

Physical Exam and Lipodystrophy Guidelines: Visit 67

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Physical Exam:

To be completed at every 6 month Full Visit (Baltimore, Pittsburgh, and UCLA) and annual Full Visit (Chicago). To be completed as requested at annual Limited Visit (Chicago)

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

Paper form:

- A. Vital Signs, Height and Weight (Page 1, Q1-Q5)*
- B. Core physical examination items (Pages 1-2, Q6-Q12)*
- C. Aging/Neuropathy examination items (Pages 3-4, Q13- Q16)*
- D. Lipodystrophy questionnaire (Page 5, Q1-Q2)*
- E. Lipodystrophy measurements completed by a clinician or trained examiner (Page 6, Q1-Q4)*
- F. Training protocol for Standing balance*
- G. Range of Joint Motion Evaluation Chart*

In MDMS

- A. Login Screen (Q1-2)*
- B. Vital Signs, Height and Weight (Module 1, Q3-4b.)*
- C. Core physical exam (Module 2, Q 6-10c.)*
- D. Anal/ rectal, genitalia examinations (Module 3, Q11-13f.)*
- E. Examiner's Impressions (Module 4, Q13)*
- F. Aging/Neuropathy examination (Module 5, Q14)*
- G. Standing Balance (Module 6, Q15a.)*
- H. Chair Stands (Module 7, Q15b.)*
- I. Alert and Oriented (Module 8, Q16)*
- J. Lipodystrophy questionnaire (Module 9, Q1-4)*

➤ If no portion of the PE was conducted, (vital signs, Q6-Q16, and Lipodystrophy) do not submit the paper form to CAMACS. If using MDMS, select "Refused/ Participant Refused Section" where indicated.

➤ If the participant does not agree to have a core physical examination:

Obtain the blood pressure, height, and weight. This is required at every visit.

Make every attempt to perform the neuropathy tests, the examiner impressions, standing balance measurements, and alert and oriented items.

Make every attempt to obtain the Lipodystrophy measurements

A. Vital Signs, Height and Weight (Page 1, Q1-Q5 on Paper Form) (MDMS: Module 1)

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Fill in the MACSID, visit number, and the Clinician number of the physical examiner in the boxes provided at the top of page 1. If using MDMS, Enter this in Module 1.

Sections not completed due to: participant refusal or clinician not available.

Pages 1-4 (Q6-Q16) on paper form, Modules 2-8 in MDMS

Never give the option to refuse. However, if the participant refuses the entire physical examination, mark the appropriate bubble (participant refused this section). If the participant agrees to part of the exam and refuses other parts, DO NOT bubble in this box.

Fill in the refusal bubbles where indicated on the form (paper or in MDMS) to distinguish between items that were missed and those that were refused. For all other refused exam items, leave the exam item bubbles blank.

If a clinician was not available to perform the physical examination, 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 blank.

Pages 5-6 on paper form, Module 9 in MDMS

If the participant refuses all of the lipodystrophy measurements, mark the appropriate bubble (participant refused the lipo section). However, if some of the measurements were completed, DO NOT fill in the bubble in this box. Instead, indicate which measurements have been refused by filling in the refusal bubble of the particular item.

Body Weight:

Measure the weight in kilograms to the 10th decimal place and record on page 1 of the Physical Exam form. The participant should be weighed while wearing minimal clothing, preferably underwear or an examination gown. At the least, he must take off his shoes, outer clothing (e.g., jacket or sweater) and empty his pockets. 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 placed 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 his head erect and his eyes looking straight ahead. Adjust the weight on the indicator until it is balanced.

Body Height:

The height should be measured while the participant inhales deeply 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.

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- ▶ 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. The participant should be positioned so that only his buttock is in contact with the vertical portion of the stadiometer and the body is positioned vertically above and below the waist so that he 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 eye socket and the opening of the external ear should be parallel to the floor.
 - ▶ Ask the participant to inhale deeply.
 - ▶ Lower the horizontal measuring piece so that it fits snugly, but not tightly, on the top of the head.
 - ▶ Take the height measurement.
 - ▶ Record to the nearest 0.1 cm.

Blood Pressure

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

Steps:

1. Let the participant sit for 5 minutes prior to the BP measurement.
2. Measure the blood pressure using an automated BP instrument.
3. Record the blood pressure readings on the PE form.
4. Repeat the blood pressure measurement starting. The deflated blood pressure cuff may be kept on the participant's arm or removed between readings

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Key Elements

- ▶ The participant should not have smoked nor have consumed any caffeine during the 30 minutes prior to the blood pressure (BP) measurement.
- ▶ Perform BP readings using the same arm from visit to visit for each participant and perform blood draws (BD) in the opposite arm.
 - Preferably, measure the blood pressure in the right arm and perform blood draw from the left arm
 - If the BP must be measured using the same arm from which blood was drawn, try to measure the BP prior to the BD. If not possible, wait 5-10 minutes between BP and BD.
- ▶ Indicate on the PE form which arm was used to measure BP
- ▶ Measure blood pressure using the bare arm, but avoid rolling up the sleeve to the extent that it forms a tight tourniquet
- ▶ The participant should be sitting in a quiet location with his legs uncrossed and his feet resting on the floor; his back should be supported.
- ▶ The arm from which BP is measured 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 BP cuff
 - Measure the circumference of the upper arm midpoint (between shoulder and elbow).
 - The bladder in the cuff should encircle 80% of arm.
 - If in doubt, use a 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 procedure may be difficult to adhere to for short arms.
- The midpoint of the bladder length should be over the brachial artery and mid-height of the cuff at heart level
- Wrap the cuff snugly and secure firmly around the bare arm.

B. Core physical examination items (Pages 1-2, Q6-Q12 on paper form) **(Modules 2-3 in MDMS)**

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Specific instructions for the following items:

Q10. Abdomen:

Q10a. Liver. Starting at v61, liver percussed size is not measured. Instead, indicate if the liver is enlarged (>3cm below the right costal margin measured at the mid-clavicle line and/or is tender.

Q10.b: Spleen. Starting at v61, size of spleen is not indicated. Instead, indicate if the spleen is palpable.

Q11. Rectal Exam:

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

Please encourage the participants to undergo annual MACS rectal exams even if they receive them regularly outside the MACS!

Starting at v61, swabs for Anal Health Study will no longer be collected.

