

## MACS V55 Physical Exam / Lipodystrophy Form Guidelines

### **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).**

#### **Pages 1-4, 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. \*

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

\* A refusal bubble is available for each item 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 option to refuse.

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### **Body Weight:**

Measure the weight in kilograms to the 10<sup>th</sup> 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.
  - 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

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### 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.

### **Q11. Rectal and Genital Exams and Anal Health Study (AHS) :**

Rectal examinations are conducted annually as part of the core MACS protocol, unless requested more frequently by the participant.

The collection of a swab for the cytology and HPV tests are performed only on participants who have consented to participate in the Anal Health Study and according to their scheduled cycle of testing (see the MACS forum for the AHS protocols and forms:  
[http://www.statepi.jhsph.edu/macs/MACS\\_forum/forumdisplay.php?f=91](http://www.statepi.jhsph.edu/macs/MACS_forum/forumdisplay.php?f=91)

The examiner may record observations, such as warts and lesions if observed while collecting an anal swab even if the participant did not agree to a digital exam.

### **Physical Examiner instructions for current visit:**

Indicate what exam items are to be performed for the participant at this visit:

- Collect cytology swab                       no                       yes

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- Collect HPV swab                      O no                      O yes
- Perform digital exam                      O no                      O yes

**Mark here if genital exam: This item bubble has been removed.**

**The genital exam is performed every 6 months. If the participant refused the entire rectal exam, fill in the bubble next to each exam component.**

### **Peripheral Neuropathy Screening:**

See training video at <http://www.calcaprt.com/macs/macs.htm>.

**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 (**sensation absent**)

Yes = the participant felt the vibration (**sensation present**)

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.

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### Lipodystrophy Questionnaire:

**Q1.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*.

**Q1.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.

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- 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 Physical Exam:**

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

### **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: **neck**, 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:**

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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.

**Circumference Measurements:** See pages 10-19

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### **Q6. and Q7. Fat Wasting and Fat Accumulation:**

#### General Definitions:

- None: Participant does not exhibit any signs of fat maldistribution. (Not noted by participant or clinician)
- Mild: Mild signs noted only after close inspection by patient or clinician.
- Moderate: Signs of fat maldistribution are noticed by patient or clinician without specifically looking for it. Patient may complain that current clothing has become tighter.
- Severe: Signs of fat maldistribution easily noted by casual observer. Symptoms have required a change in size of clothing or undergarments worn.

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

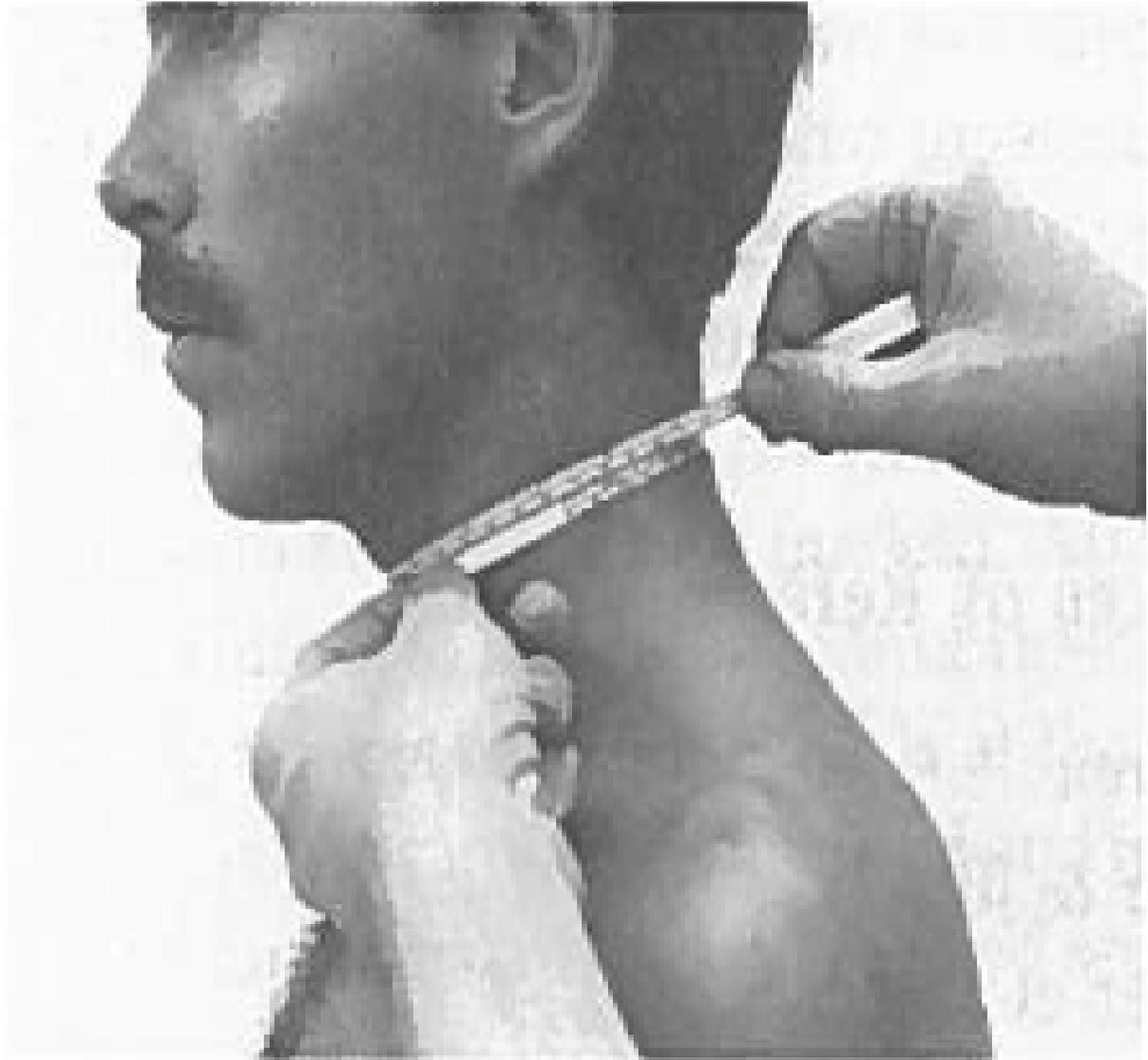
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### **CIRCUMFERENCE MEASUREMENTS:**

