V52 Physical Exam/Lipodystrophy Form

Physical Exam:

The Physical Exam form is divided into the following main components:

- Vital Signs (Page 1, Q1-Q5)
- Physical examination completed by a clinician (Pages 1-4, Q6-Q14)
- Lipodystrophy questionnaire (Page 5, Q1-Q2)
- Lipodystrophy measurements/observations completed by a clinician or trained examiner (Page 6, Q1-Q8)

Fill in your Clinician number in the box provided at the top of page 1.

Reasons for not completing the PE section (Q6-Q14) and lipodystrophy section (pages 5- 6).

Q6-Q14

If the participant refuses the entire physical examination (Q6-Q14), mark the appropriate bubble (participant refused this section). However, if any part of the physical exam is completed, DO NOT bubble in this box. Instead, indicate which exam items have been refused by bubbling the refusal bubble of each particular item.*

If a clinician was not available to perform the physical examination (Q6-Q14), mark the appropriate bubble (No clinician available). However, if any part of the physical exam is performed by the clinician, DO NOT bubble in this box. Instead, leave all uncompleted physical exam items as blank.

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Pages 5-6

If the participant refused the entire lipodystrophy section (questionnaire and the measurements), mark the appropriate bubble (participant refused the lipo section). However, if any part of the lipo section is completed, DO NOT bubble in this box. Instead, indicate which questions or measurements have been refused by bubbling the refusal bubble of the particular item.*

If the examiner was not available for the lipodystrophy measurements and observations

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* A refusal bubble has been added to each question on the Physical Exam to distinguish between missing data and refused answers. If the participant refuses a question, fill in the *"Refused"* bubble for that question. NEVER GIVE THE PARTICIPANT THE OPTION TO REFUSE.

on page 6, then mark the appropriate bubble (no lipo examiner available). However, if any part of page 6 is performed by the examiner, DO NOT bubble in this box. Instead, leave all uncompleted lipodystrophy items as blank.

If no portion of the PE was conducted, vital signs, Q6-Q14, and lipodystrophy, do not submit the form to CAMACS.

Body Weight:

Measure the weight in kilograms to the 10th decimal place and record on page 1 of the Physical Exam form. The participant is weighed in minimal clothing, preferably in underwear or in an examination gown. 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 hard floor (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.

Blood Pressure

Blood Pressure readings will be performed twice using the Dinamap Pro 100 (Harbor-UCLA already has IVACS) non-invasive blood pressure machine.

- Key Elements
  - The participant should not have smoked nor had any caffeine within the last 30 minutes prior to the blood pressure (BP) measurement.
  - Perform BP readings on the same arm visit to visit for each individual participant and blood draws (BD) in the opposite arm. It does not necessarily have to be the same arm for all participants.
    - Preferably, take blood pressure in the right arm and perform blood draw from the left arm
    - If the BP has to be taken on the same arm as the BD, try to perform the BP prior to the BD. If not possible, wait 5-10 minutes between BP and BD.
  - Bubble in the blood pressure arm on the PE form
  - Perform blood pressure on bare arm, but avoid rolling up sleeve to the extent that it forms a tight tourniquet
  - Participant should be sitting, in a quiet location, legs uncrossed with feet resting on the floor. Back should be supported.

- Arm should rest on a table in a relaxed position so that the midpoint of upper arm is heart level. (Adjust the height of the table or seat if possible.)

- Use correct size cuff

  - Measure circumference of upper arm midpoint (between shoulder and elbow)

  - The bladder in the cuff should encircle 80% of arm.
  - If in doubt, use larger cuff

- Placement of the cuff

  - Lower edge should be about 1 inch above the antecubital fossa (bend in the arm or crease of inner elbow) and not resting on it. This may be difficult to adhere to for short arms.

  - Midpoint of the bladder length should be over the brachial artery and mid-height of the cuff is at heart level

  - Wrap the cuff snugly and secure firmly around the bare arm.

- Steps:

  1. Let participant sit for 5 minutes prior to the BP measurement.

  2. Take blood pressure using an automated BP instrument.

  3. Record readings on the PE form.

  4. Repeat the blood pressure measurement starting with Step 1. The deflated blood pressure cuff may be kept on the participant's arm or removed between readings.

Abdomen:

Q10.a: Percussed Liver Size. If the clinician is unable to get a valid measurement for the percussed liver size in the mid-clavicular line, please fill in "99" for unable to measure.

Q10.b: Palpable Spleen. If the spleen is palpable, please indicate the size in the box. Otherwise, leave box blank.

Rectal and Genital Exams:

The rectal exam is performed annually by the MACS. Indicate if the rectal exam was

performed in the past 6 months, “NO”, “YES”.

If “*NO*” (no exam in past 6 months), then proceed with the rectal exam. If the participant refuses, fill in bubble, “mark here if entire rectal exam was declined”. Fill in this bubble only if the participant refuses the entire rectal exam.

