2. RECRUITMENT, ELIGIBILITY DETERMINATION, INFORMED CONSENT AND RANDOMIZATION

2.1 Overview

Each Screening Center (SC) will be responsible for identifying and recruiting participants into the study. Once potential participants are identified, the SC will collect information about them to make a determination of their eligibility for the study. Potential participants who are eligible for and are interested in the study will be asked to sign an informed consent with subsequent enrollment into the study. The SC will track potential participants from the time they are identified until they are enrolled, or not enrolled. Each SC will document and report a summary of recruitment and enrollment progress. These activities are discussed in more detail in the sections that follow.

2.2 Recruitment Materials

To aid in the recruitment process, the Coordinating Center (CC) will develop the following recruitment materials that can be provided to potential participants: introductory letter (including the "Who Can Participate" Sheet), fact sheet, and reply card. The purpose of these materials is to provide potential participants with information about the study that will allow them to determine whether they may be eligible for and are interested in the study. Additionally the materials will request their participation.

The introductory letter (including the "Who Can Participate" Sheet) is presented as Appendix 2-1. The letter should be copied onto SC stationery and signed by the principal investigator at each SC. The fact sheet describes the study and the key eligibility criteria and is presented in Appendix 2-2. The reply card will allow potential participants to indicate their interest in the study and is shown in Appendix 2-3.

To provide potential participants with a better understanding of the study, the following will be explained in one or more of the introductory materials (letters, fact sheets, etc):

- Legislative authority;
- Purpose of the study;
- Voluntary nature of any response;

- Extent of confidentiality of information;
- Time period for maintenance of records;
- Disposal of records; and
- Consequences of not responding.

Appendix 2-4 of this manual contains answers to typical questions potential participants or other persons may ask about the Lung Screening Study. These questions and answers are an additional resource to be utilized in recruitment and any development of additional recruitment materials. These materials are solely for the use of SC staff and should not be distributed to participants.

The CC-provided recruitment materials should be used as they are presented by the CC. Any modifications to CC-provided recruitment materials as well as additional recruitment materials that the SC may develop must be approved by NCI in advance of their use in the study.

2.3 Identifying Potential Participants

The SCs will begin recruiting participants on September 1, 2000. The total study goal is to recruit 3,000 participants by October 31, 2000 at six SCs. Individual SC recruitment goals will be determined by the NCI. In order to meet recruitment requirements, the SCs will conduct mass mailings of the recruitment materials. The SC may contact PLCO ineligible participants but should not rely on these as the sole target of their mailings. Mass mailings may utilize but are not limited to the following address lists: Department of Motor Vehicle listings, local hospital and HMO databases, voter registration lists, and the HCFA database. It is anticipated that the enrollment yield from a mass mailing will be approximately 0.3%. For example, to recruit approximately 500 participants, it is estimated that a SC will need to mail out approximately 166,000 recruitment packets. The eligibility criteria for the Lung Screening Study targets a retirement age population that tends to travel for extended periods of time. If such travel is expected among individuals living in the geographical area in which the SC recruits participants, there is a need to increase mailing size to meet recruitment goals. During the recruitment phase, the SC may also concurrently utilize public service announcements with local TV and radio stations. The content of all such public service announcements must be approved by NCI in advance of their use.

2.4 Eligibility Determination

Potential participants will indicate interest by returning the reply card or contacting the SC by telephone. When potential participants contact the SC by telephone, the Eligibility Screener (ES) will be completed at that time to determine whether a potential participant is eligible. The SCs should inform potential participants of the screening time period before administrating the ES. If a potential participant is not available for screening during the screening period, the SC should not attempt to recruit the individual into the study. When potential participants contact the SC by reply card, the SC will call each individual to administer the ES by telephone. A copy of the ES is presented in Appendix 2-5. The ES will ask potential participants information related to all the eligibility and exclusion criteria, including the following: date of birth, smoking history, history of spiral CT scan of the lungs or chest, history of lung cancer or removal of any portion of the lung, current cancer treatment, prior enrollment in PLCO or any other cancer screening study, and participation in a primary cancer prevention study other than a study of smoking cessation. The SC will also respond to any questions regarding the study. If the potential participant is unsure of lung cancer history or history of spiral CT scan, the SC should request that s/he contact his/her physician to obtain the information.

A potential participant will be considered eligible for the Lung Screening Study if s/he meets all of the eligibility criteria described below:

1. Individuals who at the time of randomization are at least 55 years of age but no more than 74 years of age.

2. Individuals who are smokers or individuals who are former smokers and have quit smoking within the last 10 years.

3. Individuals who have smoked no less than 30 pack years (equivalent to an average of at least 20 cigarettes per day for 30 years).

A potential participant will be considered ineligible for the Lung Screening Study if s/he meets one or more of the following exclusion criteria:

1. Individuals who have had a spiral CT scan of the lungs or chest within the past 24 months.

2. Individuals who have been diagnosed with lung cancer.

3. Individuals currently undergoing treatment for any cancer other than non-melanoma skin cancer.

4. Individuals with a previous history of removal of any portion of the lungs.

5. Individuals who are unwilling or are unable to sign the consent form.

6. Individuals who are participating in another cancer screening trial, including PLCO.

7. Individuals who are participating in a primary cancer prevention trial other than a study of smoking cessation.

The determination of eligibility will be made using the ES. In addition to questions related to the eligibility criteria, the ES will collect gender information. Specifications for completion of the ES are given in Appendix 2-6. It is not necessary to verify information recorded on the ES, except for non-participation in PLCO, with any source other than the potential participant. A potential participant's name and date of birth must be checked against the PLCO roster at some point during eligibility determination. Self-report alone is not sufficient.

The administration of the ES may be ended as soon as the potential participant is deemed ineligible.

When the ES is completed, the SC staff will perform the following tasks:

- The ES will be reviewed to determine whether the potential participant meets eligibility criteria on the form. If an individual does not know whether or not s/he meets one or more of the eligibility criteria, s/he should be asked to contact his/her physician to obtain the information. If the individual refuses or does not have a physician, or if after contacting the physician, s/he still does not know, s/he is not eligible for the study.
- The date the ES was completed will be recorded as well as selected demographic information in the potential participant's tracking record (See Section 2.8 for information on maintaining tracking records).
- If the potential participant is determined to be ineligible based on one or more of the eligibility or exclusion criteria, the SC staff will record the potential participant's status as "ineligible" on the tracking record.
- In some cases, the SC will determine that a person is potentially eligible, but for some other reason such as a language barrier, the principal investigator may recommend disqualification. The status of these potential participants will be recorded as "unable to be determined or other" on the tracking record.
- The ES for potential participants, with whom the SC has had contact but are not enrolled in the study, will be kept on file at the SC throughout the study. The ES for participants who are enrolled in the study will be kept in each participant's study folder.

If a potential participant has not been randomized within one month of eligibility determination, it is advisable to make a second determination of eligibility before randomizing the participant. If determined to be eligible, the next step is to collect a signed informed consent.

2.5 General Procedures for Obtaining Participant Informed Consent

Human research subjects are protected by informed consent procedures. The signing of an informed consent form is a criterion for eligibility to participate in the Lung Screening Study. Each Screening Center (SC) will determine the eligibility of the potential participants and will obtain their consent before enrolling them in the study.

The informed consent form addresses four major protections:

- Each participant must be fully informed of all study procedures and requirements in order to be considered a "knowing" participant;
- The study design must minimize risks to the participants and maximize the benefits;
- The study participants must be selected in a non-discriminatory way so that no class of individuals will benefit more than any other based on the selection procedures; and
- Participation is voluntary and all information provided by participants will be kept confidential.

The SC Coordinator will be formally responsible for ensuring that written informed consent to take part in the study is obtained from each participant. In addition, the Institutional Review Board (IRB) at each SC must approve the informed consent form and procedures. SCs recruiting non English-speaking individuals (or individuals who have very little knowledge of the English language) must submit to the NCI documentation of IRB approval to administer an English language Lung Screening Study consent to non English-speaking individuals.

In the development of its own informed consent, each SC will use the prototype (Appendix 2-7) as a guide. All information in the prototype informed consent must be included in the individual SC forms. Additional information may be added based on individual IRB requirements, but required information may not be excluded from the form. Any changes made by the IRB will be submitted to the NCI for review.

The method of administration of the informed consent may vary by SC. The SC will obtain a signed consent by one of the two following methods:

Method A – After completing the ES by telephone, the SC will mail out a copy of the informed consent with a cover letter (Appendix 2-8) to eligible participants. Participant questions regarding the content of this document will be clarified via a telephone call. Once the potential participant has returned a signed consent, the SC will complete an Eligibility Verification Form and enroll the participant into the study. (See Section 2.6 for more information on completing the Eligibility Verification Form.). The SC will then contact the participant and schedule the screening visit.

Method B – After completing the ES by telephone, the SC will invite interested and eligible participants for a clinic visit. The SC will schedule the visits for small groups. At that time, the SC will make a presentation providing additional information about the study and the informed consent and answering questions. The SC will complete an Eligibility Verification Form and enroll those individuals who sign the consent into the study. Depending on his/her individual schedule, the participant will either complete the screening exam after the presentation or will schedule a screening visit.

Regardless of the method, administration of the informed consent should occur after the participant has been provided with background information about the study and its requirements. This information will likely include the introductory letter (including the "Who Can Participate" Sheet) (Appendix 2-1) and fact sheet (Appendix 2-2), and a conversation with the SC Coordinator. The requirements of the study, the implications of randomization and the necessity for completing the required procedures should be emphasized with each potential participant.

When the informed consent is provided to the potential participant, s/he must be offered sufficient time to carefully read the document and must be given sufficient opportunity to have all questions regarding the study answered before s/he is asked to make a decision on enrollment.

IRB requirements regarding the need for a witness to sign the consent, in addition to the participant, will vary. The participant will be given a copy of the informed consent after it is signed. The original will be kept in the participant's file at the SC.

2.6 Assignment of Participant Identification Number/Verification of Eligibility

The Participant Identification Number (PID) is a unique 6-digit number that will be used throughout the study period to link all data associated with an individual. It is part of a common system for reporting to the CC and will be used by all SCs. The CC will assign PID ranges to individual SCs and distribute PID labels prior to the start of the study.