All circumferences are measured with the participant standing and relaxed. A Lufkin Executive Thinline 2m W606PM steel tape is used for all circumference measurements. It is preferred that the steel tape casing be held in left hand and tape extended using the leader held in the right hand. This will allow the tape with the zero mark to be positioned below the part of the tape where the measurement is read. The tape is held snug against the body with minimal compression of the underlying skin.

### **NECK CIRCUMFERENCE**

Without any clothes obscuring the neck, the participant stands erect with the head in the Frankfort Horizontal Plane (the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor). Standing on the right side of participant, the examiner palpates the neck to identify the lower border of the laryngeal prominence (Adam's apple). Note: It may be useful to ask the participant to swallow several times to assist with finding the lower border. A small mark is placed at this location. Place the steel measuring tape around the neck making sure to cover the mark; the tape may not be horizontal to the floor, yet it should be perpendicular to the long axis of the neck (see image). The pressure of the tape on the skin should be minimal while maintaining complete contact with the neck surface. From the right side of the participant, the circumference is measured to the nearest 0.1 cm.



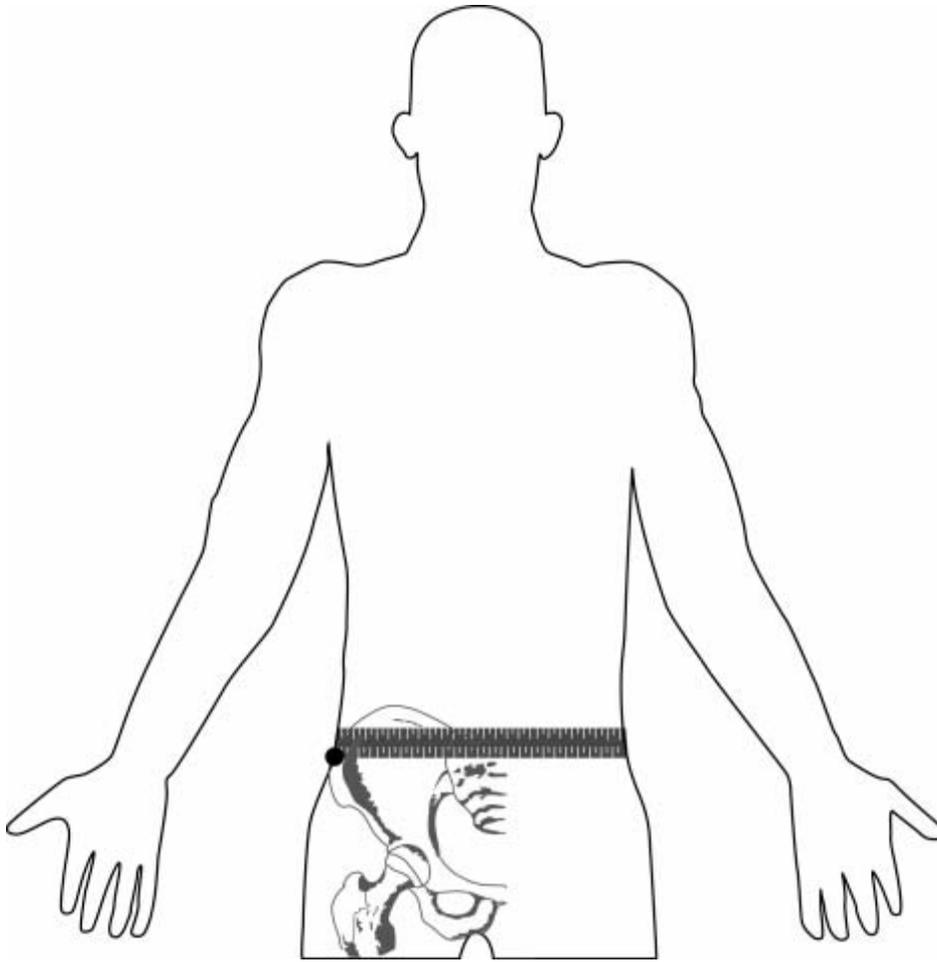
Neck

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### WAIST CIRCUMFERENCE