Physical Examiner instructions for current visit:

Q11. Indicate if an annual rectal exam is to be performed for the participant at this visit. **This will be pre-populated or pre-entered in MDMS.** The clinician should be informed prior to the exam whether the participant is due for his annual rectal exam:

- Perform annual rectal exam, including digital no yes

Mark NO to the above item if the participant is NOT scheduled to have one at the current visit. Leave all respective exam items under Q11 blank. If the participant is not scheduled, but would like to have a rectal exam, then perform the exam and mark the results of each exam item performed. Leave the items not performed blank.

If the participant refuses, mark refused for each component item he refused under Q11. For example, if he refuses to undergo the digital exam, then mark refused for just the digital items. In other words, mark the results (YES or NO) for the parts of the exam that were completed and REFUSED for the parts that the participant did not want to have performed.

Note that the ANAL/RECTAL examination was re-organized according to its 2 components.

Q11. A Visual exam

- 1) Discharge

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- 2) Herpetic lesions
- 3) Warts
- 4) Hemorrhoids, external
- 5) Laceration/fissure/fistula

Q11.b Digital exam

- 1) Tender anal canal
- 2) Prostate **If the participant has no prostate gland, mark NO for exam not completed.**
Enlarged
Tender

Q11.c Other Conditions.

Mark no if no other conditions. Mark YES, if other conditions are observed during the physical exam and note in the comments box.

Q12. Genitalia

Encourage genitalia exams at each follow-up visit.

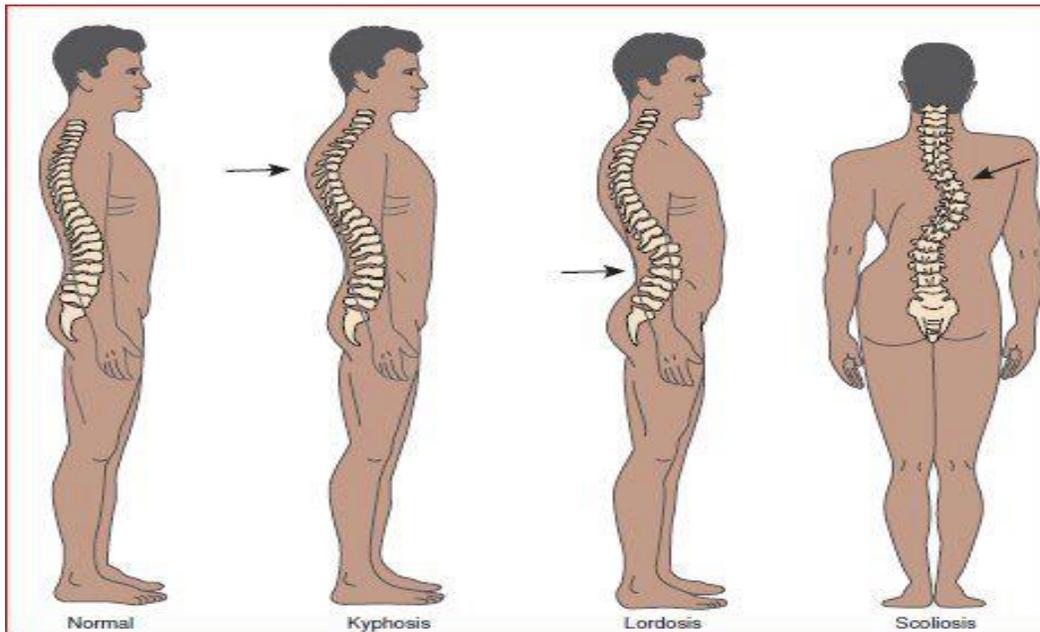
Q13. Aging/Neuropathy examination items (Pages 3-4, Q13-Q16 on paper form)
(Module 4-5)

Mark “No”, “Yes” or “Refused” and provide an explanation if not normal.

General appearance of posture, back and spine: Ask the participant to stand without an assisted device comfortably and observe the participant when observing him from the side. Observe whether he is standing upright, bent at the neck, waist or knees, and whether a curvature of the spine exists. See diagrams below. . To evaluate for scoliosis observe the participant from behind while he bends over at the waist. Compare his posture to the pictures.

- **Stands upright: Check photos to determine posture.**
- **Note whether participant uses assist device while standing.**

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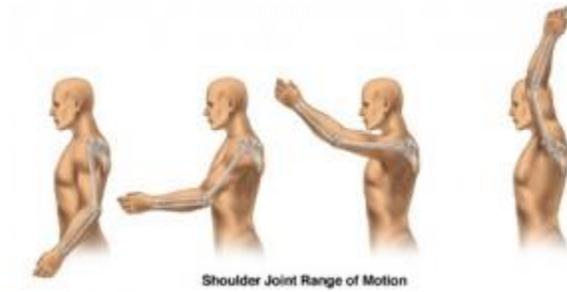
Extremities:

- **Arthritis** - observe for signs of arthritis, including joint deformities, joint swelling, tender, painful, or creaky joints .
- **Peripheral edema** - observe whether feet, ankles, lower legs or hands appear swollen.
- **Limited range of motion** – Ask the participant to maneuver his limbs as demonstrated in the following diagrams. Observe for reduced range of motion when utilizing the maneuvers depicted in the diagrams. There is no need to make measurements. Mark yes or no for reduction in range of motion.

