Home Visit SOF Visit 6 Overview and protocols

I. Overview

The purposes and order of the home visit are as follows:

- · Obtain informed consent
- Conduct the physical examination, performance tests, and vision exams
- Administer the cognitive function tests (Mini-mental and Trailmaker B)
- Review and complete the FFQ.
- · Review subject's current medications
- Review ocular history
- Review functional status questionnaire and fracture history
- · Review the self-administered questionnaire
- Ask one more time if participant would be willing to come in to the clinic just for follow-up BMD measures.
- Provide the subject with an environmental Home Safety checklist

<u>Instructions and Ouestionnaires</u>

The self-administered, FFQ, and clinic self-administered questionnaires should be sent to the participant at least one week prior to the home visit. Tell the participant to complete the questionnaires by the time of the visit. Consent should also be sent if possible according to your institutions regulations.

In addition, instructions for participants on how to prepare for the home visit are mailed one week prior to the visit. Instructions cover the following:

Footwear: To eliminate the effect of different footwear on test performance, these tests should be performed in tennis shoes or other shoes with minimal or no heels. The participant should not wear slippers. The participant may perform the tests in stocking feet if appropriate footwear is not available and floor surface is not slippery.

Clothing: Participants should wear comfortable, loose fitting slacks and tops. Skirts and dresses are discouraged.

Medications: Participants are asked to collect pill bottles and containers for all medications they have taken in the past 30 days for review by the examiner. If they no longer have the container, they should try to locate a copy of the prescription, or write down the name and/or reason for taking the medication.

Medical history: Participants should be told ahead of time that they will be asked about their ocular (visiual) history and breast cancer medical records, and thus, if appropriate, they might want to get this information handy. Ocular history can be collected over the phone by the OT (or equivalent) ahead of time if you prefer.

Questionnaire: Participants are asked to complete as much of the questionnaires as possible prior to the home visit. Participants should flag any questions that they did not understand or have questions on.

Informed consent: Participants are asked to review the informed consent prior to the visit. Any questions can be reviewed with the interviewer. This procedure may differ slightly clinic to clinic.

II. Hazardous conditions and health/social service needs.

If a potentially dangerous situation is encountered in a home visit, such as an uncontrollable dog, someone carrying a weapon, an abusive person, or threatening neighbors, leave the situation. If it appears to be a situation that is easily resolved, call the home from another location and discuss it with the participant. If the situation cannot be resolved, cancel the interview.

The home visit staff should be alert to health or life-threatening situations in the home that may need to be investigated by social service or health care personnel. Examples include: hunger/malnutrition, extremely unsafe dwellings (fire, electrical hazards), extreme isolation, unattended serious health problems, severe unattended cognitive impairment, threat of suicide or violence, or abuse.

Serious health or psychiatric problems should be referred to the study physician at your clinic who should contact the subject's physician.

Nonemergency issues regarding safety, competency, or other such problems should be discussed with the participant. If the participant is receptive to outside help, say that you will make some inquiries about available services in the area and get back in touch with the participant to discuss the next step.

Record any problems encountered during the home visit on the Home Visit Problem Report page of the interview form.

III. Questionnaires and interviews

The questionnaires for the home visit are the same as for the clinic visit. A home visit problem report form is included.

The interview should be performed with both the participant and the interviewer seated comfortably. Sit close enough to the participant to communicate effectively and maintain eye contact. Sit at the same level as the participant. Speak clearly and loud enough for the participant to hear without having to repeat what was said.

If others are present in the residence, try to conduct the interview in relative privacy. However, if a spouse wants to be present, particularly if they can be helpful with a subject that has hearing or cognitive problems, then the interviews may be conducted in their presence.

The home visit assessment covers the following topics, in the order listed below. The visit is designed so that if, for some reason, the visit is cut short, the items toward the end of the visit can be completed over the phone. If this situation arises, make sure to inform the participant that you will be calling her to finish up some of the items and decide on a mutually agreeable time.

