# CHAPTER 6

# SCREENING

**Study Documents Referred in this Chapter**

- Telephone Screening Interview
- Informed Consent
- Short Physical Performance Battery (SPPB)
- Blood Pressure, Radial Pulse and Weight
- 400 m Walk
- Mini Mental Status Exam (MMSE)
- ECG
- Physical Exam
- Behavioral Run-In (Keeping Track Run-In Diary)
- Study Eligibility Checklist
- Medication Inventory
- Medical, Hospital Admission History

# CHAPTER 6

# SCREENING

## 6.1. Overview

This chapter describes the screening activities for LIFE and the collection of screening measures. Details are provided on how to operationalize the screening measures. A more complete description of the eligibility and exclusion criteria is provided in Chapter 3. There are five primary components to the screening process: the phone screen, the Short Physical Performance Battery (SPPB), the 400 meter walk test, and health screen and the behavioral run-in. These components are typically administered over 3 contacts, a phone-interview and two screening visits (SV1 & SV2). The flow of the participant through the screening process is outlined on the LIFE Study Eligibility Checklist (See Forms Appendix). This form outlines the screening steps and helps the clinics track the progress of the participant through the screening process.

## 6.2. Pre-Screening

It is uncertain how many potential participants will be screened for each field center to recruit their target of 100 enrolled participants. However, the information collected by LIFE will be valuable to other sites if the LIFE study is expanded to a full-scale trial. Therefore, it is very important that each field center document its screening and recruitment activities carefully. The data tracking system begins tracking potential participants with the initiation of the telephone screen. Prior to this stage, contacts and yields from different sources are only captured locally. In order that this local experience is recorded, field centers should maintain logs specifying:

- Number of contacts by recruitment source
- Percent of contacts providing consent for the phone interview
- Primary reasons for refusing phone interview by recruitment source

### 6.3. Overview Of Screening Steps

The screening process is organized into five steps. Different components of eligibility are established at each step of the process. The order that the steps are accomplished is important. There is flexibility, however, in how the steps are implemented. For example, the telephone screening questionnaire can be administered either over the phone or by face-to-face interview, and the SPPB can be done either on- or off- site according to the needs of the site.

The steps of the screening process are:

- Telephone Screen
- Short Physical Performance Battery
- 400 meter walk
- Health Review
- Behavioral Run-in

#### 6.3.1. The Telephone Screen

Before participants are invited to attend the clinic for a screening visit, a number of eligibility items are to be checked on the phone. This phone interview is an inexpensive method to identify potential LIFE participants who have a high probability of being found eligible at the screening visit. The key elements to remember for the phone screen:

- Verbal consent must be obtained before administering the phone screen.
- The participant ID is assigned once verbal consent is obtained.
- Once it is established that the participant is in the proper study age-range and lives in the clinic's targeted recruitment area, the first four pages of the phone screen should be administered. It is not necessary to continue the phone screen for participants who are either geographically or age ineligible..
- Each clinic should establish a process to track potential participants with temporary exclusions, to make sure these participants are recontacted at the appropriate time.

- In some cases screenees may be unclear about certain aspects of their medical history. These participants may proceed to SV1 where the site physician can interview the participant to establish final eligibility.
- Participants with a recent history of breast, cervical, colon, prostate, rectal, uterine, thyroid, or oral cancer should be asked about the treatment status of these tumors at the first screening visit to determine whether treatments could interfere with participation in the study.
- If the participant is found to be eligible on the phone screen, this should be noted on the Eligibility Checklist.

### 6.3.2. Short Physical Performance Battery

The SPPB is used to identify participants who are at high risk of experiencing mobility disability in the subsequent year. Only participants who score less than 10 on this test are eligible for the study. To ensure the recruitment of an adequate number of frail participants, the recruitment target is to recruit 60% of participants who score >7 and 40% of participants who score $\leq$ 7 (no exclusion is considered for minority participants). Because this test might be done off-site, and because it will exclude a large number of potential participants, informed consent for this test is to be obtained separately from the main study consent. This will save time by allowing the clinics not to administer a lengthy consent to a large number of ineligible participants. The test is described more completely in Chapter 16.

When doing the SPPB Screening off-site:

- For the walk portion of the test use the 4-meter course.
- Be sure there is room for the participant to both start the test and room past the 4-meter mark to complete the test.
- The test should be done out of the sight of other potential participants.

The key elements of the SPPB administration are:

- Obtain consent for the SPPB.

- Those scoring less than 10 may be eligible for the study.
- If the participant is found to be eligible on SPPB, this should be noted on the Eligibility Checklist.

