

Lung Screening Study

Specifications for Completion of the Administrative Tracking Form (ATF)

This form is to be completed by an SC staff member to document an erroneous randomization, that is, randomization of an individual who did not meet eligibility criteria at the time of randomization.

Specifications for completing each item of the form are given below:

Administrative Section:

Date Form Completed: Record the date the ATF was completed. Month and day should be zero-filled, and two digits should be recorded for the year (e.g., 02/07/2001).

Screening Center: Enter the two-digit SC ID.

Screening Center Staff ID: Enter your four-digit staff ID number.

Barcode: This is the three character form identifier ("ATF") preprinted in barcode format on the upper right portion of the form. The barcode will be read by a barcode reader (wand) during the receipt of the form by the CC.

Participant ID: Affix a PID label to the space provided in the upper right portion of the form.

Information Regarding Randomized Ineligible Participant:

1. **Date Ineligibility Discovered:** Record the date that the ineligibility was discovered by the SC staff. Month and day should be zero-filled, and four digits should be recorded for the year (e.g., 02/07/2001).
2. **Reason for Ineligibility:** The reason for ineligibility is the criterion or criteria that should have made the participant ineligible at the time of randomization. Check either box 01, 02 or 03 corresponding to the appropriate exclusion criterion. If box 03 'other' is coded, check the subcategory under 'other' that corresponds to the participant's situation. If the participant met more than one of the exclusion criteria, check all that apply.
- 2a. **History of Lung Cancer:** If category 36 has been coded, complete Table 2A. Instructions for completing the table are given below:

Confirmation of Lung Cancer by Physician or Medical Record Review:

If the participant's lung cancer was confirmed by contacting a physician or by review of the participant's medical record, check the box for "Yes" and complete Date of Confirmation. If the participant's previous lung cancer was not confirmed by contacting a physician or by reviewing the medical record, check the box for "No."

Date of Cancer Diagnosis:

Record the month, day and year the cancer was diagnosed. If you have only the month and year, record "15" as an estimated day and check the "Estimated Day" box. If you have only the year, record the year and list "99" for month and day.

3. Method of Discovery:

The purpose of the ATF is to differentiate between types of "randomized ineligible," so the details surrounding the discovery of a randomized ineligible are important. Below are several types of situations that may involve randomization of ineligible individuals:

1. Study Participants who were randomized in error (i.e., the participant provided information to the SC indicating his/her ineligibility, but the SC failed to exclude him/her from the trial);
2. Study Participants who were randomized appropriately based on information provided at the time of randomization, but for whom it was discovered after randomization that the information provided had been incorrect

Record the details surrounding the discovery of ineligibility. These may include descriptions of:

- how the participant completed items related to eligibility on the ES;
- conversations with the participant;
- details of screening examinations;
- SC procedures for verifying eligibility and randomization.

If additional space is needed, you may write on the back of the form or attach another sheet of paper.

After completing the form:

- Send the original form to CC in the weekly shipment.
- File a copy of the form in the participant's folder.