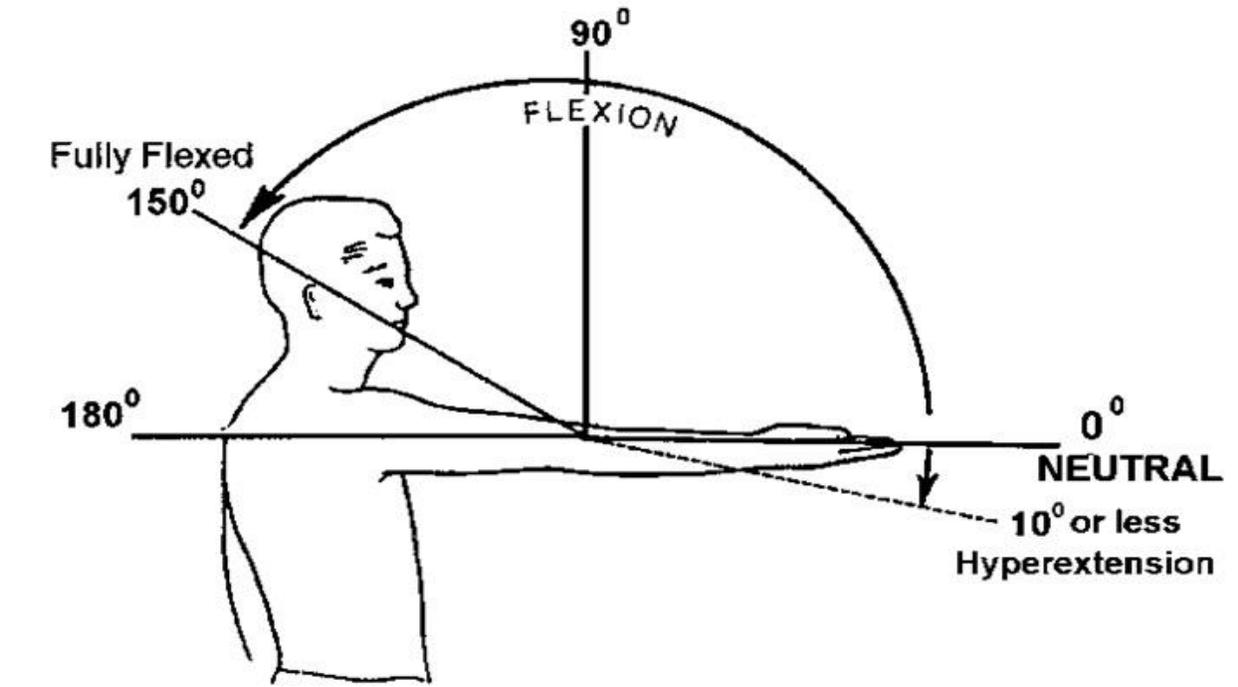
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Limited range of motion of arms – Shoulders and elbow

Shoulder



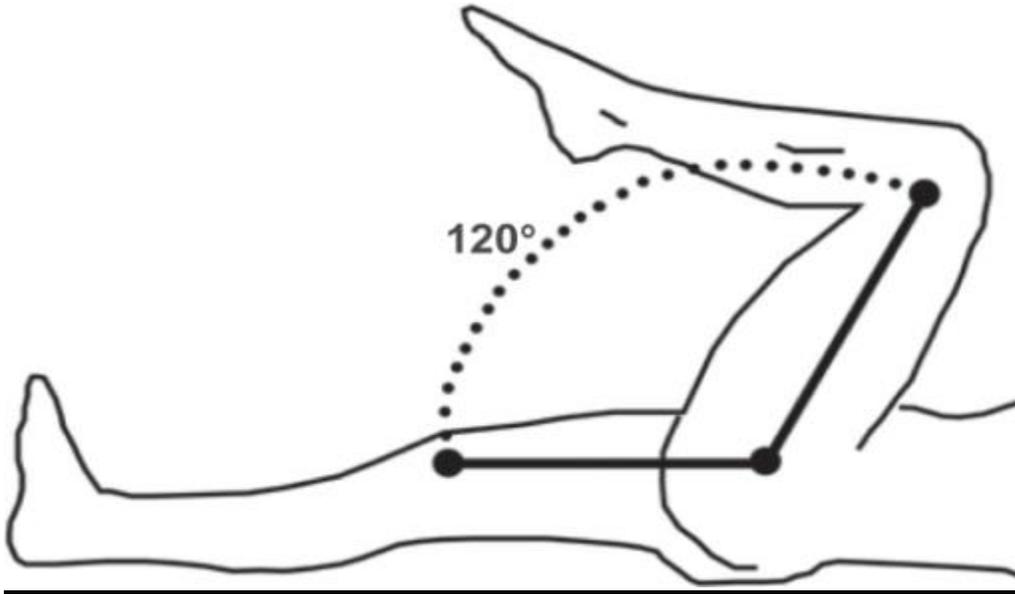
Elbow



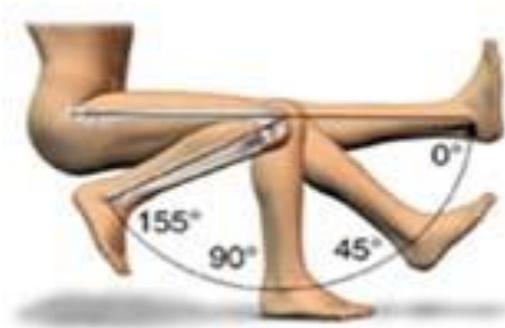
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Limited range of motion of legs – Hip and Knee

Hip



Knee



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Q14. Peripheral Neuropathy Screening:

See training video at <http://www.calcaprt.com/mac/mac.htm>. (Two boxes will pop up requiring you to repeat the entry of the user-id (“macs”) and password (“macs”).

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.

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Q15. Standing Balance (modified for v63) (Module 6):

Complete the tasks in the order described below. Use these instructions while in clinic with the participant.

These tests come from the Bone Strength Study. **If unable to do side-by-side (Q15a.1) for at least 10 seconds, do not attempt other standing balance tests (semi-tandem, tandem and single leg stand); move on to chair stands (Q15b). If able to do side-by-side, but unable to hold the semi-tandem stand for at least 10 seconds, record the time under Q15a.1, and move on to chair stands. If able to do the prior stands, but unable to hold tandem stand for at least 30 seconds, record the time under Q15.2, and move on to chair stands.**

See Appendix 1 for training guidelines.

See training videos on MDMS under the BOSS section.

Description: These timed, progressively more difficult, static balance tests are performed with the participant standing a little less than an arm's length from a wall for support if needed.

Note: walking aids, such as a cane, may not be used. Shoes may be on or off.

The standing balance test should be performed with the participant standing a little less than an arm's length from a wall to provide an additional source of support if a loss of balance does occur.

Read to participant: "I'm going to ask you to stand in several different positions that test your balance. I'll demonstrate each position then ask you to try to stand in each position for up to 30 seconds. I'll be near you to provide support, and the wall is close enough to prevent you from falling if you lose your balance. Do you have any questions?"

NOTE: If a participant refuses any item in the Standing Balance assessments, mark "refused" on the form; do not complete the remaining Q15a tasks, move to chair stands (Q15.b).

Instructions for Side-by-side Q15.a.1:

PROMPT: READ to participant: "First I would like you to try to stand with your feet together, side-by-side, for about 10 seconds. Please watch while I demonstrate."