### 6.3.3. 400 m Walk Test

Walking disability is the primary end-point for the LIFE study. Therefore it is essential to establish that participants are able to walk 400 meters at the outset of the study. To be eligible participants must be able to walk 400 meters in 15 minutes or less without sitting down or stopping for more than 60 seconds, without help or the use of any assistive device, and without developing chest pain or substantial shortness of breath. The test is described in detail in Chapter 16. The 400 meter walk test and all subsequent screening tests must be done at the Field Center assessment clinic.

Prior to initiating the 400 m walk test:

- The participant must have consented to participate in the main study.
- Collect vital signs (blood pressure, pulse, height and weight).
- Do not perform the test if the participant has a systolic blood pressure > 200 mmHg and/or diastolic blood pressure > 110 mmHg, as this is a temporary exclusion from the study.
- Administer the Disability Questionnaire.

If the participant has a systolic blood pressure > 200 mmHg and/or diastolic blood pressure > 110 mmHg, this person should not be tested. Elevated blood pressure is a temporary exclusion and this participant should be referred to his/her healthcare provider to either initiate or change blood pressure medication.

Participants are excluded from the LIFE Study if they have obvious symptoms of exercise intolerance during the 400 m walk test including: chest pain, dizziness or substantial shortness of breath. The site physician should be consulted if

there are questions about whether the symptoms are consistent with exercise intolerance.

Following the successful completion of the 400 meter walk test:

- Administer the process measures questionnaire.
- Update the Eligibility Checklist.

### 6.3.4. Health Review

The Health Review is conducted to assess whether participation in the study is safe for the participant, and to assess whether the participant has any physical, cognitive or psychologic problems that might cause him/her to be unable to fully participate in the study. It is the site physician's responsibility to review all of the assembled evidence from all of the health related assessments to make a determination of whether a given participant can proceed to randomization. Participants should be excluded by the study physician if the health data collected indicate that:

- The study interventions are unsafe for this participants,
- There are conditions of such severity that full participation in the trial is unlikely, or
- There is evidence of cognitive or psychological problems that would interfere with the delivery of the study interventions.

The Health Review Portion consists of:

- Telephone Screening Interview
- Blood Pressure, Radial Pulse, Weight, and Waist Circumference
- Mini Mental Status Exam
- Medication Inventory
- Medical and Hospital Admission History
- ECG
- Physical Exam

The list above presents the elements of the Health Review in a preferred order. These can be shifted to accommodate clinic flow, but the blood pressure will have been measured prior to the 400 m walk. It is desirable that the physical exam be done last when all of the other data are available for the examiner, should any follow-up be required. The instructions for conducting these assessments is provided elsewhere in the MOP.

The blood pressure criteria are discussed above. A Mini Mental Status Exam score less than 21 is an exclusion. There are no specific exclusions related to the medication review and the medical and hospital admission history, however, this information will be useful to the study physician in determining the final eligibility of the participant. For example, the presence of severe psychiatric problems such as schizophrenia are study exclusions. The presence of such conditions may be indicated by an affirmative response to the medical history form question 26: “Since the age of 50, have you seen a doctor for emotional, nervous, or psychiatric problems? “. Responses that require physician review on the Medical and Hospital Admission History form are marked with an asterisk.

A physician-read ECG showing a serious conduction disorder, uncontrolled arrhythmia, new Q waves or ST-segment depression are potential exclusions from the study. The study physician will determine if these conditions are permanent or temporary exclusions. If they are temporarily excluded, participants can be seen again for further evaluation without re-screening as long as no more than 28 days elapse between the date of the full study consent and randomization.

The physical exam is described in Chapter 16 of the MOP. The physical exam can be conducted by either a physician, advanced nurse practitioner or a physician’s assistant. The study physician should see prospective participants to verify eligibility if there are any questions raised during the health screening process. Specifically, the physician should see participants who: respond “Don’t

Know" to items on either the telephone screening interview or the baseline health history, give an affirmative history to cancer in the past three years to verify that the tumor is currently in remission; respond that they have seen a doctor for emotional or psychiatric problems since age 50; give concerning answers on the Medical and Hospital Admission History form (responses marked with an asterisk); or have abnormal findings on the physical exam. In these cases, the study physician should record the date on which the participant is seen on the last page of the physical exam form. The physical exam can occur during the first screening visit or at the beginning of the second screening visit.
If participants have conditions that would not be so severe as to be exclusionary if addressed, they can be excluded temporarily.

A participant may be deemed to be ineligible after the completion of the first screening visit but before the second scheduled visit. If this happens, the participant should be called and the reason(s) for exclusion should be explained.

The site physician must clear all participants prior to randomization. Medical clearance for the study is indicated by completing the Study Eligibility Checklist section entitled "Study Physician Review-Exclusions." Only the study physician should complete this section of the eligibility checklist to confirm that the participant has no medical exclusions

Following the Health Review:

- Update the Study Eligibility Checklist.

