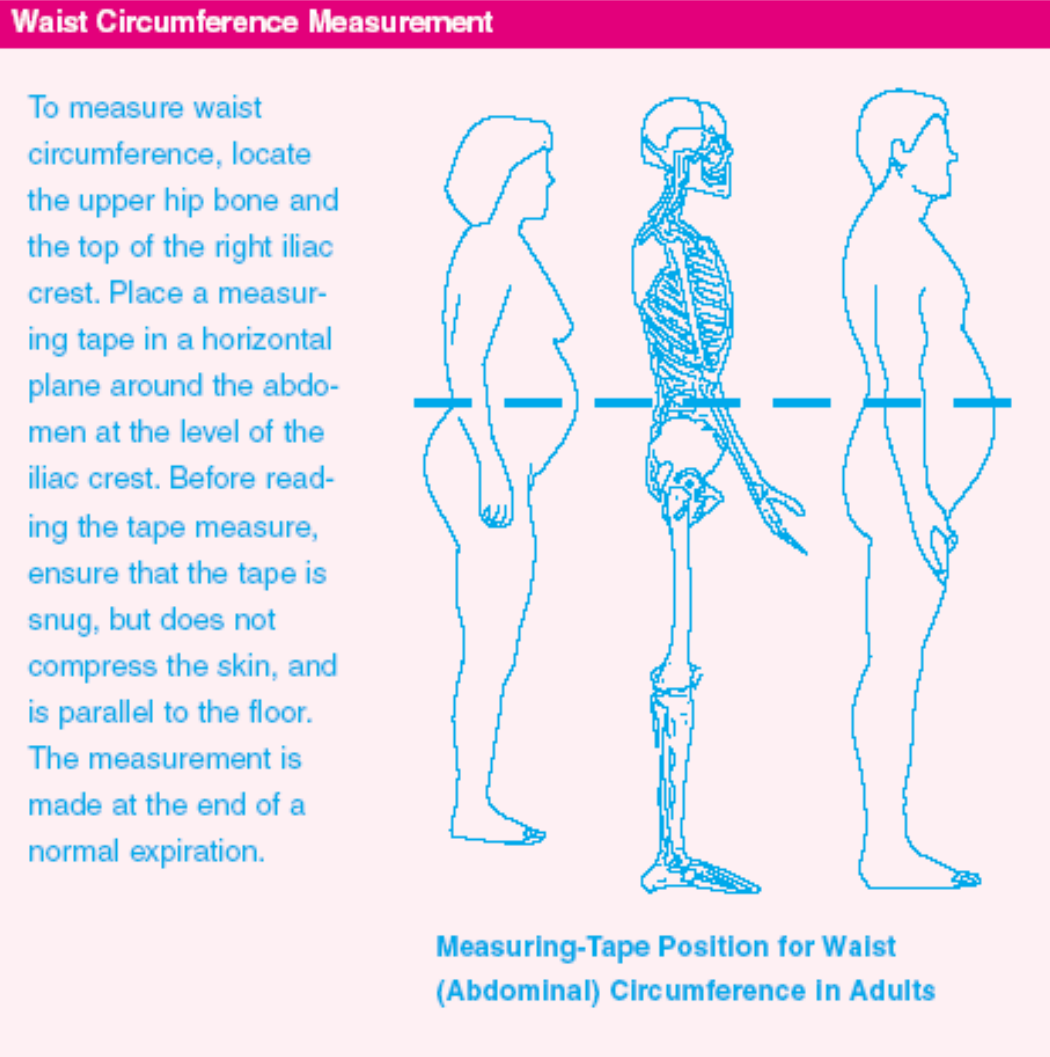
Equipment

10-foot plastic tape measure
alcohol wipe

Waist (abdominal) Girth

1. Assure the subject is prepared for the measurement and that the procedure is explained.
2. The subject is instructed to stand erect and relaxed with weight equally distributed on both feet.
3. The subject is asked to loosen any clothing so that a measurement may be taken directly against the skin.
4. Assure the beginning and the end point of the measuring tape meet on the side of the subject to prevent inappropriate positioning of the measurer
5. The tape measure is applied at the level of the umbilicus (navel) and the subject is instructed to breathe quietly. (Figure 2)
6. The tape should be snug, but not so tight as to compress tissue (see below).
7. The data collector should assure that the subject is standing erect and that the tape is horizontal. The most common source of error for this measurement is due to not having the tape horizontal. The position of the tape is checked from both the front and the back.
8. The measurement is recorded to the nearest centimeter, rounding down at the point of relaxed end exhalation.
9. If any item that interferes with measurement against the skin, that can not be removed, the approximate size and location of the item should be noted by the data collector in the Body Size Questionnaire.
10. The tape measure should be cleaned with an alcohol wipe after each use.