- 1 Consent: Review consent forms with subject and obtain informed consent.
- 2 Examinations: 1 chair stand, 2 grip strength, 3 gait speed, 4 height/weight, 5 visual acuity, 6 pin-hole acuity, and 7-tonopen. Follow the same protocol as used in the clinic except where noted on the gait speed test and height measurement below. Vision protocol deviations for the home visit are under separate cover.
- 3 Cognitive function tests: Mini-mental exam and Trailmaker B. Follow the same protocol as for the clinic visit.
- 4 <u>Medications</u>: Review and complete the medication sections of the questionnaire, based on the subject's current medications. Follow same protocol as used in the clinic.
- 5 FFQ: Review and complete according to clinic visit protocol.
- 6 <u>Functional status</u>: Complete the functional status section of the clinic questionnaire using the same protocol as in the clinic.
- 7 Questionnaire review: Review self-administered questionnaire. Complete missing and incorrect items with the participant's help. If there is not time for review of the questionnaire during the home visit, then inform the participant that you would like to complete your review over the phone. Set up a mutually agreeable time for completion.
- 8 Home Safety Checklist (optional): Explain and give participant a Home Safety Checklist.
- IV. Examinations (all aspects of vision examination will be included under separate cover)

List of equipment: The following is the list of equipment needed to carry out the assessment of physical function in the home.

- measuring tape in metric units
- 20 ft carpenters tape for measuring the walking course or premade 3,4,5, and 6 meter walking course markers
- floor markers for gait test (starting and ending line, X for target)
- right angle for height

- portable scale
- stopwatch
- grip strength dynamometer
- armless, straight backed, hard seated chair (if none available in the home fitting this description, use the one provided by the CC)
- pencils at least 2
- post-its
- clipboard
- extra set of forms

Equipment calibration: The scale, grip dynamometer should be calibrated the morning of any scheduled home visit day. Follow calibration guidelines outlined in the Visit 6 protocol manual. If home visits occur on a daily basis, the dynamometer can be calibrated weekly, however, the scale should be calibrated daily. If equipment is unused for more than a day, then recheck calibrations. Calibrations on home visit equipment are especially important since the equipment is moved around so often. Keep a log of these calibration checks at the clinic.

The following home visit protocols for home visit examinations have been adapted from the SOF Visit 6 protocol.

Instructions to participants: To some participants, the detailed verbal instructions may seem pedantic or unnecessary. It may help to say that you are going to explain each test to the participant in detail since this is the best way to make sure that everyone does the test in a similar manner. The individual examiner must determine whether a participant understands what is required and provide the appropriate level of instruction.

Follow the scripts as closely as possible, to describe the tests and how to perform them properly. Do not provide additional encouragement beyond the language provided by the detailed instructions.

Functional status screening: Ask each participant "Do you have any problems from recent surgery, injury, or other health conditions that might prevent you from standing up from a chair or walking up steps?" If the answer is yes, record on the scoring form, and after you describe each test, discuss with the participant whether he/she should attempt the test given his/her physical problems.

Refused/unable: If a test is not attempted because the participant refuses, for whatever reason, record "refused" on the scoring form. If possible, record a reason for the refusal.

If a test is attempted but cannot be completed or scored (e.g. fear of falling or pain), record "unable" on the scoring form and give the reason (e.g. fear, pain, etc.). Use the last page of the exam questionnaire to describe why specific tests were not done.

Walking Aids: Walking aids may be used for the usual walk test. Walking aids should not be used for the tandem stance or chair stand tests. If aids are used for a test, this should be recorded on the scoring form.

Demonstrations: Demonstrate each test for the participant, as indicated in the detailed instructions.

Practice trial: Allow the participant a practice trial where indicated in the detailed instructions.

Rest: The participant should be allowed to rest between tasks if out of breath or fatigued during the assessments.

Safety Precautions: The detailed instructions describe how to safely administer the tests including instructions on how to support the participant if required.

- Obstructions that could cause an accident should be moved, removed, or avoided.
- For tests where loss of balance is a possibility, use the following safety precautions. Position yourself at the subject's side, slightly behind her. Your hands should be positioned on either side close to but not touching the subject's waist. If the subject loses balance, stabilize her by grasping the trunk. If the subject begins to fall, reach under her shoulders from behind and slowly ease her down to the floor.

If the subject is not injured, help her to arise by placing a chair next to the subject and having her get down on all fours. Have the subject support herself on the chair as you help lift under the shoulders. Do not try to lift the subject directly from the floor alone.

If the subject is injured, call a local emergency number (911).

Rounding convention: Round up at .5 of smallest unit recorded on exam form.

EXAMINATION PROTOCOLS

A. NEUROMUSCULAR PERFORMANCE: STAND UP FROM A CHAIR, GRIP STRENGTH, TANDEM STAND, GAIT TEST, HIP ABDUCTOR STRENGTH, AND RANGE OF MOTION

Footwear: The subject should wear comfortably fitting shoes for each of the tests in this section. Do not perform these tests with the subject wearing high heels (≥ 1 inch) or slippers. If no other options are available, perform the tests with the subject in stocking or bare feet.

I. TIMED CHAIR STAND

1. Description:

This tests the subject's ability to stand up from a standard chair without using arms for support and the time required to stand up from a chair five times, measured with a stopwatch.