If “YES” (an exam was performed in past 6 months), the examiner may skip the rectal. However, a participant may opt for a rectal exam even if he had one in the past 6 months.

The genital exam is performed every 6 months. If the participant refuses, fill in bubble, “*mark here if entire genital exam was declined*”. Fill in this bubble only if the participant refuses the entire genital exam.

Peripheral Neuropathy Screening:

Instructions for evaluating perception of vibration: Strike the end of the 128 Hz tuning fork hard enough that the sides touch. Place the vibrating tuning fork on a bony prominence of the participant’s wrist to be sure that they can recognize the vibration or ‘buzzing’ quality of the tuning fork. Again strike the ends of the tuning fork hard enough so that the sides touch. Immediately place the vibrating tuning fork gently but firmly on the top of the distal interphalangeal (DIP) joint of one great toe and begin counting the seconds. Instruct the participant to tell you when the ‘buzzing’ stops. Repeat for the other great toe.

No = the participant did not feel the vibration
Yes = the participant felt the vibration
Unable to evaluate = the participant could not be screened (e.g., the participant had a bandaged great toe.
Refused - the participant refused to be screened even though it was possible to screen him.

Instructions for evaluating deep tendon reflexes: With the participant seated, the examiner uses one hand to press upward on the ball of the foot, dorsiflexing the participant’s ankle to 90 degrees. Using a reflex hammer (preferable long-handled), the examiner then strikes the Achilles tendon. The tendon reflex is felt by the examiner’s hand as a plantar flexion of the foot, appearing after a slight delay from the time the Achilles tendon was struck.

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 participant 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.

Lipodystrophy Questionnaire:

Question 1:

1.A - This question asks the participant if he noticed any changes in his body's fat distribution since his last visit.

- If "*No*", skip to *Q3*
- If "*Yes*", proceed to *Q1.B*.

1.B - This question asks the participant to identify: (1) what part(s) of the body experienced changes in fat distribution since the participant's last visit; (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 (*Q1.B(1-9)* = "*No*")
  - For each body part marked "*Yes*", ask if the "Increase" or "Decrease" was "Mild", "Moderate", "Severe" or "None"
    - Allow participant to make only one selection and mark accordingly.
    - Leave blank for body parts with no change (*Q1.B(1-9)* = "*No*")
    - Sometimes the most appropriate response will be "back to normal", fill in "*None*" (see example below).

"NONE" Example: Participant X reports that there were changes in his body fat. During the last visit he was using drugs and was very skinny. He stopped using drugs and has put on weight in his abdomen, waist, hips, and generally all over. So, he had an increase in his waist, abdomen, hips and other. Then we come to the severity question. There is no severity because he is now back to a normal weight.

Some more examples of coding participant X's responses:

- X had some arm fat loss but later gained approximately the same amount he lost. Mark "*No*". There is no net increase or decrease in arm fat.
- 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".

1.C - 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, but we are asking about since his last visit.

Question 2:

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)

Lipodystrophy Exam:

Fill in your examiner code in the box provided on page 6 of the Physical Exam form.

Equipment

The stadiometer is used to measure height and is mounted to the wall. **Please check the position of the stadiometer to adjust for any shifting.** The scales are used to measure weight. The Insertion tape is used to locate the midpoints of the upper arm and the thigh. The Lufkin steel tape is used to measure all circumferences. The tape measures are cleaned with an alcohol wipe prior to and after use on each participant.

General Instructions:

Measurements are taken at a body site that is healthy, dry, and uninfected. The participant is instructed to relax and avoid tensing muscles or altering his body position during the assessment. All measurements are taken on the right side of the body, unless this is not possible. In such an instance, this needs to be noted.

The participant's body is marked designating specific locations before taking the remaining body measurements. After marking, the measurements are taken in a sequence that facilitates the examination being completed quickly. This sequence is as follows: arm, chest, waist, hip and thigh circumferences. After each measurement is taken, record the value for that measurement on page 6.

For all measurements, a single value is taken and recorded. If you are uncertain of the value of a measurement, repeat the measure to check reproducibility. For circumferences, the measurement is repeated before taking the next circumference.

Body Height:

The height should be taken during deep inhalation because this maneuver tends to straighten and avoid any "slumping" effects and straightens the spine.

- Key Elements:
  - Height is measured in centimeters with a wall mounted stadiometer.
  - The floor below the stadiometer should be level.
  - The placement of stadiometer should be verified for correct positioning on the wall.
  - Measure the height at every visit.
- Steps:
  - Place the participant in correct position with shoes off:
    - The participant stands erect with his back parallel vertically to the stadiometer with buttocks, shoulders and head positioned in contact with the stadiometer.