Figure 2



http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf

Hip girth

- 1) Assure the subjects is prepared for the measurements and that the procedure is explained
- 2) The measurement can be done over clothes, but should be limited to one common weight under garment and one layer of common weight outer garment. Garment should be free of any excess items that may increase the waist measurement (i.e. empty pockets, remove billfold). If any item interferes with measurement, that can not be removed, the approximate size and location of the item should be noted by the data collector on the Body Size Questionnaire.
- 3) The subject stands erect, yet relaxed, with weight distributed equally over both feet.
- 4) The hip girth is measured at the level of the maximal protrusion of the gluteal muscles (hips). (Figure 3).
- 5) The tape measure is placed horizontally level around the subject's gluteal muscles (hips) at the level of maximal protrusion. Assure the beginning and the end point of the measuring tape meet on the **SIDE** of the subject **NOT** the front or back. The position is verified by passing the tape measure above and below the observed maximum. The position of the tape is checked from both the front and the back.
- 6) The tape is kept horizontal at this level and the measurement is recorded to the centimeter, rounding down at the point of relaxed end exhalation.

Note: The most common source of error for this measurement occurs because the tape not horizontal and the

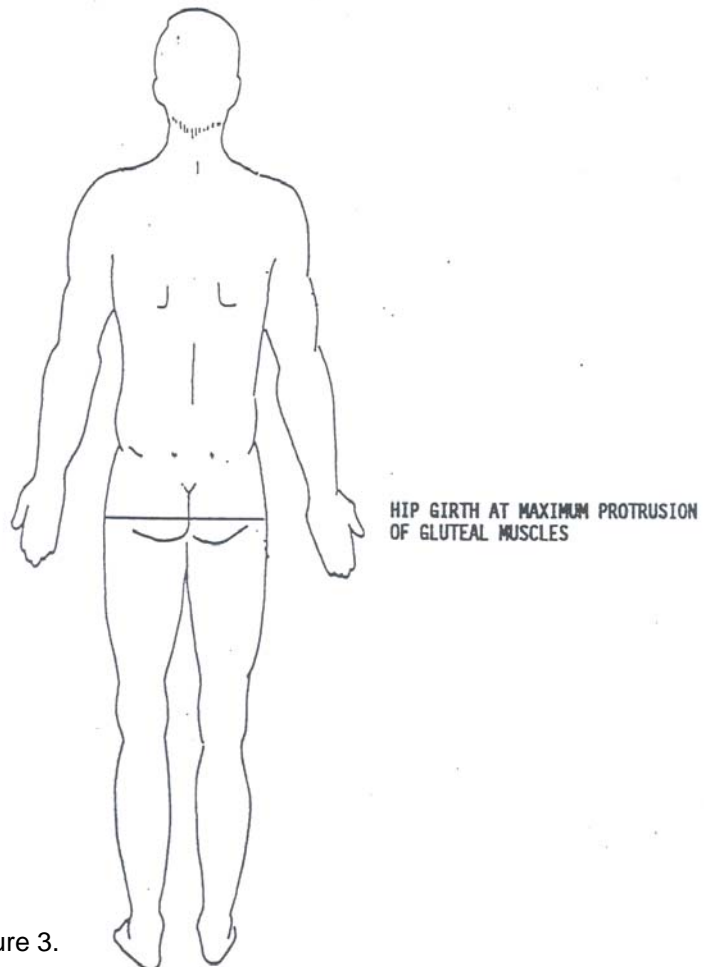


Figure 2.17.3 Location of Hip Girth Measurement

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- maximum level of gluteal muscle protrusion is not verified.
- 7) If any item that can not be removed interferes with measurement against the skin, the approximate size and location of the item should be noted by the data collector in the Body Size Questionnaire.
 - 8) The tape measure should be cleaned with an alcohol wipe after each use.

Recording the Body Measurements on the Data Form

Height, weight and body girth measurements are to be recorded on the Body Size Questionnaire in the spaces provided (See Body Size Questionnaire). The comment section of the form should be used to note any observation or occurrence during data collection which the measurer thinks may have effected the actual measurement, or explain a missing measurement. This would include deformities, physical condition (i.e. not able to stand), clothing restrictions, subject refusal, etc.

