The I9 Form is completed for each screening exam at T0, T1, and T2. At T0 (baseline), the I9 documents comparison review of the baseline screen (C2 Form) with any historical images available. At T1 and T2 (study year 1 and 2), the I9 documents comparison review of the current screening exam (C2 Form) with prior NLST screening exam(s) and other interval imaging available. The I9 Form is to be completed by the ACRIN-NLST study staff: the research associate (study coordinator) 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 and should be retained in the study file.

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

Part A. Historical Images

1. **Review of historical (including interval) images:** Record the appropriate response code (1-No, 2-Yes) indicating whether or not historical/interval images were reviewed. Interval images refer to any imaging exams performed in the time between screening studies. At T1 and T2 the current screening exam should be compared to the previous NLST screening exam(s), therefore, it is expected that this field will be “yes” at T1 and T2. If historical images were not reviewed, answer Q2, then skip to the end and sign/date the form; no action or signature is required by the radiologist.

2. **Indicate the screening exam to which this I9 Form corresponds:** Record the appropriate response (code number 1-3) identifying the current study year.

3. **Historical imaging to compare with the current screening CT:** Record the type and date of each imaging exam reviewed by the radiologist; record date as month, day, and year. If more than five comparison exams are reviewed, list the five most recent exams.

Part B. Comparison Findings (completed by the radiologist)

4. **Were any Code 51 abnormalities seen on the current screening CT:** Record the appropriate response code (1-No, 2-Yes) identifying whether any non-calcified nodules or masses (Code 51 abnormalities) were reported on the current screening exam (C2 Form for the current study year). If no, skip to Q5. If yes, complete the table provided to document comparison findings for all non-calcified nodules/masses (Code 51 abnormalities) identified on the current C2 Form. This will be cross-referenced with the C2 Form by the BDMC.

   **Column 1:** Record the corresponding F-number for each non-calcified nodule/mass (Code 51 abnormality) identified on the current screening exam (C2 Form of current study year). The F-number appears in column 1 of the C2 abnormality table, Q12-page 2, and uniquely identifies the abnormality for tracking between the C2 and I9 Forms.

   **Column 2:** Record the appropriate response (code numbers 1, 2, 99) indicating whether or not the non-calcified nodule/mass (Code 51 abnormality) identified on the current C2 Form is visible on the historical/interval images. If ‘no’ or ‘unable to determine’, columns 3-5 should be left blank; responses within these data fields may generate data queries. If ‘yes’, columns 3-5 must be completed; this logic check is programmed in the web module.

   **Column 3:** This element is required if column 2 equals yes. From the historical/interval images, record the date of the imaging exam that the non-calcified nodule/mass (Code 51 abnormality) is first visible. Record date as month, day, and year.

   **Column 4:** This element is required if column 2 equals yes. Record appropriate response (code numbers 1, 2, 99) indicating whether or not the non-calcified nodule/mass (Code 51 abnormality) identified on the current C2 Form has enlarged relative to the historical/interval images.

   **Column 5:** This element is required if column 2 equals yes. Record the appropriate response (code numbers 1, 2, 99) indicating whether or not the non-calcified nodule/mass (Code 51 abnormality) identified on the current C2 Form shows a suspicious change in attenuation. Suspicious change in attenuation is an increase in attenuation from ground glass to a combination of ground glass and soft tissue or to pure tissue attenuation.
5. **Were other potentially significant abnormalities seen on the current screening CT?** Record the appropriate response code (1-No, 2-Yes) identifying whether any other significant abnormalities were reported on the current screening exam (C2 Form for the current study year). If no, skip to Q6. If yes, complete the table provided to document comparison findings. It is left to the clinical judgment of the radiologist to determine whether a given abnormality is significant to warrant comparison with historical images, if so, it should be recorded here.

**Column 1:** Record the corresponding F-number for each potentially significant abnormality identified on the current screening exam (C2 Form of the current study year). The F-number appears in column 1 of the abnormality table, Q12-page 2, and uniquely identifies the given abnormality.

