ACRIN NLST 6654 CRF COMPLETION INSTRUCTIONS

PR Form Instructions

The PR Form is used to report protocol deviations to ACRIN. Each organization may also have separate reporting requirements for protocol deviations, follow your IRB guidelines. The PR form should be completed by the study site when/if a protocol deviation is discovered. A GCM for suppression of forms is not required when reporting protocol deviations, the PR will serve as the suppression trigger (as appropriate). Complete a separate PR Form for each case and for each deviation. Retain the form in the case study file and fax/mail a copy to ACRIN Headquarters at (215) 717-0936. A completed ACRIN Case Specific Label should be affixed to each page of the PR Form. In lieu of a label, the Participants Initials, Case Number, Institution Number, and Institution Name can be recorded in the space provided. Contact ACRIN DM for any questions regarding the PR Form.

1. **Check the Protocol Deviation being recorded:** Required data element. Place a mark in the box to the left of the protocol deviation being reported. Report only one protocol deviation (check only one box) per PR Form.

   1. **Ineligible participant randomized (complete question 1a, below).** Select this response when it is discovered that an erroneous randomization occurred, that is, randomization of an individual who did not meet eligibility criteria at the time of randomization. Eligibility is established at the time of randomization based on the protocol-specified inclusion/exclusion criteria. The E1 (Eligibility Form) is administered at the time of randomization to establish/document eligibility; it should not be completed at T1 or T2. Please reference the protocol for inclusion/exclusion criteria.

   2. **Participant randomized more than once, duplicate case #______**. Select this response when it is discovered that a participant was randomized more than once, regardless of whether the second randomization was to the same study arm or the opposite study arm. Write the duplicate (second) case number in the space provided. If this occurs, the original randomization (arm and case number) must be maintained throughout the trial. All study data should be applied to the original case number; the case number of the duplicate (second) randomization will be closed/cancelled and will not count towards accrual.

   3. **Participant completed study activity before signing consent.** Select this response when it is discovered that a participant completed a study activity before signing a consent form.

   4. **Screened eligible participant with a reported or confirmed lung cancer.** Select this response when it is discovered that an eligible participant with a reported or confirmed lung cancer was inadvertently given a screening examination. Once a participant receives a diagnosis of lung cancer, s/he should NOT continue with the annual screening examinations. Participants who receive a diagnosis of another type of cancer other than lung should continue with the annual screening examinations.

   5. **CXR screen administered to a CT arm participant.** Select this response when it is discovered that a participant randomized to the CT arm is screened with a chest x-ray instead of a CT. A DR Form should be completed, documenting the findings of the chest x-ray exam, and submitted to ACRIN. ACRIN DM will suppress the C2, I9, and C5 once the PR Form has been processed; *a GCM is not required.*

   6. **CT screen administered to a CXR arm participant.** Select this response when it is discovered that a participant randomized to the chest x-ray arm is screened with a CT instead of a chest x-ray. ACRIN DM will suppress the DR, I8, and C4 once the PR Form has been processed; *a GCM is not required.*

   7. **Erroneous results reported to participant and/or health care provider.** Select this response when it is discovered that the results letter sent to the participant or the participant’s health care provider incorrectly reported the results of the screening examination.

   8. **Duplicate screen administered.** Select this response when it is discovered that a participant was screened more than once during a study year. This does not refer to repeat attempts, per protocol 3 attempts per visit, with a total of 2 visits, can occur to obtain a diagnostic quality exam.
9. **Screening results not reported to participant/health care provider within protocol-specified time frame.** Select this response when it is discovered that the screening results were not reported within the current NLST-specified time frame of 4 weeks.

10. **Participant withdrew study consent.** Document this event on the NP Form.

11. **Participant withdrew biomarker consent.** Document this event on the NP Form.

12. **Participant withdrew Remnant Tissue consent.** Refer to RM Form Instructions.

13. **Baseline screen delayed, not performed within 4 weeks of randomization.** Select this response when it is discovered that the T0 baseline screen was not performed within 4 weeks of randomization. The screen should then be assigned per the Out of Window Screen (OOWS) timeline.

14. **Spirometry not performed.** Select this response when Spirometry was not performed on a given participant at T0. Failure to achieve ATS criteria during the spirometry exam is **not** a protocol violation. ACRIN DM will suppress the PA Form once the PR Form has been processed; **a GCM is not required.**

15. **Spirometry performed while participant is on bronchodilators.** Select this response when Spirometry was performed while the participant was on bronchodilators, both long and short acting.

16. **Baseline screening exam not performed.** Select this response when it is discovered that a “screen-eligible” participant did not receive a T0 baseline screening examination. Screens performed from the date of randomization until the end of the 10th month post randomization are considered baseline screens (reference the OOWS document). The screening window should be closed before reporting this deviation. ACRIN DM will suppress the screening forms and images once the PR Form has been processed; **no GCM is required.**

   Note: Do not report this as a deviation if the screen was not performed due to the participant receiving a diagnosis of lung cancer (submit GCM).

17. **Year 1 incidence screening exam not performed.** Select this response when it is discovered that a “screen-eligible” participant did not receive a T1 screening examination. Screens performed from the beginning of the 11th month post randomization to the end of the 22nd month post randomization are considered T1 incidence screens (reference the OOWS document). The screening window should be closed before reporting this deviation. Do not report this deviation if the screen was not performed due to the participant receiving a diagnosis of lung cancer. ACRIN DM will suppress the screening forms and images once the PR Form has been processed; **no GCM is required.**

   Note: Do not report this as a deviation if the screen was not performed due to the participant receiving a diagnosis of lung cancer (submit GCM).