Demonstration: Demonstrate and say: "You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold your feet in this position until I say stop."

Test Instructions:

- Allow participant to hold onto your arm to get balanced. Say "**Hold on to my arm while you get in position. When you are ready, let go**".
- If the participant attempts to stand incorrectly, demonstrate it again.
- Start timing when the participant lets go.
- Watch the participant, not the stopwatch.
- Stop the stopwatch if the participant takes a step or grabs for support.

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- Record to 0.01 second the time the participant could hold this position.
- Say, “STOP” after 10 seconds.

If the participant is unable to hold the side-by-side stand for at least 10 seconds, record the time under Q15a.1, and STOP. DO NOT attempt the other standing balance tests (semi-tandem, tandem or single-leg stand). Leave these items blank on the form. **Proceed to the Chair Stands.**

If you reason it would be unsafe for the participant to proceed to the more difficult positions, DO NOT proceed to Semi-Tandem, Tandem and Single-leg stands. Leave these items blank.

Instructions for Semi-tandem Q15.a.2:

PROMPT: READ to participant: “Now I would like you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 30 seconds. Please watch while I demonstrate.”

Demonstration: Demonstrate and say: “You may put either foot in front, whichever is more comfortable. You can use your arms and body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this.”



Test Instructions:

- Allow participant to hold onto your arm to get balanced. **SAY: “Hold on to my arm while you get in position. When you are ready, let go.”**
 - Start timing when the participant lets go.
 - Watch the participant, not the stopwatch.
 - Stop the stopwatch if the participant takes a step or grabs for support.
 - Record to 0.01 second how long participant is able to hold this position.
 - If the participant is unable to attain or hold the position for at least one second, mark “unable”
- Say, “STOP” after 30 seconds.

Tester instructions:

If the participant is unable to hold the semi-tandem stand for at least 10 seconds, record the time under Q15a.1, and STOP. DO NOT attempt the other standing balance tests (tandem or single-leg stand). Leave these items blank on the form. **Proceed to the Chair Stands.**

Instructions for Tandem Stand Q15.a.3:



PROMPT: READ to participant: “Now I would like you to try to stand with the heel of one foot in front of and touching the toes of the other foot. I’ll demonstrate.”

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Demonstration: Demonstrate and say: “Again, you may use your arms and body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step, like this.”

Test instructions:

- Allow participant to hold onto your arm to get balanced. **SAY: “Hold on to my arm while you get in position. When you are ready, let go.”**
- If the participant is having trouble attaining the position, allow for a second attempt. SAY: “Now, let’s do the same thing one more time. Hold onto my arm while you get into position. When you are ready, let go.”
- Start timing when the participant lets go.
- Watch the participant, not the stopwatch.
- Stop the stopwatch if the participant takes a step or grabs for support.
- Record to 0.01 second how long participant is able to hold this position.
- If the participant is unable to attain or hold the position for at least one second, mark “unable”
- Say, “STOP” after **30 seconds**.

Tester instructions: **If the participant is unable to hold for at least 30 seconds, record the time under Q15.2, and STOP.** DO NOT attempt the single leg stand (Q15.3). Leave that item blank. **Proceed to chair stands.**

Instructions for Single Leg Stand Q15.a.4:

PROMPT: READ to participant: “For the last position, I would like you to try to stand on one leg for 30 seconds. You may stand on whichever leg is more comfortable. I’ll demonstrate.”

Demonstration: Stand by lifting the opposite leg so that the toes are about 2 inches off the floor. The knee of the raised leg should be slightly flexed and foot forward. While demonstrating, say: “Try to hold your foot up until I say stop. If you lose your balance put your foot down.”

Test instructions:

- Allow participant to hold onto your arm to get balanced. **SAY: “Hold on to my arm while you get in position. When you are ready, let go.”**
- If the participant is unable to attain the position, allow for a second attempt. SAY “Now let’s do the same thing one more time.”
- Start timing when the participant lets go.
- Watch the participant, not the stopwatch.
- Stop the stopwatch if the participant takes a step or grabs for support.
- Record to 0.01 second how long participant is able to hold this position
- If the participant is unable to attain or hold the position for at least one second, mark “unable”
- Say, “STOP” after **30 seconds**.

Q15b. Chair Stands (new to V63) (Module 7)

Clarification: The important point with the chair stands is that, after the initial trial chair stand, the participant performs 10 chair stands. The clinician should do a split with the stopwatch when the person STANDS for the 5th time and then stop the watch when the person STANDS for the 10th time. The participants’ legs should be fully extended at each stand.

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Description: This is a test of lower extremity strength in which the participant stands up from a seated position ten times as quickly as possible. The time it takes to stand five times and ten times is recorded. Prior to the repeated chair stands, a single chair stand is performed.

Use the straight-backed chair without arms provided for the study, placed against a wall. Make sure the participant's feet are squarely on the floor and in front of them. Knees should be flexed slightly more than 90 degrees so that their heels are somewhat closer to the chair than the back of their knees.

The standard chair should be placed on a non-skid surface (e.g., low pile carpeting) with the back of the chair against a wall for stability. There should be adequate room in front and on the sides of the chair for the examiner and participant to move freely.

PROMPT: READ to participant: "This is a test of strength in your legs in which you stand up without using your arms."

Demonstrate and say: "Fold your arms across your chest, like this, and keep your feet on the ground. Stand when I say GO, keeping your arms in this position. OK?"

"Do you think it would be safe for you to try to stand up from a chair one time without using your arms?" If yes, begin the test. If no, record 15.b.1 as "Refused" and end chair testing. Go to Q16.

Q15b.1. Begin practice test (Single chair stand).

Ask participant to sit in the chair with his arms folded. **Say:** "Ready? Go!"

Note: If the participant's arms unfold, or he puts one or both hands down on the chair to push up, or lifts his feet, remind him to keep his arms folded snugly against his chest and feet on the ground and ask him to repeat the chair stand.

It is ok for the participant to move a little forward in the chair before standing, but knees and hips should be flexed to approximately 90 degrees before standing.

If participant cannot rise up without using arms say: "OK. Try to stand up using your arms to push off". Record Q15b.1 as "Attempted, unable to do 1". Go to Q16.

If participant successfully does a single chair stand without using arms, mark Q15.b.1 as "completed" and proceed to 15.b.2.