The CC will produce barcoded PID labels for each SC. SC personnel will affix a PID barcoded label to the EVF at the time of eligibility verification, prior to randomization. This will link the PID to the identifying information for each potential participant.

The eligibility of potential participants will be verified using the Eligibility Verification Form (EVF) presented in Appendix 2-9. The EVF collects selected demographic information such as name, date of birth, and gender, and verifies that potential participants meet all of the Lung Screening Study eligibility criteria. The SC Coordinator will use information from the ES and the informed consent to complete the EVF. The form must be completed and retained for all participants randomized into the study, but need not be completed for individuals who are found to be ineligible for the study.

The administrative section and Part A of the EVF will be completed prior to randomization. In the administrative section at the top of the form, the SC Coordinator will record the SC identifiers and the potential participant's name and date of birth and will affix a PID label as a unique study identifier. In Part A, s/he will confirm each eligibility and exclusion criterion by checking "Yes" or "No" in response to each question. Additionally, s/he will include smoking history information from the ES. Refer to Appendix 2-10 for detailed instructions on completing the EVF. In order for a participant to be successfully randomized, the answer to each question in Part A of the EVF must be "No." If any "Yes" boxes are checked, the potential participant is not eligible for the study and cannot be randomized. Reason for ineligibility will be recorded on the potential participant's tracking record, if not previously recorded. If it is discovered at the time of EVF completion that the potential participant is ineligible, the EVF should be filed with the ES. SCs will send a copy of the EVF without identifiers to the CC for any manual randomizations. Instructions for completing the manual randomization process are described in the *LSS Web-Based System User Guide Version 1.0*, Section 2.2. It is expected that completion of an EVF for an ineligible individual will be a rare occurrence.

2.7 Randomizing and Enrolling the Participant

Once the EVF has been completed, the potential participant is ready to be randomized to either the spiral CT or the chest X-ray study group. After potential participant eligibility has been verified at the SC, a randomization request should be made to the central randomization program. Each SC must designate the SC Coordinator (and a backup staff member) responsible for placing randomization requests, and will provide the PLCO staff IDs of these individuals to the CC. The CC will check the staff ID and only accept randomization requests from these designated personnel.

Westat will perform randomization using a centralized computer randomization system located on a secure web server with restricted access. This site will be accessible 24 hours per day, and will utilize an Internet Services Provider (ISP) at each SC. Such a configuration employs current, proven Internet infrastructure and is the most economical solution for real-time, reliable access to a centralized computer server.

As part of the randomization process, the program will ask the designated representative of the SC to enter the date of birth, gender, and three initials of the potential participant's first, middle, and last name and to wand in the barcoded PID. The user must zero-fill the day and month on the date of birth. It is quite easy to enter a "1" instead of "11", for example. Since the date of birth is used as one of the stratification variables in assigning the randomization group (spiral CT or X-ray), it is very important that the SC make every effort to be sure this information is correct. If the potential participant does not have a middle initial or name, the SC will enter the first two (2) letters of the first name followed by the first initial of the last name. Additionally, the randomization system will confirm eligibility, minimize duplication, and randomly assign participants to one of two study groups (spiral CT or chest X-ray) in a 1:1 ratio, stratifying on gender and age group within SC, as specified by NCI.

Each SC will be provided with a Westat-owned laptop computer equipped with the hardware and software required for accessing and using the central eligibility verification and randomization system at the CC. Use of the CC provided laptop assures that access to the Lung Screening Study web-based site is secure from outside, unauthorized intrusion and that the participant's private information is adequately protected. In addition, the CC can more efficiently support the web-based software by simply sending a replacement laptop in the event of software failure at one of the SC sites.

The CC will load Microsoft Office on the laptops for general use by SCs. To ensure operation of the laptop during the randomization period (September 1 – October 31), the SCs should not load any additional programs. The CC is taking this precaution to avoid program malfunctions or configuration changes that might cause the laptop to be unavailable for randomization. After October 31, the SCs can add other programs to the laptops to assist them in managing the study. A few notes, however, regarding SC-provided software:

- The SC is responsible for acquiring software licenses and ensuring that current licenses are obtained for any software loaded.
- The SC is responsible for backing up any software and data files that were not provided by the CC.
- If a laptop malfunctions, the CC maintenance plan is to replace the laptop within 24 hours of the report. The SC should ship the problem laptop back to the CC. The CC cannot ensure that any data the SC has on the laptop will be retrievable, but will do the best to help out. Please note that if the SC is keeping any confidential or sensitive data on the laptop, the CC will usually not attempt to retrieve it. The CC does not have IRB approval to access any confidential data for this study and will usually simply erase the disk when it is returned. Note that this also means the new laptop that is sent to the SC will not have SC software pre-loaded. The SC will have to reload it on the new equipment.
- The laptops are the property of CC and will be returned to the CC at the end of the study. The SC is responsible for ensuring that all licensing agreements are met, including removal of any software that it has loaded.

The SCs will need a dedicated phone line (not a rollover number or shared telephone line) and a printer to connect to the CC laptop. Each SC will also need to use an ISP service. If a SC does not have an ISP, the CC will procure one for them for the duration of the study. Upon completion of the study, all laptop computers will be returned to the CC. A user manual describing how to use the web site for randomization and report generation will be provided to each SC.

The Web-based randomization system will require the SCs to enter a valid staff ID to enter the system. Then the staff member will be asked to enter the pre-assigned PID affixed to the EVF, three initials representing the first character of the potential participant's first, middle and last names, date of birth and gender as they appear on the EVF. If a potential participant does not have a middle name, the second letter of his/her first name will be used. Whenever possible, the PID should be scanned using the barcode scanner rather than typed in by hand. If the SC does not have access to a bar code reader or wand, the SC needs to contact NCI to make arrangements to obtain this equipment. This will ensure a high level of accuracy for entry of the PID during randomization. After these data items are entered, the randomization program will check for the existence of the PID in the database. If found, the SC will be

notified that this PID is already in use and they will have to assign another PID. If the PID is not found, the system will check each participant's three initials in combination with their date of birth and gender. If this combination is found, the SC will receive a warning message to verify the correct data was entered. The SC staff will then have a choice to either correct the data, cancel the current participant randomization or, if all data is correct, continue with the randomization for the current potential participant.

To continue the randomization, the SC staff person will proceed to enter into the randomization system the relevant data items from the EVF. When data entry is completed and the SC staff person clicks the "Verify Eligibility" button, the program will automatically check that:

- the potential participant's age is between 55 and 74 years by calculating current age from today's date and the date of birth entered;
- none of the eligibility criteria questions has a response of "Yes" checked; and,
- the potential participant does not have fewer than 30 pack-years of tobacco exposure by running the smoking exposure algorithm to verify the SC calculations are correct.

If any errors are found in the eligibility verification, the SC will be notified of the question(s) and/or calculations that do not meet the eligibility criteria. The SC will be given an option to correct the data or cancel the current participant randomization to perhaps verify data via the participant's folder or with him/her personally. Under no circumstances will the SC be allowed to randomize a participant whose eligibility information does not pass all the eligibility checks of the randomization system. If the potential participant is determined to be ineligible, the PID assigned on the EVF form may not be re-used for another participant; this PID will be "skipped." The SC must send a copy of the EVF, minus the identifying information, and all remaining PID labels for that number to the CC to allow tracking of all unused PIDs.

If the eligibility verification is satisfied, the participant will be randomized to either the spiral CT or the chest X-ray group. The system will display a randomization screen confirming the PID, initials, date of birth, gender, randomization group, and date randomized. The SC will receive a system message reminding them to PRINT this confirmation screen to keep in the participant's folder. If the printer is unavailable, the SC staff member will copy this information from the screen onto the EVF and print this confirmation screen at a later date.

No PID, once assigned, will be changed or reassigned to another participant. If the participant is found to be ineligible after the PID has been assigned, the PID will not be reassigned. Similarly, should a participant move to a new SC area during the study, the PID will not be changed. This policy ensures that data associated with a participant will not be lost or inadvertently attributed to another participant.

2.7.1 Notifying Participants of their Group Assignment

After a participant is enrolled in the study, each participant will be notified of his/her group assignment by mail, by telephone, or in person. Additionally, a screening examination (spiral CT or chest X-ray, depending on study group) will be scheduled either in person at the time of this notification, or as soon after randomization as possible, if notification is performed via telephone or mail.

2.7.2 Randomization in the Event of Server Failure

All Web servers are physically located in a secure, locked room at the Rockville, MD campus of the CC. There are safeguards against fire, and secured access with password protection and file encryption is enabled to ensure only authorized access to systems and data. The servers are located off the "Demilitarized Zone" (DMZ) of the CC's internet firewall which offers protection against protocols (e.g., FTP), and access to the Web that is not required for the application.

All servers are dual-mirrored drives or random arrays of inexpensive disk (RAID). These configurations protect the server systems and data in the event of an isolated primary disk failure, a second disk will immediately take over operations without loss of data. The servers are backed up incrementally each night (only files that have been modified are included) and a full system and data backup is performed every week. The CC has off-site storage facilities to assist in the recovery of systems and data should a natural disaster destroy the hardware and software at the CC.

Production servers are accessible 24 hours a day, 7 days a week. The CC does not have on-site support at all times but does utilize a monitoring program to alert and contact relevant staff in case the production server fails. The CC also maintains spare servers if a swap or replacement server is required, and maintains a fractional T3 (6 megabits per second) communications line with a permanent backup T1 that will automatically become active upon a failure of the T3.

Alternative steps for randomization may need to be taken if the SC cannot contact the randomization system at the CC. Examples include severe weather conditions at either the CC or SC, disruption of telephone or ISP service at the CC or SC, in addition to an unexpected downing of the server. The CC will maintain a Web service advisory (voice) line that will inform the SCs when service is expected to be restored, if the problem is at the CC. If the problem is not at the CC, the message on this line will also advise the SC to contact the CC immediately and instructions will be provided.

User support will be available to the SCs during normal business hours, as well as on the weekends should the SCs require help. Before September 1st, each SC will be given a separate phone number and procedures to page the CC user support personnel. This number will also be posted on the recording of the user support voicemail system. The SC may dial the number, enter a phone number where they can be reached, and user support will return the call.

