CHAPTER 16
PHYSICAL MEASUREMENTS

Study Documents Referred to in this Chapter

- 400 m Walk
- Accelerometry
- SPPB
- Grip Strength
- Blood Pressure, Radial Pulse & Weight
- Waist Circumference
- Height
- Physical Exam
- Spirometry

CHAPTER 16

PHYSICAL MEASUREMENTS

16.1. 400 Meter walk (400 M Walk)

16.1.1. Overview

This is the primary outcome measure for the study. The 400 Meter Walk test (400 M Walk) is a measure of functional ability. Its potential as a predictor of morbidity and future disability makes it an important outcome measure for cross-sectional, longitudinal, and clinical intervention trials.

16.1.2. Schedule of Administration

The 400 M Walk is performed at screening visit 1 or 2 (only after the study physician, physician assistant, or nurse practitioner has determined that the participant is eligible to participate) and at all subsequent follow-up clinic visits (or assessments). The 400 m walk test will not be completed in the home unless a safe and acceptable course can be set up.

16.1.3. Required Equipment

The following equipment is required for the 400 M Walk:

- Redi-Measure distance measuring wheel or equivalent (tape measure). (Redington Counters Inc., Windsor CT)
- Stop Watch
- Small traffic cones
- 2 Standard chairs

16.1.4. Procedures

A CD-ROM that provides complete instructions for the baseline (i.e. SV1/SV2) administration of the 400 M Walk is available for training.

16.1.4.1. Overview of 400 M Walk

During all of the tests, the safety of participants is paramount. At field centers where the 400 m walk course is located more than 50 meters from the assessment area; all participants must be transported to the course by wheelchair. All procedures should be clearly demonstrated to the participants prior to performing any test and they should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, you may reread the standard instructions, but you should not reword them. To optimize the participant's understanding, go through the instructions slowly while making sure that the participant is paying attention.

You should be completely familiar with the test procedures and practice before attempting to administer the test to a participant. After watching the procedures on the training CD-ROM several times, you should practice administering the 400

M Walk with a partner who is trained or in training, or practice with a volunteer under the observation of a partner or someone experienced in administering the 400 M Walk. When practicing, the person who is acting as the participant should role-play different levels of physical limitation to give the new examiner experience with people who have difficulty with the test. Also, be sure to practice on some older volunteers, including fully completing the data collection form. After practicing several times, go back and watch the CD-ROM presentation again. To ensure reproducibility, it is imperative that all participants are given the same instructions and that quantitative measurements associated with the tests are made in a uniform manner. You should not develop your own way of giving instructions. Since they are fairly long, you may want to read them from the sheet during the test.

16.1.4.2. The 400 M Walk

In this test, the participant's ability to complete a 400 meter walking course is assessed. You will need a stopwatch and a marked walking course. If this test is being done in a new location, then a course must be laid out on the floor. A diagram for laying out the course is provided in Appendix 16.A. The walking course should be unobstructed and include at least an extra meter on each end. When training to perform this test, it is good practice to have two or more people doing the timing so that timing can be compared for accuracy.

If the participant brings a cane (or other assistive device) to the clinic, the walk is to be attempted without the cane (or other assistive device). However, if the participant brings a single straight cane to the clinic and does not feel safe doing the walk without this cane, he/she may use this to complete the test. This fact should be indicated on the form. Only a single straight cane may be used to complete the test; a walker or any other assistive device (e.g. quad cane, crutch, hemiwalker etc.) may not be used at any point during the 400 M Walk test. If a participant brings a walker or any walking aid other than a straight cane to the clinic and does not feel safe attempting the walk without this assistive device, the test should not be administered. This fact should also be indicated on the form. If possible, women wearing high heels should change into another pair of shoes before performing the 400 M Walk. The position of the examiner is critical for the walk. If you are too close, you will set the pace. If you are too far behind, you will not be in a good position if the participant falls. Unless otherwise indicated, the best position to maintain during the walk is to the side and slightly behind, outside of the participant's visual field.

The use of supplemental oxygen is permitted during the 400 m walk test, however the participant must be able to carry or push the oxygen device without assistance. Site staff should be sure to exercise safety precautions in these situations.

During the follow-up clinic visits, all participants who walk into the clinic without a walker or comparable device (e.g. quad cane, crutch, hemiwalker etc.) should be encouraged to attempt the 400 M Walk. The participant need not complete the

walk, but s/he should attempt it. This is an important distinction. Even if the participant takes only a few steps before stopping, this will allow us to confidently determine that s/he cannot complete the test. To enhance safety, some of the instructions/procedures for the 400 M Walk have been modified for the follow-up clinic visits (as described below).

16.1.4.3. The 400 M Walk Protocol

1. Accompany the participant to the starting line of the 400 meter walk with the script and stop watch. Describe the 400 meter walk:
   Script: "Now I would like to observe how you normally walk. You will be walking 10 complete laps around the course, which corresponds to about ¼ mile. **I would like you to walk at your usual pace and without overexerting yourself.** During this test, I will ask you to rate how hard you feel you are working. When I ask you to rate how hard you are working during the walk, I want you to think about the total feeling of exertion in your overall body, including your breathing and muscles. At the end of lap 4, while you continue walking, I will ask you how hard you are working. After you have completed all 10 laps, I will tell you to stop, ask you to rate the difficulty of your breathing, and then measure your heart rate. If you develop chest pain, significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments, but you may not lean against the wall or any other surface."
2. For the baseline and follow-up clinic visits, follow the relevant skip pattern for the use of a walking aid. For the follow-up clinic visits, also follow the relevant skip pattern when participant is hesitant or indicates that s/he cannot do the test. If the participant returns to the clinic in a wheelchair and is deemed unsafe to attempt the walk, go directly to Question 13 and provide an explanation.

   For baseline clinic visit

   If subject uses a cane or other assistive device: "I would like you to attempt this test without your cane (or other assistive device)." Only a single straight cane may be used to complete the test; a walker or any other assistive device may not be used.

   Participant should be prepared to begin the test and asked a final time:
   Script: "Do you feel it would be safe to try and walk up and down this hallway 10 times?"

   If the participant is uncertain ask: "Would you be willing to try it and see how you feel?"

   If No, and participant brought a cane to the clinic, ask, "Would you be willing to try the test if you could use your cane?" If No or if participant

brought a walking aid other than a single straight cane to the clinic, end the test and provide an explanation for Question 13.

For follow-up clinic visits

Determine if subject brought a cane, walker, or other walking aid to the clinic. If No, proceed to demonstration of test. If Yes, "I would like you to attempt this test without your cane (or other assistive device)." Only a single straight cane may be used to complete the test; a walker or any other assistive device may not be used.

If the participant is hesitant or indicates that s/he cannot do the test, ask: "Would you be willing to try the test and see how you feel?" If Yes, proceed to demonstration of test. If No and participant brought a cane to the clinic, ask, "Would you be willing to try the test if you could use your cane?" If No, respond "Remember, you don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try? If No or if participant brought a walking aid other than a single straight cane to the clinic, end the test and provide an explanation for Question 13.

3. Demonstrate the walk and ask participant if he/she has any questions. The assessor should check the participant's footwear at this point to make sure their shoes are tied/ secured.

For follow-up visits

For subjects who did not bring a cane or other walking aid to the clinic. If the participant is hesitant or indicates that s/he cannot do the test, state: "You don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try?" If No, end the test and provide an explanation for Question 13.

4. The subsequent scripts and procedures differ modestly for the baseline and follow-up clinic visits. The procedures below apply to all clinic visits with the following exceptions, which apply only to the follow-up clinic visits.

For follow-up visits

If the participant was hesitant to attempt the walk or is doing it without their cane, the assessor should position themselves beside the participant [to the right side] rather than behind the participant. In addition, a second assessor should time the test so that the first assessor can focus solely on the safety of the participant. The assessor should try not to set the pace of the walk.

5. When participant indicates that they feel ready to begin, the test may proceed:

   Script: "When I say 'GO", start walking at a comfortable pace you can maintain. Ready, Go."

6. Start the stop watch when the participant takes their first step. Because there is a risk that a participant may slip and fall, the evaluator should follow the participant at a reasonable distance during the test. The examiner should be close enough to the participant to be able to provide help should the participant falter during the test, but not so close as to dictate the pace of the test. The evaluator should be behind and to the side of the participant, just outside their peripheral vision. For every lap, offer standard encouragement, and call out the number of laps completed and number remaining. If participants appear short of breath (have difficulty talking while walking) or complain of dizziness, they should be asked if they feel able to continue to walk. If the participant feels that he or she is able to continue the test, it is important for the assessor to be in the correct position which is to the side and slightly behind, outside of the participant's visual field and to ask about his or her symptoms every two minutes for the rest of the walk. Participants may stop the walk at any time, but should not be allowed to lean against any wall or other surface (desk, counter etc.). Staff may stop the walk for evidence of inability to talk while walking, unstable gait, or any other staff concern about the immediate safety of the participant. All participants who exhibit the above symptoms should be escorted to a chair upon stopping the walk and should be guarded when first getting up again.

   Script: "You're doing a good job. You have completed __ laps and have __ to go."

7. When the participant completes 4 laps, their RPE should be recorded.
   Script: "Please tell me how hard you feel you are working right now. Is it "light", "somewhat hard", "hard", or "very hard"?"

8. If the participant reports "hard" or "very hard", the participant is reminded to walk their "usual pace without overexerting yourself…" (see script below).
   Script: "I would like to remind you to walk at your usual pace without overexerting yourself. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few seconds.

9. When the participants completes 400 meters (10 laps, first foot fall across the finish line), stop the stop watch.
   a. Record time
   b. Record sitting radial pulse for 30 seconds (see Section 16.8)

10. If the participant feels they need to stop and rest, they may stand in one place and rest. Participant should not lean on wall, table or elsewhere. If they do lean, they should be immediately instructed not to do so and the test can continue. If participant needs to lean on wall, table or other surface for a second time during the rest stop or needs to lean again on a subsequent rest stop, stop the test.

    After 30 seconds, ask them if they can continue walking. If they can, continue the walk and record the rest on the form. If they need to rest longer, have them continue to stand. After another 30 seconds, ask them if they can continue walking. If the participant appears to be in obvious distress (excessive sweating, unusually pale, labored breathing, unsteady/wavering gait, appears confused, or unresponsive to questions) or pain, you may recommend that he/she stand in place and rest for a moment. If they can, continue the walk and record the rest stop on the form. If they cannot continue after a 60 second rest or if they need to sit down, stop the test. There is no limit to the number of rest stops as long as they can complete the walk without sitting.

    During the walk, if the participant requests or needs their cane to complete the test, give them their cane and allow them to continue the test. Only a single straight cane may be used to complete the test; a walker or any other assistive device may not be used at any point during the test. Also, indicate that a cane was used on the form (Question 8a).

11. The test may be terminated after 15 minutes even if the participant has not walked all 400 meters. Participants who complete the walk in >15 minutes at screening visit 1 or 2 are to be excluded.

12. If the test is terminated prior to the participant completing 400 meters, the point at which they stopped should be marked by placing an object on the course. The direction in which the participant was going should also be noted. The participant should be accompanied to the nearest chair. After the participant is comfortably seated, their accomplished distance should be measured. Complete laps will be counted as 20 meters each and the remaining incomplete lap should be measured with the Redi-Measure. Record the total distance and time at termination of the test.

    Stopping Criteria for 400 Meter Walk: (1) if the participant reports chest pain, tightness or pressure in the chest, shortness of breath, feeling faint, lightheaded or dizzy, or report leg pain, stop the test. Record the reason for stopping; or (2) test duration over 15 minutes.

13. Ask the participant how they feel and note any symptoms related to walking.

If a participant requires medical attention as a result of the below symptoms during the 400 M walk or upon completion of the walk, an Adverse Event report is to be completed and entered into the web-based data entry system.

