

Lung Screening Study

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 75<sup>th</sup> 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 Raloxifene), SELECT (Selenium and Vitamin E Clinical Trial – for prostate cancer), and PCPT (Prostate Cancer Prevention Trial).

Women participating in the Women's Health Initiative (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 placed 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 entire lung removed, check "Yes." If the potential participant had a partial 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 placed 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 for the last time. 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.