Q15.b.2. Repeated Chair Stand

PROMPT: READ to participant: "This time I want you to stand up ten times as quickly as you can, keeping your arms folded across your chest. When you stand up, come to a full standing position each time, and when you sit down, sit all the way down each time. I'll demonstrate two chair stands to show you how it is done."

Repeated Chair Stand Demonstration: Tester crosses arms over his or her chest and rises two times as quickly as possible, counting as s/he stands up each time.

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Ask participant: Do you think it would be safe for you to try to stand up from a chair 10 times without using your arms? If yes, begin the test. If no, record Q15.b.2 as “Refused” and end chair testing. Go to Q16.

Test Instructions:

- Start timing as soon as you say “Go.”
- **Count: "1, 2, 3, 4, 5, 6, 7, 8, 9, 10" as the participant STANDS UP each time.**
- After the participant **STANDS** for the fifth time, glance at the time and depress the split button on the stopwatch.
- Stop the watch when the person **STANDS** for the 10th time.
- **If the participant is unable to complete the chair stands correctly (e.g., is not coming to a full stand or lifts feet), stop the procedure, repeat the demonstration, wait 1 minute, and begin the procedure again.**
- If the participant stops before completing five stands, confirm that he cannot continue by asking:
Optional script: "Can you continue?" Record Q15b.2 as “Attempted, unable to do 5”
- If the participant stops before completing ten stands, confirm he cannot continue by asking:
Optional script: "Can you continue?" Record Q15b.2 as “Attempted, but unable to do 10”
- If he says yes, continue timing. Otherwise, stop the stopwatch **and record time for first 5 stands on page 4.**

If participant successfully completes the repeated chair stand, mark Q15.b.2 as “Completed” and Record time for the first 5 stands (in seconds) and the time for all 10 stands (in seconds) stands in the box labeled “time for all 10 stands” on page 4.

Q16 Alert and Oriented (new to V61) (Module 8):

This question asks the participant to name:

- The city
- Current month, and year

Instructions for finger taps:

Training videos are available on the MDMS website. All examiners performing the finger tapping tests should watch these. There are two tabs 1) “Training Example” and 2) Pitfalls and Corrections”. The first tab demonstrates the correct the procedure from beginning to end. The second tab shows different ways that the finger tapping can be performed incorrectly and how to correct the participant.

Say:

“For the next test, which hand do you normally use to write? (Wait for response) Ok, so we’re going to use your (name non-dominant hand: “left/right”) hand. I’d like you to take the thumb and index finger of your (name non-dominant hand: “left/right”) hand and start out as wide and relaxed as possible. I’d like you to tap both fingers together [demonstrate as you explain] like this when I say “go” as quickly as you can.”

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- Ask the participant to practice tapping his fingers by starting with his index finger and thumb spread as wide and relaxed as possible, and then bringing his index finger and thumb together and then extending them to the widest position. Ask him to repeat a few times.
- Say "Ready, GO" and start the timer for 5 seconds at the same time.
- Count the number of times the participant taps his fingers together until timer goes off then say "STOP"

NOTE: Make sure the participant does not over-extend his fingers. They should be wide but not as wide as they can possibly go. If the participant does over-extend his fingers, ask him to stop. Then, demonstrate together and repeat the test. Also, be sure both fingers are moving together, not just the index finger.

There is also an option to use an internet timer from the following website:
<http://www.online-stopwatch.com/countdown-timer/> (Click the 5 button, then hit set. Click start when ready to begin. Click clear to stop the ringing after the 5 seconds have elapsed.)

- Record the number of taps done in 5 seconds.

D. Lipodystrophy questionnaire (Page 5, Q1-Q2), (Module 9)

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.

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.

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- 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 has returned to his 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:

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- 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.

E. Lipodystrophy measurements completed by a clinician or trained examiner **(Page 6, 01-04)**

Materials:

- Lufkin Executive Thinline 2m W606PM steel tape
- Maybelline black Define-A-Line eyeliner: <http://www.maybelline.com/product-explorer> or Black Flair pen, medium point: http://www.staples.com/Paper-Mate-Flair-Felt-Tip-Pens-Medium-Point-Black-Dozen/product_228452?cm_mmc=GoogleBase--Shopping--Office_Supplies%3EPens--228452-843-01&cid=CSE:GoogleBase:Office_Supplies:Pens:228452:843-01

Instructions:

All circumferences are measured with the participant standing and relaxed. A Lufkin Executive Thinline 2m W606PM steel tape is used for all circumference measurements. The steel tape casing is to be held in left hand and the extended tape with 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. This can be easily done by cross overing the tape after you have extended it around the participant so that the leader is in the left hand and the casing in the right. Marking of the anatomic sites should be made using an erasable marker, i.e. either a Maybelline black Define-A-Line eyeliner or a Black Flair pen, medium point.

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When making the measurements, the tape is held snug against the body with minimal compression of the underlying skin.

Please refer to the circumference measurement videos for more details:

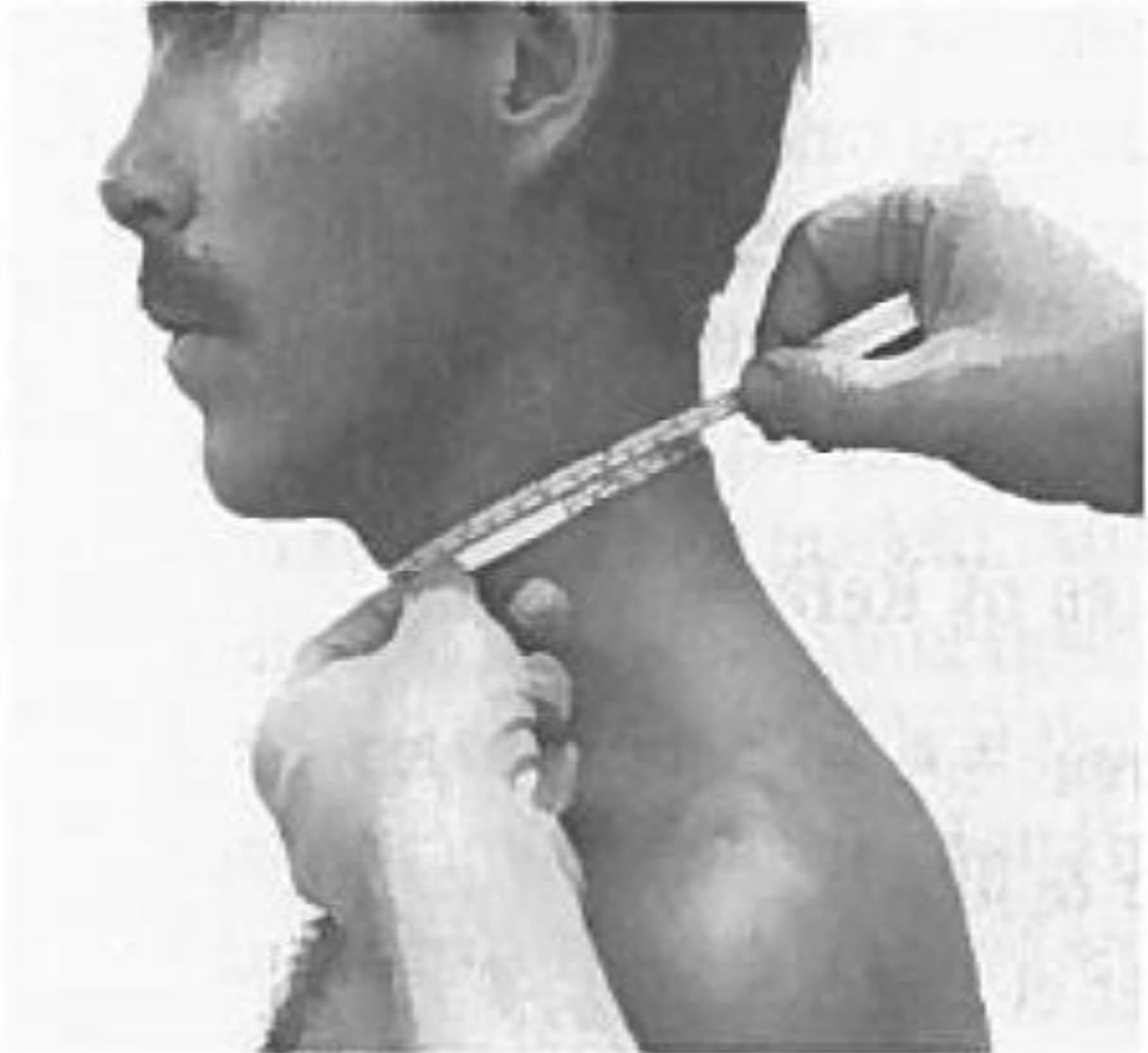
<http://statepiaps5.jhsph.edu/mdms/app/>

NECK CIRCUMFERENCE

Ask the participant to remove any clothing or neck chains that would obscure the neck. Ask him stand with his 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 in front of the participant, the examiner palpates the neck to identify the lower border of the laryngeal prominence (Adam's apple). Looking from the side may also be useful to visualize the prominence. Please note that laryngeal prominence varies greatly between men. In the case its curvature is not easily visible when looking from the right side (likely with short necks with skin folds) it may be useful to ask the participant to swallow several times to assist with finding the lower border. Standing in front of the participant, reconfirm the location of the lower border of the pharyngeal prominence by palpating the suprasternal notch and then moving your index finger or thumb up the neck. Using the finger or thumb as a horizontal guide, place a horizontal line on the lower border. Place the steel measuring tape around the neck with the cross-over making sure to cover the mark; the tape should not be horizontal to the floor but perpendicular to the long axis of the neck. The pressure of the tape on the skin should be minimal while maintaining complete contact with the neck surface. If case of tape slippage, you may tighten the tape with slight indentation, but once you have the tape positioned, you may release the tension with the tape still touching the skin. Of course, please ask the participant if the tape is too tight. This may be a challenge with a short neck with broad shoulders and necks with skins folds. If case of tape slippage, the examiner may tighten the tape with slight indentation, but once positioned correctly, the examiner may ease the tension of the tape without losing surface contact with the skin. Of course, please ask the participant if the tape is too tight. Take the measurement when the participant is not swallowing, it should be measured to the nearest 0.1 cm.

Please refer to the neck circumference measurement video for more details. Please access the video here: <http://statepiaps5.jhsph.edu/mdms/app/>

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Neck

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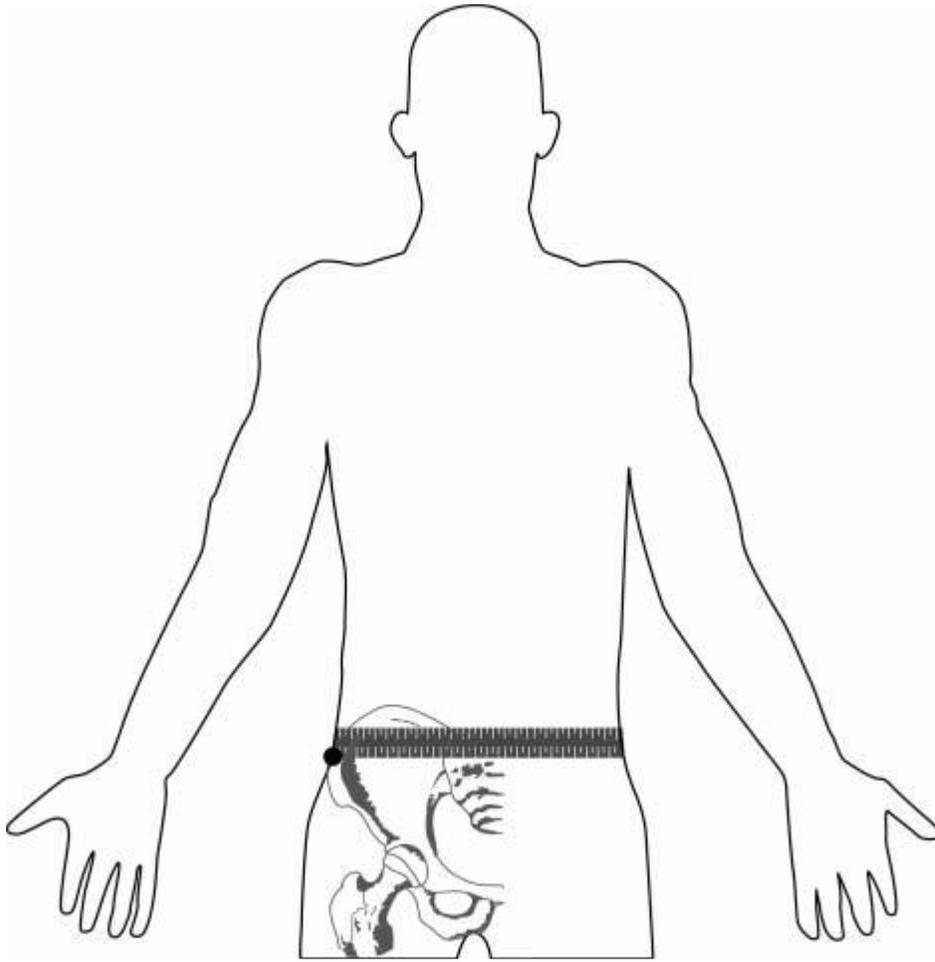
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WAIST CIRCUMFERENCE

