Appendix 20-1 ACRIN NLST Case Report Form Set

ACRIN 6654

Contemporary Screening for the Detection of Lung Cancer

Case Report Form Set

American College of Radiology Imaging Network
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ACRIN Study 6654

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SS - Smoking Status Questionnaire - Spanish Version
QP - Baseline Health Status Questionnaire - Spanish Version
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QF - Health Status questionnaire - Spanish Version

Form Revision Notices

Form Revision Notice

Study: 6654

From: ACRIN Data Management Department

Date: 3/10/2008

RE: ACRIN 6654 Form Revision Notice: F2 Coversheet Instructions, NP Instructions, NP Form

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The following form revision was:

Posted to the ACRIN study website on: 3/10/2008

- **Posted to the online web entry system:** 3/10/2008
- **Effective date revised form distributed:** 3/10/2008

Revised F2 (X forms) Coversheet Instructions (v4, March 10, 2008)

The F2 Coversheet instructions have been revised to clarify recent vital status and interval date issues. The following revisions have occurred:

Question 1: Clarification has been added to the vital status descriptions.

Question 2: Instructions were revised to complete the interval date field whether or not the follow-up form was completed. Further instructions for completing the follow-up time interval dates were added to clarify what start and stop dates should be used when the participant does not complete the previous F1/F2 Follow-up Form.

Question 2b: The instructions have been further defined to state that "Lost participant, unable to locate participant" and "Lost to follow-up, unable to establish contact for a consecutive 18 month period" can be chosen only if the patient's vital status is "Unknown" . If, after 3 consecutive 6 month interval periods, the vital status of the patient is unknown, then "Lost to follow-up, unable to establish contact for a consecutive 18 month period" should be chosen on the X form. If the patient is alive (or known to be alive as documented from a reliable source) then "No response, multiple contact attempts made but participant has not replied" can be chosen on each X form where an F2 has not been completed (even if there are more than 3 consecutive 6 month intervals where the participant or proxy has not responded). The rationale for these changes is to ensure that those participants who are alive or known to be alive cannot be considered "Lost". Participants will only be "lost" if they cannot be located, therefore, their vital status cannot be ascertained.

Instructions have been added that 'no attempt made to administer Follow-up Form" should be chosen when the coversheet is being completed to document annual vital status only for all NP Level 3 Withdraws.

Two examples have been added to clarify the most frequently asked questions about interval dates.

Revised NP Form (v3, March 10, 2008)

Instructions: Withdrawal documentation will no longer need to be submitted to ACRIN along with the NP form. The instructions written at the top of the current NP form have been revised to remove the following "Submit all withdrawal documentation to ACRIN with NP form".

Revised NP Form Instructions (v3, March 10, 2008)

Question 2: Further clarification has been added to describe when investigator-initiated withdrawals should occur.

Question 2b:

- "Submit a copy of any withdrawal documentation with the NP Form" has been removed from options 2, 3, and 4.
- Language describing the withdrawal template letters has been removed.
- For withdrawal level 4, the participant should be asked whether NLST may conduct the NCHS database search.

Instructions detailing what to do when a participant chooses to return from a withdrawal have been added.

Decision Log #4 negates the previous decision log of 7.27.05 in which sites were instructed to use the Withdrawal Letters A & B from Appendix C & D of the NP instructions. NP Appendix C and D (Withdrawal Letters A & B) are now obsolete and should no longer be used.

For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

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M E M O R A N D U M

TO: ACRIN 6654 Principle Investigators and Research Associates

FROM: Sharlene Snowdon, AS, RT (R) (CT) (MR)
ACRIN Senior Research Associate

Patricia Blair, BS, RT (R) (CT)
ACRIN Research Associate

DATE: October 26, 2006

RE: **ACRIN Study 6654 F2 (Interval Follow-up Form) Revision Effective 10/30/2006**

CC: Irene Mahon, RN, MPH
ACRIN, Project Manager

Constantine Gatsonis, PhD
Protocol Statistician
Center for Statistical Sciences, Brown University

Pamela Harvey, M Mgt
Director, ACRIN Data Management

Anthony Levering, RT (R) (CT) (MR),
ACRIN Imaging Research Coordinator

#6654 FORM REVISION NOTICE

Implementation Date: 10/30/2006

Below is a list of the F2 form revision. An implementation date of 10/30/2006 has been established for these forms.

Questions or comments should be directed to ACRIN data management staff.

F2 Form: New version date is 02/21/2006
Revisions:

Revised page 8, question A7, a. from “Complications from a lung or chest procedure?” to “Care for complications from a lung or chest procedure?”

Revised page 9, question A8, a. from “Complications from a lung or chest procedure?” to “Care for complications from a lung or chest procedure?”

#6654 FORM REVISION NOTICE

Implementation Date: 6-17-04

Below is a detailed list of each form revision. An implementation date of 6-17-04 has been established for these forms, they should not be used until 6-17-04. As of 6-17-04 the web data collection modules will reflect these revisions. The web modules will continue to accept submission of forms completed prior to 6-17-04. The revised forms will be posted to the ACRIN web site on 6-16-04 and a reminder will be sent.

In most cases these revisions will not need IRB approval but this will be site specific. If your site requires IRB review/approval of the CRF revisions, and approval has not been obtained by 6-17-04, continue to use the 7-31-03 version until IRB approval is obtained.

Questions or comments should be directed to ACRIN data management staff.

C2 Form: New version date is 6-17-04
Revisions: Revised instructions, added, "The C2 Form serves as the source document for the interpretation of the CT screening exam and must be signed by the interpretating radiologist.

Q6 and Q7, for consistency, revised instructions to read "based on the CT equipment and platform report either mA or effective mAs."

Q13, response 3, added instructions to "provide a follow-up recommendation." For this negative category, the radiologist is asked to provide a diagnostic follow-up recommendation in Q15.

Q13, response 4 now reads "Positive screen, nodule(s) 4-10mm, suspicious for lung cancer." Deleted "…or enlarging nodule(s) <7mm…" as this is not appropriate for the C2 Form since the C2 is read blind. This remains part of Q8, response 4, on the I9 Form.

Q13, response 5 now reads "Positive screen, nodule(s) > 10mm, mass(es), other non-specific abnormalities suspicious for lung cancer." Deleted "...enlarging nodule(s) > 7mm…" as this is not appropriate for the C2 Form since the C2 is read blind. This remains part of Q8, response 5, on the I9 Form.

Q13, response 6 revised to clarify use of this code; now reads "Inadequate CT, non-diagnostic exam." This code should only be used if Q11=3 Non-diagnostic exam, thus no result or recommendation can be made. If Q11=1 or 2, a result and recommendation should be documented.

Q15, first recommendation revised to read "No diagnostic intervention necessary," deleted "continue NLST screening." This response should be selected ONLY if no diagnostic, follow-up recommendation is indicated. If this element 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.

Q18, now reads "Reader Signature."

DR Form: New version date is 6-17-04
Revisions: Revised instructions, added, "The DR Form serves as the source document for the interpretation of the CXR screening exam and must be signed by the interpretating radiologist.

Typo corrected in Part A instructions "…for Q6-10 record the technical parameters of the highest exposure that was performed." Previously read Q6-11.

Q15, response 3, added instructions to "provide a follow-up recommendation." For this negative category, the radiologist is asked to provide a diagnostic follow-up recommendation in Q17.

Q15, response 5 revised to clarify use of this code; now reads "Inadequate CXR, non-diagnostic exam." This code should only be used if Q13=3 Non-diagnostic exam, thus no result or recommendation can be made. If Q13=1 or 2, a result and recommendation should be documented.

Q17, first recommendation revised to read "No diagnostic intervention necessary," deleted "continue NLST screening." This response should be selected ONLY if no diagnostic, follow-up recommendation is indicated. If this element 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.

Q17, "Low-dose helical CT" has been added to the list of possible recommended next step(s), same as C2 and I9 Forms.

Q20, now reads "Reader Signature."

I8: New version date is 6-17-04
Revisions: Q1 now reads "Review of historical (including interval) imaging?" For clarification, the term interval imaging was added to the definition of historical imaging. At T0, historical images refer to all imaging exams prior to NLST entry/screen. At T1 and T2, historical/interval images refer to all prior imaging exams, previous NLST screening exam(s), and imaging exams performed since the last NLST screen.

Q3, PET Scan (response 6) added to response options for historical imaging review.

Q4, as clarification, now reads, " Were any Code 51 abnormalities seen on the current screening CXR?" All Code 51 abnormalities reported on the DR Form (of the current study year) should be identified by F-Number and compared with the historical images using the chart provided. The BDMC will crosscheck the DR/I8 Forms to ensure all Code 51 abnormalities reported on the DR Form have a comparison review documented on the I8 Form

Q5, as clarification, now reads, "Were any other potentially significant abnormalities seen on the current screening CXR?" Based on the findings reported on the DR Form (of the current study year), potentially significant abnormalities should be identified and compared with the historical images using the chart provided. The abnormalities documented here are left to the clinical judgment of the radiologist; there will not be a one-to-one accounting of the DR/I8 Forms by the BDMC.

Q6, as clarification, now reads, " In reviewing the historical images, are there now abnormalities visible on the current screening CXR that you did not record on the DR Form this study year?" Q6 refers only to the abnormalities not seen/recorded at the time of the initial-blind review and interpretation of the current study year's screening exam but seen after review of the historical/interval imaging.

Q7, as clarification, now reads, "Did the review of historical images change the current screening CXR result and/or recommendation?" Q7 refers only to the results of the current screening exam as reported on the DR Form this study year.

Q8, response 3, added instructions to "provide a follow-up recommendation." For this negative category, the radiologist is asked to provide a diagnostic follow-up recommendation in Q10.

Q8, response 6, new response added and reads, "Positive screen, stable abnormality potentially related to lung cancer, no significant change." This response is appropriate only at T1 and/or T2. Although the level of suspicion may change (Q9), positive screening exams due to non-calcified nodules/masses (code 51 abnormality) should be coded as positive and followed for a period of 24 months. This response should be used if the previous screen was positive and the T1/T2 screening exam shows no significant change.

Q10, first recommendation revised to read "No diagnostic intervention necessary," deleted "continue NLST screening." This response should be selected only if no diagnostic, follow-up recommendation is indicated. All study participants continue NLST screening through T2 unless diagnosed with lung cancer. "Continue NLST screening" should be added to the T0 and T1 screening result letters/template so that the participant's provider is aware.

Q10, "Low-dose helical CT" has been added to the list of possible recommended next step(s), same as C2 and I9 Forms.

Q13, now reads "Reader Signature." When historical images are reviewed the I8 serves as the source document for the comparison review of the screening CXR and historical images. Therefore, the signature of the interpretating radiologist must be on the completed paper form.

I9: New version date is 6-17-04

Revisions: Q1 now reads "Review of historical (including interval) imaging?" For clarification, the term interval imaging was added to the definition of historical imaging. At T0, historical images refer to all imaging exams prior to NLST entry/screen. At T1 and T2, historical/interval images refer to all prior imaging exams, previous NLST screening exam(s), and imaging exams performed since the last NLST screen.

Q3, PET Scan (response 6) added to response options for historical imaging review.

Q4, as clarification, now reads, " Were any Code 51 abnormalities seen on the current screening CT?" All Code 51 abnormalities reported on the C2 Form (of the current study year) should be identified by F-Number and compared with the historical images using the chart provided. The BDMC will cross-check the C2/I9 to ensure all Code 51 abnormalities reported on the C2 have a comparison review documented on the I9.

Q5, as clarification, now reads, "Were any other potentially significant abnormalities seen on the current screening CT?" Based on the findings reported on the C2 Form (of the current study year), potentially significant abnormalities should be identified and compared with the historical images using the chart provided. The abnormalities documented here are left to the clinical judgment of the radiologist; there will not be a one-to-one accounting of the C2/I9 Form by the BDMC.

Q6, as clarification, now reads, " 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?" Q6 refers only to the abnormalities not seen/recorded at the time of the initial-blind review and interpretation of the current study year's screening exam but seen after review of the historical/interval imaging.

Q7, as clarification, now reads, "Did the review of historical images change the current screening CT result and/or recommendation?" Q7 refers only to the results of the current screening exam as reported on the C2 this study year.

Q8, response 3, added instructions to "provide a follow-up recommendation." For this negative category, the radiologist is asked to provide a diagnostic follow-up recommendation in Q10.

Q8, response 6, new response added and reads, "Positive screen, stable abnormality potentially related to lung cancer, no significant change." This response is appropriate only at T1 and/or T2. Although the level of suspicion may change (Q9), positive screening exams due to non-calcified nodules/masses (code 51 abnormality) should be coded as positive and followed for a period of 24 months. This response should be used if the previous screen was positive and the T1/T2 screening exam shows no significant change.

Q10, first recommendation revised to read "No diagnostic intervention necessary," deleted "continue NLST screening." This response should be selected only if no diagnostic, follow-up recommendation is indicated. All study participants continue NLST screening through T2 unless diagnosed with lung cancer. "Continue NLST screening" should be added to the T0 and T1 screening result letters/template so that the participant's provider is aware.

Q13, now reads "Reader Signature." When historical images are reviewed the I8 serves as the source document for the comparison review of the screening CXR and historical images. Therefore, the signature of the interpretating radiologist must be on the completed paper form.

IM: New version date is 6-17-04
Revision: Q5, new response added and reads, "Positive screen, stable abnormality potentially related to lung cancer, no significant change since prior screening exam."

Complete Forms List: All current 6654 forms and version dates.

Participant Contact	1-2-2003	**QF**	3-7-03
MRRA	4-16-02	**CS**	7-31-03
PC	7-02	**C2**	7-31-03
ST	8-02	**DR**	7-31-03
E1	10-16-02	**I8**	7-31-03
A0	10-14-02	**I9**	7-31-03
BL	3-7-03	**IM**	7-31-03
DP	3-7-03	**PR**	7-31-03
PA	3-7-03	**Annual Contact**	10-30-03
SS	3-7-03	**F1**	10-30-03 or 10-30-03.b
QP	3-7-03	**FC**	10-30-03 or 10-30-03.b
QL	3-7-03	**FS**	10-30-03 or 10-30-03.b

Pending: DE, TF, CX, PQ

FORM REVISION NOTICE 7-31-2003

Forms Revisions for ACRIN-NLST Study #6654

Below is a detailed list of each form revision. In most cases these revisions will not need IRB approval but this will be site specific. A 7-31-2003 implementation date has been established for these forms. As of 7-31-2003 the web data collection modules will reflect these revisions. The revised forms will be posted to the ACRIN web site on 7-31-2003. Any questions or comments should be directed to ACRIN HQs data management staff.

CS: New version date is 7-31-03
Revisions: Q1, response 3 now reads "QF (Positive screening or matched control)" and response 4 now reads "PQ (Non-medical costs sub-study)". Both of these were incorrectly described on the previous version.

Q2 on previous version has been deleted, these data points are derived from the QOL form submitted.

Q3 on previous version is now Q2.

Q3b on previous version is now Q3.

C2: New version date is 7-31-03
Revisions: Q1, response 4 has been deleted. Each screening exam corresponds to a protocol specified time point as listed in Q1 responses 1-3. The screening window for each study time point is listed below and will be included with the next protocol amendments.
1 baseline=within 4 weeks of randomization (preferably 2 weeks)
2 incidence year 1=1 month prior to 3 months post the randomization anniversary date
3 incidence year 2=1 month prior to 3 months post the randomization anniversary date

Additional instructions have been added to Part A referencing the source for CT imaging parameters. The instructions now read: "…(completed by technologist; please refer to NLST CT Technique Comparison Chart for platform specific imaging parameters)"

Q11, "reschedule CT" has been deleted from response 3. If the first screening visit does not yield a diagnostic quality exam the CT should be rescheduled but the C2 form should not be completed until a diagnostic quality exam is obtained. If after 6 exam attempts (3 exam attempts x 2 visits) a diagnostic quality CT is not obtained, indicate so by using this response, but no further attempts should be made.

Q15, recommended next step “Thin-section chest CT” now reads “Thin-section chest CT or repeat low dose helical CT.” Report either recommendation with a suggested time point, as appropriate.

DR: New version date is 7-31-03
Revisions: Q1, response 4 has been deleted. Each screening exam corresponds to a protocol specified time point as listed in Q1 responses 1-3. The screening window for each study time point is listed below and will be included with the next protocol amendments.
1 baseline=within 4 weeks of randomization (preferably 2 weeks)
2 incidence year 1=1 month prior to 3 months post the randomization anniversary date
3 incidence year 2=1 month prior to 3 months post the randomization anniversary date

Additional instructions have been added to Part A explaining which set of technical factors to record in the event more than one exposure is made to obtain a diagnostic quality CXR. The instructions now read: “…(completed by technologist; for Q6-11 record the technical parameters of the highest exposure that was performed)”. In the event multiple exposures were performed, the highest exposure the participant received should be documented in this section, the highest exposure may or may not correspond to the final images submitted to ACRIN.

Q4 has been deleted.

Q4a added. “Total number of exposures performed to complete Screening CXR exam” Multiple exposures may be performed to acquire a diagnostic quality exam. For example, repeat exposure due to respiratory motion. *2 exposures were performed, first exposure was non-diagnostic (4a=2, 4b=1).*

Q4b added. “Number of images submitted to ACRIN that comprise this exam” Multiple exposures may be performed to acquire a diagnostic quality exam, record the number of images submitted as the final exam. For example, participant with long lungs which requires 2 exposures to cover complete anatomy, first set of exposures were over-exposed so exam was repeated. *4 exposures were performed, first set non-diagnostic so only 2 images were submitted to ACRIN as the diagnostic quality exam (4a=4, 4b=2).*

Q6-9, to serve as a reference, the protocol specified CXR imaging parameters were added to the form. They are listed individually below:
6. kVp (acceptable kVp range: 100-150)
7. mAs (based on CXR equipment report either mAs or mA and time; mAs should be <10 except for large participants)
8. mA (based on CXR equipment report either mAs or mA and time; mA should be between 100-1000)
9. Time (msec): exposure time should normally not exceed 40 msec

Q11, revised instructions now reference the CXR Equipment Data Form.

Q12, revised instructions now specify identifying the technologist exposing the participant.

Q13, “reschedule CXR” has been deleted from response 3. If the first screening visit does not yield a diagnostic quality exam the CXR should be rescheduled but the DR form should not be completed until a diagnostic quality exam is obtained. If after 6 exam attempts (3

exam attempts x 2 visits) a diagnostic quality CXR is not obtained, indicate so by using this response, but no further attempts should be made.

I8: New version date is 7-31-03
Revisions: The skip pattern for Q1 has been altered, the form now captures Q2 also. If no historical images are reviewed complete Q1 and 2 then skip to the end of the form and sign/date.

Q4 Chart, instructions added to assist appropriate completion of the chart. Columns 3-5 should be left blank if the reported Code 51 abnormality was not pre-existing. Added instructions read: If abnormality was pre-existing (column 2=2, yes) complete columns 3-5.

Q5 Chart, instructions added to assist appropriate completion of the chart. Columns 3-4 should be left blank if the reported abnormality was not pre-existing. Added instructions read: If abnormality was pre-existing (column 2=2, yes) complete columns 3-4.

I9: New version date is 7-31-03
Revisions: The skip pattern for Q1 has been altered, the form now captures Q2 also. If no historical images are reviewed complete Q1 and 2 then skip to the end of the form and sign/date.

Q4 Chart, instructions added to assist appropriate completion of the chart. Columns 3-5 should be left blank if the reported Code 51 abnormality was not pre-existing. Added instructions read: If abnormality was pre-existing (column 2=2, yes) complete columns 3-5.

Q5 Chart, instructions added to assist appropriate completion of the chart. Columns 3-4 should be left blank if the reported abnormality was not pre-existing. Added instructions read: If abnormality was pre-existing (column 2=2, yes) complete columns 3-4.

Q7, typo corrected, now reads: Did the review of historical images change the screening CT result and/or recommendation?

Q10, recommended next step “Thin-section chest CT” now reads “Thin-section chest CT or repeat low dose helical CT.” Report either recommendation with a suggested time point, as appropriate.

IM: New version date is 7-31-03
Revisions: New data element added (Q3a) to be answered only if screening result letter was not sent to the participant’s physician of record.
Q3a. Reason screening result letter not sent to physician of record:
1 Participant declined to identify a physician of record (document on participant contact sheet)
2 Participant requested physician of record not be notified of screening results (documentation with participant signature must be retained in case study file)
3 Other, specify:_____

New data element added (Q6) to capture the screening exam time point.
Q6. Indicate the screening exam to which this IM Form corresponds:
1 Baseline
2 Incidence Screen, year 1
3 Incidence Screen, year 2

PR: New version date is 7-31-03
Revisions: Form now collects imaging parameter deviations, discovery date and description for all reported events.

Complete Forms List: All final 6654 forms and current version dates.

Participant Contact Sheet	1-2-2003
MRRA	4-16-02
PC	7-02
ST	8-02
E1	10-16-02
A0	10-14-02
BL	3-7-03
DP	3-7-03
PA	3-7-03
SS	3-7-03
QP	3-7-03
QL	3-7-03
QF	3-7-03
CS	7-31-03
C2	7-31-03
DR	7-31-03
I8	7-31-03
I9	7-31-03
IM	7-31-03
PR	7-31-03

Pending: F1, DE, TF, CX, PQ

If you have any questions, contact the Data Management Department at (215) 574-3245.

FORM REVISION NOTICE 3-12-2003

Forms Revisions for ACRIN-NLST Study #6654.

Below is a detailed list of each form revision. The decision was made to separately document the person completing the form and the person web entering the form, no new data points were added. In most cases these revisions will not need IRB approval but this is site specific. New versions should be in use by 3-24-2003, if unable to meet this requirement please inform data management. Please discard all unused old versions you may have and replace with the current versions available on the ACRIN web site.

BL: New version date is 3-07-03
Revision: Signature line revised. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF.

PA: New version date is 3-07-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

DP: New version date is 3-07-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for reviewing the CRF responses with the participant for completeness/accuracy. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

SS: New version date is 3-7-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for reviewing the CRF responses with the participant for completeness/accuracy. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

QP: New version date is 3-7-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for reviewing the CRF responses with the participant for completeness/accuracy. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

QF: New version date is 3-7-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for reviewing the CRF responses with the participant for completeness/accuracy. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

QL: New version date is 3-7-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for reviewing the CRF responses with the participant for completeness/accuracy. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

DR: New version date is 3-7-03
Revision: Q10-DR added to instructions, now reads "for CR/DR units, if known." Use this field to report the Exposure Value (aka S-Value, Exposure Index, Dose Monitoring Tool) for CR or DR images if displayed and available; this is an optional web field.

Q14 chart-revised chart completion instructions, please read.

Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

C2: New version date is 3-7-03
Revision: Q12 chart -revised chart completion instructions, please read.

Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

I8: New version date is 3-7-03
Revision: Q6 chart-revised chart completion instructions, please read.

Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

I9: New version date is 3-7-03
Revision: Q6 chart-revised chart completion instructions, please read.

Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

IM: New version date is 3-7-03
Revision: Signature line revised and added line to capture data entry person. "Research Associate" now reads "Signature of person responsible for data," this should be the site staff responsible for collating the data and completing the CRF. "Signature of person entering data onto web," this should be the site staff responsible for data entry of the CRF.

Complete Forms List: All final 6654 forms and current version dates.

Participant Contact Sheet	**1-2-2003**
MRRA	**4-16-02**
E1	**10-16-02**
A0	**10-14-02**
QP	**3-7-03**
SS	**3-7-03**
DP	**3-7-03**
PA	**3-7-03**
BL	**3-7-03**
DR	**3-7-03**
C2	**3-7-03**
I8	**3-7-03**
I9	**3-7-03**
IM	**3-7-03**
QF	**3-7-03**
QL	**3-7-03**
PC	**7-02**
ST	**8-02**

Pending: C3, F1, DE, TF, CX

If you have any questions, contact the Data Management Department at (215) 574-3245.

FORM REVISION NOTICE: 1-2-2003

Forms Revisions for ACRIN-NLST Study #6654.

Please discard all unused old versions you may have and replace with the current versions available on the ACRIN web site. For consistency, current versions should be in use no later than 1-20-2003. The ACRIN-NLST web data collection modules will reflect the new paper form.

Participant Contact Information Sheet: New version date is 1-2-03.
Revision: Instructions revised, group 1 sites only need to fax information sheet to Brown University.

DR: New version date is 1-2-03.
Revision: Instructions added to Q7-10. Typo corrected in Q14-chart, F15 and F16 now read F1 and F2. Revised skip pattern for Q15, response 5 now skips to Part D versus Q17.

C2: New version date is 1-2-03.
Revision: Skip pattern for Q13, response 6 now skips to Part D versus Q15.

I8: New version date is 1-2-03.
Revision: Skip pattern for Q8, response 5 now skips to Part D versus Q10.

I9: New version date is 1-2-03.
Revision: Skip pattern for Q8, response 6 now skips to Part D versus Q10.

IM: New version date is 1-2-03.
Revision: Correction box added to form.

Complete Forms List: All final 6654 forms and current version dates.

Participant Contact Information Sheet, 1-2-2003
MRRA, 4-16-02
E1, 10-16-02
A0, 10-14-02
CS, 10-3-02
QP, 10-3-02
SS, 10-28-02
DP, 10-25-02
PA, 10-3-02
BL, 08-02
PC, 07-02

ST, 08-02
DR, 1-2-03
C2, 1-2-03
IM, 1-2-03
I8, 1-2-03
I9, 1-2-03
QF, 10-3-02
QL, 10-3-02

If you have any questions, contact the Data Management Department at (215) 574-3245.

FORM REVISION NOTICE: 10/29/2002

Form Revisions for ACRIN-NLST Study # 6654.

Please discard all old versions you may have and replace with the current versions available on the ACRIN web site. For consistency, current versions should be in use no later than 11/04/2002. The ACRIN-NLST web data collection modules will reflect the new paper form.

E1: New version date is 10/16/2002
Revision: Q1-ACRIN is now collecting DOB as mm/dd/yyyy and typo on page 3 corrected. Prior version dates already mailed to and/or completed by participants are acceptable if DOB is captured as mm/dd/yyyy.

A0: New version date is 10/14/2002
Revision: Q8-ACRIN is now collecting DOB as mm/dd/yyyy. Web programming for this change is in progress.

SS: New version date is 10/28/2002
Revision: Typos corrected and instructions added to better identify data skip patterns for participant; no data content changes. Prior version dates already mailed to and/or completed by participants are acceptable.

DP: New version date is 10/25/2002
Revision: Typo corrected and deleted smoking questions (Q32-37). This data is collected on the E1; to eliminate inconsistent participant responses the duplicate questions were removed from the DP. The web module of the DP will include these questions at the end and should be abstracted from the E1. Prior version dates already mailed to and/or completed by participants are acceptable, but please reference the smoking questions with the E1 for consistency.

CS: New version date is 10/03/2002
Revision: Aesthetic changes, no data content changes.

QP, QL, QF: New version date is 10/03/2002.
Revision: Aesthetic changes, no data content changes.

PA: New version date is 10/03/2002
Revision: Aesthetic changes, no data content changes.

IM: New version date is 10/07/2002
No revisions-new form to document that result letters were sent, protocol requirement.

DR: New version date is 10/16/2002
Revision: Aesthetic changes to 10/07/2002 version. Completed forms with version date prior to 10/07/2002 must be reconciled with current version-Q17. The web programming for this form is in progress and will reflect the data content of the 10/16/2002 version.

C2: New version date is 10/16/2002
Revision: Aesthetic changes to 10/03/2002 version. Completed forms with version date prior to 09/18/2002 must be reconciled with current version-Q13,15. The web programming for this form is in progress and will reflect the data content of the 10/16/2002 version.

I8: New version date is 10/17/2002
Revision: Data content changes Q4, Q5, Q10. Completed forms with version date prior to 10/17/2002 must be reconciled with the current form. The web programming for this form is in progress and will reflect the data content of the 10/17/2002 version.

I9: New version date is 10/17/2002
Revision: Data content changes Q4, Q5. Completed forms with version date prior to 10/17/2002 must be reconciled with the current form. The web programming for this form is in progress and will reflect the data content of the 10/17/2002 version.

Pending: C3, F1, DE, TF

If you have any questions, contact the Data Management Department at (215) 574-3245.

Registration/Randomization

E1

ACRIN 6654 NLST Pre-Registration Eligibility Worksheet

Site # _____

Case # _____

Instructions: Items indicated below make up the questions determining eligibility for registration into the ACRIN 6654 National Lung Screening Trial (NLST). The form MUST be completed PRIOR to participant registration. For the participant to be registered as an ELIGIBLE case, the responses coded must reflect those indicated as eligible responses on the attached RA instruction sheet (page 3). This form is to be retained at the study site and is not submitted to ACRIN Headquarters.

Contact information for potential participant:

_____ Name (or initials) of potential participant

_____ Telephone 1 (home)

_____ Telephone 2 (work/other, specify_____)*

_____ E-mail address *

_____ Mailing Address *

_____

_____

_____ Other contact information*

_____ ** Optional data*

A. Age

1. What is your date of birth? |__|__|-|1|9|__|__| **(mm-yyyy)**

2. What was your age at your last birthday? |__|__| **years of age**

B. Cigarette Smoking History

3. |__| **Have you ever smoked cigarettes?**
1 no
2 yes

4. |__|__| **At what age did you start smoking cigarettes?**

5. |__| **Do you smoke cigarettes now?**
1 no
2 yes

6. |__| **When was your last cigarette?**
1 less than 6 months ago
2 6 months to 3.9 years ago
3 4 years to 9.9 years ago
4 10 years to 15 years ago
5 more than 15 years ago

7. |__|__| **For how many years total have you smoked cigarettes?**

8. |__|__|__| **How many cigarettes smoked per day (on average)?**

9. |__|__| **How many packs per day do you/did you smoke (on average)?**

10. |__|__|__| **How many Pack-Years of cigarette smoking (question 7 x question 9)?**

C. Factors / Medical conditions that may affect participation in this trial:

Please answer **1 No** or **2 Yes** to the following questions.

11. ☐ **Are you able to lie on your back, with your arms resting above your head?**

12. ☐ **Do you have any metallic implants in your chest or back** (e.g. Harrington fixation rods, pace maker)**?**

13. ☐ **Have you ever been diagnosed or treated for *lung cancer*?**

14. ☐ **In the past five (5) years, have you been treated for cancer or been told by a doctor that you have evidence of cancer** (other than non-melanoma skin cancer)**?**

15. ☐ **Have you had any portion of your lungs removed?**

16. ☐ **Are you on home oxygen supplementation?**

17. ☐ **Are you currently participating in any cancer screening trial** (such as ELCAP or PLCO)**?**

18. ☐ **Do you/have you participated in any cancer prevention trial, other than a smoking cessation program?**

19. ☐ **Have you had unexplained weight loss of over 15 pounds within the past year or experienced hemoptysis** (spitting up blood)**?**

20. ☐ **Have you experienced pneumonia, or an acute respiratory infection that was treated with antibiotics, under a doctor's supervision, within the last 12 weeks?**

21. ☐ **Have you been treated with cytotoxic agents for any condition within the last 6 months?**

22. ☐ **Have you had a chest CT scan within the past 18 months?**

Comments: _____

_____

_____

_____

_____

Person completing form

__ __-__ __-2 0 0 __

Date form completed (mm-dd-yyyy)

E1

Site # _____

Case # _____

The responses provided on this page are for RA reference ONLY. These responses are not to be distributed to the participant.

RA instructions: Below are eligible responses for the E1 worksheet for ACRIN 6654, NLST. For a participant to be registered, responses for the questions listed must correspond to the eligible responses indicated. Potential participants may complete pages 1 and 2. This page lists eligible responses for the RA to refer to when reviewing the responses on pages 1 and 2.

Question	Eligible Response
2.	between 55 years and 74 years + 364days
3.	2 (yes)
5.	2 (yes)/1 (no)
6.	Codes 1-4 only
9.	Formula: Packs Per Day (PPD) = Cigarettes per day x 0.05
10.	Formula: Pack years = PPD x years smoked (question 7 x question 9) Required: Greater than or equal to 30 pack years
11.	2 (yes) allow for lying on the back with 1-2 pillows, legs/knees supported
12.	1 (no)
13.	1 (no)
14.	1 (no) / other than non-melanoma skin cancer
15.	1 (no) / excluding simple biopsy and percutaneous needle biopsy. Question any lung related surgery.
16.	1 (no) / CPAP is OK.
17.	1 (no) / Such as Early Lung Cancer Action Program (ELCAP), Prostate Lung Colorectal Ovarian (PLCO), Lung Health Study, etc.
18.	1 (no) / Smoking cessation is OK.
19.	1 (no)
20.	1 (no) / if yes, postpone eligibility for NLST, for 12 weeks from the date of the first dose of antibiotics
21.	1 (no) / if yes, postpone eligibility for NLST, for 6 months from the last dose of the drug from the final cycle
22.	1 (no) / if yes, postpone eligibility for NLST, for 18 months from the date of the last chest CT scan

A0

ACRIN 6654
NLST
Registration Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: The Eligibility Checklist (E1) must be completed prior to registration to determine and confirm study eligibility. At the time of enrollment, the participant is to review, sign and date the consent, MRRA and E1. The following questions will be asked at study registration. This data is submitted via the ACRIN Website. Submit a paper form only in the event the website is down.

Part 1: The following questions will be asked at Registration

_____ **1. Name of institutional person registering this case?** *(Initials only, please)*

|__|__| **2. Has the Eligibility Checklist (E1) been completed?**
1 No
2 Yes

|__|__| **3. Is the participant eligible for this study?**
1 No
2 Yes

___ - ____ - 200___ **4. Date the study-specific Consent Form was signed** *(Must be prior to study entry)*

|__|__| **5. Participant Initials** *(Last, First)*

_____ **6. Verifying Physician** *(Site PI)*

_____ **7. Participant's ID Number** *(Do Not utilize a medical record number or radiology assigned number)*

___ - ____ -19____ **8. Date of Birth** (mm-dd-yyyy)

|__| **9. Ethnic Category**
1 Hispanic or Latino
2 Not Hispanic or Latino
9 Unknown

|__| **10. Race**
1 American Indian or Alaskan Native
2 Asian
3 Black or African American
4 Native Hawaiian or other Pacific Islander
5 White
6 More than one race
9 Unknown

|__|__| **11. Gender**
1 Male
2 Female

|__| **12. Participant's Country of Residence**
1 USA
2 Canada
3 Other

_____ **13. Zip Code** *(U.S. Residents)*

|__| **14. Participant's Insurance Status**
0 Other
1 Private Insurance
2 Medicare
3 Medicare and Private Insurance
4 Medicaid
5 Medicare and Medicaid
6 Military or Veterans Administration
7 Self Pay
8 No Means of Payment
9 Unknown/Decline to answer

|__|__| **15. Will any component of the Participant's care be given at a military or VA facility?**
1 No
2 Yes

A0

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I: Continued

___ - ___ - 200 **16. Calender Base Date** *(mm-dd-yyyy)*

___ - ___ - 200 **17. Randomization Date** *(mm-dd-yyyy)*

18. Other Country of Residence, specify: _____

__ **19. Participant's Age Group**

1 55-59
2 60-64
3 65-69
4 70-74

Part 2: The following questions are specific for ACRIN -NLST 6654

__ **20. Has the participant signed consent to have his/her tissue kept for use to learn about, prevent or treat cancer?**

1 No
2 Yes

__ **21. Has the participant signed consent to have his/her tissue kept for use to learn about, prevent or treat other health problems?**

1 No
2 Yes

__ **22. Did the participant come to the study via the 1-800-4-CANCER hotline?**

1 No
2 Yes

__ **23. What prompted the participant to contact the study site?**

1 Local/National Radio advertisements
2 Local/National TV advertisements
3 Physician/Clinic referral
4 Word of mouth
5 Targeted mailing
9 Other recruitment efforts

__ **24. The participant has signed an annual Medical Record Release Authorization (MRRA)?**

1 No
2 Yes

__ **25. Has the participant signed consent to have his/her blood, urine, sputum kept for use to learn about, prevent or treat cancer?**

1 No
2 Yes

__ **26. Has the participant signed consent to have his/her blood, urine, sputum kept for use to learn about, prevent, or treat other health problems?**

1 No
2 Yes

__ **27. Has the participant signed consent to allow someone from ACRIN NLST to contact him/her in the future to ask them to take part in more research?**

1 No
2 Yes

For any questions regarding participant eligibility, contact ACRIN Data Management at 1-800-227-5463.

_____
Research Associate

__-__-2000
Date form completed (mm-dd-yyyy)

AUTHORIZATION FORM FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

You have agreed to participate in the Contemporary Screening for the Detection of Lung Cancer study trial and have signed a separate informed consent that explained the procedures of the study. This authorization form provides information about how your health information will be protected and permits the release of your medical records from health care facilities where you have been seen. Information from your medical records will be used for the National Lung Screening Trial (NLST) being conducted by the American College of Radiology Imaging Network (ACRIN) and the National Cancer Institute (NCI).

What personal health information is collected and used in this study, and might be disclosed?

Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you. Information disclosed during this study may include information from your medical records such as progress notes, operative reports, discharge summaries, history and physical exams, radiology reports, image data from radiology examinations, and tissue or cytologic samples. Additional information collected will include your telephone number, the telephone number of a family member, your social security number, your family medical history and your medical record number. Study records that identify you will be kept confidential as required by law.

Which of the study personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team
- Institutional Review Boards, committees charged with overseeing research on human subjects)
- Authorized members of the research workforce who may need to access your information in the performance of their duties. For example: to provide treatment, to abstract information from your medical records for the study's research database, to ensure integrity of the research and accounting or billing matters.

