Manual of Procedures (MOP)
Section 11. Physical Measurements and Procedures

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Accuracy and reliability are the two most critical components of data on height and weight and are a function of the quality of the equipment and the skill of the person taking the measurements. Equipment must be properly maintained and calibrated.

11.1 HEIGHT

Height is measured at every scheduled visit.

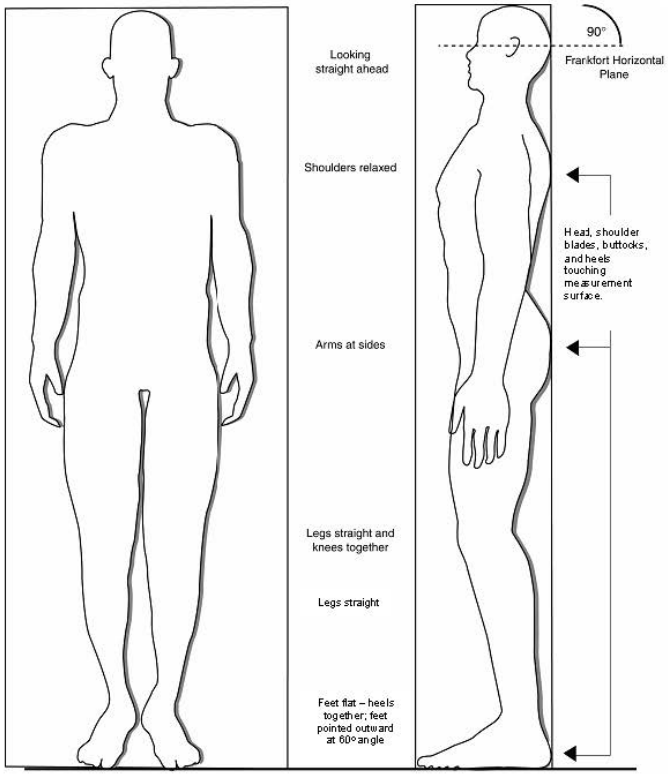
11.1.1 Instruments Required

- Stadiometer

11.1.2 Procedure

1. The participant should stand on the footplate with back parallel to the stadiometer ruler.
2. Shoes should be off but socks can stay on.
3. Legs should be together (in contact at some point), and straight. The participant's arms should be at his sides and shoulders relaxed.
4. The back of the body should touch the stadiometer at some point, preferably with heels, buttocks, upper back and head touching the measuring surface.
5. The body should be in a straight line (mid-axillary line parallel to the stadiometer).
6. The participant should be looking ahead with his head positioned such that a level horizontal line is formed by the hole in the ear and the bottom of the eye socket (Frankfort Plane).
7. The participant is asked to inhale and hold his breath.

Figure 1 (From NHANES Manual 2007)



8. Lower the headpiece until it is touches the crown of the head firmly, compressing the hair, but not tightly.
9. Measure to the nearest 0.1 cm.
10. Record the height in the source document and enter in EDC.

11.2 WEIGHT

Weight is measured at every scheduled visit.

11.2.1 Instruments Required

- A properly calibrated, high quality balance beam or electronic digital scale.

The scale must be: (1) on a stable hard surface (e.g. not carpet) (2) calibrated regularly per the site institution's policies (either through a professional service or the institution's medical equipment/medical engineering department).

11.2.2 Procedure:

1. Balance the scale so that it reads zero.
2. The participant should be weighed wearing a light layer of clothing (pants, shirt, socks);
   ⇒ Shoes and belt should be removed and pockets should be emptied.
3. Have the participant step on the scale platform, facing away from the scale read out, with both feet on the platform, and remain still with arms hanging naturally at side and looking forward. If a participant cannot stand independently, a chair or alternate scale may be used.
4. Read the weight value to the nearest 0.1 kilogram (e.g., scale reads 62.56 kg, record as 62.6 kg)
5. Record the weight on the source document and enter in EDC.

