The C2 Form is completed for each screening exam at T0, T1, and T2. The C2 Form is to be completed by each of the following ACRIN-NLST study staff: the research associate (study coordinator), CT technologist, and radiologist. Complete the form in black or blue ink. The data is submitted via the ACRIN web site. The original paper CRF serves as the source document for the screening exam interpretation and should be retained in the study file.

An ACRIN Case Specific Label should be affixed at the top right corner of each page of the form. Alternatively, the institution name, institution number, participant initials, and participant case number can be recorded in the identified spaces provided.

1. **Indicate Screening Visit:** Record the appropriate response (code numbers 1-3) identifying the appropriate study year of the visit.

2. **Date of Screening CT Exam:** Record the date of the current screening exam (month, day, and last digit of the year). The baseline screening exam should be performed within 4 weeks of randomization and the incidence screens (T1 and T2) should be performed within 1-month prior to 3-months post the randomization anniversary date.

3. **Visit number (for above screening visit):** Record the number of times the participant visited the site to complete the screening exam for the current study year. A screening visit is defined as any visit in which an exposure occurs. Participants may have two visits in order to complete a technically adequate screening exam in any one study-year; no more than three exam attempts per visit for a total of 6 allowable exam attempts.

---

**Part A. Technical Parameters:** Refer to NLST CT Technique Chart for platform-specific imaging parameters.

The following technical parameters should be recorded for each CT exam. The study radiologist, the CT technologist, or the study coordinator may record these parameters. In all cases, the data should be checked for completeness and accuracy by the radiologist. The radiologist is also responsible for ensuring the quality of the image data and adherence to the technical parameters specified by the protocol and the NLST CT Technique Chart for all screening exams.

4. **Number of exam attempts:** An exam typically consists of a single scout view and a single low-dose helical sequence of images through the entire lung field. Record the number of attempts made to complete the CT exam. An exam attempt is defined as an exposure (image) being performed, whether it is successfully completed or not. No more than three attempts per visit should be performed in order to complete a technically adequate CT exam; no more than three exam attempts per visit for a total of 6 allowable exam attempts.

5. **kVp:** Record the kVp used to obtain the completed CT exam. Platform-specific technical parameters are detailed in the NLST CT Technique Chart.

6. **mA:** Based on the CT equipment and platform record either the mA or effective mAs (Q7) for the CT exam. Platform-specific technical parameters are detailed in the NLST CT Technique Chart. If reporting effective mAs leave mA field blank; this logic check is programmed in the web module.

7. **Effective mAs:** Based on the CT equipment and platform record either the mA (Q6) or effective mAs. Platform-specific technical parameters are detailed in the NLST CT Technique Chart. If reporting effective mAs leave mA field blank; this logic check is programmed in the web module.

8. **Display FOV (cm):** Record the imaging display field of view in centimeters (no decimals; round if necessary).

9. **Indicate CT reconstruction algorithm/filter:** Check the box(es) that corresponds to the CT manufacturer and reconstruction algorithm(s) that were used for image acquisition and reconstruction. The protocol requires the CT images to be acquired or reconstructed in a "soft tissue/smoothing algorithm without high spatial frequency enhancement" (e.g. GE standard, Toshiba FC51, Siemens B30, Philips B or C). If additional algorithms are used (e.g. GE bone, Toshiba FC10, Siemens B50f, Philips D) please record these also. All data sets should be
transferred to the ACRIN Image Archive. Platform-specific technical parameters are detailed in the NLST CT Technique Chart.

10. Technologist ID: Record the internal, unique ID used by the site to identify the technologist performing the exam (i.e. name, number).

Part B. Screening CT Findings (completed by the radiologist based on the screening CT)
The study radiologist will complete the following interpretative findings.

11. Indicate the overall diagnostic quality of the CT examination: Record the appropriate response (code numbers 1-3) indicating the quality of the current screening exam.
   1 = Diagnostic exam (skip to Q12)
   2 = Limited CT, but interpretable
      Using the list provided, identify the parameter(s) that affected the quality of the screening exam, and continue to Q12.
   3 = Non-diagnostic CT
      Using the list provided, identify the parameter(s) that affected the quality of the screening exam. The participant should be rescheduled for another visit and the C2 form for visit 1 should be retained in the study file with Q1-11 completed (do not submit to ACRIN); this is to document the first visit and to provide potentially useful information for the technologist and/or radiologist regarding the reason for the repeat exam. As described previously, the protocol specifies only two screening exam visits per study year, with three exam attempts per visit. If both screening visits yield a non-diagnostic exam (Q11=3) submit a C2 Form for the second visit to ACRIN. Document this, second, inadequate screen by coding the quality of the exam non-diagnostic (Q11=3) and completing Q12-13.