Who, outside of the principal investigator and the research workers, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, your personal health information will be disclosed to the following:

- Research data coordinating office: *American College of Radiology Imaging Network (ACRIN)*
- Research data management office: *Brown University*
- Government agency: *National Cancer Institute*

AUTHORIZATION FORM FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Once information is disclosed to others outside the research study, the information may no longer be covered by the federal privacy protection regulations. In all disclosures outside of the principal investigator and the study team, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

Does My Authorization Expire?
This authorization does not expire. At any time you may cancel the authorization in writing by contacting the principal investigator. If you decline to provide this authorization, you will not be able to participate in the research study. However, information gathered before the cancellation date may be used if necessary in completing the research study or any follow-up for this study.

By signing this form you authorize **< insert Study Site Name>** to use and disclose personal health information and authorize the release of your medical records from health care facilities where you have been seen during the course of your participation in this research study.

_____
Participant's Name **[print]**

_____ _____
Participant's Signature **[print]** **Date**

PA

ACRIN 6654 NLST Pulmonary Function Test Form

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form documents the spirometry performed at the enrollment visit. Responses to Parts A and B will be retained at the site. The RA is to submit only part C of this form via the ACRIN website. Submit part C via paper only in the event of a revised or corrected form via fax to ACRIN Data Management.

A. Preliminary Questions to Ask Participant Prior to Testing. A "yes" answer will require that spirometry be postponed. *Note*: Postpone spirometry for the time(s) indicated.

1. ☐ **Have you had a respiratory infection in the past 3 weeks (including today)?**
1 No
2 Yes*
If yes, **reschedule tests for 3 weeks** from time of resolution of symptoms.

2. ☐ **In the past 6 hours, have you used a short-acting inhaled bronchodilator, such as Albuterol® (brand names Proventil® or Ventolin®) or Ipratropium (brand name Atrovent®)?**
1 No
2 Yes*
If yes, **postpone tests for 6 hours** or more from the last time of inhalant usage.

3. ☐ **In the past 24 hours, have you used a long-acting inhaled bronchodilator, such as Salmeterol (brand name Serevent®), or a long-acting oral bronchodilator, such as Proventil Repetabs® or a twice-daily Theophylline (brand name Theodur® or Theobid®).**
1 No
2 Yes*
If yes, **postpone test 24 hours** or more.

4. ☐ **In the past 6 hours, have you used a short-acting oral bronchodilator (such as Proventil® 2 mg or 4 mg) or an over-the-counter preparation for chest congestion, wheezing or asthma?**
1 No
2 Yes*
If yes, **postpone test for 6 hours** or more from the time the medication was taken.

B. Participant data

5. ☐☐ **Age of participant**

6. ☐ **Gender (sex) of participant**
1 Male
2 Female

7. ☐☐☐ **cm** **Height of participant** (with shoes removed)

PA

If this is a revised or corrected form, please check box and fax page 2 only to 215-717-0936. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

C. Spirometry: Perform the spirometry per the recommendations of the American Thoracic Society (ATS) utilizing the SpiroPro device provided to each study site.

8a. Date of spirometry ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

8b. ☐ **Date reflects postponed spirometry date:**

1 No
2 Yes

8c. ☐ **Verify that flow-volume measurements were performed as per ATS criteria:**

1 No
2 Yes

9. FVC (L-BTPS)
From the best trial
☐.☐☐☐

10. FVC% predicted
☐☐☐.☐

11. FEV_1
From the best trial
☐.☐☐☐

12. FEV_1 % predicted
FEV_1 % predicted = 100 x (observed FEV_1 /predicted FEV_1)
☐☐☐.☐

13. FEV_1/FVC
Calculated using the best FEV_1 and best FVC
☐.☐☐

Comments (may include comments on effort, etc.):_____

_____

_____

_____
Signature of person responsible for data

☐☐-☐☐-2 0 0☐
Date form completed (mm-dd-yyyy)

_____
Signature of person entering data onto web

Participant- Completed Questionnaires

DP

ACRIN 6654
NLST
Demographic/Health Status/Health Habit/ Symptom Questionnaire

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Participant Instructions: As part of the study, we are interested in acquiring some general demographic and health information. Your answers are important to us, so please try to answer every question. If you are unsure about how to answer a question, give the best answer you can. Please return this questionnaire to the research associate once you have completed it.

Medical History

1. What is your current weight? ☐☐☐ lbs.

2. How tall are you? ☐ feet ☐☐ inches

3. Has a doctor ever told you that you have any of the conditions or illnesses listed below?
Please answer **YES** or **NO** for each of the following, if **YES**, indicate the age at which you were diagnosed. If you prefer not to answer or an answer is unknown, code 99.

1 No **2 Yes** **99 Unknown / I prefer not to answer**

			If yes, age at first diagnosis:
3a.	☐	**Asbestosis**	☐☐
3b.	☐	**Asthma - first diagnosed as a *child***	☐☐
3c.	☐	**Asthma - first diagnosed as an *adult***	☐☐
3d.	☐	**Bronchiectasis**	☐☐
3e.	☐	**Chronic Bronchitis**	☐☐
3f.	☐	**Chronic Obstructive Pulmonary Disease (COPD)**	☐☐
3g.	☐	**Emphysema**	☐☐
3h.	☐	**Diabetes**	☐☐
3i.	☐	**Heart Disease or Heart Attack**	☐☐
3j.	☐	**Fibrosis of the Lung**	☐☐
3k.	☐	**Pneumonia**	☐☐
3l.	☐	**Sarcoidosis**	☐☐
3m.	☐	**Silicosis**	☐☐
3n.	☐	**Tuberculosis (TB)**	☐☐
3o.	☐	**High Blood Pressure (Hypertension)**	☐☐
3p.	☐	**Stroke**	☐☐

DP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

4. Has a doctor ever told you that you have any of the cancers listed below?
Please answer **YES** or **NO** for each of the following, if **YES**, indicate the age at which you were diagnosed. If you prefer not to answer or an answer is unknown, code 99.

1 No **2 Yes** **99 Unknown / I prefer not to answer**

			If yes, age at diagnosis:
4a.	☐	**Lung Cancer**	☐☐
4b.	☐	**Bladder Cancer**	☐☐
4c.	☐	**Transition Cell Cancer**	☐☐
4d.	☐	**Cervical Cancer**	☐☐
4e.	☐	**Mouth (Oral) Cancer**	☐☐
4f.	☐	**Pharynx Cancer**	☐☐
4g.	☐	**Larynx Cancer**	☐☐
4h.	☐	**Nasal Cancer**	☐☐
4i.	☐	**Esophageal Cancer**	☐☐
4j.	☐	**Stomach (Gastric) Cancer**	☐☐
4k.	☐	**Pancreatic Cancer**	☐☐
4l.	☐	**Kidney Cancer**	☐☐
4m.	☐	**Colon-Rectal Cancer**	☐☐
4n.	☐	**Breast Cancer**	☐☐
4o.	☐	**Thyroid Cancer**	☐☐
4p.	☐	**Other, specify** _____	☐☐

5. Have any of the following blood relatives ever had lung cancer:

1 No
2 Yes
98 Does not apply
99 Unknown / I prefer not to answer

☐ Father

☐ Mother

☐ Brother(s), including half-brothers

☐ Sister(s), including half-sisters

☐ Child (biological)

DP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Demographic Information

6. ☐ **Indicate the highest grade or level of schooling completed** (select one)

1 8th grade or less
2 9-11th grade
3 High school graduate or high school equivalency
4 Post high school training, other than college (for example, Vocational/technical school)
5 Associate degree / some college
6 Bachelor's degree
7 Graduate or Professional school
8 Other, specify: _____
99 Unknown / I prefer not to answer

7. ☐ **Indicate your marital status**

1 Never married
2 Married or living as married
3 Widowed
4 Separated
5 Divorced
99 Unknown / I prefer not to answer

8. ☐ **Indicate household Income** (select one which most closely describes the TOTAL average yearly gross income for your household)

1 Less than $8,000 per year
2 $8,000 to $14,999 per year
3 $15,000 to $24,999 per year
4 $25,000 to $34,999 per year
5 $35,000 to $49,999 per year
6 $50,000 to $64,999 per year
7 $65,000 to $79,999 per year
8 $80,000 to $100,000
10 > $100,000 per year
99 Unknown / I prefer not to answer

9. ☐ **Including yourself, how many people are supported by the income listed above?**

99 Unknown / I prefer not to answer

10. ☐ **In what country were you born?**

1 United States of America (answer question 10a)
2 Other country (answer question 10b)
99 Unknown / I prefer not to answer

10a. ☐☐ **If born in the USA, please enter the 2 digit numeric code for the state in which you were born** (see list, page 8)

10b. ☐ **If born in another country, specify the continent of that country.**

1 North America
2 South America
3 Europe
4 Africa
5 Asia
6 Australia
99 Unknown / I prefer not to answer

11. ☐ **In what country have you lived the longest?**

1 United States of America (answer question 11a)
2 Other country (answer question 11b)
99 Unknown / I prefer not to answer

11a. ☐☐ **If you lived the longest in the USA, please enter the 2 digit numeric code for the state in which you have lived the longest** (see list, page 8).

11b. ☐ **If you lived the longest in another country, specify the continent of that country.**

1 North America
2 South America
3 Europe
4 Africa
5 Asia
6 Australia
99 Unknown / I prefer not to answer

Occupational History

12. Have you ever worked for 1 year or more at any of the occupations listed below? Please answer **YES** or **NO** for each of the following. If your answer is **YES**, please provide number of years worked in that occupation and indicate whether you wore a respirator the majority of the time while at work. If an answer is unknown or you prefer not to answer, please code 99.

1 No **2 Yes** **99 Unknown / I prefer not to answer**

		No. of years worked	Did you wear a respirator?
12a. ☐	**Baking**	☐☐	☐
12b. ☐	**Butchering / Meat packing**	☐☐	☐
12c. ☐	**Chemical or plastics manufacturing**	☐☐	☐
12d. ☐	**Coal mining**	☐☐	☐
12e. ☐	**Cotton or jute processing**	☐☐	☐
12f. ☐	**Farming**	☐☐	☐
12g. ☐	**Fire fighting**	☐☐	☐
12h. ☐	**Flour, feed or grain milling**	☐☐	☐
12i. ☐	**Foundry or steel milling**	☐☐	☐
12j. ☐	**Hard rock mining**	☐☐	☐
12k. ☐	**Painting**	☐☐	☐
12l. ☐	**Sandblasting**	☐☐	☐
12m. ☐	**Welding**	☐☐	☐
12n. ☐	**Working with asbestos**	☐☐	☐

DP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Symptom History: Cough

Please answer **YES** or **NO** to the following questions. If you are in doubt about your answer, respond with **NO**. Include cough with first cigarette or on first going out doors. Exclude clearing of your throat.

1 No **2 Yes** **99 Unknown / I prefer not to answer**

13. ☐ **Do you usually have a cough?** If **No**, skip to question 19.

14. ☐ **Do you usually cough as much as 4-6 times a day, 4 or more days out of the week?**

15. ☐ **Do you usually cough at all upon getting up, or first thing in the morning?**

16. ☐ **Do you usually cough at all during the rest of the day or at night?**

If your answer to any of the above is YES, answer questions 17 and 18.

17. ☐ **Do you usually cough like this on most days for 3 consecutive months or more during the year?**

18. ☐☐ **For how many years have you had this cough?**

Symptom History: Shortness of Breath

Please answer **YES** or **NO** to the following questions. If you are in doubt about your answer, respond with **NO**.

1 No **2 Yes** **99 Unknown / I prefer not to answer**

19. ☐ **Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?**

20. ☐ **Do you have to walk slower than people of your age on level ground because of breathlessness?**

21. ☐ **Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on level ground?**

22. ☐ **Are you too breathless to leave the house or do you get breathless upon dressing or undressing?**

23. ☐☐ **For how many years have you experienced shortness of breath?**

DP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

General Alcohol History

24. ☐ **Have you ever consumed alcoholic beverages?** If **NO**, skip to question 32.
1 No
2 Yes
99 Unknown / I prefer not to answer

25. ☐ **Do you presently drink alcoholic beverages?** If **NO**, answer Part A. If **YES**, answer Part B.
1 No
2 Yes
99 Unknown / I prefer not to answer

Part A. Former Alcohol History (if you prefer not to answer, code 99)

26. ☐ **How long has it been since you last had an alcoholic drink?** (wine, beer, liquor)
1 Less than 1 year
2 1 year to 2 years
3 More than 2 years

27. ☐☐ **For how many years did you drink alcoholic beverages?**

28. ☐☐ **What was the usual number of drinks you had per week before you stopped drinking alcoholic beverages?** (one drink means 1 beer or 1 glass of wine or 1 shot of liquor, record 0 if less than 1 drink per week)

Part B. Current Alcohol History (if you prefer not to answer, code 99)

29. ☐☐ **For how many years have you been drinking alcoholic beverages?**

30. ☐☐ **What is the usual number of drinks you have per week?** (one drink means 1 beer or 1 glass of wine or 1 shot of liquor, record 0 if less than 1 drink per week)

31. ☐☐ **During the past 24 hours, how many drinks have you had?**

Social Security Number (SSN)

We are asking for your SSN because data from this study will be linked with data supplied by the National Center for Health Statistics. It will be kept confidential according to the Privacy Act of 1974, and will be used only for research purposes. Providing this information is extremely important for the purposes of this study, but is entirely **voluntary** on your part. If you prefer not to disclose your SSN, code all 9's.

32. What is your SSN? ☐☐☐-☐☐-☐☐☐☐

Sometimes dependents or spouses can apply for Medicare benefits using the Social Security Number of another family member.

33. ☐ **Did you ever get Medicare benefits using a Social Security Number other than your own?** If you prefer not to disclose the SSN, code all 9's.

1 No
2 Yes*
99 Unknown / I prefer not to answer

***If yes, what is that SSN?**

☐☐☐-☐☐-☐☐☐☐

Conclusion

34. ☐ **Did you require any assistance completing this questionnaire?**

1 No (skip to question 37)
2 Yes
99 Unknown / I prefer not to answer

35. ☐ **Specify the person who assisted you.**

1 ACRIN-NLST Staff member
2 Family
3 Other, specify:_____
99 Unknown / I prefer not to answer

36. Specify the extent of assistance (check all that apply)

☐ Read items to me
☐ Marked items as I responded
☐ Other, specify:_____
☐ Unknown / I prefer not to answer

37. ☐ **Specify the method used to complete this questionnaire.**

1 At my appointment
2 By mail (include having questionnaire mailed to you and brought to the site completed)
3 By telephone
99 Unknown / I prefer not to answer

Comments:_____

Please check that you have completed every question. At the time you return this questionnaire, please sign and date below.

_____
Participants signature

☐☐-☐☐-2 0 0☐
Date form completed (mm-dd-yyyy)

_____
Signature of person responsible for data

_____
Signature of person entering data onto web

DP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

2 Digit State Codes

01 Alabama
02 Alaska
03 Arizona
04 Arkansas
05 California
06 Colorado
07 Connecticut
08 Delaware
09 Florida
10 Georgia
11 Hawaii
12 Idaho
13 Illinois
14 Indiana
15 Iowa
16 Kansas
17 Kentucky
18 Louisiana
19 Maine
20 Maryland
21 Massachusetts
22 Michigan
23 Minnesota
24 Mississippi
25 Missouri
26 Montana
27 Nebraska
28 Nevada
29 New Hampshire
30 New Jersey
31 New Mexico
32 New York
33 North Carolina
34 North Dakota
35 Ohio
36 Oklahoma
37 Oregon
38 Pennsylvania
39 Rhode Island
40 South Carolina
41 South Dakota
42 Tennessee
43 Texas
44 Utah
45 Vermont
46 Virginia
47 Washington
48 West Virginia
49 Wisconsin
50 Wyoming
51 District of Columbia

SS

ACRIN 6654
NLST
Smoking Status Questionnaire

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Participant Instructions: As part of the study, we are interested in learning about smoking habits. Your answers are important to us, so please try to answer every question. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the research associate once you have completed it.

Smoking History:

1. ___ ___ How old were you the first time you EVER smoked even a puff of a cigarette?

When you first started smoking a few cigarettes (between 2-10 cigarettes), how much did you feel dizzy?

2a. ___

Not at all	A slight amount	A moderate amount	An intense amount	Don't know
1	2	3	4	9

When you first started smoking a few cigarettes (between 2-10 cigarettes), how much did you feel a pleasurable rush or buzz?

2b. ___

Not at all	A slight amount	A moderate amount	An intense amount	Don't know
1	2	3	4	9

3. ___ ___ How old were you when you began smoking daily, (at least one cigarette per day or more)?

For the next questions, think about the time period when you smoked the most.

4. ___ ___ ___ Think about the time that you smoked the most, how many cigarettes did you smoke per day?

5. ___ ___ During the time that you smoked, how many different times in your life did you go without smoking for THREE MONTHS or longer?

6. ___ Did you find it difficult to not smoke in places where it is forbidden such as in church, at a library, or in a movie theater?
   1 No
   2 Yes

7. ___ Did you smoke MORE during the first hours after you woke up or during the rest of the day?
   1 When I first woke up
   2 During the rest of the day

8. ___ How soon after you woke up in the morning did you smoke your first cigarette?
   1 Within 5 minutes
   2 Within 6 to 14 minutes
   3 Within 15 to 29 minutes
   4 Within 30 minutes but less than 1 hour
   5 Within 1 hour but less than 2 hours
   6 Within 2 hours but less than 8 hours
   7 More than 8 hours

9. ___ Did you smoke even if you were so ill that you were in bed most of the day?
   1 No
   2 Yes

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

10. ___ When you smoked the most, how often did you inhale?
    1 All of the time
    2 Some of the time
    3 None of the time

11. ___ Which cigarette of the day did you hate to give up the most?
    1 First one in the morning
    2 One later in the morning
    3 One at mid day
    4 One in the afternoon
    5 One after work
    6 One in the evening
    7 One late at night
    8 One before bedtime

12a. ___ When you smoked the most, what was your usual brand of cigarette? **Please, refer to the list of cigarette brands; pages 6-8 of this form**

12b. If your brand is not listed, please write it here:_____

The next questions are about your usual brand of cigarette when you were smoking the most.

13. ___ Was the type..
    1 Regular
    2 Lights
    3 Ultralights

14. ___ Was the flavor
    1 Regular
    2 Menthol

15. ___ Was the packaging
    1 Hard
    2 Soft

16. ___ Were the cigarettes
    1 Filtered
    2 Unfiltered

17. ___ Have you ever switched to a low tar, low nicotine or ultralight cigarette?
    1 No (skip to Q21)
    2 Yes

18. ___ How old were you when you switched? (answer only if Q17 was 'yes')

19. ___ During the time that you were smoking low tar, low nicotine or ultralight cigarettes, about how many cigarettes did you usually smoke per day? (answer only if Q17 was 'yes')

20. ___ How many years TOTAL did you smoke low tar, low nicotine or ultralight cigarettes?

SS

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Smoking Cessation Questions:

Next are statements that smokers have said about quitting. Please tell me which statement best represents what you think right now.

21. ___ 1 I enjoy smoking so much I will never consider quitting no matter what happens (Skip to Q24)
2 I never think about quitting but I might someday (Skip to Q24)
3 I rarely think about quitting and have no specific plans to quit (Skip to Q23)
4 I sometimes think about quitting but have no specific plans to quit (Skip to Q23)
5 I often think about quitting but have no specific plans to quit (Skip to Q23)
6 I plan to quit in the next 6 months (Skip to Q23)
7 I plan to quit in the next 30 days (Skip to Q23)
8 I have already begun to cut down and I have set a quit date (Skip to Q23)
9 I have already quit but I worry about slipping back or relapsing (Answer Q22 then skip to Q25)
10 I have quit and I am 100% confident that I will never smoke again (Answer Q22 then skip to Q25)
99 I decline to answer

Former Smokers Only:

22. ___ How old were you when you stopped smoking cigarettes for good?

Current Smokers Only:

23. ___ How many times in the PAST YEAR have you quit smoking for 24 hours or longer?

24. Since you started smoking, what was the LONGEST period of time that you were able to not smoke cigarettes at all? (answer only one)

___ hours
___ days
___ weeks
___ years

All Participants:

25. ___ Have you EVER smoked any other forms of tobacco?
1 No (Skip to Q28)
2 Yes

26. ___ Do you currently smoke any other forms of tobacco?
1 No
2 Yes

27. What forms of tobacco did/do you smoke? (check all that apply)

☐ 1 Pipe
☐ 2 Cigar
☐ 3 Tiparillos
☐ 4 Marijuana

SS

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Second Hand Smoke:

The next questions are about exposure to other people's smoking, otherwise known as second hand smoke.

28. ___ Have you EVER lived with someone who smoked in your home?
1 No (Skip to Q31)
2 Yes

29. ___ Do you currently live with someone who smokes in your home? (answer only if Q28 was 'yes')
1 No
2 Yes

30. ___ Not including yourself, how many people smoke(d) in your home? (answer only if Q28 was 'yes')
1 1 other smoker in home
2 2 other smokers in home
3 More than 2 other smokers in home

31. ___ Have you EVER worked in a place where you were exposed to other people's smoking?
1 No (Skip to Q34)
2 Yes

32. ___ Do you currently work in a place where you are exposed to other people's smoking? (answer only if Q31 was 'yes')
1 No
2 Yes

33. ___ Not including yourself, how many people smoke(d) at the place that you work(ed)? (answer only if Q31 was 'yes')
1 1 other smoker
2 2 other smokers
3 More than 2 other smokers

34. ___ ___ Thinking about all of the times that you may have been exposed to other people's smoking, about how many years in total would you say that you have been exposed to second hand smoke?

Conclusion:

35. ___ Did you require any assistance in completing this questionnaire?
1 No (Skip to Q38)
2 Yes
99 Unknown

36. ___ Specify the person who assisted you:
1 ACRIN-NLST Staff member
2 Family
3 Other, specify:_____
99 Unknown

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

37. Specify the extent of assistance: (check all that apply)

- ☐ Read items to me
- ☐ Marked items as I responded
- ☐ Other, specify:_____
- ☐ Unknown

38. |__| Specify the method used to complete this questionnaire:

1 At my appointment
2 By mail (include having questionnaire mailed to you and brought back to site completed)
3 By telephone
99 Unknown

Comments:_____

Please check that you have completed every question. At the time you return this questionnaire, please sign and date below.

_____ |__|__|-|__|__|-2|0|0|__|

Participants signature **Date form completed (mm-dd-yyyy)**

_____ _____

Signature of person responsible for data **Signature of person entering data onto web**

SS

Cigarette Brands

(NF)=non-filter

1 1st Choice
2 Alpine
3 Alpine Lights
4 Always Save
5 American Filter
6 American Lights
7 Austin
8 Barclay
9 Bargain Buy
10 Bargain King
11 Basic
12 Basic (NF)
13 Basic Lights
14 Basic Ultra Lights
15 Beacon
16 Belair
17 Belair Lights LoPrice
18 Belair Lo Price
19 Benson & Hedges
20 Benson & Hedges Deluxe Ultralights
21 Benson & Hedges DeNic
22 Benson & Hedges Lights
23 Benson & Hedges Multi
24 Best Buy
25 Best Choice
26 Best Value
27 Big Money
28 Black & Yellow
29 Bonus Value
30 Bristol (NF)
31 Bristol Full Flavor
32 Bristol Lights
33 Bristol Lowest
34 Bristol UltraLights
35 Bucks
36 Bucks Lights
37 Bull Durham
38 Bull Durham Lights
39 Cambridge Full Flavor
40 Cambridge Lights
41 Cambridge Lowest
42 Cambridge UltraLights
43 Camel
44 Camel (NF)
45 Camel UltraLights
46 Camel Wides
47 Camel Wides Lights
48 Capri 100's
49 Capri 120's
50 Cardinal
51 Carlton 120's
52 Carlton Kings
53 Carlton Ultra
54 Cartier Vendome
55 Cavalier
56 Century 25 Lights
57 Century 25's
58 Chelsea
59 Chesterfield Full Flavor
60 Chesterfield Kings (NF)
61 Chesterfield Lights
62 Chesterfield Regular (NF)
63 Citation
64 Class A Deluxe Full Flavor
65 Class A Deluxe Lights
66 Class A Deluxe UltraLights
67 Class A Full Flavor
68 Class A King (NF)
69 Class A Kings (NF)
70 Class A Lights
71 Class A Regular (NF)
72 Class A UltraLights
73 Commander (NF)
74 Cost Cutter
75 Covington Full Flavor
76 Covington Lights
77 Covington UltraLights
78 Dakota Full Flavor
79 Dakota Lights
80 Director's Choice
81 Doral
82 Doral Full Flavor
83 Doral Lights
84 Doral Ultra Lights
85 Eagle 20's
86 Econo Buy
87 English Oval (NF)
88 Epic
89 Eve Light 120's
90 Eve Slim Light 100's
91 Eve Slim Lights
92 Eve Slim UltraLights
93 Eve UltraLights
94 Extra Value
95 F&L
96 Falcon Lights
97 Famous Value
98 Federated
99 Focus
100 Genco
101 Generic

102 Generic Lights
103 Generic Ultra Lights
104 Golden Lights
105 GPA
106 GPC
107 Gridlock
108 Harley Davidson
109 Harley Davidson Lights
110 Herbert Tareyton (NF)
111 Heritage Lights
112 Highway
113 HiLite
114 Horizon Lights
115 Jacks
116 Jasmine Slim Lights
117 Jasmine Slims
118 Kent
119 Kent III
120 Kingsport
121 Kool Deluxe Lights
122 Kool Deluxe Ultra Long
123 Kool Kings
124 Kool Lights
125 Kool Mild
126 Kool Regular (NF)
127 Kool Super Long
128 Kool Ultra Lights
129 L&M
130 Lark Full Flavor
131 Lark Lights
132 Lucky Strike
133 Lucky Strike Lights
134 Lucky Strike Regulars (NF)
135 Magna
136 Magna Lights
137 Malibu
138 Malibu Lights
139 Malibu UltraLights
140 Marker
141 Marlboro
142 Marlboro Lights
143 Marlboro Medium
144 Marlboro UltraLights
145 Max 120's
146 Meridian
147 Merit
148 Merit DeNic
149 Merit Ultima
150 Merit UltraLights
151 Misty Slims
152 Monarch
153 Money
154 Montclair
155 Montclair Lights
156 Montclair UltraLights
157 More 100 Lights
158 More 120 Lights
159 More 120's
160 More 120's White Lights
161 Newport
162 Newport Lights
163 Newport Stripe
164 Next DeNic
165 No Frills
166 Now
167 Old Gold
168 Old Gold Lights
169 Old Gold Straight (NF)
170 Omni
171 Pall Mall (NF)
172 Pall Mall Gold
173 Pall Mall Lights
174 Pall Mall Red
175 Parliament Lights
176 Philip Morris
177 Philip Morris International
178 Phillip Morris Regular (NF)
179 Picayune (NF)
180 Pilot
181 Players
182 Players (NF)
183 Players Lights
184 Price Breaker
185 Price Master
186 Price Saver
187 Pyramid (NF)
188 Pyramid Full Flavor
189 Pyramid Lights
190 Pyramid UltraLights
191 Quality Lights
192 Quality Smokes
193 Raleigh
194 Raleigh (NF)
195 Raleigh Extra
196 Raleigh Extra (NF)
197 Raleigh ExtraLights
198 Raleigh Extra UltraLights
199 Raleigh Lights
200 Ralph's
201 Richland 100's
202 Richland Kings
203 Richland Lights
204 Ritz
205 Riviera

206 Salem
207 Salem Lights
208 Salem Slim Lights
209 Salem UltraLights
210 Saratoga 120's
211 Satin
212 Savvy
213 Scotch Buy
214 Sebring
215 Shurfine
216 Silva Thins
217 Sincerely Yours
218 Slim Price
219 Spring
220 Spring Lights
221 Sterling Full Flavor
222 Sterling Lights
223 Sterling UltraLights
224 Style Lights
225 Style UltraLights
226 Sundance
227 Tall 120's
228 Tareyton
229 Tareyton Lights
230 Tourney
231 Tourney Slim Lights
232 Tri Brand
233 Triumph
234 True 100's
235 Turney Slims
236 Upland
237 Value & Quality
238 Value Buy
239 Value Price
240 Value Sense
241 Vantage
242 Vantage UltraLights
243 Viceroy
244 Viceroy Lights
245 Virginia Slim Light 100's
246 Virginia Slims 100's
247 Virginia Slims 100's UltraLights
248 Virginia Slims Light 120's
249 Virginia Super Slim 100s
250 Winston
251 Winston Lights
252 Winston UltraLights
253 Worth
254 Yours
255 Other brand, not listed

CS

ACRIN 6654 NLST Coversheet for Quality of Life Questionnaires

Revised or corrected form, check box and fax to 215-717-0936. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This coversheet represents the first page of the Quality of Life (QOL) questionnaires and is completed by a Research Associate each time a participant is scheduled to complete any of the QOL questionnaires. This form is submitted via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

1. ☐ **This coversheet submission represents:** (select one)
- 1 QP (*Baseline enrollment)*
- 2 QL (*Annual re-screening*)
- 3 QF (*Positive screening or matched control)*

Questionnaire Compliance

2. ☐ **Did participant answer any questionnaire items?**
- 1 No (answer Q3, skip Q4-6)
- 2 Yes, date questionnaire completed:

__-__-2000 (Skip to Q4)
(mm/dd/yyy)

3. ☐ **If no, please state reason:**
- 1 Participant refused
- 2 Participant ill or hospitalized
- 3 Participant deceased
- 4 Participant out of the country
- 5 Incorrect contact information
- 6 Telephone disconnected
- 7 Participant unable to be contacted
- 8 Other, specify: _____

4. ☐ **Indicate the language of the QOL questionnaire by participant:**
- 1 English
- 2 Spanish

5. ☐ **Did the participant require any assistance in completing the questionnaire?**
- 1 No (skip to Q6)
- 2 Yes
- 99 Unknown (skip to Q6)

5a. ☐ **Specify the person who assisted the participant in completing the questionnaire:**
- 1 Staff member
- 2 Family
- 3 Other, specify: _____
- 99 Unknown

5b. **Extent of assistance (check all that apply):**
- ☐ Read items to participant
- ☐ Marked items per participant's response
- ☐ Interpreted items for participant
- ☐ Other, specify: _____
- ☐ Unknown

6. ☐ **Specify method of completion:**
- 1 At appointment
- 2 By mail (include mailed questionnaire brought to the site completed)
- 3 By telephone
- 99 Unknown

Comments: _____

_____

_____

_____

_____
Signature of person entering data onto web

_____
Signature of person responsible for data

__-__-2000
Date form completed (mm-dd-yyyy)

QP

ACRIN 6654
NLST
Baseline Health Status Questionnaire (SF-36v2™, EQ-5D)

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the NLST research associate once you have completed it.

Part 1 SF-36v2

1. In general, would you say your health is: (check the circle that best describes your answer)

Excellent	**Very good**	**Good**	**Fair**	**Poor**
O 1	O 2	O 3	O 4	O 5

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	**Somewhat better now than one year ago**	**About the same as one year ago**	**Somewhat worse now than one year ago**	**Much worse now than one year ago**
O 1	O 2	O 3	O 4	O 5

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much?

(mark an X in a circle on each line)

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
3a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports	O 1	O 2	O 3
3b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O 1	O 2	O 3
3c. Lifting or carrying groceries	O 1	O 2	O 3
3d. Climbing *several* flights of stairs	O 1	O 2	O 3
3e. Climbing *one* flight of stairs	O 1	O 2	O 3
3f. Bending, kneeling, or stooping	O 1	O 2	O 3
3g. Walking *more than a mile*	O 1	O 2	O 3
3h. Walking *several hundred yards*	O 1	O 2	O 3
3i. Walking *one hundred yards*	O 1	O 2	O 3
3j. Bathing or dressing yourself	O 1	O 2	O 3

QP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4a. Cut down on the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
4b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
4c. Were limited in the *kind* of work or other activities	O 1	O 2	O 3	O 4	O 5
4d. Had *difficulty* performing the work or other activities (for example, it took extra effort)	O 1	O 2	O 3	O 4	O 5

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5a. Cut down the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
5b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
5c. Did work or activities *less carefully than usual*	O 1	O 2	O 3	O 4	O 5

6. During the past 4 *weeks*, to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

7. How much *bodily* pain have you had during the *past 4 weeks*?

None	Very Mild	Mild	Moderate	Severe	Very Severe
O 1	O 2	O 3	O 4	O 5	O 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
9a. Did you feel full of life?	O 1	O 2	O 3	O 4	O 5
9b. Have you been very nervous?	O 1	O 2	O 3	O 4	O 5
9c. Have you felt so down in the dumps that nothing could cheer you up?	O 1	O 2	O 3	O 4	O 5
9d. Have you felt calm and peaceful?	O 1	O 2	O 3	O 4	O 5
9e. Did you have a lot of energy?	O 1	O 2	O 3	O 4	O 5
9f. Have you felt downhearted and depressed?	O 1	O 2	O 3	O 4	O 5
9g. Did you feel worn out?	O 1	O 2	O 3	O 4	O 5
9h. Have you been happy?	O 1	O 2	O 3	O 4	O 5
9i. Did you feel tired?	O 1	O 2	O 3	O 4	O 5

10. During the *past 4 weeks*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the the time	Most of the time	Some of the time	A little of the time	None of the time
O 1	O 2	O 3	O 4	O 5

11. How TRUE or FALSE is *each* of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
11a.I seem to get sick a little easier than other people	O 1	O 2	O 3	O 4	O 5
11b.I am as healthy as anybody I know	O 1	O 2	O 3	O 4	O 5
11c.I expect my health to get worse	O 1	O 2	O 3	O 4	O 5
11d.My health is excellent	O 1	O 2	O 3	O 4	O 5

QP

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part 2 Euroqol EQ-5D

EQ-5D is a measure of health status for use in evaluating health and healthcare. By selecting one box in each group below, please indicate which statement best describes your own health state today.

1. MOBILITY

☐ 1 I have no problems in walking about

☐ 2 I have some problems in walking about

☐ 3 I am confined to bed

2. SELF-CARE

☐ 1 I have no problems with self-care

☐ 2 I have some problems washing or dressing myself

☐ 3 I am unable to wash or dress myself

3. USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)

☐ 1 I have no problems with performing my usual activities

☐ 2 I have some problems with performing my usual activities

☐ 3 I am unable to perform my usual activities

4. PAIN/DISCOMFORT

☐ 1 I have no pain or discomfort

☐ 2 I have moderate pain or discomfort

☐ 3 I have extreme pain or discomfort

5. ANXIETY/DEPRESSION

☐ 1 I am not anxious or depressed

☐ 2 I am moderately anxious or depressed

☐ 3 I am extremely anxious or depressed

Please check that you have completed every question. At the time you return this questionnaire, please sign and date below.

_____ **Participants signature**

__ __ - __ __ - 2 0 0 __ **Date form completed (mm-dd-yyyy)**

_____ **Signature of person responsible for data**

_____ **Signature of person entering data onto web**

QL

ACRIN 6654
NLST
Annual Health Status Questionnaire (SF-36v2™, EQ-5D)

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the NLST research associate once you have completed it.

Part 1 SF-36v2

1. In general, would you say your health is: (check the circle that best describes your answer)

Excellent	Very good	Good	Fair	Poor
O 1	O 2	O 3	O 4	O 5

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
O 1	O 2	O 3	O 4	O 5

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much?

(mark an X in a circle on each line)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports	O 1	O 2	O 3
3b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O 1	O 2	O 3
3c. Lifting or carrying groceries	O 1	O 2	O 3
3d. Climbing *several* flights of stairs	O 1	O 2	O 3
3e. Climbing *one* flight of stairs	O 1	O 2	O 3
3f. Bending, kneeling, or stooping	O 1	O 2	O 3
3g. Walking *more than a mile*	O 1	O 2	O 3
3h. Walking *several hundred yards*	O 1	O 2	O 3
3i. Walking *one hundred yards*	O 1	O 2	O 3
3j. Bathing or dressing yourself	O 1	O 2	O 3

QL

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4a. Cut down on the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
4b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
4c. Were limited in the *kind* of work or other activities	O 1	O 2	O 3	O 4	O 5
4d. Had *difficulty* performing the work or other activities (for example, it took extra effort)	O 1	O 2	O 3	O 4	O 5

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5a. Cut down the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
5b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
5c. Did work or activities *less carefully than usual*	O 1	O 2	O 3	O 4	O 5

6. During the past 4 *weeks*, to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

7. How much *bodily* pain have you had during the *past 4 weeks*?

None	Very Mild	Mild	Moderate	Severe	Very Severe
O 1	O 2	O 3	O 4	O 5	O 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

QL

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
9a. Did you feel full of life?	O 1	O 2	O 3	O 4	O 5
9b. Have you been very nervous?	O 1	O 2	O 3	O 4	O 5
9c. Have you felt so down in the dumps that nothing could cheer you up?	O 1	O 2	O 3	O 4	O 5
9d. Have you felt calm and peaceful?	O 1	O 2	O 3	O 4	O 5
9e. Did you have a lot of energy?	O 1	O 2	O 3	O 4	O 5
9f. Have you felt downhearted and depressed?	O 1	O 2	O 3	O 4	O 5
9g. Did you feel worn out?	O 1	O 2	O 3	O 4	O 5
9h. Have you been happy?	O 1	O 2	O 3	O 4	O 5
9i. Did you feel tired?	O 1	O 2	O 3	O 4	O 5

10. During the *past 4 weeks*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
O 1	O 2	O 3	O 4	O 5

11. How TRUE or FALSE is *each* of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
11a. I seem to get sick a little easier than other people	O 1	O 2	O 3	O 4	O 5
11b. I am as healthy as anybody I know	O 1	O 2	O 3	O 4	O 5
11c. I expect my health to get worse	O 1	O 2	O 3	O 4	O 5
11d. My health is excellent	O 1	O 2	O 3	O 4	O 5

QL

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. MOBILITY

☐ 1 I have no problems in walking about

☐ 2 I have some problems in walking about

☐ 3 I am confined to bed

2. SELF-CARE

☐ 1 I have no problems with self-care

☐ 2 I have some problems washing or dressing myself

☐ 3 I am unable to wash or dress myself

3. USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)

☐ 1 I have no problems with performing my usual activities

☐ 2 I have some problems with performing my usual activities

☐ 3 I am unable to perform my usual activities

4. PAIN/DISCOMFORT

☐ 1 I have no pain or discomfort

☐ 2 I have moderate pain or discomfort

☐ 3 I have extreme pain or discomfort

5. ANXIETY/DEPRESSION

☐ 1 I am not anxious or depressed

☐ 2 I am moderately anxious or depressed

☐ 3 I am extremely anxious or depressed

Please check that you have completed every question then sign and date below.

