

Appendix 9-8
Lung Screening Study

SPECIFICATIONS FOR COMPLETION OF THE PROTOCOL VIOLATION FORM (PVF)

This form is to be completed by an SC staff member to document any violation of the requirements of the protocol for study enrollment or screening.

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

Administrative Section:

Date Form Completed: Record the date the PVF 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.

Page ___ of ___: If this form has multiple pages, indicate the page number of this page and the total number of pages (e.g., Page 1 of 4).

Barcode: This is the three character form identifier ("PVF") 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 in the box provided.

Protocol Violation Information:

Put a check in the box to the left of the type of protocol violation being reported.

- **Participant randomized twice:** Check this box when it is discovered that a participant was randomized twice, regardless of whether the second randomization was to the same group or a different group.
- **Participant randomized without a signed consent form:** Check this box when it is discovered that a participant was randomized before the SC received a signed consent form from the participant.
- **Participant with lung cancer (randomized ineligible) received a chest X-ray or spiral CT examination:** Check this box when a spiral CT or X-ray is administered to a participant who was a randomized ineligible and the reason for his/her ineligibility was a diagnosis of lung cancer. (Note that the PVF only documents the erroneous screen. The randomization error should be documented on the ATF).
- **Chest X-ray administered to spiral CT group participant:** This box is checked when a participant randomized to the spiral CT group is screened with a chest X-ray instead of a spiral CT scan.
- **Spiral CT screening administered to chest X-ray group participant:** This box is checked when a participant randomized to the chest X-ray group is screened with a spiral CT scan instead of a chest X-ray.

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- **Erroneous results reported to participant or physician:** Check this box when it is discovered that the results letter to the participant and/or physician incorrectly reported the results of the screening examination.
- **Other, Specify:** Check this box if there is a violation of the study protocol other than those listed above and indicate the nature of the violation in the space provided.

List the PIDs of the participant or participants affected by the violation. There will be more than one PID only in situations where a single violation affects more than one participant. For example if Participant A's folder was used for Participant B's screening, you would list the PIDs for both Participants A and B. For a single violation, list the PID of the affected participant. In the second column record XRY if the participant was randomized to the chest X-ray group and SCT if s/he was randomized to the spiral CT group. Record the date that the violation took place.

Describe the violation. On the lines provided on page 2 provide a short, clear explanation of what happened. Include the forms completed, and participant contact from the time of the violation. Describe what was done to rectify the situation and prevent a recurrence.

After completing the form:

- Send the original form to the CC in the weekly shipment.
- File a copy of the form in the SC files.