The I8 Form is completed for each screening exam at T0, T1, and T2. At T0 (baseline), the I8 Form documents comparison review of the baseline screen (DR Form) with any historical images available. At T1 and T2 (study year 1 and 2), the I8 Form documents comparison review of the current screening exam (DR Form) with prior NLST screening exam(s) and other interval imaging available. The I8 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.

Per protocol, the screening CXR consists of an upright PA projection CXR. If a lateral projection was performed in error, the radiologist should not use the lateral CXR projection for the current screening interpretation and results (DR Form). However, the lateral projection can/should be reviewed as part of historical/interval imaging (I8 Form). If the lateral projection is reviewed and used to complete the DR, a PR Form documenting this should be submitted to ACRIN.

Part A. Historical Images

1. Review of historical or 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 I8 Form corresponds: Record the appropriate response (code number 1-3) identifying the current study year.

3. Historical or interval imaging to compare with the current screening CXR: 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 CXR: 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 (DR 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 DR Form. This will be cross-referenced with the DR 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 (DR Form for current study year). The F-number appears in column 1 of the DR abnormality table, Q14-page 2, and uniquely identifies the abnormality for tracking between the DR and I8 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 DR 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 DR 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 DR 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 CXR? Record the appropriate response code (1 - No, 2 - Yes) identifying whether any other significant abnormalities were reported on the current screening exam (DR 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 (DR 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 DR 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 DR 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 CXR that you did not record on the DR 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 (DR 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 25 (Location of Epicenter, Dimensions, Margins) should be completed ONLY for non-calcified nodule(s) or mass(es), Code 51 abnormalities.
- If 6 or more nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- Use text lines in Column 1 to specify abnormalities ONLY for Codes 63, 64, and 65.
- If multiple non-calcified nodules/masses are visible, 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 are visible, code as 51 and provide descriptive data within the table (columns 2-5).
If more than 14 non-calcified nodules/masses are visible 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 2-5), then use 63 to document the others. In this event, the study will not dictate the number of nodules 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 just right of the F-number. The text line just right of this data field should be used when reporting Code 63-65 abnormalities ONLY.

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 2-5 of this table must be completed. When reporting this abnormality Q8 must be coded 4 or 6.

53= Benign lung nodule(s) (benign calcification)
Code only once, regardless of 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 DR 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 – Location of Epicenter:
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.

1 = Rt. Upper Zone
   The abnormality was found in the upper 1/3 of the right lung field.

2 = Rt. Middle Zone
   The abnormality was found in the middle 1/3 of the right lung field.

3 = Rt. Lower Zone
   The abnormality was found in the lower 1/3 of the right lung field.

4 = Lt. Upper Zone
   The abnormality was found in the upper 1/3 of the left lung field.

5 = Lt. Middle Zone
   The abnormality was found in the middle 1/3 of the left lung field.

6 = Lt. Lower Zone
   The abnormality was found in the lower 1/3 of the left lung field.

7 = Other, specify
   Use this response if the epicenter of the abnormality is difficult to identify. The web text field allows up to 20 characters.

Column 3 – Dimension / Longest Diameter:
Record the maximum length of the nodule/mass in millimeters, using whole integers. If unable to determine the length of the nodule/mass, 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 4 – Dimensions / Longest Perpendicular Diameter:
Record the maximum perpendicular length of the nodule/mass using whole integers. If unable to determine the perpendicular length of the nodule/mass, 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 – Margins:
Categorize the appearance of the nodule/mass margins by recording the appropriate response (code numbers 1-3, 99). 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

Part C. Results and Recommendations  (completed by the radiologist)

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

8. Indicate the current screening CXR result based upon the review of historical or interval images: Record the appropriate response (code numbers 1-6) based upon the presence and type of abnormalities reported on both the current DR and I8 Forms.
ACRIN-NLST 6654 CRF COMPLETION INSTRUCTIONS

**I8 COMPLETION INSTRUCTIONS**

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), mass(es) or other abnormalities suspicious for lung cancer**
   Code 51, non-calcified nodule or mass, is always considered a positive screen. Based on clinical judgment, the interpreting radiologist will determine whether other abnormalities visualized may be suspicious for lung cancer. Proceed to Q9.

5 = **Inadequate CXR, non-diagnostic exam**
   If the screening exam for the current study-year yielded an inadequate screen (as documented on the DR), 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 I8 will not be submitted for the study year. Skip to Part D.

6 = **Positive screen, stable abnormalities potentially related to 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). 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). Proceed to Q9.

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 Q8-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.
- Follow-up CXR to better determine whether the finding observed on screening CXR is indeed a lung abnormality and its location (check all that apply)
  - PA/LAT
  - Apical-lordotic
  - Shallow oblique views
I8 COMPLETION INSTRUCTIONS

- PA/LAT with nipple markers
- Other, specify (web module will accept up to 50 characters)
  - Chest fluoroscopy to better determine whether the finding observed on screening CXR is indeed a lung abnormality and its location
  - Low kV chest x-ray to determine whether the screening abnormality is calcified
  - Follow-up chest x-ray in three (3) months
  - 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.
  - 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

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 RA/staff member responsible for collating/reviewing the data and ensuring completion of the CRF.

Date form completed: Record the date the CRF was completed (data recorded); 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.