      It may not be possible for some participants to place their buttocks, shoulders and head against the stadiometer due to adipose tissue on the buttocks. These participants are positioned so that only the buttocks are in contact with the vertical portion of the stadiometer and the body is positioned vertically above and below the waist so that the participant is standing straight when viewed from the side.
    - The participant's heels are together so that he is standing straight

when viewed from the side.

- The participant's arms hang freely by the side of the trunk with the palms facing the body.
- Position the head horizontally and parallel to the floor vertically from left to right, and with the participant looking straight ahead. The line from the lower margin of the bony socket containing the eye and the opening of the external ear is parallel to the floor.

- Ask the participant to inhale deeply.
- Lower horizontal measuring piece snugly, but not tightly, on the top of the head.
- Take the height measurement.
- Record to the nearest 0.1 cm.

Marking the Participant:

Mid-point of the Upper Arm: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the right arm flexed 90 degrees at the elbow with the palm facing up. Stand behind the subject and locate and mark the upper edge of the posterior border of the right acromium. Hold the insertion tape extended down the posterior surface of the right arm so that the number at the acromium matches the number at the tip of the olecranon process. Keeping the tape in position, locate half the distance from the acormium to the olecranon as indicated by the arrow on the tape. This is the midpoint of the upper arm, which is marked for measuring arm circumference.

Iliac Crest: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The pants and underclothing are lowered to directly palpate the right hip area for the iliac crest. A horizontal line is made with the marker at the high point of the right iliac crest in the mid-axillary line of the body. **This is marked for measuring the waist circumference.**

Mid-point of the Right Thigh: The participant sits upright with his right knee bent at a 90 degree angle. The proximal border of the patella or knee cap is located and marked and one end of the insertion tape measure is held at this mark. The tape is extended centrally along the length of the right thigh toward the abdomen and the inguinal crease is located. Keeping the tape in position, locate the arrow indicating half the distance from the inguinal crease to the mark on the patella. This is the midpoint of the right thigh and it is marked for measuring thigh circumference.

Circumference Measurements:

All circumferences are taken with the participant standing and relaxed. The steel tape measure is used for all circumference measurements. The chest, waist and hip circumferences are all taken with the plane of the tape around the body parallel to the floor. The arm and thigh circumferences are taken with the plane of the tape perpendicular to the upper arm or thigh at the indicated marks. The steel tape is held in one hand by the leader, which is about 2 inches in front of the zero mark on the tape. The other hand holds the tape and not the tape measure casing. For all circumference measurements, the tape is held snug against the body with minimal compression of the underlying skin. On some individuals, there will be gaps between the tape measure and the body, such as on the back of the trunk between the shoulder blades for chest circumference and on the inside of the arm for arm circumference. These gaps cannot be corrected by attempting to adjust the tape to conform to the surface of the skin.

Arm Circumference: The right arm is extended and the steel measuring tape is placed around the upper arm over the marked point perpendicular to the long axis of the upper arm. 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 0.1 cm.

Chest Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms extended to the side. Chest girth is measured at the level of the level of the nipples. The tape measure is placed horizontally around the trunk, over the shoulder blades in the back and over the nipples in the front. Once the tape is in place, the arms are lowered to the side of the body and the tape is held snugly but without compressing the skin. The measurement is taken at the end of a normal expiration. The chest girth is recorded to the nearest 0.1 centimeter.

Waist Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The pants and underclothing are lowered and the mark on the right hip over the iliac crest is located. The examiner sits next to the participant's right side and places the steel measuring tape around the abdomen in a horizontal plane at this level marked on the right side of the trunk. The tape is held parallel to the floor and snug without compressing the skin. The measurement is made at mid-respiration to the nearest 0.1 cm.

Hip Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The examiner places the measuring tape around the buttocks on the right side of the subject. The steel tape is placed over the buttocks at the maximum extension of the buttocks. Adjust the sides of the tape and check the front and sides so that the plane of the tape is horizontal. The tape is held snugly but not tight. The measurement is taken to the nearest 0.1 cm.

Thigh Circumference: The participant stands comfortably with his feet at about 6 inches apart and weight evenly distributed. The subject takes a small step backwards with the left leg so that the subject's weight is now shifted to the left leg and there is no tension in the quadriceps muscle of the right leg. The examiner stands at the subject's right side and the steel measuring tape is placed around and perpendicular to the mid-thigh at the marked point. The tape rests firmly on the skin without compressing the skin. The thigh circumference is recorded to the nearest 0.1 cm.

Q7. and Q8. Fat Wasting and Fat Accumulation:

The examiner observes and grades the lipoatrophy (both facial and limb) according to the following standards:

For facial lipoatrophy:

a) mild- clearly visible deepened nasolabial folds

b) moderate- evidence of "hollowing out" of cheeks

c) severe- hollowed cheek areas with underlying muscle clearly visible

For limb (arms and legs) lipoatrophy:

a) mild- increased prominence of veins

b) moderate- increased prominence of both veins and muscles

c) severe - a+b with overall thinning appearance of the limb