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. Standing in front of the participant, locate and palpate the iliac crest by placing your hands on both sides of the pelvis. This will allow you to assess the height symmetry of the pelvis. In certain circumstances, e.g. the lateral flank of the abdomen is too large; it may be helpful to stand in the back of the participant to palpate the iliac crest. Standing in front of the participant, draw a horizontal line at the mid-axillary line of the trunk at the uppermost border of the right iliac crest using your finger as a marking guide. Note: In many cases the examiner will likely need to press into the skin to identify the border of the iliac crest. If so, please release the pressure of your finger so that your finger is sitting on the surface of the skin without indenting before you make the mark. Place the measuring tape in a horizontal plane around the torso to give yourself enough tape leeway at the level mark to perform the tape crossover. Again the zero end of the tape should be below the measurement value. The examiner should squat (or preferably use a rolling exam stool) to check the front, side and back of the trunk to ensure correct horizontal alignment of the measuring tape. This will ensure that the examiner is at eye level to the measuring tape, the tape is parallel to the floor and that the tape is snug without compressing the skin. If the body shape makes it difficult to keep the tape from falling off the mark, it is permissible to tighten the tape to secure it in place, but when the examiner is ready to take the measurement, loosening the tension. On some individuals, there will be gaps between the tape and the body, such as the concavity of the lower back. These gaps cannot be corrected by attempting to adjust the tape to conform to the surface of the skin. Also, if there are large abdominal folds in the measurement plane, the tape should be placed over the folds, for example, abdominal pannus. With normal breathing, record the measurement to the nearest 0.1 cm.

Please refer to the waist circumference measurement video for more details. Please access the video here: <http://statepiaps5.jhsph.edu/mdms/app/>

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Waist

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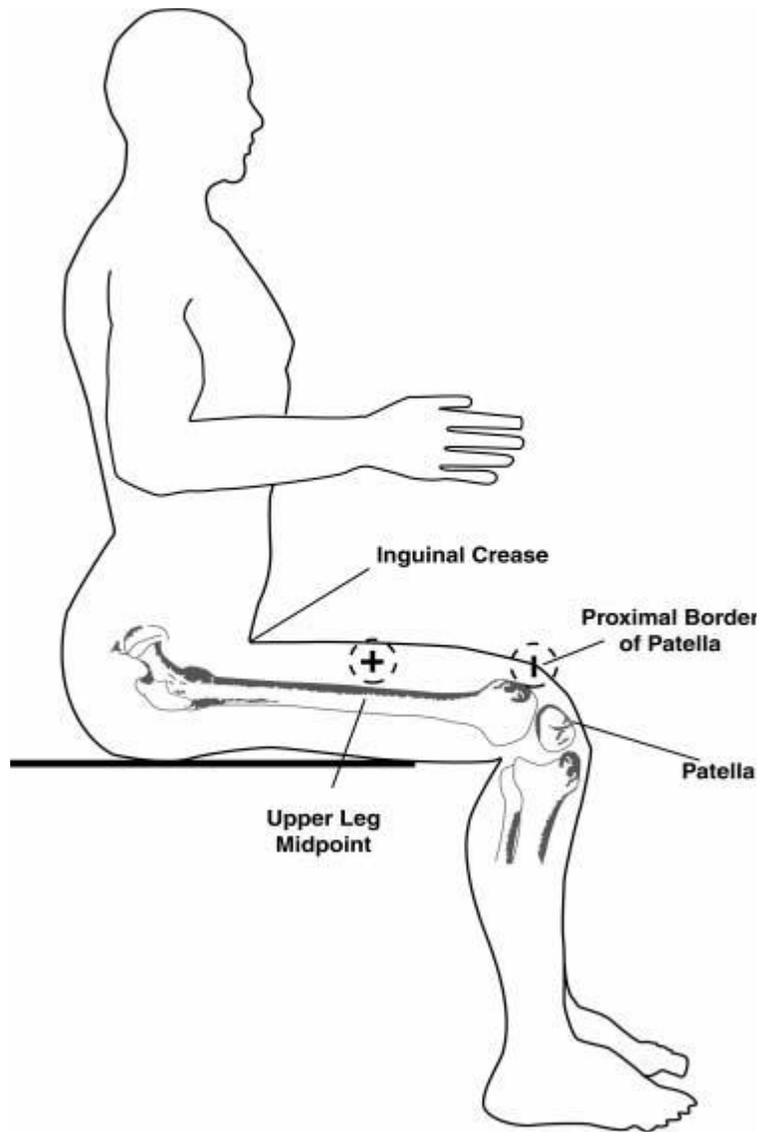
MID-THIGH CIRCUMFERENCE

Mid-point of the Right Thigh Circumference: The participant sits upright with his right knee bent at a 90 degree angle. Palpate the upper border of the patella. If the patella is prominent, palpate it with your hand clawed to identify the upper border. If using your clawed hand does not work adequately, ask the participant to extend his leg parallel to the floor. This maneuver will accentuate the patella such that it will be easier to palpate the upper border. Placing your finger on the border, ask the participant to lower his leg completely, marking a line at the surface of the upper border. The examiner may have to do this maneuver a couple of times if you are unsure that you have identified the border correctly. Subsequently, ask the participant to lower the waistband of his undergarment to the upper part of his thigh to identify the inguinal crease. If there are abdominal folds that obscure the inguinal area, please ask the participant to lift the folds upwardly and lean backward slightly or you can the participant to slightly lift his thigh such that a tightening of the muscle tendon will help the examiner visualize the inguinal crease. Place the zero end of the tape at the crease using your index finger. The examiner should apply slight pressure so that the zero end is securely in place. Ask the participant to lower his thigh and remind the participant to sit upright. Extend the tape tautly (particularly if the tape is riding over a lot of cloth from an undergarment) down the anterior midline of the thigh to the mark that was made at the upper border of the patella. Record the measurement to the nearest 0.1 cm. Divide the leg measurement to find the midpoint mark. Mark the midpoint with a horizontal line while keeping the tape in position; the examiner may ask the participant to hold the tape in place to avoid slippage of the tape.