18. **Year 2 incidence screening exam not performed.** Select this response when it is discovered that a “screen-eligible” participant did not receive a T2 screening examination. Screens performed from the beginning of the 23rd month post randomization to the end of the 34th month post randomization are considered T2 incidence screens (reference OOWS document). The screening window should be closed before reporting this deviation. Do not report this deviation if the screen was not performed due to the participant receiving a diagnosis of lung cancer. ACRIN DM will suppress the screening forms and images once the PR Form has been processed; **no GCM is required.**

   Note: Do not report this as a deviation if the screen was not performed due to the participant receiving a diagnosis of lung cancer (submit GCM).

19. **Year 1 incidence screen not performed within protocol-specified time frame.** Select this response when it is discovered that the T1 screen was performed outside the 4-month screening window (one month prior to three months post randomization anniversary date). The screen should then be assigned per the Out of Window Screen (OOWS) timeline.
20. **Year 2 incidence screen not performed within protocol-specified time frame.** Select this response when it is discovered that the T2 screen was performed outside the 4-month screening window (one month prior to three months post randomization anniversary date). The screen should then be assigned per the Out of Window Screen (OWWS) timeline.

21. **Revised gender, correct gender. 1 – Male, 2 – Female.** Select this response when it is discovered that the participant’s gender was erroneously reported at the time of randomization (A0 web module). Include a corrected A0 when submitting the PR Form.

22. **Revised age group, correct age group _______(from A0 q19, response 1 – 4).** Select this response when it is discovered that the participant’s age group was erroneously reported at the time of randomization (A0 web module). Include a corrected A0 when submitting the PR Form.

23. **Institution transfer.** Complete Participant Transfer Form.

24. **Screening Images lost/unavailable.** Select this response when it is discovered that the screening images were lost and will not be submitted to ACRIN. ACRIN DM will suppress the images once the PR Form has been processed; a GCM is not required.

25. **Imaging-Related deviation (complete section 1b below).** Select this response when it is discovered that one or more technical parameters used for the screening examination were outside the range specified in the protocol/technical documents. Complete section 1b to document the specific imaging deviation.

90. **Other, specify.** Select this response if there is a violation of the study protocol. In the event that another type of violation/deviation from the protocol occurs, please specify the type of occurrence on this part of the form. In the event that you still have questions regarding the type of violation please contact an ACRIN data manager prior to submitting the form.

1a. **Reason for Ineligibility:** Required data element if Q1=1, ineligible participant randomized. The reason of ineligibility is the criterion that made the participant ineligible at the time of randomization. Eligibility is determined at the time of randomization based on the eligibility/exclusion criteria; events occurring AFTER randomization do not alter the participant’s eligibility status. Place a mark in the box to the left of the reason for ineligibility; if the participant met more than one of the exclusion criteria, check all that apply.

1b. **Imaging Deviations:** Required data element if Q1=25, Imaging-related deviation. Place a mark in box to the left of the imaging deviation being reported. Questions related to the NLST imaging parameters should be directed to the ACRIN Imaging Department, 215-717-2753.

2. **Date the protocol deviation was discovered:** Required data element. Record the date that the study staff discovered the protocol deviation. For ineligible participant randomized, record the date that the ineligibility was discovered. Record date as month, day, year in the space provided.

3. **Describe the protocol deviation:** Required data element, 60-character limit. Provide a description of the protocol deviation. The description should include the following elements:
   - How the protocol deviation was discovered
   - How the protocol deviation occurred
   - Ramifications for the participant

   One of the purposes of this form is to differentiate between types of “randomized ineligibles.” If the protocol deviation being described is a randomized ineligible, the description should also include details that specify the type of randomized ineligible, as described below:
   - Participant was randomized in error (i.e., the participant provided information to the study staff indicating his/her ineligibility, but the study staff failed to exclude him/her from the trial).
Participant was randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization that the information provided was verifiably incorrect (i.e., participant stated that s/he had no Chest CT within 18 months prior to randomization, however, a Chest CT was later discovered by the study staff). This does not refer to seemingly inconsistent responses regarding smoking history on the E1 and SS Forms. The SS Form is designed to capture smoking attitudes; hence the smoking history questions differ than those on the E1 Form and were not designed to elicit comparable responses. The E1 responses provided by the participant at the time of randomization establish eligibility.

4. What was done to rectify the situation and / or prevent future occurrence: Required data element, 60-character limit. Provide a detailed description of the protocol deviation resolution. The description should include the following elements:
   - What was done to rectify or “clean-up” after the protocol deviation.
   - The steps that have been taken to prevent future occurrences of this type of protocol deviation.
   - If the protocol deviation was the result of participant action/inaction and not the result of study staff action/inaction, provide statement documenting this.

5. Date the protocol deviation occurred: Record the date that the protocol deviation actually occurred. If reporting randomization of ineligible participant, record the date that the participant was randomized.

6. Study year this deviation applies to: This is a required element. Place a mark in the box to the left of the time-point that the deviation pertains to.

Comments: Optional element, limited to 120 characters. Provide comments, as appropriate, in support of the information reported above.

Signature of person responsible for data: Legible signature of the study staff responsible for the PR data.

Date Form Completed: Record the date that the PR form was completed; record date as month, day, and year.

Investigator Signature: Before submitting the form to ACRIN, ALL PR Forms must be reviewed and signed by the site investigator.