2. Equipment:

A straight-backed, armless, hard seated chair (such as plastic molded chair) approximately 45 centimeters high at the front edge. The seat should incline no more than a few degrees from front to back. Whenever possible, use the chair that was used in previous visits.

Place the back of the chair against a wall to steady it. Stand next to the participant to provide assistance if she loses her balance.

Stopwatch.

3. Measurement Procedures:

a) Have the participant sit in the chair, assuming the position from which she would normally stand up from a chair (but no more than half-way forward on the seat of the chair) with the feet resting on the floor and the arms folded across the chest. Say:

"The next test measures the strength in your legs. Please fold your arms across your chest. When I say 'Ready? Stand!,' please stand up straight as rapidly as you can five times without stopping in between and without using your arms to push off. After standing up each time, sit down and then stand again without stopping. Now watch while I demonstrate the correct way and the incorrect way to stand." (Demonstrate both for the participant, exaggerating the incorrect way).

"When you stand up, you want to make sure that your knees are straight and your body is straight."

Then ask her to stand up one time for practice.

If a participant can not stand up one time unassisted (she may use her arms), then do not test the 5 rapid chair stands. Record her as unable.

- b) When the subject is properly seated after practicing say
- "Okay, now I'll be timing you with the stopwatch as you stand up 5 times. Please try to do this as fast as you can while still feeling safe. Ready! Stand."

Count out loud as she arises each time, up to 5. Stop the stopwatch when she has straightened up completely the fifth time.

c) If she is unable to arise without using her arms say:

"O.K., try to stand up using your arms to push off."

Be sure to record arm use on the form.

d) If the participant fatigues before completing 5 stand-ups, confirm that she can't do any more by asking:

"Can you continue?"

If she says yes, keep timing. If she says no, record that she could not complete five standups and do not record a time for her.

e) For ALL participants who completed all 5 stands, ask:

"Do you think that was as fast as you can do it while still feeling safe?"

If participant says no - then ask her to repeat the test emphasizing that she should stand as fast as she can while still feeling safe.

Record the time for the second trial.

- f) Record:
 - i) whether she can stand up five times without help,
 - ii) arm use (none, some stands, all stands),
 - iii) the time to complete five stands to the nearest tenth of a second.

4. OC Checklist - Chair stand

Participant keeps arms across chest
Participant sits no more than halfway forward on sear
Chair stable (set against wall)
Examiner demonstrates correct and incorrect way
Repeat if not as fast as participant is able

II. GRIP STRENGTH WITH DYNAMOMETER

1. Description:

Grip strength is a measure of hand muscle strength that also is a good representation of upper body muscle strength. It is one of the most widely used measures of strength because of its simplicity and ease of measurement.

2. Equipment:

Preston Grip Dynamometer, Jackson MI (Takei Kiki Kogyo; "Smedley" Lightweight Hand Dynamometer) or the dynamometer from baseline (TEC). The handle should be adjusted so that the individual holds the dynamometer comfortably.

The grip dynamometer should be calibrated weekly by hanging at least 2 different weights (5 lb, 10 lb, 15 lb, etc) from the handle and recording the measure. The weights can be attached using velcro or any other means that works. Record the weight used and the result in a log book. Deviations of more than ± 2 kg should be reported to the Coordinating Center and the company should be called for repair.

3. Measurement Procedure:

a) Grip strength will be measured in both arms unless the participant has had a recent flare-up of extreme arthritis or recent surgery - in this case the unaffected side is not tested (see below). If the participant has a history of stroke or injury causing weakness (this injury occurred in the past and is not the cause of acute pain presently), still measure BOTH sides. Even though one side may be weaker, it does not have acute pain and thus can be tested.

<u>Scoring</u>: The scoring categories are mutually exclusive, so either each hand is tested and has a value <u>or</u> it is suffereing from an acute flareup of pain and is thus "weakened" <u>or</u> the participant refused or is unable. There should not be a score and a box checked - this will result in logic errors.

• For each hand, determine if the subject has an <u>acute</u> flare-up of arthritis in the hand, or surgery in the hand or wrist in the past 3 months (12 weeks). If the subject has had an acute flare-up of arthritis or is less than 13 weeks post fusion, arthroplasty, tendon repair, synovectomy, etc. then do not test grip on the affected side (mark "weakened" on the form).

"Have you had a recent worsening of pain or arthritis in your hands, or have you had surgery on your hands in the past 3 months (12 weeks)?"

If yes, test grip strength in unaffected side only. Mark "weakened" on the form for the affected side only.

