

Lung Screening Study

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.