_____
Participants signature

__-__-2 0 0__
Date form completed (mm-dd-yyyy)

_____
Signature of person responsible for data

_____
Signature of person entering data onto web

QF

ACRIN 6654
NLST
Health Status Questionnaire
(SF-36v2™, EQ-5D, STAI Y-1)

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Part 1 SF-36v2

1. In general, would you say your health is: (check the circle that best describes your answer)

Excellent	**Very good**	**Good**	**Fair**	**Poor**
O 1	O 2	O 3	O 4	O 5

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	**Somewhat better now than one year ago**	**About the same as one year ago**	**Somewhat worse now than one year ago**	**Much worse now than one year ago**
O 1	O 2	O 3	O 4	O 5

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much?

(mark an X in a circle on each line)

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
3a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports	O 1	O 2	O 3
3b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O 1	O 2	O 3
3c. Lifting or carrying groceries	O 1	O 2	O 3
3d. Climbing *several* flights of stairs	O 1	O 2	O 3
3e. Climbing *one* flight of stairs	O 1	O 2	O 3
3f. Bending, kneeling, or stooping	O 1	O 2	O 3
3g. Walking *more than a mile*	O 1	O 2	O 3
3h. Walking *several hundred yards*	O 1	O 2	O 3
3i. Walking *one hundred yards*	O 1	O 2	O 3
3j. Bathing or dressing yourself	O 1	O 2	O 3

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4a. Cut down on the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
4b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
4c. Were limited in the *kind* of work or other activities	O 1	O 2	O 3	O 4	O 5
4d. Had *difficulty* performing the work or other activities (for example, it took extra effort)	O 1	O 2	O 3	O 4	O 5

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5a. Cut down the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
5b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
5c. Did work or activities *less carefully than usual*	O 1	O 2	O 3	O 4	O 5

6. During the past 4 *weeks*, to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

7. How much *bodily* pain have you had during the *past 4 weeks*?

None	Very Mild	Mild	Moderate	Severe	Very Severe
O 1	O 2	O 3	O 4	O 5	O 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
9a. Did you feel full of life?	O 1	O 2	O 3	O 4	O 5
9b. Have you been very nervous?	O 1	O 2	O 3	O 4	O 5
9c. Have you felt so down in the dumps that nothing could cheer you up?	O 1	O 2	O 3	O 4	O 5
9d. Have you felt calm and peaceful?	O 1	O 2	O 3	O 4	O 5
9e. Did you have a lot of energy?	O 1	O 2	O 3	O 4	O 5
9f. Have you felt downhearted and depressed?	O 1	O 2	O 3	O 4	O 5
9g. Did you feel worn out?	O 1	O 2	O 3	O 4	O 5
9h. Have you been happy?	O 1	O 2	O 3	O 4	O 5
9i. Did you feel tired?	O 1	O 2	O 3	O 4	O 5

10. During the *past 4 weeks*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
O 1	O 2	O 3	O 4	O 5

11. How TRUE or FALSE is *each* of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
11a.I seem to get sick a little easier than other people	O 1	O 2	O 3	O 4	O 5
11b.I am as healthy as anybody I know	O 1	O 2	O 3	O 4	O 5
11c.I expect my health to get worse	O 1	O 2	O 3	O 4	O 5
11d.My health is excellent	O 1	O 2	O 3	O 4	O 5

QF

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part 2 Euroquol EQ-5D

EQ-5D is a measure of health status for use in evaluating health and healthcare. By selecting one box in each group below, please indicate which statement best describes your own health state today.

1. MOBILITY

☐ 1 I have no problems in walking about

☐ 2 I have some problems in walking about

☐ 3 I am confined to bed

2. SELF-CARE

☐ 1 I have no problems with self-care

☐ 2 I have some problems washing or dressing myself

☐ 3 I am unable to wash or dress myself

3. USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)

☐ 1 I have no problems with performing my usual activities

☐ 2 I have some problems with performing my usual activities

☐ 3 I am unable to perform my usual activities

4. PAIN/DISCOMFORT

☐ 1 I have no pain or discomfort

☐ 2 I have moderate pain or discomfort

☐ 3 I have extreme pain or discomfort

5. ANXIETY/DEPRESSION

☐ 1 I am not anxious or depressed

☐ 2 I am moderately anxious or depressed

☐ 3 I am extremely anxious or depressed

QF

Part 3 STAI Y-1

For the participant: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate value to the right of the statement to indicate how you feel right now, that is, ***at this moment***. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Complete the following:	Not At All	Somewhat	Moderately So	Very Much So
1. I feel calm.	1	2	3	4
2. I feel secure.	1	2	3	4
3. I am tense.	1	2	3	4
4. I feel strained.	1	2	3	4
5. I feel at ease.	1	2	3	4
6. I feel upset.	1	2	3	4
7. I am presently worrying over possible misfortunes.	1	2	3	4
8. I feel satisfied.	1	2	3	4
9. I feel frightened.	1	2	3	4
10. I feel comfortable.	1	2	3	4
11. I feel self-confident.	1	2	3	4
12. I feel nervous.	1	2	3	4
13. I feel jittery.	1	2	3	4
14. I feel indecisive.	1	2	3	4
15. I am relaxed.	1	2	3	4
16. I feel content.	1	2	3	4
17. I am worried.	1	2	3	4
18. I feel confused.	1	2	3	4
19. I feel steady.	1	2	3	4
20. I feel pleasant.	1	2	3	4

Please provide the following information: Age ___

Gender ___ 1 Male 2 Female

Please check that you have completed every question then sign and date below.

Participants signature

___-___-2000

Date form completed (mm-dd-yyyy)

Signature of person responsible for data

Signature of person entering data onto web

Biomarker Forms

BL

ACRIN 6654 NLST

Biomarker Collection Form

ACRIN Study **6654**

Institution _____ **Institution No.** _____

Case No. _____

Instructions: This form is used to document all biomarker specimens obtained on study participants. The site RA completes the form. The completed form is enclosed with the specimens and sent to the Colorado Specimen Bank. One copy of the BL Form is retained at the study site and one copy is to be submitted to ACRIN via fax (215-717-0936).

If this is a revised or corrected form, check box and fax to 215-717-0936. ☐

Blood Collection:

1. ☐ **Was blood drawn?**
1 No
2 Yes

2. Date of blood collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

3. ☐ **Were blood specimens processed within two hours of venipuncture?**
1 No
2 Yes
99 Unknown

3b. If no, what was the interval between venipuncture and freezing of specimen? ☐☐.☐ **hrs.**

Urine Collection:

4. ☐ **Was urine collected?**
1 No
2 Yes

5. Date of urine collection: ☐ **If same date as #2, check here**

If other than #2, record date of collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

Sputum Collection:

6. ☐ **Were sputum collection and mailing materials given to the participant for home collection?**
1 No
2 Yes

7. Date sputum materials were given to participant: ☐ **If same date as #2, check here**

If other than #2, record date of collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

Blood Processing and Labeling:

8. ☐ **Number of Citrate Plasma cryotubes prepared (labeled below)**

If other than #2, record date of collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

☐ Citrate Plasma 1 Orange Cap	☐ Citrate Plasma 3 Orange Cap
☐ Citrate Plasma 2 Orange Cap	☐ Citrate Plasma 4 Orange Cap

BL

ACRIN Study 6654

Institution _____ Institution No. _____

Case No. _____

9. ☐ **Number of <u>Citrate Buffy Coat</u> cryotubes prepared (labeled below)**

If other than #2, record date of collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

☐	Citrate Buffy Coat 1 Pink Cap	☐	Citrate Buffy Coat 3 Pink Cap
☐	Citrate Buffy Coat 2 Pink Cap	☐	Citrate Buffy Coat 4 Pink Cap

Urine Processing and Labeling

10. ☐ **Number of <u>Urine</u> cryotubes prepared (labeled below)**

If other than #2, record date of collection: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

☐	Urine 1 Yellow Cap	☐	Urine 2 Yellow Cap

11. Date specimen mailed to Colorado Specimen Bank: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

12. ☐ **Check here if the participant signed an IRB approved consent to have blood, urine and sputum specimens obtained and stored at the University of Colorado specimen bank for use in future studies?**

FAX completed form to:

American College of Radiology
ACRIN 6654 NLST
FAX: (215) 717-0936
Attention: ACRIN 6654 NLST Data Management

COMMENTS _____

_____

_____

_____
Signature of person responsible for data

☐☐-☐☐-2 0 0☐
Date form completed (mm-dd-yyyy)

ACRIN NLST 6654 CRF COMPLETION INSTRUCTIONS

BL Form Instructions

BL forms are to be completed for all participants who have consented to provide Biomarkers for the NLST Study. Ideally, blood, urine, and sputum samples are collected at the T0-baseline visit, T1 visit and T2 visit. Participants may provide all or part of the biomarker specimens requested. BL Forms are to be submitted regardless of the level of specimen collection including instances when no specimens are collected. In this instance, questions 1, 4, and 6 would be completed reporting that no specimens were collected (Q1, 4, 6= No). If no specimens are collected the BL form is sufficient. No additional paperwork (GCM, PR, etc.) is required.

The site RA completes the Form. The completed form is enclosed with the specimens and sent to the Colorado Specimen Bank. One copy of the BL Form is retained at the site in the participant's file and one copy is to be mailed to ACRIN HQ. A completed ACRIN Case Specific Label should be affixed to each page of the BL Form. In lieu of a label, the Participants Initials, Case Number, Institution Number and Institution Name can be recorded in the space provided.

Blood Collection:

1. **Was Blood Drawn:** Required element. Record the appropriate response (code numbers 1-2) indicating whether or not a specimen was obtained. If no blood was drawn (Q1=No), skip to Q4.

2. **Date of Blood Collection:** Record the date of blood collection.

3. **Were Blood specimens processed within two hours of venipuncture:** Record the appropriate response (code numbers 1, 2, 99) indicating if specimens were processed within 2 hours.

3b. If NO, what was the interval between venipuncture and processing: Record the appropriate interval in hours.

Urine Collection:

4. **Was Urine Collected:** Required element. Record the appropriate response (code numbers 1-2) indicating whether or not a specimen was obtained. If no urine was collected (Q4=No), skip to Q6.

5. **Date of Urine Collection:** If the date of urine collection is the same as blood collection (Q2) use the checkbox provided, if not, record the date of urine collection.

Sputum Collection:

6. **Were Sputum collection and mailing materials given to the participant:** Required element. Record the appropriate response (code numbers 1-2) indicating if the sputum kit was given to the participant. If the participant did not receive a sputum kit (Q6=No), skip to Q8.

7. **Date Sputum materials were given to participant:** If the of sputum collections is the same blood collection (Q2), use the checkbox provided, if not, record the date the kit was given to the participant.

Blood Processing and Labeling:

8. **Number of Citrate Plasma cryotubes prepared:** Record the appropriate number of cryotubes used in the space provided. Number of cryotubes recorded should match number of cryotubes sent to specimen lab. If less than four cryotubes of blood were collected, cross-out (single line through) the BL label(s) corresponding to the unused cryotubes indicating which cryotubes were not used and which were used and sent to Colorado. If date of cryotube preparation is different from date of blood collection please record date of preparation.

9. **Number of Citrate Buffy Coat cryotubes prepared:** Record the appropriate number of cryotubes used in the space provided. Number of cryotubes recorded should match number of cryotubes sent to specimen lab If less than four cryotubes of blood were collected, cross-out (single line through) the BL label(s) corresponding to the unused cryotubes indicating which cryotubes were not used and which were used and sent to Colorado. If date of cryotube preparation is different from date of blood collection please record date of preparation.

Urine Processing and Labeling:

10. Number of Urine cryotubes prepared: Record the appropriate number of cryotubes used in the space provided. Number of cryotubes recorded should match number of cryotubes sent to specimen lab. If less than four cryotubes of blood were collected, cross-out (single line through) the BL label(s) corresponding to the unused cryotubes indicating which cryotubes were not used and which were used and sent to Colorado. If date of cryotube preparation is different from date of blood collection please record date of preparation.

---

11. Date Specimens mailed to Colorado Specimen Bank: Record the date that the blood and urine specimens were mailed to the Colorado Spore Bank.

12. Check here if the participant signed an IRB approved consent to have Blood, Urine and Sputum specimens obtained and stored at the University of Colorado Specimen Bank for use in future studies: Check box if appropriate. Only participants consenting to biomarkers should have specimens collected. If a participant withdraws biomarker consent, report this event on an NP Form.

Comments: Provided for clinical notes, not entered into database.

Signature of person responsible for data: Signature of RA, or other study personnel, responsible for collating data and completing the BL Form. All forms must be signed to be considered complete.

Date Form Completed: Record the data the BL Form was completed. All forms must be dated to be considered complete.

Mail completed forms to:
American College of Radiology
1818 Market St. Suite 1600
Philadelphia, PA 19103
Attn: ACRIN 6654 Data Management

PC

ACRIN 6654
NLST
Specimen Packing Form (Blood / Urine)

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: To be completed by the Colorado Specimen Bank and submitted via mail to the address listed below to document the receipt of biomarker specimens.

If this is a revised or corrected form, indicate by checking box. ☐

Date specimen received: ☐☐-☐☐-2☐0☐ (mm/dd/yyyy)

Shipping Contents Received:

Specimen Type(s)	Number of Cryotubes Received	Shipment Code
Citrate plasma	☐	☐
Citrate buffy coat	☐	☐
Urine	☐	☐

Shipment Codes

1 Acceptable
2 Discrepancy in participant ID*
3 Discrepancy in shipping contents*
4 Problems with specimen packaging*
5 Specimen Breakage*

*If the shipment was coded 2-5, please notify the site of the issue(s) via telephone.

Site notified of problem(s) by: _____ ☐☐-☐☐-2☐0☐
Name Date (mm/dd/yyyy)

COMMENTS: _____

FORWARD this completed Specimen Packing Form as soon as possible to:

AMERICAN COLLEGE OF RADIOLOGY
ACRIN-Protocol 6654 NLST
Data Support Department
1101 Market Street - 14th Floor
Philadelphia, PA 19107

Fax: 215-717-0936

ST

ACRIN 6654
NLST
Sputum Transmittal Form

ACRIN Study **6654**

Institution_____ **Institution No.**_____

Case No._____

Intructions for Site RA: This form is used to document all sputum specimens obtained on study participants. Instructions for collecting the samples are provided below. Each participant should receive a kit containing material for collecting sputum at home. Please ensure the following when giving materials to the participant:

- Include your contact information should the participant have questions about sputum collection
- Indicate the location on the ST Form where the date of collection should be written by the participant
- Advise the participant that the ST Form should accompany the specimen mailing
- Mark on the BL Form that you have provided the participant with the sputum collection materials

RA Name:_____ **Telephone:** ___-___-____

Instructions for participant: You have been given two (2) specimen cups containing a special preservative (Saccamanos solution). These cups should be used to collect sputum (phlegm) specimens for the ACRIN 6654 NLST. Upon arising in the morning, you should thoroughly rinse your mouth with water. You must cough deeply into the sputum cup. It is often easier to produce sputum after your morning shower. Cough on three successive mornings into the red labeled cup. Follow the sample procedure by coughing three more successive mornings into the blue labeled cup.

Once you have provided the sputum, scew the caps tightly place them in the postage-paid container that has been provided to you. This ST Form should be also enclosed with your two specimens in the container provided. The samples do not need to be refrigerated prior to mailing, but should be stored at room temperature in a safe place so that they are not inadvertently lost. These containers go through regular mail and can be mailed from your home or any mail box. Mail the container directly to the Colorado Specimen Bank.

Please indicate the last day (date) of collection for each cup.

Date sputum specimen collected:

1. **Red labeled cup:** __-__-2000 (mm-dd-yyyy)
2. **Blue labeled cup:** __-__-2000 (mm-dd-yyyy)

Sputum 1 (Red)

Sputum 2 (Blue)

Instructions to Colorado Specimen Bank: Please complete the following, and enter into the ACRIN 6654 NLST Web utility. Fax a copy of this form to ACRIN Data Management.

Date sputum specimens received at laboratory __-__-2000 (mm-dd-yyyy)

Indicate number of sputum cups received __

Comments _____

Please FAX a copy of this ST Form to:
American College of Radiology
ACRIN 6654-NLST
FAX: (215) 717-0936
Attention: ACRIN 6654 NLST Data Management

_____
Person completing form (Colorado Specimen Bank)

__-__-2000
Date form completed

Screening Forms

C2

ACRIN 6654
NLST
Screening CT Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is to be completed for each CT screening exam. The C2 form serves as the source document for the interpretation of the CT screening exam and must be signed by the interpreting Radiologist. Submit this form via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

If this is a revised or corrected form, indicate by checking box ☐ and fax to 215-717-0936.

1. ☐ Indicate Screening Visit:

1 Baseline Screen
2 Incidence Screen, year 1
3 Incidence Screen, year 2

2. Date of Screening CT Exam: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

3. ☐ Visit number (for above screening visit):

1 One
2 Two

Part A. Technical Parameters
(completed by technologist; please refer to NLST CT Technique Chart for platform specific imaging parameters)

4. ☐ Number of exam attempts:

1 One
2 Two
3 Three

5. ☐☐☐ kVp

6. ☐☐☐ mA (based on the CT equipment and platform report either mA or effective mAs)

7. ☐☐☐ Effective mAs (based on the CT equipment and platform report either mA or effective mAs)

8. ☐☐ Display FOV (cm)

9. Indicate CT reconstruction algorithm/filter:

☐ GE Bone
☐ GE Standard
☐ GE, other: _____
☐ Philips D
☐ Philips C
☐ Philips, other: _____
☐ Siemens B50F
☐ Siemens B30
☐ Siemens, other: _____
☐ Toshiba FC10
☐ Toshiba FC51
☐ Toshiba, other: _____

10. Technologist ID: _____

Part B. Screening CT Findings (completed by radiologist based on the screening CT)

11. ☐ Indicate the overall diagnostic quality of the CT examination:

1 Diagnostic CT(skip to Q12)
2 Limited CT, but interpretable (complete table below)
3 Non-diagnostic CT (complete table below)

Which of the following affected the quality of the limited or non-diagnostic Screening CT? (check all that apply)

☐ Submaximal inspiratory breath-hold
☐ Motion artifact
☐ Respiratory misregistration
☐ Incorrect technical parameter(s)
☐ Lungs not completely imaged
☐ Severe beam hardening artifact
☐ Excessive quantum mottle or graininess
☐ Other, specify: _____

C2

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

12. ☐ Are there any abnormalities to report on this CT?

1 No (skip to Q13)
2 Yes (complete chart below)

Record each CT finding below using CONSECUTIVE F-numbers. DO NOT SKIP F-NUMBERS

- Record data in fields for location, dimensions, margin, and attenuation ONLY for Code 51 abnormalities.
- If multiple micronodules < 4mm are seen, record Code 52 only ONCE.
- If ≥ 6 nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- Use text lines to specify abnormalities ONLY for Codes 63, 64, and 65.
- To document additional text data, use "Part D Other observations/comments;" this will be web-entered.
- Descriptive data NOT intended for web-entry should appear outside of data entry fields.

Abnormality Codes	Complete for Code 51 Nodules or Masses Only					
	CT Slice Location	Anatomic Location	Dimensions (same CT slice)		Margins	Predominant Attenuation
51 Non-calcified nodule or mass (opacity ≥4 mm diameter) 52 Non-calcified micronodule(s) (opacity < 4 mm diameter) 53 Benign lung nodule(s) (benign calcification) 54 Atelectasis, segmental or greater 55 Pleural thickening or effusion 56 Non-calcified hilar/mediastinal adenopathy or mass (≥ 10 mm short axis) 57 Chest wall abnormality (bone destruction, metastasis, etc.) 58 Consolidation 59 Emphysema 60 Significant cardiovascular abnormality 61 Reticular/reticulonodular opacities, honeycombing, fibrosis, scar 62 6 or more nodules, not suspicious for cancer (opacity ≥4 mm) 63 Other potentially significant abnormality above diaphragm, (specify below) 64 Other potentially significant abnormality below the diaphragm, (specify below) 65 Other minor abnormality noted (specify below)	Indicate the single slice number with the greatest diameter, or identify a representative slice CT Slice #	1 RUL 2 RML 3 RLL 4 LUL 5 Lingula 6 LLL 7 Other, specify: Abnormality Center	Longest Diameter (mm) 999 Unable to determine	Longest Perpendicular Diameter (mm)	1 Spiculated (Stellate) 2 Smooth 3 Poorly defined 99 Unable to determine	1 Soft tissue 2 Ground Glass 3 Mixed (1+2) 4 Fluid/Water 5 Fat 6 Other, specify
F1 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F2 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F3 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F4 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F5 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F6 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F7 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F8 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F9 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F10 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F11 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F12 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F13 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____
F14 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐ _____

C2

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

13. ☐ Indicate the result for this screening CT:

1 Negative screen, no significant abnormalities (skip to Q15)
2 Negative screen, minor abnormalities not suspicious for lung cancer (skip to Q15)
3 Negative screen, significant abnormalities not suspicious for lung cancer (skip to Q15, provide a follow-up recommendation)
4 Positive screen, nodule(s) 4-10 mm suspicious for lung cancer
5 Positive screen, nodule(s) > 10 mm or other non-specific abnormalities suspicious for lung cancer
6 Inadequate CT, non-diagnostic exam (skip to Part D)

14. ☐ Indicate the overall suspicion for primary lung cancer (subjective impression) based on this screening CT:

1 No suspicion
2 Low suspicion
3 Intermediate suspicion
4 Moderately high suspicion
5 High suspicion

15. What is the recommended next step for this participant? (check all that apply)

☐ No diagnostic intervention necessary
☐ Comparison with historical images. If not available, recommend...NOTE: must check other procedure(s) in the event that historical images are not available
☐ Thin-section chest CT or repeat low-dose helical chest CT (check all that apply)
  ☐ 3 months from screening exam
  ☐ 6 months from screening exam
  ☐ 3 to 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.)
☐ Other, specify: _____

Part D. Conclusion

Other observations / comments: _____

_____

_____

16. Reader ID: ☐☐☐☐☐☐☐ (Stamp acceptable)

17. Date of CT Interpretation: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

18. Reader Signature: _____

_____
Signature of person responsible for data [1]

☐☐-☐☐-2 0 0☐
Date form completed (mm-dd-yyyy)

_____
Signature of person entering data onto web [2]

C2 COMPLETION INSTRUCTIONS

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.

C2 COMPLETION INSTRUCTIONS

- 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.

C2 COMPLETION INSTRUCTIONS

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 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 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 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.

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.

DR

ACRIN 6654 NLST Screening Chest Radiograph (CXR) Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is to be completed for each CXR screening exam. The DR form serves as the source document for the interpretation of the CXR screening exam and must be signed by the interpreting Radiologist. Submit this form via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

If this is a revised or corrected form, indicate by checking box ☐ and fax to 215-717-0936.

1. ___ **Indicate Screening Visit:**

1 Baseline Screen
2 Incidence Screen, year 1
3 Incidence Screen, year 2

2. Date of Screening CXR: __-__-2000 (mm-dd-yyyy)

3. ___ **Visit number (for above screening visit):**

1 One
2 Two

Part A. Technical Parameters
(completed by technologist; for Q6-10 record the technical parameters of the highest exposure that was performed)

4a. ___ **Total number of exposures performed to complete Screening CXR exam**

4b. ___ **Number of images submitted to ACRIN that comprise this exam**

5. ___ **How was the CXR obtained?**

1 Screen Film (SF)
2 Computed Radiography (CR)
3 Direct Digital Radiography (DR)
4 Thoravision

6. ___ **kVp** (acceptable kVp range: 100-150)

7. ___.___ **mAs** (based on CXR equipment report either mAs or mA and time; mAs should be <10 except for large participants)

8. ____ **mA** (based on CXR equipment report either mAs or mA and time; mA should be between 100-1000)

9. ___ **Time** (msec: exposure time should normally not exceed 40 msec)

10. _____ **Exposure Value** (for digital units, if known)

11. ___ **CXR Unit ID** (as identified on CXR Equipment Data Form)

12. Technologist ID: _____ (technologist exposing the participant)

Part B. Screening CXR Findings (completed by radiologist)

13. ___ **Indicate the overall diagnostic quality of the CXR:**

1 Diagnostic CXR (skip to Q14)
2 Limited CXR, but interpretable (complete table below)
3 Non-diagnostic CXR (complete table below)

Which of the following affected the quality of the limited or non-diagnostic CXR? (check all that apply)

☐ Low lung volumes
☐ Lungs incompletely imaged
☐ Poor positioning
☐ Motion degradation
☐ Incorrect exposure or other technical parameter
☐ Artifacts obscure anatomy
☐ Incorrect processing algorithm
☐ High image noise
☐ Other, specify: _____

DR

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

14. ☐ Are there any abnormalities to report on this CXR?

1 No (skip to Q15)
2 Yes (complete chart below)

Record each finding below using CONSECUTIVE F-numbers. DO NOT SKIP F-NUMBERS

- Record data in fields for location, dimensions and margins ONLY for Code 51 abnormalities.
- If ≥ 6 nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- Use text lines to specify abnormalities ONLY for Codes 63, 64, and 65.
- To document additional text data, use "Part D Other observations/comments;" this will be web-entered.
- Descriptive data NOT intended for web-entry should appear outside of data entry fields.

Abnormality Codes		Complete for Code 51 Nodules or Masses Only			
		Location of Epicenter	Dimensions		Margins
51 Non-calcified nodule or mass 53 Benign nodule(s) (benign calcification) 54 Atelectasis, segmental or greater 55 Pleural thickening or effusion 56 Non-calcified hilar/mediastinal adenopathy or mass (≥10mm short axis) 57 Chest wall abnormality (bone destruction, metastasis, etc.) 58 Consolidation 59 Emphysema 60 Significant cardiovascular abnormality 61 Reticular/reticulonodular opacities, honeycombing, fibrosis, scar 62 6 or more nodules not suspicious for cancer (opacities ≥4mm) 63 Other potentially significant abnormality above the diaphragm, (specify below) 64 Other potentially significant abnormality below the diaphragm, (specify below) 65 Other minor abnormality noted (specify below)		1 Rt upper zone 2 Rt mid zone 3 Rt lower zone 4 Lt upper zone 5 Lt mid zone 6 Lt lower zone 7 Other, specify	Longest Diameter (mm) 999 Unable to determine	Longest Perpendicular Diameter (mm)	1 Spiculated (Stellate) 2 Smooth 3 Poorly defined 99 Unable to determine
F1	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F2	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F3	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F4	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F5	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F6	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F7	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F8	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F9	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F10	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F11	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F12	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F13	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F14	☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐

DR

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

15. ___ Indicate the result for this screening CXR:

1 Negative screen, no significant abnormalities (skip to Q17)
2 Negative screen, minor abnormalities not suspicious for lung cancer (skip to Q17)
3 Negative screen, significant abnormalities not suspicious for lung cancer (skip to Q17, provide a follow-up recommendation)
4 Positive screen, nodule(s), mass(es) or other abnormalities suspicious for lung cancer
5 Inadequate CXR, non-diagnostic exam (skip to Part D)

16. ___ Indicate the overall suspicion for primary lung cancer (subjective impression) based on this screening CXR:

1 No suspicion
2 Low suspicion
3 Intermediate suspicion
4 Moderately high suspicion
5 High suspicion

17. What is the recommended next step for this study participant? (check all that apply)

- ☐ No diagnostic intervention necessary
- ☐ Comparison with historical images. If not available, recommend...NOTE: must check other procedure(s) in the event that historical images are not available
- ☐ Follow-up chest x-ray 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
  - ☐ PA/LAT with nipple markers
  - ☐ Other, specify: _____
- ☐ 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.)
- ☐ Other, specify: _____
- ☐ Low-dose helical CT (check all that apply)
  - ☐ 3 months from screening exam
  - ☐ 6 months from screening exam
  - ☐ 3 to 6 months from screening exam
  - ☐ 12 months from screening exam
  - ☐ 24 months from screening exam

Part D. Conclusion

Other observations / comments: _____

18. Reader ID: _____ (Stamp acceptable)

19. Date of Interpretation: __-__-2000 (mm-dd-yyyy)

20. Reader Signature: _____

_____
Signature of person responsible for data [1]

_____
Signature of person entering data onto web [2]

__-__-2000
Date form completed (mm-dd-yyyy)

DR COMPLETION INSTRUCTIONS

The DR Form is completed for each screening exam at T0, T1, and T2. The DR Form is to be completed by the ACRIN-NLST study staff: the research associate (study coordinator), radiology 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 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 CXR 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 (year 1 and year 2) 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 up to two visits in order to complete a technically adequate screening exam in any one study-year with a total of 6 allowable exam attempts. An exam attempt is defined as an exposure (image) being performed, whether it is successfully completed or not.

Part A. Technical Parameters: Completed by technologist; for Q6-10 record the technical parameters of the highest exposure that was performed. Refer to protocol section 13.0 for the CXR techniques and procedures.

The following technical parameters should be recorded for the screening CXR exam. Per protocol, the screening CXR consists of an upright PA projection CXR. If more than one PA image is performed, record the highest exposure factors used even if this does not correlate with the final image(s) submitted to ACRIN. The technologist should record these parameters at the time the exam is performed. In all cases, the data should be checked for completeness and accuracy by the radiologist.

If a lateral CXR projection is performed in error: Submit the entire CXR exam, including the lateral projection, to ACRIN. Document the occurrence on a PR Form and submit to ACRIN. The lateral projection should be accounted for in Q4a and 4b. To maintain the study design, 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 Form, this should be documented on an additional PR Form and submitted to ACRIN.

The radiologist is responsible for ensuring the quality of the image data and adherence to the technical parameters specified by the protocol for all screening exams.

4a. Total number of exposures performed to complete the Screening CXR exam: Record the number of exposures made to complete the CXR exam. Example: A tall participant required two PA projections to acquire the entire length of lung field (the two PA images equates to 1 exam). The first exam was over-exposed, therefore non-diagnostic, so another exam was performed. Q4a=4, Q4b=2, Q6-10=the higher exposure factors of the first exam even though the images submitted to ACRIN will be from the second exam.

4b. Number of images submitted to ACRIN that comprise this exam: Record the number of images submitted to ACRIN that make up the diagnostic exam. Example: Respiratory motion yielded a non-diagnostic exam; a second PA projection was performed. Q4a=2, Q4b=1, Q6-10=values from the image yielding the highest exposure factor.

5. **How was the CXR obtained:** Record the appropriate response (code numbers 1-4) indicating the CXR system used to perform the screening exam.

DR COMPLETION INSTRUCTIONS

6. **kVp:** Record the kVp used to obtain the CXR exam. Refer to protocol section 13.0 for the CXR techniques and procedures. *If kVp value is unknown, record 999.*

7. **mAs:** Record either mAs (Q7) or mA and time (Q8-9), based on the CXR equipment used to perform the screening exam. If reporting mA, leave this field blank; this logic check is programmed in the web module. Refer to protocol section 13.0 for the CXR techniques and procedures. General guideline, mAs should be less than 10 except for large participants. *If mAs value is unknown, record 99.9.*

8. **mA:** Record either mAs (Q7) or mA and time (Q8-9), based on the CXR equipment used to perform the screening exam. If reporting mAs, leave this field blank; this logic check is programmed in the web module. Refer to protocol section 13.0 for the CXR techniques and procedures. General guideline, mA should be between 100-1000. *If mA value is unknown, record 9999.*

9. **Time:** If reporting mA (Q8), record exposure time in milliseconds. If mAs reported (Q7), leave this field blank; this logic check is programmed in the web module. Refer to protocol section 13.0 for the CXR techniques and procedures. General guideline, exposure time should not exceed 40 milliseconds. *If time value is unknown, record 999.*

10. **Exposure Value:** If the screening exam was performed using a digital CXR system, record the exposure factor. Dependent on the CXR system used, the exposure value may be a S-value or an Exposure Index Value. General guideline: Fuji "S" number should be 100-400; Kodak "EI" number should be 1400-2000; Agfa "LgM number should be 1.9-2.5. *If the digital CXR system used does not display the exposure factor enter 9999.*

11. **CXR Unit ID:** Report the CXR Unit used by recording the ID number assigned to the unit on the CXR Equipment Data Form completed by the physicist. *If the unit ID is unknown, record 99*.

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

13. **Indicate the overall diagnostic quality of the CXR:** Record the appropriate response (code numbers 1-3) indicating the quality of the current screening exam.

    1 = Diagnostic exam (skip to Q14)

    2 = Limited CXR, but interpretable

    Using the list provided, identify the parameter(s) that affected the quality of the screening exam, and continue to Q14.

    3 = Non-diagnostic CXR

    Using the list provided, identify the parameter(s) that affected the quality of the screening exam. As described previously, the protocol specifies up to two screening exam visits per study year with a total number of 6 exam attempts are allowed to obtain a diagnostic quality screening exam. If a second visit is required, the DR Form for visit 1 should be retained in the study file with Q1-13 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. If after 6 exam attempts, the screening visit(s) yields a non-diagnostic exam (Q13=3) submit a DR Form to ACRIN. Document this inadequate screen by coding the quality of the exam non-diagnostic (Q11=3) and completing Q14-15; code Q14 appropriately (1-No, 2-Yes), indicating whether any abnormalities were reportable, Q15 would then be coded as an inadequate CT exam (code 5).

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

14. **Are there any abnormalities to report on this CXR?** 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 Q14 is no, proceed to Q15. If Q14 is yes, complete the abnormality table below Q14, 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 2-5 (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 code 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 code 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 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 adjacent to 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 Q15 must be coded 4.

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 C2 form.

61= Reticular/reticulonodular opacities, honeycombing, fibrosis, scar
Use this code to record the presence of subpleural fibrosing alveolitis, the typical fibronodular changesof 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 appropriate response (code number 1-7) indicating the approximate center of the nodule/mass within the lung field. 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

DR COMPLETION INSTRUCTIONS

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

Record the results of the current screening exam only. The 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 I8 Form. The focus of the screening examination is to identify and report abnormalities suspicious for lung cancer.

15. Indicate the result for this screening CXR: Based upon the presence and type of abnormalities reported in Q14, record the appropriate response (code numbers 1-5).

1 = Negative screen, no significant abnormalities
Review of the screening exam reveals no significant abnormalities. Skip to Q17.

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 Q17.

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 Q17, 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 and recorded in Q14 may be suspicious for lung cancer. Proceed to Q16.

5 = Inadequate CXR, non-diagnostic exam
The CT screening exams were diagnostically inadequate and insufficient information was obtained to determine the screening examination result. Per protocol, up to 2 screening visits with a total of 6 exam attempts are allowed to complete the screening exam. This category should be used only after 6 exam attempts or two screening visits yield 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.

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

17. What is the suggested next step for this participant? The radiologist should record her/his recommendation by placing a mark in the appropriate box. If Q15-screening result category equals 3 or 4, 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 5, 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
  - 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.

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

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

20. Reader Signature: This form serves as the source document for the DR data 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 original 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.

I8 ACRIN 6654 NLST Historical Images Form - CXR

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Baseline - completion of this form is based on comparison review of prevalence CXR screen with historical images. Year 1, 2 - completion of this form is based on comparison review of Incidence CXR screen with prior study CXR screen(s) and historical images. This form is submitted via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

If this is a revised or corrected form, indicate by checking box ☐ and fax to 215-717-0936.

Part A. Historical Images

1. ☐ Review of historical (including interval) images?

1 No (answer Q2 then skip to end, sign and date form)
2 Yes

2. ☐ Indicate the screening exam to which this I8 Form corresponds:

1 Baseline CXR Screen
2 Incidence CXR Screen, year 1
3 Incidence CXR Screen, year 2

3. Historical imaging to compare with current screening CXR:

Historical Image Types
1 Baseline Screen
2 Incidence Screen, year 1
3 CT
4 CXR
5 MRI
6 PET scan

Historical Image Type(s)	Date(s) of Historical Images (mm-dd-yyyy)
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐

Part B. Comparison Findings (completed by radiologist based on the current screening CXR and historical images)

4. ☐ Were any Code 51 abnormalities seen on the current screening CXR?

1 No (skip to Q5)
2 Yes

Compare all Code 51 abnormalities reported on the current screening CXR to the historical images available.
List each Code 51 abnormality using the assigned F number from the corresponding DR Form. If abnormality was pre-existing (column 2=2, Yes) complete columns 3-5.

Code 51 Abnormality F Number from DR	Was Abnormality Pre-Existing?	Earliest Date Visible	Interval Growth of Abnormality?	Interval *suspicious change in attenuation?
	1 No 2 Yes	mm-dd-yyyy	1 No 2 Yes	1 No 2 Yes
	99 Unable to determine		99 Unable to determine	
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐

*Suspicious change in attenuation = increase in attenuation from ground glass to a combination of ground glass and soft tissue.

