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## **Summary of Edits**

### **Summary of changes between Version 1.0 and 1.1:**

- Height: participant's buttocks must touch the wall or height board.
- Stadiometers: perform QC twice each year while in use. Time QC to precede the beginning of each new cohort.
- Title of Form #322 changed from "Quarterly Stadiometer Accuracy Check Form" to "Stadiometer Accuracy Check Form.
- Confirm accuracy of a fixed height measurement system if it appears to have moved from its original position.
- Scales: perform QC quarterly, rather than every other month.

### **Summary of changes between Version 1.1 and 1.2:**

- Procedure added for off-site measurement of weight
- Procedure added for off-site measurement of waist circumference

## **20. Other Clinical Measurements**

### ***Height***

Height measurement to the nearest 0.1 cm is taken by a certified PREMIER clinical staff member at the first screening visit. Height is measured in metric units with the participant standing on a firm, level surface which is at a right angle to the vertical board of the height measurement device. A height board mounted at a 90° angle to a calibrated vertical height bar is used. Prior to the beginning of screening for the first cohort, use a level to check that the floor is level and that the wall on which the height bar is mounted is straight. Check that the vertical height bar is mounted at a 90° angle to the floor.

Instruct the participant to remove shoes and headgear (hats and unusually large hairpieces) and to stand erect with feet flat on the floor and both heels together, touching the base of the vertical board. The participant stands erect with back, shoulder blades, and buttocks in contact with the vertical height board. If the participant cannot be positioned so that all of the above are in contact with the board, position so that the participant is standing erect with buttocks in contact with the board. The participant's weight is evenly distributed on both feet, and arms remain relaxed at the sides with palms facing inward. The participant stands facing straight ahead with her head in the horizontal (Frankfort) plane. The eyes of the examiner should be at the same level as the height indicator bar to obtain the most accurate measurement (Figure 1, Frankfort Horizontal Plane).

Ask the participant to inhale deeply and maintain a fully erect position without altering the load on the heels. Bring the height board down snugly, but not tightly, on the top of the participant's head. Record the height to the nearest 0.1 centimeter on the SV1 Visit Form (Form #3).

### ***Weight***

Body weight measurements are taken to the nearest 0.25 lb by certified PREMIER clinical staff throughout the study. The weight measurement taken at SV1 is used with the height measurement to calculate body mass index (BMI,  $\text{kg}/\text{m}^2$ ) to exclude candidates whose body mass index is in excess of  $45.0 \text{ kg}/\text{m}^2$  or under  $18.5 \text{ kg}/\text{m}^2$ .

Instruct the participant to remove shoes, headgear, coat, etc., and heavy items in the pockets (e.g., keys or wallet) in order to be weighed in light indoor clothing. All body weights in PREMIER are measured on a balance beam or digital scale, which is placed on a firm, level surface. If this surface is carpeted, a sheet of wood or hard plastic should be placed beneath a balance beam scale.

Ask the participant to stand in the center of the scale platform, since standing off-center may affect the weight measurement. It is suggested that marks be made on the platform to insure the proper position of the participant's feet. The participant should stand with arms relaxed at the sides, head erect, and eyes looking straight ahead.

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### *Balance Beam Scale:*

Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. Before each weight is measured, the sliding scale weights must be moved to zero. Adjust the weight on the indicator until it is balanced, and record the results to the nearest 0.25 lb. Use extreme care in adding the lower beam weight to the upper beam weight, as they use different increments. Advise the subject to remain standing in position on the scale until the weight has been recorded. This eliminates the possibility of the weight measure being accidentally altered by the balance beam moving as the subject dismounts.

### *Digital Read-out Scale:*

Make sure the scale reads "0" before the subject stands on the measurement platform. When the digital readout stabilizes, record the observed weight to the nearest 0.25 lb.

### *Weight for Home or Office Visit*

The UC-300 portable scale is the only device approved to obtain weight at visits conducted outside the clinic setting (i.e. in a participant's home or office). Validate the scale by comparing it to the in-clinic calibrated scale before and after the visit.

- Prior to the home visit, a staff member should weigh herself on the calibrated clinic scale and then immediately on the portable scale. If portable scale weight is not within 4 pounds of the calibrated scale, the portable scale should not be used for the home/office visit.
- When measuring weight, the scale is to be placed on a non-carpeted surface. If only carpeted surfaces are available, place a sheet of wood or hard plastic between the carpet and scale prior to obtaining a weight.
- Upon return from the home/office visit, re-check the portable scale against the clinic scale. If the scales differ by more than four pounds, that home/office measurement cannot be used.

### *Waist (Abdominal) Circumference Measurements*

Waist circumference measurements are taken with an anthropometric measuring tape. Skin should show no marked compression. **BE CERTAIN THAT THE TAPE IS KEPT HORIZONTAL WHEN MAKING MEASUREMENTS.** To make certain that the tape is kept horizontal, it is best to have an assistant present when taking the measurements, or to mount a full length mirror on a wall approximately 1½ to 2 feet from the floor. Since circumference measurements are made over the participant's undergarments only, a hospital gown may be worn during measurements but the tape should go under the gown. Take one measurement, recording it to the nearest 0.1 cm, then remove the tape from the participant and reposition to take the second measurement.

