

Lung Screening Study

**PROTOCOL VIOLATION FORM (PVF)**

Date Form Completed: . |\_\_| |\_\_| | - |\_\_| |\_\_| | - | 2 | 0 | |\_\_| |\_\_| |  
 MO DY YEAR

Screening Center:..... |\_\_| |\_\_|

Screening Center Staff ID:..... |\_\_| |\_\_| |\_\_| |\_\_|

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PVF

Participant ID Label

**INSTRUCTIONS:** Please check the type of protocol violation below. Depending on the type of violation, please provide the information requested on all pages. Attach additional sheets as necessary.

- \* PLEASE COMPLETE A SEPARATE FORM FOR EACH INSTANCE OF A PROTOCOL VIOLATION.
- \* PLEASE DO NOT INCLUDE ANY PARTICIPANT NAMES OR IDENTIFYING INFORMATION. USE PIDs OR INITIALS ONLY TO IDENTIFY PARTICIPANTS.

**CHECK THE TYPE OF PROTOCOL VIOLATION BEING REPORTED**

- Participant randomized twice
- Participant randomized without a signed consent form
- Participant with lung cancer (randomized ineligible) received a chest X-ray or spiral CT examination
- Chest X-ray screening administered to spiral CT group participant
- Spiral CT screening administered to chest X-ray group participant
- Erroneous results reported to participant or physician
- Other, Specify (This includes any error not listed above.)

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\_\_\_\_\_

\_\_\_\_\_

List the affected PIDs for single violation only. For each PID, describe all actions that have been taken, including any forms completed, received, and scanned on separate sheet. Also describe all contact with the affected participant(s)

<u>PID(s)</u>	<u>Study Group (XRY or SCT)</u>	<u>Date of Violation</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