### 6.3.5. Behavioral Run-In

All participants will be required to satisfactorily complete a one-week behavioral run-in, which involves recording fruits and vegetables and physical activity data in a LIFE Keeping Track Run-In Diary. A trained staff member will explain this task to the participant during the first screening visit (SV1). Participants will be asked to record:

1. The number and type of fruits and vegetables consumed each day;
2. The type of physical activity they complete and its duration (or to check a box if no activity).

Prior to the run-in, participants will be given a list of fruits and vegetables. Physical activity should be logged in minutes. Any activity that the participant chooses to record is acceptable. The purpose is to assess the behavior of logging the activity, not necessarily the precision or accuracy of the data.

A trained behavioral scientist will review the participant's records for compliance with the behavioral run-in during the randomization visit. The randomization visit will be scheduled approximately 1-week after the first screening visit (not more than 2 weeks). If during the period of the run-in, the participant is deemed to be ineligible, you may call the participant to stop (or in the case of a temporary exclusion, delay) the run-in.

### 6.3.6. Review of Behavioral Run-In

A trained behaviorist or interventionist will review the participant's records for compliance with the behavioral run-in task during the randomization visit. Minimum criteria for acceptable completion include:

1. At least 6 of 7 days recorded;
2. A type of fruits/vegetables, or indication that no fruits or vegetables were consumed;
3. Minutes of physical activity for each day, or indication that no physical activity was engaged in during the behavioral run-in time period.

If the behavioral run-in recording is deemed not acceptable, a second opportunity to complete the task may occur. Participants may not be randomized until this eligibility criterion is met. There is no option of a third chance.

There is no specific form to record a successful run-in. This is to be collected on the eligibility checklist.

### 6.4. Randomization

Randomization occurs at the end of the second screening visit. The randomization process is described in Chapter 7. After completing all SV1 eligibility assessments and the run-in review at the beginning of SV2, the completed eligibility check-list should be entered into the data system. It should be clear from the form that the participant is eligible for the study, and at this point the data system can provide a group assignment for the participant. Any questions that arise should be discussed with the study physician and the field center PI. Randomization must occur within 28 days of obtaining the informed consent. If a participant falls out of this window, he/she must repeat screening visit 1 assessments.

### 6.5. Suggested Schedule

Most of the elements of the screening and baseline assessment process are to be done according to protocol. The orders of assessments are listed below. Assessments that can be done out of order are noted.

1. Telephone Screen
2. Screening Visit 1 -- SPPB Consent & SPPB
3. Screening Visit 1
   Main Study Consent
   Blood Pressure, Radial Pulse, Weight and Waist Circumference (Weight and Waist Circumference may be obtained any time during SV1)
   Disability Questionnaire (Must be done prior to the 400 m walk)
   400 m Walk
   Process Measures (Should be done immediately after the 400 m walk)
   MMSE
   Medication Inventory
   Medical and Hospital Admission History

ECG
Physical Exam
Height (May be done at any time during SV1)
Contact Information (Questionnaires can be administered if there are waits for other components)
Demographic Questionnaire (Questionnaires can be administered if there are waits for other components)
Participants should get the Run-In Diary and the Quality of Well-Being Scale and Health Care Utilization Questionnaires to take home.

4. Screening Visit 2 – This should be a Fasting Visit (a minimum of 8 Hours)
Review of Behavioral Run-In
Phlebotomy (Optional for each participant– check consent form )
Study Eligibility Checklist
Review of Quality of Well-Being Scale and Health Care Utilization Questionnaire
Grip Strength
Blouse/Shirt Test
Lateral Mobility Task (Wake Forest Only)
CHAMPS
Health Related Quality of Life Questionnaire
Late Life Disability Questionnaire (Questionnaires can be administered if there are waits for other components)
Cognitive Tests (Wake Forest and Stanford only)
Randomization

## 6.6. Components That Can Be Re-Screened (Temporary Exclusions)

There are several exclusion criteria that may change over time for which a participant can be re-screened at a later date. If, upon re-screening, the

participant now meets the eligibility criteria, he/she may go on and be randomized. These are described in the Chapter 3.

For each of these re-screening attempts, if the re-screening still allows for the appropriate window (28 days) between initial screening and randomization, the only item that needs to be re-screened is the item in question. Consequently, the screening forms do not need to be repeated; only the item in question should be repeated and recorded on the appropriate screening form. Draw a line through the original value, record the new value above it then initial and date the corrections. The corrected data should then be data entered. The same ID number should be used if the participant is re-screened. Otherwise, the screening process must be repeated. However, the same ID number should still be used.

Temporary exclusions (and other interruptions or variations from the screening schedule) may results in data on forms being collected on different days. If this occurs, the date of the visit listed on the form should reflect the earliest date when data elements on the form were recorded. This will allow limits for the window when data may be collected prior to randomization to be enforced.