9. ADMINISTRATIVE PROCEDURES

9.1 Overview

The SC Coordinator will serve as the main contact point for interaction with the CC. It is the responsibility of the SC Coordinator to:

- Oversee the personnel and administrative procedures within the SC;
- Distribute forms and PID labels once participants are randomized;
- Complete and edit all study forms prior to sending them to the CC;
- Transmit required forms to the CC;
- Report and track participant status;
- Send weekly cumulative recruitment reports.

This chapter describes the SC management activities and the tools provided to perform these activities.

9.2 Training and Registration of Staff

The CC is responsible for training the SC Coordinators in the protocol and procedures for conducting the study. The primary reason for training the SC staff is to ensure that the protocol is clearly understood and to ensure that standard procedures are followed across all SCs. Central training sessions conducted by the CC offer the opportunity for hands-on practice with reference materials and data collection instruments. The CC will conduct an initial training session for SC Coordinators prior to the start of the study. The purpose of this training is to familiarize the SC Coordinators with all requirements of the study.

The SC Coordinator has ongoing responsibility for training all staff on form use and administrative procedures. Training/certification requirements for examiners are described in Chapters 4 and 5. Training/certification requirements for abstractors and nosologists are described in Chapter 7. For each staff member, the SC Coordinator must document the individual's qualifications for the Lung Screening Study on a Record of Experience, Credentials and Training (ECT) (Appendix 9-1). The ECT must be approved by the NCI before a staff member may perform duties for the Lung Screening Study. Specifications for the ECT form are provided in Appendix 9-2.

If an individual is currently a registered staff member for PLCO, a new ECT must be completed for the Lung Screening Study; however, the SC Coordinator should assign that person the same staff ID number as his/her PLCO staff ID number.

9.3 Documenting Non-Response

The SC Coordinator will complete a Missing Data Form (MDF) (Appendix 9-3) when a participant is unable or unwilling to complete a study activity. This may be due to a variety of reasons such as participant refusal, inability to locate the participant, suspected death of the participant, etc. The MDF should be used only when all efforts to obtain data have been unsuccessful and the data will never be obtained. If a participant decides to withdraw from the study, the SC should complete an MDF for all remaining study forms.

Specifications for the MDF are included in Appendix 9-4. After the form has been completed, the original should be sent to the CC. A copy of the completed MDF should be filed in the participant's study file. If a situation arises in which an MDF must be deleted from the central records (for example, if the actual study form is received or found, or if the MDF was completed in error), the SC should notify the CC of the necessary deletion, but keep the hardcopy MDF in the participant's folder. SC staff should document on the MDF why the form was deleted from the central records and initial and date the form.

9.4 Documenting Randomization Errors

Two types of randomization errors can occur: the randomization of an ineligible participant, and the duplicate randomization of one participant. Steps to be taken in both situations are outlined below.

9.4.1 Randomized Ineligibles

If the SC becomes aware that a randomized participant was ineligible at the time of randomization, the participant should be documented as a "randomized ineligible" on an Administrative Tracking Form (ATF) (Appendix 9-5). The following information should be recorded on this form:

- the date the SC discovered that an ineligible individual was randomized;
- the reason the individual was not eligible for the study at the time of randomization;
- the method of discovery.

The purpose of the ATF is to differentiate between the following types of situations that may involve randomization of ineligible individuals:

1. Individuals who were randomized in error (i.e., the participant provided information to the SC indicating his/her ineligibility, but the SC failed to exclude him/her from the study);

2. Individuals who were randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization that the information provided had been incorrect.

The randomization of an ineligible individual is a protocol violation and the SC should follow the steps to be taken in the event of a protocol violation, as described in Section 9.5 of this chapter. The CC will use ATF reports to determine the number of randomized ineligible protocol violations that have occurred for each SC within a given timeframe. It is therefore important that the SC completes the "Method of Discovery" section of the ATF so it is clear to the CC whether or not the participant provided accurate eligibility information prior to randomization.

Refer to Appendix 9-6 for Specifications for Completion of the Administrative Tracking Form.