"This device measures your arm and upper body strength. I will demonstrate how it is done. Bend your elbow at a 90° angle, with your forearm parallel to the floor. Don't let your arm touch the side of your body. Lower the device slowly, taking about 3 seconds,

squeezing as hard as you can. Once your arm is fully extended, release your grip."

- b) Place the dynamometer in the right hand with the dial facing the palm. The arm should be flexed 90° at the elbow and the forearm parallel to the floor. As you demonstrate, instruct the individual to squeeze the hand maximally while simultaneously lowering the arm on a three second count. The grip should be released when the arm is completely extended, hanging straight at the side.
- c) Allow one submaximal practice trial using the right arm.

"Does that feel like a comfortable grip?"

Adjust the handgrip, if necessary.

"Now try it once just to get the feel of it. For this practice, just squeeze gently. Don't let your arm touch the side of your body. One, two, three."

d) Perform two trials on the right side.

"Good. Now this time it counts. We'll repeat this twice on the right side and then twice on the left side. Be sure to squeeze as hard as you can.

Ready? Ok. Squeeze as hard as you can! One, two, three (count out loud for the participant as she lowers her arm) "

Record the kilograms from the dial to the nearest 1 kg. Reset the dial. Perform the second trial.

e) Repeat the procedure for the left arm. No practice trial is needed for the left, but ask the subject if the grip is comfortable.

<u>Precautions</u>: The arm should not contact the body. The gripping action should be a slow sustained squeeze rather than an explosive jerk.

- f) On the scoring form, there should either be a value for strength attained OR one of the three boxes refused, unable, or weakened, should be checked (this will automatically put the correct special values for this participant in the field). The weakened box should only be checked if the participant has had recent arthritis or surgery on that side (and that side is not tested). (Weakened = 6's. Refused = 7's. Unable (unable to test) = 8's.)
- g) If the participant has trouble standing, this exam can be performed sitting or lying down. Make a note of these instances in the comments section of the exam form.

4. QC	Checklist	<u>- Grip</u>	strength
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	If stroke, test both sides
	Elbow kept near 90° (±15°)
	One practice given on right side
_	Comfortable grip checked
	Instructed to "Squeeze as hard as you can"
	Slow sustained (3 second) extension
	Arm does not touch side of body
	Both right and left sided completed twice
	Only one response entered on data form
	Calibration logs up to date

III. GAIT (WALKING SPEED, STEP LENGTH AT USUAL AND RAPID PACE)

1. Description:

Time required to walk a six meter course (seconds), average step length (centimeters), at usual (2 trials) and rapid (1 trial) pace.

2. Equipment:

Adequate space for the gait test. Identify an obstacle free pathway, as close to 6 meters if possible. If possible, use an area with bare floor or thin (low pile) carpeting. There should be about an extra meter of space on either end of the course for stopping. If space is limited, then the course can be designed to have the participant just walk in one direction, returning to the same starting point for each trial. Less space would be required at the starting line, with just the toes behind the starting line and then at least one meter on the other side of finish line.

Ideally, the walking course will cover just one type of surface (ie bare floor or low pile carpeting). However, if necessary, the course can be set up across two different surfaces to get an adequate length. The participant probably walks these areas in her home on a daily basis and thus they should not incur any undo hazard.

If possible, choose an area where the examiner can view the subject from the side about midway between the end markers, such as by standing in a doorway along a hallway. The examiner may need to walk next to very frail subjects or those with severe postural instability. In this case, choose an area with enough space for two people to walk side by side.

Premeasured 3, 4, 5, and 6 meter strings.

Flexible (plastic or cardboard) floor starting and ending line markers, about 1 meter long (marked with a red line at 1/2 meter) and 5 centimeters wide. Place the markers flat across both ends of the obstacle free pathway. Place an X on the other side of the finish line as a goal for the participant to walk to.

Stopwatch.

3. Subject Preparation:

The participant should be wearing slacks and comfortable walking shoes. She may use a walking aid, but should be encouraged to walk without one.

"Now I am going to observe how you normally walk. If you use a cane or other walking aid and would feel more comfortable with it, then you may use it. However, if possible, I would like you to walk without using any aids.

4. Measurement Procedures:

A. WALKING SPEED AND STEP LENGTH, USUAL PACE

a) Ask the subject to stand behind the line at one end of the course, at the red center mark.

"When I say 'begin', I would like you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store. Walk all the way to the X at the other end before you stop.

b) Ask the subject to begin the usual walk.

"Remember, walk at your <u>usual</u> pace all the way past the line at the other end before you stop. Ready? Begin."