12. Are there any abnormalities to report on this CT? Record the appropriate response code (1-No, 2-Yes) indicating whether or not abnormalities were seen on the current screening exam. Record all relevant findings. If Q12 is no, proceed to Q13. If Q12 is yes, complete the abnormality table below Q12, as appropriate.

Abnormality Table: This section allows recording of up to fourteen abnormalities. If more than fourteen abnormalities are present, document the 14 most significant within the table. If needed, additional clinical information can be recorded in Part D, Other observations/comments. The table identifies a list of abnormalities, each with a corresponding unique code number. The abnormalities listed are not exhaustive, but are intended to include a range of findings that may suggest possible lung cancer or other significant conditions that would warrant additional evaluation or medical attention.

- Complete the table by recording the appropriate abnormality code number in the designated data field just right of the F-number in the first column.
- Columns 2-7 (CT slice location, anatomic location, longest diameter, longest perpendicular diameter, margins, and predominant attenuation) should be completed ONLY for Code 51 abnormalities.
- If multiple micronodules <4mm diameter are seen, record Code 52 only ONCE.
- If 6 or more nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- If multiple non-calcified nodules/masses >= 4 mm are seen, some suspicious and some not, record each suspicious nodule/mass as code 51 and the others as 53 or 62 or 63 (as appropriate).
- If multiple suspicious non-calcified nodules/masses more >=4mm are seen, code as 51 and provide descriptive data within the table (columns 2-7).
- If more than 14 non-calcified nodules/masses >=4mm are seen, and all are suspicious: dependent on the radiologist's clinical judgment, the most suspicious or clinically relevant non-calcified nodules/masses should be coded as 51 and detailed in the table (columns 2-7), then use code 63 to document the others. In this event, the study will not dictate the number of nodules/masses to be detailed since there are too many "ifs" and relies on the clinical, as well as, subjective impression of the interpreting radiologist.
- To document additional descriptive text data use Part D, Other observations/comments.
Descriptive data NOT intended for web-entry should appear outside of table/data fields (e.g., size/location of non-51 abnormalities).

**Column 1 – Abnormality Codes:**
Record the appropriate abnormality code number, from the list provided, in the data field adjacent to the F-number. The text line just right of this data field should be used ONLY when reporting Code 63-65 abnormalities.

51= **Non-calcified nodule or mass (opacity > 4mm diameter)**
Record non-calcified nodules or masses that are suspicious for lung cancer. When reporting this abnormality, columns 2-7 of the table must be completed. When reporting this abnormality Q13 must be coded 4 or 5.

52= **Non-calcified micronodule(s) (opacity < 4mm diameter)**

53= **Benign lung nodule(s) (benign calcification)**
Code only once, regardless of the number of these nodules.

54= **Atelectasis, segmental or greater**
Do not record minor basal or dependent atelectasis.

55= **Pleural thickening or effusion**

56= **Non-calcified hilar/mediastinal adenopathy or mass (> 10mm short axis)**
Do not record calcified adenopathy consistent with previous granulomatous infection.

57= **Chest wall abnormality (bone destruction, metastases, etc.)**
Do not record acute or healed post-traumatic fracture deformities that do not appear to have a neoplastic basis.

58= **Consolidation**

59= **Emphysema**

60= **Significant cardiovascular abnormality**
Use this code to record a thoracic aortic aneurysm, aortic dissection, marked cardiomegaly, pulmonary hypertension, coronary artery calcifications, valvular calcifications, etc. (exclude mitral annular calcification). The particular cardiovascular abnormality should be further characterized in Part D, Other observations/comments, at the conclusion of the C2 Form.

61= **Reticular/reticulonodular opacities, honeycombing, fibrosis, scar**
Use this code to record the presence of subpleural fibrosing alveolitis, the typical fibronodular changes of previous granulomatous disease commonly observed in the upper lobes, or non-specific scarring in the lung.

62= **6 or more nodules, not suspicious for cancer (opacity > 4mm)**
Use this code to record the presence of multiple nodules (non-calcified or mixed calcified/non-calcified) of uniform size and smooth margins presumed to reflect the fibrous residuals of benign granulomatous infection or other benign condition. This code should NOT be used to record suspected metastases or malignancy of any kind.