All individuals discovered to be ineligible after the time of randomization (with the exception of those who did not sign a consent form) will continue to be study participants regardless of the method of discovery. This includes receiving the allocated screening examination. If the reason for ineligibility is prior lung cancer, the cancer should be confirmed by a review of medical records or by contact with the participant's physician. The ATF should be completed indicating whether or not the cancer is confirmed.

As with all other participants, if a randomized ineligible refuses a screening test, the test should not be performed.

9.4.2 Duplicate Randomization

If a participant is randomized twice, the first assignment, both PID and group, should be used. Regardless of whether the two randomizations resulted in assignment to the same group or different groups, a Protocol Violation Form (PVF) should be completed and sent to the CC (see Section 9.5). The CC and the participant should be informed of the error and if an incorrect screening examination was performed (e.g., a chest X-ray for a participant who was first randomized to the spiral CT group), results from the examination should still be sent to the participant and his/her physician; the participant should not receive another screening examination. Exam forms for erroneous screens should be sent to the CC with the PVFs. Maintenance of the participant's files is at the discretion of the SC: the charts can be combined or left separate but complete documentation must be kept so that both PIDs are easily identified and the correct records can be traced if necessary.

If a participant is randomized twice, the following activities should be completed to document and resolve the error:

1. Follow steps to be taken in the event of a protocol violation, as described in Section 9.5 of this chapter. Send the original PVF to the CC and place a copy in the participant's study file.

2. Inform the participant of the error. It is recommended that this be done both in writing and by a telephone call from the Study Coordinator.

9.5 Documenting Protocol Violations

All investigators are expected to adhere to the procedures set out in the Lung Screening Study protocol. Some examples of protocol violations are:

- randomizing the same individual twice;
- screening a participant with a history of lung cancer;
- screening a participant without a signed consent form;
- performing a chest X-ray for a participant randomized to the spiral CT group;
- performing a spiral CT for a participant randomized to the chest X-ray group;
- reporting erroneous results to participants or physicians.

In the event that a violation of the protocol is discovered, the SC Coordinator must complete the Protocol Violation Form (PVF) (Appendix 9-7). Specifications for completing the PVF are included in Appendix 9-8. The original form should be sent to the CC and a copy of the form should be placed in the participant's files. Protocol violations should be reported to the CC in the SC's weekly report to the CC.

9.6 Reporting Adverse Events

SCs are responsible for reporting the occurrence of any adverse events among the participants in the study that may be related to their participation in the Lung Screening Study. Medical complications that occur at the SC during the screening procedure should be documented in the comments section of the appropriate screening examination form (See Chapters 4 and 5). This information will be communicated to the CC using the Chest X-ray or Spiral CT Screening Examination Forms.

Serious adverse events that occur as a result of the Lung Screening Study need to be reported to the CC on a separate form. The SCs should use the following criteria to determine whether or not the event should be classified as serious:

- Death
- Threat to life
- Inpatient hospitalization
- Persistent or significant disability/incapacity
- Medical or surgical intervention to prevent one of the above outcomes

If the event is serious and reported to the SC's local IRB, the SC will complete a Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE) (Appendix 9-9). The adverse event should be thoroughly described on this report. Specifications for completion of the RAE are provided in Appendix 9-10. The RAE should be kept in the participant's file and appropriate follow-up with the participant and his/her physician should be conducted until the problem is resolved. When the problem is resolved, the original RAE should be sent to the CC and a copy should be kept in the participant's file.

If additional space is needed for comments related to adverse events, complete a Comments Continuation Form (CCF). This form is provided as Appendix 9-11. Specifications for completion of the CCF appear in Appendix 9-12.

9.7 Processing and Shipping Forms to the CC

SC Coordinators will be responsible for the preparation of forms for transmittal to the CC. Preparation includes editing, data retrieval, completion of the transmittal log, and shipment of forms in the appropriate manner. All original data collection forms are to be copied before shipment to the CC. Copies of all study forms should be maintained on site at each SC in secure participant study files.