5. ☐ Were any other potentially significant abnormalities seen on the current screening CXR?
Non-significant observations can be excluded from comparison.

1 No (skip to Q6)
2 Yes

I8

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Compare all other potentially significant abnormalities reported on the current screening CXR to the historical images.

List each potentially significant abnormality using the assigned F number from the corresponding DR form.
If abnormality was pre-existing (column 2=2, Yes) complete columns 3-4.

F Number from DR	Was Abnormality Pre-Existing?	Earliest Date Visible	Interval Change Warrants Further Investigation?
	1 No 2 Yes	mm-dd-yyyy	1 No 2 Yes
	99 Unable to determine		99 Unable to determine
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐

6. ☐ **In reviewing the historical images, are there now abnormalities visible on the current screening CXR that you did not record on the DR form this study year?**

1 No (skip to Q7)
2 Yes (record in chart below)

Record each finding below using CONSECUTIVE F-numbers. DO NOT SKIP F-NUMBERS

- Record data in fields for location, dimensions and margins ONLY for Code 51 abnormalities.
- If ≥ 6 nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- Use text lines to specify abnormalities ONLY for Codes 63, 64, and 65.
- To document additional text data, use "Part D, Other observations/comments;" this will be web-entered.
- Descriptive data NOT intended for web-entry should appear outside of data entry fields.

Abnormality Codes	Complete for Code 51 Nodules or Masses Only			
	Location of Epicenter	Dimensions		Margins
51 Non-calcified nodule or mass 53 Benign nodule(s) (benign calcification) 54 Atelectasis, segmental or greater 55 Pleural thickening or effusion 56 Non-calcified hilar/mediastinal adenopathy or mass (≥10mm short axis) 57 Chest wall abnormality (bone destruction, metastasis, etc.) 58 Consolidation 59 Emphysema 60 Significant cardiovascular abnormality 61 Reticular/reticulonodular opacities, honeycombing, fibrosis, scar 62 6 or more nodules not suspicious for cancer (opacities ≥4mm) 63 Other potentially significant abnormality above the diaphragm, (specify below) 64 Other potentially significant abnormality below the diaphragm, (specify below) 65 Other minor abnormality noted (specify below)	1 Rt upper zone 2 Rt mid zone 3 Rt lower zone 4 Lt upper zone 5 Lt mid zone 6 Lt lower zone 7 Other, specify	Longest Diameter (mm)	Longest Perpendicular Diameter (mm)	1 Spiculated (Stellate) 2 Smooth 3 Poorly defined
		999 Unable to determine		99 Unable to determine
F15 ☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F16 ☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F17 ☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F18 ☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐
F19 ☐☐ _____	☐ _____	☐☐☐	☐☐☐	☐☐

I8

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part C. CXR Results and Recommendations (completed by the radiologist based on the screening CXR and historical images)

7. ☐ **Did the review of historical images change the current screening CXR result and/or recommendation?**
1 No (skip to Part D)
2 Yes

8. ☐ **Indicate the current screening CXR result based upon the review of historical images:**
1 Negative screen, no significant abnormalities (skip to Q10)
2 Negative screen, minor abnormalities not suspicious for lung cancer (skip to Q10)
3 Negative screen, significant abnormalities not suspicious for lung cancer (skip to Q10, provide a follow-up recommendation)
4 Positive screen, nodule(s), mass(es) or other abnormalities suspicious for lung cancer
5 Inadequate CXR (skip to Part D)
6 Positive screen, stable abnormalities potentially related to lung cancer, no significant change since prior screening exam

9. ☐ **If a positive screen, what is your suspicion for primary lung cancer (subjective impression)?**
1 No suspicion
2 Low suspicion
3 Intermediate suspicion
4 Moderately high suspicion
5 High suspicion

10. What is the recommended next step for this study participant? (check all that apply)

☐ No diagnostic intervention necessary
☐ Comparison with historical images. If not available, recommend...NOTE: must check other procedure(s) in the event that historical images are not available
☐ 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
  ☐ PA/LAT with nipple markers
  ☐ Other, specify:_____
☐ 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 CXR in three (3) months
☐ Diagnostic chest CT
☐ Contrast-enhanced CT nodule densitometry
☐ FDG-PET
☐ Tech-99m depreotide scintigraphy
☐ Biopsy (percutaneous, thoracoscopic, open, etc.)
☐ Other, specify:_____
☐ Low-dose helical CT (check all that apply)
  ☐ 3 months from screening exam
  ☐ 6 months from screening exam
  ☐ 3 to 6 months from screening exam
  ☐ 12 months from screening exam
  ☐ 24 months from screening exam

Part D. Conclusion

Other observations / comments: _____

11. Reader ID: ☐☐☐☐☐☐☐ (Stamp acceptable)

12. Date of Interpretation: ☐☐-☐☐-2000

13. Reader Signature: _____
(When historical images are reviewed, this form serves as the source document for the comparison review of the screening CXR and historical images; the signature of the interpretating Radiologist must be on the completed paper form)

_____ ☐☐-☐☐-2000
Signature of person responsible for data [1] Date form completed (mm-dd-yyyy)

_____
Signature of person entering data onto web [2]

I8 COMPLETION INSTRUCTIONS

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 of 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.

I8 COMPLETION INSTRUCTIONS

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 2-5 (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).

I8 COMPLETION INSTRUCTIONS

- 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.

I8 COMPLETION INSTRUCTIONS

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.

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

  - 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.

I9

ACRIN 6654
NLST
Historical Images Form - CT

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Baseline - completion of this form is based on comparison review of prevalence CT screen with historical images. Year 1, 2 - completion of this form is based on comparison review of Incidence CT screen with prior study CT screen(s) and historical images. This form is submitted via the ACRIN website. Submit a paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

If this is a revised or corrected form, indicate by checking box ☐ and fax to 215-717-0936.

Part A. Historical Images

1. ☐ Review of historical (including interval) images?

1 No (answer Q2 then skip to the end, sign and date form)
2 Yes

2. ☐ Indicate the screening exam to which this I9 Form corresponds:

1 Baseline CT Screen
2 Incidence CT Screen, year 1
3 Incidence CT Screen, year 2

3. Historical imaging to compare with current screening CT:

Historical Image Types
1 Baseline Screen
2 Incidence Screen, year 1
3 CT
4 CXR
5 MRI
6 PET scan

Historical Image Type(s)	Date(s) of Historical Images (mm-dd-yyyy)
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐
☐	☐☐ - ☐☐ - ☐☐☐☐

Part B. Comparison Findings (completed by radiologist based on the current screening CT and historical images)

4. ☐ Were any Code 51 abnormalities seen on the current screening CT?

1 No (skip to Q5)
2 Yes

Compare all Code 51 abnormalities reported on the current screening CT to the historical images available.
List each Code 51 abnormality using the assigned F number from the corresponding C2 Form. If abnormality was pre-existing (column 2=2, Yes) complete columns 3-5.

Code 51 Abnormality F number from C2	Was Abnormality Pre-Existing?	Earliest Date Visible	Interval Growth of Abnormality?	Interval *suspicious change in attenuation?
	1 No 2 Yes	mm-dd-yyyy	1 No 2 Yes	1 No 2 Yes
	99 Unable to determine		99 Unable to determine	
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐	☐☐

*Suspicious change in attenuation = increase in attenuation from ground glass to a combination of ground glass and soft tissue.

5. ☐ Were other potentially significant abnormalities seen on the current screening CT?

Non-significant observations can be excluded from comparison.

1 No
2 Yes

I9

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Compare all other potentially significant abnormalities reported on the current screening CT to the historical images.

List each potentially significant abnormality using the assigned F number from the corresponding C2 form.
If abnormality was pre-existing (column 2=2, Yes) complete columns 3-4.

F Number from C2	Was Abnormality Pre-Existing?	Earliest Date Visible	Interval Change Warrants Further Investigation?
	1 No 2 Yes	mm-dd-yyyy	1 No 2 Yes
	99 Unable to determine		99 Unable to determine
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐
F ☐☐	☐☐	☐☐-☐☐-☐☐☐☐	☐☐

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?

1 No (skip to Q7)
2 Yes (record in chart below)

Record each CT finding below using CONSECUTIVE F-numbers. DO NOT SKIP F-NUMBERS

- Record data in fields for location, dimensions, margin, and attenuation ONLY for Code 51 abnormalities.
- If multiple micronodules < 4mm are seen, record Code 52 only ONCE.
- If ≥ 6 nodules not suspicious for lung cancer are seen, record as 62; do not record individual nodules.
- Use text lines to specify abnormalities ONLY for Codes 63, 64, and 65.
- To document additional text data, use "Part D, Other observations/comments;" this will be web-entered.
- Descriptive data NOT intended for web-entry should appear outside of data entry fields.

Abnormality Codes	Complete for Code 51 Nodules or Masses Only					
	CT Slice Location	Anatomic Location	Dimensions (same CT slice)		Margins	Predominant Attenuation
51 Non-calcified nodule or mass (opacity ≥4 mm diameter) 52 Non-calcified micronodule(s) (opacity < 4 mm diameter) 53 Benign lung nodule(s) (benign calcification) 54 Atelectasis, segmental or greater 55 Pleural thickening or effusion 56 Non-calcified hilar/mediastinal adenopathy or mass (≥ 10 mm short axis) 57 Chest wall abnormality (bone destruction, metastasis, etc.) 58 Consolidation 59 Emphysema 60 Significant cardiovascular abnormality 61 Reticular/reticulonodular opacities, honeycombing, fibrosis, scar 62 6 or more nodules, not suspicious for cancer (opacity ≥4 mm) 63 Other potentially significant abnormality above diaphragm, (specify below) 64 Other potentially significant abnormality below the diaphragm, (specify below) 65 Other minor abnormality noted (specify below)	Indicate the single slice number with the greatest diameter, or identify a representative slice CT Slice #	1 RUL 2 RML 3 RLL 4 LUL 5 Lingula 6 LLL 7 Other, specify: Abnormality Center	Longest Diameter (mm) 999 Unable to determine	Longest Perpendicular Diameter (mm)	1 Spiculated (Stellate) 2 Smooth 3 Poorly defined 99 Unable to determine	1 Soft tissue 2 Ground Glass 3 Mixed (1+2) 4 Fluid/Water 5 Fat 6 Other, specify
F15 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐_____
F16 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐_____
F17 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐_____
F18 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐_____
F19 ☐☐ _____	☐☐☐	☐☐ _____	☐☐☐	☐☐☐	☐☐	☐☐_____

I9

If this is a revised or corrected form, please check box ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

7. ☐ Did the review of historical images change the current screening CT result and/or recommendation?

1 No (skip to Part D)
2 Yes

8. ☐ Indicate the current screening CT result based upon the review of historical images:

1 Negative screen, no significant abnormalities (skip to Q10)
2 Negative screen, minor abnormalities not suspicious for lung cancer (skip to Q10)
3 Negative screen, significant abnormalities not suspicious of lung cancer (skip to Q10, provide a folllow-up recommendation)
4 Positive screen, nodule(s) 4-10 mm or enlarging nodule(s) <7mm suspicious for lung cancer
5 Positive screen, nodule(s) >10 mm, enlarging nodule(s) ≥7 mm, mass(es), or other non-specific abnormalities suspicious for lung cancer
6 Inadequate CT (skip to Part D)
7 Positive screen, stable abnormalities potientially related to lung cancer, no significant change since prior screening exam

9. ☐ If a positive screen, what is your suspicion for primary lung cancer (subjective impression)?

1 No suspicion
2 Low suspicion
3 Intermediate suspicion
4 Moderately high suspicion
5 High suspicion

10. What is the recommended next step for this study participant? (check all that apply)

☐ No diagnostic intervention necessary
☐ Comparison with historical images. If not available, recommend...NOTE: must check other procedure(s) in the event that historical images are not available
☐ Thin-section chest CT or repeat low dose helical chest CT (check all that apply)
  ☐ 3 months from screening exam
  ☐ 6 months from screening exam
  ☐ 3 to 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.)
☐ Other, specify: _____

Part D. Conclusion

Other important comments: _____

11. Reader ID: ☐☐☐☐☐☐☐ (Stamp acceptable)

12. Date of Interpretation: ☐☐-☐☐-2000

13. Reader Signature: _____

(When historical images are reviewed, this form serves as the source document for the comparison review of the screening CT and historical images; the signature of the interpretating Radiologist must be on the completed paper form.)

_____ ☐☐-☐☐-2000

Signature of person responsible for data [1] Date form completed (mm-dd-yyyy)

_____

Signature of person entering data onto web [2]

I9 COMPLETION INSTRUCTIONS

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.

I9 COMPLETION INSTRUCTIONS

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).

I9 COMPLETION INSTRUCTIONS

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

I9 COMPLETION INSTRUCTIONS

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.

IM

ACRIN 6654 NLST (CT/CXR) Screening Result Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: This form documents the screening result letter sent to the participants of ACRIN 6654 NLST and their physician of record. This form is submitted by the RA via the ACRIN website. Submit paper only in the event of a revision.

If this is a revised or corrected form, indicate by checking box ☐ and fax to 215-717-0936.

1. ☐ **Was a screening result letter sent to the participant?**

1 No
2 Yes

2. Date screening result letter sent to participant: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

3. ☐ **Was a screening result letter sent to the physician of record?**

1 No (complete Q3a)
2 Yes (skip to Q4)

3a. ☐ **Reason screening result letter not sent to physician of record:**

1 Participant declined to identify a physician of record (document on participant contact sheet)
2 Participant requested physician of record not to be notified of screening results (documentation with participant signature must be retained in case study file)
3 Other, specify: _____

4. Date screening result letter sent to the physician of record: ☐☐-☐☐-2 0 0☐ (mm-dd-yyyy)

5. ☐ **Record the type of letter sent:**

1 Negative screen, no significant abnormalities
2 Negative screen, minor abnormalities not suspicious for lung cancer
3 Negative screen, significant abnormalities not suspicious for lung cancer
4 Positive CXR screen, nodule(s), mass(es) or other abnormalities suspicious for lung cancer
5 Positive CT screen, nodule(s) 4-10 mm or enlarging nodule(s) <7 mm
6 Positive CT screen, nodule(s) >10 mm, enlarging nodule(s) ≥ 7mm, mass(es), or other non-specific abnormalities suspicious for lung cancer
7 Positive screen, stable abnormality potentially related to lung cancer, no significant change since prior screening exam

6. ☐ **Indicate the screening exam to which this IM Form corresponds:**

1 Baseline Screen
2 Incidence Screen, year1
3 Incidence Screen, year 2

Comments: _____

_____

_____

_____

_____

Signature of person responsible for data

☐☐-☐☐-2 0 0☐

Date form completed (mm-dd-yyyy)

_____

Signature of person entering data onto web

IM COMPLETION INSTRUCTIONS

The IM Form is completed for each screening exam at T0, T1, and T2. The IM documents whether the screening results letters were sent to the participant and her/his provider, as specified by the protocol, and the type of letter sent. The IM Form is to be completed by the ACRIN-NLST study staff. If completing a paper CRF, this form should be completed in black or blue ink. The data is submitted via the ACRIN web site. The original CRF (paper or web) 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 the form. Alternatively, the institution name, institution number, participant initials, and participant case number can be recorded in the spaces provided.

1. **Was a screening result letter sent to the participant:** Record the appropriate response (code numbers 1-2) indicating whether or not a screening result letter was sent to the participant, as required by protocol.
2. **Date screening result letter sent to participant:** Record the date the letter was mailed to the participant; record date as month, day, and year.
3. **Was a screening result letter sent to the physician of record:** Record the appropriate response (code numbers 1-2) indicating whether or not a screening result letter was sent to the participant's physician of record, as required by protocol. If no, complete Q3a then skip to Q5. If yes, skip to Q4.

3a. **Reason screening result letter not sent to physician of record:** Record the appropriate response (code numbers 1-3) indicating the reason the screening result letter was not sent to the participant's provider. According to protocol, at enrollment each participant should identify her/his physician of record to receive the screening results. If the participant declines to identify a provider or declines to have the results sent to her/his provider, documentation of this should added to the study file via a progress note or the Screening Results Withheld Statement. If "Other," code 3, the text field must be completed (the web module will accept 100 characters). Skip to Q5.

4. **Date screening result letter sent to the physician of record:** Record the date the letter was mailed to the participant's provider; record date as month, day, and year.
5. **Record the type of letter sent:** Record the appropriate response (code numbers 1-7) indicating the result letter sent to the participant/provider. Use caution when recording the appropriate result letter, since the IM is used for both study arms the response code may not align directly with the screening results response codes on the I8, I9, C2, DR Forms.
6. **Indicate the screening exam to which this IM form corresponds:** Record the appropriate response (codes 1-3) identifying the current study year.

Comments: The comment field is an optional field provided for site use (relevant clinical or study notations, etc.). Some sites utilize the option of completing certain forms via the web modules (no paper CRF) so the comment section is included on the web module. If a paper CRF is completed, comments recorded on the paper CRF should, in keeping with general GCP concepts, be entered on the web but this is not an auditable requirement. The comment section is not intended for "actionable" information you need to relate to DM and is not intended for analyzable data. The web module will allow 100 characters.

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 (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the NLST staff member submitting the data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

QC ACRIN 6654 NLST Quality Control CT Images

Reader ID:	Date of review (mm/dd/yyyy):	Reader Signature:
Case Number:	Date of Study on Stamp:	

1. Number of scout images: _____

2. Total number of images in helical data set: _____ (series utilizing smooth filter)

CT Subjective Image Quality

3. Is the overall quality of the CT acceptable? [ ] No [ ] Suboptimal [ ] Yes

****Record any comments in the Comments Section below**

ANSWER Q4-Q11 **FORM IS COMPLETED**

4. [ ] No [ ] Yes Are the lung volumes sub-maximal?

5. [ ] No [ ] Yes Is there significant motion artifact?

6. [ ] No [ ] Yes Is there significant respiratory misregistration?

7. [ ] No [ ] Yes Are the lungs NOT completely imaged?

8. [ ] No [ ] Yes Is there beam hardening artifact?
(If YES, identify the anatomic locations of beam hardening under comments)

9. [ ] No [ ] Yes Are there other problems to report?

If Yes, specify: _____

10. [ ] No [ ] Yes Are there issues with image annotation (participant name appears, etc.)?

11. [ ] No [ ] Yes Do image technical parameters appear to be INCORRECT?

If YES please identify all parameters contributing to suboptiomal or inadequate image quality.
ANSWER Q12-Q18

12. [ ] No [ ] Yes kV is NOT appropriate for exam (Protocol mandates 120 kVp)

13. [ ] No [ ] Yes mAs is NOT appropriate for the participant size (e.g. excessive quantum mottle)

14. [ ] No [ ] Yes dFOV is NOT appropriate (too large *or* too small)

15. [ ] No [ ] Yes The nominal slice thickness is NOT 1-2.5 mm

16. [ ] No [ ] Yes The reconstruction filter is NOT smooth

17. [ ] No [ ] Yes The image is NOT properly centered (Right to Left; Top to Bottom)

18. [ ] No [ ] Yes Other technical parameters are INCORRECT

If Yes, specify: _____

COMMENTS: _____

QT ACRIN 6654 NLST Quality Control CXR Images

Reader ID:	Date of review (mm/dd/yyyy):	Reader Signature:
Case Number:	Date of Study on Stamp:	Date of Assessment:

1. Total number of images in screening CXR data set: _____

2. Was a lateral projection view submitted as part of the examination: [ ] No [ ] Yes

CXR Subjective Image Quality

3. Is the overall quality of the CXR diagnostic? [ ] No [ ] Suboptimal [ ] Yes

****Record any comments in the Comments Section below**

ANSWER Q4-Q12 **FORM IS COMPLETED**

4. [ ] No [ ] Yes Are the lung volumes sub-maximal?

5. [ ] No [ ] Yes Are the lungs NOT completely imaged?

6. [ ] No [ ] Yes Is positioning adequate?

7. [ ] No [ ] Yes Is there motion degradation?

8. [ ] No [ ] Yes Are there artifacts that obscure anatomy?

9. [ ] No [ ] Yes Is image noise UNACCEPTABLE?

10. [ ] No [ ] Yes Are there issues with image annotation (participant name appears, etc.)?

11. [ ] No [ ] Yes Are there other problems to report?

If Yes, specify: _____

12. [ ] No [ ] Yes Do image technical parameters appear to be INCORRECT?

If YES please identify all parameters contributing to suboptiomal or inadequate image quality.

ANSWER Q13-Q18

13. [ ] No [ ] Yes kV is NOT appropriate for exam (By protocol kV = 100-150)

14. [ ] No [ ] Yes mAs is NOT appropriate for exam

15. [ ] No [ ] Yes Collimation is NOT appropriate

16. [ ] No [ ] Yes The Look-up = Table (Image Processing Algorithm) is INCORRECT (This would influence image gray scale)

17. [ ] No [ ] Yes The frequency enhancement is INCORRECT? (This would affect the edge enhancement of the image)

18. [ ] No [ ] Yes Other technical parameters are INCORRECT

If Yes, specify: _____

COMMENTS: _____

Follow-up Forms

F1

ACRIN NLST 6654
Interval Follow-Up Questionnaire

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions to the participant on completing the questionnaire:

As part of our evaluation of lung cancer screening, we are very interested in knowing about your health and any changes in your cigarette smoking habits or beliefs since we last contacted or saw you.

Please complete all parts of this form. We expect that completing this form may take 15-20 minutes of your time. In addition to general smoking status, the form consists of questions about medical visits, hospital admissions, and medical tests that you have had since:

____/____/20____ to today

Do NOT report medical visits, medical tests, or hospital admissions that happened before this date. However, if you are not sure of the date and don't think that you have reported the visit to us before, please do list the visit and answer the questions about it. All of your answers will be kept strictly confidential. Information within the boxed areas of the following pages are for follow-up purposes and will be kept at the study site only, this information will not be submitted to ACRIN.

If your have any questions regarding the form, please do not hesitate to contact our NLST site below:

When you have finished all sections, please remember the following:

- Sign and date the questionnaire on the last page.
- Return this questionnaire and the Annual Contact Sheet (if provided) by mail to the NLST clinic in the enclosed self-addressed, stamped envelope. Or, if you are visiting the NLST clinic, simply bring both forms with you.

Thank you for your participation in the NLST!

F1

ACRIN NLST 6654
Interval Follow-Up Questionnaire

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part A. Interval Cancer Diagnosis

A1. Since the date on the front of this form, have you been diagnosed with lung cancer?

- ☐ No
- ☐ Yes (complete A1a and A1b)
- ☐ I don't know

a. Date of diagnosis: _____/_____/20_____ (mm/dd/yyyy)

b. Name of hospital or clinic where you received the diagnosis:

_____

A2. Since the date on the front of this form, have you been diagnosed with any other cancer?

- ☐ No
- ☐ Yes (record <u>any</u> diagnosed cancers below)
- ☐ I don't know

Type of cancer diagnosed: _____

c. Date of diagnosis: _____/_____/20_____ (mm/dd/yyyy)

d. Name of hospital where you received the diagnosis:

_____

Type of cancer diagnosed: _____

e. Date of diagnosis: _____/_____/20_____ (mm/dd/yyyy)

f. Name of hospital where you received the diagnosis:

_____

Type of cancer diagnosed: _____

g. Date of diagnosis: _____/_____/20_____ (mm/dd/yyyy)

h. Name of hospital where you received the diagnosis:

_____

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

Part B. Smoking Habits

We would like to know about any changes in your smoking over the **past six (6) months**. Please answer the following questions to the best of your ability.

B1. In the past six (6) months, have you smoked any cigarettes?

- ☐ No (skip to B8)
- ☐ Yes

B2. Do you NOW smoke cigarettes (one or more cigarettes per week)?

- ☐ No (skip to B4)
- ☐ Yes

B3. How many cigarettes do you usually smoke per day, on average?

- ☐ Fewer than 1 per day
- ☐ _____ Cigarettes per day (enter a whole number)

B4. Did you visit your primary care provider this past year?

- ☐ No (skip to B5)
- ☐ Yes (complete a – g)

If yes, did your primary care provider do any of the following?

a. Ask you about smoking?

- ☐ No
- ☐ Yes

b. Advise you to stop smoking?

- ☐ No
- ☐ Yes

c. Ask you about your interest in quitting smoking?

- ☐ No
- ☐ Yes

d. Talk with you about how to quit smoking?

- ☐ No
- ☐ Yes

e. Recommend using nicotine replacement therapy (patch, gum, inhaler or spray) and/or Zyban® (Wellbutrin®, Bupropion) to help you quit smoking?

- ☐ No
- ☐ Yes

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

f. Recommend counseling (classes, quit line) to help you quit smoking?

☐ No
☐ Yes

g. Suggest a follow-up visit or phone call about quitting smoking?

☐ No
☐ Yes

B5. In the past six (6) months, have you done any of the following?

h. Used nicotine patch, gum, inhaler or nasal spray

☐ No
☐ Yes

i. Used Zyban® (Wellbutrin® or Bupropion)

☐ No
☐ Yes

j. Participated in a smoking cessation program such as a quit smoking group or individual or group counseling?

☐ No
☐ Yes

k. Participated in a smoking cessation program because you were referred by this study?

☐ No
☐ Yes

l. Talked by telephone with a smoking counselor

☐ No
☐ Yes

B6. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 24 hours?

☐ I did not intentionally try to quit smoking
☐ I intentionally quit smoking _____ times for at least 24 hours (enter a whole number)

B7. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 7 days?

☐ I did not intentionally try to quit smoking
☐ I intentionally quit smoking _____ times for at least 7 days (enter a whole number)

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

B8. Next are statements that smokers have said about quitting. Please put a check in the box next to the <u>one</u> statement that best represents what you think right now. (select only one)

- ☐ I enjoy smoking so much I will never consider quitting no matter what happens
- ☐ I never think about quitting but I might someday
- ☐ I rarely think about quitting and have no specific plans to quit
- ☐ I sometimes think about quitting but have no specific plans to quit
- ☐ I often think about quitting but have no specific plans to quit
- ☐ I plan to quit in the next 6 months
- ☐ I plan to quit in the next 30 days
- ☐ I have already begun to cut down and I have set a quit date
- ☐ I have already quit but I worry about slipping back or relapsing
- ☐ I have quit and I am 100% confident that I will never smoke again

Please continue to next page. . . .

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

Part C. Other Clinical Trials

C1. Since the date on the front of this form, have you enrolled or participated in any other clinical trial?

☐ No (skip to Part D)
☐ Yes (complete a-c)

a. Name of clinical trial: _____

b. When did you enroll in this trial? _____/_____ (mm/yyyy)

c. As part of the trial, did your care consist of any of the following tests or examinations?
(Check all that apply)

☐ Clinical lab test(s)
☐ Medication or supplements administered and/or prescribed
☐ Chest CT
☐ Chest X-ray
☐ Other imaging test, specify _____
☐ None of the above, care did not consist of any treatment (i.e., observational study or control arm)
☐ Other, specify: _____
☐ I don't know

☐ Additional clinical trials: Check here if you are participating in more clinical trials.

Part D. Health Care Visits

We need to find out about all health care visits you have had **since the time point identified on page 1 of this form.** Please answer the following questions as best you can. *If you cannot remember an exact date, please give a date as close as you can to the medical visit.* We may call you for more information about your answers. If you have questions as you are completing this form, please contact our NLST Office as listed on Page 1 of this form.

F1

ACRIN NLST 6654
Interval Follow-Up Questionnaire

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

D1. Since the date on the front of this form, have you visited your primary health care provider (e.g. the practitioner whom you consider to be your main provider)? Include visits only to your primary provider here; information about other doctors, specialists, or health practitioners whom you have seen can be entered on the pages that follow. Visits to dentists, optometrists, podiatrists and ophthalmologists need *not* be included.

☐ No (skip to question D2)
☐ Yes (continue below)

If yes, please provide the following information for your primary care provider (if different from the Contact Information Sheet):

Health care provider name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

If yes, please list all the date(s) on which you visited this medical provider and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Reason for this visit** Please place only one (1) check per visit row			**Record the tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional visits: Check here if you have more than five (5) visits to report for this provider.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	Procedure Type
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

D2. Since the date on the front of this form, have you visited any other health care provider or clinic (doctors, specialists, or health practitioners)? Outpatient visits to dentists, optometrists, podiatrists, and ophthalmologists need *not* be included.

☐ No (skip to D5)
☐ Yes (continue below)

If yes, please provide the following information for this care provider or clinic:
Health care provider name: _____
Address: _____
City, State, Zip: _____
Phone: (_____)_____

If yes, please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Reason for this visit** Please place only one (1) check per visit row			**Record the tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional visits: Check here if you have more than five (5) visits to report for this provider.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

D3. Since the date on the front of this form, have you visited any other health care provider or clinic (doctors, specialists, or health practitioners)? Outpatient visits to dentists, optometrists, podiatrists and ophthalmologists need *not* be included.

☐ No (skip to D5)
☐ Yes (continue below)

If yes, please provide the following information for this care provider or clinic:
Health care provider name: _____
Address: _____
City, State, Zip: _____
Phone: (_____)_____

If yes, please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Reason for this visit** Please place only one (1) check per visit row			**Record the tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional visits: Check here if you have more than five (5) visits to report for this provider.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

D4. Since the date on the front of this form, have you visited any other health care provider or clinic (doctors, specialists, or health practitioners)? Outpatient visits to dentists, optometrists, podiatrists and ophthalmologists need *not* be included.

☐ No (skip to D5)
☐ Yes (continue below)

If yes, please provide the following information for this care provider or clinic:

Health care provider name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

If yes, please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Reason for this visit** Please place only one (1) check per visit row			**Record the tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ___/___/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional visits: Check here if you have more than five (5) visits to report for this provider.

☐ **g.** Additional providers or clinics: Check here if you have more health care providers or clinics to report.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

D5. Since the date on the front of this form, have you been hospitalized (stayed overnnight in the hospital)?

☐ No (skip to D7)
☐ Yes (continue below)

If yes, please provide the following information for the hospital:
Hospital name: _____
Address: _____
City, State, Zip: _____
Phone: (_____)_____

If yes, please list all the date(s) you were **first admitted** to the hospital, and whether the hospitalization was lung or chest-related. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of admission(s) mm/dd/yyyy	**Reason for this admission** Please place only one (1) check per visit row			**Record the tests done for this admission by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional hospitalizations: Check here if you have more than five (5) admissions to this facility to report.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

Place Label Here
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

D6. Since the date on the front of this form, have you been hospitalized (stayed overnight in the hospital) at another hospital?

☐ No (skip to D7)
☐ Yes (continue below)

If yes, please provide the following information for the hospital:
Hospital name: _____
Address: _____
City, State, Zip: _____
Phone: (_____)_____

If yes, please list all the date(s) you were **first admitted** to the hospital, and whether the hospitalization was lung or chest-related. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of admission(s) mm/dd/yyyy	**Reason for this admission** Please place only one (1) check per visit row			**Record the tests done for this admission by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional hospitalizations: Check here if you have more than five (5) admissions to this facility to report.

☐ **g.** Additional hospitals: Check here if you were admitted to another hospital.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

ACRIN NLST 6654
Interval Follow-Up Questionnaire

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

D7. Since the date on the front of this form, have you visited an emergency room?

☐ No (skip to Part E)

☐ Yes (continue below)

If yes, please provide the following information for Emergency Room Facility:

Emergency room name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

If yes, please list all the date(s) that you visited this Emergency Room and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. If no tests were performed for the visit please record response code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Reason for this visit** Please place only one (1) check per visit row			**Record the tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
a. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
b. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
c. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
d. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
e. ____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

☐ **f.** Additional visits: Check here if you have more than five (5) visits to this emergency room to report.

☐ **g.** Additional emergency rooms: Check here if you visited another emergency room.

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	Procedure Type
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

F1

ACRIN NLST 6654
Interval Follow-Up Questionnaire

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part E. Questionnaire Completion

Please provide your signature and write the date that you completed this questionnaire below. Your name will be kept confidential at the study site and will not be submitted to ACRIN.

_____ _____

Print your name (Participant name) **Your Signature (Participant signature)**

____/____/**20**____ (mm/dd/yyyy)

Date of Questionnaire Completion

Enter the date you finished the questionnaire

Congratulations! You have completed this survey. Thank you for your time! Your cooperation in providing this information is very important to the success of the NLST.

Please use the enclosed self-addressed stamped envelope to mail your survey back to the NLST clinic. Or, if you are visiting the NLST clinic, simply bring the form with you.

You may have questions for us about this survey or other study related matters, please let us know by checking a response below.

☐ No, I have no questions at this time.

☐ Yes, please call me; I have questions about this questionnaire.

☐ Yes, please call me; I have other study related questions.

We may need to contact you to clarify some of your answers to these questions.

_____ ____/____/**20**____ (mm/dd/yyyy)

Signature of person responsible for data Date of interview / questionnaire completion

_____

Signature of person entering data onto web

F1 Completion Instructions

The F1 Follow-Up Questionnaire is a participant completed form designed to collect interim health status and medical interventions. The F1 is to be completed every six months (window: -1 month to +3 months of F1 due date) for all participants for the duration of the trial. The F1 may be completed by the participant during a visit to the site (T1 and T2), as a telephone interview, or administered via mail. The shaded/boxed areas of this form are not web-entered on the ACRIN web site.

If the F1 is administered by mail:

- Prior to mailing, each page of the F1 Form must be labeled with the participant identifiers (at minimum, the case number and participant initials). If the participant identifiers do not appear, there may be no reliable way to identify who completed the form.
- Include a self-addressed, stamped envelope for the return of the form.
- Provide the NLST site contact information in the space provided on page 1.
- Record the date mailed and document on the FC Form (F1 Coversheet, Question 1).
- Record the date returned and document on the FC Form (F1 Coversheet, Question 1).
- If the questionnaire has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received and completed.
- Once received, the RA should review the questionnaire for completeness, an attempt should be made to collect any outstanding information and correct all errors or discrepant data (by telephone or in-person), particularly for the critical data elements. If a blank data element cannot be completed (data not obtained) it should remain blank, document this on the F1 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. If discrepant data cannot be resolved it should remain as it was recorded by the participant and not changed. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).
- Unsuccessful attempts to contact participants for further information should be recorded in the chart.

If the questionnaire is administered by in-person or telephone interview:

- Record the date of the interview and document on the FC Form (F1 coversheet, Question 1).
- The RA should review the questionnaire for completeness, an attempt should be made to collect any outstanding information and correct all errors or discrepant data before the interview is concluded, particularly for the critical data elements. If a data element cannot be completed (data not obtained) it should remain blank, document this on the F1 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).

Coversheet

Participant Label: Affix a Case Specific Label to each page in the box provided at the top right corner of the form. These labels are supplied by ACRIN once a participant has been randomized and contain all the participant identifiers (case number, participant initials, and institution name/number). To receive additional labels, submit a Request For Case Specific Labels to ACRIN HQ; this form can be printed from the ACRIN web site. In lieu of a Case Specific Label, record the Institution, Institution Number, Participant Initials, and Case Number in the box provided at the top right corner of the form.

F1 data collection interval: _____/_____/20_____
Prior to mailing or administering this form, the time interval for participant F1 Form completion must be indicated on page 1. The interval extends from the date that the participant last completed (i.e. dated) an F1 Form (Part E, Date of Participant Questionnaire Completion) to the present. If this is the first F1 Follow-up, the interval extends from the date of randomization. For example, if the participant recorded 4/28/03 in Part E of their last F1 Form, the interval for the current follow-up period extends from 4/28/03 until the present.

NLST Site Contact Information: Provide appropriate site contact information in the space provided on page 1.

Part A. Interval Cancer Diagnosis

This information is intended for collection every 6 months, but should be collected for the time interval since the last interview (as specified on page 1).

All questions in Part A are critical data elements*, attempts should be made to collect this data*. Please encourage the participant to provide as much information as possible. This may require additional contacts. A" yes" response will trigger data submission of the DE, CX, and TF forms by certified medical chart abstractors.

A1. **Since the date on the front of this form, have you been diagnosed with lung cancer?** Instruct the participant to answer "no" or "yes" depending on whether or not s/he was diagnosed with lung cancer by a health care provider during this time period. This does not include self-diagnosis.

If the response is "no," skip to A2.

If the response is "yes," the participant was diagnosed with lung cancer, complete the following:

Date of diagnosis:
Instruct the participant to provide the date of diagnosis as month, day, year. If the participant is unable to provide any portion of the date, record 99 in the blank space and initial/date (e.g. participant response 10/2003, RA should record 99 for day on paper and web form = 10/99/2003). WEB: mm/dd/yyyy required. If unknown, use 99 as directed above.

Name of hospital or clinic where you received the diagnosis:
Instruct the participant to provide the name of the facility where the diagnosis was made. WEB: data field is not web-entered.

A2. **Since the date on the front of this form, have you been diagnosed with any cancer?** Instruct the participant to answer "no" or "yes" depending on whether or not s/he was diagnosed with a cancer, other than lung cancer, by a health care provider during this time period. This does not include self-diagnosis. Data fields have been provided to allow for the reporting of 3 other cancer diagnoses.

If the response is "no," skip to Part B.

If the response is "yes," the participant was diagnosed with a cancer other than lung cancer, complete the following:

Type of cancer diagnosed:
Instruct the participant to provide the type of cancer s/he was diagnosed as having. WEB: data field limited to 100 characters.

Date of diagnosis:
Instruct the participant to provide the date of diagnosis as month, day, year. If the participant is unable to provide any portion of the date, record 99 in the blank space and initial/date (e.g. participant response 10/2003, RA should record 99 for day on paper and web form = 10/99/2003). WEB: mm/dd/yyyy required. If unknown, use 99 as directed above.

Name of hospital or clinic where you received the diagnosis:
Instruct the participant to provide the name of the facility where the diagnosis was made. WEB: data field is not web-entered.