63= **Other potentially significant abnormality above the diaphragm (specify below)**
Use this code to record any abnormality of potential malignant or other medical significance in the chest not covered by existing codes. Use the text line just to the right of the data field to record this abnormality.

64= **Other potentially significant abnormality below the diaphragm (specify below)**
Use this code to record any abnormality of potential malignant or other medical significance below the chest not covered by existing codes (for example: renal mass, adrenal mass, etc). Use the text line just to the right of the data field to record this abnormality.

65= **Other minor abnormality noted (specify below)**
Use this code to record any minor abnormality that is not considered to require medical follow-up. Use the text line just to the right of the data field to record this abnormality.

**Column 2 – CT Slice Location:**
Record the CT slice number (#) on which the nodule/mass has the greatest axial diameter. This will be used primarily to identify the location of the nodule/mass for follow-up. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.
Column 3 – Anatomic Location:
Record the anatomic location of the nodule/mass by lobe (code numbers 1-6); if located in more than one lobe, code by identifying the center of the nodule/mass. Use the text line in this column is for “7=other” ONLY; if completed for locations 1-6, a data query may be generated. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.

1 = RUL
   The nodule/mass was found in the upper right lobe.

2 = RML
   The nodule/mass was found in the middle right lobe.

3 = RLL
   The nodule/mass was found in the lower right lobe.

4 = LUL
   The nodule/mass was found in the upper left lobe.

5 = Lingula
   The nodule/mass was found in the lingula.

6 = LLL
   The nodule/mass was found in the lower left lobe.

7 = Other, specify
   If you cannot determine the location of the nodule/mass (such as within the right mid-lung intimate to the right minor fissure) record “7=other.” The text line just right of the data field should be used to specify this location ONLY.

Column 4 – Dimensions / Longest Diameter:
Record the maximum dimension (mm) of the nodule/mass using whole integers. If dimensions cannot be determined, record 999. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.

Column 5 – Dimensions / Longest Perpendicular Diameter:
Record the maximum perpendicular dimension (mm) of the nodule/mass using whole integers. If dimensions cannot be determined, record 999. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.

Column 6 – Margins:
Categorize the appearance of the nodule/mass margins by recording the appropriate response. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.

1 = Spiculated
   Stellate or having a pleural tag.

2 = Smooth
   Having a predominately featureless border, although may have occasional tendrils.

3 = Poorly defined
   Margins are poorly visualized or vague, which is most common in ground glass opacities.

99= Unable to determine

Column 7 – Predominant Attenuation:
Categorize the appearance of the nodule/mass by recording the appropriate response (code numbers 1-6, 99). Use the text line in this column for “6=other” ONLY; if completed for attenuation codes 1-5 a data query may be generated. Complete this column for Code 51 abnormalities ONLY. If recorded/submitted for abnormalities other than Code 51 a data query may be generated.

1 = Soft tissue

2 = Ground Glass

3 = Mixed (1 + 2)
   Refers to nodules of mixed soft tissue (solid) and ground glass attenuation. These have been referred to as “semi-solid” by some investigators in the radiology literature.

4 = Fluid/Water
5 = Fat
6 = Other, specify
   If attenuation cannot be categorized using one of the responses above record as “6, other.” The text line just right of the data field should be used to specify this attenuation ONLY.
99 = Unable to determine

Part C. Results and Recommendations (completed by the radiologist based on the screening CT)

Record the results of the current screening exam only. The C2 screening result should be rendered from a “blind” review of the screening exam; the participant’s prior medical history or historical/interval images should not be reviewed at this point. Comparison results of historical images and/or prior study screens will be documented on the I9 Form. The focus of the screening examination is to identify and report abnormalities suspicious for lung cancer.

13. Indicate the result for this screening CT: Based upon the presence and type of abnormalities reported in Q12, record the appropriate response (code numbers 1-6).

1 = Negative screen, no significant abnormalities
   Review of the screening exam reveals no significant abnormalities. Skip to Q15.

2 = Negative screen, minor abnormalities not suspicious for lung cancer
   Review of the screening exam reveals only minor abnormalities that are not suspicious for lung cancer. Based on clinical judgment, the interpreting radiologist will determine whether the abnormality is minor. Skip to Q15.

3 = Negative screen, significant abnormalities not suspicious for lung cancer
   Review of the screening exam reveals an abnormality that requires further evaluation, but is not suspicious for lung cancer. Based on clinical judgment, the interpreting radiologist will determine whether the abnormality is clinically significant. For this result category it is suggested that the radiologist include in the text field, “Other observations/comments” (Part D), the abnormality (or code number) and/or use free text to explain the significant finding. This text can then be put into the Results Letters sent to the participant and her/his physician of record. Skip to Q15, a follow-up recommendation should be made.