1. Chest pain, pressure and/or other "anginal symptoms".
2. Severe shortness of breath defined as greater than anticipated for the level of physical exertion during the 400 M walk.
3. Loss of consciousness or an acute or new-onset bout of "dizziness" and/or "lightheadedness" that does not resolve with termination of the test and/or quiet sitting.
4. Persistent severe lower extremity pain that does not resolve with termination of the test.

16.1.4.5. Data Collection

The data for the 400 M Walk test is recorded on the data collection form. Be sure to include the distance covered if a participant does not complete 400 M, the time it takes to complete or when the participant stops.

16.1.4.6. Quality Control

All staff performing the 400 M Walk on LIFE participants must be certified. Certification must be renewed annually.

Course Preparation

The test will be administered on a 20 meter course, with small traffic cones marking each end. There should be approximately 1 meter of clearance around each end of the course past the traffic cones. Ten laps will be performed for a total of 400 meters. The cones should be placed prior to the test and distance between them measured with the Redi-Measure. Two chairs should be placed, one just beyond the cone marking the start line and one just beyond the turn around. The course used for the test should be isolated as much as possible.

16.1.4.7. Alternative 400 M Walk Course

When a participant refuses to come into the clinic, a suitable walking course may be set up in an alternative location that is identical to the layout of the course in the clinic. This might be done in an apartment hallway, outdoors on a flat surface, or in another building such as a community center. If this is not possible an alternative course can be laid out in the home. Requirements for this course are:

1. For a back and forth course, cones should be at least 5 m apart, with no obstruction to walking.

2. A second option is to create a circular course. A circular course of a least 10 m can be used if the home layout allows it.

3. Instructions for the walk should be modified to fit the course. Verbal support should only be given at the same distance intervals as for the standard course.

The Alternate Course 400 m Walk Worksheet (Appendix B) can be used to help the assessor in tracking the number of laps completed and timing of the verbal encouragements and level of effort question.

16.2. Accelerometry

It is important for participants to wear an accelerometer during the 400 m walk test. This procedure will the record the amount of movements and number of steps that each person takes during the 400 m walk test. This information will help LIFE investigators make comparisons to the accelerometry information that is collected at home during free-living conditions. The accelerometer will be placed on the subjects at baseline, 6 mo, 12 mo and 24 mo. For the baseline visit, the 400 m walk test can be performed on either SV1 or SV2. If the 400 meter walk occurs on SV1, initialize monitor and place on the subject prior to the 400 meter walk according to instructions outlined in the LIFE accelerometry MOP Chapter 11. The subject will wear the monitor home with data that was collected from the 400 m walk stored in the memory of the accelerometer. If the 400 meter walk occurs on SV2, the subject will be wearing the monitor upon arrival to the clinic. Do not remove the monitor until after the 400 m walk test has been completed. Instructions on how to download stored information on the monitor is described in MOP Chapter 11.

16.3. Short Physical Performance Battery (SPPB)

16.3.1. Overview

The SPPB, originally developed for the Established Populations for the Epidemiologic Study of the Elderly (EPESE), is a brief performance battery based on timed short distance walk, repeated chair stands, and a set of balance tests. The SPPB can be used to assess how well older persons perform simple movements that represent the building blocks of daily activities that require good lower extremity function. The information concerning functional ability provided by these tests adds valuable insight to the assessment of the older person. The test takes about 10-15 minutes to administer and can be done in the clinic or the home setting. The battery has an excellent safety record. It has been administered to well over 10,000 persons in various studies and no serious injuries are known to have occurred.

16.3.2. Schedule of Administration

The SPPB is performed at screening visit 1 (or prescreening session) and 6, 12, 24, 36 months, and at the close-out visit, if applicable. The SPPB will also be performed at the 18, 30, and 42 month visits if the 400 m walk test is not attempted.

16.3.3. Required Equipment

The following equipment is required for the SPPB: stopwatch, masking tape, chain with fine links measuring just over 4 meters (approximately) in length (for home or off-site administration), script, score sheet, and a straight-backed chair with a hard seat. If this type of chair is not available, a chair with a softer seat or a chair with arms may be substituted. Do not use a folding chair, a soft chair, a deep chair, or a chair on wheels.

16.3.4. Procedures

A CD-ROM that provides complete instructions for the administration of the SPPB is available for training.

16.3.4.1. Overview of SPPB

During all of the tests, safety of the participants is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participants prior to performing any test and they should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, you may reread the standard instructions, but you should not reword them. Remember that you will be demonstrating each maneuver and that someone who may not completely understand the verbal instructions may still be able to perform the test following the demonstration. These tests have been successfully used in persons with cognitive impairment. To optimize the participant's understanding, go through the instructions slowly while making sure that the participant is paying attention.

You should be completely familiar with all of the test procedures and practice them before attempting to administer the test battery to a participant. After watching the procedures on the training CD-ROM several times, you should practice administering the battery with a partner who is in training or trained, or practice with a volunteer under the observation of a partner or someone experienced in administering the battery. When practicing, the person who is acting as the participant should role-play different levels of physical limitation to give the new examiner experience with people who have difficulty with the tests. Also, be sure to practice on some older volunteers, including fully filling out the

score sheets. After practicing several times, go back and watch the CD-ROM again. To ensure reproducibility, it is imperative that all participants are given the same instructions and that quantitative measurements associated with the tests are made in a uniform manner. You should not develop your own way of giving instructions. The instructions can be memorized or read but since some of them are fairly long, you may want to read them from the sheet during the test. There are certain parts of the assessment where it is awkward to try to read the instructions and simultaneously demonstrate or administer the test. These portions of the instructions must be memorized.

The SPPB consists of three types of physical maneuvers: the balance tests, the gait speed test, and the chair stand test. The tests are always performed in this order. Each of these three maneuvers is scored separately by the examiner. While the actual performance times can be used to evaluate specific functional abilities, it has also proven useful to classify performance into categories and provide a numerical score. The scores from each of the tests can then be added together to obtain an aggregate or summary score for each participant. Inability to perform any individual component of the battery results in a score of 0, while completion of the maneuver results in a score of 1 to 4. The maximum aggregate score is therefore 12.

If a specific maneuver is not attempted, you should explain why no attempt was made. Select one of the options on the score sheet. It is critical but sometimes very difficult to distinguish between someone who is unable and therefore unwilling to try a test and a person who simply refuses to do the test because they are not interested in participating. This is a judgment that rests with the examiner. If someone refuses to participate in any of these tests, you would generally mark that they had refused on the answer sheet unless it is quite clear that they are refusing because they just can't do the test or are afraid to attempt it. Refusals are considered missing data and this person will not contribute to the research or clinical evaluation being performed. A participant who is unable to perform the test is scored zero for the particular test. Knowing someone is unable to perform the test is valuable information.

16.3.4.2. Balance Tests

16.3.4.2.1. Overview

The tests of balance provide an assessment of the participant's ability to hold three basic standing positions with the eyes open. No equipment other than a stopwatch, script, and score sheet is needed.

The three positions are side-by-side stand, semi-tandem stand, and full tandem stand (or heel-to-toe) and are performed in this order. Participants taking this test must be able to stand unassisted without using a cane or a walker. Don't assume that a participant who arrives for testing using a cane or walker can't stand unassisted. Ask them if they can stand without the device and are willing to try the test. If they say yes, you can assist them to assume the correct position for testing. Each test is timed and the participant is allowed only one chance to maintain each position.

For each position, the examiner first describes and then demonstrates the appropriate stand. The participant then assumes the correct foot position while supported by the examiner. Once the participant appears to be steady, ask if he or she is ready. When they say yes, the examiner relinquishes support, says "Ready, begin," and starts timing. The timing is continued until the participant moves his or her feet, grasps the examiner for support, or 10 seconds have elapsed. Record any time less than 10 seconds to the nearest hundredth of a second.

16.3.4.2.2. Side-by-Side Stand

The first position tested is the side-by-side stand. In this balance test, participants are requested to stand for 10 seconds with their feet together in a side-by-side position. Participants who are unable to hold the side-by-side stand for less than 10 seconds do not proceed further with the balance tests and are given a score of 0 for this portion of the battery. Participants who successfully complete the side-by-side test receive 1 point and proceed to the semi-tandem balance test.

You may stabilize the participant by lightly holding their arm until their feet are in the correct position. Many people will need little support to help them into position but others will need strong support until they are in position and steady. Wait until they feel steady before moving on to the next step. If you cannot steady them with support, then do not try the maneuver. Code it as "not attempted" and then circle "Not attempted, you felt unsafe." This applies to all three balance tests.

Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. During this and all other balance tests, the examiner should stand next to the participant as they gets into position and then step back a half step as they perform the test. It is important not to crowd the participant so much that they have trouble using their arms to keep their balance. On the other hand, you must be close enough to grab their arm or let them grab your arm if they lose their balance. Based on prior experience, most participants simply step out of position if they lose balance.

It's not important to stop the clock and the test at exactly 10 seconds. The time does not have to be measured exactly if the participant holds the position for more than 10 seconds. Don't watch the stopwatch continuously during the test. Watch the participant and be prepared to stop the watch if the participant steps out of position or grabs your arm. Glance at the watch occasionally to see if the position has been held for 10 seconds.

16.3.4.2.3. Semi-Tandem Stand

In the semi-tandem balance test, each participant starts with the heel of one foot placed to the side of the big toe of the other foot. Either foot can be placed in the forward position. Participants who successfully hold the semi-tandem position for 10 seconds are given 1 additional point and proceed to the final balance test. Those who fail to hold the position for 10 seconds receive no points and do not perform the tandem balance test.

Stabilize the participant by lightly holding their arm until their feet are in the correct position. Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. Stay close to the participant so they can grab your arm if they lose their balance but not so close that they can't use their arms for balance.

16.3.4.2.4. Tandem Stand

The final position evaluated in the balance tests is the tandem position. To assume the tandem position, the heel of one foot is placed directly in front of the toes of the other foot. Either foot can be placed in the forward position. Participants who hold this position for 10 seconds are awarded 2 additional points. Those who hold the position for 3 to 9.99 seconds are given 1 additional point. Holding the position for less than 3 seconds results in no points.

Stabilize the participant by lightly holding their arm until their feet are in the correct position. Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. Stay close to the participant so they can grab your arm if they lose their balance but not so close that they can't use their arms for balance.

16.3.4.3. Gait Speed Test

In this test, the participant's ability to walk 4 meters is assessed. You will need a stopwatch and a marked walking course. If this test is being done in a new location, then a course must be laid out on the floor. Detailed instructions for laying out the course are provided in Appendix 16.B.

The walking course should be unobstructed and include at least an extra one-half meter on each end. Participants are instructed to walk at their usual speed, and timing is stopped when the first foot completely crosses the 4-meter mark. The faster of two timed walks is used for scoring purposes. When training to perform this test, it is good practice to have two or more people doing the timing so that timing can be compared for precision.

At the screening visit, those participants who must use a walker are excluded. A cane or walker may be used during the walk, but if people with such devices can walk short distances without them, they should be encouraged to do so. Many people with assistive devices use them only when they walk outdoors or for long distances indoors. Doing the test without the device provides a much more accurate assessment of the functional limitations of the participant. Ask the participant if she ever walks at home without the device. Then ask the participant if they think that they can walk a short distance for the test. Participants who normally use assistive devices should be watched particularly closely during the test to prevent falling.

If possible, women wearing high heels should change into another pair of shoes before performing the gait speed test. Timing begins when the foot starts to move across the starting line. Wait until the participant actually begins to move before starting the watch. Do not start the watch when you say "begin."

The position of the examiner is critical for the walk. If you are too close you will set the pace. If you are too far behind you will not be in a good position if the participant falls. You also need to be in a good position to observe the foot crossing the finish line. The best position to maintain during the walk is to the side and slightly behind, outside of the participant's visual field. Record the time when the participant's first foot crosses the 4-meter line. If the foot lands on the line but doesn't cross it, this is not the end of the test. You need to anticipate when a foot will fully cross the line and be ready to stop the watch as it crosses the line. You should imagine a plane of glass at the finish line that the foot breaks when it crosses. This is the time to stop the watch. Record the time to the nearest hundredth of a second.