**Column 2:** Record the appropriate response (code numbers 1, 2, 99) indicating whether or not the abnormality identified on the current C2 Form is visible on the historical/interval images. If ‘no’ or ‘unable to determine’, columns 3 and 4 should be left blank; responses within these fields may generate data queries. If ‘yes’, columns 3 and 4 must be completed; this logic check is programmed in the web module.

**Column 3:** This element is required if column 2 equals yes. From the historical/interval images, record the date of the imaging exam that the non-calcified nodule/mass (Code 51 abnormality) is first visible. Record date as month, day, and year.

**Column 4:** This field is required if column 2 equals yes. Record the appropriate response (code numbers 1, 2, 99) indicating whether or not the abnormality identified on the current C2 Form appears to have changed in a manner that warrants further investigation.

6. **In reviewing the historical images, are there now abnormalities visible on the current screening CT that you did not record on the C2 this study year?** Record the appropriate response code (1-No, 2-Yes) indicating whether the comparison review of historical/interval imaging revealed an abnormality that was not previously seen on the “blind review” of the current screening exam (C2 Form for current study year). If no, skip to Q7. If yes, complete the table provided.

**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 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 the 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 just right of 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 Q8 must be coded 4, 5, or 7.

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

53= Benign lung nodule(s) (benign calcification)
Code only once, regardless of the number or 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 data field 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 right upper lobe.
2 = RML
   The nodule/mass was found in the right middle lobe.
3 = RLL
   The nodule/mass was found in the right lower lobe.
4 = LUL
   The nodule/mass was found in the left upper lobe.
5 = Lingula
   The nodule/mass was found in the lingula.
6 = LLL
   The nodule/mass was found in the left lower 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 data field 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 data field 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 data field 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. Use the text line just right of the data field ONLY to specify this attenuation.
99= Unable to determine
Part C. Results and Recommendations (completed by the radiologist)

7. Did the review of historical or interval images change the current screening CT result and/or recommendation: Record the appropriate response (code numbers 1-2) indicating whether the screening CT result or recommendation has changed upon review of historical/interval imaging exams. If ‘no’, skip to part D. If ‘yes’, continue to Q8.

8. Indicate the current screening CT result based upon the review of historical or interval images: Record the appropriate response (code numbers 1-7) based upon the presence and type of abnormalities reported on both the current C2 and I9 Forms.

   1 = Negative screen, no significant abnormalities
   Review of the screening exam reveals no significant abnormalities. Skip to Q10.

   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 Q10.

   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 Q10, a follow-up recommendation should be made.

   4 = Positive screen, nodule(s) 4-10mm or enlarging nodule(s) <7mm
   Review of the screening exam reveals nodule(s) 4-10 mm in size (Code 51) or other nodules that have increased in size since a previous imaging exam but are still less than 7 mm. Proceed to Q9.

   5 = Positive screen, nodule(s) > 10mm, enlarging nodule(s) > 7mm, mass(es), or 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 number (code number) from Q12 and/or 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 Q9.

   6 = Inadequate CT
   If the screening exam for the current study-year yielded an inadequate screen (as documented on the CT), in most cases, a comparative review will not be possible. This should be documented in the study file and a GCM submitted to ACRIN DM documenting that an I9 will not be submitted for the study year.

   7 = Positive screen, abnormalities suspicious for lung cancer, no significant change
   Review of the T1 or T2 screening exam reveals no significant change from previous positive screening exam. Per protocol, indeterminate nodules/masses (Code 51 abnormalities) should be followed and considered positive for a period of 24 months, although the level of suspicion may change (Q9, below). Proceed to Q9. For example: Baseline exam was positive due to a Code 51 nodule. At T1, the nodule appears stable or is not visible. The T1 screen remains positive based on the previous screen. If at T2 the nodule is still stable or not visible, then the screening result can be negative (if appropriate, based on possible other findings).

9. If a positive screen, what is your suspicion for primary lung cancer (subjective impression): The radiologist should report her/his subjective suspicion for all positive screening examinations; record the appropriate response (code numbers 1-5).

10. What is the recommended next step for this study 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 in 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.

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

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

13. Reader Signature: When historical images are reviewed this form serves as the source document for the comparative review 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 NLST staff member submitting the data on-line.