The SCs should confine off-hour questions to emergencies that prevent conducting randomizations. As a reminder, each SC has a manual backup for the randomization process, for emergency use only. For instructions on the manual randomization process, please refer to the *LSS Web-Based System User Guide Version 1.0*, Section 2.2. If the SC chooses to randomize the person(s) manually without discussing the situation with user support, the SC should leave a message on the user support line detailing the problem. This will ensure that the problem is investigated and addressed immediately during regular hours.

2.7.3 Randomization Errors

The randomization process carries the potential of randomization errors. These may include:

- randomizing a participant twice;
- randomizing a participant who is not eligible for the study.

Both of these errors are protocol violations and should be documented appropriately, either with an Administrative Tracking Form or a SC Report of Protocol Violation (see Sections 9.4 and 9.5). The CC must be contacted in either case for correction in the central study database.

2.8 Tracking Potential Participants and Enrollees

The SCs will track potential participants from identification through the recruitment and enrollment process to document either their entry into the study or their reason for non-participation. Documentation of tracking efforts is critical for the management of the recruitment process and is useful as a tool for the evaluation of the recruitment effort. Each SC will record recruitment data in a manner that allows for easy retrieval in the future.

Each SC will have a system, manual or automated, for tracking potential participants. This system will include at the minimum, a tracking record for each potential participant for whom the SC has completed or attempted to complete an ES. For SCs using mass mailing, summary totals of potential participants listed on mass mailing lists should be maintained. When an individual responds to the ES, a tracking record should be created for that individual in the SC's active recruitment system. The following information, some of which will be required in reports of recruitment efforts, should be included in the tracking record:

- Full name,
- Date of birth,
- Gender,
- Address (including zip code),
- Telephone number,
- Date Eligibility Screener was completed,
- Recruitment status, and
- Reason for ineligibility.

The valid reasons for ineligibility will be based on the eligibility and exclusion criteria. For documentation purposes, only one reason for ineligibility need be coded. If the potential participant does not meet more than one eligibility or exclusion criterion, then the first reason for ineligibility encountered should be documented.

All potential participants who are contacted are initially recorded in the SC tracking database as "Eligibility Pending." As recruitment progresses, each of these pending individuals will be updated to a final recruitment status as follows:

Eligible (E): A potential participant should be classified as "eligible" if s/he meets all of the eligibility criteria.

Ineligible (I): A potential participant should be classified as "ineligible" for one of the following three reasons:

1. The potential participant reports that s/he has had a spiral CT scan of the lungs or chest within the past 24 months.
2. The potential participant does not meet one or more of the eligibility criteria #1, #2 or #3 (see Section 2.4) or meets one or more exclusion criteria #2, #3, #4, #6 or #7 (see Section 2.4).
3. The potential participant refuses or is unable/unwilling to sign the informed consent.

Unable to Determine (U): A potential participant should be classified as "unable to determine" if s/he responds to a mass mailing or telephone contact but does not have eligibility determined (due to lack of interest or some other reason), or if the PI determines that s/he should not be randomized for reasons other than provided by the eligibility and exclusion criteria, such as a language barrier.

Randomized (R): A potential participant should be classified as "randomized" if a participant meets all the eligibility criteria and is randomized into the study.

Tracking records must be maintained either individually or as part of a log. A sample potential participant tracking log, containing tracking records for several individuals is included as Appendix 2-11. Such a log may be maintained manually or on a computerized tracking system. Summary information regarding potential participants listed on mass mailing lists should also be maintained manually or on a computerized tracking system. The sample tracking log is for use by each SC to aid its tracking of participants. Completed copies should not be sent to the CC.

2.9 Summarizing and Reporting Recruitment and Enrollment Efforts

Each SC will summarize and report the status of its recruitment efforts to the CC. As noted earlier, the purpose of reporting summary recruitment data is to enable the NCI to monitor recruitment. The following recruitment data will be summarized and reported to the CC on a weekly basis:

Total Number of Recruitment Packets Mailed:

This refers to the cumulative number of persons identified for possible participation in the study through the current week. This number will include the total number of persons that were sent the recruitment packet through mass mailings.

Total Number of Eligible:

This is the cumulative number of potential participants to whom the ES was administered and was determined to be eligible through the current week.

Total Number of Ineligible:

This is the cumulative number of potential participants who were determined to be ineligible through the current week. The SCs should report reasons for ineligibility as follows:

1. Has had a spiral CT exam within the past 24 months,
2. Does not meet eligibility criteria #1, #2, and #3 (see Section 2.4) or meets one or more exclusion criterion #2, #3, #4, #6, and #7 (see Section 2.4.), or
3. Unable or unwilling to sign the consent form

Total Number of Unable to Determine:

This is the cumulative number of potential participants for whom eligibility could not be determined. This includes:

- Individuals who responded to a recruitment mailing or a telephone contact but did not complete an Eligibility Screener (due to lack of interest or some other reason),
- Individuals for whom the PI determines that s/he should not be randomized for reasons other than provided by the eligibility and exclusion criteria, such as a language barrier.

Total Number of Participants Randomized:

This is the cumulative number of potential participants who were found to be eligible, were willing and able to sign the informed consent, and were subsequently randomized into the Lung Screening Study to date. This number should be less than or equal to the "Total Eligible."

On a weekly basis, the SC Coordinator will summarize recruitment data at the close of business each Thursday according to the categories outlined above and will keep a record of these summary data. The SC Cumulative Recruitment Summary Form (Appendix 2-12) will be faxed to the CC every Monday by 10:00 a.m. eastern time. If the SC anticipates being unable to fax the form on Monday, it should be faxed the preceding Friday. If Monday is a study holiday, the form should be faxed on Tuesday. Specifications for completing the SC Cumulative Recruitment Summary Form are included in Appendix 2-13.

It is the SC's responsibility to track the total number of individuals to whom recruitment packets were mailed and to reduce duplication as much as possible. The SC should also track the response rate to mailings.

2.10 Monitoring Recruitment and Enrollment Efforts

The SC Coordinator will monitor recruitment against the SC's contract commitments to the NCI. This monitoring activity will enable the SC Coordinator to identify any problems with recruitment and to redirect recruitment resources, if necessary. The following report will be used for monitoring recruitment.

The Cumulative Recruitment Summary Report (Appendix 9-21) will be produced by the CC and will be based on the information transmitted to the CC on the SC Cumulative Recruitment Summary Form. This report will be posted every Wednesday on the designated CC Web site. The report will show the following summary totals for the project to date:

Total Recruitment Packets Mailed

Total Eligible

Total Ineligible

- CT Scan within 24 months
- Other Reasons
- Unable/unwilling to sign consent

Total Unable to Determine Eligibility

Total Eligibility Pending

Total Participants Randomized

- Spiral CT
- Chest X-ray

The Cumulative Recruitment Summary Report will enable the SC Coordinator to monitor the number of potential participants whose eligibility is pending. This number represents "work in process" for the SC recruiting staff. The SC can compare the report posted on the web site to the previous week's report to monitor and track recruitment data.

Appendices for Chapter 2

2.1 Sample Introductory Letter

2.2 Fact Sheet

2.3 Sample Reply Card

2.4 Answers to Potential Participant Questions

2.5 Eligibility Screener (ES)

2.6 Specifications for the Eligibility Screener

2.7 Informed Consent

2.8 Informed Consent Cover Letter

2.9 Eligibility Verification Form (EVF)

2.10 Specifications for the Eligibility Verification Form

2.11 Sample Participant Tracking Log

2.12 SC Cumulative Recruitment Summary Form

2.13 Specifications for the SC Cumulative Recruitment Summary Form

Appendix 2-1

Lung Screening Study
Sample Introductory Letter

(Date)

(Participant Name)
(Participant Address)
(City, State, Zip Code)

Dear *(Participant Name)*:

The National Cancer Institute (NCI) and *(Screening Center)* are sponsoring a nationwide study of older Americans who have a history of long-time and/or heavy cigarette smoking. The study is called the Lung Screening Study and the cancer being studied is lung cancer. The purpose of the study is to determine the ability of screening spiral CT (low radiation-dose computed tomography) to detect lung cancer relative to screening chest X-ray in men and women ages 55-74.

We would like to ask for your participation in this important study. Enclosed is a fact sheet that provides further details about the study. Please look at the "Who Can Participate?" sheet in this package to determine whether you might be eligible.

Let us assure you that your participation is voluntary, and there are no penalties for not participating or for withdrawing from the study at any time. Participation will not influence your relationship with *(Screening Center)*, its staff, or with any federal program such as Social Security or Medicare. If you do participate, all of the information you provide will be kept confidential and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. No names or other identifying information will appear in any report of the study. The information will be combined for all study participants and reported as statistical summaries. Study records will be kept for approximately 7 years and then destroyed.

For your information, this study is authorized by the Public Health Service Act, Section 412 [42 USC 285 a-1], and your rights as a study participant are protected by the Privacy Act of 1974.

If you are interested in the study, please return the enclosed reply card or contact me or my colleague, *(Name of Screening Center Coordinator)* at *(telephone number)*. If you have questions, feel free to contact either of us.

We hope you will consider participating in this important study.

Sincerely,

(Name of Investigator)

WHO CAN PARTICIPATE?

You may be eligible to participate in the Lung Screening Study if:

- You are between the ages of 55 and 74 years.
- You are currently a smoker or have quit smoking within the last 10 years.
- You have a history of long-time and/or heavy cigarette smoking (30 pack-years), for example:

  -at least 1 pack a day for at least 30 years
  -at least 1 1/2 packs a day for at least 20 years
  -at least 2 packs a day for at least 15 years
  -at least 2 1/2 packs a day for at least 12 years
  -at least 3 packs a day for at least 10 years

- You have NOT been diagnosed with lung cancer.
- You are NOT currently undergoing treatment for any cancer other than non-melanoma skin cancer.
- You do NOT have a history of removal of any portion of your lung.
- You are NOT participating in another cancer screening trial, including PLCO.
- You are NOT participating in a cancer prevention trial, other than a trial to help you stop smoking.

If you think you may be eligible to participate in this study, please return the enclosed reply card or contact us at [*SC telephone number*].

Appendix 2–2

Lung Screening Study

Fact Sheet

National Institutes of Health, National Cancer Institute

- **What is the Lung Screening Study?**

The Lung Screening Study is a national health study to determine the lung cancer detection capability of spiral CT and chest X-ray technologies. The study, sponsored by the National Cancer Institute, will involve approximately 3,000 people between the ages of 55 and 74, recruited from centers across the nation.