If you have trouble with the stopwatch or you think that the timing wasn't accurate, the gait speed test should be repeated.

Scoring of the gait speed test is based on established categories of completion times that were previously shown to divide the older population into four equal groups. Participants who require more than 8.70 seconds to complete the walk receive 1 point; participants whose completion times fall in the range of 6.21-8.70 seconds receive 2 points; participants who finish in 4.82-6.20 seconds receive 3 points. Participants who finish the walk in less than 4.82 seconds receive the full 4 points. Inability to complete the walk in less than 60 seconds results in a score of 0. If the walk was not attempted or not completed, you should select a reason from the options on the score sheet.

Although 4 meters is the preferred walk distance, an alternate walk distance of 3 meters can be used in those areas (for example, some home settings) where an unobstructed course of 4 meters is not available. Quartiles of completion times and associated scores for the 3-meter course are shown on the score sheet**.**

16.3.4.4. Chair Stand Test

The final portion of the SPPB is the chair stand test. In this test, participants are first instructed to fold their arms across their chest and to try to stand up one time from an armless chair placed against a wall. To perform this test you will need a stopwatch, the script, a score sheet, and a straight-backed chair with a hard seat. If this type of chair is not available, a chair with a softer seat or a chair with arms may be substituted.

If the participant is successful rising from the chair once, they are then asked to stand up and sit down 5 times as quickly as possible. Timing begins as soon as the command to stand is given and continues until the participant straightens at the end of the fifth stand. When learning to do this, it is useful for two or more people to time the test so that the times can be compared for precision.

For efficiency, it is valuable to have two chairs available so that the examiner can do the demonstration while the participant sits in the other chair and watches. If only one chair is available then the participant will have to get up to watch the demonstrations.

To ensure safety, the examiner should stand in front of the participant and be prepared to catch them if they fall forward. However, do not stand so close that the participant feels hemmed in and slows their pace during the chair stands.

For the first portion of the test, simply record whether the participant was able to rise from the chair without the use of their arms. If the participant is unsuccessful, the examiner should ask the participant to try to stand using their arms. Inability to complete the single chair stand with arms folded or being able

to do it only with use of the arms ends the chair stand test and results in a score of zero for this portion of the battery.

For the second portion of the test (multiple chair stands), instruct the participant to stand up straight as quickly as they can five times without stopping in between. After standing up each time, the participant must sit down and then stand up again, keeping their arms folded across their chest. Emphasize the word "quickly" and perform the demonstration quickly to further reinforce this point. The gait speed test is done at normal speed but the chair stand test should be done as quickly as possible. Count the stand number only after the participant has straightened up. Do not pace the test with your counting. If the participant does not stand up completely, stop the test and redemonstrate.

Timing begins when the command to stand is given and continues until the participant straightens their body at the end of the fifth rise. This contrasts with the gait speed test where timing begins only when the participant begins to move. During the test, count out loud as the participant rises up to five times. Do not coach or encourage the participant during the test. Watch the participant closely and stop the test if the participant is tired or short of breath during the repeated chair stands. The test should be stopped if the participant has to use their arms to rise at any time or if the participant has not completed the five chair rises after one minute. You should also stop the test at your discretion if, for any reason, you are concerned about the participant's safety. If the participant stops before completing the five rises, you should ask them if they can continue. If the participant says yes, continue timing. If the participant says no, stop the test.

Scoring of the chair stand test is based on established categories of completion times of five repetitions that have been shown to divide the older population into four equal groups. Participants who require more than 16.70 but less than 60 seconds receive 1 point. Participants whose completion times fall in the range 13.70-16.69 seconds receive 2 points, while those in the range 11.20-13.69 seconds receive 3 points. Participants who finish the 5 repetitions in less than 11.20 seconds receive the full 4 points.

16.3.4.5. Summary of Scoring

The composite score for the SPPB is simply the sum of the scores of the three individual components. The maximum score that a participant can receive is 12 points. A schematic summary of the scoring for each of the three individual components is provided in Appendix 16.C.

16.3.4.6. Quality Control

All staff performing the SPPB on LIFE participants must be certified. Certification must be renewed annually.

16.4. MEASUREMENT OF GRIP STRENGTH

16.4.1. Overview

Hand grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty with predictive validity for both mortality and functional limitation. Other than possible temporary discomfort during the test itself, there are no known risks for the participant.

16.4.2. Schedule of Administration

Hand grip strength is performed at screening visit 2 and at the 12 month annual follow-up clinic visits.

16.4.3. Required Equipment & Personnel

The Jamar Handheld Dynamometer is used to measure grip strength.

16.4.4. Exclusion Criteria

If the participant reports current flare-up of pain in the wrist or hand, or has undergone fusion, arthroplasty, tendon repair, synovectomy, or other related surgery of the hand or wrist in the past 3 months, the affected side should not be tested.

16.4.5. Procedures

This test should be done with the participant in a seated position. Determine whether the participant is right- or left-handed. The test should be completed in the dominant hand unless an exclusion criterion in 16.4.4 is met.

Set the dynamometer handgrip at **position two.** Adjust it for a smaller or larger hand when necessary. Check that arrow is set at ZERO.

The dynamometer is fairly heavy, so caution the participant when handing out the instrument. Allow one practice try to familiarize participant with the feel of the instrument. Ensure that the bars are the proper distance apart for a comfortable grip. The participant's arm should be resting on the table with the elbow bent.

There is slight variability in the arm position between LIFE field centers. Sites should continue to instruct the participant to either (1) rest only the elbow on the table with the dynamometer raised in the air or (2) rest the entire forearm and

dynamometer on the table. (Northwestern University and Yale University should continue with method #1 and all other field centers should continue with method #2.)

Complete two measurements. Record each value to the nearest 2 kilograms, e.g. 40 (kg). If < 10 kg, right justify and zero fill, e.g. 8 (kg) = 08. After each reading, reset the arrow to ZERO.

For each measurement, instruct the participant to squeeze as hard as they can. Allow 10 seconds between each measurement. Discontinue a measurement with anyone complaining of pain, then code 'unable' noting reason why unable.

16.4.6. Quality Control

All staff performing the grip strength measurements on LIFE participants must be certified. Certification must be renewed annually. The dynamometer should be calibrated monthly. If the device is dropped or mishandled, the calibration should be checked. This is done by slowly lifting 20 kilograms strapped to the handle. The dial reading should be within 2 kilograms of the referenced weight.

16.5. Intentionally Blank

16.6. MEASUREMENT OF HEIGHT, WEIGHT AND WAIST CIRCUMFERENCE

16.6.1. Overview of Body Size Measurements

Although weight can be measured with accuracy and precision using relatively simple equipment, the preparation of the participant, standardization of procedure, and maintenance of equipment are critical in order to obtain reliable data.

Body weight relative to height, expressed as Quetlet's index, or body mass index (BMI, kg/m^2), is highly correlated with more direct measures of body fat.

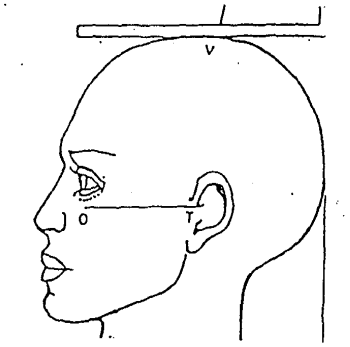
All measurements are to be made with the participants wearing light clothing, e.g., a short sleeve shirt or blouse (or surgical gown), shorts, socks and without shoes (for weight and height). A supply of shirts and shorts (or gowns) should be maintained at the clinic for participants who forget to wear or bring the appropriate clothes for body size measurements. Assessors should instruct participants to empty their pockets before the assessments begin.

Body weight will be measured at baseline, the 6-, 18-, and 30-month follow up

clinic visit. Body height will be measured at baseline only. Waist circumference will be measured at baseline and the 24 month follow up clinic visits.

16.6.2. Body Height

A wall-mounted stadiometer graduated in centimeters with a horizontal measuring block (or fixed angle) is to be used. If the stadiometer is not wall-mounted, you will need a level to ensure that the horizontal measuring block is



ORBITALE:	Lower margin of eye socket
TRAGION:	Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE:	Orbitale tragion line horizontal

level.

The participant stands erect on the platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch -the notch just above the anterior cartilaginous projections of the external ear). The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The participant's height is recorded to the nearest 0.1 cm. The participant should be instructed to stand as straight as possible with feet flat on the floor, with shoes off.

16.6.2.1. Deviations and exceptions to standard positioning:

Obese participants and those with a kyphotic posture may not be able to place the heels, buttocks, and scapulae in a single vertical plane while maintaining a reasonable natural stance. These participants may be positioned so that only the buttocks, and possibly the scapula, are in contact with the wall-plate. The essential point is that the participant stands erect with the buttocks in contact with the wall plate and the legs as close together as possible. In very obese participants, if it is not possible to obtain contact between the headboard and the

top of the skull, then the participant may need to lean back slightly (without tilting the head) until proper contact can be made.

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 plate, together with heels and buttocks.

For participants with extreme kyphotic posture, it may not be possible to obtain contact between the headboard and scalp when the participant's back is against the wall-plate. In this case, measure height with the participant standing sideways (side of arm and shoulder in contact with the wall-plate) and positioned so that the headboard contacts the scalp. The head should be in the Frankfurt Horizontal Plane. Record that the participant was measured in the sideways position on the scoring form so that follow-up measurements will be made in the same position.

If the participant has 'knock-knees' then have them separate the heels so that the knees are in contact but do not overlap. Obese participants may also not be able to stand comfortably with the heels touching and may stand with the legs together and the heels separated.

16.6.2.2. Quality Control

All staff who measure body height must be certified. Certification must be renewed annually.

16.6.3. Body Weight

16.6.3.1. Overview

Weight is measured in kilograms using a standard certified scale.

16.6.3.2. Required Equipment

Standard certified scale.

Maintenance

If a balance beam scale is used:

- Rest the counterweight (larger weight) in the far right position.
- The top weight should rest in the left or zero position.
- The counterweight should always be lifted carefully before it is moved across the beam. This prevents wear on the notches which could lead to erroneous readings.
- Keep the scale on a level surface and move it as little as possible.

16.6.3.3. Calibration Procedure

Calibration checks should be carried out on equipment in its normal location. A class F certified 20 kg calibration weight will be used for checking scale calibration. The calibration weights should be stored and used according to manufacturer's instructions (which should be saved and filed along with accompanying certificates).

The calibration weights should be stored on the floor against the wall near the scale, NOT on an elevated surface. This will keep carrying the weights to a minimum. Staff should review the recommended procedures for lifting heavy objects (bend at the knees, keep back straight, etc.) Sites might assign a staff member who is more physically capable to do the calibration on a regular basis. Finally, the 20 kg weight could be replaced with two calibrated 10 kg weights. A good procedure for placing the calibration weight is to put the weight in the center of the scale platform leaving some room at the edges for the feet.

The following procedure checks the repeatability of readings and the linearity of the scale in a portion of the working range.

1. Place the 20 kg weight (gently) on the scale platform. Record the weight indicated on the scale.
2. Remove the weight from the scale platform and allow the display to return to zero.
3. Step (or have an assistant step) on the scale. Record the weight indicated on the scale.
4. Step off the scale. Allow the display to return to zero.
5. Have the assistant step on the scale platform while holding the 20 kg weight. Record the scale reading.
6. Step off the scale. Allow the display to return to zero.

Repeat the six steps above at least once, then compare the values obtained.

If the repeated weighing of the calibration weight, or the assistant's weight, or the weight of the assistant plus the calibration weight do not yield the same values each time, or, if the weight of the assistant plus the calibration weight is more than 0.1 kg different from the sum of the two weighed individually then the scale is probably faulty. .