Part B. Smoking Habits

These questions are concerned with overall changes in participant smoking habits. All questions should be answered appropriately following the skip patterns. Unlike Part A, this section is intended to collect smoking information pertaining *only* to the preceding 6 months despite missed data time points. An attempt should be made to collect responses to each question. WEB: If unable to collect responses for questions the participant left blank, document the blank data fields by selecting the "Blank/Unknown" web response.

B1. In the past six 6 months, have you smoked any cigarettes?
Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he has smoked any cigarettes in the last 6 months.

- If the response is "no," skip to B8 (B2-7 should be blank).
- If the response is "yes," continue to B2.
- If no response is provided, select "unknown" at web entry.

B2. Do you NOW smoke cigarettes (one or more cigarettes per week)?
Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he is smoking at least one cigarette a week.

- If the response is "no," skip to B4 (B3 should be blank).
- If the response is "yes," continue to B3.
- If no response is provided, select "unknown" at web entry.

B3. How many cigarettes do you usually smoke per day, on average?
Instruct the participant to provide, to the best of her/his ability, a numeric response (whole number) based on their daily average of cigarettes. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4).

- If the response is less than 1 cigarette a day, mark this response on the CRF.
- If the response is greater than 1, record the numeric response on the line provided.
- If no response is provided, enter '999' for unknown/blank at web entry.

B4. Did you visit your primary care physician this past year?
Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by her/his primary care provider (physician, nurse practitioner, etc.) this past year.

- If the response is "no," skip to B5 (B4a-g) should be blank.
- If the response is "yes," B4a-g should be completed. For B4a-g, instruct the participant to mark/answer "no" or "yes" to each of these questions.
- If no response is provided, select "unknown" at web entry.

B5. In the past six (6) months, have you done any of the following? (B5h-l)
Instruct the participant to answer "no" or "yes" to each of these questions. If no response is provided, select "unknown" at web entry.

B6. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 24 hours?
Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter '99' for unknown at web entry.

B7. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 7 days?

Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter '99' for unknown at web entry.

B8. Next are statements that smokers have said about quitting. Please put a check in the box next to the one statement the best represents what you think right now. (select only one)

Instruct the participant to mark the statement that most appropriately reflects her/his current attitude toward smoking. If no response is provided, select "unknown" at web entry.

Part C. Other Clinical Trials

This section documents any contamination or confounding variables that result from participants receiving care from clinical trials other than NLST. As an eligibility criterion, the participant may not already be enrolled in another cancer prevention or screening trial. However, once enrolled, we cannot hinder a participant from enrolling in another trial. Therefore, this section serves to document the care provided within other trials. This information is intended for collection every 6 months, but should be collected for the time interval since the last interview (as specified on page 1).

C1. Since the date on the front of this form, have you enrolled or participated in any other clinical trial?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he has enrolled in a clinical trial other than NLST within the last 6 months or since the last follow-up.

- If the response is "no," skip to Part D (1a-c should be blank).
- If the response is "yes," 1a-c should be completed.
- If no response is provided, select "unknown" at web entry.

a. Name of clinical trial:

Instruct the participant to provide the name of the clinical trial. If unknown, attempt to determine the nature of the trial, the site, the investigators, a phone number, or similar information that will enable the determination of trial name (such as web search). WEB: data element is limited to 100 characters.

b. When did you enroll in this trial?

Instruct the participant to provide the date of enrollment in the clinical trial. The participant should provide the date as month and year. If the participant is unable to provide any portion of the date, record 99 in the blank space and initial/date (e.g. participant response is 2003, RA should record 99 for month on paper and web form = 99/2003).

c. As part of the trial, did your care consist of any of the following tests or examinations?

Instruct the participant to select, from the list provided, all tests provided as part of the other clinical trial. Choose all that apply. There is space to record other tests/exams performed that are not listed on the data form. WEB: Other data fields are limited to 100 characters.

Additional clinical trials:

If the participant enrolled in other clinical trials, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person).

Part D. Health Care Visits

This section documents the participant's health care visits since the date on the front of this form. All information should be provided to the best of the participant's recollection. A medical diary can be provided to participants in advance to record visits rather than relying on recall for completion of the F1 form.

D1. Since the date on the front of this form, have you visited your primary health care provider (e.g., the practitioner whom you consider your main provider)? This page documents visits to the participant's primary health care provider only. Other provider visits are collected on the following pages. Visits to dentists, optometrists, ophthalmologists, and podiatrists need not be included. Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by her/his primary care provider during this time period.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to D2.

If the response is "yes," the participant should provide:

- The name, address, phone number of the primary health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if / when it becomes necessary.

Date of visit:
Instruct the participant to provide the date of each visit to her/his primary care provider. The date should be recorded as month/day/year. If the participant is unable to provide any portion of the date, record '99'. For example: if the participant records 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use'99' as directed.

Reason for this visit:
For each visit date, instruct the participant to record the reason for the visit by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*
- The participant should indicate whether the reason for the visit was due to a "lung problem" or "other" problem. "Lung problems" refer to a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I don't know" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F1 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F1. Efforts to obtain the information should be noted on the form with initials and date.

Record the tests done for this visit by code number:
For each visit date, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The appropriate response should be recorded using the numerical codes provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

f. Additional visits:
If the participant had more than 5 visits to her/his primary care provider, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

D2-4. Since the date on the front of this form, have you visited any other health care provider or clinic (doctors, specialists, health practitioners, etc)? Outpatient visits to dentists, optometrists, ophthalmologists, and podiatrists need not be included. Questions D2-5 should be used to document visits to other health care providers. Each question D2-5 should be used to document a specific provider. For example, if a participant saw 3 other providers (pulmonologist, cardiologist, and neurologist), the pulmonologist information would be recorded in D2, cardiologist in D3, and the neurologist in D4.

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by a health care provider other than primary care provider.

***This is a critical data element**, attempts should be made to collect this data.*

If response is "no," skip to D6.

If the response is "yes," the participant should provide:

- The name, address, phone number of the health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if / when it becomes necessary.

Date of visit:
Instruct the participant to provide the date of each visit to the health care provider or clinic. The date should be recorded as month/day/year. If the participant is unable to provide any portion of the date record '99'. For example, if the participant records 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use '99' as directed.

Reason for this visit:
For each visit date, instruct the participant to record the reason for the visit by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*
- The participant should indicate whether the reason for the visit was due to a "lung problem" or "other" problem. "Lung problems" refer to a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I don't know" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F1 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F1. Efforts to obtain the information should be noted on the form with initials and date.

Record the tests done for this visit by code number:
For each visit date, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The appropriate response should be recorded using the numerical codes provided.
- At least one response code must be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' (Unknown") indicating a blank data field; this response is not included on the questionnaire.

f. Additional visits:
If the participant had more than 5 visits to the health care provider/clinic, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

g. Additional providers or clinics:
If the participant visited another provider or clinic, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

D5-6. Since the date on the front of this form, have you been hospitalized (stayed over night in the hospital)?

Instruct the participant to answer "no" or "yes" indicating whether or not s/he was admitted to a hospital within this time period.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to D7.

If the response is "yes," the participant should provide:

- The name, address, phone number of the hospital. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if / when it becomes necessary.

Date of admission:
Instruct the participant to provide the date of each admission to the hospital identified above. The date should be recorded as month/day/year. If the participant is unable to provide any portion of the date record '99'. For example, if the participant records 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use '99' as directed.

Reason for this admission:
For each admission date, instruct the participant to record the reason for the visit by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*
- The participant should indicate whether the reason for the visit was due to a "lung problem" or "other" problem. "Lung problems" refer to a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I don't know" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F1 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F1. Efforts to obtain the information should be noted on the form with initials and date.

Record the tests done for this admission by code number:
For each admission date, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The appropriate response should be recorded using the numerical codes provided.
- At least one response code must be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

f. Additional hospitalizations:
If the participant had more than 5 admissions to this hospital, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

g. Additional hospitals:
If the participant was admitted to another hospital, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

D7. Since the date on the front of this form, have you visited an emergency room?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen in an emergency room within this time interval.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to D8.

If the response is "yes," the participant should provide:

- The name, address, phone number of the emergency room facility. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if / when it becomes necessary.

Date of visit:
Instruct the participant to provide the date of each ER visit. The date should be recorded as month/day/year. If the participant is unable to provide any portion of the date, record '99'. For example, if the participant records 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use '99' as directed.

Reason for this visit:
For each ER visit date, instruct the participant to record the reason for the visit by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*
- The participant should indicate whether the reason for the visit was due to a "lung problem" or "other" problem. "Lung problems" refer to a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I don't know" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F1 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F1. Efforts to obtain the information should be noted on the form with initials and date.

Record the tests done for this visit by code number:
For each ER visit date, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The appropriate response should be recorded using the numerical codes provided.
- At least one response code must be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire

f. Additional visits:
If the participant had more than 5 visits to this emergency room, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

g. Additional emergency rooms:
If the participant visited another emergency room, the box indicating this should be checked. This requires the FS be administered (by telephone or in-person interview).

The RA should review the questionnaire for completeness and an attempt should be made to collect any outstanding information and correct all errors or discrepant data. If a data element was not completed and cannot be obtained, document this on the questionnaire adjacent to the appropriate question. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (e.g., follow the rules of Good Clinical Practice).

Part E. Form Completion

If the F1 questionnaire is completed by the participant via mail:

- Unsuccessful attempts to contact participants for further information should be recorded in the chart.
- The participant should have printed her/his name on the line provided, but this is not mandatory. This field does not require completion by the RA. WEB: not submitted to ACRIN.
- The participant should have signed her/his name on the line provided. If the participant returns the form without signing: make a copy of the F1 for the study file, return the original F1 to the participant for her/his signature, document this and the date the F1 was returned for the study file. The study site should contact the participant by telephone to inform her/him that the questionnaire is being returned for her/his signature and returned to the study site using the self -addressed, stamped envelope provided.
- The participant should have recorded the date the questionnaire was completed. The date should be recorded as mm/dd/yyyy. If the participant returns the questionnaire without recording the date or submits a partial date, the RA should record the date on which the F1 was sent to the participant, initial and date (this date will be used as the starting time point for the next F1). WEB: submitted to ACRIN.

If the F1 questionnaire is completed by telephone interview:

- The fields for participant name and signature should be left blank. WEB: not submitted to ACRIN.
- The RA should record the date the form was completed by the participant, date of interview (this date will be used as the starting time point for the next F1). WEB: submitted to ACRIN.
- The FC will capture the method of questionnaire administration as telephone interview.

If the F1 questionnaire is completed by in-person interview:

- Instruct the participant to print her/his name on the line provided. WEB: not submitted to ACRIN.
- Instruct the participant to sign her/his name on the line provided. WEB: not submitted to ACRIN.
- Instruct the participant to record the date the questionnaire is completed (mm/dd/yyyy). WEB: submitted to ACRIN.

If the participant indicates s/he has questions regarding the questionnaire and/or study, follow-up by the site is required.

Signature of person responsible for data: Legible signature of the RA responsible for the interview data or for reviewing the completeness of the participant completed data.

Date of interview/questionnaire completion: Record the date that the interview/questionnaire was completed and/or reviewed by the RA.

Signature of person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

ADDENDUM:

Unreturned F1 Forms: If, after mailing the questionnaire, it has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received. Urge/remind the participant to complete and return the questionnaire and/or offer to obtain a phone interview (either then, at the time of contact, or schedule a future interview). Document contact attempts .

If a participant refuses to complete the F1 Form: Due to the importance of the F1 data, and the lower than desired participant response rates for the full form, it's better we collect some (partial) data than no data. Therefore, if a

participant refuses to complete the F1 Form, attempt to collect an abbreviated follow-up phone interview. Contact the participant stating that you understand s/he does not want to complete the form at this time but to enable the study site to follow her/him properly could s/he please participate in a shortened follow-up interview. If the participant (or proxy) is adamant about not participating in the follow-up questions let her/him know you understand and thank her/him for her/his time. If the participant (or proxy) is willing to participate in an "abbreviated" follow-up, attempt to collect the following information.

- **Part A, Q1-2:** These questions are critical to the trial. At a minimum, try to obtain this information, including the provider/facility so that medical records relating to the cancer can be requested.

- **Part D, Q1-7:** If the participant is willing, try to collect a subset of this information - the provider and whether any visits were lung or chest-related. You may skip the requirement to provide each provider/facility visit date and procedures/testing information. For example:

    - D1. "Since the date on the front of this form, have you visited your primary health care provider (e.g., the practitioner whom you consider your main provider)?" No or Yes

    - If yes, capture provider name and provider contact information.

    - "Were any of your visits for a lung or chest-related condition?" If yes, document by placing a check mark in the box under 'Lung Problem' in the first row. Skip collecting the visit dates and procedures.

All F1 questions not asked/collected as part of the abbreviated F1 interview should remain blank on the F1 Form, indicate this at the time of web entry by using the "web only" response option for the given question (as previously instructed within this document). For thorough documentation, it is suggested that you note, either on either the F1 or FC Form, that an abbreviated interview was performed.

FC

ACRIN NLST 6654
Vital Status Update
Interval Follow-Up Coversheet

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Date of vital status update / follow-up: ____/____/20____ to ____/____/20____ (mm/dd/yyyy)

2. Participant vital status:

- ☐ Alive (go to Q3)
- ☐ Deceased (complete 2a-e, then skip Q3-5)
- ☐ Unknown (go to Q3)

2a. Date of death: ____/____/20____ (mm/dd/yyyy)

2b. Cause of death (if known): _____

_____

2c. Indicate source of information:

- ☐ Participant family member or friend
- ☐ Participant's health care provider
- ☐ Medical document or death certificate
- ☐ Other, specify: _____

2d. Place of death

- ☐ Known (provide address)
- ☐ Unknown

Address: _____

City, State, Zip: _____

County: _____ Phone: (_____)_____

2e. Has a copy of the death certificate been requested?

- ☐ No
- ☐ Yes, date of request: ____/____/20____ (mm/dd/yyyy)

3. Follow-up reporting period:

☐ 6 months	☐ Year 2.5	☐ Year 4.5	☐ Year 6.5
☐ Year 1	☐ Year 3	☐ Year 5	☐ Year 7
☐ Year 1.5	☐ Year 3.5	☐ Year 5.5	☐ Year 7.5
☐ Year 2	☐ Year 4	☐ Year 6	☐ Year 8

4. Source of follow-up contact: (check all that apply)

- ☐ In-person interview with participant
- ☐ Telephone interview with participant
- ☐ Mailing
- ☐ Contact made but participant refused F1 completion (also indicate type of contact from list above)
- ☐ Contact with a representative for the participant: participant is incapacitated; participant is unable to represent him/herself and provide information (F1 not completed)
- ☐ No contact made; date of last direct contact: ____/____/20____ (mm/dd/yyyy)
- ☐ Other, specify: _____

5. Was there any change in the participant contact information since last contact or study follow-up?

- ☐ No
- ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
- ☐ Not Applicable (e.g., interim time point, no contact made)

_____ ____/____/20____ (mm/dd/yyyy)

Signature of person responsible for data — Date of form completion

_____

Signature of person entering data onto web

FC Completion Instructions

The purpose of the FC Form is to report the vital status of the participant (deceased/alive) and to document how the vital status and follow-up information (F1) was obtained. The purpose of the Q1-dates is to document your follow-up efforts, as they correspond to the follow-up time-points. The "F1 interval period" is an entirely different issue and is derived from the time-point and completion date of the previous F1 Form. The FC Form is submitted every 6 months whether the F1 Form was completed or not. The FC Form is completed by the RA and is NOT given to the participant as part of the F1. The shaded/boxed areas of the coversheet are not submitted to ACRIN.

Basically, the first date field is the date follow-up was initiated and the second date is the date the follow-up was completed (whether you successfully administered the F1 or not). Please refer to revised FC instructions.

1. **Date of vital status update/follow-up:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/yyyy.

If submitting the FC to report a participant death (vital status change):

- Record the date of discovery (the date the site became aware of the death) in the first and second date fields.
- Refer to Section XXX for full description of vital status/death reporting.

If the F1 Form is administered by mail:

- Record the date the F1 Form was mailed in the first date field.
- Record the receipt date of the completed F1 Form in the second date field.
- If the F1 Form has not been returned after approximately 3 weeks, the RA should call the participant to ensure that the form was received and completed. The F1 Form may need to be administered by phone.
- If, by the end of the follow-up window, you are unable to obtain a completed F1 Form after multiple attempts (mail/phone), record the date of last attempt in the second date field and submit the FC.

If the F1 Form is administered by phone interview:

- Record the date of the first phone interview and/or attempt in the first date field.
- Record the date of the last phone interview and/or attempt in the second date field.
- If the F1 Form is completed during the first interview attempt record the date of the interview in the first and second date fields.
- If the F1 Form is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

If the F1 Form is administered by in-person interview:

- Record the date of the interview in the first and second date fields.
- If the F1 Form is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

If the F1 Form is administered by more than one method:

- Record the date the follow-up was initiated, whether by mail, phone, or in-person interview.
- Record the date the follow-up was completed, whether by mail, phone, or in-person interview.

NOTE: Regardless of the method of administration, it is expected that you make multiple attempts to contact the participant for completion of the F1 Form, if need be (refer to MOP, Appendix 8-3). At a minimum, obtaining the participant's vital status (dead or alive) at each time point is important, as this relates to the primary endpoint. If at the end of the follow-up window the F1 Form is not completed, submit the FC. For each time point, a FC Form should be completed, whether the F1 is completed or not.

2. **Participant vital status:** Report the vital status of the participant (Alive, Deceased, Unknown) by placing a check mark in the appropriate response box.

If the participant is alive or vital status is unknown, skip to 3.

If the participant is deceased, complete Q2a-e then skip Q3 and complete Q3-5.

a. If the participant is deceased, record the date of death in the space provided. The date must be recorded as month/day/year. If unable to obtain any portion of the date, record '99'. For example, if the contact is unable to provide the day and provides only 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use '99' as directed.

b. If the participant is deceased, record the cause of death on the line provided. WEB: data field is limited to 100 characters.

c. Indicate the source of the information by checking the appropriate response(s).

d. If able to obtain, record the place of death. WEB: not submitted to ACRIN.

e. Indicate whether or not the death certificate has been requested. If requested, document the date of the request.

3. **Follow-up reporting period:** Select the follow-up time point from the list provided. The FC and F1 are completed every 6 months from the date of randomization, with the annual time points corresponding with the annual imaging windows.

4. **Source of follow-up contact:** Select each appropriate response from the list provided indicating all sources of follow-up information. When direct contact with the participant was unsuccessful, some sites have chosen to record the type of contact attempts made (in-person, telephone, or mailing) for their own tracking purposes and 'no contact'. This method is fine as long as the FC documents when no direct contact is made with the participant.

- **In-person interview:** Select this response if all or part of the follow-up data (vital status, F1) was collected during an in-person interview. This response, absent of the 'no contact' response, signifies direct contact with the participant and expectation of F1 Form submission.
- **Telephone interview:** Select this response if all or part of the follow-up data (vital status, F1) was collected during a phone interview. This response, absent of the 'no contact' response, signifies direct contact with the participant and expectation of F1 Form submission.
- **Mailing:** Select this response if all or part of the follow-up data (vital status, F1) was collected via the mail (i.e., return of completed F1). An unreturned F1 Form is not considered a direct contact. Unreturned F1 Forms should be followed up on, as described in the F1 Form instructions. If direct contact attempts with the participant were unsuccessful (mail or phone), the 'no contact' response should be utilized so that the date of last direct contact is known. This response, absent of the 'no contact' response, signifies direct contact with the participant and expectation of F1 Form submission.
- **Contact made by participant refused F1 completion:** Select this response if the participant/proxy refused F1 completion or an abbreviated F1 interview (as described in F1 instructions addendum). Every attempt should be made to meet the participant's needs for F1 completion. This response will trigger suppression of the F1 Form.
- **No contact:** Select this response if no contact was made, despite multiple attempts (mail, phone, certified mail), record the date of last direct contact with the participant. Date must be recorded as mm/dd/yyyy. This response will trigger suppression of the F1 Form.
- **Other:** Select this response only if unable to use the above responses. Document the other source of follow-up contact on the line provided. WEB: data field is limited to 60 characters. Using this field to document non-response or an unreturned F1 will NOT trigger suppression of the F1 Form, you will need to submit a GCM.

5. **Was there any change in the participant contact information since last contact or study follow-up?**

Check "No," if the participant reported no change in her/his contact information.

Check “Yes,” if the participant reported a change in her/his contact information. Both group 1 and group 2 sites should update their local database/records. Group 1 sites are required to fax/mail the annual contact sheet to the Biostatistical Center.

Check “Not applicable,” if the participant did not complete an annual contact worksheet associated with this reporting period (e.g. interim time point, no contact made).

Signature of person responsible for data: Legible signature of the RA responsible for the data recorded and completed of the form.

Date of form completion: Date the FC form was completed by the responsible RA.

Person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

FC Completion Instructions

The FC serves as a participant vital status update and as a coversheet to the F1 Questionnaire. The FC is submitted every 6 months whether the F1 was completed or not. The FC is completed by the RA and is NOT given to the participant as part of the F1. The shaded areas of the coversheet are not submitted to ACRIN.

1. **Date of vital status update/follow-up:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/yyyy.

If submitting the FC to report a participant death (vital status change):

- Record the date of discovery (the date the site became aware of the death) in the first and second date fields.
- Refer to Section XXX for full description of vital status/death reporting.

If the F1 is administered by mail:

- Record the date the F1 was mailed in the first date field.
- Record the receipt date of the completed F1 in the second date field.
- If the F1 has not been returned after approximately 3 weeks, the RA should call the participant to ensure that the form was received and completed. The F1 may need to be administered by phone.
- If the F1 is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

If the F1 is administered by phone interview:

- Record the date of the first phone interview and/or attempt in the first date field.
- Record the date of the last phone interview and/or attempt in the second date field.
- If the F1 is completed during the first interview attempt record the date of the interview in the first and second date fields.
- If the F1 is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

If the F1 is administered by in-person interview:

- Record the date of the interview in the first and second date fields.
- If the F1 is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

2. **Participant vital status:** Report the vital status of the participant (Alive, Deceased, Unknown) by placing a check mark in the appropriate response box.

If the participant is alive or vital status is unknown, skip to 3.

If the participant is deceased, complete Q2a-e then skip Q3-5.

a. If the participant is deceased, record the date of death in the space provided. The date must be recorded as month/day/year. If unable to obtain any portion of the date record 99. For example, if the contact is unable to provide the day and provides only 10/2003, the RA should record the day as 99. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use 99 as directed.

b. If the participant is deceased, record the cause of death on the line provided. WEB: data field is limited to 100 characters.

c. Indicate the source of the information by checking the appropriate response(s).

d. If able to obtain, record the place of death. WEB: not submitted to ACRIN.

e. Indicate whether or not the death certificate has been requested. If requested, document the date of the request.

3. **Follow-up reporting period:** Select the follow-up time point from the list provided. The FC and F1 are completed every 6 months with the annual time points corresponding with the annual imaging windows.

4. **Source of follow-up contact:** Select each appropriate response from the list provided indicating all sources of follow-up information.

- If direct contact (in-person or telephone) was made the RA should document her/his initials on the line provided.
- If contact with the participant was made but the participant refused to complete the F1, check this response on the FC. Every attempt should be made to meet the participant's needs for F1 completion. This response applies ONLY if the participant clearly expresses s/he does not intend to complete the F1 regardless of the collection method (mail, phone, in-person).
- If no contact was made after multiple attempts (mail, phone, certified mail), record the date of last direct contact with the participant. Date must be recorded as mm/dd/yyyy.
- If documenting "other" source of contact, record on the line provided. WEB: data field is limited to 100 characters.

5. **Was there any change in the participant contact information since last contact or study follow-up?**

Check "No," if the participant reported no change in her/his contact information.

Check "Yes," if the participant reported a change in her/his contact information. Both group 1 and group 2 sites should update their local database/records. Group 1 sites are required to fax/mail the annual contact sheet to the Biostatistical Center.

Check "Not applicable," if the participant did not complete an annual contact worksheet associated with this reporting period (e.g. interim time point, no contact made).

Signature of person responsible for data: Legible signature of the RA responsible for the data recorded and completed of the form.

Date of form completion: Date the FC form was completed by the responsible RA.

Person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution ____________________ Institution No. ________________

Participant Initials _____________ Case No. ___________________

These pages are provided as a continuation of the F1 Form, Section C-D. Use F1-3 to record additional visits, for providers or facilities recorded in Section D of the F1 Form. Use G1-3 to record visits to providers or facilities not recorded in Section D of the F1 Form. Use H1-3 to record participation in clinical trials not recorded in Section C of the F1 Form.

Part F. Additional Visits / Hospitalizations

F1. In Section D of the F1 Form you reported you had more than five visits (or hospitalizations) to:

- ☐ The health care provider or clinic reported in **D_____ (D1-4)**
- ☐ The hospital facility reported in **D5-6**
- ☐ The emergency room reported in **D7**

Please list all the date(s) on which you visited this medical provider/facility whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row **Lung Problem**	**Other**	**I Don't Know**	**Please list tests done for this visit by code number (see list below for codes)**
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	Procedure Type
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution ____________________ Institution No. ________________

Participant Initials _____________ Case No. ___________________

F2. In Section D of the F1 Form you reported you had more than five visits (or hospitalizations) to:

- ☐ The health care provider or clinic reported in **D_____ (D1-4)**
- ☐ The hospital facility reported in **D5-6**
- ☐ The emergency room reported in **D7**

Please list all the date(s) on which you visited this medical provider/facility whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row			**Please list tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	Procedure Type
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS	**ACRIN NLST 6654** **Follow-Up Supplement**

Place Label Here

Institution ____________________ Institution No. _______________

Participant Initials _____________ Case No. __________________

F3. In Section D of the F1 Form you reported you had more than five visits (or hospitalizations) to:

- ☐ The health care provider or clinic reported in **D_____ (D1-4)**
- ☐ The hospital facility reported in **D5-6**
- ☐ The emergency room reported in **D7**

Please list all the date(s) on which you visited this medical provider/facility whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row			**Please list tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20_____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	Procedure Type
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This section is a continuation of the F1 Form, Section D. Please use G1-3 to record additional health care providers and/or clinics, hospitals, or ER facilities not recorded on the F1 Form.

Part G. Additional Health Care Providers / Hospitals / Emergency Rooms

G1. In Section D of the F1 Form you reported you had visits (or hospitalizations) to another:

- ☐ Health care provider or clinic not recorded in **D1-4**
- ☐ Hospital not reported in **D5-6**
- ☐ Emergency room not reported in **D7**

Please provide the following information for this care provider or facility:

Health care provider name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

Please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row			**Please list tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
___/___/20____	☐	☐	☐	____, ____, ____, ____, ____
___/___/20____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

G2. In Section D of the F1 Form you reported you had visits (or hospitalizations) to another:

- ☐ Health care provider or clinic not recorded in **D1-4**
- ☐ Hospital not reported in **D5-6**
- ☐ Emergency room not reported in **D7**

Please provide the following information for this care provider or facility:

Health care provider name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

Please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row			**Please list tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test /response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

G3. In Section D of the F1 Form you reported you had visits (or hospitalizations) to another:

- ☐ Health care provider or clinic not recorded in **D1-4**
- ☐ Hospital not reported in **D5-6**
- ☐ Emergency room not reported in **D7**

Please provide the following information for this care provider or facility:

Health care provider name: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____

Please list all the date(s) on which you visited this medical provider/clinic and whether the visit was for a lung or chest-related condition, such as cough, shortness of breath or chest pain, etc. Include routine visit(s) for any known lung conditions you may have. If no tests were performed for the visit please record as code "1," do not leave blank.

Date of visit(s) mm/dd/yyyy	**Please indicate the reason for this visit / admission** Please place only one (1) check per visit row			**Please list tests done for this visit by code number (see list below for codes)**
	Lung Problem	**Other**	**I Don't Know**	
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____
____/____/20____	☐	☐	☐	____, ____, ____, ____, ____

Did you have any of the following tests performed in relation to a visit to this provider / facility? Write the number of each test / response (1-12) on the lines provided in the far right column above for each visit:

Code #	**Procedure Type**
1	I had NO tests performed
2	Chest X-ray
3	Chest CT scan (include cardiac CT, heart scan, or lung CT)
4	Chest MRI (Magnetic Resonance Imaging of the chest or heart)
5	FDG-PET scan of the body
6	Nuclear Medicine scan of the chest or lungs
7	Surgery to chest or lungs
8	Biopsy of chest or lung.
9	Bronchoscopy (tube inserted into the trachea or airways to examine the lungs)
10	Pulmonary Function Test
11	Other test
12	I don't know what tests were performed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This section is a continuation of the F1 Form, Section C. Please use H1-2 to record participation in other clinical trials not recorded on the F1 Form.

Part H. Additional Clinical Trials

H1. In Section C of the F1 Form you reported you had enrolled or participated in another clinical trial. Please provide the following information pertaining to the trial.

a. Name of clinical trial: _____

b. When did you enroll in this trial? _____/_____ (mm/yyyy)

c. As part of the trial, did your care consist of any of the following tests? (Check all that apply)

- ☐ Clinical lab test(s)
- ☐ Medication or supplements administered and/or prescribed
- ☐ Chest CT
- ☐ Chest X-ray
- ☐ Other imaging test, specify _____
- ☐ None of the above, care did not consist of any treatment (i.e., observational study or control arm)
- ☐ Other, specify: _____
- ☐ I don't know

H2. In Section C of the F1 Form you reported you had enrolled or participated in another clinical trial. Please provide the following information pertaining to the trial.

a. Name of clinical trial: _____

d. When did you enroll in this trial? _____/_____ (mm/yyyy)

e. As part of the trial, did your care consist of any of the following tests? (Check all that apply)

- ☐ Clinical lab test(s)
- ☐ Medication or supplements administered and/or prescribed
- ☐ Chest CT
- ☐ Chest X-ray
- ☐ Other imaging test, specify _____
- ☐ None of the above, care did not consist of any treatment (i.e., observational study or control arm)
- ☐ Other, specify: _____
- ☐ I don't know

Thank you for your time! Your cooperation in providing this information is very important to the success of the NLST.

Please use the enclosed self-addressed, stamped envelope to mail your survey back to the NLST clinic. Or, if you are visiting the NLST clinic, simply bring the form with you.

_____

Signature of participant

_____/_____/**20**_____ **(mm/dd/yyyy)**

Date form completed

FS

ACRIN NLST 6654
Follow-Up Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This page should be completed by the study site RA and not given to the participant as part of the FS.

Questionnaire Completion

1. Date of supplemental follow-up: _____/_____ /20_____ to _____/_____ /20_____ (mm/dd/yyyy)

2. Follow-up reporting period:

☐ 6 months	☐ Year 2.5	☐ Year 4.5	☐ Year 6.5
☐ Year 1	☐ Year 3	☐ Year 5	☐ Year 7
☐ Year 1.5	☐ Year 3.5	☐ Year 5.5	☐ Year 7.5
☐ Year 2	☐ Year 4	☐ Year 6	☐ Year 8

3. Source of follow-up contact: (check all that apply)

- ☐ In-person interview with participant
- ☐ Telephone interview with participant
- ☐ Mailing
- ☐ Contact made but participant refused FS completion (also indicate type of contact from list above)
- ☐ Contact with a representative for the participant: participant is incapacitated; participant is unable to represent him/herself and provide information (FS not completed)
- ☐ No contact made; date of last direct contact: _____/_____ /20_____ (mm/dd/yyyy)
- ☐ Other, specify: _____

_____ **Signature of person responsible for data**

_____/_____/**20**_____ **(mm/dd/yyyy) Date form / interview completed**

_____ **Signature of person entering data onto web**

XB

ACRIN NLST 6654
1-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (receipt of form confirmed)
   - ☐ Lost participant , unable to locate participant (phone, address, contacts attempted; begin tracing activities)
   - ☐ Lost to follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XC

ACRIN NLST 6654
1.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (receipt of form confirmed)
   - ☐ Lost participant , unable to locate participant (phone, address, contacts attempted; begin tracing activities)
   - ☐ Lost to follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XD

ACRIN NLST 6654
2-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XE

ACRIN NLST 6654
2.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XF

ACRIN NLST 6654
3-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XG

ACRIN NLST 6654
3.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XH

ACRIN NLST 6654
4-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XI

ACRIN NLST 6654
4.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XJ

ACRIN NLST 6654
5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XK

ACRIN NLST 6654
5.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant , unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XL

ACRIN NLST 6654
6-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant, unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XM

ACRIN NLST 6654
6.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify:

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant, unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XN

ACRIN NLST 6654
7-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant, unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XO

ACRIN NLST 6654
7.5-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant, unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

XP

ACRIN NLST 6654
8-Year Follow-up Coversheet
Vital Status Update

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Participant vital status: (check only one)
   - ☐ Alive (go to Q 2)
   - ☐ Deceased (complete Q 1a – b)
   - ☐ Unknown (go to Q 2)

   1a. Date of death: ____ - ____ - 20____ (mm-dd-yyyy)

   1b. Indicate source of information: (check all that apply)
   - ☐ Participant family member or friend
   - ☐ Participant's health care provider
   - ☐ Medical document or death certificate
   - ☐ Mailing returned as deceased
   - ☐ Other, specify: _____

2. Was the Follow-up Form for this reporting period completed? (check only one)
   - ☐ No (complete Q 2b)
   - ☐ Yes (complete Q 2a)

   2a. Method(s) the Follow-up Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)
   - ☐ Proxy Follow-up time interval collected: (previous F1/F2 to current F2)

   2b. Reason the Follow-up Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ Lost participant, unable to contact / locate participant (tracing activities should be initiated)
   - ☐ Lost to Follow-up, unable to establish contact for a consecutive 18-month period (3 follow-up time points)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

3. Was there any change in the participant contact information since last contact or study follow-up? (check only one)
   - ☐ No
   - ☐ Yes (group 1 sites, fax/mail updated contact sheet to BC)
   - ☐ Unknown

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for Follow-up data — Date form completed

_____

Person entering data on web

F2 Coversheet Completion Instructions

Participant follow-up is to occur every 6 months based on the date of randomization, as indicated by the participant case calendar. The purpose of the Follow-up Coversheet is to report the vital status of the participant (deceased/alive) and to document how the vital status and follow-up information (F2) was obtained. The Coversheets are now time-point-specific; XB represents the 1year follow-up, XC represents the 1.5year follow-up, XD represents the 2year follow-up and so on down to the XP, which represents the 8year follow-up. The Coversheet is completed by the RA and is NOT given to the participant as part of the F2.

1. Participant vital status: Report the vital status of the participant (Alive, Deceased, Unknown) by placing a check mark in the appropriate response box.

- Mark **Alive**: If the participant is known to be alive by any means (self-report, family member or other proxy, health care provider, or NLST staff). **Note: Participant status cannot be recorded as "Alive" if the participant is later described as "Lost" on this form (see below, 2b, and example).**
- Mark **Deceased**: If the participant is known to be deceased by any means.
- Mark **Unknown**: If participant vital status cannot be determined.

1a. Date of Death: If the participant is deceased, record the date of death in the space provided. The date must be recorded as MM/DD/YYYY. If unable to obtain any portion of the date, record '99'. For example, if the contact is unable to provide the day and provides only 10/2003, the RA should record the day as '99'. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use '99' as directed.

1b. Indicate source of information: (check all that apply) Check the appropriate box or boxes to indicate how you obtained the death information. If the reason cannot be found use the "other, specify" option. WEB: data field is limited to 100 characters.

- **Participant family member or friend**: Select this if information regarding the participant's vital status is obtained directly from the participant or through a reliable proxy. The reliability of sources is a site decision.
- **Participant's health care provider or other health care source**: Select this if a provider or NLST staff are aware of the vital status, in the absence of direct contact with the participant. This may occur if the participant is observed outside the setting of the NLST.
- **Medical document or Death Certificate:** Medical documentation or a death certificate serves to document participant death. In the case of the former, the site should initiate efforts to secure the death certificate of the decedent within 6-9 months of the reported date of death.
- **Mailing returned as "Deceased":** The site should initiate efforts to secure the death certificate of the decedent within 6-9 months of the reported date of death.
- **Other, specify:** Record any other mechanism through which the site is aware of the vital status of the participant.

2. Was the Follow-up Form for this reporting period completed?

- If **NO**, complete the follow-up time interval and Q2b to indicate the reason the F2 Form was not completed.
- If **YES**, complete the follow-up time interval and Q2a to indicate the method of completion of the F2 Form.

Follow-up time interval collected: Record the current follow-up interval (previous F1/F2 to current F2).

- **Start date: Date participant completed the last F1/F2 Form.** If the participant did not complete the previous F2 Form, use the completion date from the most recent F2 Form completed. If the participant never completed an F2 Form, then the randomization date should be used.
- **End date: Date the participant completed the current F2 Form.** If the F2 Form was not completed/ returned, then this date should be the date that the vital status was confirmed or able to be determined.

Both date fields are required data elements. The date fields must be completed as MM/DD/YYYY.

2a. Method(s) the Follow-up Form was completed: Select each appropriate response from the list provided indicating all sources of follow-up information.

- **In-person interview:** Select this response if all or part of the follow-up data (vital status, F2) was collected during an in-person interview. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Telephone interview:** Select this response if all or part of the follow-up data (vital status, F2) was collected during a phone interview. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Mailing:** Select this response if all or part of the follow-up data (vital status, F2) was collected via the mail (i.e., return of completed F2). An unreturned F2 Form is not considered a direct contact. Unreturned F2 Forms should be followed up on, as described in the F2 Form instructions. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Proxy:** Select this response if the participant is incapacitated or unavailable and the information was obtained from another person or representative of the participant.

