Instructions for V38 PE/Lipodystrophy Form

Physical Exam

Q3. Body Weight

The patient should be weighed in his clothing. However, heavy clothes such as coats, thick sweaters and shoes should be removed. Also ask the participant to empty his pockets of keys, wallets, loose change, etc.

A balance scale should be used. Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale should be level and on a firm surface (not a carpet). The participant should be instructed to stand in the middle of the platform of the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced. Have the subject step off the scale, reset the balance to zero and repeat. If measures differ by more than 1.0 lb, repeat a third time. Use the first measurement when a third measurement is not needed. If a third measurement is done, record that measurement as long as it is within 1.0 lb of either of the two previous measurements. If the third measurement is not within 1.0 lb of either of the first two measurements, repeat measurements until you get two measurements within 1.0 lb and use the last of these two measurements.

Lipodystrophy Form

The following items refer to the lipodystrophy questionnaire. This questionnaire should be administered to ALL participants regardless of serostatus. It should be administered after the physical exam by the examiner. The examiner should first ask the participants the questions on the self-report portion of the questionnaire and then conduct the lipodystrophy physical exam. The guidelines below and the videotape provided should be used as a reference for making the measurements.

Self Report:

Q1a.

This question asks the participant if he noticed any changes in his body’s fat distribution.

- If no, skip to Q3
- If yes, proceed to Q1b.
Q1b.

This question asks the participant to identify (1) what part(s) of the body experienced changes in fat distribution in the past 6 months, (2) the direction of that change i.e., an increase or decrease in fat, and (3) the severity of the change, i.e., mild, moderate, or severe.

- Mark “Yes” or “No” for each body part including “Other” that had a change in fat distribution.

- Do not leave blanks.

- If participant identifies “Other” record the body part in the specify box.

  - For each body part marked “Yes”, ask if the amount of fat decreased or increased.
    - Mark “Increase” or “Decrease” for each body part.
    - Leave blank for body parts with no change (Q1b. 1-10 = “No”)

  - For each body part marked “Yes”, ask if the “Increase” or “Decrease” was “Mild”, “Moderate”, or “Severe”
    - Allow participant to make only one selection and mark accordingly.
    - Leave blank for body parts with no change (Q1b. 1-10 = “No”)

Some examples of coding participant X’s response are:

- X had some arm fat loss but later gained approximately the same amount he lost. Mark “No”.

- At visit 33 X had “severe” facial fat loss. But, in the past 6 months, he gained about half of it back. Mark “Increase” for direction of change and current severity as “Moderate”.

Q1c.

This question asks participant since he noticed these changes, has he taken any action to influence them or correct them. Note that the participant could have noticed these changes prior to 6 months ago. Actions to influence these changes is not restricted to the past 6 months.
Q2.

The amount of change since last visit should be the net increase or decrease in shirt neck or trouser size from last visit to the current visit.

An example of coding participant X’s response is:

- X increased his trouser waist size by 3 inches, but a few months later he lost 2 inches from his waist.
  - Mark “Increase”
  - Mark “1-2 in.” (3-2=1 for a net gain of 1 inch)

Q3 & Q4

An uncontrolled condition means having an elevated blood glucose or cholestertol, or high blood pressure despite the medication and/or special diet. The participant may need higher doses of the meds, additional meds or need to be more adherent to his diet.

Exam:

Body Height

Height needs to be measured at every visit according to protocol. A clinic stadiometer is to be used whenever possible. The subject stands erect on the horizontal platform with his back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead. The head should be in the horizontal plane defined by the lower margin of the bony socket containing the eye and the most forward point in the notch just above the anterior cartilaginous projections of the external ear. The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject’s height is recorded to the nearest 1.0 in. Ask the subject to step off the platform, raise measuring block and ask subject to return to the platform. Repeat the measure. If measure differs by more than 1.0 in., repeat a third time. The subject should be instructed to stand as straight as possible but with feet flat on the floor. (If a stadiometer is not used, a tape mounted to the wall should be used. In this case, a check should be made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and the measuring tape is mounted perpendicular to the floor). Use the first measurement when a third measurement is not needed. If a third measurement is done, record that measurement as long as it is within 1.0 in of either of the two previous measurements. If the third measurement is not within 1.0 in of either
of the first two measurements, repeat measurements until you get two measurements within 0.5 in and use the last of these two measurements.

Chest Girth

The chest girth is measured at the level of the fourth costo-sternal joints, which laterally corresponds to the level of the sixth ribs. The fourth costo-sternal joint can be located by a two-handed palpitation method whereby the examiner places both the index fingers on the superior surfaces of the clavicles, while the thumbs locate the first intercostal space. The index fingers then replace the thumbs, which are lowered to the second intercostals spaces. This procedure can then be repeated until the fourth ribs are located. The fourth rib and their costal cartilages are followed medially to their articulations at the sternum, and this point is marked. The participant should be standing with the feet at the shoulder width. The measuring tape should be placed horizontally at the marked point. Once the tape is in place, the arms can be lowered to their regular position. Take the measurement at the end of a normal expiration. The chest girth is recorded to the nearest centimeter.

Waist Girth

The study participant is in a standing position. The participant is asked to hold up his gown. The examiner stands behind the participant and palpates the hip area for the right iliac crest. (see Exhibit A) The examiner marks a horizontal line at the high point of the iliac crest and then crosses the line to indicate the midaxillary line of the body. The pants and underclothing of the participant must be lowered slightly for the examiner to directly palpate on the hip area for the iliac crest. The examiner then stands on the participant’s right side and places the measuring tape around the trunk in a horizontal plane at this level marked on the right side of the trunk. Make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. The measurement is made at minimal respiration to the nearest 1.0 cm.

Hip Girth

The study participant stands erect with feet together and weight evenly distributed on both feet. The participant is holding up the examination gown. The examiner places the measuring tape around the buttocks. The tape is placed at the maximum extension of the buttocks. (see Exhibit B) The examiner then adjusts the sides of the tape and checks the front and sides so that the plane of the tape is horizontal. The zero end of the tape is held under the measurement value. The tape is held snugly but not tight. The examiner takes the measurement from the right side. The measurement is taken to the nearest 1.0 cm.
Arm Girth

The study participant is standing with the right elbow relaxed so that the right arm hangs freely to the side. The examiner marks the point halfway between the lateral projection of the acromian process of the scapula (bump on backside of shoulder) and the interior part of the olecranon process (elbow). The measuring tape is placed around the upper arm at the marked point perpendicular to the long axis of the upper arm. The tape is again held so that the zero end is held below the measurement value. The tape rests on the skin surface, but is not pulled tight enough to compress the skin. **The arm circumference is recorded to the nearest 1.0 cm.**

Thigh Girth

The study participant is sitting as shown on the instructional video. The examiner marks the point midway between the inguinal crease and the nearest border of the patella or kneecap. The examiner stands on the participant’s right side and the measuring tape is placed around the mid-thigh at the marked point. The tape is positioned perpendicular to the long axis of the thigh with the zero end of the tape held below the measurement value. The tape rests firmly on the skin without compressing the skin. **The thigh circumference is measured to the nearest 1.0 cm.**