Results of the above tests should be recorded in the calibration log, signed and dated by the person performing the calibration, and the form will be retained as part of the study documentation. If the tests indicate that the equipment is out of tolerance or faulty, the nature of the deviation and the action taken should be noted as a comment on the calibration form.

Safety Issues and Exclusions

The measurement of weight using a standard certified scale poses no safety concerns or reasons for exclusion.

Subject and Exam Room Preparation

Study participants are encouraged to empty their bladders and/or bowels prior to the measurement.

Weight is measured without shoes or heavy jewelry and wearing the standard clinic gown; pockets of gown must be emptied of keys and other heavy objects.

If a balance beam scale is used, the scale should be positioned so that the examiner can stand behind the beam facing the subject, and can move the beam weights without reaching around the subject.

Detailed Measurement Procedures
If a balance beam scale is used:

- Before the participant steps onto the scale, lift the counterweight and position it at zero. The participant should stand quietly in the center of the platform, facing the balance beam, with their weight equally distributed on both feet, and not touching or supporting themselves on anything.

- If a participant requires support from a cane while being weighed, 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.
- Adjust the counterweight, and then the top weight, until the beam is evenly balanced.
- Weight is recorded to the nearest 0.1 kg.

A chart for converting kilograms to pounds should be mounted near the scale, so that participants can be told their weight in pounds. Script: "In order to measure your weight, please remove your shoes and heavy jewelry, and empty your pockets. Please step forward onto the center of the scale."

16.6.3.4. Quality Control

All staff who measure body weight must be certified. Certification must be renewed annually.

16.6.4. WAIST CIRCUMFERENCE

Waist circumference will be measured at SV1 and at the 24 month follow up clinic visits. The Gulick II Tape Measure (model 67020) will be used as it accurately and reliably measures waist girth. The design of the tape measure eliminates the guesswork by applying a known amount of tension (four ounces) to the measuring tape. When used properly, tape tension is always four ounces. Therefore, accurate measurements are possible no matter who is doing the measuring.

If an ordinary tape measure (without the special 4 ounce tension indicator device) is used to measure waist circumference, the measurement will depend on how tightly the tape is pulled. If you pull harder and harder, tissue compression will be greater and greater, and the measured circumference will become smaller and smaller. Two consecutive measurements are usually quite different. If two or more people take the same measurement, the results rarely agree. It is clear that only by applying a constant tension (as the Gulick II does), can accurate and repeatable measurements be taken.

The Gulick II Tape Measure uses a no-stretch, retractable tape with both Metric and English gradations (centimeters and inches). The tape is not metallic to avoid the discomfort of a cold object touching the skin and to eliminate any possibility of scratches or cuts. The self-retracting tape is kept at the desired length until the retract button is pushed.

The most important part of the Gulick II Tape Measure is the tensioning device attached to the measuring tape. Its function is to provide a known amount of tension while a measurement is being taken.

Each individual tensioning device is calibrated to indicate precisely a 4-ounce tension. Note that a stainless-steel compression spring is used. This guarantees that the calibration will last a lifetime, since it is impossible to "over-compress" a spring of this type.

To take measurements: Pull an appropriate amount of tape out of the housing. Wrap the tape once around the waist (see instructions below). Align the tape's "zero line" along side of the tape graduations. Use the Metric units (cm). Now simply pull on the end of the tensioning mechanism until the calibration point is just seen. Read the measurement next to the tape's "zero line".

What is meant by "calibration point": When you pull slightly harder and harder on the tensioning device, two colored beads will be seen separated by a silver disk. When you are pulling with exactly 4 ounces of force, you will see a silver disk separating the two beads.

When you see one of the two beads, you are at the "calibration point". Remember, four ounces is not a great deal of force, in fact, it is approximately equal to the force required to lift a stack of 20 U.S. quarters. So don't pull so hard that the beads start to disappear into the end cap of the tensioning device. That is too much force.

Ideally, waist circumference would be measured in the morning after voiding and before breakfast. If this is not possible efforts should be made to measure each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids.) The participant should remove their clothing on the upper body so that the measurement can be taken on bare skin.

Participants should stand with feet together. The measure should be taken around the abdomen horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. Mark the midpoint on both sides using a washable marker. (Subject may be asked to assist in passing the tape around the abdomen by holding the end of the tape in position). When the tape is positioned in the horizontal plane at the correct height, the subject should be asked to keep arms at their side and breathe naturally. Ask the subject to breathe in, out, and hold at the end of a normal

exhalation. Record circumference to the nearest 0.1 centimeter. Remove the tape and repeat the procedure. If the tape cannot be made horizontal across the waist markings, default to the right hip. If the difference between the first and second measure is more than 0.5 centimeters, obtain a third measure.

16.6.5. Quality Control

All staff who measure waist circumference must be certified. Certification must be renewed annually.

16.7. SEATED BLOOD PRESSURE

16.7.1. Overview

Blood pressure measurements will be taken to document baseline blood pressure at baseline and 6-, 18-, and 30-month follow-up assessments.

16.7.2. Required Equipment

- conventional aneroid sphygmomanometer
- blood pressure cuffs (small, regular, large and thigh cuffs)
- stethoscope: standard stethoscope and ear pieces with bell, tubing to be maximum of 14 inches long
- tape measure
- chair with back support

16.7.3. Equipment Maintenance

General:

Check the blood pressure cuffs on a monthly basis to assure all sizes of cuffs are available.

16.7.4. Safety Issues and Exclusions

None.

16.7.5. Participant and Exam Room Preparation

Caffeine (from coffee, tea, or soda), eating, heavy physical activity, smoking and alcohol should be proscribed for 30 minutes prior to recording the blood pressure.

16.7.6. Procedures

Arm Circumference Measurement

Measure the participant's right arm to determine the appropriate cuff size before allowing the participant to rest. If the participant's right arm is injured or missing, use the left arm for the arm circumference and blood pressure measurement. Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder. The participant will be wearing a gown or loose-fitting top provided by the clinic.
- Request the participant to stand, bend the elbow, and put the forearm straight across the chest. The upper arm should be at a 90 degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax their arm along the side of the body.
- Draw the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin.
- Use the measurement to determine the correct cuff size.

Do not use the markings on the blood pressure cuff for reference. Instead, use the following criteria for determining the appropriate cuff size for the participant:

Arm Circumference (cm/in.)	Cuff's Bladder Size (cm)*
16.0 - 22.5 cm (6.4 - 9.0 in)	small cuff (9.0 cm)
22.6 - 30.0 cm (9.1 - 12.0 in)	regular cuff (12.0 cm)
30.1 - 37.5 cm (12.1 - 15.0 in)	large cuff (15.0 cm)
37.6 - 43.7 cm (15.1 - 17.5 in)	thigh cuff (17.5 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

Detailed measurement procedures

In measuring the participant's blood pressure, the participant should rest for approximately five minutes with their feet flat on the floor and legs uncrossed. Participants should not talk during the rest period or during the measurement. The maximum inflation level should be determined and two blood pressure readings obtained. If both blood pressure readings are high (systolic >=200 or diastolic >=110), the participant should rest for approximately 10-15 minutes and the measure should be taken again. If the reading is still high, the participant should be temporarily excluded and the alert values should be reported as outlined in MOP Chapter 9. For simplicity, all blood pressure measurements will be made on the participant's right arm. Where this is not feasible, the left arm should be used and the exception noted on the comments section of the form.

After the baseline measure, the same arm will be used (if possible) throughout the study.

Application of the Cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor.
- Make sure that the participant's arm is resting on the table at a 90 degree angle with the palm facing up.
- Palpate the brachial artery.
- Mark the brachial artery with an eyebrow pencil.
- Place the appropriate-sized cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area that it overlaps the cuff. You should be able to insert two fingers under the cuff.
- If it is not feasible to measure blood pressure using the right arm, the left arm may be used. The change in arm and the reason for the change should be noted on the comments section of the form.

Rest Period

Ask the participant to sit with both feet flat on the floor and to rest without smoking or talking for five minutes before measuring their blood pressure. Instruct the participant on the correct posture with the back supported and both feet flat on the floor. The work station should be free of excessive noise and the participant should not be interviewed nor asked to read anything at this time.

Determining the Maximal Inflation Level (MIL)

Ausculatory Gap

An ausculatory gap is the fading or disappearance of sound after the first sounds are heard. The sound then reappears at a level well above the diastolic pressure. The radial pulse can still be felt during the silent phase and the gap usually occurs between Phase I and II. This phenomenon is seen more frequently in older participants.

This means that in an adult with an ausculatory gap, the real systolic pressure may be missed and read as a much lower BP. For example:

Real systolic is 172 but sounds fade at:
168 and reappear at
152 and disappear at

98.

If the correct procedure (inflating to MIL) for BP measurement is not used, this participant's BP may be read as 152/98 instead of 172/98. The only way to avoid this error is to obtain the MIL before BP measurement.

Determine the pressure to which to inflate the cuff for the measurement of the systolic blood pressure. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and allows you to hear the first Korotkoff sound. The procedures for determining maximal inflation level are as follows:

- Attach the cuff tubing to the conventional aneroid sphygmomanometer.
- Palpate the radial pulse (if the radial pulse is difficult to palpate, the brachial pulse may be used).
- Inflate the cuff to 70 mmHg. Then increase by 10 mmHg increments until the radial pulse is no longer felt (palpated systolic).
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mmHg above the palpated systolic pressure for all subsequent readings.
- Repeat the MIL if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the MIL. Wait 30 seconds before making a second attempt if the first is unsatisfactory. If the second attempt is unsatisfactory, terminate the procedure and note the problem on the form.
- If the radial pulse is still felt at a level of 270 mm Hg or higher (which means that the MIL is 30 mm Hg higher) repeat the MIL. If the MIL is still 300 mm Hg, terminate the blood pressure measurements and write in "300/MIL" on the form.

Performing the Measurement

- Place the ear pieces of the stethoscope, with the tips turned forward, into your ears.
- Apply the bell of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. Effective use of the bell requires careful palpation of the brachial artery to know exactly where to place the bell. Place the bell just below, but not touching, the cuff or tubing.
- Close the thumb valve and squeeze the bulb, inflating the cuff at a rapid but smooth and continuous rate to the maximal inflation level. Note: Your eyes should be level with the mid-range of the manometer scale and focused on the level to which you will raise the pressure.
- Open the thumb valve very slightly and maintain a constant rate of deflation at no more than 2-3 mm per second, allowing the cuff to deflate. Listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) until 10 mmHg below the level of the diastolic reading (i.e., 10 mmHg below the level where you hear the last regular sound).

The systolic value (Phase I) is the pressure at which you hear the first of two or more knocking sounds in appropriate rhythm. The diastolic sound (Phase V) is the pressure at which you hear the last muffled sound.

- Deflate the cuff fully by separating the tubing and remove the stethoscope ear pieces.
- Record the systolic and diastolic values from the first reading in the spaces provided on the form.
- Hold the participant's arm vertically above their head for a full five seconds to relieve blood pooling.
- Have the participant sit quietly for 30 seconds, then repeat the blood pressure measurement and record the systolic and diastolic values from the second blood pressure measurement on the form.

Criteria for Systolic and Diastolic Blood Pressure

To identify correctly systolic (Phase I) and diastolic (Phase V) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the manometer.

- The systolic value is the pressure level at which you hear the first of two or more knocking sounds in the appropriate rhythm. Note: A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) does not alter the interpretation of blood pressure).
- The diastolic value can be identified as the pressure level at which you hear the last of these rhythmic sounds (usually muffled).
- Make the manometer drop at 2 to 3 mmHg per second, from the maximum inflation pressure until 10 mmHg below that of the last regular sound heard. The control of the deflation rate at 2 to 3 mmHg per second is essential for accurate readings and depends on the handling of the bulb and its control valve.

Guidelines for Blood Pressure Readings

Record all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between markings to the next higher even marking).