BODY SIZE QUESTIONNAIRE

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Next, I will be asking several questions about your body size. In addition to asking you questions, I will also be measuring your height, weight, hips and waist. You may choose not to answer any of the questions I ask or decline any or all body measurements.

Respondent's Reported Measurements:

(Note Scale id# here)

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1. What was your usual weight 1 year ago? [if you don't remember exactly, please make your best guess.]

lbs

--	--	--

 Don't Know Refused

2. Thinking back to when you were about 25 years old, what was your usual weight at age 25? [if you don't remember exactly, please make your best guess.]

lbs

--	--	--

 Don't Know Refused

3. How tall were you without shoes at about age 25? [if you don't remember exactly, please make your best guess.]

ft

--	--

 inches

--	--

 Don't Know Refused

Interviewer's Measurements:

1. Measured standing height (to the nearest cm, rounding down.)

cm

--	--	--

 Can't measure Refused

2. Measured weight (to the nearest .05 kg, rounding down.)

kg

--	--	--	--	--

 Can't measure Refused

3. Measured girths:

3a. Waist cm

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 Refused

3b. Hip cm

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 Refused

4. Interviewer's notes regarding measurements (e.g., participant confined to wheelchair)

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IV. TRAINING AND CERTIFICATION

1) **Training**

Data Collectors are trained centrally and are responsible for the local training of newly hired research nurses.

a) Pre-Certification

- i) Trainee reads PCaP Body Measurement MOP
- ii) Trainer reviews with trainee
 - (a) rationale for body size measurements
 - (b) expected limits of reproducibility
 - (c) common causes of measurement errors
- iii) Trainer demonstrates the how to properly collect Body Measurements
- iv) Trainer demonstrates common measurement errors and how to avoid or correct
- v) Trainee practices body measurement procedures on 4 models of different body types
 - (1) lean
 - (2) obese
 - (3) athletic
 - (4) aged.

b) Certification

- i) Trainee is deemed certified after successfully demonstrating procedures associated with the PCaP Body measurement Questionnaire, as outlines in the Body Measurement Data Collection Certification/ Recertification check list and
 - ii) Obtaining measurements on one model that meets the criteria described below:
 - (1) The standing height measurement must agree within **1 cm** of the trainer
 - (2) The weight must agree within **0.1 kg** of the trainer.
 - (3) The waist and hip circumference measurements must agree within **1 cm** of the trainer.
- b) In the event a trainee fails certification continue training by the trainer will occur until certification is achieved. Once successful certification is achieved research subject study measurements can be obtained.

2) **Re-certification**

Trained data collectors, in Body measurement procedures, are to be recertified:

- i) after every 100 body measurements or every 6 months, whichever is more frequent or.
- ii) When statistical analysis (QC) of the project data indicates that a specific data collector demonstrates deviation from standardized protocol, including:
 - (a) digit preference, and/or
 - (b) systematic differences in mean values from other data collectors.

Recertification is achieved by accomplishing the same tasks as those described for certification (see certification).

Recertification can be achieved locally or with the central trainer.

Once re-certification is completed successfully research subject study measurements can be obtained.

V. EQUIPMENT CHECKLIST

- a. After ever 25 measurements or 30 days, which ever is more frequent
 - i. The scale is to be calibrated by research nurse-(See procedure III)
 - ii. all body size measurement equipment including tri square, body tape measures and height tape measures will be assessed to determine any need for servicing or replacement
- b. Completed monthly equipment logs should be kept together in a notebook at each study center for review at site and monitoring visits.

VI. CONTACT INFORMATION FOR SUPPLIES

Tanita HD-351 Large Capacity Digital Bathroom Scale

eGeneral Medical Inc.
Heidi
Six Forks Office Center, 8384 Six Forks Road Unit 201 Raleigh, NC 27615-5089 Phone: 919-844-9402 Fax: 919-844-9403

Stanley hardwood tri-square
Stanley tape rule 12 ft.

ENESCO	
Jerry	
2308 Atlantic Avenue, Raleigh, NC 28217	
Phone: 800-868-8848, 919-832-5546	Fax: 919-832-5554

PCaP

CHECKLIST BODY SIZE MEASUREMENT DATA COLLECTION
 Certification/ Recertification Check List

Center: _____

Date: _____

Research Nurse: _____ ID Code # _____

Supervisor/Trainer: _____ ID Code # _____

Trainee's are deemed certified/ recertified after successfully demonstrating procedures associated with the PCaP Body measurement Questionnaire, as outlined below. These procedure are to completed in the order listed and without prompting.