11.3 BODY MASS INDEX

The accurate measurement of height and weight will be used to calculate the participant's BMI, which will be used to screen participants and in the analysis of the variability of response to the intervention. The BMI will also contribute to ancillary study endpoints. The measurements should be done consistently at each visit using the same scale and stadiometer.

Body mass index (BMI) will be calculated by the EDC system. Upon entry of height and weight, EDC will automatically calculate the participant's BMI, which will appear below the height and weight. During the screening visit, a new participant can be added to the EDC system and site research staff can proceed to answer the height and weight questions on the Vital Signs e-CRF to calculate the BMI directly in EDC. Alternatively, the BMI can be calculated using the NIH calculator: http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm.

11.4 WAIST CIRCUMFERENCE

Waist circumference is measured at the baseline visit only. Waist circumference is used in secondary analyses and may also be used in ancillary studies.

Ideally, two members of the research staff will be available to perform the measurement of waist circumference. One person will take the measurements while the other person confirms that the measuring tape is correctly positioned and records the measurement stated by the measurer. If only one person is available, a mirror may be used to confirm correct placement of the measuring tape.

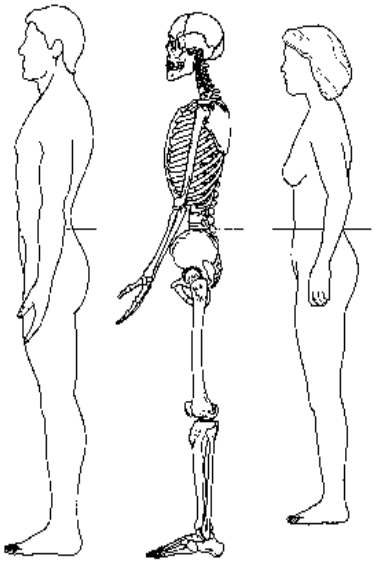
11.4.1 Instruments Required

- Gulick tape measure
- Mirror (optional, see above)

11.4.2 Procedure

1. Participant stands with his arms at side, in a straight and upright position, with his feet together.
2. The measurer is positioned at the right of the participant.
3. Expose the waist with undergarments pulled below waist level.
4. Palpate the upper hip-bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn (a make-up pencil works well), then crossed with a vertical mark on the mid-axillary line.
5. Pull an appropriate amount of tape out of the measure. Measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk. The plane of the tape is parallel to the floor and the tape is snug, but not compressing the skin. Align the tape's "zero line" along side of the tape graduations
6. Pull on the end of the tensioning mechanism until the calibration mark is just seen. This will allow the tape measure to achieve the standardized amount of tension.
7. Read the measure in centimeters (to the nearest 0.1 cm) at the end of a normal expiration.
8. Record the measurement in the source document and enter in EDC.

Figure 2 (From NHANES Manual 2007)



11.5 BLOOD PRESSURE

Blood pressure (BP) will be measured at all study visits. Blood pressure will be measured twice, 5 minutes apart. Each BP measure will be recorded in the EDC system. The EDC system will automatically average the two measures. At the Screening visit, the average of the two measures calculated by the EDC system will be used in determining the participant's eligibility in the study. For consistency, the left arm should be used unless there is a specific reason not to use the left arm. The same arm should be used consistently throughout the study. If there is a need to use a different arm than the one used previously, please record the reason in the source document.

11.5.1 Instruments Required

- Comfortable upright chair with a back
- Automatic oscillometric blood pressure machine (maintained regularly per the site institutions policies) with varied cuff sizes (small adult, adult, large adult, and adult thigh)