Repeat the MIL whenever a systolic blood pressure reading is less than 10 mmHg from the MIL, or if sounds are heard immediately.

If a measurement was interrupted, use the following guidelines:

1. Repeat the MIL only if the cuff was removed or more than five minutes has lapsed between the MIL and the first blood pressure reading or between any two blood pressure readings.
2. Note on the form in the comments section that the measurement was repeated, and indicate why.

If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. Take care to wait at least 30 seconds between measurements. Use the procedure to enhance the sounds (see below) and take the second reading, placing the stethoscope in the same position. Note the use of the enhancement procedures in the comments section of the form.

Procedures to Enhance the Brachial Pulse Sounds

If you are having difficulty hearing the blood pressure sounds, there are three methods that can be used to increase the intensity and loudness of the sounds.

1. Reduce room noise.
2. Instruct the participant to open and close their fist 8 to 10 times. Inflate the cuff and take the BP immediately.
3. Have the participant raise their arm and forearm over their head and make a fist several times for at least 60 seconds. Inflate the cuff while the arm is still overhead, but the hand relaxed, to a level 50 mm Hg above the expected systolic level. Then lower the arm rapidly and measure the blood pressure in the usual manner.

16.7.7. Quality Control

All staff who measure blood pressure must be certified. Certification must be renewed annually.

16.8. Radial Pulse

Be sure to wait until the participant has been resting for 5 minutes. Have the participant turn their palm upward. Palpate the radial pulse with your index and middle fingers. Use the stopwatch to count the pulse for 30 seconds and record the number of beats in 30 seconds as Measurement 1 on the Blood Pressure, Radial Pulse and Weight form; Count the pulse for 30 seconds again, and record the number of beats as Measurement 2.

16.8.1. Quality Control

All staff who measure radial pulse must be certified. Certification must be renewed annually.

16.9 Screening Physical Examination

16.9.1 Purpose and Overview

The purpose of the screening physical examination is to detect medical concerns that would create unacceptable risks from the proposed LIFE walking exercise program. All participants who reach the physical examination visit in the LIFE study will have undergone a telephone screen for medical symptoms or recent medical events that preclude exercise (Telephone Screening Interview) (see flow diagram MOP Chapter 21 Participant Safety). Participants who respond in the

affirmative to telephone screening items about high risk medical symptoms or events will have been excluded. The screening physical examination is designed to be used in combination with the Telephone Screening Interview, Medication Inventory, Medical and Hospital Admission History forms, vital signs and the screening electrocardiogram to make a determination of medical safety for participation. Since medical problems and physical findings among older adults are common, extremely heterogeneous and of greatly varying clinical significance, the physical examination form can only provide general guidelines and requires professional judgement and clinical experience. The professional who carries out these examinations should have prior training and experience in physical examination of the major body systems and should be familiar with abnormal findings in the older adult. The health professional can be an advanced nurse practitioner, physician assistant, or physician and must be licensed to practice in the state in which the study site is located. A major purpose of the physical examination is to detect high risk problems that are asymptomatic or unreported by the participant. In case of borderline or questionable findings, the participant's clinical status should be reviewed with the site physician and additional medical information may be required.

16.9.2 Schedule of Administration

The Physical Examination must be performed prior to the 400 Meter Walk, at either SV1 or SV2.

16.9.3 Equipment

The Physical Examination requires the use of a stethoscope.

16.9.4 Skin

Examine the feet for open lesions, especially on the plantar surfaces and bony prominences.

16.9.5 Lungs

Auscultate anterior and posterior fields bilaterally. Note presence of crackles or wheezes. If present, query patient about dyspnea with exertion and examine extremities for edema.

16.9.6 Cardiovascular

Auscultate anterior chest for heart sounds. Note murmurs that are grade 3 or higher. All such murmurs should be reviewed by a study physician. Note rate and rhythm.

16.9.7 Extremities

Examine range of motion of the major lower extremity joints. Range of motion should be at least 90 degrees flexion at the hip and 120 degrees at the knee. Knee extension should be full or restricted no more than 5 degrees. Ankle

dorsiflexion should be to at least neutral (plus 0 degrees) and plantarflexion to at least 30 degrees.

16.9.8. Vascular

Palpate the abdomen for a pulsatile mass suspicious for an aortic aneurysm.

16.9.9 Neurological

Note gross abnormalities.

16.9.10 Comments

Any additional significant abnormalities that have the potential to affect the safety of exercise should be noted here.

16.9.11 Exclusion based on the physical examination

Are any medical findings suggestive of a condition that would affect the safety of this participant in a walking program? If yes, review with study physician. Items marked under Exclusions, will not allow a participant to be randomized.

16.9.12 Need for study physician review

Review all available data including the Medication Inventory, Physical Examination, telephone screening interview, blood pressure, waist circumference, radial pulse, weight, medical and hospital admission history and ECG forms. Any areas of concern should be reviewed with the study physician and documented on the form accordingly. The study physician should recommend approval, exclusion or further information collection. Further information might include medical records or additional physical assessment by the physician or referral to the primary care provider for further evaluation and management.

16.10. VENTILATORY CAPACITY

16.10.1. Overview

16.10.1.1. Spirometry

Spirometry measures how much and how fast air is forcefully expelled from fully inflated lungs. It is recommended for the diagnosis and monitoring of respiratory diseases, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). Although not a favorite test -- because of the athletic breathing efforts needed -- spirometry was successfully done by almost all of the elderly participants in the Cardiovascular Health Study (CHS) during the baseline exam and during two follow-up clinic visits. In the LIFE Study, spirometry will be performed by a certified assessor at Screening Visit 2, 6, 18, 30 month follow up assessment visits.

The important spirometric measurements are forced vital capacity (FVC) or the greatest volume of air exhaled as rapidly as possible from a maximal inspiration to a complete exhalation; FEV1 (the forced expiratory volume in one second); and the ratio between these two values: FEV1/FVC (x100%). Since FEV6 (the forced expiratory volume in six seconds) is a valid measure of FVC and easier for participants to complete, we will use this measure in place of FVC in the LIFE study (unless otherwise stated, the terms FEV6 and FVC are interchangeable). Our spirometry test procedures conform to current American Thoracic Society (ATS) guidelines. Results for each patient are compared to predicted values determined from the National Health and Nutrition Examination Study III (NHANES III) reference equations.

16.10.1.2. Maximal Inspiratory Pressure (MIP)

The MIP is a measure of respiratory muscle strength. In the LIFE Study, MIP testing will be performed by a certified assessor.

16.10.2. Exclusions

To determine whether the participant can safely complete spirometry and MIP testing, the first three questions of the Spirometry Data Collection Form are administered, as follows:

Q.1. Have you been told that you had a heart attack or stroke in the last three months?

- If the participant answers "yes" or "don't know" or "refused", DO NOT PERFORM SPIROMETRY OR MIP TESTING. If the participant reports a transient ischemic attack (TIA) in the last three months, follow the same procedure and do not perform spirometric or MIP testing. If the participant had a more remote heart attack, stroke, or TIA, it is fine to proceed with spirometry and MIP testing.
- If the participant has NOT been told that he/she had a heart attack or stroke in the last month, proceed to Question 2.

Q.2. Have you had eye, chest, or stomach surgery or eye injection in the last three months?

- If the participant answers "yes" or "don't know" or "refused", DO NOT PERFORM SPIROMETRY OR MIP TESTING. If the participant had a more remote surgery, it is fine to proceed with spirometry and MIP testing.
- If the participant has NOT been told that he/she had **eye, chest, or stomach surgery or eye injection in the last three months**, proceed to Question 3.

Q.3. Have you had any significant problems doing spirometry or MIP testing in the past?

Ask if the participant has had any significant problems doing spirometry or MIP testing in the past. If the answer is "yes" or "don't know" or "refused", DO NOT PERFORM SPIROMETRY OR MIP TESTING.

- **Significant** problems include fainting and angina (chest pain that is thought to come from the heart). These complications are extremely rare. Other prior problems encountered with spirometry or MIP testing, such as coughing, transient dizziness, seeing stars, and headache, should not be considered significant and are not a contraindication to proceeding with spirometry or MIP testing.
- If you are uncertain if the problem is significant and/or likely to recur, consult with the Spirometry Reading Center before performing the test.

In addition, if the patient is unable to understand the instructions for the procedure or has physical complaints that make them unable to perform the procedure, do not perform spirometry or MIP testing.

16.10.3. Required Equipment

16.10.3.1. Spirometry

We have chosen the EasyOne PLUS, an accurate, new, diagnostic quality spirometer, to be used by all field centers. Unlike traditional volume spirometers, this hand-held spirometer is easily carried and uses disposable mouthpieces (Spirettes) which eliminate the risk of cross-contamination and cleaning of hoses. Unlike other small flow-sensing spirometers, there are no screen or capillary tubes to become clogged. During the performance of spirometry, the EasyOne PLUS will be linked to a PC laptop via a spirometry adapter cable (see 16.10.5.2.)

16.10.3.2. Maximal Inspiratory Pressure (MIP)

The MIP is recorded by using a mechanical differential pressure gauge (Magnehelic 2000-200). The gauge has a 200 cmH_2O full scale, a 5 cmH_2O resolution (minor division marks on the scale), and a 2% accuracy. The negative pressure port is connected to 3 feet of plastic tubing, which is then connected to a custom mouthpiece adaptor.

16.10.4. Equipment Maintenance

16.10.4.1. Spirometry

Use a 3.00 liter calibration syringe with the provided adaptor once each week of testing to verify the volume accuracy of each spirometer that you use for this program. You may use a single Spirette over and over again for all calibration checks.

1) Choose “Check Calibration” from the Main menu.
2) Choose “Calibration Check” from the Calibration menu.
3) Firmly insert the calibration Spirette into the spirometer, matching the arrows. Firmly attach the Spirette to the calibration syringe using the grey plastic ndd adapter.
4) Press Enter.
5) Fill the syringe with room air (listen for a click).
6) Inject the full 3-liters from the syringe smoothly into the spirometer (taking about one second), and then pull back fully on the syringe (until you hear it

click again). To avoid damage, don't "slam" the syringe at the end of the injection by pushing the air out too vigorously as this may cause erroneous calibrations.

7) The goal of the calibration check is to verify that the spirometer measures volumes with better than 3% accuracy. Since a 3.00 liter syringe is used, the resulting volume should all be between 2.90 and 3.10 liters.
8) If the calibration check fails, check for correct insertion of the Spirette into the spirometer (triangular arrows aligned), ensure that you are using an ndd calibration syringe adaptor, and check for air leaks inside the syringe and at the connections. Repeat the cal check. If it fails again, try a new Spirette. If it fails again, call ndd Customer Service (see contact information in section 16.10.9). We cannot change the factory preset calibration factors, so the spirometer must be returned to the factory for repair. Do not continue to use an inaccurate spirometer. Ask for a loaner spirometer from the ndd customer service (to be shipped overnight).
9) Print and save a report of the calibration check.

16.10.4.2. Maximal Inspiratory Pressure (MIP) Maintenance

The MIP gauge is a Magnehelic 2000-200 (Dwyer Instruments, Michigan City, Indiana). It has an adaptor that accepts a 1 1/16 inch OD disposable cardboard mouthpiece (Vacumetrics, Ventura, California). The hose is connected to a white plastic mouthpiece adaptor (Vacumetrics model 1085), with a #5 rubber stopper in one end, drilled to accept a 1/8 inch diameter black plastic hose barb. A single 1 mm diameter hole has been drilled into the mouthpiece adaptor, midway along its length, to serve as a leak (to prevent cheek muscles from contributing to the measured negative pressure).

When the pressure transducer is first received, a small screwdriver may be needed to adjust the pointer to the zero pressure mark. The zero adjustment silver screw is located at the six-o-clock position on the face of the meter.