2b. Reason the Follow-up Form was not completed. If the F2 Form is not completed please check the appropriate box indicating the reason. *Check only one selection.*

- **Participant deceased:** Choose this option if the participant is deceased as indicated in question 1.
- **No response, multiple contact attempts made but participant has not replied:** Record this option should a participant fail to return a completed F2 Form after repeated mailings and attempted telephone contacts. All attempts (and dates) to contact the participant should be documented in the participant chart. A time frame of 3 months is generally considered ample time to contact a participant. If a participant has not been contacted by that time, submit the F2 coversheet for that time point using this response. Continued attempts should be made to contact the participant. This option is appropriate if the participant vital status is "Alive" or "Unknown".
- **Participant or Proxy refused completion of the Follow-Up Form:** If the participant responds to contact but refuses to complete the follow-up Form please select this option.
- **Participant or Proxy failed to return Follow-Up Form:** If receipt of the F2 Form is confirmed, by registered mail, phone or other method, and the participant fails to return the form please select this option.
- **Lost participant, unable to locate participant (phone, address, contacts attempted: begin tracing activities):** Choose this selection if you are unable to contact the participant after exhausting all methods available. NOTE: This option *cannot* be recorded if participant vital status is listed as "Alive". Similarly, although a participant may refuse to complete F2 Forms, they are not "Lost". Choose this option only if the participant is lost (site cannot locate the participant, and therefore cannot determine vital status).
- **Lost to follow-up, unable to establish contact for a consecutive 18 month period (3 follow-up time points):** Participants will be considered lost to follow-up if no contact of any kind can be established for a period of 18 consecutive months. NOTE: This option *cannot* be recorded if participant vital status is listed as "Alive". Choose this option *only* if the participant is lost to follow-up with vital status unknown for a *consecutive 18 month period*. This will prompt a suppression of the F2 Coversheet collection from every 6 months to yearly completion. As such, efforts to locate the participant should continue on at least an annual basis. If a participant is successfully relocated, then enter the appropriate X Form data and F2 data into the database (Data Management may need to be contacted to add these forms on the calendar).
- **No attempt made to administer Follow-Up Form:** Choose this option if your site inadvertently forgot to administer a Follow-Up Form or if the participant is an NP level 3 (annual X Forms still required for vital status).
- **Physical illness / cognitive impairment:** Choose this option if the participant is too ill to complete the form.
- **Other, specify:** _____ Choose this option if a reason other than one that appears in the list is the cause for not completing the form.

Example 1: A participant may not complete the F2 Form and may not respond to repeated telephone calls; however, the NLST staff knows their vital status is "alive" based on the fact that the participant has been seen in the institution, newspaper, etc. The participant is *not* lost. The option "No response, multiple contacts made but participant has not replied" would be appropriate. The start date should correspond to the end date of the last F1/F2 form or coversheet. The end date should be the actual date that the NLST staff member saw the participant in the institution. Ultimately: If you know their vital status, they are not lost!

Example 2: When the previous interval ends without an F2 Form being completed, the start date of the next interval will still be the last date an F2 Form was completed. If the participant completed a F2 Form for year 3 and has not completed one since, then the start date for all subsequent intervals is the date the year 3 F2 Form was completed. If the participant has never completed an F2, then the start date should be the randomization date (WEB: Enter 7/1/03 as the start date for any randomization before this date). The purpose is to limit any gaps in intervals for recording care.

NOTE: Regardless of the method of administration, it is expected that you make multiple attempts to contact the participant for completion of the F2 Form (refer to MOP, Appendix 8-3). At a minimum, obtaining the participant's vital status (dead or alive) at each time point is important, as this relates to the primary endpoint. If at the end of the follow-up window the F2 Form is not completed, then submit the appropriate Coversheet. For each time point, a Coversheet should be completed, whether the F2 is completed or not.

3. Was there any change in the participant contact information since last contact or study follow-up?

- Check **NO** if the participant reported no change in her/his contact information.
- Check **YES** if the participant reported a change in her/his contact information. Both Group 1 and Group 2 sites should update their local database/records. Group 1 sites are required to fax/mail the annual contact sheet to the Biostatistical Center.
- Check **Not Applicable** if the participant did not complete an annual contact worksheet associated with this reporting period (e.g. interim time point, no contact made).

Signature of person responsible for data: Legible signature of the RA responsible for the follow-up data recorded on the form.

Date of form completion: Date the Coversheet was completed by the RA responsible for the follow-up data.

Person entering data onto web: Legible signature of staff member web entering the data from this form. Signature should be done at web entry.

F2

ACRIN NLST 6654
Interval Follow-Up Form

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Participant Instructions for completing the form:

As part of this study of lung cancer screening, it is important for us to understand various aspects of your health care and the doctor or clinic visits, ER visits, and hospitalizations you have had. Please answer all of the questions as best you can. All information you give us should be for the time period from:

to TODAY

It should take about 10-15 minutes to complete the form. Please answer all questions, even if you feel that they may not be important to this trial. All of your answers will be kept strictly confidential.

When you answer the questions in Part A, Health Care Visits, it is not necessary to include visits to dentists, eye specialists, podiatrists (foot doctors), chiropractors, acupuncture specialists, or mental health specialists (such as psychiatrists, psychologists, counselors).

All other types of health care providers should be included, even if you do not believe they are important for purposes of this trial. If you have any questions regarding the form, please do not hesitate to contact our NLST site below:

SITE-SPECIFIC CONTACT INFO

Please remember the following:

- Complete this form using **blue or black ink,** indicate your answers by placing an **X** or checkmark **(√)** in the box next to your answer. Please answer every question on all pages of the form.
- Sign and date the last page of this form after you have completed all parts of the form.
- Return the form and the Annual Contact Information Sheet (if provided) by mail to the NLST clinic using the enclosed self-addressed, stamped envelope. If you are visiting the NLST clinic, you can also bring the forms with you.
- We may need to contact you to clarify some of the information you provided on this form.

Thank-you for your participation in the NLST!

NLST Staff Only: Follow-up Time Period

☐ 6 mo	☐ 2.5Y	☐ 4.5Y	☐ 6.5Y
☐ 1Y	☐ 3Y	☐ 5Y	☐ 7Y
☐ 1.5Y	☐ 3.5Y	☐ 5.5Y	☐ 7.5Y
☐ 2Y	☐ 4Y	☐ 6Y	☐ 8Y

F2

ACRIN NLST 6654
Interval Follow-Up Form

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part A. Health Care Visits

A1. Since the date on the front of this form, have you visited your PRIMARY PROVIDER (the person whom you consider to be your main provider)? Include visits only to your primary provider here; you do NOT need to describe visits to the types of providers listed in the box on the front of this form.

☐ No ⟶ **(SKIP TO QUESTION A2, PAGE 3)**

☐ Yes

Health care provider name (first and last): _____

Type of provider: ☐ Generalist / Family Doctor ☐ Specialist, specify: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX:(____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

A2. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front of this form.

☐ No → **(SKIP TO QUESTION A5, PAGE 6)**
☐ Yes

Health care provider name (first and last): _____
Type of provider: _____
Address: _____
City, State, Zip: _____
Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

A3. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front this form.

☐ No ⟶ **(SKIP TO QUESTION A5, PAGE 6)**
☐ Yes

Health care provider name (first and last): _____
Type of provider: _____
Address: _____
City, State, Zip: _____
Phone: (____) FAX: (____)

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

A4. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front of this form.

☐ No → **(SKIP TO QUESTION A5, PAGE 6)**
☐ Yes

Health care provider name (first and last): _____
Type of provider: _____
Address: _____
City, State, Zip: _____
Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Did you visit any other doctor or health care provider? ☐ No ☐ Yes

A5. Since the date on the front of this form, have you been seen in an EMERGENCY ROOM (ER) for medical care?

☐ No → **(SKIP TO QUESTION A7, PAGE 8)**
☐ Yes

Name of Facility: _____

Address: _____

City, State, Zip: _____

Phone: (____)_____ FAX: (____)_____

a. Did you receive any of the following at this ER?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did you have any of the following procedures at this ER?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

A6. Since the date on the front of this form, have you been seen in another EMERGENCY ROOM (ER) for medical care?

☐ No ⟶ **(SKIP TO QUESTION A7, PAGE 8)**
☐ Yes

Name of Facility: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this ER?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did you have any of the following procedures at this ER?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Were you seen at any other ER? ☐ No ☐ Yes

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

A7. Since the date on the front of this form, have you been HOSPITALIZED (stayed overnight in the hospital)?

☐ No → **(SKIP TO PART B, PAGE 10)**
☐ Yes

Hospital name: _____

Address: _____

City, State, Zip: _____

Phone: (____) FAX: (____)

a. Did you receive any of the following at this hospital?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

A8. Since the date on the front of this form, have you been HOSPITALIZED (stayed overnight) at another facility?

☐ No → **(SKIP TO PART B, PAGE 10)**
☐ Yes

Hospital name: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this hospital?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below. . _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures (SEE APPENDIX FOR DESCRIPTIONS, PAGES 13-15)	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Were you hospitalized at another facility? ☐ No ☐ Yes

Part B. Cigarette Smoking Habits

We would like to know about any changes in your **cigarette smoking** over the past **six (6) months**. Please answer the following questions to the best of your ability.

B1. In the past six (6) months, have you smoked any cigarettes?

- ☐ No → (SKIP TO B8)
- ☐ Yes

B2. Do you NOW smoke cigarettes (one or more cigarettes per week)?

- ☐ No → (SKIP TO B4)
- ☐ Yes

B3. How many cigarettes do you usually smoke per day, on average?

- ☐ Fewer than 1 per day
- ☐ _____ Cigarettes per day (enter a whole number)

B4. Did you visit your primary care provider in the last six (6) months?

- ☐ No → (SKIP TO B5)
- ☐ Yes → (COMPLETE a – g)

If yes, did your primary care provider do any of the following?

a. Ask you about cigarette smoking?
- ☐ No
- ☐ Yes

b. Advise you to stop smoking cigarettes?
- ☐ No
- ☐ Yes

c. Ask you about your interest in quitting smoking cigarettes?
- ☐ No
- ☐ Yes

d. Talk with you about how to quit smoking cigarettes?
- ☐ No
- ☐ Yes

e. Recommend using nicotine replacement therapy (patch, gum, inhaler, spray, or lozenges) and/or Zyban® (Wellbutrin® or Bupropion) to help you quit smoking cigarettes?
- ☐ No
- ☐ Yes

f. Recommend counseling (classes, quit line) to help you quit smoking cigarettes?
- ☐ No
- ☐ Yes

g. Suggest a follow-up visit or phone call about quitting smoking cigarettes?
- ☐ No
- ☐ Yes

B5. In the past six (6) months, have you done any of the following?

h. Used nicotine patch, gum, inhaler or nasal spray?
- ☐ No
- ☐ Yes

i. Used Zyban® (Wellbutrin® or Bupropion)?
- ☐ No
- ☐ Yes

j. Participated in a cigarette smoking cessation program such as a quit smoking group or individual or group counseling?
- ☐ No
- ☐ Yes

k. Participated in a cigarette smoking cessation program because you were referred by this study?
- ☐ No
- ☐ Yes

l. Talked by telephone with a smoking counselor?
- ☐ No
- ☐ Yes

B6. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 24 hours?

- ☐ I did not intentionally try to quit smoking
- ☐ I intentionally quit smoking _____ times for at least 24 hours (enter a whole number)

B7. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 7 days?

- ☐ I did not intentionally try to quit smoking
- ☐ I intentionally quit smoking _____ times for at least 7 days (enter a whole number)

B8. Next are statements that cigarette smokers have said about quitting. Please put a check in the box next to the one statement that best represents what you think right now. (select only one)

- ☐ I enjoy smoking so much I will never consider quitting no matter what happens
- ☐ I never think about quitting but I might someday
- ☐ I rarely think about quitting and have no specific plans to quit
- ☐ I sometimes think about quitting but have no specific plans to quit
- ☐ I often think about quitting but have no specific plans to quit
- ☐ I plan to quit in the next 6 months
- ☐ I plan to quit in the next 30 days
- ☐ I have already begun to cut down and I have set a quit date
- ☐ I have already quit but I worry about slipping back or relapsing
- ☐ I have quit and I am 100% confident that I will never smoke again

Part C. Other Clinical Trials (research studies)

C1. Since the date on the front of this form, have you enrolled or participated in any other research study?

- ☐ No → (SKIP TO PART D, BELOW)
- ☐ Yes
  - **a.** Name of research study: _____
  - **b.** When did you enroll: _____ - **20**_____ (mm-yyyy)
  - **c.** Since the date on the front of this form, did you have any of the following tests or examinations as part of this research study? (Check all that apply)
    - ☐ Cholesterol test
    - ☐ Blood pressure check
    - ☐ Chest CT or whole body scan (not with NLST)
    - ☐ Chest X-ray (not with NLST)
    - ☐ Other imaging test, specify below: _____
    - ☐ Other test, specify below: _____
  - **d. Since the date on the front of this form, did you enroll in any other study other than the one listed above?**
    - ☐ No
    - ☐ Yes

Part D. Conclusion

D1. Current insurance status: (CHECK ONLY ONE)

- ☐ Other
- ☐ Private Insurance (includes employer provider)
- ☐ Medicare
- ☐ Medicare and Private Insurance
- ☐ Medicaid
- ☐ Medicare and Medicaid
- ☐ Military or Veterans Administration
- ☐ Self Pay
- ☐ No Means of Payment
- ☐ I don't know / I prefer not to answer

D2. Who completed this form?

- ☐ Participant
- ☐ Participant with assistance from other person (complete D2a, below)
- ☐ Proxy (family member or friend), participant unable to provide information
  - **a.** Specify the person who assisted you (check all that apply)
    - ☐ ACRIN-NLST Staff member
    - ☐ Family member
    - ☐ Other, specify: _____

Please provide your signature and write the date that you completed this form.

_____ **Your Signature** (participant or proxy)

_____ - _____ - **20**____ (mm-dd-yyyy) **Date you completed this form**

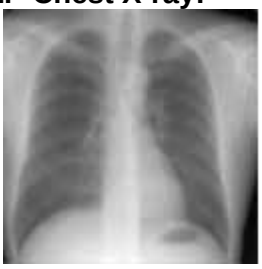
Thank you for your time and effort in completing this form. Your cooperation is very important to the success of NLST.

Appendix: Introduction

This document is a supplement to the F2 Form and provides descriptions of the procedures listed in the tables throughout the F2. If you read the information below and have additional questions as to whether or not you received one of these procedures, please contact your Research Associate.

Description of Procedures

1. Chest X-ray:



Chest x-ray is the most commonly performed diagnostic x-ray exam and is usually done to evaluate the lungs, heart, and chest wall. Pneumonia, heart failure, emphysema, lung cancer, and other medical conditions can be diagnosed or suspected on a chest x-ray. The test is performed in a hospital radiology department or in a health care provider's office by an x-ray technician. The patient stands in front of the machine and must hold her/his breath when the x-ray is taken.

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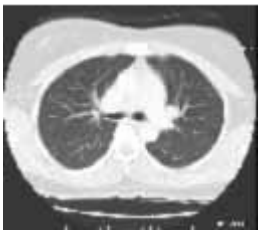
2. Chest CT scan (i.e. CAT scan, cardiac or heart CT, or lung CT):



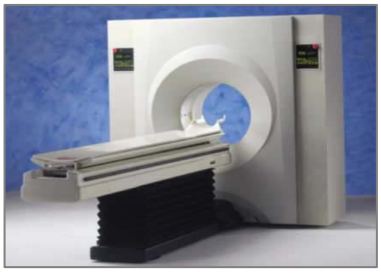
Computed tomography (CT scan) of the chest uses special equipment to obtain multiple cross-sectional images of the organs and tissues of the chest. The CT scanner is a large unit with a hole running directly through the center, giving the appearance of a doughnut. The patient lies on a table that slides through the center of the hole to obtain pictures of the internal body. The CT unit is not loud but does make a whirling sound as the x-ray tube rotates in a circle around the inside of the hole.

---

3. Chest MRI (Magnetic Resonance Imaging of the chest or heart):

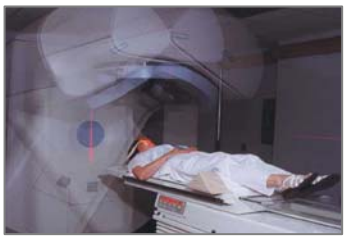
A chest MRI uses powerful magnets and radio waves to construct pictures of the internal body. Because of the strong magnets, certain metallic objects such as jewelry, watches, and credit cards are not allowed into the room. The patient is asked to lie on a narrow table that slides into a large tunnel-like tube within the scanner. The machine produces loud thumping and humming noises during operation. Because of this, earplugs are usually given to the patient to reduce the noise.

4. FDG – PET Scan of the Body (PET scan):



An FDG-PET scan is used most often to detect cancer and to examine the effects of cancer therapy. A radioactive contrast substance is injected into the patient and its emissions are measured by the PET scanner. The PET scanner has a hole in the middle and looks like a large doughnut. While lying on a cushioned exam table, the patient is moved into the hole of the machine. PET measures the amount of metabolic activity at a site in the body and, because cancer cells have higher metabolic rates than normal cells, these areas show up as denser areas on a PET scan.

5. Nuclear Medicine Scan of chest, lungs or heart:



The scanner can look like a large round metallic unit suspended from a tall, moveable post or a sleek one-piece metal arm that hangs over the examination table. The camera can also be within a large, doughnut-shaped structure similar in appearance to a CT scanner. A radioactive liquid is injected into the patient. The liquid collects in the part of the body to be imaged. Instruments detect the substance in the body and process the information into an image.

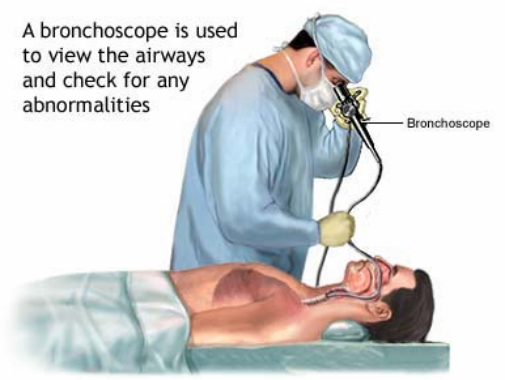
6. Surgery to the chest or lungs:

Surgery is performed on the chest or lungs to: (1) confirm the diagnosis of lung cancer; (2) remove a lung cancer; or (3) remove scar tissue or fix an air leak in the lung. Surgery to remove all or part of a lung involves opening one side of the chest (thorax) during a procedure called a thoracotomy. After the chest is opened, surgery to remove all or part of the lung is done depending on the location, size, and type of lung tumor that is present. Additional procedures, such as lymph node biopsies, may be done at the same time. Lung surgery requires you to stay in the hospital after the procedure.

7. Biopsy of chest or lung:

When lung disease or lung cancer is suspected, a lung biopsy can be used to remove a small sample of lung tissue that can then be examined under a microscope. The biopsy may be done on an outpatient basis or may require a hospital stay if the method of sampling the lung tissue requires that the chest wall be opened.

8. Bronchoscopy:



Bronchoscopy is a diagnostic procedure in which a tube with a tiny camera on the end is inserted through the nose or mouth into the lungs. The procedure provides a view of the airways of the lung and allows doctors to collect lung secretions or tissue specimens. The test may require an overnight stay in the hospital. Fasting is required for 6-12 hours before the test.

9. Lung cancer chemotherapy:

Lung cancer chemotherapy is one of the most common treatments for cancer and involves the use of medicines (or drugs) to treat disease. This type of treatment is sometimes called just “chemo.” Although surgery and radiation therapy destroy or damage cancer cells in a specific area, chemotherapy works throughout the body. Chemotherapy drugs can destroy cancer cells that have metastasized or spread to parts of the body far from the original tumor in the lungs.

10. Lung cancer radiation therapy:

Lung cancer radiation therapy uses high doses of radiation to destroy cancer cells in the lungs. Radiation damages the genetic material of cells in the area being treated, leaving the cells unable to continue to grow. Although radiation damages normal cells as well as cancer cells, the normal cells can repair themselves and function, while the cancer cells cannot. Radiation therapy is often used in combination with chemotherapy as treatment for cancer.

F2 Completion Instructions

The F2 Follow-Up Questionnaire is a participant completed form designed to collect interim health status and medical interventions. The F2 is to be completed every six months for all participants for the duration of the trial. The F2 may be completed by the participant during a visit to the site (T1 and T2), as a telephone interview, or administered via mail. The provider information in the boxed areas of this form (Sections A1-A8) is not web-entered on the ACRIN web site.

If the F2 is administered by mail:

- Prior to mailing, each page of the F2 Form must be labeled with the participant identifiers (at minimum, the case number and participant initials). If the participant identifiers do not appear, there may be no reliable way to identify who completed the form.
- Include a self-addressed, stamped envelope for the return of the form.
- Provide the NLST site contact information in the space provided on page 1.
- If the questionnaire has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received and completed.
- Once received, the RA should review the questionnaire for completeness and an attempt should be made to collect any outstanding information and correct all errors or discrepant data (by telephone or in-person), particularly for the critical data elements. If a blank data element cannot be completed (data not obtained) it should remain blank. Document this on the F2 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. **If discrepancies in data cannot be resolved they should remain as recorded by the participant and not changed.** All original responses, edits, corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).
- Unsuccessful attempts to contact participants for further information should be recorded in the chart.

If the questionnaire is administered by in-person or telephone interview:

- The RA should review the questionnaire for completeness, an attempt should be made to collect any outstanding information and correct all errors or discrepant data before the interview is concluded, particularly for the critical data elements. If a data element cannot be completed (data not obtained) it should remain blank. Document this on the F2 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).

If the F2 questionnaire is completed by in-person interview:

- Instruct the participant to sign her/his name on the line provided. WEB: not submitted to ACRIN.
- Instruct the participant to record the date the questionnaire is completed (mm/dd/yyyy). WEB: submitted to ACRIN.

If the participant indicates s/he has questions regarding the questionnaire and/or study, follow-up by the site is required.

Page one: Interval Follow-Up Form

Participant Label: Affix a Case Specific Label to each page in the box provided at the top right corner of the form. These labels are supplied by ACRIN once a participant has been randomized and contain all the participant identifiers (case number, participant initials, and institution name/number). To receive additional labels, submit a Request for Case Specific Labels to ACRIN HQ; this form can be printed from the ACRIN web site. In lieu of a Case Specific Label, record the Institution, Institution Number, Participant Initials, and Case Number in the box provided at the top right corner of the form.

F2 data collection interval: _____/_____/20_____ to Today
Prior to mailing or administering this form, the time interval for participant F2 Form completion must be indicated on page 1. The interval extends from the date that the participant last completed (i.e. dated) an F1/F2 Form **(Part D,**

Date you completed this form) to the present. If this is the first F2 Follow-up, the interval extends from the date of randomization. For example, if the participant recorded 4/28/04 in Part D of their last F1/F2 Form, the interval for the current follow-up period extends from 4/28/04 until the present.

NLST Site Contact Information: Provide appropriate site contact information in the space provided on page 1.

NLST Staff Only: Follow-up Time Period: Site Staff should check the appropriate box to indicate the time point for the form. F2 time point should match the F2 Coversheet time point. Coversheet time points are indicated in the coversheet header from XB (one year coversheet) to XP (8 year coversheet).

Part A. Health Care Visits

This section documents the participant's health care visits since the date on the front of this form. All information should be provided to the best of the participant's recollection. A medical diary can be provided to participants in advance to record visits rather than relying on recall for completion of the F2 form.

A1. Since the date on the front of this form, have you visited your PRIMARY PROVIDER (the person whom you consider to be your main provider)? Include visits only to your primary provider here; you do NOT need to describe visits to the types of providers listed in the box on the front of this form. This page documents a visit to the participant's primary health care provider only. Other provider visits are collected on the following pages. Visits to dentists, optometrists, ophthalmologists, and podiatrists, etc. need not be included. Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by her/his primary care provider during this time period.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to A2.

If the response is "yes," the participant should provide:

- The name, address, phone number of the primary health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following from this provider?
For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data..*
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did this provider send you for any of the following procedures?
For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

A2. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front of this form. Outpatient visits to dentists, optometrists, ophthalmologists, and podiatrists need not be included. Questions A2-4 should be used to document visits to other health care providers. Each question A2-4 should be used to document a specific provider. A typical example would be if a participant saw 3 other providers (Pulmonologist, Cardiologist, and Neurologist), the Pulmonologist information would be recorded in A2, Cardiologist in A3, and the Neurologist in A4.

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by a health care provider other than primary care provider.

***This is a critical data element**, attempts should be made to collect this data.*

If response is "no," skip to A5.

If the response is "yes," the participant should provide:

- The name, address, phone number of the health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following from this provider?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data..*
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did this provider send you for any of the following procedures?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

A3. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front of this form. Outpatient visits to dentists, optometrists, ophthalmologists, and podiatrists need not be included. Questions A2-4 should be used to document visits to other health care providers. Each question A2-4 should be used to document a specific provider. A typical example would be if a participant saw 3 other providers (Pulmonologist, Cardiologist, and Neurologist), the Pulmonologist information would be recorded in A2, Cardiologist in A3, and the Neurologist in A4.

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by a health care provider other than primary care provider.

***This is a critical data element**, attempts should be made to collect this data.*

If response is "no," skip to A5.

If the response is "yes," the participant should provide:

- The name, address, phone number of the health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following from this provider?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element****, attempts should be made to collect this data.*.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did this provider send you for any of the following procedures?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

A4. Since the date on the front of this form, have you visited ANOTHER HEALTH CARE PROVIDER? You do NOT need to describe visits to the types of providers listed in the box on the front of this form. Outpatient visits to dentists, optometrists, ophthalmologists, and podiatrists need not be included. Questions A2-4 should be used to document visits to other health care providers. Each question A2-4 should be used to document a specific provider. A typical example would be if a participant saw 3 other providers (Pulmonologist, Cardiologist, and Neurologist), the Pulmonologist information would be recorded in A2, Cardiologist in A3, and the Neurologist in A4.

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by a health care provider other than primary care provider.

This is a critical data element*, attempts should be made to collect this data.*

If response is "no," skip to A5.

If the response is "yes," the participant should provide:

- The name, address, phone number of the health care provider. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following from this provider?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element****, attempts should be made to collect this data.*.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did this provider send you for any of the following procedures?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

Did you visit ANOTHER DOCTOR / HEALTH CARE PROVIDER?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by another doctor/health care provider within this time interval. If "no" continue to data enter the F2 form. If "yes" an FP form will be generated to the calendar to allow recording of additional visits.

A5. Since the date on the front of this form, have you been seen in an EMERGENCY ROOM (ER) for medical care?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen in an emergency room within this time interval.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to A7.

If the response is "yes," the participant should provide:

- The name, address, phone number of the emergency room facility. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following at this ER?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did you have any of the following procedures at this ER?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

A6. Since the date on the front of this form, have you been seen in another EMERGENCY ROOM (ER) for medical care?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen in another emergency room within this time interval.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to A7.

If the response is "yes," the participant should provide:

- The name, address, phone number of the emergency room facility. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following at this ER?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element**, attempts should be made to collect this data.*.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did you have any of the following procedures at this ER?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit, and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

c. Were you seen at another ER?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen in another Emergency Room within this time interval. If "no" continue to data enter the F2 form. If "yes" an FE form will be generated to the calendar to allow recording of additional visits.

A7. Since the date on the front of this form, have you been HOSPITALIZED (STAYED OVERNIGHT AT A HOSPITAL)?

Instruct the participant to answer "no" or "yes" indicating whether or not s/he was admitted to a hospital within this time period.

***This is a critical data element**, attempts should be made to collect this data.*

If the response is "no," skip to Part B.

If the response is "yes," the participant should provide:

- The name, address, phone number of the hospital. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following at this hospital?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element****, attempts should be made to collect this data.*.
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did you have any of the following procedures while hospitalized?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

A8. Since the date on the front of this form, have you been HOSPITALIZED (stayed overnight) AT ANOTHER FACILITY?

Instruct the participant to answer "no" or "yes" indicating whether or not s/he was admitted to a hospital within this time period.

This is a critical data element*, attempts should be made to collect this data.*

If the response is "no," skip to Part B.

If the response is "yes," the participant should provide:

- The name, address, phone number of the hospital. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval, if/when it becomes necessary.

a. Did you receive any of the following at this hospital?

For this visit, instruct the participant to answer each question in the table by placing a check mark at the appropriate response.

- ***This is a critical data element****, attempts should be made to collect this data.*
- If the *participant* does not know/remember the reason for the visit, the response should be recorded by checking the "I'm not sure" response.
- If the participant leaves this data element blank, the RA should make an attempt to obtain the information (e.g. by telephone, letter). If able to obtain the data, record the participant's response on the F2 form, initial and date. If the data element cannot be obtained despite best efforts, check the "Unknown" web response; this response is not included on the F2. Efforts to obtain the information should be noted on the form with initials and date.

b. Did you have any of the following procedures while hospitalized?

For this visit, instruct the participant to indicate whether any procedures were performed as part of this visit and if so, the types of procedures completed.

- The 'yes' or 'no' response should be recorded in the box provided.
- At least one response code should be recorded in the data spaces provided. If no procedures were completed record as code "1," do not leave the data field blank.
- If the participant did not provide a procedure type and the data is not obtained, the data field should remain blank. WEB: record '99' ("Unknown") indicating a blank data field; this response is not included on the questionnaire.

c. Were you hospitalized at ANOTHER FACILITY?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was hospitalized in another facility within this time interval. If "no" continue to data enter the F2 form. If "yes" an FH form will be generated to the calendar to allow recording of additional visits.

Part B. Smoking Habits

These questions are concerned with overall changes in participant smoking habits. All questions should be answered appropriately following the skip patterns. This section is intended to collect smoking information pertaining *only* to the preceding 6 months despite missed data time points. An attempt should be made to collect responses to each question. WEB: If unable to collect responses for questions the participant left blank, document the blank data fields by selecting the "Blank/Unknown" web response.

B1. In the past six 6 months, have you smoked any cigarettes?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he has smoked any cigarettes in the last 6 months.

- If the response is "no," skip to B8 (B2-7 should be blank).
- If the response is "yes," continue to B2.
- If no response is provided, select "unknown" at web entry.

B2. Do you NOW smoke cigarettes (one or more cigarettes per week)?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he is smoking at least one cigarette a week.

- If the response is "no," skip to B4 (B3 should be blank).
- If the response is "yes," continue to B3.
- If no response is provided, select "unknown" at web entry.

B3. How many cigarettes do you usually smoke per day, on average?

Instruct the participant to provide, to the best of her/his ability, a numeric response (whole number) based on their daily average of cigarettes. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4).

- If the response is less than 1 cigarette a day, mark this response on the CRF.
- If the response is greater than 1, record the numeric response on the line provided.
- If no response is provided, enter '999' for unknown/blank at web entry.

B4. Did you visit your primary care physician this past year?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he was seen by her/his primary care provider (physician, nurse practitioner, etc.) this past year.

- If the response is "no," skip to B5 (B4a-g) should be blank.
- If the response is "yes," B4a-g should be completed. For B4a-g, instruct the participant to mark/answer "no" or "yes" to each of these questions.
- If no response is provided, select "unknown" at web entry.

B5. In the past six (6) months, have you done any of the following? (B5h-l)
Instruct the participant to answer "no" or "yes" to each of these questions. If no response is provided for qB5 select "unknown" at web entry.

B6. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 24 hours?
Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter '99' for unknown at web entry.

B7. In the past six (6) months, how many times have you INTENTIONALLY quit smoking (not even a puff) for at least 7 days?
Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter '99' for unknown at web entry.

B8. Next are statements that smokers have said about quitting. Please put a check in the box next to the one statement that best represents what you think right now. (choose only one statement)
Instruct the participant to mark the statement that most appropriately reflects her/his current attitude toward smoking. If no response is provided for qB5 select "unknown" at web entry.

Part C. Other Clinical Trials

This section documents any contamination or confounding variables that result from participants receiving care from clinical trials other than NLST. As an eligibility criterion, the participant may not already be enrolled in another cancer prevention or screening trial. However, once enrolled, we cannot hinder a participant from enrolling in another trial. Therefore, this section serves to document the care provided within other trials. This information is intended for collection every 6 months, but should be collected for the time interval since the last interview (as specified on page 1).

C1. Since the date on the front of this form, have you enrolled or participated in any other research study?
Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he has enrolled in a research trial other than NLST within the last 6 months or since the last follow-up.

- If the response is "no," skip to Part D (C1a-c should be blank).
- If the response is "yes," C1a-c should be completed.
- If no response is provided, select "unknown" at web entry.

a. Name of research study:
Instruct the participant to provide the name of the research study. If unknown, attempt to determine the nature of the study, the site, the investigators, a phone number, or similar information that will enable the determination of the study name (such as web search). WEB: data element is limited to 100 characters.

b. When did you enroll in this study?
Instruct the participant to provide the date of enrollment in the research study. The participant should provide the date as month and year. If the participant is unable to provide any portion of the date, record 99 in the blank space and initial/date (e.g. participant response is 2005, RA should record 99 for month on paper and web form = 99/2005).

c. Since the date on the front of this form, did you have any of the following tests or examinations as part of this research study?

Instruct the participant to select, from the **list** provided, **all tests** provided as part of the other clinical trial. Choose all that apply. There is space to record other tests/exams performed that are not listed on the data form. WEB: Other data fields are limited to 100 characters.

d. Since the date on the front of this form, did you enroll in another research study?

If the participant enrolled in another clinical trial, the box indicating this should be checked.

Part D. Conclusion

D1. Current Insurance Status: (check only one)

The participant should indicate the type of insurance or payment method they use for Medical Care. Only one option should be selected. If no response is provided for qD1 select "unknown" at web entry.

D2. Who completed this form?

The F2 was designed to be a participant completed form. Some study participants may require assistance with completion of the form. If the participant is unable to provide information the F2 form may also be completed by proxy. Please check the appropriate box to indicate who completed the form.

a. Specify the person who assisted you (check all that apply)

Participants may ask for assistance when completing the F2. Please select from the list provided or specify the person assisting the participant with the form. Please check all that apply.

Your signature (participant or proxy)
The participant should sign her/his name on the line provided, but this is not mandatory. This field does not require completion by the RA. WEB: not submitted to ACRIN.

Date you completed this form: Record the date that the interview/questionnaire was completed and/or reviewed by the RA.

ADDENDUM:

Unreturned F2 Forms: If, after mailing the questionnaire, it has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received. Urge/remind the participant to complete and return the questionnaire and/or offer to obtain a phone interview (either then, at the time of contact, or schedule a future interview). Document contact attempts.

If a participant refuses to complete the F2 Form: Due to the importance of the F2 data, and the lower than desired participant response rates for the full form, it is better we collect some (partial) data than no data. Therefore, if a participant refuses to complete the F2 Form, attempt to collect information via an abbreviated follow-up phone interview. Contact the participant stating that you understand s/he does not want to complete the form at this time but to enable the study site to follow her/him properly could s/he please participate in a shortened follow-up interview. If the participant (or proxy) is adamant about not participating in the follow-up questions tell her/him you understand and thank her/him for her/his time. If the participant (or proxy) is willing to participate in an "abbreviated" follow-up, attempt to collect the following information.

Part A2, A5, A7. This information is critical to the trial. At a minimum, try to obtain the provider/hospital/emergency room name and provider/hospital/emergency room contact information so that medical records relating to the cancer can be requested. All F2 questions not asked/collected as part of the abbreviated F2 interview should remain blank on the F2 Form. Indicate this at the time of web entry by using the "web only" response option for the given question (as

previously instructed within this document). For thorough documentation, it is suggested that you note, either on either the F2 or Coversheet, that an abbreviated interview was performed.

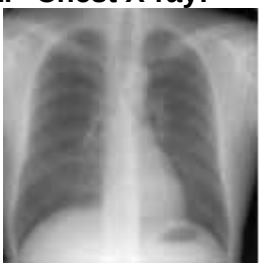
APPENDIX 1: Description of Radiologic Procedures. Appendix 1 has been provided as a reference for participants. If they are unsure of the type of test they had at a certain facility the appendix will be available as part of each form.

Appendix: Introduction

This document is a supplement to the F2 Form and provides descriptions of the procedures listed in the tables throughout the F2. If you read the information below and have additional questions as to whether or not you received one of these procedures, please contact your Research Associate.

Description of Procedures

1. Chest X-ray:



Chest x-ray is the most commonly performed diagnostic x-ray exam and is usually done to evaluate the lungs, heart, and chest wall. Pneumonia, heart failure, emphysema, lung cancer, and other medical conditions can be diagnosed or suspected on a chest x-ray. The test is performed in a hospital radiology department or in a health care provider's office by an x-ray technician. The patient stands in front of the machine and must hold her/his breath when the x-ray is taken.

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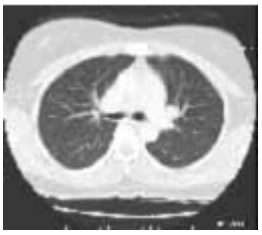
2. Chest CT scan (i.e. CAT Scan, Cardiac or Heart CT, or Lung CT):



Computed tomography (CT scan) of the chest uses special equipment to obtain multiple cross-sectional images of the organs and tissues of the chest. The CT scanner is a large unit with a hole running directly through the center, giving the appearance of a doughnut. The patient lies on a table that slides through the center of the hole to obtain pictures of the internal body. The CT unit is not loud but does make a whirling sound as the x-ray tube rotates in a circle around the inside of the hole.