Then ask the participant to stand up, take a step back with his left leg keeping his right leg forward with the knee slightly flexed and the soles of both feet flat on the floor. With his stepping back with his left leg, the weight should shift to that leg. The right leg should be relaxed (e.g. the leg muscles should not be tensed.) Stand on the participant's right side and place the measuring tape with cross-over 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. The tape should be snug without compressing the skin. Check to make sure the tape is positioned correctly (the tape is NOT parallel to the floor by looking at all sides of the thigh. Again this should be done with your squatting or sitting on a rotating stool so the examiner is eye level to the measuring tape, which is parallel to the floor.. To minimize slippage of the tape, the examiner can tighten the tape to secure it but release the tape tension so that you are not indenting the skin when you are ready to take the measurement. Record the mid-thigh circumference to the nearest 0.1 cm.

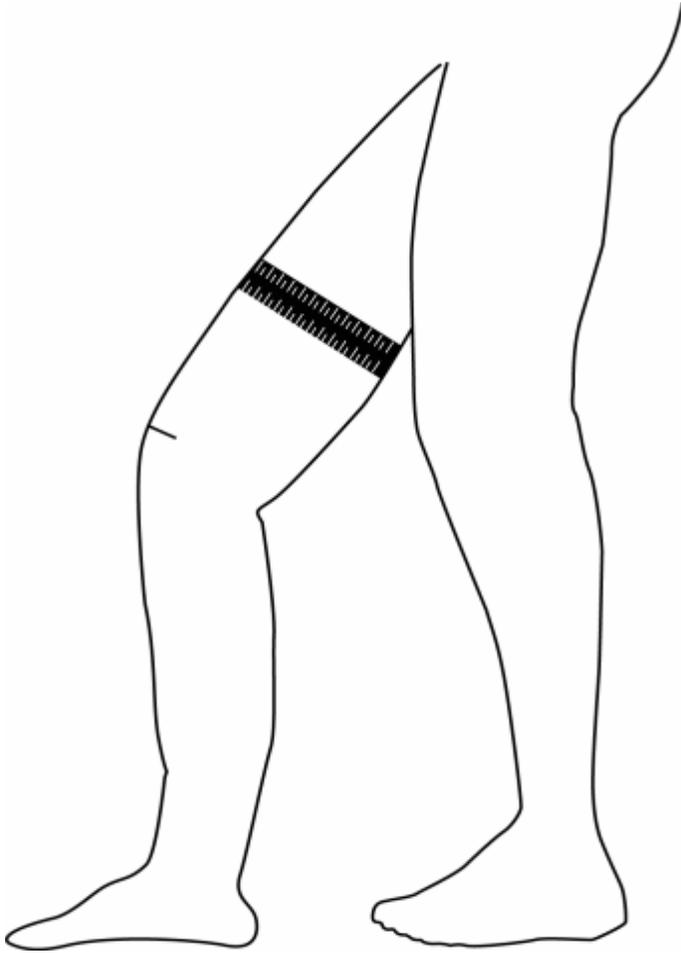
Please refer to the mid-thigh circumference measurement video for more details. Please access the video here: <http://statepiaps5.jhsph.edu/mdms/app/>

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Mid-thigh

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Mid-thigh

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HIP CIRCUMFERENCE

Wearing undergarments, the participant is standing with feet apart and weight evenly distributed on both feet. Ask the participant to cross his arms over his chest. The examiner should squat on the right side of the participant or sit on a rolling stool and place the measuring tape with cross-over around the maximal extension of the buttocks. Squatting will ensure that the examiner is at eye level to determine this anatomic location. As necessary, the examiner should unruffle any bunched up cloth of the undergarments. The examiner should place the tape with cross-over around the hips tightly if needed to avoid slippage of the tape and check the front, back and other side to ensure that the tape is parallel to the floor and the zero end of the tape is held below the measurement value. If there is an abdominal pannus that covers the measurement plane of the hip, please ask the participant **to pull up the folds** and then place the tape underneath the folds. The examiner takes the measurement from the right side and records the measurement to the nearest 0.1 cm.

Please refer to the hip circumference measurement video for more details. Please access the video here: <http://statepiaps5.jhsph.edu/mdms/app/>

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HIP

Appendix 1

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Appendix 1

V64 PE Standing Balance Assessment Training

In order to have standardized administration of the PE Standing Balance Assessments across MACS centers, all clinicians not trained to do the BOSS substudy will be trained remotely for the semi-tandem, tandem, and single leg stands.

Steps to follow for the person in training:

- Read the V64 PE Guidelines (pages 7 and 8).
- Watch the BOSS training video available on the MDMS website: <http://statepiaps5.jhsph.edu/mdms/app/index.html>. Contact Andrea Stronski (astronsk@jhsph.edu) to gain access to the website. The video is located under the BOSS tab> BOSS Training> Video> Standing balance and functional reach.
- Practice the stands with a co-worker or another person (i.e., at home) until you feel comfortable with the script and motions.
- Have a co-worker use a smart phone to record your performance of these assessments on another person. You may read the fall risk script from the PE guidelines. It's fine to either record each standing assessment as separate video clip files (i.e., a total of three files) or keep them together in one file. Include the clinician's first name and center number in the name of the file.
- Email or send the video file(s) to Todd Brown (tbrown27@jhmi.edu) via Drop box:

Instructions for Drop Box:

- Go to <http://www.dropbox.com> and create a free account
- Upload the files from your phone using the Dropbox app (see <https://www.dropbox.com/help/84/en>) or from your computer (see <https://www.dropbox.com/help/90/en>)
- Go to your list of files and folders and select the folder you want to share by clicking on the empty space to the right of the folder's name. (Clicking on the folder name or icon will open the folder instead).
- If the folder is currently unshared, click **Invite to folder** in the toolbar
- Enter the email address of the people you want to invite
- Add a personal message (i.e., MACS standing balance training) and click **Share folder**.
- For more information on sharing files, see the help section: <https://www.dropbox.com/help/19/en>