The FL Form is completed by the site RA and mailed to ACRIN Data Management for data entry. It is used only for the selected sample of cases identified in the report (Positive Screen Sample). Documentation should be completed as follows:

- Participants with positive T0 screens and no reported diagnostic follow-up. Complete the FL Form using all information (Follow-up Forms, notes, physician/participant contacts) from a 12-month period from the date of the T0 screen or until the T1 screen (if performed).

- Participants with positive T1 screens and no reported diagnostic follow-up. Complete the FL Form using all information (Follow-up Forms, notes, physician/participant contacts) from a 12 month period from the date of the T1 screen or until the T2 screen (if performed).

- Participants with positive T2 screen and no reported diagnostic follow-up. After receiving the participant’s T3 Follow-up Form, determine whether the participant reported any diagnostic follow-up on the T2.5 and/or T3 Follow-up Form. If no diagnostic follow-up was reported, attempt to determine if diagnostic follow-up occurred (notes, provider). Complete the FL Form using all information from a 12-month period from the date of the T2 screen.

- If the participant did not complete a T2.5 or T3 Follow-up Form, attempt to determine if diagnostic follow-up occurred (notes, provider and/or participant). Complete the FL Form using all information from a 12-month period from the date of the T2 screen.

1. **Screening:** Indicate the screen for which the form is being completed by recording a check mark in the box next to the appropriate screening year. Check only one response.

2. **Date of Exam:** Record the date of the screening exam for which the form is being completed. Record date as month, day, and year (mm-dd-yyyy).

3. **Source of information for completion of FL Form:** Indicate the information source(s) for completion of the FL Form (question 4 and 5) by recording a check mark in the box next to the appropriate response. Check all that apply. For example: [a] If the chart indicated that no diagnostic follow-up occurred and participant’s PCP was called to confirm this information, check both “NLST chart notes” and “primary care provider.” [b] If the study chart contains no information pertaining to the relevant screening exam and you are unable to contact either the provider or the participant, check “no information available”.

   1. **1 NLST chart notes:** Check this response if there is any information in the study file indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).

   2. **2 Medical records:** Check this response if you found any information within in-house or external medical records indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).

   3. **3 Primary care provider:** Check this response if you contacted the office of the primary care provider and obtained information indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).
4 Other provider(s): Check this response if you contacted a health care provider, other than the participant’s PCP, and obtained information indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below). This box should be checked if your information source was a provider, other than PCP, to whom the results letter was sent.

5 Participant: Check this response if the participant was contacted to confirm/establish whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below). Check this box only if the participant was contacted during the course of the FL investigation. Do not check this box if information came from F1/F2/chart note based on previous participant contact.

6 Representative for participant (participant unable to provide information): Check this response if an individual other than the participant provided information indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering question 4 and 5 below). This may occur if / when contacting the participant, a family member provides information indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).

7 Other source: Check this response and provide source if the source is other than those listed above (1-6), provided information indicating whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).

8 No information available: Check this response if you are unable to contact the participant or provider and neither the study chart or other medical records contain information relevant to determining whether or not diagnostic follow-up of the positive screen occurred (or any information relevant to answering questions 4 and 5 below).

4. Did the participant, at any time during the interval between annual screens, undergo any diagnostic follow-up as a result of the positive screen? For participants who missed their annual screen, or if positive T2 screen, was there any diagnostic follow-up within 12 months of the positive screen*? Record a check mark in the box next to the appropriate response.

   1 No: Check this response if you were able to determine that diagnostic follow-up of the positive screen did NOT occur. Answer question 5.

   2 Yes: Check this response if you were able to determine that diagnostic follow-up of the positive screen DID occur. Request medical records from appropriate provider(s) on the provider summary ID sheet for medical chart abstraction. Skip question 5.

   3 Unable to determine: Check this response if you were unable to determine whether diagnostic follow-up of the positive screen did or did not occur. For example: No information available (q3=8) or investigation was indeterminate (F1/F2=no care/test and site was unable to confirm this with primary care provider). Skip question 5.
5. **Reason why diagnostic follow-up of the positive screen did not occur**: Record a check mark in the box next to the appropriate response, as determined through the FL investigation. Check only one response.

1 **Provider was not aware of screening results or recommendations**: Check this response if it is determined that the participant’s provider of record was unaware of the screening results or recommendations. For example, the participant may have signed a waiver requesting the screening results not be sent to her/his provider or the participant may have refused to provide participant contact information for results/recommendations to be sent.

2 **Provider was aware of screening results and recommendations but advised no follow-up**: Check this response if it is determined that the participant’s provider explicitly advised/recommended no diagnostic follow-up for the positive screen. For example, [a] progress note from the provider stating no additional work-up was required (or similar language) or [b] direct interview of the provider (or provider’s staff), as part of the FL investigation, to include a statement that the provider did not recommend additional follow-up of the positive screen (or similar language).

3 **Participant declined to undergo follow-up for primarily financial reasons**: Check this response if it is determined that the participant refused/declined additional work-up for the positive screen due to financial reasons. For example, [a] a note was made in the study chart, based on a previous participant interview, where the participant stated that s/he refused diagnostic work-up for the positive screen (or similar language) because of the cost of follow-up/financial reasons or [b] direct interview of the participant, as part of the FL investigation, to include a statement by the participant that s/he decided not to undergo follow-up for the positive screen due to the cost of follow-up/financial reasons (or similar language).

4 **Participant declined to undergo follow-up for other reasons (not primarily financial)**: Check this response if it is determined that the participant refused/declined additional work-up for the positive screen for reasons other than financial. For example, [a] a note was made in the study chart, based on a previous participant interview, where the participant stated that s/he refused diagnostic work-up for the positive screen (or similar language) or [b] direct interview of the participant, as part of the FL investigation, to include a statement by the participant that s/he decided not to undergo follow-up for the positive screen (or similar language).

5 **Provider recommended repeat exam in one year / next annual NLST screen**: Check this response if it is determined that the provider did explicitly recommend follow-up of the positive screen but the recommended follow-up was a repeat screen in one year, coinciding with the next NLST screen. For example, [a] progress note from the provider stated repeat exam in one year (or similar language) or [b] direct interview of the provider (or provider’s staff), as part of the FL investigation, to include a statement that the provider recommended another CT/CXR in one year (or similar language).
6 Provider recommended diagnostic follow-up to be done at future date (outside the expected time interval). For participants who have undergone consecutive annual screens, the follow-up interval is the interval between annual scans. For participants who missed their annual screen, or if the [+ screen was at T2, the follow-up interval is 12 months. Check this response if it is determined that the provider did explicitly recommend follow-up for the positive screen but recommended follow-up beyond the follow-up interval. For example, [a] progress note from the provider stated participant should have a follow-up procedure in 18 months (or similar language) or [b] direct interview with the provider (or provider’s staff), as part of the FL investigation, to include a statement that the provider recommended follow-up of the positive screen in ~13-18 months (or similar language).

7 Unable to determine: Check this response if the FL investigation yields no explicit information as to why diagnostic follow-up was not performed. For example, [a] you were unable to contact the provider (due to waiver or no provider identified by participant) or [b] lack of documentation as to ‘why’ follow-up did not occur.

8 Other, specify: Check this response if it is determined that diagnostic follow-up did not occur due to a reason other than those identified above (1-6) and provide reason.

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 of form completion: Record the date the original CRF was completed (data recorded); record date as month, day, and year (mm-dd-yyyy).