- **Why is this study being conducted?**

  Lung cancer is a serious disease. Each year, over 150,000 men and women die from lung cancer. The Lung Screening Study is designed to evaluate the ability of screening spiral CT to detect lung cancer relative to screening chest X-ray in men and women. Results from this study will enable the National Cancer Institute to determine whether further study of the spiral CT examination should be conducted, and the feasibility of studying this screening examination on a larger scale.

- **Who can participate?**

  Women and men between the ages of 55-74 can participate. You may be eligible if you meet the following criteria.

  1. You are between the ages of 55 and 74 years.
  2. You are currently a smoker or have quit smoking within the last 10 years.
  3. You have a history of long-time and/or heavy cigarette smoking (30 pack-years), for example:
     -at least 1 pack a day for at least 30 years
     -at least 1 1/2 packs a day for at least 20 years
     -at least 2 packs a day for at least 15 years
     -at least 2 1/2 packs a day for at least 12 years
     -at least 3 packs a day for at least 10 years
  4. You have not been diagnosed with lung cancer.

5. You are not currently undergoing treatment for any cancer other than non-melanoma skin cancer.
6. You do not have a history of removal of any portion of your lung.
7. You are not participating in another cancer screening trial, including PLCO.
8. You are not participating in a cancer prevention trial, other than a trial to help you stop smoking.

- **What will I be asked to do if I decide to join?**

  If you are eligible and you decide to join, you will be asked to undergo either a spiral CT (low radiation-dose computed tomography) examination or a chest X-ray as a screening test for lung cancer. You also may be asked to fill out a brief questionnaire 6 months following this screening examination.

- **What is a screening test?**

  A screening test is a medical examination used to look for disease. Screening tests for cancer are used to detect cancer before any symptoms are present. In the Lung Screening Study, screening tests will include either a spiral CT or a chest X-ray.

- **Are the tests free?**

Yes. For all participants in the Lung Screening Study, there will be no charge for the screening tests. Results will be shared with you and your personal physician. Additional medical tests and procedures will be the responsibility of the study participant and his/her insurance company.

NO POSTAGE
NECESSARY IF
MAILED IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO 2926
BIRMINGHAM AL
POSTAGE WILL BE PAID BY ADDRESSEE

SCREENING CENTER
<<Address>>
<<City, State Zip>>

Reply today:

I am interested in learning more about participation in the Lung Screening Study. Please contact me:

Name:_____

Address:_____

City:_____State:_____Zip:_____

Daytime phone:_____

Evening phone:_____

Best time to call you: _____

Remember, you must be between the ages of 55 and 74.

Appendix 2–4

Lung Screening Study
Answers to Potential Participant Questions

Participation:

1. Why should I participate?

The study is designed to determine the capabilities of spiral CT and chest X-ray technologies to detect lung cancer. In order to answer this question, the participation of many people in your community is important. By participating, you will help determine the ability of these two procedures to detect cancers.

2. Why should I participate if I don't get the Spiral CT screening test?

By participating you will make an important contribution to lung cancer research. Lung cancer remains the chief cause of cancer death in men and women. We don't know whether the spiral CT is useful in detecting lung cancer. To determine whether or not it is useful, it is important to compare the participants who receive the spiral CT according to the study protocol to a very similar group of study participants who receive chest X-rays. Therefore, persons who receive chest X-rays play a critical role in this study.

3. What other hospitals are in the study?

Six Screening Centers from different areas in the country will participate in the study. The Screening Centers include the following:

- Georgetown University Medical Center, Lombardi Cancer Research Center
- Henry Ford Health System
- University of Minnesota School of Public Health/Virginia L. Piper Cancer Institute
- Washington University School of Medicine
- Marshfield Medical Research and Education Foundation
- The University of Alabama at Birmingham

4. I had a bad experience with the hospital/the government lately, why should I help them?

I'm sorry that your experience was not good. However, this is a special research study sponsored by the National Cancer Institute. We are committed to making your participation in this study a positive experience. By participating in the study you are helping us to learn more about the ability of the spiral CT and chest X-ray screening tests to detect lung cancer at an early stage.

5. How will I benefit from the study?

We don't know if you will personally benefit but if the study shows that the spiral CT screening test is effective, then this type of screening for lung cancer may become common practice in the future. If this study shows that this screening test does not improve detection, doctors will know not to use it, saving you and others unnecessary inconvenience and expense.

6. Are there any downsides to participating?

There are certain risks that might be associated with the screening procedures.

- A small amount of radiation is received as part of the spiral CT. This amount is similar to the amount received from a mammogram and poses no measurable risk. A small amount of radiation is also received as part of the single-view chest x-ray. This amount is smaller than the amount received from a normal chest x-ray and poses no measurable risk.
- It is possible that the screening spiral CT or single-view chest x-ray may falsely suggest that you have cancer. In this case, it is possible that you may suffer pain, anxiety and expense that could have been avoided if you had never undergone the screening test.
- It is possible that diagnosis (and treatment) of cancers detected in this study may not prolong your life and may result in medical complications.

Eligibility:

1. Am I eligible to participate in this study even though I have _____ (another serious medical problem which is not an exclusion criteria)?

If the medical problem would not interfere with your ability to participate in the screening exam, and if it were acceptable to your doctor and to [PI] here at [SC] who is directing the study, you would be eligible to participate.

2. If I have _____ (symptom) am I still eligible for the study?

[If a potential participant reports a symptom, s/he should be advised to make an appointment with a doctor so that the symptom can be evaluated. The potential participant should be asked to contact the SC after the medical evaluation so that eligibility may be determined.]

3. If I recently had _____ (lung exam), am I still eligible for the study?

[If the screening examination was a spiral CT performed in the last 24 months, then explain to the potential participant that s/he is not eligible for the study. If it was some other test, the Coordinator might ask what the result was, and if normal s/he is eligible. If result was abnormal and s/he is currently undergoing diagnostic work up, s/he should contact the SC when results of the work up are known.]

4. I'm (54 years old/75 years old) why can't I be in the study?

We are sorry that you cannot participate. The best way to conduct a study like the Lung Screening Study is to examine people with a similar chance of being diagnosed with the disease under study. By including people between 55 and 74 years old, we have identified a group of people at similar risk of lung cancer.

5. I am not a smoker, or have only lightly smoked in my lifetime, why can't I be in the study?

We are sorry that you cannot participate. The best way to conduct a study like the Lung Screening Study is to examine people with a high chance of being diagnosed with the disease under study. By including heavy smokers, we have identified a group of people at high risk for lung cancer.

Screening:

1. Who will be conducting these tests? Are they qualified?

The tests will be conducted by qualified hospital/clinic staff: doctors, and X-ray technologists. These individuals have been trained and have experience conducting these tests.

2. Is the spiral CT or chest X-ray painful?

Most people do not find these tests to be painful or uncomfortable. A trained medical professional will tell you exactly what to expect before the exam is given and will work with you to ensure a pleasant experience.

3. Will you screen my husband/wife/relative/friend?

If your husband/wife/relative/friend is interested in participating in the study, s/he should call the recruitment coordinator [appropriate person at SC] to determine if s/he is eligible. Remember that an eligible participant has an equal chance of being assigned to either the spiral CT group or the chest X-ray group. If assigned to the spiral CT group, your husband/wife/relative/friend would receive the spiral CT test; if assigned to the chest X-ray group, your husband/wife/relative/friend would not receive the spiral CT test.

Screening Test Results:

1. If my test results are abnormal, does that mean I have cancer?

Not necessarily. An abnormal screening test result usually means that further information is needed before a diagnosis can be made. Screening tests do identify cancer, but they also identify other conditions, some of which are harmless. All participants with test results which are suspicious for cancer will be referred to their doctor for diagnostic evaluation.

2. I don't have a doctor. Who will get my test results?

All test results will be sent to you and to the doctor of your choice. If you do not have a doctor and you have an abnormal test result, we will be happy to refer you to a doctor here at [SC associated hospital].

3. Can I have the results of my test?

Yes. Your test results will be sent to you within 3 weeks of your screening exam.

4. If something abnormal is found, do I have to go to a doctor here, or can I go to my own doctor?

You may go to the doctor of your choice. All test results will be sent to your doctor. If you would like to be referred to a doctor here at [SC], we will be happy to give you a referral list of recommended doctors.

5. Who will see the results of my tests?

You and the doctor of your choice will be notified as to whether the results of your test are normal or abnormal. Results will be seen by certain study personnel. All study personnel must conform to the hospital and federal regulations regarding confidentiality. They must keep all information provided by study participants and all test results confidential.

Diagnostic Evaluation:

1. Will you recommend specific diagnostic examinations if abnormalities are detected on the screening exams?

Although we will not recommend specific diagnostic examinations, we will be happy to assist you in any way possible to obtain the best medical care. We [SC] will send a letter notifying you and your doctor as to the results of the examination. When abnormalities are detected, the letter states that we recommend that you make an appointment to discuss these findings with your doctor. Your doctor may recommend specific diagnostic examinations or refer you to a specialist who can evaluate the abnormality found on the screening examination.

If you do not have a primary care physician and would like us [SC] to provide you with a list of recommended physicians, we will be happy to do so.

2. If my screening exam detects abnormalities, will you recommend specific doctors, if I ask, to perform a diagnostic work up?

If the screening exams detect abnormalities and you would like us [SC] to give you a list of recommended physicians, we will be happy to do so.

3. Will the screening center recommend specific surgeons if I ask?

If you would like us [SC] to give you a list of recommended surgeons, we will be happy to do so.

General Questions About Cancer:

1. What can I do to lower my risk of lung cancer?

The [Health Education/Risk Reduction/_____ Clinic here at SC\Cancer Information Service at 1-800-4-CANCER] has/have information about what you can do to lower your risk of lung cancer. I'll be glad to tell you how to contact them.

2. If I have already been diagnosed with lung cancer, do I have an increased risk of developing other types of cancer?

I'll be happy to [make an appointment/give you the telephone number] so you can speak with _____ here at [SC associated medical center] who is very knowledgeable in this area, and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

3. Do you have additional information on lung cancer?

I'll be happy to give you the telephone number so you can speak with _____ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

4. My relative had lung cancer. Does that mean I'll get it too?

If you have a close relative with lung cancer, your chance of having lung cancer yourself does become stronger. This does not mean, however, that you will definitely get the disease. In fact, lung cancer is a rare disease even among people with relatives who have had the disease.