GENERAL

ITEM	Successfully Peformed
Procedure is explained to research subject	
Subject has removed all excess clothing	
Assure subject has emptied his bladder	
Measurement is taken before eating or drinking if currently on fast	
Assure subject has removed all items from pockets or on their body	
Assure subject has barefoot or wearing socks	
Comments:	

WEIGHT:

ITEM	Successfully Peformed
Procedure is explained to research subject.	
The nurse assures the subject is in barefoot or wearing socks.	
Assure the scale is on a firm surface.	
Assure the scale reads zero when no weight is on the scale.	
Nurse assures the subject is standing in the middle of the scale.	
The nurse assures the subject is standing with head erect and eyes looking straight ahead.	
The nurse assures the subject is standing still over the center of the scale	
The nurse assures the subject's body weight evenly distributed over both feet	
The nurse assures the subject's arms are hanging freely by their side.	
The nurse assures the subject's is holding his head up and facing forward.	
The nurse assures the subject is not leaning to one side	

The nurse assures the subject's head is stationary.	
What actions should be taken if the measurement is drastically fluctuating while the subject is standing on the scale: Assure he is standing in the exact middle of the scale base Assure his feet beside each other.	
Trainee's measurement is within 0.1 kg of the weight achieved by the trainer on the same model and scale Nurse: _____kg Trainer: _____kg	
Nurse records measurements on Body Size Questionnaire	
Nurse records measurement to the nearest 0.1 kg	
How often is calibration to take place: every 25 ,measurements or every 30 days which ever is more frequent	
How is the scale calibrated: The 5 kg weight should be placed in the center of the scale resulting in a reading equal (within 0.3 kg (plus or minus)) to the calibration weight recorded on the scale (the initial weight of 5 kg weight when scale was purchased).	
Where are calibrations recorded: in equipment log book	
Corrective actions to attempt if scale does not initially calibrate: change batteries check position of scale check position of weight	
Action to take if the scale can not able to be successfully calibrated: Removed from use Give to project manager	

Comments: _____

HEIGHT

ITEM	Successfully Peformed
Procedure is explained to research subject	
The nurse assures that if the subject has a hair accessory or hairstyle which interferes with the measurement, he removes the accessory or changes his hairstyle.	
What action does the nurse take if the subject refuses to comply with regard to hairstyle or accessory? Subject will still be measured, and the measurer makes a note in the comment section of the Body Measurement Questionnaire form regarding the potential hair style or accessory that may have altered the accuracy of the measurement.	
The nurse assures the subject is stands erect on the floor.	
The nurse assures the subject's back is against the wall.	
The nurse assures the subject's heels are placed together and positioned against the wall.	

The nurse assures the subject is standing as straight as possible.	
The nurse assures the subject is standing with feet flat on the floor.	
The nurse assures the subject's weight is distributed evenly on both feet.	
The nurse assures the subject's arms are hanging freely by his sides with palms facing thighs.	
The nurse assures the subject places his ankles or knees together, whichever come together first.	
What should the nurse do if the subject has knock-knees? The nurse should allow the subject to separate his feet so that the medial borders of his knees are in contact but not overlapping.	
The nurse assures the subject's scapulae and buttocks are in contact with the wall if possible.	
The nurse assures the subject is standing erect with his mid-axillary line perpendicular to the floor.	
How does the nurse verify that the subject is standing erect with his mid-axillary line perpendicular to the floor: by viewing his body position from the right side of his body.	
How should the nurse position the subject if their heels, buttocks, scapulae, and the posterior aspect of the cranium (head) cannot be placed in one vertical plane while maintaining a reasonable natural stance? The nurse should position the subject so that only the buttocks and the heels or the cranium are in contact with the wall.	
Nurse should assure the subject's head is in the Frankfurt Horizontal plane	
The nurse assures the subject inhales deeply	
The nurse assures the subject is maintaining a fully erect position without altering the load on his heels.	
The nurse assures the the subjects's head is in the Frankfurt plane and Reposition it if necessary	
The nurse moves the tri-square down on to the most superior point of the subject's head with sufficient pressure to compress his hair	
The nurse brings down the right angle of the tri square snugly, but not tightly, on the top the subject's head, assuring the vertical rod against the wall.	
The nurse marks the point on the wall in which the inferior aspect of the tri-square meets the wall using either a post it note or erasable pencil	
After the the point is marked, the nurse removes the tri-square and asks the subject may step away	
Using the tape measure, the nurse measures the exact height from the floor to the inferior tri-square point.	
The nurse records the models's measurement in the correct location, to the nearest centimeter – rounding down, on the Body Measurement Questionnaire	
The standing height measurement obtained by the trainee agrees within 1 cm of the measurement achieved by the Nurse: _____kg	
Trainer: _____kg	
The nurse erases the inferior tri square point mark after the measurement is taken	