To define the level at which the waist circumference is measured, the examiner must first locate and mark a bony landmark, the lateral border of the right iliac crest. Have the participant stand comfortably with his feet apart and weight evenly distributed. Ask the participant to cross his arms over his chest. If needed, slightly lower the top of his underclothing to palpate the iliac crest. (see diagram). Standing on the participant's right side, draw a horizontal line at the mid-axillary line of the trunk at the uppermost lateral border of the right iliac crest. Remaining on the participant's right side, place the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk so that the zero end of the tape is held below the measurement value. The examiner should squat to check the front, side and back of the trunk to ensure correct horizontal alignment of the measuring tape. Squatting will ensure that the examiner is at eye level to the measuring tape. The tape needs to be parallel to the floor and that the tape is snug without compressing the skin. On some individuals, there will be gaps between the tape and the body, such as the lower back. These gaps cannot be corrected by attempting to adjust the tape to conform to the surface of the skin. With normal breathing, record the measurement to the nearest 0.1 cm.

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Waist

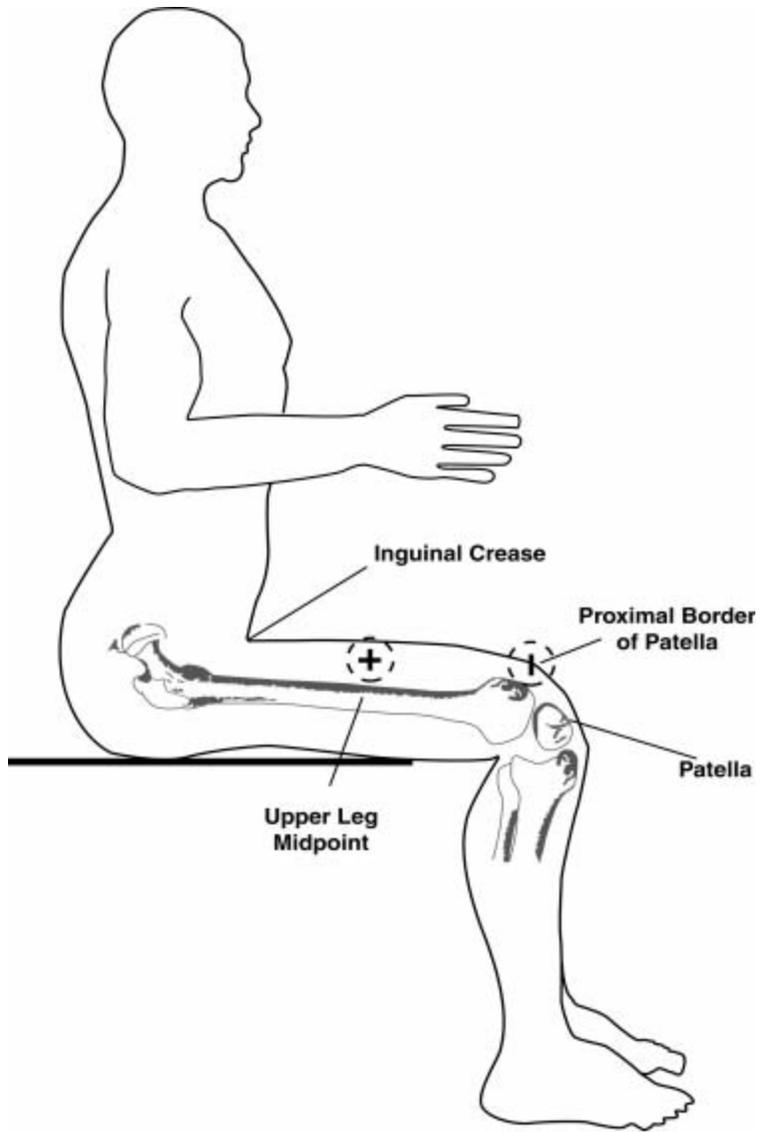
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### MID-THIGH CIRCUMFERENCE