If you'd like me to, I'll be happy to [make an appointment/give you the telephone number] so you can speak with _____ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

5. There's a lot of cancer in my family, that worries me.

If you have a close relative with lung cancer, your chance of having lung cancer yourself does become stronger. This does not mean, however, that you will definitely get the disease.

If you like, I'll be happy to [make an appointment/give you the telephone number] so you can speak with _____ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

6. My relative was recently diagnosed with lung cancer. I wonder if s/he's getting the right treatment?

I'll be happy to [make an appointment/give you the telephone number] so you can speak with _____ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

7. Do you have a support group for individuals who have lung cancer?

Yes, I'll be happy to give you the name and telephone number of the contact person/I'm not sure, so I will give you the telephone number of _____ here at [SC associated medical center] who will know what support groups are available/give you the telephone number of Cancer Information Service of the National Cancer Institute, 1-800-4-CANCER. Either one can tell you what support groups are available.

8. I think I am at high risk for cancer and I should be in the group that receives the spiral CT examination.

For scientific reasons, assignments need to be made at random. If you choose to participate, you will have an equal chance of being assigned to either the spiral CT or to the chest-X-ray group. Please remember that at this time, it is not known whether screening with spiral CT is beneficial or not beneficial for individuals at high risk of lung cancer.

E L I G I B I L I T Y S C R E E N E R

Date Completed: ... |___|___|-|___|___|-|_2_|_0_|__|__|
MO DAY YEAR

Screening Center: |___|___| Screening Center Staff ID: |___|___|___|___|

NAME: MR./MRS./MISS/MS.	FIRST	MIDDLE	LAST	(JR., SR., etc.)
CURRENT STREET ADDRESS:				APT. NO.
CITY		STATE		ZIP
TELEPHONE NUMBER: HOME: ( )		WORK: ( )		OTHER: ( )

1. What is your date of birth?

|___|___| / |___|___| / 19 |___|___|
Month Day Year

CALCULATE AGE: _____

2. What is your gender?

☐ Male
☐ Female

3. Have you had a spiral CT scan of your lungs or chest within the last 24 months? (CHECK YES OR NO)

☐ Yes
☐ No

4. Are you currently participating in any other cancer screening study? (This includes the PLCO Cancer Screening Trial.) (CHECK YES OR NO)

☐ Yes
☐ No

5. Are you currently participating in a primary prevention study other than a study to help you stop smoking? (CHECK YES OR NO)

☐ Yes
☐ No

6. Have you ever been told by a physician that you have lung cancer? (CHECK YES OR NO)

☐ Yes
☐ No

7. Have you ever had any portion of your lungs removed? (CHECK YES OR NO)

☐ Yes
☐ No

8. Are you currently being treated for any kind of cancer other than non-melanoma skin cancer? (CHECK YES OR NO)

☐ Yes
☐ No

9.	Are you a current or former smoker? (CHECK THE APPROPRIATE BOX BELOW)

☐ Current Smoker
☐ Former Smoker
└→ How long ago did you quit?
☐ More than 10 years ago
☐ 10 or fewer years ago
☐ Never Smoked

10.	At what age did you begin to smoke?

|___|___|

Age

11.	During the times that you've smoked, how many cigarettes did you usually smoke per day?

|___|___|
cigarettes per day

CURRENT SMOKERS GO TO 13

FORMER SMOKERS GO TO 12

12.	At what age did you quit smoking for the last time?
	|___|___| Age

13.	In the years you have smoked, was there ever a period of one year or more years in which you did not smoke cigarettes?
	☐ Yes ☐ No

14.	Between when you started smoking and when you quit smoking or now, for how many years in total did you not smoke cigarettes?
	|___|___| . |___| Years

READ: Thank you. Those are all the questions I have for now. Please give me a few minutes to review your answers and tell you if you are eligible for the study.

- COMPLETE THE **ELIGIBLITY WORKSHEET** (next page).
- IF PERSON IS **INELIGIBLE** READ: I'm afraid you do not meet the eligibility requirements. Thank you very much for your interest in the study.
- IF PERSON IS **ELIGIBLE** READ: You are eligible to participate in this study. If you are interested in participating, I will mail you information about the study as well as a consent form for you to read, sign and return to us. For your convenience, there will be a prepaid and preaddressed envelope for you to return the consent form. Meanwhile, if you have any questions, please feel free to call our study coordinator, [NAME] at [NUMBER]. Once again, thank you very much for your interest in this study.

ELIGIBILITY WORKSHEET

A. CALCULATE AGE ELIGIBILITY

1. IF MONTH AND DAY OF BIRTH (IN Q1) IS **ON OR BEFORE** TODAY'S MONTH AND DAY, CALCULATE AGE:

   a. Current Year ..... | 2 | 0 | 0 | 0 |

   b. MINUS Year of Birth (Q1) ..... | 1 | 9 | | |

   c. EQUALS Age .....

2. IF MONTH AND DAY OF BIRTH (IN Q1) IS **AFTER** TODAY'S MONTH AND DAY, CALCULATE AGE:

   a. Current Year ..... | 2 | 0 | 0 | 0 |

   b. MINUS Year of Birth (Q1) ..... | 1 | 9 | | |

   c. MINUS **1** ..... | | | | 1 |

   d. EQUALS Age

IF AGE LESS THAN 55 OR GREATER THAN 74, THE PERSON IS **INELIGIBLE.** (RETURN TO SCREENER)
IF AGE BETWEEN 55 AND 74, THE PERSON IS **ELIGIBLE** (CONTINUE BELOW)

B. CALCULATE DURATION OF SMOKING HISTORY IN PACK YEARS.

1. ENTER *Age* (Q1 For Current Smokers) or
   Age Quit (Q12 for Former Smokers) ..... _____

2. MINUS *Age Started Smoking* (Q10) ..... _____

3. EQUALS *Years since start of smoking* ..... _____

4. MINUS *Years not Smoked* (Q14) ..... _____

5. EQUALS **TOTAL YEARS SMOKED** .....

6. DIVIDE *Average number of cigarettes per day* (Q11)
   by **20** for **PACKS PER DAY** .....

7. MULTIPLY**:**
   TOTAL YEARS SMOKED [5] X PACKS PER DAY [6] = PACK-YEARS

_____ **X** _____ **=** _____

IF PACK-YEARS IS LESS THAN 30, THE PERSON IS **INELIGIBLE.**

IF PACK-YEARS IS EQUAL TO OR GREATER THAN 30, THE PERSON IS **ELIGIBLE**.

(RETURN TO SCREENER)

COMMENTS:

Specifications for Completion of the Eligibility Screener

The Eligibility Screener will be administered by telephone by a SC staff member. The following are specifications for the administration of the form by telephone with a sample script for introducing the screener. These specifications may also be used as a reference document for answering questions from potential participants.

Date Completed: Record the current month and day the Eligibility Screener is completed. Zero-fill month and day, if applicable.

Screening Center: Record the two-digit SC ID.

Screening Center Staff ID: Record the four-digit staff ID of the person completing the Eligibility Screener.

Name and Address: If desired, the SC may affix a mailing label showing the potential participant's name and address in the space provided. Alternatively, the SC may hand write the name and address information.

Telephone Number(s): Record the telephone number(s) that have been provided by the potential participant, including a home number, work number, or other number if provided.

Sample Script for Introduction of Screener:

"Hello, my name is _____ and I'm calling on behalf of (NAME OF SCREENING CENTER). Recently, we received a postcard from you requesting information about the Lung Screening Study being conducted with the National Cancer Institute. I'd like to tell you more about the study."

"The purpose of this study is to determine the ability of screening spiral CT to detect lung cancer relative to screening chest X-ray. Since doctors are not sure which screening test is more effective in screening for lung cancer, some of the study participants will receive screening spiral CT exam, others will receive a screening chest X-ray, and the two groups will be compared. You would be notified of the results of the screening exam after three weeks. We will also send the results to your regular doctor.

We would like to ask for your participation in the study. The study will provide invaluable information that may help save lives, and we hope you will agree to help. Your participation, however, is voluntary. Are you interested in participating?"

YES	(CONTINUE BELOW)
NO	(END INTERVIEW)

"In order to participate in the trial, you must meet certain eligibility criteria. For example, you must be between the ages of 55 and 74, and you cannot have a history of lung cancer. To determine whether you are eligible to participate in the trial, I would like to ask you a few questions." For your information, (READ STATEMENT OF CONFIDENTIALITY BELOW):

Collection of this information is authorized by the Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by the Privacy Act of 1974. Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. Participation will not influence a person's relationship with any provider of medical care or any federal program such as Social Security or Medicare. The information collected in this study will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and reported as statistical summaries. Study records will be kept for approximately two years past the end of the study, and then destroyed.

(CONTINUE WITH NAME AND ADDRESS VERIFICATION.)

NAME AND ADDRESS:

Complete this section to collect the potential participant's name, address, and telephone number(s). If the reply card containing name and address information is available, the information should be verified and the full corrected address and phone number(s) should be recorded in the spaces provided on the ES. If there are no changes to the information on the reply card, it may simply be attached to the ES.

The sample script below may be used in cases where the reply card is available.

"First, I would like to verify your name, address and telephone number."

NAME *"I have your name listed as (FULL NAME FROM REPLY CARD). Is that correct?"*

If there is a correction, record the corrected name in the space provided. Include title and suffix (such as Jr., Sr., etc.), if applicable. Verify all spelling.

ADDRESS *"I have your address listed as (ADDRESS FROM REPLY CARD). Is that correct?"*

If there is a correction, record the corrected address in the space provided. Verify all spelling.

PHONE NUMBER "*I have your evening phone number listed as (EVENING PHONE NUMBER FROM REPLY CARD). Is that your correct home phone number?"*

If there is a correction, record the corrected evening phone number, including the area code, in the space provided for home phone number. This should be the number that corresponds to the home address.

"I have your daytime phone number listed as (DAYTIME PHONE NUMBER FROM REPLY CARD). Is that your correct work number? "

If there is a correction, record the corrected daytime phone number, including the area code, in the space provided for the work phone number.

"Do you have another contact phone number such as a beeper or cell phone number?

Record the number, including the area code in the space provided.

