

### **3. SCHEDULING AND CONDUCTING THE SCREENING VISIT**

#### **3.1 Introduction and Overview**

All participants randomized to either the spiral CT or chest X-ray group of the study must be scheduled for a screening visit. The SC may schedule the screening visit either at the time of enrollment and randomization or for a later, more convenient date. Screening visits should be scheduled as soon as possible after enrollment and must be completed by January 31, 2001. The SC should make every effort to schedule appointments based upon participant availability. This is especially important in areas where older adults may travel for long periods during the winter months (i.e. “snowbirds”). During the screening visit the participant will be asked to complete the screening exam. In addition to being screened, the participant will be asked to complete the Participant Contact Form and Medical Record Release Authorization Form.

This chapter provides an overview of the procedures and forms that will be completed during the participant’s screening visit.

#### **3.2 Scheduling a Screening Visit**

Once participants who need appointments are identified, the SC staff will contact the participants (in-person or by phone) to schedule an appointment. All appointments will be recorded in a scheduling system. Each SC will develop its own manual or automated scheduling system for tracking participant contact and appointment times.

It is recommended that each participant be recontacted in advance of the appointment date either by phone or mail and given a reminder of the appointment time and place, with maps or parking instructions, as appropriate and a written or verbal description of the screening procedures.

### **3.3 Explaining Procedures**

When the participant arrives for the screening procedure, s/he should be greeted and given a verbal description of what will happen during the visit. Written materials describing the procedures may also be provided at this time. Questions that participants may ask about the Lung Screening Study and suggested answers are found in Appendix 2-4. The SC staff should become familiar with them. The participant will be told that the examination is a screening for lung cancer, not a routine examination, and that s/he should consult his/her own physician for evaluation of any symptoms and for routine medical care. The participant will be told that s/he will receive written documentation of the results of the screening examination within three weeks and that s/he will be contacted by telephone if there is a positive screen. After explaining the procedures and answering participant questions, the SC Coordinator should review the participant's file to determine what, if any, forms need to be completed before the screening procedure.

### **3.4 Obtaining Contact Information**

The SC will have the study participant complete a Participant Contact Form (PCF) (Appendix 3-1). The PCF is used to collect information that will help the SC contact the participant in the future, including name, Social Security number, and names of two persons who will know where the participant can be located. This form will also be used to document the name, address, and telephone number of the participant's primary care physician. Appendix 3-2 contains the specifications for the PCF. This form may be completed at the time of the visit or may be sent in advance. If sent in advance, the participant should be asked to bring the PCF to the screening exam appointment. SCs that prefer to send the PCF to potential participants with the informed consent (before randomization) must obtain local IRB approval for this procedure in order to meet OMB requirements.

The SC Coordinator should review the form at the screening visit for legibility and completeness and have participant fill in any missing items before proceeding to the screening procedures. When the form is completed it will be kept in each participant's folder.

### **3.5 Obtaining Permission to Obtain Medical Records**

The Medical Record Release Authorization Form shown in Appendix 3-3 should be completed by each study participant during the screening visit and kept in the participant's file. Many hospitals will not accept the Lung Screening Study informed consent as sufficient for release of the participant's medical records. This additional authorization needs to be requested from each participant and put into the participant's study folder before the screening procedure begins.

### **3.6 Conducting the Screening Examination**

Chapters 4 and 5 describe procedures for conducting the spiral CT and chest X-ray screening examinations, respectively.

### **3.7 Exiting the Screening Visit**

At the completion of the screening examination, the SC will remind the participant that results of the screening will be sent within three weeks and that s/he will be contacted by phone with any significant findings. The participant should be thanked for participating in the study and given a card containing the name and telephone number of a contact person at the SC who can respond to any study-related questions or problems that the participant might have.

### **3.8 Following Up No-Shows and Rescheduling for Inadequate Exams**

Each SC should make prompt and aggressive efforts to locate and contact participants who miss their scheduled screening visits. SC staff contacting no-shows should be prepared to explain the procedures and allay concerns of the participants that may have led to the missed appointments. Attempts to contact the participants and reschedule a screening visit must be completed before January 31, 2001.

The SC is responsible for setting up procedures to review the results of the screening examination in a timely manner. If it is determined in reviewing a participant's chest X-ray or spiral CT scan that the results are inadequate or indeterminate, a second screening visit should be scheduled before January 31, 2001.

### **3.9 Tracking, Reporting and Monitoring Screening Visits**

The SC is responsible for the development of a system to track all study participants to ensure that they are completing the screening visits. This effort will be aided by the reports available from the CC. From the weekly shipment of completed forms sent from each SC to the CC, the CC will generate an Expected Forms Report (Appendix 9-19) listing all delinquent forms. The SC will monitor the reports to follow up on all participants who have yet to complete their screening examinations. During the study, the CC will post weekly reports on the CC web site detailing problems and progress on the study. The CC will use receipted forms from the SCs to generate these reports. The CC-generated reports are described in Section 9-10.

## **Appendices for Chapter 3**

- 3-1 Participant Contact Form (PCF)
- 3-2 Specifications for the Participant Contact Form
- 3-3 Medical Record Release Authorization Form