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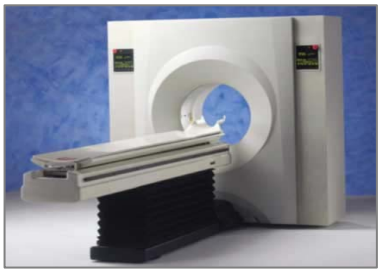
3. Chest MRI (Magnetic Resonance Imaging of the chest or heart):

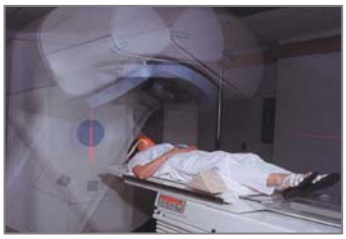
A chest MRI uses powerful magnets and radio waves to construct pictures of the internal body. Because of the strong magnets, certain metallic objects such as jewelry, watches, and credit cards are not allowed into the room. The patient is asked to lie on a narrow table that slides into a large tunnel-like tube within the scanner. The machine produces loud thumping and humming noises during operation. Because of this, earplugs are usually given to the patient to reduce the noise.

4. FDG – PET Scan of the Body (PET scan):



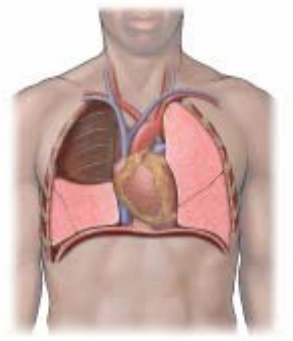
An FDG-PET scan is used most often to detect cancer and to examine the effects of cancer therapy. A radioactive contrast substance is injected into the patient and its emissions are measured by the PET scanner. The PET scanner has a hole in the middle and looks like a large doughnut. While lying on a cushioned exam table, the patient is moved into the hole of the machine. PET measures the amount of metabolic activity at a site in the body and, because cancer cells have higher metabolic rates than normal cells, these areas show up as denser areas on a PET scan.

5. Nuclear Medicine Scan of chest, lungs or heart:



The scanner can look like a large round metallic unit suspended from a tall, moveable post or a sleek one-piece metal arm that hangs over the examination table. The camera can also be within a large, doughnut-shaped structure similar in appearance to a CT scanner. A radioactive liquid is injected into the patient. The liquid collects in the part of the body to be imaged. Instruments detect the substance in the body and process the information into an image.

6. Surgery to the chest or lungs:

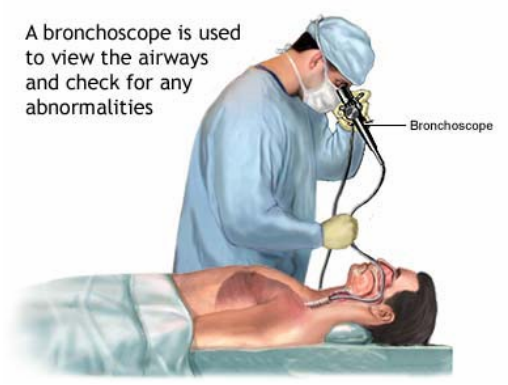


Surgery is performed on the chest or lungs to: (1) confirm the diagnosis of lung cancer; (2) remove a lung cancer; or (3) remove scar tissue or fix an air leak in the lung. Surgery to remove all or part of a lung involves opening one side of the chest (thorax) during a procedure called a thoracotomy. After the chest is opened, surgery to remove all or part of the lung is done depending on the location, size, and type of lung tumor that is present. Additional procedures, such as lymph node biopsies, may be done at the same time. Lung surgery requires you to stay in the hospital after the procedure.

7. Biopsy of chest or lung:

When lung disease or lung cancer is suspected, a lung biopsy can be used to remove a small sample of lung tissue that can then be examined under a microscope. The biopsy may be done on an outpatient basis or may require a hospital stay if the method of sampling the lung tissue requires that the chest wall be opened.

8. Bronchoscopy:



Bronchoscopy is a diagnostic procedure in which a tube with a tiny camera on the end is inserted through the nose or mouth into the lungs. The procedure provides a view of the airways of the lung and allows doctors to collect lung secretions or tissue specimens. The test may require an overnight stay in the hospital. Fasting is required for 6-12 hours before the test.

9. Lung cancer chemotherapy:

Lung cancer chemotherapy is one of the most common treatments for cancer and involves the use of medicines (or drugs) to treat disease. This type of treatment is sometimes called just “chemo.” Although surgery and radiation therapy destroy or damage cancer cells in a specific area, chemotherapy works throughout the body. Chemotherapy drugs can destroy cancer cells that have metastasized or spread to parts of the body far from the original tumor in the lungs.

10. Lung cancer radiation therapy:

Lung cancer radiation therapy uses high doses of radiation to destroy cancer cells in the lungs. Radiation damages the genetic material of cells in the area being treated, leaving the cells unable to continue to grow. Although radiation damages normal cells as well as cancer cells, the normal cells can repair themselves and function, while the cancer cells cannot. Radiation therapy is often used in combination with chemotherapy as treatment for cancer.

F3 ACRIN NLST 6654
Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Dear Participant:

Your continued support of the NLST is **greatly** appreciated.

To simplify your ongoing participation, we have significantly shortened your bi-annual follow-up form. The health care provider questions on this form relate *only* to the diagnosis and/or treatment of lung cancers and the diagnosis of other cancers. Please answer all of the questions to the best of your knowledge. The information you give us should be for the time period from:

_____ [1] to **TODAY**

SITE-SPECIFIC CONTACT INFO

Please note the following when completing this form:

- The form should only take about 5-10 minutes to complete.
- Please complete the form with blue or black ink.
- Sign, date and return in the stamped, addressed envelope (enclosed).
- Call us if you have questions about the form, we would love to hear from you.

Thank-you for your participation in the NLST!

NLST Staff Only: Follow-up Time Period [2]

☐ 6 mo	☐ 2.5 Y	☐ 4.5 Y	☐ 6.5 Y
☐ 1 Y	☐ 3 Y	☐ 5 Y	☐ 7 Y
☐ 1.5 Y	☐ 3.5 Y	☐ 5.5 Y	☐ 7.5 Y
☐ 2 Y	☐ 4 Y	☐ 6 Y	☐ 8 Y

F3 ACRIN NLST 6654
Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Initials _____ Case No. _____

Part A: Lung Cancer Diagnosis and Treatment

1. Since the date on the front of this form, have you received a diagnosis or treatment of lung cancer by any health care provider? [3]

- ☐ 1 No (If no, skip to Part B)
- ☐ 2 Yes (If yes, please complete the rest of the page)
- ☐ 3 I'm not sure (Skip question 2, but do list any providers seen during this time period in the boxes below)

2. Please record the date of lung cancer diagnosis _____ [4] - _____ [5] - **20**_____ [6] *(mm-dd-yyyy)*

Please provide the names and contact information for providers/hospitals that were associated with the **diagnosis and/or treatment of lung cancer.**

I.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [7] ☐ **Treatment** [8] ☐ **Not sure** [9]	

II.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [10] ☐ **Treatment** [11] ☐ **Not sure** [12]	

III.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [13] ☐ **Treatment** [14] ☐ **Not sure** [15]	

3. Were any other providers/hospitals involved in your diagnosis and/or treatment of lung cancer? [16]

- ☐ 1 No
- ☐ 2 Yes

F3 ACRIN NLST 6654
Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Part B: Other Cancer Diagnosis

1. **Since the date on the front of this form, have you been diagnosed with any other type of cancer by a health care provider?** [17]

   Do not list diagnoses of squamous cell skin cancer or basal cell skin cancers. (If you are unsure of the type of skin cancer, please include it here.)

   ☐ 1 No (If no, skip to Part C)
   ☐ 2 Yes (If yes, please complete the rest of the page)
   ☐ 3 I'm not sure (Skip questions 2 and 3, but do list any providers seen during this time period in the boxes below)

2. **Please record the date of diagnosis of this other type of cancer** _____ [18] - _____ [19] - **20**_____ [20] *(mm-dd-yyyy)*

3. **Please specify the site or type of this other cancer:** _____ [21]

Please provide the name and contact information for the providers/hospitals that were associated with the **diagnosis** of the cancer you recorded above. *You do not need to provide the names of providers or clinics where you may have been **treated** for this cancer.*

I.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

II.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

III.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

4. **Were any other providers/hospitals involved in your diagnosis of the cancer recorded above?** [22]

   ☐ 1 No
   ☐ 2 Yes

F3 ACRIN NLST 6654 Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Initials _____ Case No. _____

Part C: Cigarette Smoking Questions

1. Do you now smoke cigarettes (one or more cigarettes per week) [23]

- ☐ 1 No (If no, skip to Part D)
- ☐ 2 Yes

2. How many cigarettes do you usually smoke per day, on average? [24]

- ☐ 1 Fewer than 1 per day
- ☐ 2 _____ [25] Cigarettes per day (enter a whole number)

3. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 24 hours? [26]

- ☐ 1 I did not intentionally try to quit smoking
- ☐ 2 I intentionally quit smoking _____ [27] times for at least 24 hours (enter a whole number)

Part D: Conclusion

1. What is your present insurance status: (check only one) [28]

- ☐ 0 Other
- ☐ 1 Private Insurance
- ☐ 2 Medicare
- ☐ 3 Medicare and Private Insurance
- ☐ 4 Medicaid
- ☐ 5 Medicare and Medicaid
- ☐ 6 Military or Veterans Administration
- ☐ 7 Self Pay
- ☐ 8 No Means of Payment
- ☐ 9 Unknown/Decline to answer

2. Who completed this form [29]

- ☐ 1 Participant
- ☐ 2 Participant with assistance from other person (complete D2a below)
- ☐ 3 Family member or friend (participant unable to provide the information)

2a. Specify the person who assisted you (check all that apply)

- ☐ ACRIN-NLST Staff member [30]
- ☐ Family member [31]
- ☐ Other, [32] specify _____ [33]
- ☐ Unknown [34]

Please provide your signature and write the date that you completed this form.

_____ Your Signature (participant or proxy)

_____ - _____ - **20**_____ *(mm-dd-yyyy)* [35]
Date you completed this form

Thank-you for your time and effort in providing this information.
Your cooperation is very important to the success of the NLST!

F3 ACRIN NLST 6654
Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Dear Participant:

Your continued support of the NLST is **greatly** appreciated.

To simplify your ongoing participation, we have significantly shortened your bi-annual follow-up form. The health care provider questions on this form relate *only* to the diagnosis and/or treatment of lung cancers and the diagnosis of other cancers. Please answer all of the questions to the best of your knowledge. The information you give us should be for the time period from:

_____ [1] to **TODAY**

SITE-SPECIFIC CONTACT INFO

_____

_____

_____

_____

_____

Please note the following when completing this form:

- The form should only take about 5-10 minutes to complete.
- Please complete the form with blue or black ink.
- Sign, date and return in the stamped, addressed envelope (enclosed).
- Call us if you have questions about the form, we would love to hear from you.

Thank-you for your participation in the NLST!

NLST Staff Only: Follow-up Time Period [2]

☐ 6 mo	☐ 2.5 Y	☐ 4.5 Y	☐ 6.5 Y
☐ 1 Y	☐ 3 Y	☐ 5 Y	☐ 7 Y
☐ 1.5 Y	☐ 3.5 Y	☐ 5.5 Y	☐ 7.5 Y
☐ 2 Y	☐ 4 Y	☐ 6 Y	☐ 8 Y

F3 ACRIN NLST 6654
Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Initials _____ Case No. _____

Part A: Lung Cancer Diagnosis and Treatment

1. Since the date on the front of this form, have you received a diagnosis or treatment of lung cancer by any health care provider? [3]

- ☐ 1 No (If no, skip to Part B)
- ☐ 2 Yes (If yes, please complete the rest of the page)
- ☐ 3 I'm not sure (Skip question 2, but do list any providers seen during this time period in the boxes below)

2. Please record the date of lung cancer diagnosis _____ [4] - _____ [5] - **20**_____ [6] *(mm-dd-yyyy)*

Please provide the names and contact information for providers/hospitals that were associated with the **diagnosis and/or treatment of lung cancer.**

I.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [7] ☐ **Treatment** [8] ☐ **Not sure** [9]	

II.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [10] ☐ **Treatment** [11] ☐ **Not sure** [12]	

III.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )
Type of care received: (check all that apply)	☐ **Diagnosis** [13] ☐ **Treatment** [14] ☐ **Not sure** [15]	

3. Were any other providers/hospitals involved in your diagnosis and/or treatment of lung cancer? [16]

- ☐ 1 No
- ☐ 2 Yes

F3 ACRIN NLST 6654 Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Initials _____ Case No. _____

Part B: Other Cancer Diagnosis

1. **Since the date on the front of this form, have you been diagnosed with any other type of cancer by a health care provider?** [17]

   Do not list diagnoses of squamous cell skin cancer or basal cell skin cancers. (If you are unsure of the type of skin cancer, please include it here.)

   ☐ 1 No (If no, skip to Part C)
   ☐ 2 Yes (If yes, please complete the rest of the page)
   ☐ 3 I'm not sure (Skip questions 2 and 3, but do list any providers seen during this time period in the boxes below)

2. **Please record the date of diagnosis of this other type of cancer** _____ [18] - _____ [19] - **20**_____ [20] *(mm-dd-yyyy)*

3. **Please specify the site or type of this other cancer:** _____ [21]

Please provide the name and contact information for the providers/hospitals that were associated with the **diagnosis** of the cancer you recorded above. *You do not need to provide the names of providers or clinics where you may have been **treated** for this cancer.*

I.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

II.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

III.

Name of provider:		Provider Type:
Address:		
City, State, Zip:		
Telephone:	( )	Fax: ( )

4. **Were any other providers/hospitals involved in your diagnosis of the cancer recorded above?** [22]

   ☐ 1 No
   ☐ 2 Yes

F3 ACRIN NLST 6654 Interval Follow-up Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Initials _____ Case No. _____

Part C: Cigarette Smoking Questions

1. Do you now smoke cigarettes (one or more cigarettes per week) [23]

- ☐ 1 No (If no, skip to Part D)
- ☐ 2 Yes

2. How many cigarettes do you usually smoke per day, on average? [24]

- ☐ 1 Fewer than 1 per day
- ☐ 2 _____ [25] Cigarettes per day (enter a whole number)

3. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 24 hours? [26]

- ☐ 1 I did not intentionally try to quit smoking
- ☐ 2 I intentionally quit smoking _____ [27] times for at least 24 hours (enter a whole number)

Part D: Conclusion

1. What is your present insurance status: (check only one) [28]

- ☐ 0 Other
- ☐ 1 Private Insurance
- ☐ 2 Medicare
- ☐ 3 Medicare and Private Insurance
- ☐ 4 Medicaid
- ☐ 5 Medicare and Medicaid
- ☐ 6 Military or Veterans Administration
- ☐ 7 Self Pay
- ☐ 8 No Means of Payment
- ☐ 9 Unknown/Decline to answer

2. Who completed this form [29]

- ☐ 1 Participant
- ☐ 2 Participant with assistance from other person (complete D2a below)
- ☐ 3 Family member or friend (participant unable to provide the information)

2a. Specify the person who assisted you (check all that apply)

- ☐ ACRIN-NLST Staff member [30]
- ☐ Family member [31]
- ☐ Other, [32] specify _____ [33]
- ☐ Unknown [34]

Please provide your signature and write the date that you completed this form.

_____ ____ - ____ - **20**____ *(mm-dd-yyyy)* [35]

Your Signature (participant or proxy) Date you completed this form

Thank-you for your time and effort in providing this information.
Your cooperation is very important to the success of the NLST!

F3 Completion Instructions

The F3 Follow-Up Questionnaire is a participant-completed form designed to collect information about the diagnosis and/or treatment of lung cancer and the diagnosis of other cancers. The F3 is to be completed every six months for all participants for the remainder of the trial. The F3 may be completed by the participant during a visit to the site, as a telephone interview, or administered via mail. NOTE: The F3 has replaced the F2 and F1 as the participant completed follow-up form.

If the F3 questionnaire is administered by mail:

- Prior to mailing, each page of the F3 Form must be labeled with the participant identifiers (at minimum, the case number and participant initials). If the participant identifiers do not appear, there may be no reliable way to identify who completed the form.
- Include a self-addressed, stamped envelope for the return of the form.
- Provide the NLST site contact information in the space provided on page 1.
- If the questionnaire has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received and completed.
- Once received, the RA should review the questionnaire for completeness and an attempt should be made to collect any outstanding information and correct all errors or discrepant data (by telephone or in-person), particularly for the critical data elements. **If a blank data element cannot be completed (data not obtained) it should remain blank.** Document this on the F3 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. **If discrepancies in data cannot be resolved they should remain as recorded by the participant and not changed.** All original responses, edits, corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).
- Unsuccessful attempts to contact participants for further information should be recorded in the chart.

If the F3 questionnaire is administered by in-person or telephone interview:

- The RA should review the questionnaire for completeness. An attempt should be made to collect any outstanding information and correct all errors or discrepant data before the interview is concluded, particularly for the critical data elements. **If a data element cannot be completed (data not obtained) it should remain blank.** Document this on the F3 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the "Unknown" response indicating that the data was not obtained. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).

If the F3 questionnaire is completed by in-person interview:

- Instruct the participant to sign her/his name on the line provided. WEB: not submitted to ACRIN.
- Instruct the participant to record the date the questionnaire is completed (mm/dd/yyyy). WEB: submitted to ACRIN.

If the participant indicates s/he has questions regarding the questionnaire and/or study, follow-up by the site is required.

Interval Follow-Up Form

Participant Label: Affix a Case Specific Label to each page in the box provided at the top right corner of the form. These labels are supplied by ACRIN once a participant has been randomized and contain all the participant identifiers (case number, participant initials, and institution name/number). To receive additional labels, submit a Request for Case Specific Labels to ACRIN HQ. You can also print case labels yourself by going to the ACRIN Web site in the Data Login Center. Type in your user name and password, select your institution and select extra labels. In lieu of a Case Specific Label, record the Institution, Institution Number, Participant Initials, and Case Number in the box provided at the top right corner of the form.

F3 data collection interval: _____/_____/_____ to TODAY

Prior to mailing or administering this form, the time interval for participant F3 form completion must be indicated on page 1. The interval extends from the date that the participant last completed (i.e. dated) an F1/F2/F3 Form **(Part D, Date you completed this form)** to the present. If this is the first follow-up form, the interval extends from the date of randomization. For example: if the participant recorded 4/28/04 as the form completion date of their last F1/F2/F3 Form, the interval for the current follow-up period extends from 4/28/04 until the present.

NLST Site-Specific Contact Info: Provide appropriate site contact information in the space provided on page 1.

NLST Staff Only: Follow-up Time Period: Site Staff should check the appropriate box to indicate the time point for the form. The F3 time point should match the F2/F3 Coversheet time point.

Part A: Lung Cancer Diagnosis and Treatment:

This section documents diagnosis or treatment of lung cancer since the date on the front of this form. All information should be provided to the best of the participant's recollection. A medical diary can be provided to participants in advance to record visits rather than relying on recall for completion of the F3 form.

Q1. Since the date on the front of this form, have you received a diagnosis or treatment of lung cancer by any health provider?

Document any diagnosis or treatment of lung cancer not previously reported. ***This is a critical data element; attempts should be made to collect this data.***

If the response is "no", skip to Part B, Question 1.

If the response is "not sure", skip Question 2, but do list any providers seen during this time period in boxes I-III below.

- If 'not sure' is checked and no other providers are listed, the RA should contact the participant to review this element. Please verify that the participant is not sure about the diagnosis of cancer & collect ANY providers seen during the interval to verify with those providers if a diagnosis of cancer was made.

If the response is "yes," the participant should provide:

- **Q2:** The date of diagnosis of lung cancer (mm/dd/yyyy). Use 99 if month, day, or year is unknown.
- **Boxes I- III:** The name, address, phone number of any health care provider/hospital that was associated with the diagnosis and/or treatment of lung cancer. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval. Please specify the type of care received (check all that apply).
- **Q3:** If additional providers/hospitals were involved in the participant's diagnosis and/or treatment please check yes. Follow up with the participant to record the names for medical records retrieval.

Part B: Other Cancer Diagnosis:

This section documents diagnosis of any other cancer, besides lung cancer, since the date on the front of this form. All information should be provided to the best of the participant's recollection. *Do not record diagnoses of squamous cell skin cancer or basal cell skin cancers.*

Q1. Since the date on the front of this form, have you been diagnosed with any other type of cancer by a health care provider?

Document any diagnosis of any other type of cancer not previously reported. ***This is a critical data element; attempts should be made to collect this data.***

If the response is "no", skip to Part C, Question 1.

If the response is "not sure", skip Questions 2 and 3, but do list any providers seen during this time period in boxes I-III below.

- If 'not sure' is checked and no other providers are listed, the RA should contact the participant to review this element. Please verify that the participant is not sure about the diagnosis of cancer & collect ANY providers seen during the interval to verify with those providers if a diagnosis of cancer was made.

If the response is "yes," the participant should provide:

- **Q2:** The date of diagnosis of other cancer (mm/dd/yyyy). Use 99 if month, day, or year is unknown.
- **Q3:** The site or type of other cancer.
- **Boxes I-III:** The name, address, phone number of any health care provider/hospital that was associated with the diagnosis of other cancer. Do not provide the names of providers or clinics where treatment for this other cancer occurred. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval.
- **B4:** If additional providers/hospitals were involved in the participant's diagnosis please check yes. Follow up with the participant to record the names for medical records retrieval.

Part C. Cigarette Smoking Questions

These questions are concerned with overall changes in participant cigarette smoking habits. This section is intended to collect smoking information pertaining *only* to the preceding 6 months despite missed data time points. An attempt should be made to collect responses to each question. WEB ENTRY: If unable to collect responses for questions the participant left blank, document the blank data fields by selecting the "Blank/Unknown" response during web entry.

C1. Do you now smoke cigarettes (one or more cigarettes per week)?

Instruct the participant to answer "no" or "yes" to this question, indicating whether or not s/he is smoking at least one cigarette a week.

- If the response is "no," skip to Part D.
- If the response is "yes," continue to Part C, Question 2.
- If no response is provided, select "unknown" at web entry.

C2. How many cigarettes do you usually smoke per day, on average?

Instruct the participant to provide, to the best of her/his ability, a numeric response (whole number) based on their daily average of cigarettes. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4).

- If the response is less than 1 cigarette a day, mark this response on the CRF.
- If the response is greater than 1, record the numeric response on the line provided.
- If no response is provided, enter '99' at web entry.

C3. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 24 hours?

Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter '99' at web entry.

Part D. Conclusion

D1. Present Insurance Status: (check only one)

The participant should indicate the type of insurance or payment method they use for Medical Care. Only one option should be selected. If no response is provided, please select "unknown" at web entry.

D2. Who completed this form?

The F3 was designed to be a participant completed form. Some study participants may require assistance with completion of the form. If the participant is unable to provide information the F3 form may also be completed by a family member or friend.

a. Specify the person who assisted you (check all that apply)

Participants may ask for assistance when completing the F3. Please select from the list provided or specify the person assisting the participant with the form. Please check all that apply.

Your signature (participant or proxy)
The participant should sign her/his name on the line provided, but this is not mandatory. This field does not require completion by the RA and is not submitted to ACRIN.

Date you completed this form: Record the date that the interview/questionnaire was completed and/or reviewed by the RA.

ADDENDUM:

Unreturned F3 Forms: If, after mailing the questionnaire, it has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received. Urge/remind the participant to complete and return the questionnaire and offer to obtain a phone interview (either then, at the time of contact, or schedule a future interview). Document contact attempts.

If a participant refuses to complete the F3 Form: Due to the importance of the F3 data, and the lower than desired participant response rates for the full form, it is better we collect some (partial) data than no data. Therefore, if a participant refuses to complete the F3 Form, attempt to collect information via an abbreviated follow-up phone interview. Contact the participant stating that you understand s/he does not want to complete the form at this time but to enable the study site to follow her/him properly could s/he please participate in a shortened follow-up interview. If the participant is adamant about not participating in the follow-up questions tell her/him you understand and thank her/him for her/his time. If the participant is willing to participate in an "abbreviated" follow-up, attempt to collect the following information.

Part A and Part B: This information is critical to the trial. At a minimum, try to obtain the provider name and contact information so that medical records relating to the cancer can be requested. All F3 questions not asked/collected as part of the abbreviated F3 interview should remain blank on the F3 Form. Indicate this at the time of web entry by using the 'unknown' response option for the given question. For thorough documentation, it is suggested that you note, on either the F3 or the Coversheet, that an abbreviated interview was performed.

F4 ACRIN NLST 6654 Follow-up Procedure Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Name _____ Patient's I.D. No. _____

1. Between January 1st 2009 and December 31st 2009 did you have any of the following procedures performed?

	No	Yes	Unk	If yes, was it for lung cancer screening?
Chest X-ray [1]	☐	☐	☐	☐ [2]
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT) [3]	☐	☐	☐	☐ [4]
Chest MRI (magnetic resonance imaging of chest or heart) [5]	☐	☐	☐	☐ [6]
FDG-PET scan of the body [7]	☐	☐	☐	☐ [8]
Nuclear medicine scan of chest, lungs, or heart [9]	☐	☐	☐	☐ [10]
Surgery to chest or lungs [11]	☐	☐	☐	
Biopsy of chest or lung [12]	☐	☐	☐	
Bronchoscopy (tube inserted in airways to study lungs) [13]	☐	☐	☐	
Lung cancer chemotherapy [14]	☐	☐	☐	
Lung cancer radiation therapy [15]	☐	☐	☐	
Other lung test or lung cancer therapy, specify other test below [16] _____ [17]	☐	☐	☐	

2. Who completed this form [18]

- ☐ 1 Participant
- ☐ 2 Participant with assistance from other person *(complete 2a below)*
- ☐ 3 Family member or friend *(participant unable to provide the information)*

2a. Specify the person who assisted you *(check all that apply)*

- ☐ ACRIN-NLST Staff member [19]
- ☐ Family member [20]
- ☐ Other, [21] specify _____ [23]
- ☐ Unknown [22]

Please provide your signature and write the date that you completed this form.

_____ Signature of person completing the form (participant or site RA)

_____ - _____ - **20**_____ *(mm-dd-yyyy)* [24] Date you completed this form

This is the annotated version of this form

F4 Completion Instructions

The F4 Form is a subset of questions from the F2 Form. This form will be administered to a 2.5% subset of the NLST participants for purposes of determining contamination, e.g., the proportions of participants in each arm that have undergone the screening test originally assigned to the other screening arm. Each site will be given the case numbers of specific participants to whom the F4 Form should be administered.

Form Administration:

The form should be administered by telephone. If it is *not possible* to collect the information by telephone, it is acceptable to send this form by mail.

The form should be administered beginning in January 2010.

It is not necessary to document the provider who requested the examination/procedure. The assessment of contamination will be based on participant-provided information and will not require that the source document associated with the procedure by obtained.

Question 1: Between January 1, 2009 and December 31, 2009 did you have any of the following procedures performed?

Instruct the participant to indicate whether each of the procedures was performed during the time interval.

- The 'yes' or 'no' response should be recorded in the box provided.
- The 'unknown' is provided should the participant be uncertain as to whether the specific procedure was performed during the time interval.
- Mark the appropriate box if any of the first five tests were performed for screening; defined as a test performed to detect the presence of lung cancer in an individual without signs or symptoms.

Question 2: Who completed this form?

Some study participants may require assistance with completion of the form. Please check the appropriate box to indicate who provided the information.

WEB ONLY: If the questionnaire was unable to be administered, please select 'form not administered', complete the 'date form completed' field, and submit the form.

a.) Specify the person who assisted you (check all that apply).

If the F4 form is completed by telephone, record 'ACRIN-NLST Staff'. If additional assistance was provided by another, select from the list provided or record 'other' and specify who assisted with the form. Please check all that apply.

Signature of person completing the form

The participant should sign her/his name on the line provided if completed by mail. The site RA should sign her/his name on the line provided if completed over the telephone.

Date you completed this form: Record the date that the interview/questionnaire was completed and/or reviewed by the RA.

F4 Sample Phone Script

The F4 Form is a subset of questions from the F2 Form. This form should be administered by telephone. Please see below for a sample phone script.

Example:

"Hello, my name is _____ and I'm calling on behalf of (Local ACRIN NLST Center). Thank you for your participation in the NLST. We would like to receive some additional information about your recent health care. We are interested in the time from January 1, 2009 to December 31, 2009.

The questionnaire is very brief and will take about five minutes to complete. It contains a series of questions to determine the extent to which participants receive screening examinations outside of the NLST *(administer questionnaire).*

Please be assured that all information you provide will be kept strictly confidential. Your name or other indentifying information will not appear on any study report and all results will be reported as statistical summaries only.

Do not hesitate to call the study office at (Telephone number) if you have any questions or concerns about this questionnaire or any aspect of the National Lung Screening Trial. Your participation represents a valuable contribution to medical research, and we thank you again for your cooperation."

FE

ACRIN NLST 6654
Additional ERs - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This form serves as a continuation of the F2 Form. If a participant reports a visit to another ER (F2-bottom of page 7), use this form to document each additional ER facility. If more than 5 ERs in total, an additional FE Form will need to be completed (contact data management to calendar an additional FE Form). It is suggested that this form be administered by telephone or in-person interview. Page 1 of this form serves as the coversheet and should not be given to the participant. If completed by the RA there will be no participant signature on page 4. If completed by participant, whether by mail or in-person, the participant should sign and date the form on page 4. Refer to F2 Form Instructions for general form instructions.

1. F2 Follow-up Interval: ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)

2. Follow-up reporting period: (check only one)

☐ 6 month	☐ 2.5Y	☐ 4.5Y	☐ 6.5Y
☐ 1Y	☐ 3Y	☐ 5Y	☐ 7Y
☐ 1.5Y	☐ 3.5Y	☐ 5.5Y	☐ 7.5Y
☐ 2Y	☐ 4Y	☐ 6Y	☐ 8Y

3. Was the FE Form completed?
   - ☐ No (complete 3b)
   - ☐ Yes (complete 3a)

3a. Method(s) the FE Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail
   - ☐ Proxy

3b. Reason the FE Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (receipt of form confirmed)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for follow-up data — Date form completed

_____

Person entering data on web

FE

ACRIN NLST 6654
Additional ERs - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

ER # ____ (3) (6)

On the F2 Form you reported you were seen at another Emergency Room during this interval.

Name of Facility: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this ER?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did you have any of the following procedures at this ER?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FE

ACRIN NLST 6654
Additional ERs - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

ER # ____ (4) (7)

On the F2 Form you reported you were seen at another Emergency Room during this interval.

Name of Facility: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this ER?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did you have any of the following procedures at this ER?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FE

ACRIN NLST 6654
Additional ERs - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

ER # ____ continued from F2 (5) (8)

On the F2 Form you reported you were seen at another Emergency Room during this interval.

Name of Facility: _____

Address: _____

City, State, Zip: _____

Phone: (_____)_____ FAX: (_____)_____

a. Did you receive any of the following at this ER?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Care for complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did you have any of the following procedures at this ER?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Did you visit additional ER's during this time period? ☐ No ☐ Yes

	_____ - _____ - **20**_____ (mm-dd-yyyy)
Participant Signature	Date you completed this form

FE Completion Instructions

The purpose of the FE Form is to report additional participant Emergency Room visits. This form serves as a continuation of the F2 Form. If a participant reports a visit to another Emergency Room (Qc Section A6 of the F2 form) use this form to document each additional Emergency Room visit. It is suggested that this form be administered by telephone or in-person interview. Page 1 of the FE Form serves as a coversheet and should not be given to the participant. If the FE form is completed by the RA there will be no participant signature on the form. If the FE form is completed by the participant, whether by mail or in-person, the participant should sign and date the form in the space provided.

1. **F2 Follow-up Interval:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/20yy.

2. **Follow-up reporting period:** Select the follow-up time point from the list provided. The FE reporting period should be the same as the F2 follow-up reporting period. Please choose only one time point. If multiple FE forms are needed for the same time point please indicate the same time point for each FE form submitted.

3. **Was the FE Form completed?** Please provide an answer to q3. If the answer to q3 is 'no', indicate the reason the form was not completed in q3b. If the answer to q3 is 'yes', indicate the method of completion in q3a.

3a. **Method(s) the FE Form was completed (check all that apply).** Select each appropriate response from the list provided indicating all sources used to complete the FE Form.

- **In-person interview:** Select this response if all or part of the FE Form data was collected during an in-person interview. This response signifies direct contact with the participant and expectation of FE Form submission.
- **Telephone interview:** Select this response if all or part of the FE Form data was collected during a phone interview. This response signifies direct contact with the participant and expectation of FE Form submission.
- **Mailing:** Select this response if all or part of the FE Form data was collected via the mail (i.e., return of completed FE).
- **Proxy:** If a participant is incapacitated or otherwise unable to complete the FE form a proxy may completed the form.

3b. **Reason the FE Form was not completed: (check only one)**

- **Participant Deceased:** Select this response if the participant is deceased at the time of contact. This response will trigger suppression of the FE Form.
- **No response, multiple contact attempts made but participant has not replied:** Select this response if no contact was made, despite multiple attempts (mail, phone, or certified mail). This response will trigger suppression of the FE Form.
- **Participant or proxy refused completion of the follow-up form:** Select this response if the participant refuses to complete the FE Form. This response will trigger suppression of the FE Form.
- **Participant or proxy failed to return follow-up form (receipt of form confirmed):** Select this response if the form is not returned and you have received confirmation of receipt of the form via registered mail receipt or via phone. This response will trigger suppression of the FE Form.
- **No attempt made to administer follow-up form:** Select this response if a follow-up form is not administered to a participant. This response wil trigger suppression of the FE Form.
- **Physical Illness / cognitive impairment:** Select this response if a follow-up form is not administered to a participant due to their illness. This response wil trigger suppression of the FE Form.
- **Other, specify:** Select this response if the FE form is not completed for any other reason.

Signature of person responsible for data: Legible signature of the RA responsible for the data recorded and completed of the form.

Date of form completion: Date the FE form was completed by the responsible RA.

Person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

ER# _____ The Emergency Room Number should be inserted here. This number will indicate the next Emergency Room visited by the participant.

On the F2 Form you reported you were seen at another Emergency Room during this interval. Please provide the Name, Address, Phone and Fax Numbers of the treating facility. Medical Records may be obtained from the treating facilities at some future time.

a. **Did you receive any of the following at this ER?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. **Did you have any of the following procedures at this ER?** These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.
   Chest X-Ray
   Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
   Chest MRI (magnetic resonance imaging of chest or heart)
   FDG-PET scan of the body
   Nuclear Medicine scan of chest, lungs, or heart
   Surgery to chest or lungs
   Biopsy of chest or lung
   Bronchoscopy (tube inserted in airways to study lungs)
   Lung cancer chemotherapy
   Lung cancer radiation therapy
   Other lung test or lung cancer therapy, specify other test below

ER#_____ The Emergency Room Number should be inserted here. This number will indicate the next Emergency Room visited by the participant.

On the F2 Form you reported you were seen at another Emergency Room during this interval. Please provide the Name, Address, Phone and Fax Numbers of the treating facility. Medical Records may be obtained from the treating facilities at some future time.

a. **Did you receive any of the following at this ER?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. Did you have any of the following procedures at this ER? These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.

Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

ER#_____ The Emergency Room Number should be inserted here. This number will indicate the next Emergency Room visited by the participant.

On the F2 Form you reported you were seen at another Emergency Room during this interval. Please provide the Name, Address, Phone and Fax Numbers of the treating facility. Medical Records may be obtained from the treating facilities at some future time.

a. Did you receive any of the following at this ER? These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.

Diagnosis of Lung Cancer
Care related to a lung or chest condition
Care for complications from a lung or chest procedure
Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. Did you have any of the following procedures at this ER? These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.

Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

c. Did you visit additional ER's during this time period? Please answer yes or no if you have been to any additional ER's. Another FE form will be required if more ER's were visited during this time period.

Participant Signature. If the participant completes the form via mail or live interview they must sign the form. If the form is completed via phone no signature is required but site RA's should note in the signature space that the form was completed by phone.

Date Form Completed: This date is required for all forms regardless of who completes the form.

FH

ACRIN NLST 6654
Additional Hospitals - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This form serves as a continuation of the F2 Form. If a participant reports a hospitalization at another facility (F2-bottom of page 9), use this form to document each additional hospital / facility. If more than 5 hospitals in total, an additional FH Form will need to be completed (contact data management to calendar an additional FH Form). It is suggested that this form be administered by telephone or in-person interview. Page 1 of this form serves as the coversheet and should not be given to the participant. If completed by the RA there will be no participant signature on page 4. If completed by participant, whether by mail or in-person, the participant should sign and date the form on page 4. Refer to F2 Form Instructions for general form instructions.

1. F2 Follow-up Interval: ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)

2. Follow-up reporting period: (check only one)

☐ 6 month	☐ 2.5Y	☐ 4.5Y	☐ 6.5Y
☐ 1Y	☐ 3Y	☐ 5Y	☐ 7Y
☐ 1.5Y	☐ 3.5Y	☐ 5.5Y	☐ 7.5Y
☐ 2Y	☐ 4Y	☐ 6Y	☐ 8Y

3. Was the FH Form completed? (check only one)
   - ☐ No (complete 3b)
   - ☐ Yes (complete 3a)

3a. Method(s) the FH Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail
   - ☐ Proxy

3b. Reason the FH Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of the follow-up form
   - ☐ Participant or proxy failed to return follow-up form (participant receipt of form confirmed)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for follow-up data — Date form completed

_____

Person entering data on web

FH

ACRIN NLST 6654
Additional Hospitals - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Hospital #____ (3) (6)

On the F2 Form you reported you were admitted to another hospital during this interval.

Hospital name: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this hospital?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below. . _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FH

ACRIN NLST 6654
Additional Hospitals - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Hospital #____ (4) (7)

On the F2 Form you reported you were admitted to another hospital during this interval.