Start the stopwatch at the word "Begin" and stop timing when one foot is all the way across the end line. Count the number of steps taken to cover the course. One step is counted when either foot is placed down on the floor, including the first step and the step which first takes a participant's foot completely across the end line.

c) When the participant crosses the end line, ask her to turn around and stand at the end line as before. Or if the same starting line is being used, ask the participant to proceed back to the starting line for a second trial.

"Now we will repeat the same thing (in the other direction). Walk at your usual pace and go all the way to the X at the other end. Ready? Begin."

d) Record time and steps for the two trials.

B. RAPID PACE

a) For the third trial, ask the participant to walk at a rapid but safe pace.

"This time I would like you to walk at a <u>rapid</u>, <u>but safe</u>, pace. Walk as fast as you can while still feeling safe".

b) Record the time and number of steps.

C. RECORD THE LENGTH OF THE WALKING COURSE ON THE EXAM FORM. Also record the type of surface that the course covered.

B. ANTHROPOMETRY: WEIGHT AND HEIGHT

I. WEIGHT IN KILOGRAMS

1. Equipment:

Weight is measured in pounds using a portable scale. Pounds should be converted to kilograms once back at the clinic.

The scale should be calibrated in the clinic prior to each home visit day against 2 50 lb weights, or a 50 kg or 2 25 kg weights.

2. Subject preparation:

Weight is measured without shoes and without outer clothing or heavy sweaters. All heavy objects, such as keys or changes, should be removed from participant's pockets.

3. Measurement Procedure:

a) The participant should stand in the center of the scale with weight equally distributed on both feet and not touching or supporting herself on anything.

"In order to measure your weight, I would like you to remove your shoes (and any heavy outer clothing) and step forward onto the center of the scale."

- b) Some participants may require support while being weighed. If it is necessary for the participant to use a cane for support while weighing, weigh yourself with and without the participant's cane, etc., to determine its weight. Subtract the weight of the aid from the participant's weight before recording. In the event that it is necessary for the examiner to support the participant during weighing, provide the minimum support that is safe.
- c) Weight is recorded to the nearest pound (half pound if scale allows it). Convert pounds to kilograms for data entry when back at the clinic.

II. STATURE (STANDING HEIGHT)

1. Equipment:

Height is measured in centimeters against a wall using a right angle on the top of the scalp and a measuring tape. Find a blank wall in a room with a bare floor or thin (low pile) carpeting) with adequate space on the side for the examiner to stand to make an accurate measure.

2. Subject preparation: Height is measured without shoes.

3. Measurement Procedure:

a) The participant stands with her back against the wall with the heels together and both heels touching the wall plate. The back (scapulae) and buttocks should be in contact with the wall.

"Please stand against the this wall. Your heels should be together (as close as possible) and both heels should be touching the wall (or molding). Look straight ahead. (If necessary say: I will position your head so that I can measure your height more accurately.)"

b) Be sure that in this position the participant maintains erect posture, i.e., no slouching. Heels should be together with the weight equally distributed and the head in the "Frankfort Horizontal Plane." The line through the lowest point on the inferior orbital margin (orbitale) and the upper margin of the external auditory meatus (tragion) should be horizontal. The right angle is brought down firmly onto the top of the head. It may be necessary, upon occasion, to remove or alter the hairdress of some of the participants. This is necessary for the right angle to make contact with the top of the scalp.

Occasionally, it will be impossible to position the participant's heels, buttocks, scapulae and the back of the head in one vertical plane against the wall and still have her stand naturally and comfortably. If the back is arched due to large buttocks, move the participant forward and have only one part (usually the buttocks) in contact with the wall. Similarly for participants with severe spinal curvature, if the spine is the part that protrudes the farthest, then that should be the part that is touching the wall.

c) Once in position, say:

"Take a deep breath."

Have the participant inhale deeply, again not altering position by, for example, raising the heels off the floor.

d) Stature is measured just <u>before</u> exhaling. Mark the position where the bottom of the right angle touches the wall with a small piece of tape or a post-it.

"Exhale."

- e) Ask participant to step away from the wall. Measure the distance from the floor at the base of the wall to the piece of tape. Record height to the nearest tenth of a centimeter.
- f) Repeat procedure obtaining second height measure.

C. COGNITIVE FUNCTION, MIF, AND FUNCTIONAL STATUS

Follow the same protocols as used for the clinic visit for these measures.

Home Visit Problem Report Form SOF Home Visit - Visit 6

Record any problems encountered during the home visit, such as dangerous situations, health or life threatening situations in the home, serious health or psychiatric problems and other nonemergency issues. Each clinic should determine follow-up for situations encountered in their area.					