The following original forms will be prepared and shipped to the CC in weekly Federal Express shipments:

- Log of Mailed Results Letters
- Follow-Up Log
- Spiral CT Screening Examination Form
- Spiral CT Screening Examination Quality Assurance Form
- Chest X-ray Screening Examination Form
- Chest X-ray Screening Examination Quality Assurance Form
- Diagnostic Evaluation Form
- Health Assessment Questionnaire
- Record of Experience, Credentials and Training
- Missing Data Form
- Protocol Violation Form
- Administrative Tracking Form
- Report of Adverse Events for NIH-Sponsored Clinical Trials
- SC Edit Form (see Section 9.7.2)
- CC Edit Form (see Section 9.7.4)
- Other _____

The CC should <u>not</u> receive copies of any forms that contain identifying information from Lung Screening Study participants or potential participants. The CC should <u>not</u> receive the following forms:

- Eligibility Screener
- Eligibility Verification Form
- Participant Contact Form
- Medical Record Release Authorization Form

Preparation and shipment of forms to the CC are described in the sections that follow.

9.7.1 Editing

Editing is the review of completed forms to ensure that they have been filled out completely and accurately. For all forms originating at the SC, the editing tasks will be the responsibility of the SC Coordinator. Editing will also be conducted at the CC by a data editing system. The staff member completing the form at the SC should comprehensively review all forms before the participant leaves the SC. The SC Coordinator should also review all forms when a shipment of forms is being prepared for transmittal.

The following are guidelines for manual editing:

1. Review the form for completeness and legibility.
2. Make any changes that do not require data retrieval.
3. Determine whether or not there are critical data items that require data retrieval.
4. Perform data retrieval and annotate the form as follows:
   - If the item in question was left blank and, upon data retrieval, the participant or examiner is unwilling or unable to supply the data, leave the item blank, and mark your initials and the date near the question.
   - If the item in question was left blank and, upon data retrieval, the participant or examiner supplies the data, complete the item and mark your initials and the date near the question. If the new data involve a verbatim response, record the data in another color ink or pencil from the participant's original response.
   - If the item in question was completed incorrectly (e.g., an incorrect examination result) or required clarification, and the participant or physician supplied different or additional data, make the changes and mark your initials and the date near the question. If the changes involve a verbatim response, using another color ink or pencil, cross out the original verbatim response with one line and write the corrected response near it; original verbatim responses should never be erased.

The specifications for the data collection forms should be consulted, as necessary, during manual editing. All changes to individual items on data collection forms should be initialed and dated. Any erasure or change that has not been initialed or dated will be considered a participant/examiner change rather than an edit.

9.7.2 SC Data Retrieval

The SC Coordinator must comprehensively edit all forms at the time a transmittal is prepared. If missing items are discovered, attempts should be made to contact the participant or refer to study records to complete the data items before shipping the form to the CC. If the SC Coordinator discovers an error after forms have been sent to the CC, the SC Edit Form (Appendix 9-13) should be completed and sent to the CC. Specifications for completing the SC Edit Form are found in Appendix 9-14.

9.7.3 Shipping Forms to the Coordinating Center

All data forms for this study will be shipped to the CC via Federal Express in original hard copy with an accompanying Forms Transmittal Log detailing the contents of the shipment. Shipments will be sent once a week, on Friday, for Monday delivery. The CC will compare forms received and the PIDs listed on the transmittal. SC Coordinators will be notified by the CC of any discrepancies between the transmittal and receipts.

All forms must be copied at the SC. Copies should be filed at the SC before the original forms are shipped to the CC. All identifying or personal information should be removed from the forms prior to transmittal to the CC.

All study forms may be shipped in the same weekly shipment. However, each type of study form shipped must have a separate Forms Transmittal Log (FTL) (Appendix 9-15). Specifications for completing the Forms Transmittal Log are found in Appendix 9-16. Each form that has been completed and edited should be batched according to type. Sort all forms by type and use one Forms Transmittal Log for each type of form. Place forms in order by PID and affix PID label to the Forms Transmittal Log. Attach forms and transmittals together.

Do not send forms that require data retrieval. Study forms should only be sent when the form has been comprehensively edited and all data has been retrieved. The SC Coordinator is responsible for checking the forms prior to sending any materials to the CC.

9.7.4 Processing Study Data

Once the study forms for each participant have been transmitted to the CC, they will be reviewed for completeness and accuracy. In addition, the CC will produce monitoring reports for the SCs for additional data retrieval.