11.5.2 Procedure

1. If participant is on BP medications, confirm that she has taken her BP medications the morning of the visit.
2. At the screening visit, if participant has not taken her BP medications and systolic BP>160 or diastolic BP>100, then she can take her BP medications and vital signs can be measured in 30 to 60 minutes.
3. The participant should be seated comfortably for 5 minutes prior to the first BP measurement.
4. The upper arm should be bare and sleeves should not be rolled up as this may have a tourniquet effect (participant may wear a short sleeve shirt or gown). The palm of the hand should be turned upward and the elbow slightly flexed. The arm should be positioned so that the midpoint of the upper arm is at the level of the heart.
5. Select the correct cuff size. The cuff should have a bladder length that is 80% and a width that is at least 40% of upper arm circumference (a length-to-width ratio of 2:1). The recommended cuff sizes are:
    a. For upper arm circumference of 22 - 26 cm, the cuff should be "small adult" size: 12×22 cm
    b. For upper arm circumference of 27 - 34 cm, the cuff should be "adult" size: 16×30 cm
    c. For upper arm circumference of 35 - 44 cm, the cuff should be "large adult" size: 16×36 cm
    d. For upper arm circumference of 45 - 52 cm, the cuff should be "adult thigh" size: 16×42 cm
6. The arm and back should be supported and the legs should be uncrossed with both feet flat on the floor.
7. Palpate the brachial artery in the ante-cubital fossa, place the midline of the bladder of the cuff (commonly marked on the cuff) so that it is over the arterial pulsation. The lower end of the cuff should be 2 to 3 cm above the ante-cubital fossa.
8. After proper placement of the cuff, take the BP. Do not speak to the participant during the active measurement.
9. The participant should remain seated for 5 minutes after the first BP measurement is completed then check placement of the cuff and take the second blood pressure.
10. Record the blood pressure measurements, the arm used, and the cuff sized used in the source documents and enter in EDC.

11. If the systolic or diastolic blood pressure measurements differ between the first and second BP measurement by more than 20 mmHg, please repeat the measurement and select the 2 measurements in which both the systolic and diastolic BP fall within 20 mmHg and enter in EDC.

11.6 HEART RATE

Heart rate is measured at every scheduled visit.

11.6.1 Instruments Required

- Timer

11.6.2 Procedure

1. The participant should be seated comfortably for 5 minutes prior to measuring the heart rate
2. Heart rate will be measured using the radial pulse.
3. The number of beats per 1 minute will be recorded in the source document and enter in EDC.

   Alternate methodology: If using an automatic blood pressure monitor that also provides heart rate read-out, heart rate read-out can be used.

11.7 ORAL GLUCOSE TOLERANCE TEST

The 75-gram oral glucose tolerance test (OGTT) is a key procedure for the D2d study. Therefore, it is essential that the procedure be consistently followed at each site and at every visit. Correct timing of blood draws is essential to the accurate interpretation of the OGTT. Utmost care should be taken in adhering to the blood draw times. Actual times, not expected times, must always be recorded. Deviations from standard procedure need to be avoided, but if they occur, they must be documented in the source document so the results can be interpreted.

Participants will have an OGTT done at the following visits:

- *Baseline (BAS) and annually (M12, M24, M36, M48).* Plasma for glucose and serum for insulin at 0, 30 minutes and 120 minutes after the 75-gram glucose beverage will be collected and sent to the Central Laboratory.
- *Confirmatory*, as needed – in between scheduled visits – to confirm the diagnosis of diabetes. At the confirmatory visit, only plasma for glucose at 0 and 120 minute time-points will be collected and sent to Central Laboratory.

⇒ During the OGTT, the participant should be interrupted minimally. For example, a complete physical examination should not be completed during the OGTT.

The **OGTT should be postponed** if the participant experienced any condition that in the judgment of the site investigator could affect glucose tolerance, for example:

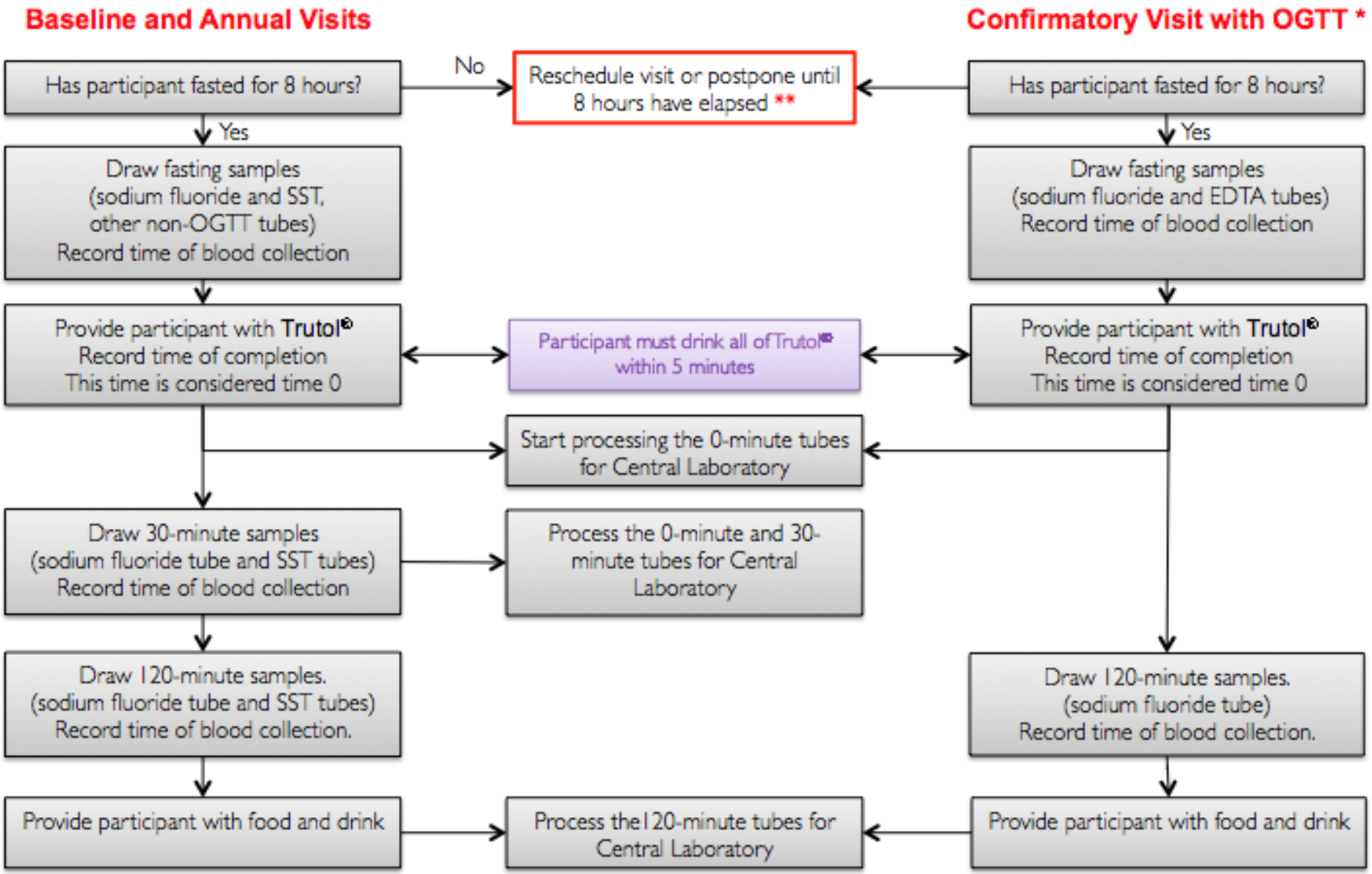
- Active infection within the last week.
- Use of medications that could affect glucose tolerance within the past 2 weeks.
- Blood transfusion within the past 12 weeks

- Blood donation within the past 12 weeks

11.7.1 Procedure

1. Prior to the visit, research staff will recommend to participant that they wear loose clothes for the OGTT to increase comfort.
2. Please refer to MOP section 9, Laboratory Procedures for OGTT-specific steps.

Figure 3. Overview of OGTT (see MOP section 9 for details).



*Confirmatory Visit with OGTT is done between scheduled visits to confirm the diagnosis of diabetes, if the 2hPG was the only abnormal test at the scheduled OGTT.

** For example, if participant fasted for 7 hours, the start of the OGTT can be postponed for 60 minutes. Note: The OGTT must be started before 11AM.