16.10.5. Instructions and Preparation

16.10.5.1. Questionnaire

16.10.5.1.1 Short-term Influences

Prior to spirometric and MIP testing, the participant is first queried regarding factors that may have a short-term influence on performance. This will require administering Questions 4 through 6 of the Spirometry Data Collection Form, as follows:

Q.4. Did you have any caffeinated coffee, tea, or cola, or other caffeinated drink, in the past 2 hours?
Select "yes" or "no" or "don't know" or "refused".

Q.5. Did you smoke a cigarette, pipe or cigar during the last hour?
Select "yes" or "no" or "don't know" or "refused".

Q.6. Have you had a respiratory infection in the past 2 weeks, for instance, cold, flu, bronchitis or pneumonia?
Select “yes” or “no” or “don’t know” or “refused”.

These questions only inform subsequent interpretation of spirometry and MIP results. These three questions do not serve as a basis for exclusions (see Section 16.10.2).

16.10.5.1.2. Documentation of completion of spirometry and MIP testing

In order to document completion of spirometric and MIP testing, the assessor will need to complete Question 7 of the Spirometry Data Collection Form, as follows;

Q.7. Spirometry and MIP complete?

- If completed, in the space provided, record the best results for spirometry and MIP. For spirometry, this would include the best FEV1 and FEV6 from any of ATS acceptable maneuver, while the FEV1/FEV6 is simply the ratio of these best values. For the MIP, record the two highest values.
- If not completed, in the space provided, specify the reason(s) why the spirometry or MIP was not completed. Select one or more from the provided options, including “refused”, “physically unable”, “cognitive unable”, or “equipment problem”. For other reasons, check “Other” and specify in the provided blank.

16.10.5.2. Spirometry Instructions

Spirometry will be performed only by a certified assessor.

Connect the PC laptop (powered on) with the spirometer via a spirometry adapter cable, and turn the spirometer on. The screen on the spirometer should read “PC Interface Mode” after a few blinks. On the computer, open the “EasyWare” software by double-clicking on the appropriate icon on the laptop. Under the “View” menu, select “Test On-line.” The testing window will open on the laptop and the screen on the spirometer will revert to the Main menu.

1) Chat with the patient to achieve rapport. Wash your hands (and use disposable gloves if desired).
2) Suggest that the participant use the bathroom, if they have not done so recently. The hard blowing involved with spirometry may result in some participants losing some urine and recent urination will minimize this.
3) On the spirometer, select “Perform Test” and “New” from the “Display Menus.”
4) In the ID field, enter the participant’s ID number and the visit code. Because this field does not accept alpha characters, enter the last two digits of the visit code (e.g.,SV2 = 123456702, F06 = 123456706)
5) In the Name field, enter the participant’s acrostic
6) Enter the participant’s age, height, weight (from Height/Weight form or screen), ethnicity, and gender in the corresponding fields

7) In the Tech ID field, enter your assessor ID number (press each number button 4 times to get the number).
8) Once entered, you will see the “Test Menu.”
9) Explain the purpose of the examination and the need for extra effort from the patient to get maximal results. Say “I want to measure how much and fast you can breathe out.”
10) Ask the patient to loosen any tight clothing. If they have dentures that are not secure, ask them to remove the dentures for the test. (Provide clean denture cups for such participants.)
11) Take your personal Spirette (with your name written on the mouthpiece). **Demonstrate a DEEP inspiration, exaggerate body language, eyes wide, shoulders back, on your tiptoes.** Demonstrate proper placement of the mouthpiece (stick out your tongue and place the mouthpiece on top of it). BLAST out the air using exaggerated body language.
12) Ask the patient to sit up straight during the examination and not to bend over very much while exhaling. If after one maneuver you feel that the patient would give much better results while standing, it is alright, but be sure to place a solid chair directly behind them and don’t encourage them to squeeze the air out towards the end of the exhalation maneuvers.
13) Get a new Spirette for the patient’s use. Allow them to see the package being opened so that they know that it’s clean.
14) Have the patient do a short trial exhalation using the Spirette (not attached to the spirometer). Coach them through each step of the maneuver, as follows:
15) “Place the Spirette on top of your tongue, seal it with your lips, but don’t bite down on it.”
16) “Take a great big deep breath of air as far as you can inhale.
17) “BLAST your air into the tube as hard and fast as you can. (The exhalation should be made with the lips tight around the mouthpiece with maximal force and speed.)
18) “Keep on blowing out until I tell you to stop.” (Tell them to pretend to blow out all of the candles on a birthday cake with one breath.)
19) Carefully watch their body language and correct any problems.

Start the Actual Maneuvers:

1) Insert and twist the patient's Spirette so that the arrow on the Spirette lines up with the arrow on the spirometer. Push the Spirette in firmly.
2) **Select "FVC"** to begin the testing sequence (even though we are actually testing FEV6).
3) Place a nose clip on their nose during the spirometry maneuvers. The nose clip may be removed between the breathing maneuvers. If the nose clip falls off or is uncomfortable, the patient may hold his nose during the maneuver.
4) Before the first trial for each patient, you must set a no-flow baseline. The display will prompt you to "Block Spirette until prompted to Blast out." This is accomplished by leaving the Spirette partially bagged or covering the bottom of the Spirette with your thumb.
5) Select "Next." You will hear a buzzing sound -- wait until it stops.
6) The display will indicate that the baseline is being set, which takes only 1-2 seconds.
7) The spirometer will then read "Blast out."
8) Hand the spirometer to the patient, instruct regarding the placement of the spirette as previously described (stick out the tongue and place the spirette on top of it) and coach them to take a maximal inhalation. Watch their body language. Don't hold the spirometer while they blow into it (since this would restrict their deep breaths. Try to position the laptop so that you and the patient can see the laptop screen.
9) Coach the patient loudly to BLAST out as hard and fast as possible immediately after taking a maximal inhalation (i.e., Tell the patient not to hold his/her breath after the maximal inhalation). After a second, quietly tell them to continue blowing out for six seconds. Watch their body language. The spirometer will give a longer beep at six seconds to let you know that you can stop the test. The laptop also shows a blue 'X' at 6 seconds on the volume-time graph.
10) Tell the patient it is now okay to come off the mouthpiece.
11) Take the spirometer from the patient and observe the small flow-volume curve displayed on the LCD and/or laptop screen. Learn to recognize the patterns of unacceptable maneuvers.
12) Press "Enter" to see the quality of the curve. If the quality is less than "A", the patient will need additional coaching. If the patient looks like they're not taking a big enough breath or is not blasting out quickly enough, they will also need additional coaching.
13) Repeat the maneuvers until a quality grade of A or B is obtained. If you feel that the inspiration was inadequate, try another test regardless of the quality grade.
14) For another maneuver, press "Next."
15) It is important to perform up to 8 maneuvers if needed to achieve good quality results (a test session with a grade of A or B). If this does not occur after 5 trials, considering asking another assessor to help by coaching the patient for the final maneuvers.
16) The spirometer will display the message "Session Complete!" when quality results are achieved.

NOTE: spirometry will not be specifically performed after the administration of an inhaled bronchodilator (i.e., reversibility testing). Rather, the LIFE assessor will simply need to record the use of breathing medications by the participant prior to spirometry testing (see ATS-DLD-78-A baseline (question #11) and follow-up (question #4) questionnaires).

16.10.5.3. Maximal Inspiratory Pressure (MIP) Instructions and Preparation

The same method will be used as previously published by the Cardiovascular Health Study. The MIP test is performed after completion of spirometry.

Nose clips will be placed for the MIP test, which should be done in the sitting position. The assessor will demonstrate the maneuver, using a spare mouthpiece. The participant will be asked to attach a new cardboard mouthpiece to the white plastic adaptor, then exhale slowly and completely (near residual volume), seal his/her lips firmly around the mouthpiece, and then inhale with as much force as possible “like trying to suck a thick chocolate malt through a narrow straw.”

16.10.6. Safety and Emergency Procedures

16.10.6.1. Spirometry and MIP Safety

The use of disposable Spirettes for spirometry and cardboard mouthpieces for the MIP pressure-gauge eliminates the need for cleaning the spirometry and the MIP pressure-gauge between participants and minimizes the risk of cross-contamination (transmission of infection from one patient to another). The Spirette and cardboard mouthpiece are for single patient use only, and must be removed and thrown away after each patient has completed spirometry and MIP testing. You may dispose of the Spirette and cardboard mouthpiece in the same manner in which you dispose of items such as used tongue depressors or tissues (or give it to the patient as a souvenir).

At the end of each day, the spirometer and the MIP pressure-gauge should be cleaned. Wear gloves. Clean the spirometer and its Spirette cavity, as well as the MIP pressure-gauge and its cavity, using an alcohol wipe, or a soft cloth lightly moistened with isopropyl alcohol.

Unless battery powered, plug all equipment into a grounded electrical outlet.

16.10.6.2. Spirometry and MIP Emergency

The spirometry and MIP examinations pose minimal risk to the patient. The breathing maneuvers may occasionally cause dizziness and very rarely, actual fainting. The risk is minimized by having the patient seated during the test. A patient who feels faint should be guided onto the chair with head down towards knees and encouraged to breathe slowly and deeply until recovered. A physician should be summoned whenever a patient fails to recover normal breathing, faints or reports feeling ill. A physician should be notified immediately, and will assume command of the emergency response. A physician should always be consulted if

there is any question regarding a patient's status during the exam. Follow local procedures for problems in the clinic or home.

16.10.7. Performance Procedures

Spirometry and MIP testing should ideally be done in a quiet room. Distracting third parties should not be in the same room

16.10.7.1. Spirometry

16.10.7.1.1. Using the EasyOne PLUS Keys to Navigate the Menus

ON/OFF: Press and hold this key for about 2 seconds to turn the unit ON. It turns itself off after 3 minutes of inactivity. No data is lost.

Enter key: Selects highlighted menu items and enters highlighted or typed-in data items.

Keys 1 to 9: Allows entry of numbers and letters. In fields in which both numbers and letters appear, enter letters by pressing the appropriate key in rapid succession. This causes the corresponding number and letter sequence to scroll through the highlighted position in the data field. Simply stop when the desired number or letter is displayed. Both upper case letters, numbers, and lower case letters are available (in that order). It's not necessary to use lower case letters.

Esc (0) key: Serves as both the numeric zero and the escape key. Press briefly to enter a zero. Press and hold the key to activate the escape function. The Escape function moves the cursor sequentially to previous menus, menu items, or data fields, depending on the cursor position. To enter a blank space, press the Esc key rapidly to toggle between the number zero and a blank space.

Arrow keys < > move the cursor. In menus, the arrow keys allow scrolling up or down through menu items. In data fields, the left arrow key either erases previously entered numbers or letters (like a backspace key), or scrolls left through a data list. The right arrow key acts either like an Enter key or scrolls right through a data list.

Recording Results: After completing testing/recording a participant's results, you need to close the "On-line Test" window (on the laptop screen), in order to move on to the next participant. Always close this window.

Back Up the Data: The spirometer automatically stores the results of participants in its internal memory (about 200 spirometries). Every time the spirometer is connected to the laptop, the data stored in the spirometer will be sent to the laptop automatically. Since you will be using more than one spirometer at your Field Center, make sure that **BOTH spirometers have been connected to the laptop EVERY WEEK;**

1) Connect the cradle to the computer, using the serial cable.

2) Place the spirometer in the cradle.
3) Press and hold the number "1." (This will synchronize the spirometer with the computer and transfer the data).
4) To view the stored data, double click on the EasyWare software icon.
5) The individual data will be displayed by name in the order in which the tests were performed.
6) Click on an individual entry to view the flow-volume and volume-time plots as well as the numerical data in column form.
7) Toggle between data from the two spirometers by selecting "View" and then the specific "configuration device."

16.10.7.1.2. Initial Configuration of the EasyOne:
It is *very important* that all spirometers used for this study be configured identically because the factory-set default configuration will not store the numeric results and the curves from the three 3 best maneuvers. Once configured for this study, please don't change the configurations. If you get a loaner spirometer, be sure to configure it before use. The custom configuration is retained by the spirometer even if the batteries are removed or become dead.