Comments: _____

WAIST

ITEM	Successfully Performed
Procedure is explained to research subject	
The Nurse assures the subject is standing erect	
The Nurse assures the subject is relaxed with weight equally distributed on both feet.	
Nurse assures the subject has loosened any clothing so that a measurement may be taken directly against the skin.	
Where should the nurse position themselves to take the measurements? On the subjects side	
The nurse assures the measurement is taken at the level of the umbilicus	
The nurse assures the subject is breathing quietly during the measurement	
How tight should the tape measure be? Snug, but not so tight as to compress tissue	
The nurse assure that the subject is standing erect	
The nurse assures that the tape is horizontal.	
What is the most common source of error for girth measurements? Not having the tape horizontal.	
The nurse assures the tape is horizontal by checking both the front and the back.	
The measurement is recorded to the nearest centimeter, rounding down at the point of <u>relaxed</u> end exhalation.	
The waist circumference measurements obtained by the trainee agrees within 1 cm of the measurement achieved by the trainer on the same model measurements on model is within 1 cm of the trainer Nurse: _____cm Trainer: _____cm	
What does the nurse do if there is an item that interferes with measurement against the skin that can not be removed? The nurse documents the approximate size and location of the item on the Body Size Questionnaire.	
The tape measure should be cleaned with an alcohol wipe after each use	

Comments: _____

HIPS

ITEM	Successfully Performed
Procedure is explained to research subject.	
The nurse should assure the subject has on only one common weight under garment and one layer of common weight outer garment.	

The nurse should assure the subject's garments are free of any excess items that may increase the hip measurement.	
Where should the nurse position themselves to take the measurements? On the subjects side.	
The nurse assures the measurement is taken at the level of the maximal protrusion of the gluteal muscles.	
How does the nurse verify the measurement is being taken at the correct position? By passing the tape measure above and below the observed maximum.	
The nurse assures the subject is breathing quietly during the measurement	
How tight should the tape measure be? snug, but not so tight as to compress tissue	
The nurse assure that the subject is standing erect	
The nurse should assure the subject is relaxed with weight distributed equally over both feet	
The nurse should assure the subject's weight distributed equally over both feet.	
The nurse assures that the tape is horizontal.	
What is the most common source of error for girth measurements? Not having the tape horizontal and not verifying maximal position.	
The nurse assures the tape is horizontal by checking in the front and back.	
The measurement is recorded to the nearest centimeter, rounding down at the point of <u>relaxed</u> end exhalation.	
What does the nurse do if there is an item that interferes with measurement that can not be removed? The nurse documents the approximate size and location of the item on the Body Size Questionnaire.	
The tape measure should be cleaned with an alcohol wipe after each use	

Comments: _____

PCaP
BODY SIZE MEASUREMENT EQUIPMENT LOG

Field Site: _____

Equipment: Tenita HD-351 weight scale:

ID # _____

Calibration weight: _____

Procedure:

1. Record the ID # of the scale (written on the scale) on the Equipment Log
2. Record the calibration weight (written on the scale) on the Equipment Log.
 - a. Each scale will have a unique calibration weight that will be identified at the time of purchase by placing the standard 5 kg weight on the scale to identify the scale's calibration weight to 0.1 kgs.
3. Place 5 kg weight on scale (in the center of the platform).
4. Wait for scale to equalize (no fluctuations)
5. Record in the table below under the column heading "Weight Measured".

DATE	WEIGHT MEASURED	ACTION	SIGNATURE

PCaP

BODY SIZE MEASUREMENT EQUIPMENT LOG

Field Site: _____

Equipment: Measuring Tape #_____

Procedure:

1. Evaluate excess wear or damage – such as wearing of the markings/numbers on the tape measure.
2. Length of tape measure should be compared to a hard rule (metal rule mounted on wall). Align the zero mark of the tape measure with the 120 cm mark of the hard rule and extend the tape measure toward the zero mark of the hard rule.

Note: If this measure is outside the 119.5-120.5 cm range, the tape should be replaced.

DATE	MEASURE TAKEN	ACTION	SIGNATURE