ELIGIBILITY QUESTIONS:

Read each question in the order listed. Read each question exactly as it is written, to the potential participant and record his/her response. Do not attempt to elicit a "Don't Know" response to any question; however, if the potential participant indicates that s/he does not know the answer, record "DK" in the white space next to the question. As soon as the potential participant answers a question in a way that makes him/her ineligible for the trial, you may, if desired, terminate the call by skipping the remaining questions and go to the conclusion section of the screener for ineligible individuals. If a person does not meet the age-eligibility criteria, the spiral CT question does not need to be asked. Alternatively, you may complete the entire screener, regardless of the response to each question.

Specifications for each question are given below.

QUESTION 1: This question asks about the individual's birthdate. Record the month, day and year of the participant's birthdate. Zero-fill the month and day, if applicable.

At the end of administering the ES questions, calculate the age of the individual using the Eligibility Worksheet and record the age in the space provided.

Final age eligibility for a potential participant is based on the date of randomization. However, when filling out the Eligibility Screener, age will be calculated based on the date of administration. This will not be a problem unless the participant is not quite 55 or is nearing his/her 75th birthday. If the participant is nearly 55, the SC can opt to delay randomization to a date when the participant will be 55 (as long as it is between September 1, 2000 and October 31, 2000). If the participant is nearly 75, the SC should expedite randomization so that the participant is 74 on the date randomization is done. It is up to the SC to manage these workarounds to its advantage in enrolling participants.

QUESTION 2: This question asks whether the respondent is male or female. Record a response to this question without asking the respondent, unless you are unable to determine his/her gender.

QUESTION 3: This question asks whether the potential participant has had a spiral CT scan of the lungs or chest within the last 24 months (2 years). Potential participants who have had a CT scan of the lungs or chest within the past 24 months are ineligible for this study.

- If the potential participant does not know whether or not he has had a CT scan of the lungs or chest within the last 24 months (2 years), record "DK" (Don't Know) in the white space next to the question. S/He should be asked to contact his physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

QUESTION 4: This question asks about whether the potential participant is currently participating in a cancer screening study. Participation in the PLCO Cancer Screening Trial is included as a cancer screening trial. It is necessary to verify that a potential participant is not a PLCO participant. Self-report is not acceptable. The potential participant's name and date of birth must be checked against the PLCO roster during eligibility determination. If the potential participant is unsure of the nature of the study, probe for the name of the study or any other information the potential participant can provide about the study, such as the name of the doctor associated with the study, the location where interventions take place, etc. Record this information in the space next to the "Yes" response category. If the potential participant is currently enrolled in a cancer screening trial, then s/he is ineligible for the study.

If the participant is unable to answer the question "Yes" or "No," but is able to provide information about a study in which s/he is participating, the SC should investigate the nature of the study to determine whether or not the potential participant is eligible for the trial.

A cancer screening study/trial is a study that enrolls persons who are asymptomatic for a specific disease and then administers a test to determine whether they are likely to have that disease. The test can either involve machinery (e.g., spiral CT scan) or draining of a biologic sample (e.g., PSA blood test). If you are unsure of whether a study is a cancer screening study/trial, contact the CC or the NCI.

QUESTION 5: This question asks about whether the potential participant is currently participating in a primary prevention study, other than smoking cessation trials. If the potential participant is unsure of the nature of the study, probe for the name of the study or any other information the potential participant can provide about the study, such as the name of the doctor associated with the study, the location where interventions take place, etc. Record this information in the space next to the "Yes" response category. If the potential participant is currently enrolled in a primary prevention study other than a study of smoking cessation, then s/he is ineligible for the study.

If the participant is unable to answer the question "Yes" or "No," but is able to provide information about a study in which s/he is participating, the SC should investigate the nature of the study to determine whether or not the potential participant is eligible for the trial.

A primary prevention trial of cancer enables individuals who have never had the cancer of interest but are at elevated risk of developing that disease. The purpose of the study is to examine whether cancer risk can be reduced. A primary prevention trial may administer a chemopreventive agent (e.g., a drug or a vitamin) or may require participants to behave in a specific manner (e.g., reducing their fat intake).

Large on-going (or soon to start) primary prevention studies include STAR (Study of Tamoxifen and Raloxifine), SELECT (Selenium and Vitamin E Clinical Trial – for prostate cancer), and PCPT (Prostate Cancer Prevention Trial).

Women participating in the Women's Health Initiate (WHI) are eligible for the Lung Screening Study.

If you are unsure of whether a study is a primary prevention study, please call the CC or the NCI.

QUESTION 6: This question asks about a history of lung cancer. Potential participants who have been diagnosed with lung cancer are ineligible for this study.

- If the potential participant has been told by a physician that s/he has/had lung cancer check "Yes." Include both metastatic and primary cancer, and cancers that are in remission.

- If the potential participant says s/he had a "tumor", probe to find out whether it was "malignant" or "cancerous." If so, check "Yes."

- If the potential participant says s/he has a pre-cancerous lesion, check "No." This includes conditions described as carcinoma in situ and atypical adenomatous hyperplasia.

- If the potential participant does not know whether or not s/he has been diagnosed with lung cancer, s/he should be asked to contact his/her physician to obtain the information. The ES should be place in a pending file and the potential participant should be recontacted at a later date to complete eligibility determination. If, after contacting the physician, the potential participant still does not know whether or not lung cancer was diagnosed, s/he is not eligible for the trial.

QUESTION 7: This question asks about surgery to remove any portion of the lungs or an entire lung. Other terms for removal of a lung are "pneumonectomy" or "lobectomy." If the potential participant had an <u>entire</u> lung removed, check "Yes." If the potential participant had a <u>partial</u> lobectomy, that is only part of a lung removed, also check "Yes." If the potential participant reports a history of having any portion of the lung(s) removed, then s/he is ineligible for this study.

QUESTION 8: This question asks whether the potential participant is undergoing any treatment for cancer at this time, other than non-melanoma skin cancer. Basal-cell or squamous-cell skin cancers are considered non-melanoma skin cancers. If the potential participant is currently undergoing treatment for any cancer other than non-melanoma skin cancer, then s/he is ineligible for this study.

- If the potential participant is undergoing treatment for cancer (other than non-melanoma skin cancer) at this time, check "Yes."

- If the potential participant underwent a course of cancer therapy in the past, but on the date s/he completed the screener was not involved in a course of cancer therapy, or if the cancer is basal-cell or squamous-cell skin cancer, check "No."

- If the potential participant does not know whether or not s/he is undergoing treatment for cancer at this time, s/he should be asked to contact his/her physician to obtain the information. The ES should be place in a pending file and the potential participant should be recontacted at a later date to complete eligibility determination. If, after contacting the physician, the potential participant still does not know whether or not s/he is undergoing treatment for cancer at this time, s/he is not eligible for the trial.

QUESTION 9: This question asks whether the potential participant is a current or former smoker. Note that this question refers to tobacco cigarette smoking, not pipe or cigar smoking.

If a potential participant asks for clarification on who is a current smoker, answer that a current smoker is someone who smokes cigarettes on a regular basis.

- If the potential participant is a current smoker, check "current smoker" box.
- If the potential participant is a former smoker, then the followup question must be asked as indicated by the arrow.
- If the potential participant was a smoker in the past, but no longer smokes and quit more than 10 years ago, check "former smoker-more than 10 years since you quit" box. The individual is ineligible for the study and the interview may be ended.
- If the potential participant was a smoker in the past, but no longer smokes and quit 10 or fewer years ago, check "former smoker-10 or fewer years since you quit" box.
- If the potential participant has never smoked in his/her life, check "Never smoked" box. The individual is ineligible for the study and the interview may be ended.

QUESTION 10: This question asks the age in which the potential participant began to smoke. If the potential participant is unsure of the age, probe to obtain an estimated age.

QUESTION 11: This question asks the potential participant at the times s/he has smoked, how many cigarettes did/does s/he smoke per day. Remind the potential participant to provide this information for the entire period of time they smoked.

NOTE: CURRENT SMOKERS (Q9) should skip Question #12 and continue with Question #13. Question #12 should only be answered for potential participants identified as former smokers.

QUESTION 12: To be answered by Former smokers only (Q9). This question asks the potential participant the age at which s/he quit smoking <u>for the last time</u>. If the participant quit smoking at one time, but started again and quit again, probe for the most recent age at which s/he stopped smoking. If the potential participant quit smoking (for the last time) more than 10 years ago, then s/he is ineligible for the study.

QUESTION 13: This question asks the potential participant whether there was a period of one year or more in which s/he did not smoke cigarettes.

QUESTION 14: This question must be specific to whether the person is a former smoker or a current smoker. If the person is a former smoker, read "…started smoking and when you quit smoking, for how many…". If the person is a current smoker, read " started smoking and now…". Unless this question is read as indicated above, former smokers might be confused and include the years after they stopped smoking for the last time.

This question asks the potential participant for the number of years in total in which s/he did not smoke cigarettes between the time when s/he started smoking and when s/he quit smoking. If a fraction of a year is given, ask the participant to estimate it to the nearest half year (e.g., 2 ½ years rather than 2 ¾ years). Let the participant determine whether to round up or down to the nearest half year. If the estimate is a whole number, record "0" in the space to the right of the decimal point.

READ: *"Thank you. Those are all the questions I have for now. Please give me a few minutes to review your answers and tell you if you are eligible for the study."*

Complete the Eligibility Worksheet, using the appropriate information from the Eligibility Screener. This worksheet provides the information for determining the age eligibility and pack-year smoking eligibility for the potential participant.

NOTE: Q# refers to the question # and responses on the Eligibility Screener.

A. CALCULATE AGE ELIGIBILITY

1. If month and day of birth (in Q1) is on or before today's month and day, calculate age:

    a. Record the last two digits of the current year
    b. Subtract the individual's year of birth.
    c. This calculation will be the individual's age. Record this age in Q1 on the screener in the space provided. If the age is less than 55 or greater than 74, the individual is not eligible for the study.

2. If month and day of birth (in Q1) is after today's month and day, calculate age:

    a. Record the last two digits of the current year
    b. Subtract the individual's year of birth.
    c. Subtract 1.
    d. This calculation will be the individual's age. Record this age in Q1 on the screener in the space provided. If the age is less than 55 or greater than 74, the individual is not eligible for the study.