**Mid-point of the Right Thigh Circumference:** The participant sits upright with his right knee bent at a 90 degree angle. Palpate the proximal border of the patella and mark a line on the anterior surface of the thigh. Place the zero end of the tape at the inguinal crease. To ensure proper location, ask the participant to slightly lift his thigh, a tightening of the muscle tendon will be felt. After lowering his thigh and if necessary, reminding the participant to sit upright, extend the tape down the anterior midline of the thigh to the mark that was made at the proximal patella. Record the measurement to the nearest 0.1 cm. Divide the leg measurement to find the midpoint mark. Keeping the tape in position, mark the midpoint with a horizontal line (See first diagram).

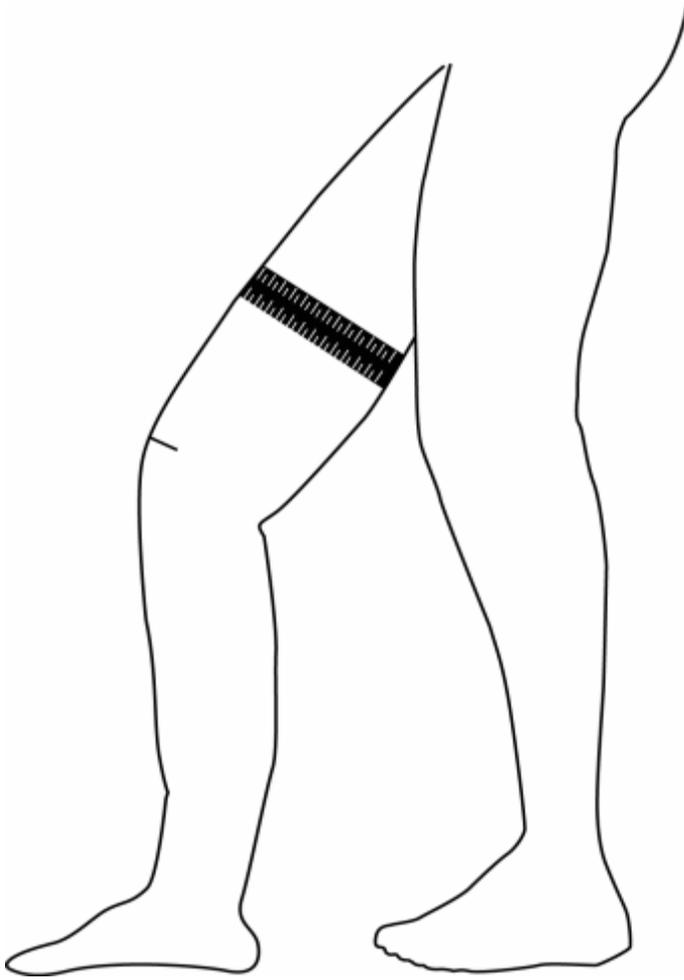
Ask the participant to stand and then ask him to step back with his left leg with his right leg forward, knee slightly flexed and soles of both feet flat on the floor. His weight should be shifted to his left leg. Stand on the participant's right side and place the measuring tape around the mid-thigh at the mark... Position the tape perpendicular to the long axis of the thigh with the zero end of the tape held below the measurement value. Rest the tape firmly on the skin but without compressing it. Check to make sure the tape is positioned correctly by looking at all sides of the thigh. Record the mid-thigh circumference to the nearest 0.1 cm (See second diagram).

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Mid-thigh

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Mid-thigh

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### **HIP CIRCUMFERENCE**

Wearing undergarments, the participant stands erect with feet apart and weight evenly distributed on both feet. Ask the participant to cross his arms over his chest. The examiner squats on the right side of the participant and places the measuring tape around the maximal extension of the buttocks (see diagram). Squatting will ensure that the examiner is at eye level to determine this anatomic location. As necessary, the examiner should unruffle or smooth out any bunched up cloth of the undergarments. The examiner adjusts the sides of the tape and checks the front, back and other side so that the plane of the tape is parallel to the floor. The tape is held snug but not tight with the zero end of the tape held below the measurement value. The examiner takes the measurement from the right side and records the measurement to the nearest 0.1 cm.



HIP