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### *Overview of Procedure*

Waist circumference is measured from the horizontal plane at one centimeter (1cm) above the navel (measure 1 cm from the top of the navel with a firm ruler and mark this spot in ink). This usually coincides with the narrowest circumference, but has the added advantage of being easily reproducible. Be sure that the tape is kept horizontal when making the measurement (either in front of a mirror or with an assistant). Measurement is made with the participant standing erect, abdomen relaxed, arms at the side, and feet together with weight equally divided over both legs. Tell participants to breathe normally, to breathe out gently at the time of measurement, and not to hold in his abdomen or hold his breath (i.e., at the end of a normal expiration of air). At the R/I Visit, record the value obtained on the Randomization Checklist (Form #60). At the 6 Month Follow-Up Visit, record the value obtained on the 6 Month Visit Form (#57). At the 18 Month Follow-Up Visit, record the value obtained on the 18 Month Visit Form (#59).

### *Waist Circumference for Home or Office Visit*

To measure the waist circumference at a home or office visit, staff will need to make prior arrangements with the participant.

- Arrange to perform measurement in a safe area to insure both privacy for the participant and safety for the staff (i.e. not in someone's bedroom, possibly the office bathroom)
- Ask participant if a mirror is available (If neither an assistant nor mirror is available, turn the participant from side to side while holding the tape securely to check tape position).
- Ask participant to wear clothing that will allow her/him to expose the navel area.

If satisfactory arrangements can be made, follow the in-clinic procedure for waist circumference.

### *Equipment Maintenance and QC*

#### *Scales*

Scales are certified at the start of the trial by the local Bureau of Weights and Measures or an equivalent body. Re-certification must be completed annually thereafter and posted in the appropriate column of the Weight Scale(s) quarterly check and Yearly Certification Log (Form #310), along with any documents provided by the inspector. Form #310 is also used to record scale accuracy. The scale is tested quarterly at two levels to ensure accuracy in the range of weights measured during the trial. The lower range is checked using 20-30 kg weights. The upper range is checked using 40-50 kg weights.

1. The technician is weighed on the scale first and this weight recorded.
2. The lower weight is then placed on the scale and this weight recorded.
3. The technician then gets on the scale with the lower weight and this weight recorded.
4. The sum of the value obtained in step 1 and the value obtained in step 2 should equal the weight measured in step 3.
5. Next, the higher weight is placed on the scale by itself and this weight is recorded.

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6. The technician now gets on the scale with the higher weight; this combined weight is recorded.
7. The sum of the value obtained in step one and the value obtained in step 5 should equal the weight measured in step 6.

These records are requested periodically and checked during site visits. Scales which fail to meet standards within 0.5 kg at any weight level should not be used for collection of study data and should be immediately reconditioned and re-certified by the Bureau of Weights and Measures or an equivalent body. All scales used must be uniquely identifiable, either by serial number or by a study-specific number printed in indelible ink.

### *Stadiometers*

If height is measured using a stadiometer, perform QC twice each year while in use, timed to precede the beginning of recruitment for each cohort. Stadiometer QC during cohort 4 would occur just prior to cohort 4 recruitment, and again every 6 months while in use. to verify accuracy as follows. This information is recorded on the Stadiometer Accuracy Check Form (#322). If the stadiometer cannot be successfully calibrated, it may not be used for participant height measurements.

1. Place a 600 mm (60 cm) height rod against stadiometer and lower the height gauge to the top of the rod.
2. If the counter does not record the correct length of the rod:
  - loosen by undoing the two metal retaining screws and pull away from the main fiber cog of the carriage;
  - turn until the counter records the true length of the metal rod;
  - press against the backplate so that the teeth of the counter cog and the carriage cog engage;
  - tighten the retainer screws;
  - move headboard up and down the backboard a number of times;
  - re-check calibration
3. When accurate, record recalibration on Form #322

### *Fixed height measurement devices*

Monitor these devices for obvious signs that they have been moved. If the device appears to have moved from its original position, confirm accuracy of measurements from floor level. Remount if inaccurate.

### *Certification of Trainers and Technicians*

Certification of a master trainer is done annually at a central location. At that time the study wide trainer reviews the appropriate techniques for measuring and recording height, weight, and waist circumference.

## **PREMIER Clinical Manual of Procedures**

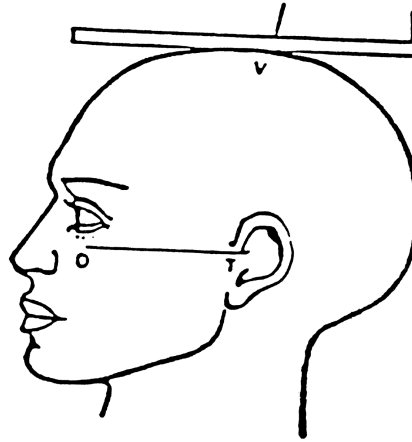
All technicians take duplicate measurements on two individuals. The technician takes the first measurement of both the height and weight on the individual, then repeats the process for the second measurement of height and weight on the same individual. The average of the duplicate measurements on a given individual must be within 0.2 kg weight and 1 cm height of the master trainer's measurement. Both measurements on a given individual must be within 0.2 kg/1cm of each other. All technicians measure waist circumference twice on two individuals also. Average waist circumference measurements on a given individual must agree with the master trainer's measurement within 2 cm, and both readings on a given individual must agree with each other within 2 cm. Individuals at the sites may be trained as appropriate by the master trainers. For each person trained, the following forms are completed by the master trainer and copies are sent to the Coordinating Center:

1. Weight Certification Form (#309)
2. Weight Observation Checklist Form (#308)
3. Height Certification Form (#312)
4. Height Observation Checklist Form (#311)
5. Waist Circumference Certification Form (#314)
6. Waist Circumference Observation Checklist Form (#313)

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**Figure 1 Frankfort Horizontal Plane for Measuring Body Height**

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- ORBITALE: Lower margin of eye socket.
- TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point.
- FRANKFORT PLANE: Orbitale tragion line horizontal.