B. CALCULATE DURATION OF SMOKING HISTORY IN PACK YEARS

1. Record the Age (Q1 for current smokers) or Age Quit (Q12 for former smokers) in the space provided.

2. Record the age started smoking (Q10) where indicated.

3. Subtract age in (Item 2) from age in (Item 1). Record this number where indicated in Item 3 "years since start of smoking."

4. Record the years not smoked (Q14) where indicated.

5. Subtract years in (Item 4) from years in (Item 3). Record this number where indicated in Item 5 "TOTAL YEARS SMOKED."

6. Divide the average number of cigarettes per day (Q11) by 20. Record this answer where indicated in Item 6 "PACKS PER DAY" to one decimal place.

7. Multiple Total years smoked (Item 5) by packs per day (Item 6). Record this answer where indicated in Item 7 "PACK-YEARS."

If pack-years (Item 7) is less than 30 even by a fraction of a year (e.g., 29.9), then the potential participant is ineligible. Return to the concluding section of the Eligibility Screener for ineligible individuals.

If pack-years (Item 7) is equal to or greater than 30, the potential participant is eligible. Return to the concluding section of the Eligibility Screener for eligible individuals.

Review the screener to determine whether or not the potential participant is eligible for the trial (see Chapter 2 of the Manual of Operations and Procedures).

After Completing the Form:

IF THE POTENTIAL PARTICIPANT IS **INELIGIBLE**, READ: *"Thank you for taking the time to complete our screener. I'm afraid you do not meet the eligibility requirements. Thank you very much for your interest in the study."*

IF THE POTENTIAL PARTICIPANT IS **ELIGIBLE**, READ: *"You are eligible to participate in this study. In the next week, you should receive by mail a consent form for you to read and sign and return to us. There will be a prepaid and preaddressed envelope for you to return the consent form for your convenience. In the meantime, if you have any questions, please feel free to call our study coordinator, [NAME] at [NUMBER]. Once again, thank you very much for your interest in this study."* **For the SCs including the Participant Contact Form in the mailing, inform the participant that this will be included and s/he should complete the form and return it with the consent form.**

- If the participant is randomized into the trial, file the completed Eligibility Screener in the participant's folder.

- If the potential participant is not randomized into the trial, file the completed Eligibility Screener in a separate file of non-randomized individuals.

Appendix 2-7

LUNG SCREENING STUDY

PROTOTYPE CONSENT FORM

NAME OF SCREENING CENTER

DESCRIPTION OF STUDY

I have been invited to take part in the lung screening study sponsored by the National Cancer Institute, LOCAL SCREENING CENTER, and other centers across the country. The purpose of this study is to determine the effectiveness of screening spiral CT (low radiation-dose computed tomography) in detecting lung cancer relative to screening chest X-ray. This study will enroll 3000 men and women who are smokers or former smokers between the ages of 55 and 74.

STUDY PROCEDURES

By agreeing to participate in the Lung Screening Study, I agree to be assigned by a random process to either a spiral CT group or a X-ray group. I understand that I have an equal chance of being assigned to either group.

If I am assigned to the X-ray group, I will receive a single-view chest X-ray, which is a common type of X-ray for the lungs, which will be performed at LOCAL SCREENING CENTER. I will be asked to inhale deeply and to hold my breath for a couple of seconds while the X-ray is being taken.

If I am assigned to the spiral CT group, I will receive a spiral CT scan, which will be performed at LOCAL SCREENING CENTER. Spiral CT uses X-rays to scan the entire chest quickly (in 15 to 20 seconds) during a single breath hold. During the procedure, I will lie very still on a table that will move through an X-ray machine shaped like a doughnut with a large hole. Inside the machine, the X-ray will quickly rotate, after which a computer will create a three-dimensional ("3D") model of the lungs.

By agreeing to participate in this study, I agree to have the screening test performed as required by the study. The examinations that are part of this study are tests that doctors use frequently to diagnose problems in patients with certain symptoms of lung disease. They have not been established as standard of care for early detection of lung cancer. Their effectiveness in early detection of lung cancer is being tested in this study. I also understand that chest X-ray as a lung cancer screening test is available outside this study. It is unknown if these tests will provide any benefit to me.

After I have received my results from this study, I may be randomly selected to complete a short, questionnaire. The questionnaire will ask about my recent medical care. This questionnaire will be mailed to my home with a pre-paid, pre-addressed envelope to return the questionnaire to the screening center. There will also be the name and phone number of a person to contact should I have any questions.

BENEFITS

I understand that I will receive a free lung cancer screening test. I further understand that if I have lung cancer, it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life; however, this has not been demonstrated scientifically.

RISKS

I understand that there are certain risks that might be associated with the screening procedures.

- A small amount of radiation is received as part of the spiral CT. This amount is similar to the amount received from a mammogram and poses no measurable risk. A small amount of radiation is also received as part of the single-view chest X-ray. This amount is smaller than the amount received from a normal chest X-ray and poses no measurable risk.
- It is possible that the screening spiral CT or single-view chest X-ray may falsely suggest that I have cancer. In this case, it is possible that I may suffer pain, anxiety and expense that could have been avoided if I had never undergone the screening test.
- It is possible that diagnosis (and treatment) of cancers detected in this study may not prolong my life and may result in medical complications.

NOTIFICATION AND COSTS

I understand screening test results will be sent to me as soon as they become available. If I have provided the name of a primary physician, he/she will receive the results. If the results indicate a potential medical problem, I will be offered a referral to a physician specialist from whom I can receive further medical evaluation, if I so choose. The costs of diagnostic tests beyond screening will not be covered by the study and are my personal responsibility.

If I am diagnosed with cancer, I may be referred to a cancer specialist, if I so request. The costs of cancer treatment will not be covered by this study.

COMPENSATION FOR RESEARCH-RELATED INJURIES

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment for medical treatment is available from the National Cancer Institute for any such injury.

EXCLUDED PROCEDURES

This study includes only the screening tests listed above. Other medical procedures are not part of this study.

INFORMATION ON NEW FINDINGS

I understand that any significant new findings about screening for lung cancer discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

CONFIDENTIALITY

I understand that information concerning my participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. Personal identifying information such as name, address, and social security number will be used only for the purposes of identifying cancer cases through state registries, including the APPLICABLE STATE REGISTRY, or locating me in future years. No individual will be identified in any report or presentation.

RIGHT TO WITHDRAW

I understand my participation is voluntary and that I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

PERMISSION TO REVIEW MEDICAL RECORDS

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

CONTACTS AND QUESTIONS

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

_____

PARTICIPANT'S NAME (PRINT)

_____

PARTICIPANT'S SIGNATURE DATE

_____

WITNESS SIGNATURE

Appendix 2-8

Lung Screening Study
Sample Informed Consent Cover Letter

(Date)

(Participant Name)
(Participant Address)
(City, State, Zip Code)

Dear *(Participant Name)*:

Thank you for answering questions about your eligibility to participate in the Lung Screening Study. Your response is very valuable to us and your effort is greatly appreciated.

As explained to you on the telephone, by signing the enclosed consent form and returning it in the postage-paid envelope, you will be giving us your permission to enroll you in the Lung Screening Study. The purpose of the study is to determine the effectiveness of screening spiral CT (low radiation-dose computed tomography) in detecting lung cancer relative to screening chest X-ray in men and women ages 55-74 who are smokers or former smokers. The information you continue to provide is vital to the success of the study.

The confidentiality of all information collected will be protected, except as required by law, and will be used for research purposes only. No identifying information will be released.

Thank you again for your continued support of this important research. If you have any questions regarding this study, please contact me or my colleague, *(Name of Screening Center Coordinator)* at *(telephone number)*.

Sincerely,

(Name of Investigator)
Principal Investigator

Lung Screening Study

ELIGIBILITY VERIFICATION FORM

Participant Name: |___|_____|____|_____|___|
Last First Middle

Participant Date of Birth: ..... |___|___| - |___|___| - 19 |___|___|
MO DY YR

Participant Gender (M/F) ..... |___|

Screening Center: ..... |___|___|

Screening Center Staff ID: ..... |___|___|___|___|

EVF

Participant ID Label

PART A: ELIGIBILITY VERIFICATION

ELIGIBILITY CRITERIA	CHECK YES OR NO. IF YES CHECKED, STOP. IF NO CHECKED, CONTINUE.
1. Is this individual younger than 55 years of age or older than 74 years of age?	YES ☐ NO ☐
2. Has this individual had a spiral CT scan of the lungs or chest in the past 24 months?	YES ☐ NO ☐
2.5. Has this individual never smoked, or did the individual stop smoking more than 10 years ago?	YES ☐ NO ☐
3. Does this individual have fewer than 30 pack-years of tobacco exposure? ES-Q10: At what age did you begin to smoke? |___|___| Age ES-Q11: During the times that you've smoked, how many cigarettes did you usually smoke per day? |___|___| # per day ES-Q12: At what age did you quit smoking for the last time? |___|___| Age ES-Q14: Between when you started smoking and when you quit smoking or now, for how many years in total did you not smoke cigarettes? |___|___| . |___| Years	YES ☐ NO ☐

ELIGIBILITY CRITERIA	CHECK YES OR NO. IF YES CHECKED, STOP. IF NO CHECKED, CONTINUE.
4. Is this individual currently participating in another cancer screening study, including the PLCO Screening Trial?	YES ☐ NO ☐
5. Is this individual currently participating in a primary prevention study other than a study to help him/her stop smoking?	YES ☐ NO ☐
6. Has this individual ever been diagnosed with lung cancer?	YES ☐ NO ☐
7. Is this individual currently undergoing treatment for any cancer other than non-melanoma skin cancer?	YES ☐ NO ☐
8. Has this individual ever had any portion of the lungs removed?	YES ☐ NO ☐
9. Is this individual unwilling or unable to sign the study consent form?	YES ☐ NO ☐

PART B: RANDOMIZATION AND ENROLLMENT

This individual can only be randomized and enrolled into the Lung Screening Study if "No" is checked for each of the questions above and on the previous page.

After randomization is complete, the randomization confirmation will be displayed on the screen. Print the randomization information using a local printer, or, if a printer is not available, handwrite it in the space below.

