ACRIN 6654
PROTOCOL DEVIATION FORM

Instructions: Complete a separate PR Form for each case and for each deviation (Q1). Retain the original copy of the form in the case study file and mail a copy to ACRIN Headquarters.

1. Check the Protocol Deviation Being Reported: (check only one) [1]
   - [ ] 1 Ineligible participant randomized (complete 1a, below)
   - [ ] 2 Participant randomized more than once, duplicate case # _______________ [3]
   - [ ] 3 Participant completed study activity before signing consent
   - [ ] 4 Screened eligible participant with a reported or confirmed lung cancer
   - [ ] 5 CXR screen administered to a CT arm participant
   - [ ] 6 CT screen administered to a CXR arm participant
   - [ ] 7 Erroneous results reported to participant and/or health care provider
   - [ ] 8 Duplicate screen administered
   - [ ] 9 Screening results not reported to participant/health care provider within protocol-specified time frame
   - [ ] 10 Participant withdrew study consent --- report on NP
   - [ ] 11 Participant withdrew biomarker consent --- report on NP
   - [ ] 12 Participant withdrew remnant tissue consent --- refer to RM Form instructions
   - [ ] 13 Baseline screen delayed, not performed within 4 weeks of randomization (assign screen per OOWS)
   - [ ] 14 Spirometry not performed
   - [ ] 15 Spirometry performed while participant on bronchodilator
   - [ ] 16 Baseline screening exam not performed
   - [ ] 17 Year 1 incidence screening exam not performed
   - [ ] 18 Year 2 incidence screening exam not performed
   - [ ] 19 Year 1 incidence screening exam not performed within protocol-specified time frame (assign per OOWS)
   - [ ] 20 Year 2 incidence screening exam not performed within protocol-specified time frame (assign per OOWS)
   - [ ] 21 Revised gender, correct gender: [23] □ - 1 Male □ - 2 Female
   - [ ] 22 Revised age group, correct age group: [24] ___________ (A0, Q19, response = 1 - 4)
   - [ ] 23 Institution transfer --- complete Participant Transfer Form
   - [ ] 24 Screening images lost/unavailable
   - [ ] 25 Imaging-related deviation (complete 1b, page 2)
   - [ ] 90 Other, specify: [2]

1a. Reason for Ineligibility
   - [ ] 4 Unwilling / unable to provide consent
   - [ ] 5 Age < 55 or > 74 years at study entry
   - [ ] 6 Non-smoker or quit smoking more than 15 years ago
   - [ ] 7 Unable to lie on back with arms resting above head
   - [ ] 8 Metallic implants in chest or back
   - [ ] 9 Diagnosed with lung cancer prior to study entry
   - [ ] 10 Evidence or cancer or treatment of cancer within the past 5 years (excluding non-melanoma
       skin cancer or in-situ cancers other than transition cell or bladder)
   - [ ] 11 Had a lung or portion of a lung surgically removed
   - [ ] 12 Home oxygen supplementation required
   - [ ] 13 Participant in other cancer screening trial (such as ELCAP or PLCO)
   - [ ] 14 Participant in other cancer prevention trial
   - [ ] 15 Unexplained weight loss greater than 15 pounds within the last year or recent Hemoptysis
   - [ ] 16 Pneumonia or acute respiratory infection requiring antibiotics within 12 weeks of study entry
   - [ ] 17 Treated with cytotoxic agents within 6 months prior to study entry
   - [ ] 18 Chest CT within 18 months prior to study entry
   - [ ] 19 Smoking history less than 30 pack years
1b. Imaging Deviation:

- [25] Incorrect KV utilized
- [26] Incorrect gantry rotation time utilized
- [27] Incorrect mA / mAs utilized
- [28] Incorrect reconstructed slice width utilized
- [29] Incorrect reconstructed interval utilized
- [30] Incorrect reconstructed algorithm utilized
- [31] Incorrect number of slices for a specific algorithm
- [32] Other deviation, specify: [33]
- [36] Lateral CXR projection performed as part of the screening exam
- [37] Lateral CXR used for screening exam interpretation – DR (can be used for I8)
- [38] Screening exam performed using non-NLST-certified equipment

2. Date the protocol deviation was discovered: [20] _____ - _____ - 20____ (mm-dd-yyyy)

3. Describe the protocol deviation: (60-character limit) [39]

4. What was done to rectify the situation and / or prevent future occurrence: (60-character limit) [40]

5. Date the protocol deviation occurred: [41] _____ - _____ - 20____ (mm-dd-yyyy)

6. Study year this deviation applies to: [42] □ T0 □ T1 □ T2

Comments: (120-character limit) [43, 44]


Signature of person responsible for data Date form completed

Investigator Signature