Operating Mode. Use the "Diagnostic" mode (not the Front-Line mode). The diagnostic mode allows the EasyOne to display the flow-volume curve after each maneuver, and store the 3 best curves. Select "Configuration" from the Main Menu and then choose "General Settings." Press "Enter" until you see "Mode." Use the arrow key to select "Diagnostic." There are three categories of configuration settings to be selected from the CONFIGURATION menu: Test Settings, General Settings, and Report Settings. First select "Test Settings."

Bolded settings are NOT factory default and need to be set by you.

<u>The Test Settings:</u>
Adult Normals: choose "NHANES III"
Additional Pediatric Normals: choose "None"
Best Value Selection Criteria: Choose "Best Value"
Interpretation: choose "Yes"
Lung Age: choose "Off"
Automated Test QC: Choose "On"
FVC Selection: Choose "FEV6" **VERY IMPORTANT**
Peak Flow Units: Choose "L/s"
Asian Ethnic: Choose "88%"
African-American, Hispanic, and Other Ethnic Corrections: Choose "100%"
Storage: Save All Curves setting **VERY IMPORTANT**

<u>The General Settings:</u>
Time Format: Choose "am/pm"
Date Format: Choose "mm/dd/yy"
Date and Time: Enter the current date and time
Alpha-numeric ID: Choose "No"

Technician ID: Choose "Yes"
Calibration Syringe Volume: Choose "3.00 L"
Height Units: Choose "m/cm"
Weight Units: Choose "kg"
Age Entry: Choose "Age".
LCD Contrast: Adjusts display contrast to maximize visibility
Language: Choose "English"
Altitude: Choose "zero" (assuming at sea level)
Operating Mode: Choose "Diagnostic" **VERY IMPORTANT**
Temperature Units: Choose "°F"
Humidity: Choose "40%"

The Report Settings:
Printer Type: Select the printer type that you are using
Data Option: Choose "3 Best Data"
Curve Option: Choose "3 Best Curves"
Graph Options: Choose "Small FV and VT"
Report Headers: Enter "LIFE Exam"

It is very important to configure the spirometer by selecting "3 Best Curves" under the curve options, so that all of the data is saved.

16.10.7.2. Maximal Inspiratory Pressure (MIP)

Subsequent to patient instructions and preparation (see 16.10.5.2), the assessor will hold the pressure gauge so that both the participant and the assessor can see the face of the meter. When the needle moves, the assessor will then coach the subject to "suck harder" and then after about one second, state "that's enough." The assessor will note the maximal negative pressure (to the nearest 5cmH_2O), manually enter the MIP reading on a data entry screen on the laptop, wait at least 30 seconds, and then repeat the MIP maneuver.

Five readings are needed, with a goal of repeating the highest reading within 10 cm H_2O (two small divisions on the gauge). The assessor will manually enter the five MIP readings on a data entry screen on the laptop, including the assessor's impression of the degree of understanding and effort made by the participant (excellent, good, fair, or poor). Mean MIP values of 60 and 85 cmH2O have been reported in healthy women and men, respectively, but the range is very large, so we don't plan to interpret the result for participants.

After each participant, discard the cardboard mouthpiece and wipe the white adaptor with an alcohol pad to disinfect it. The same assessor should retest each participant during follow-up visits.

16.10.7.3. Alert Values

Based on current practice, the following spirometric alert values will require a prompt response from the assessor.

If the **BEST value** for the Forced Expiratory Volume in 1-Second (FEV1) is **<80% Predicted but >50% Predicted**, or the **BEST value** for the Forced Expiratory Volume in 6-Seconds (FEV6) is **less than 50 %Predicted**, the participant will need to be examined by a qualified LIFE staff member who will evaluate the patient for signs of respiratory distress (i.e., severe shortness of breath), as well as initiate a referral to the primary care provider for further evaluation and management.

No alert values are required for the MIP testing, because severe reductions in the MIP will be also associated with reductions in the FEV1 and FEV6.

16.10.7.4. Data Transfer

Spirometric and MIP data from each field center will be transferred weekly to a secured web-site (SSL) that is operated by Hankinson Consulting, Inc. This is done by linking the EasyOne PLUS spirometer to a dedicated laptop/PC via a spirometry adapter cable, and by specialized software onto the laptop/PC. The software (EZLife.exe) selects the most recent test results and encrypts the data into a compressed, password protected zip file. The zip file is then transferred to the above secure web-site (SSL). The passwords for the web-site and zip file are automatically provided by the software, eliminating the need to remember a password and adding password security. Manual upload of zip files is possible if firewall or virus protection software interfere with the process.

The instructions for transferring the MIP and spirometry data are as follows.

Step 1. If your Easyone spirometer has not been connected to the laptop using the adapter cable and with the Easyware software running, this must be done to insure that all tests stored on the Easyone spirometer have been transferred from the spirometer to the laptop.

Step 2. Run the EZLife software by double-clicking on the icon located on your laptop desktop. Enter your technician ID and select your computer identification if it has not been previously selected. A text message box is available if you want to send a message to the reviewer.

Step 3. Click the Upload File button and the tests not previously uploaded will be selected and compressed into the zip file. After the zip file is created a dialog box will appear where you click Ok, to continue the upload process. Then click the “Upload File” button to connect to the web-site and transfer the file. A “display details” check box is available if you have problems and need to see all error messages.

In the unlikely event that a manual upload is necessary, click the “Use Browser of Upload” button and additional instructions for manually uploading a file will be provided by the software.

Instructions for installing and using the EZLife software can be found at http://lifehelp.occspiro.com . This site has a "sample video" and shows step-by-step clicks for a typical MIP entry and MIP/spirometry file Upload. If the EZLife software is not already installed on your computer, please contact john@occspiro.com for the necessary access information.

16.10.8. Quality Assurance Program

16.10.8.1. Spirometry

16.10.8.1.1. Spirometry Training

Spirometry training and final spirometry certification will take place in three phases.

Phase 1 training provides didactic educational programs, including –
1) A 45-minute spirometry educational program, “Spirometry Fundamentals” (Enright), administered on-line at a University of Washington website.
2) An on-line 4 to 6-hour spirometry training tutorial (Hankinson Consulting) that is comprised of a 10-chapters of text, sample tests, video or animated presentations, and 94 review questions at the end of chapter sections. The course will be followed by completion of a 50-question exam of basic knowledge — the completed exam is to be subsequently reviewed by the spirometry reading center. This on-line tutorial provides the pertinent pulmonary background, including many sample spirometric flow-curve and volume-time curves and test results where the student will be taught how to evaluate the curves and tests results to determine the best coaching instruction and whether additional maneuvers are needed.
3) A one-hour WebX seminar, during which Dr. Paul Enright will host a PowerPoint presentation followed by a question-answer session, regarding spirometry and MIP testing.
Phase 1 training must be completed prior to January 28th, at which time Phase 2 training is initiated.

In *Phase 2 training,* LIFE assessors from each field center will be trained centrally at the LIFE coordinating center (FLA) on January 28th and 29th (2010), by Spirometry Reading Center consultants. This will involve 2 hours of “hands-on” spirometry training, including the following (among others):
1) Spirometer data entry and transfer.
2) Modeling the FVC maneuver.
3) Monitoring participant effort during the FVC maneuver, including whether acceptability and reproducibility criteria have been met. This will also involve testing of classmates.

4) Spirometer leak and calibration checks.
5) Spirometry cleaning.

In Phase 3 training, which takes place subsequent to the completion of phase 1 and phase 2 training, LIFE assessors must perform at least 10 additional practice spirometry tests on individuals aged 70 years or older, and then submit these spirometry tests for review to the spirometry reading center. This must be done prior to the recruitment period. **If these 10 spirometry tests meet American Thoracic Society acceptability and reproducibility criteria, and there is documentation of completion of phase 1 and phase 2 spirometry training, the LIFE assessor is then granted spirometry certification.**

Spirometry Assessor WebX Conferences. For sharing problems and solutions, these will be conducted every three to six months throughout the study. They will be scheduled and hosted by the Spirometry Reading Center staff who will use the computer graphics to show examples of good and poor quality spirometries for discussion.

16.10.8.1.2. Spirometry Quality Control (QC) Procedures

Each month, statistics will be compiled by the spirometry reading center for each LIFE certified spirometry assessor, summarizing the quality of the spirometry tests done. The reports may indicate the need for additional training.

A QC summary (periodically) and operator-report (at the completion of testing at a study site) will be sent by e-mail to each LIFE certified spirometry assessor. The operator report (password protected “pdf” files sorted by assessor ID) contains copies of all tests performed by the LIFE certified spirometry assessor, including flow-volume, volume-time curves, FVC and FEV1 quality grades, and specific comments for each test. In addition to the periodic QC summary report, a calibration summary report is also provided. Trends of average FVC and FEV1 quality scores will be monitored during the study to determine if quality issues need to be addressed. The latter may include further on-line educational training and, if problems persist, a visit to the field center by staff from the spirometry reading center.

16.10.8.2. Maximal Inspiratory Pressure (MIP)

16.10.8.2.1. MIP Training

At the January 2010 central training, LIFE assessors will be instructed in the performance of MIP testing, based on procedures as described in 16.10.7.2.

16.10.8.2.2. Quality Assurance Program

The MIP QA program is limited to assessing whether MIP testing on a given individual has included five attempts, and assessing whether two of the highest MIP readings were within 10 cm H_2O.

Each month, a QC summary report will be sent by e-mail to each LIFE certified MIP assessor, periodically and at the completion of testing at a study site. The operator report (password protected "pdf" file) contains copies of all MIP tests performed by the LIFE certified MIP assessor.

16.10.8.3 DMAQC QC REPORTS

On a monthly basis, based on spirometric calibration factors, assessor's impression of the participant and the maneuver quality, and the QC supervisor's impression of test session quality, the final FEV1, FEV6, and MIP results, formatted in an Excel file, will be sent by a secure site from the Spirometry Reading Center to DMAQC. This process will be guided by the Reviewer QC software (Hankinson Consulting).

As a general rule, all data will be reviewed, summarized, and transferred to DMAQC within 30 days of receipt from a field center.

16.10.8.4 Spirometry and MIP Retraining

16.10.8.4.1 Spirometry and MIP Retraining Sessions

Certification of new assessors after the initial central training will follow a similar format as previously described for the LIFE Central Training meeting of January 2010 (16.10.8.1.1), with some modifications - please see below.

Phase 1 training provides an online didactic educational program:
(1) A 45-minute spirometry educational program, "Spirometry Fundamentals" (Enright), administered on-line at a University of Washington website (http://depts.washington.edu/spirofun/online/) and (2) an online Spirometry training course at: http://tech.spirotrain.com administered by Dr. John Hankinson of Hankinson Consulting.

Please contact the ACC at LIFEACC@aging.ufl.edu to obtain a User Account for the online training program administered by the University of Washington; and contact J__ to obtain a user account
for the online training program administered by him.

In Phase 2 training, the new assessor will receive “hands-on” spirometry and MIP training by a spirometry-certified LIFE assessor at the local field center (see attached certification forms). This will involve “hands-on” training, including the following;

A. Spirometry:

1) Spirometer data entry and transfer.
2) Modeling the FVC maneuver.
3) Monitoring participant effort during the FVC maneuver, including whether acceptability and reproducibility criteria have been met. This will also involve testing of classmates.
4) Spirometer leak and calibration checks.
5) Spirometry cleaning.

B. MIP

1) Review patient instructions and preparation
2) Review how to hold the pressure gauge, and the number of readings needed
3) Review MIP data entry on the laptop
4) Review handling of cardboard mouthpiece and white adaptor, after the MIP testing has been completed.