Date of Randomization/Enrollment: |___|___| - |___|___| - |_2_|_0_|_0_|_0_|
MO DY YR

Participant ID: |___|___|___|___|___|-|___|

Randomization Group (CHECK ONE): Spiral CT ☐
Chest X-ray ☐

Specifications for Completion of the Eligibility Verification Form (EVF)

This form is to be completed by the SC Coordinator or a staff member who has been approved to perform the eligibility verification procedures. Each of the eligibility criteria listed must be satisfied if the participant is to be randomized and enrolled in the Lung Screening Study. Use the Eligibility Screener as a source of information when answering the questions.

Administrative Section:

Participant ID Label: Before initiating the on-line randomization process, affix the pre-assigned PID label to the front of the form in the space provided.

Participant Name: Record the participant's last, first, and middle names and initials in the boxes provided. If the participant does not have a middle name, record the second letter of his/her first name in the space provided for the middle initial and record "no middle name" in the margin of the form.

Participant Date of Birth: Record two digits each for the month, day and year of the participant's date of birth. Zero-fill month and day of birth, if applicable.

Participant Gender: Record an "M" if the participant is male or an "F" if the participant is female.

Screening Center: Record the 2-digit SC ID.

Screening Center Staff ID: Record the 4-digit PLCO ID number of the staff member completing the form.

Part A - Eligibility Verification:

For each of the eligibility verification questions, check "Yes" for a yes answer or "No" for a no answer. If "Yes" is checked, the potential participant is not eligible to be enrolled in the Lung Screening Study.

1. **Is this individual younger than 55 years of age or older than 74 years of age?** This question asks about the age of the potential participant. A participant must be between the ages of 55 and 74 on the day of enrollment in order to be eligible for the trial. Refer to the Eligibility Screener (Question 1).

2. **Has this individual had a spiral CT scan of the lungs or chest in the past 24 months?** This question asks about lung cancer screening history. In order to be eligible, a potential participant must not have received a spiral CT screening examination for lung cancer in the 24 months prior to the completion of the Eligibility Screener.

2.5 Has this individual never smoked, or did the individual stop smoking more than 10 years ago? This question asks about the smoking history of the potential participant. In order to be eligible, an individual must have a history of smoking, and that smoking habit must have occurred within 10 years of the date listed on the Eligibility Screener.

3. **Does this individual have fewer than 30 pack-years of tobacco exposure**? This question asks about total tobacco exposure, as measured in pack-years. Pack-years is the product of duration of exposure (measured in years), and intensity of exposure (measured in packs of cigarettes per day). One pack contains 20 cigarettes. For example, one pack-year of exposure is equal to all of the following: a) smoking 20 cigarettes per day for 1 year; b) smoking 10 cigarettes per day for 2 years; c) smoking 40 cigarettes per day for 6 months. For a potential participant, the number of years smoked should be multiplied by the typical number of packs smoked per day (number of cigarettes per day divided by 20), to derive the pack-years of exposure. In order to be eligible, a participant must have 30 or more pack-years of tobacco exposure. A series of smoking history questions are also included here from the Eligibility Screener:

   ES-Q10: At what age did you begin to smoke? Enter the age exactly as it appears on the ES in question 10.

   ES-Q11: During the times that you've smoked, how many cigarettes did you usually smoke per day? Enter the number of cigarettes exactly as it appears on the ES in Question 11.

   ES-Q12: At what age did you quit smoking for the last time? Enter the age exactly as it appears on the ES in Question 12.

   ES-Q14: Between when you started smoking and when you quit smoking or now, for how many years in total did you not smoke cigarettes? Enter the number of years exactly as it appears on the ES in Question 14.

4. **Is this individual currently participating in another cancer screening study, including the PLCO Screening Trial?** In order to be eligible, a potential participant must not be currently enrolled in the Prostate, Lung, Colorectal, and Ovarian (PLCO) Screening Trial or any other cancer screening trial.

5. **Is this individual currently participating in a primary prevention trial other than a study to help him/her stop smoking?** In order to be eligible, a potential participant must not be currently participating in a primary prevention study other than a study for the purpose of smoking cessation.

6. **Has this individual ever been diagnosed with lung cancer?** This question asks about a prior history of lung cancer. In order to be eligible, a potential participant must not have ever been diagnosed as having lung cancer of any kind.

7. **Is this individual currently undergoing treatment for any cancer other than non-melanoma skin cancer?** This question asks about the treatment of cancer. Any individual undergoing treatment for a cancer other than non-melanoma skin cancer will not be eligible to participate. Carcinoma in situ is not considered to be cancer.

8. **Has this individual ever had any portion of the lungs removed?** In order to be eligible, a potential participant must not have had any procedure resulting in the removal of part of the lung.

9. **Is this individual unwilling or unable to sign the study consent form?** This question asks about the potential participant's willingness/ability to sign the informed consent for the study. This information should be obtained through in-person or mail contact with the potential participant. If the individual does not sign the informed consent for any reason, s/he is not eligible to participate in the study. The SC must have a signed informed consent on file in order to check "No" for this question.

Part B - Randomization and Enrollment:

After randomization is complete, the following information will be displayed on the computer screen. Print the randomization information using a local printer, or, if a printer is not available, handwrite it in Part B of the EVF. If the information is handwritten, it should be copied onto the EVF exactly as it is conveyed from the CC.

Date of Randomization/Enrollment: Record two digits each for the month and day the participant was randomized and enrolled.

Participant ID: The randomization system will display the PID number that has been assigned.

Randomization Group: Check one box to indicate to which arm of the study the participant was assigned, spiral CT or chest X-ray.

After completing the form:

Attach the printout of the randomization information to the EVF.

File a copy of the forms and the extra PID labels in the participant's folder.

Lung Screening Study

SAMPLE POTENTIAL PARTICIPANT TRACKING LOG

Screening Center _____ Screening Center Coordinator _____

Full Name	Address (incl. zip code)	Home Telephone	Work Telephone	Other Telephone	Date of Birth	Sex (M or F)	Date Screener Completed	Eligibility Status (E, I, U or R)	Reason for Ineligibility (1, 2 or 3)
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		
					/ /		/ /00		

CODES

Eligibility Status:
- E = Eligible
- I = Ineligible
- U = Unable to determine eligibility or other (includes PI discretion)
- R = Randomized

Sex:
- M = Male
- F = Female

Ineligibility:
1. Spiral CT scan of lungs or chest in last 24 months
2. Other - one or more of the following:
   - Age <55 or > 74
   - Never smoked or quit smoking > 10 years ago
   - Fewer than 30 pack-years of tobacco exposure
   - Participating in PLCO or other cancer screening study
   - Participating in primary prevention trial
   - Lung cancer diagnosis
   - Treatment for cancer other than non-melanoma skin cancer
   - Portion of lungs removed
3. Unable or unwilling to sign consent form

Appendix 2-12

Lung Screening Study

SC CUMULATIVE RECRUITMENT SUMMARY FORM

Screening Center: |___|___| **Report Date:** |___|___| / |___|___| / | 2 | 0 | 0 | 0 |

Staff ID: |___|___|___|___|

Reporting Period From | 0 | 9 | / | 0 | 1 | / | 2 | 0 | 0 | 0 | To |__|__| / |__|__| / | 2 | 0 | 0 | 0|:	
Total Recruitment Packets Mailed	|___|___|___|___|___|
Total Eligible	|___|___|___|___|
Total Ineligible Reasons for Ineligibility: 1. History of spiral CT scan 2. Other Reasons 3. Unable/unwilling to sign consent	|___|___|___|___| |___|___|___|___| |___|___|___|___| |___|___|___|___|
Total Unable to Determine Eligibility	|___|___|___|___|
Total Randomized _____ = Spiral CT Group _____ = Chest X-ray Group	|___|___|___| |___|___|___| |___|___|___|

Specifications for Completion of the SC Cumulative Recruitment Summary Form

This form is required to maintain a record of recruitment summary data and to provide these data on a weekly basis. On a weekly basis, the SC will submit this completed form to the CC.

Screening Center: Record the two-digit screening center ID.

Staff ID: Record the four digit staff ID of the person completing the form.

Report Date: Record the month and day the form is completed. Zero-fill month and day, if applicable.

Reporting Period: Record the ending month and day corresponding to the period for which the recruitment results are summarized.

For each total, zero-fill the number if it is fewer digits than provided on the form.

Total Recruitment Packets Mailed: Record the total number of potential participants mailed recruitment materials to date. This number includes the total number of persons that were sent the recruitment packet.

Total Potential Participants Eligible: Record the total number of potential participants who have been determined to be eligible for participation in this study. Determination of eligibility has been performed through completion of the Eligibility Screener.

Total Potential Participants Ineligible: Record the total number of potential participants who have been determined to be ineligible for participation in this study. The three categories listed below detail the reasons for ineligibility for these potential participants.

> **History of Spiral CT Scan:** Record the number of ineligibles from above that are ineligible because of a history of a spiral CT within the last 24 months.
>
> **Other Reasons:** Record the number of ineligibles from the total ineligibles reported above that are ineligible for reasons other than a prior history of a CT scan or unable/unwilling to sign consent. Other reasons include failure to meet one or more of eligibility criteria #1, #2, or #3 in section 2.4 of the manual or meets one of the exclusion criteria #2, #3, #4, #6, or #7 in section 2.4 of the manual.
>
> **Unable/Unwilling to Sign Consent:** Record the number of potential participants who were unable or unwilling, for any reason, to the sign consent form.

Total Potential Participants for Whom Unable to Determine Eligibility: Record the total number of potential participants for whom eligibility could not be determined. This includes the following:

- Individuals who have responded to a recruitment mailing but did not complete an Eligibility Screener (due to lack of interest or some other reason),

- Individuals who were excluded at the discretion of the PI for some reason other than the study exclusion criteria (e.g., a language barrier).

Total Participants Randomized: Record the total number of potential participants randomized into the study to date. These participants were found to be eligible, were willing and able to sign and return the informed consent, and have been subsequently randomized into the study.

Spiral CT Group: Record the number of participants from above that were randomized into the Spiral CT group of the study.

Chest X-ray Group: Record the number of participants from above that were randomized into the chest X-ray group of the study.

After Completing the Form:

- Fax it to the CC by 10 AM the Monday after the weekly reporting period ends. If the SC anticipates not being able to fax the form on Monday, it should be faxed the preceding Friday. If Monday is a study holiday, the form should be faxed on Tuesday.