Errors that are identified during CC editing and processing will be recorded on the CC Edit Form (Appendix 9-17), which will be sent to the SCs for review and resolution. The SC will fill in the resolution column and return the report with an edited copy of the original form to the CC. Additional data retrieval may be required to resolve the error.

9.8 Record Keeping

Each SC should establish a record keeping system. Records should be reviewed for completeness prior to randomization, as well as quality reviewed before transmittal to the CC. The file for each participant should include individual folders with all the study materials associated with that individual. At the end of the screening visit, the SC Coordinator should make certain that completed forms for each participant are appropriately filed. It is suggested that all correspondence, study forms, and documents supporting eligibility determination be labeled with the PID. It is also suggested that files be organized in PID order as many of the study forms will not have the participant name recorded on them.

Study documents and data may not be stored in the participant's regular medical record at any hospital or institution with which the SC may be affiliated. Copies of screening results, however, may eventually become part of a participant's regular medical record as a result of referral of the participant to a physician for follow-up of an abnormal screening result. Study documents will be kept for seven years after the end of the study and then destroyed.

9.9 Data Security

All study materials that carry identifying information such as name, address, and social security number should be kept in a locked and secure area at the SC. The SC Coordinator will control access to this area. If the central file is computerized, the system must be protected from outside access (e.g., password control, locked system, or data encrypted). Similarly, all reports produced from the system that carry such data must have controlled distribution and be destroyed when no longer needed (e.g., shredded).

Some SCs may wish to use a mailing house to distribute recruitment materials. Any SC wishing to release participant information to a mailing house must first obtain from the organization a written statement assuring that participant confidentiality will be maintained. A copy of the statement should be submitted to the NCI and the CC. If the SC is providing a list or file of names and addresses of potential participants, without any data elements linking the potential participant to enrollment in the study, it is not necessary to obtain an assurance of confidentiality.

Access to the Lung Screening Study web site will also be controlled. As described above, each SC staff member will be assigned a four-digit ID. If the staff member already has a PLCO ID, s/he must use that ID.

9.10 Monitoring

Each week, the CC will monitor data collection through the production of reports. These reports will provide each SC with a list of the data collection forms that have been receipted and will allow each SC to monitor whether any forms that were submitted were not receipted by the CC. In addition, the CC will generate weekly data management and summary reports regarding recruitment, screening exam results and protocol discrepancies. All reports will be made available to the SCs on the CC web site. Data management reports that include PIDs will be available to each SC individually, while summary reports will be available to all SCs, the CC and NCI.

Data Management reports:

- Screening Exam Results Report (Appendix 9-18): This will be a two-part report that shows the results of the screening exams and whether or not the results were sent. Part 1 shows completed exams with results pending or notification letters not sent. Part 2 shows completed exams with results reported and notification letters sent. This report is available to each SC individually and to the CC and NCI.

- Expected Forms Report (Appendix 9-19): For each participant, this report shows the data collection forms that are expected but have not yet been receipted. The report may be generated by form type and by PID. This report is available to each SC individually and to the CC and NCI.
- Protocol Discrepancy Report (Appendix 9-20): This report shows participants for whom the incorrect screening exam was performed (e.g., a participant randomized to the chest-X-ray group was given a spiral CT exam). This report is generated on an as-needed basis by the CC study manager, who will discuss it with the SC Coordinator individually The NCI will receive a copy whenever this report is generated.

Summary Reports:

- Cumulative Recruitment Summary (Appendix 9-21): This report will provide the cumulative totals for each SC for total mailed, total eligible, total ineligible (by reason), and total enrolled. This report is available to all SCs, the CC and NCI.
- Exam Results Sent Report Summary (Appendix 9-22): This report provides weekly totals for each SC for the number of results sent to participants, sent to physicians, and pending. This report is available to all SCs, the CC and NCI.
- Summary Data Receipt Report (Appendix 9-23): This report summarizes the receipt of exam forms (SCT or XRY2), DE forms and HAQ forms for each SC. If a form or an MDF for that form was not receipted, it will be shown as pending. This report is available to all SCs, the CC and NCI.

APPENDICES FOR CHAPTER 9