4 = Positive screen, nodule(s) 4-10mm suspicious for lung cancer
   Review of the screening exam reveals nodule(s) 4-10 mm in size (Code 51). Proceed to Q14.

5 = Positive screen, nodule(s) > 10mm, mass(es), other non-specific abnormalities suspicious for lung cancer
   Review of the screening exam reveals nodule(s) larger than 10 mm in size, mass(es), or other clinically suspicious abnormality (as determined by the interpreting radiologist). For this code it is suggested that the radiologist include in the text field, “Other observations/comments” (Part D), the abnormality (or code number) from Q12 and/or use free text to explain the significant finding. This text can then be put into the Results Letters sent to the participant and her/his physician of record. Proceed to Q14.

6 = Inadequate CT, non-diagnostic exam
   The CT screening exams were diagnostically inadequate and insufficient information was obtained to determine the screening examination result. Per protocol, only 2 screening visits with three exam attempts per visit are allowed to complete the screening exam. This code should ONLY be used in the event the second screening visit also yields a non-diagnostic exam. Skip to Part D. If the screening exam is considered inadequate, but based on what is visible on the exam, there is a suspicion of lung cancer, than the screening exam should be recorded as positive. Proceed to Q14.

14. Indicate the overall suspicion for primary lung cancer (subjective impression) based on this screening CT: The radiologist should report her/his subjective suspicion for all positive screening examinations; record the appropriate response (code numbers 1-5).

15. What is the recommended next step for this participant? The radiologist should record her/his recommendation by placing a mark in the appropriate box. If Q13-screening result category equals 3, 4, or 5, a diagnostic follow-up recommendation should be made, either from the list provided or recorded within the “Other, specify” field. The recommendations listed map to the diagnostic recommendations on the “Results
Letter" templates for the participants and her/his physician of record. If Q13-screening result category equals 1, 2 or 6 a follow-up recommendation may not be warranted. If this is the case, select “no diagnostic intervention necessary” from the list provided.

- No diagnostic intervention necessary
  This response should be selected ONLY if no diagnostic, follow-up recommendation is indicated. If this recommendation is selected, no other recommendations in the list should be selected. Per protocol, all study participants continue NLST screening through T2 unless diagnosed with lung cancer. “Continue NLST screening” can be added to the T0 and T1 screening result letters/template if you chose to do so, this will alert the participant’s provider of the additional NLST screening exams.

- Comparison with historical images. If not available, recommend…NOTE: must check other procedure(s) in the event that historical images are not available. This logic is checked upon web entry.

- Thin-section chest CT or repeat low-dose helical CT (check all that apply)
  - 3 months from screening exam
  - 6 months from screening exam
  - 3-6 months from screening exam
  - 12 months from screening exam
  - 24 months from screening exam

- Diagnostic chest CT
- Contrast-enhanced CT nodule densitometry
- FDG-PET
- Tech-99m depreotide scintigraphy
- Biopsy (percutaneous, thoracoscopic, open, etc)
  It is recommended that the specific recommendation be included in the Part D, Other observations/comments.

- Other, specify:
  If selected, the adjacent text field must be populated and should be used ONLY for this recommendation. The web module will accept up to 50 characters.

Part D. Conclusion

Other observations/comments: The text field is optional and should be used, or not used, per site needs. The text field will not be reviewed by ACRIN, nor will it be included in any data analysis. The text field can be used to record findings that should be reported to the participant and physicians, including minor abnormalities not requiring immediate follow-up, significant abnormalities NOT suggestive of lung cancer, abnormalities resulting in a positive screening exam, or other pertinent observations. This text can then be directly input into the Results Letter sent to the participant and her/his physician of record. The web module will accept 150 characters.

16. Reader ID: Each study radiologist has a unique ACRIN ID, record the appropriate ID number.

17. Date of CT Interpretation: Record the date that the screening CT interpretation was completed; record date as month, day, and last digit of the year.

18. Reader Signature: This form serves as the source document for the C2 data and must be signed by the radiologist.

Signature of person responsible for data: Legible signature/name of the NLST staff member responsible for collating/reviewing the data and ensuring completion of the CRF.

Date form completed: Record the date the original CRF was completed (data recorded on form); record date as month, day, and last digit of the year.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the data on-line.