In Phase 3 training, which takes place subsequent to the completion of phase 1 and phase 2 training, LIFE assessors must perform at least 10 additional practice spirometry tests (5 additional practice spirometry tests for recertification) on individuals aged 70 years or older, and then submit these spirometry tests for review to the spirometry reading center (see Data Transfer section, 16.10.7.4.**)**. This must be done prior to the recruitment period. If these 10 spirometry tests meet American Thoracic Society acceptability and reproducibility criteria, and there is documentation of completion of phase 1 and phase 2 spirometry and MIP training, the LIFE assessor is then granted spirometry and MIP certification.

16.10.8.4.2 Re-Training of Assessors with Suboptimal FEV1 QC Scores

Previously certified assessors who have monthly FEV1 QC scores that average < 3.00 will be asked to stop performing spirometry until mandatory re-training has been successfully completed, including the following:

1) Review of the pulmonary MOP;
2) Review of 'Spirometry Fundamentals' at the University of Washington website (http://depts.washington.edu/spirofun/online/);
3) Review of 'Hankinson Spirometry', in particular Chapter 4 (including summary for 4D and 4E) and chapter 9 (http://tech.spirotrain.com). and
4) Resubmission of 5 new training spirometries for QC review.

For assessors who have monthly FEV1 QC scores that average ≥ 3.00 but < 3.50, they may continue to perform spirometry but will require successful

completion of mandatory re-training, including items 1 through 4 as described above and at the discretion of the spirometry QC supervisor (__
).

16.10.8.4.3 Routine Annual Recertification

For routine annual recertification of spirometry, the following protocol is to be applied:

1. The LIFE assessor will first complete Phase I and Phase II training, as outlined on the spirometry recertification form. The completed form is then forwarded to LIFEACC@aging.ufl.edu. LIFEACC will then submit the form to __.

2. Once the recertification form is received by __ completion of the phase 3 training will be based on __ review of the next 5 spirometries that the LIFE assessor has performed during the subsequent month. For phase 3 training to be successfully completed, at least 5 spirometries must have been reviewed, with the FEV1 QC score averaging >/= 3.0.

16.10.9. Contact Information

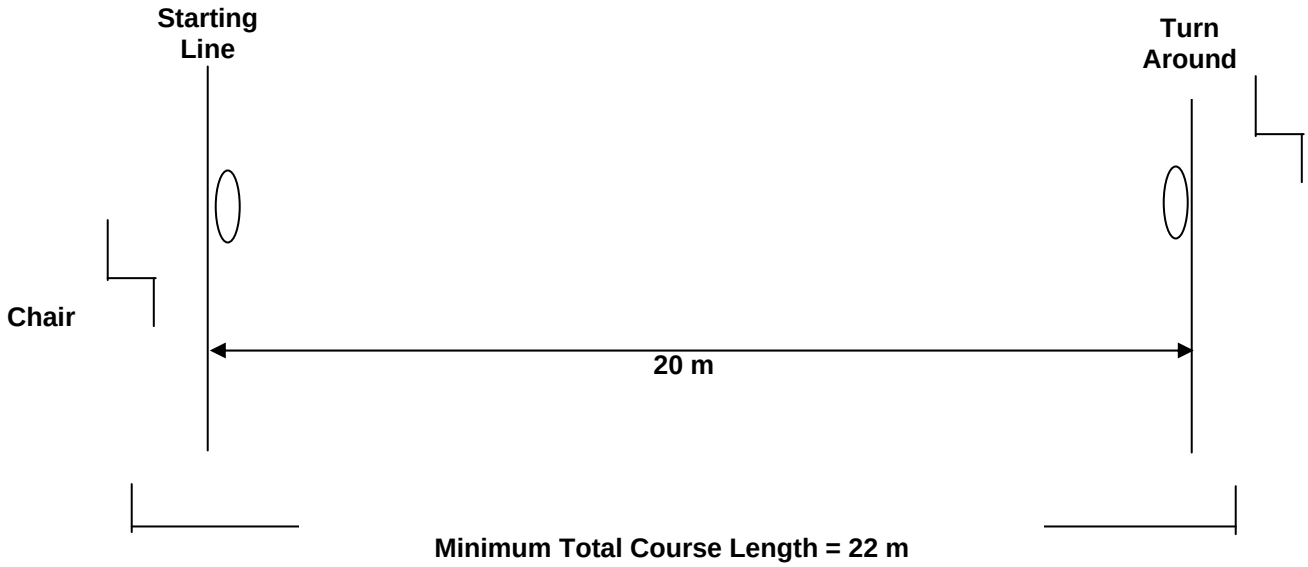
Spirometry and MIP Reading Center:

Spirometry and MIP Reading Center Consultants:
1. _____ _____

2.

EasyOne Spirometer: ndd Medical Technologies
Andover, MA
ndd website: www.nddmed.com
Call ndd Customer Service (Jerry Masiello at 877-904-0090) to order additional Spirettes, if you repeatedly get error messages, or for spirometer malfunctions.
MIP gauge: Magnehelic 2000-200 from Dwyer Instruments
Michigan City, Indiana (219-879-8000)
website: dwyerinst.com/htdocs/pressure/2000.html)http://www.iiirespiratory.com/.

Appendix A. Diagram for 400 m Walk



Appendix B. Alternate Course 400 m Walk Course Worksheet

1 Lap = Distance (in meters) from cone to cone and back again (2 X distance between cones) or distance of the full circle if doing a round course in the home

When you complete Item 1, the rest of the form will auto-fill.

1) Distance for 1 lap = L; L = ___ meters (minimum of 10 meters required)
2) Total laps to walk 400 meters = 400/L; Total laps to walk 400 meters = ___
3) N = # of laps to reach 40 M (1 lap in standard 400 M walk), N = ___
4) Give count of laps and encouragement according to standard protocol at every ___ laps
5) N X 4 = lap at which to ask about level of effort as per standard protocol; N X 4 = ___

Instructions for grid below:

First, cross off the laps that you will not need in this home test. Cross off all numbers higher than the total laps you will use.

Second, circle the following laps: ___, ___, ___, ___, ___, ___, ___, ___, ___, ___ to remind you to give lap count and encouragement at that lap.

Third, put an X in the box for lap ___ (N X 4 laps), when you will ask about level of effort.

As test is done, put a check mark as each lap is completed

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8
❑ 9	❑ 10	❑ 11	❑ 12	❑ 13	❑ 14	❑ 15	❑ 16
❑ 17	❑ 18	❑ 19	❑ 20	❑ 21	❑ 22	❑ 23	❑ 24
❑ 25	❑ 26	❑ 27	❑ 28	❑ 29	❑ 30	❑ 31	❑ 32
❑ 33	❑ 34	❑ 35	❑ 36	❑ 37	❑ 38	❑ 39	❑ 40

Appendix C. Course Layout for the Gait Speed Test of SPPB

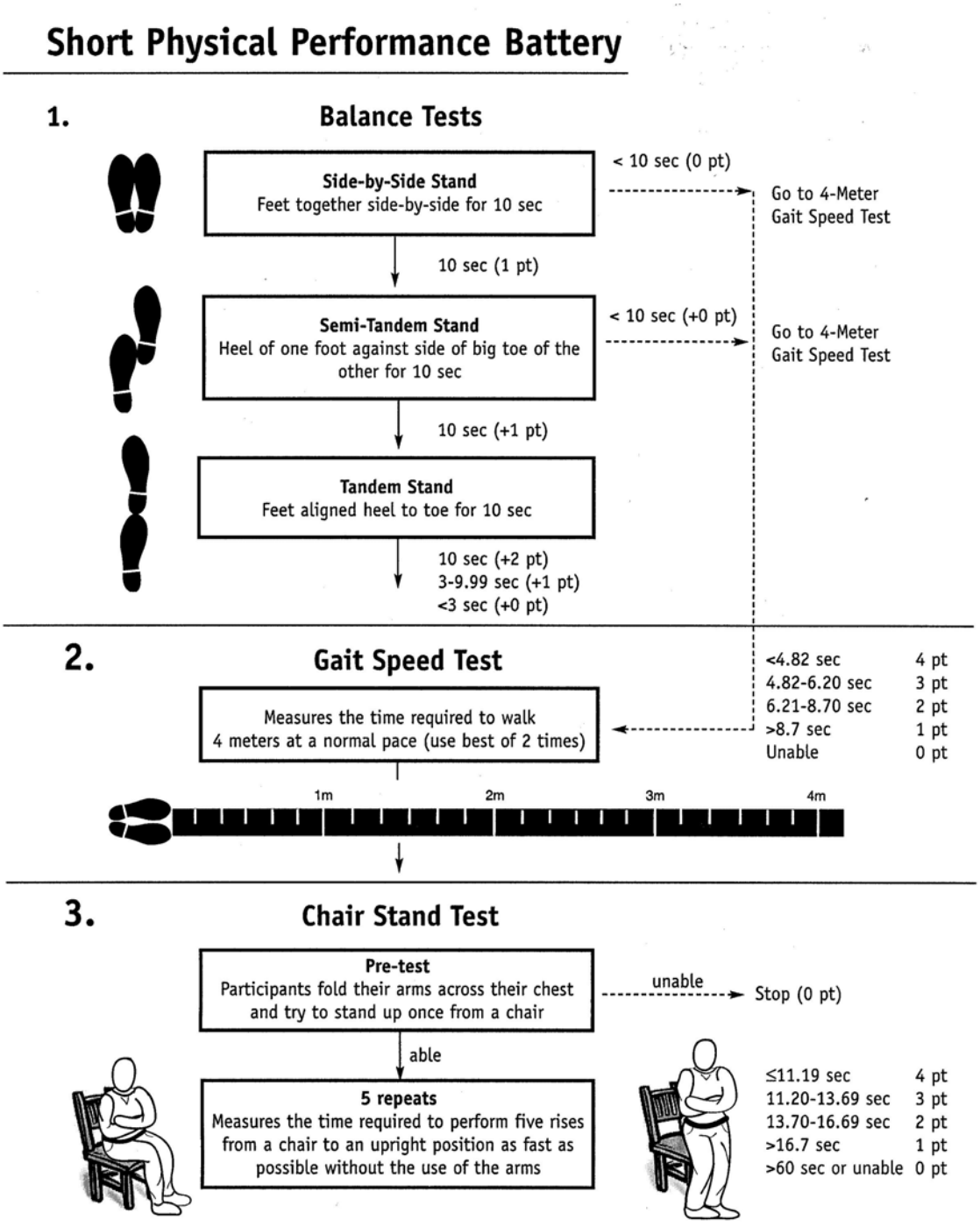
To prepare the course for the gait speed test, first obtain a length of chain with fairly fine links that is just over 4 meters long, approximately 14 feet. These can be readily obtained from a hardware store. Mark the chain with nail polish at 0, 3, and 4 meters. These marks should be the width of a piece of masking tape. The 3- and 4-meter distances should be measured from the front edge of the zero mark to the front edge of the 3- and 4-meter marks, respectively.

The course should preferably be laid out on a hard surface. A carpet is acceptable if this is the only surface available. Avoid laying the course out over the edge of a rug, a throw rug, or any irregular surface that could cause the participant to trip.

Try to find a space that is at least 5 meters long for laying out the 4-meter course. If you are in a home, you can move small furniture with the permission of the owner. If there is insufficient space for the 4-meter course, the alternate 3-meter course can be used. To check whether the available space is sufficient, tape one end of the chain to the floor with masking tape and then pull the chain tight and move around until the best course is found. Once the best course is found, tape down the other end of the tape.

Once the chains is taped down taut, tear off a 2- to 3-foot piece of masking tape and place it directly under the nail polish mark, that indicates the starting line. Place another piece of masking tape of similar length under the 3- or 4-foot mark, whichever is being used. Once the start and end lines are laid down, the chain can be removed and the course is ready for use.

Appendix D. Summary of SPPB Scoring



Appendix E. Scale Calibration Log

Scale Model & S/N:							
Date	20 kg	Tech. Wt.	Tech + 20 kg	20 kg	Tech. Wt.	Tech + 20 kg	Initials/Comments