Hospital name: _____

Address: _____

City, State, Zip: _____

Phone: (____) _____ FAX: (____) _____

a. Did you receive any of the following at this hospital?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below. . _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FH

ACRIN NLST 6654
Additional Hospitals - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Hospital #____ (5) (8)

On the F2 Form you reported you were admitted to another hospital during this interval.

Hospital name: _____

Address: _____

City, State, Zip: _____

Phone: (____) FAX: (____) _____

a. Did you receive any of the following at this hospital?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Complications from a lung or chest procedure?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below. . _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Were you hospitalized at another facility? ☐ No ☐ Yes

_____ _____ - _____ - **20**_____ (mm-dd-yyyy)

Participant Signature Date you completed this form

FH Completion Instructions

The purpose of the FH Form is to report additional participant Hospitalizations visits. This form serves as a continuation of the F2 Form. If a participant reports a visit to another Hospital (Qc Section A8 of the F2 form) use this form to document each additional Hospital visit. It is suggested that this form be administered by telephone or in-person interview. Page 1 of the FH Form serves as a coversheet and should not be given to the participant. If the FH form is completed by the RA there will be no participant signature on the form. If the FH form is completed by the participant, whether by mail or in-person, the participant should sign and date the form in the space provided.

1. **F2 Follow-up Interval:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/20yy.

2. **Follow-up reporting period:** Select the follow-up time point from the list provided. The FH reporting period should be the same as the F2 follow-up reporting period. Please choose only one time point. If multiple FH forms are needed for the same time point please indicate the same time point for each FH form submitted.

3. **Was the FH Form completed?** Please provide an answer to q3. If the answer to q3 is 'no', indicate the reason the form was not completed in q3b. If the answer to q3 is 'yes', indicate the method of completion in q3a.

3a. **Method(s) the FH Form was completed (check all that apply).** Select each appropriate response from the list provided indicating all sources used to complete the FH Form.

- **In-person interview:** Select this response if all or part of the FH Form data was collected during an in-person interview. This response signifies direct contact with the participant and expectation of FH Form submission.
- **Telephone interview:** Select this response if all or part of the FH Form data was collected during a phone interview. This response signifies direct contact with the participant and expectation of FH Form submission.
- **Mailing:** Select this response if all or part of the FH Form data was collected via the mail (i.e., return of completed FH).
- **Proxy:** If a participant is incapacitated or otherwise unable to complete the FH form a proxy may completed the form.

3b. **Reason the FH Form was not completed: (check only one)**

- **Participant Deceased:** Select this response if the participant is deceased at the time of contact. This response will trigger suppression of the FH Form.
- **No response, multiple contact attempts made but participant has not replied:** Select this response if no contact was made, despite multiple attempts (mail, phone, or certified mail). This response will trigger suppression of the FH Form.
- **Participant or proxy refused completion of the follow-up form:** Select this response if the participant refuses to complete the FH Form. This response will trigger suppression of the FH Form.
- **Participant or proxy failed to return follow-up form (receipt of form confirmed):** Select this response if the form is not returned and you have received confirmation of receipt of the form via registered mail receipt or via phone. This response will trigger suppression of the FH Form.
- **No attempt made to administer follow-up form:** Select this response if a follow-up form is not administered to a participant. This response wil trigger suppression of the FH Form.
- **Physical Illness / cognitive impairment:** Select this response if a follow-up form is not administered to a participant due to their illness. This response wil trigger suppression of the FH Form.
- **Other, specify:** Select this response if the FH form is not completed for any other reason.

Signature of person responsible for data: Legible signature of the RA responsible for the data recorded and completed of the form.

Date of form completion: Date the FH form was completed by the responsible RA.

Person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

Hospital# _____ The Hospital Number should be inserted here. This number will indicate the next Hospital visited by the participant.

On the F2 Form you reported you were seen at another Hospital during this interval. Please provide the Name, Address, Phone and Fax Numbers of the hospital. Medical Records may be obtained from the hospital at some future time.

a. **Did you receive any of the following at this hospital?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Treatment for Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. **Did you have any of the following procedures at this hospital?** These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.
   Chest X-Ray
   Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
   Chest MRI (magnetic resonance imaging of chest or heart)
   FDG-PET scan of the body
   Nuclear Medicine scan of chest, lungs, or heart
   Surgery to chest or lungs
   Biopsy of chest or lung
   Bronchoscopy (tube inserted in airways to study lungs)
   Lung cancer chemotherapy
   Lung cancer radiation therapy
   Other lung test or lung cancer therapy, specify other test below

Hospital#_____The next hospital number should be inserted here. This number will indicate the next hospital visited by the participant.

On the F2 Form you reported you were seen at another hospital during this interval. Please provide the Name, Address, Phone and Fax Numbers of the treating facility. Medical Records may be obtained from the treating facilities at some future time.

a. **Did you receive any of the following at this hospital?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Treatment for Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. **Did you have any of the following procedures at this hospital?** These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.
Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

Hospital#_____The next hospital Number should be inserted here. This number will indicate the next hospital visited by the participant.

On the F2 Form you reported you were seen at another hospital during this interval. Please provide the Name, Address, Phone and Fax Numbers of the hospital. Medical Records may be obtained from this hospital at some future time.

a. **Did you receive any of the following at this hospital?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
Diagnosis of Lung Cancer
Treatment for Lung Cancer
Care related to a lung or chest condition
Care for complications from a lung or chest procedure
Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. **Did you have any of the following procedures at this hospital?** These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.
Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

c. **Were you hospitalized at another facility?** Please answer yes or no if you have been to any other hospital. Another FH form will be required if more hospitals were visited during this time period.

Participant Signature. If the participant completes the form via mail or live interview they must sign the form. If the form is completed via phone no signature is required but site RA's should note in the signature space that the form was completed by phone.

Date Form Completed: This date is required for all forms regardless of who completes the form.

FP

ACRIN NLST 6654
Additional Providers - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This form serves as a continuation of the F2 Form. If a participant reports visits to additional providers (F2-bottom of page 5), use this form to document each additional provider. If more than 7 providers in total, an additional FP Form will need to be completed (contact data management to calendar an additional FP Form). It is suggested that this form be administered by telephone or in-person interview. Page 1 of this form serves as the coversheet and should not be given to the participant. If completed by the RA there will be no participant signature on page 4. If completed by participant, whether by mail or in-person, the participant should sign and date the form on page 4. Refer to F2 Form Instructions for general form instructions.

1. F2 Follow-up Interval: ____ - ____ - 20____ to ____ - ____ - 20____ (mm-dd-yyyy)

2. Follow-up reporting period: (check only one)

☐ 6 month	☐ 2.5Y	☐ 4.5Y	☐ 6.5Y
☐ 1Y	☐ 3Y	☐ 5Y	☐ 7Y
☐ 1.5Y	☐ 3.5Y	☐ 5.5Y	☐ 7.5Y
☐ 2Y	☐ 4Y	☐ 6Y	☐ 8Y

3. Was the FP Form completed? (check only one)
   - ☐ No (complete 3b)
   - ☐ Yes (complete 3a)

3a. Method(s) the FP Form was completed (check all that apply)
   - ☐ In-person
   - ☐ Telephone
   - ☐ Mail
   - ☐ Proxy

3b. Reason the FP Form was not completed: (check only one)
   - ☐ Participant deceased
   - ☐ No response, multiple contact attempts made but participant has not replied
   - ☐ Participant or proxy refused completion of this follow-up form
   - ☐ Participant or proxy failed to return follow-up form (receipt of form confirmed)
   - ☐ No attempt made to administer follow-up form
   - ☐ Physical illness / cognitive impairment
   - ☐ Other, specify: _____

_____ ____ - ____ - 20____ (mm-dd-yyyy)

Person responsible for follow-up data — Date form completed

_____

Person entering data on web

FP

ACRIN NLST 6654
Additional Providers - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Provider #____ (5) (8)

On the F2 Form you reported you had visits to another health care provider during this interval.

Health care provider name (first and last): _____

Type of provider: _____

Address: _____

City, State, Zip: _____

Phone: (_____) _____ FAX: (_____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FP

ACRIN NLST 6654
Additional Providers - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Provider #____ (6) (9)

On the F2 Form you reported you had visits to another health care provider during this interval.

Health care provider name (first and last): _____

Type of provider: _____

Address: _____

City, State, Zip: _____

Phone: (_____) _____ FAX: (_____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

FP

ACRIN NLST 6654
Additional Providers - F2 Supplement

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Provider #____ (7) (10)

On the F2 Form you reported you had visits to another health care provider during this interval.

Health care provider name (first and last): _____

Type of provider: _____

Address: _____

City, State, Zip: _____

Phone: (_____) FAX: (_____) _____

a. Did you receive any of the following from this provider?

	No	Yes	I'm not sure
Diagnosis of lung cancer?	☐	☐	☐
Treatment for lung cancer?	☐	☐	☐
Procedures to evaluate a finding from your NLST screening results letter?	☐	☐	☐
Care related to a lung or chest condition?	☐	☐	☐
Diagnosis of any other cancer? If yes, please specify the type of cancer below _____	☐	☐	☐

b. Did this provider send you for any of the following procedures?

Procedures	No	Yes
Chest X-ray	☐	☐
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)	☐	☐
Chest MRI (magnetic resonance imaging of chest or heart)	☐	☐
FDG-PET scan of the body	☐	☐
Nuclear medicine scan of chest, lungs, or heart	☐	☐
Surgery to chest or lungs	☐	☐
Biopsy of chest or lung	☐	☐
Bronchoscopy (tube inserted in airways to study lungs)	☐	☐
Lung cancer chemotherapy	☐	☐
Lung cancer radiation therapy	☐	☐
Other lung test or lung cancer therapy, specify other test below _____	☐	☐

c. Did you visit any other doctor or health care provider? ☐ No ☐ Yes

_____
Participant Signature

____-____-20____ (mm-dd-yyyy)
Date you completed this form

FP Completion Instructions

The purpose of the FP Form is to report additional participant Provider visits. This form serves as a continuation of the F2 Form. If a participant reports a visit to another Provider (Qc Section A4 of the F2 form) use this form to document each additional Provider visit. It is suggested that this form be administered by telephone or in-person interview. Page 1 of the FP Form serves as a coversheet and should not be given to the participant. If the FP form is completed by the RA there will be no participant signature on the form. If the FP form is completed by the participant, whether by mail or in-person, the participant should sign and date the form in the space provided.

1. **F2 Follow-up Interval:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/20yy.

2. **Follow-up reporting period:** Select the follow-up time point from the list provided. The FP reporting period should be the same as the F2 follow-up reporting period. Please choose only one time point. If multiple FP forms are needed for the same time point please indicate the same time point for each FH form submitted.

3. **Was the FP Form completed?** Please provide an answer to q3. If the answer to q3 is 'no', indicate the reason the form was not completed in q3b. If the answer to q3 is 'yes', indicate the method of completion in q3a.

3a. **Method(s) the FP Form was completed (check all that apply).** Select each appropriate response from the list provided indicating all sources used to complete the FP Form.

- **In-person interview:** Select this response if all or part of the FP Form data was collected during an in-person interview. This response signifies direct contact with the participant and expectation of FP Form submission.
- **Telephone interview:** Select this response if all or part of the FP Form data was collected during a phone interview. This response signifies direct contact with the participant and expectation of FP Form submission.
- **Mailing:** Select this response if all or part of the FP Form data was collected via the mail (i.e., return of completed FP).
- **Proxy:** If a participant is incapacitated or otherwise unable to complete the FP form a proxy may completed the form.

3b. **Reason the FP Form was not completed: (check only one)**

- **Participant Deceased:** Select this response if the participant is deceased at the time of contact. This response will trigger suppression of the FP Form.
- **No response, multiple contact attempts made but participant has not replied:** Select this response if no contact was made, despite multiple attempts (mail, phone, or certified mail). This response will trigger suppression of the FP Form.
- **Participant or proxy refused completion of the follow-up form:** Select this response if the participant refuses to complete the FP Form. This response will trigger suppression of the FP Form.
- **Participant or proxy failed to return follow-up form (receipt of form confirmed):** Select this response if the form is not returned and you have received confirmation of receipt of the form via registered mail receipt or via phone. This response will trigger suppression of the FP Form.
- **No attempt made to administer follow-up form:** Select this response if a follow-up form is not administered to a participant. This response wil trigger suppression of the FP Form.
- **Physical Illness / cognitive impairment:** Select this response if a follow-up form is not administered to a participant due to their illness. This response wil trigger suppression of the FP Form.
- **Other, specify:** Select this response if the FP form is not completed for any other reason.

Signature of person responsible for data: Legible signature of the RA responsible for the data recorded and completed of the form.

Date of form completion: Date the FH form was completed by the responsible RA.

Person entering data onto web: Legible signature of staff entering the data, signed upon completion of this task.

Provider# _____ The Provider Number should be inserted here. This number will indicate the next provider visited by the participant.

On the F2 Form you reported you were seen by another provider during this interval. Please provide the Name, Address, Phone and Fax Numbers of the provider. Medical Records may be obtained from this provider at some future time.

a. **Did you receive any of the following from this provider?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Treatment for Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. **Did you have any of the following procedures from this provider?** These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.
   Chest X-Ray
   Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
   Chest MRI (magnetic resonance imaging of chest or heart)
   FDG-PET scan of the body
   Nuclear Medicine scan of chest, lungs, or heart
   Surgery to chest or lungs
   Biopsy of chest or lung
   Bronchoscopy (tube inserted in airways to study lungs)
   Lung cancer chemotherapy
   Lung cancer radiation therapy
   Other lung test or lung cancer therapy, specify other test below

Provider#_____ The next provider number should be inserted here. This number will indicate the next provider visited by the participant.

On the F2 Form you reported you were seen by another provider during this interval. Please provide the Name, Address, Phone and Fax Numbers of the provider. Medical Records may be obtained from this provider at some future time.

a. **Did you receive any of the following from this provider?** These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.
   Diagnosis of Lung Cancer
   Treatment for Lung Cancer
   Care related to a lung or chest condition
   Care for complications from a lung or chest procedure
   Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. Did you have any of the following procedures from this provider? These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.

Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

Provider#____The next provider Number should be inserted here. This number will indicate the next provider visited by the participant.

On the F2 Form you reported you were seen by another provider during this interval. Please provide the Name, Address, Phone and Fax Numbers of the provider. Medical Records may be obtained from this provider at some future time.

a. Did you receive any of the following from this provider? These questions are to ascertain whether the participant has received a diagnosis of Lung Cancer or other cancer or if they have had any Lung or Chest treatments of any kind. Respond with Yes, No, or I'm not sure for each answer.

Diagnosis of Lung Cancer
Treatment for Lung Cancer
Care related to a lung or chest condition
Care for complications from a lung or chest procedure
Diagnosis of any other cancer. If yes, please specify the type of cancer below.

b. Did you have any of the following procedures from this provider? These questions are to ascertain whether the participant has had any procedures relating to Lung, Chest or Cancer diagnoses. A list of the most frequent tests done for Lung Cancer/Chest Disease work up is listed. Please indicate yes or no for each test or therapy listed.

Chest X-Ray
Chest CT scan (i.e., CAT scan, cardiac or heart CT, or lung CT)
Chest MRI (magnetic resonance imaging of chest or heart)
FDG-PET scan of the body
Nuclear Medicine scan of chest, lungs, or heart
Surgery to chest or lungs
Biopsy of chest or lung
Bronchoscopy (tube inserted in airways to study lungs)
Lung cancer chemotherapy
Lung cancer radiation therapy
Other lung test or lung cancer therapy, specify other test below

c. Did you visit any other providers during this interval? Please answer yes or no if you have been to any other providers.
Another FP form will be required if more providers were seen during this time period.

Participant Signature. If the participant completes the form via mail or live interview they must sign the form. If the form is completed via phone no signature is required but site RA's should note in the signature space that the form was completed by phone.

Date Form Completed: This date is required for all forms regardless of who completes the form.

Additional Forms and Worksheets

AE

6654 Adverse Event Case Report Form

ACRIN Study #### **Case #**

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

All questions regarding Adverse Events should be directed to ACRIN Regulatory. All Adverse Events (AEs) and Serious Adverse Events (SAEs), as defined in the 6654 protocol, require routine reporting via this AE CRF within 30 days of the event. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI and ACRIN within 24 hours of knowledge (deaths only); (b) AdEERS report faxed to both NCI and ACRIN within 10 days of knowledge; and (c) hard copy AdEERS mailed to NCI (only). Submit this form to ACRIN via mail or fax, (215) 717-0936.

	AE Description	AE Short Name CTCAE v3.0	CTCAE Grade 1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening or disabling 5 = Fatal	Attribution 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	1 = Expected 2 = Unexpected	AdEERS Submitted for SAEs 1=No 2=Yes	Action Taken 1 = None 2 = Medication Therapy 3 = Procedure 4 = Hospitalization 5 = Other	Outcome 1 = Recovered 2 = Improved 3 = Ongoing 4 = Death 5 = Unknown	Date of AE Onset and Resolution (mm-dd-yyyy) check box "on-going" if the AE is on-going at the time of report ☐ On-going (X or √)
1									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
2									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
3									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going

Comments:

☐	If there are more than 3 AEs for a given visit, check this box and use another AE Form. Page ___ of ___	**Investigator Signature**	**Date: ____ - ____ - 20____ (mm-dd-yyyy)**

CC

ACRIN 6654 - NLST
CANCER NOTIFICATION FORM

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This form is completed when the study site is notified of a cancer diagnosis outside the Follow-up Form. Complete one (1) CC Form per reported cancer. The CC Form is completed by the site RA and submitted via mail/fax (215) 717-0936.

1. Reported cancer: (check only one) [1]

- ☐ Lung cancer
- ☐ Other cancer, specify: [2] _____

2. Date of cancer diagnosis: _____ - _____ - **20**_____ (mm-dd-yyyy); use 99 for unknown date fields [3,4,5]

3. Method of cancer notification: (check all that apply)

- ☐ Participant [6]
- ☐ Relative, spouse, or friend [7]
- ☐ Provider [8]
- ☐ Medical record (other than death certificate) [9]
- ☐ Other, specify: [10, 11] _____

All cancer notifications (CC, Follow-up Form, death certificate) will require medical records collection and abstraction for DE Form completion. Obtain provider information at the time of cancer notification, whenever possible, and document on page 2.

_____ _____ - _____ - **20**_____

Person responsible for data [12] **Date form completed** [13]

CC

ACRIN 6654 - NLST
CANCER NOTIFICATION FORM

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Provider/Facility for cancer diagnosis:
This section is provided as an optional tool to document information for purposes of obtaining medical records; this information is not submitted to ACRIN.

a. Identify main provider or place (hospital/clinic) for cancer diagnosis / treatment:

Name: _____

Address: _____

_____

Phone: _____

b. Identify other provider or place (hospital/clinic) for cancer diagnosis/treatment:

Name: _____

Address: _____

_____

Phone: _____

c. Identify other provider or place (hospital/clinic) for cancer diagnosis/treatment:

Name: _____

Address: _____

_____

Phone: _____

_____

Comments: (site use only, not submitted to ACRIN)

_____

_____

_____

_____

CC FORM COMPLETION INSTRUCTIONS

The purpose of the CC Form is to document a cancer diagnosis reported by a method outside the Follow-up Form. In the event that subsequent Follow-up Forms are not completed and to guard against losing important cancer and medical data, provider information should be obtained at the time of cancer notification, if possible. Each cancer reported outside the F1/F2 Follow-up Form should be recorded on a separate CC Form; caution should be used to avoid duplicate reporting of the same cancer. All reported cancers documented by the CC Form or the Follow-up Form will require medical records collection for completion of the DE Form which will provide confirmation and staging of the cancer. Additionally, cancers reported on a participant's death certificate, if previously undocumented (CC, F1/F2, DE), will require medical records collection for completion of the DE Form. The CC Form is to be completed by the ACRIN-NLST study staff and should be completed in black or blue ink. The CC Form is then submitted to ACRIN via mail or fax (215) 717-0936.

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 spaces provided.

1. **Reported cancer:** Check the appropriate response (Lung or Other) indicating the type of cancer being reported. If reporting a cancer other than lung cancer, specify the type of cancer in the text field adjacent to "Other cancer." If more than one cancer was reported, a separate CC Form should be completed.
2. **Date of cancer diagnosis:** If known, record the date the above cancer was diagnosed; record date as month, day, and year. If any portion of the date field is unknown, code as 99. For example, participant knows the cancer diagnosis occurred in April of 2005 but does not recall the day, report as 4-99-2005.
3. **Method of cancer notification:** Check each applicable response indicating the method in which you became aware of the above cancer diagnosis.

Comments: The comment field is an optional field provided for site use (relevant clinical or study notations, etc.) and/or reference for data related questions. The comment section is not intended for "actionable" information you need to relate to DM and is not intended for data analysis. Comments should be limited to 60 characters.

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.

Page 2:

Provider/Facility for cancer diagnosis: Record the contact information for the participant's cancer provider(s). This section is provided as an optional tool to document the information needed to assist in obtaining medical records; these are not a web-entered fields and are not submitted to ACRIN.

So that pertinent cancer and medical data is not lost, this information should be recorded at the time of cancer diagnosis notification in the event that the subsequent Follow-up Forms are not completed. If the participant or proxy reports the cancer diagnosis, remind her/him to continue to include all cancer-related provider and care information on the next Follow-up Form.

NP

ACRIN 6654
Non-Participation Form

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: If a participant withdraws or is withdrawn from the study prior to completion of all study activities, document the requested information below. The Site Investigator must sign the NP Form.

1. Date of withdrawal: _____ - _____ - **20**_____ (mm-dd-yyyy) [1]

2. Type of withdrawal: [2]

☐ 1 Investigator-Initiated: Subject to review by the Executive Committee, specify reason in Comments below.

☐ 2 Participant-Initiated (complete 2a-b below)

2a. Reason for withdrawal: (check all that apply)

☐ Transportation problems [3]
☐ Concerned about privacy [4]
☐ Physical illness/cognitive impairment [5]
☐ Refused randomized arm [6]
☐ Family responsibilities [7]
☐ Loss of interest in study [8]
☐ Dissatisfied with study [9]
☐ Concerned about medical costs responsibility [10]
☐ Concerned about health care effects [11]
☐ Participating in other research study [12]
☐ Work demands [13]
☐ Out of area [14]
☐ No reason given [15]
☐ Other: [16] _____ [17]

2b. Type of participant withdrawal: [18]

☐ 1 Participant elected to cease further participation in one or more of the protocol sub-studies (check all that apply):

- ☐ Quality of Life [19]
- ☐ Smoking – Risk Perception [20]
- ☐ Biomarkers [21]

☐ 2 Participant refuses further active study participation but agrees to limited contact.

Specify contact interval: [23] _____

- ☐ With records collection [28]
- ☐ Without records collection [29]

☐ 3 Participant refuses further active study participation and contact.

- ☐ With records collection [28]
- ☐ Without records collection [29]

☐ 4 Participant explicitly withdraws study consent/authorizations.

- ☐ With NCHS database search [30]
- ☐ Without NCHS database search [31]

Comments: (120-character limit) [24, 25]

Signature of person responsible for data (RA, study staff) [26]	**Date:** _____ - _____ - **20**_____ [27]
Investigator signature	**Date:** _____ - _____ - **20**_____

NP Form Instructions

The study site completes the NP Form to document participant and investigator-initiated study withdrawals. As addressed in the study consent, participants are free to withdraw from the study at any time. That said, the level of withdrawal a participant desires can vary, which may result in confusion regarding the participant's intention. Withdrawal is defined by the Clinical Data Interchange Standards Consortium (CDISC) as "the act of reducing the degree of future participation in a clinical trial. Participants may withdraw permission of privacy waivers, study consent, or withdraw from the active treatment component of a clinical trial but continue to be observed or followed for study end points." Therefore, since there are various degrees of withdrawal, it is important to initiate a discussion and ask questions to determine (1) the degree of withdrawal the participant desires and (2) whether some level of contact can be agreed upon – such as an annual phone call or a call/letter at the end of the study to "check in with them and see how they are", allowing determination of vital status. This discussion will help the study team avoid having to make their own interpretation as to the participant's choices regarding study participation. With this in mind, refusal of a study activity (screening exam, questionnaires, etc.) should not be interpreted as refusal of all future study activities or withdrawal from the study. Refusal of a study activity should be documented on a PR or GCM, per study-specific guidelines (refusal to complete the F1/F2 should be documented on the Follow-up Form Coversheet). Furthermore, the issue of withdrawal should not be confused with participants considered Non-responders, Lost, or Lost to Follow-up; withdrawal involves an active, explicit request by the participant.

The site investigator must sign all NP Forms. A copy of the form is retained in the participant's file, and one copy is to be mailed to ACRIN HQ. A completed ACRIN Case Specific Label should be affixed to each form. In lieu of a label, the Participant's Initials, Case Number, Institution Number and Institution Name can be recorded in the space provided.

1. **Date of withdrawal:** Required element. Record the date of withdrawal notification.

2. **Type of withdrawal:** Required element. Please indicate the type of withdrawal by checking the appropriate box.

   Investigator-initiated: Rare circumstances may lead the site investigator to withdraw a participant (i.e. cognitive impairment or physical impairment). Please use the comment section at the bottom of the form to provide a brief description of the circumstances leading to this decision. All investigator-initiated withdrawals will be reviewed/approved by the ACRIN-NLST Executive Committee and/or Group Chair. ACRIN will forward the NP description to each member of the Executive Committee and the discussion/decision will be added to the agenda of the next Executive Committee Meeting. Skip questions 2a and 2b.

   If the withdrawal type is "Investigator Initiated" the 6 month F2 coversheet forms will be suppressed by Data Management (DM) on the calendar, and yearly F2 coversheets will still be required for vital status update.

   Participant-initiated: A participant may choose to cease further participation in the study or one or more of the various sub-studies. This is not to be confused with participant refusal of a given study activity at a specific time point.

2a. Reason for withdrawal: Required element, check all that apply. Indicate all reasons for withdrawal expressed by the participant using the code table provided (mark appropriate boxes). To document a reason for withdrawal not captured within the code table, mark the "other" box and provide a brief description (limited to 40 characters). Additional comments can be documented in the Comment section below, if needed.

2b. Type of participant withdrawal: Required element, mark the box indicating the level of participant withdrawal.

(1) Participant elected to cease further participation in one or more of the protocol sub-studies: Withdrawal from sub-studies does not impact the participant's overall study participation. Mark the appropriate box or boxes from the list provided. Once the NP Form is processed, DM will revise the case calendar appropriately and forward the revised case calendar/data collection requirements to the study site.

(2) Participant refuses further active study participation but agrees to limited contact: A participant may choose to cease active participation in the study but agree to some level of contact, allowing for continued follow-up and vital status determination (study end-points). The study site should work with the participant to establish a mutually agreeable contact schedule (e.g. annual phone/mail contact or phone/mail contact at the end of the trial); indicate the modified contact interval in the space provided (web field is limited to 40 characters). For purposes of the Endpoint Verification Process (EVP) and other study end-points, the participant should be asked whether records collection can continue. Participants agreeing to medical records collection should be informed that Medical Records Release Authorizations may be required periodically. Once the NP Form is processed, DM will revise the case calendar appropriately and forward the revised case calendar/data collection requirements to the study site. Case status will remain Open for vital status updates and EVP.

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(3) Participant refuses further active study participation and contact: A participant may choose to cease all active participation/contact in a trial without revoking study consent/authorization; sometimes referred to as drop-outs. Follow-up data, as related to the study aims, can be collected from various sources without action by the participant; these sources can include the participant's doctor(s), monitoring medical records, internet searches, and database searches (SSDI, NDI, etc). This allows continued follow-up of the participant while respecting the participant's decision to cease participation in the trial. For purposes of EVP and other study end-points, the participant should be asked whether records collection can continue. Participants agreeing to medical records collection should be informed that Medical Records Release Authorizations may be required periodically. Once the NP Form is processed, DM will revise the case calendar appropriately and forward the revised case calendar/ data collection requirements to the study site. Case status will remain Open for vital status updates and EVP.

(4) Participant explicitly withdraws study consent/authorizations: Withdrawal of study consent should be obtained in writing, if possible. At a minimum, withdrawal of study consent must be clearly understood and articulated by both the site and the participant and documented by the study site. Once the NP Form is processed, ACRIN will close the case and send notification of the "closed" case status to the study site; the case will be closed to vital status updates and EVP. For purposes of EVP, the participant should be asked whether NLST may conduct the National Center for Health Statistics (NCHS) database search.

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

Signature of person responsible for data: Required element. Legible signature of the study staff responsible for the NP Form information.

Date: Required element. Record the date that the NP Form was completed.

Investigator Signature: Required element. Before submitting to ACRIN, the site investigator must review the withdrawal information and sign-off on the NP Form.

Date: Required element. Record the date the NP Form was signed by the site investigator.

Note: If a withdrawn participant chooses to return to the trial after an NP Form has already been submitted, please contact Data Management to reinstate the Follow-up Forms on the participant calendar. The appropriate X Form and F2 Form data should be entered into the database. With regards to the previously submitted NP Form, draw a line through the entire NP Form, initial and date, and submit the NP Form to Data Management so that its contents can be deleted from the database. These participants will be reinstated into the study for data collection.

PR

ACRIN 6654
PROTOCOL DEVIATION FORM

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Complete a separate PR Form for each case and for each deviation (Q1). Retain the original copy of the form in the case study file and mail a copy to ACRIN Headquarters.

1. Check the Protocol Deviation Being Reported: (check only one) [1]

- ☐ 1 Ineligible participant randomized (complete 1a, below)
- ☐ 2 Participant randomized more than once, duplicate case # _____ [3]
- ☐ 3 Participant completed study activity before signing consent
- ☐ 4 Screened eligible participant with a reported or confirmed lung cancer
- ☐ 5 CXR screen administered to a CT arm participant
- ☐ 6 CT screen administered to a CXR arm participant
- ☐ 7 Erroneous results reported to participant and/or health care provider
- ☐ 8 Duplicate screen administered
- ☐ 9 Screening results not reported to participant/health care provider within protocol-specified time frame
- 10 Participant withdrew study consent --- report on NP
- 11 Participant withdrew biomarker consent --- report on NP
- 12 Participant withdrew remnant tissue consent --- refer to RM Form instructions
- ☐ 13 Baseline screen delayed, not performed within 4 weeks of randomization (assign screen per OOWS)
- ☐ 14 Spirometry not performed
- ☐ 15 Spirometry performed while participant on bronchodilator
- ☐ 16 Baseline screening exam not performed
- ☐ 17 Year 1 incidence screening exam not performed
- ☐ 18 Year 2 incidence screening exam not performed
- ☐ 19 Year 1 incidence screening exam not performed within protocol-specified time frame (assign per OOWS)
- ☐ 20 Year 2 incidence screening exam not performed within protocol-specified time frame (assign per OOWS)
- ☐ 21 Revised gender, correct gender: [23] ☐ - 1 Male ☐ - 2 = Female
- ☐ 22 Revised age group, correct age group: [24] _____ (A0, Q19, response = 1 - 4)
- 23 Institution transfer --- complete Participant Transfer Form
- ☐ 24 Screening images lost/unavailable
- ☐ 25 Imaging-related deviation (complete 1b, page 2)
- ☐ 90 Other, specify: [2] _____

1a. Reason for Ineligibility

- ☐ [4] Unwilling / unable to provide consent
- ☐ [5] Age < 55 or > 74 years at study entry
- ☐ [6] Non-smoker or quit smoking more than 15 years ago
- ☐ [7] Unable to lie on back with arms resting above head
- ☐ [8] Metallic implants in chest or back
- ☐ [9] Diagnosed with lung cancer prior to study entry
- ☐ [10] Evidence or cancer or treatment of cancer within the past 5 years (excluding non-melanoma skin cancer or in-situ cancers other than transition cell or bladder)
- ☐ [11] Had a lung or portion of a lung surgically removed
- ☐ [12] Home oxygen supplementation required
- ☐ [13] Participant in other cancer screening trial (such as ELCAP or PLCO)
- ☐ [14] Participant in other cancer prevention trial
- ☐ [15] Unexplained weight loss greater than 15 pounds within the last year or recent Hemoptysis
- ☐ [16] Pneumonia or acute respiratory infection requiring antibiotics within 12 weeks of study entry
- ☐ [17] Treated with cytotoxic agents within 6 months prior to study entry
- ☐ [18] Chest CT within 18 months prior to study entry
- ☐ [19] Smoking history less than 30 pack years

1b. Imaging Deviation:

- ☐ [25] Incorrect KV utilized
- ☐ [26] Incorrect gantry rotation time utilized
- ☐ [27] Incorrect mA / mAs utilized
- ☐ [28] Incorrect reconstructed slice width utilized
- ☐ [29] Incorrect reconstructed interval utilized
- ☐ [30] Incorrect reconstructed algorithm utilized
- ☐ [31] Incorrect number of slices for a specific algorithm
- ☐ [32] Other deviation, specify: [33] _____
- ☐ [36] Lateral CXR projection performed as part of the screening exam
- ☐ [37] Lateral CXR used for screening exam interpretation – DR (can be used for I8)
- ☐ [38] Screening exam performed using non-NLST-certified equipment

2. Date the protocol deviation was discovered: [20] ____ - ____ - 20____ (mm-dd-yyyy)

3. Describe the protocol deviation: (60-character limit) [39]

_____

_____

4. What was done to rectify the situation and / or prevent future occurrence: (60-character limit) [40]

_____

_____

5. Date the protocol deviation occurred: [41] ____ - ____ - 20____ (mm-dd-yyyy)

6. Study year this deviation applies to: [42] ☐ T0 ☐ T1 ☐ T2

Comments: (120-character limit) [43, 44]

_____

_____

_____

[21] _____ [22] ____ - ____ - 20____ (mm-dd-yyyy)

Signature of person responsible for data **Date form completed**

_____

Investigator Signature

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 T1 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 (OOWS) 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.

ACRIN-NLST GENERAL COMMUNICATION MEMO

Instructions: Be sure to properly identify the study, case, form, and the calendar due date your memo refers to. Do not use this memo to respond to data queries or report data corrections. Use this memo to:

- Communicate non-submission of a required calendar item (data form, study report, etc.) and reason for non-submission. Once processed, DM will suppress the item on the case calendar.
- Communicate information pertinent to a forms due request.
- Communicate case specific information that cannot be reported on a data form.

USE A SEPARATE FORM FOR EACH CASE

Institution Name or No. #:	ACRIN Protocol #:
Case #:	Participant Initials:

Study Form	Calendar Due Date (mm-dd-yyyy)	Reason Code	Explanation / Comments
	____ - ____ - 20___		
	____ - ____ - 20___		
	____ - ____ - 20___		
	____ - ____ - 20___		

If GCM is in reference to a Forms Due Report, date of report:

Additional Comments / Reporting Other Case-Specific Information:

Reason codes for non-submission of calendar-required study item(s)

01 = Physical illness/cognitive impairment 02 = Unable to contact 03 = No translator 04 = Institutional error 05 = Institution refused 06 = Participant refused – no reason given 07 = Other 08 = *CODE NOT IN USE FOR NLST* 09 = Unknown 10 = No show for scheduled appointments 11 = No response 12 = Incorrect exam/study activity performed 13 = Participant refused randomized arm 14 = Refused repeat study activity – technical factors 15 = Refused to re-schedule study activity – study site factors	16 = Images lost 17 = Transportation problems 18 = Concerned about privacy 19 = Family responsibilities 20 = Work demands 21 = Concerned about medical cost responsibility 22 = Concerned about health effects of participation 23 = Participating in other research study 24 = Loss of interest in study 25 = Dissatisfied with study 26 = Out of area 27 = Refused to release medical record(s) 28 = No response to records requests 29 = Reported lung cancer
Person responsible for GCM data (RA, study staff)	Date GCM completed: ____ - ____ - 20____

GCM Instructions

The General Communication Memo is completed by the site (1) when a protocol/calendar required item is unavailable or unable to be submitted to ACRIN requiring calendar suppression; (2) to communicate information pertinent to a forms due request; or (3) to communicate case-specific information, not data, that is not collected on a data form. Each submitted GCM must be case specific, one case number per GCM. Retain the GCM 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 form. In lieu of a label, the Participants Initials, Case Number, Institution Number, and Institution Name can be recorded in the space provided.

Study Form: Required data field if GCM is related to a calendar-required item. Please indicate the item (data form, report, imaging) by the two-character Form ID (i.e., C1, QL, etc.) in the box provided.

Calendar Due Date: Required data field if GCM is related to a calendar-required item. Indicate the applicable form due date in the space provided; record date as month, day, year.

Reason Code: Required data field if GCM is submitted to report non-submission of a calendar-required item. Choose a reason code from the list provided on the lower portion of the form, list of codes and descriptions on following page. A reason is required for each form type listed. If reporting **'other' or 'unknown'** provide a short explanation in the additional comments section of the form.

1 = Physical illness/cognitive impairment:
The participant refuses to complete a data collection form or study activity because s/he has a physical illness or cognitive impairment. This code may also be selected if the participant's family member or health care provider reports that s/he is unable to participate in study activities due to a physical illness or cognitive impairment.

2 = Unable to be contacted:
Site is unable to locate the participant during the activity period, despite multiple attempts (as outlined by NLST guidelines).

3 = No translator:
Participant does not speak English. Participant is unable to complete a data collection form or study activity because there is no translator available.

4 = Institutional error:
Study site failed to administer a calendared data form or study activity.

5 = Institution refused

6 = Participant refused – no reason given:
The participant refuses to complete a data collection form or study activity and would not cite a specific reason for her/his refusal.

7 = Other:
Calendared data item will not be submitted due to a reason not identified in this code table.

8 = *CODE NOT IN USE FOR NLST*

9 = Unknown:
If reason is unknown please provide comment.

10 = No show for scheduled appointments:
The study site has scheduled study visits but s/he repeatedly fails to show up for visits.

11 = No response:
The participant was contacted multiple times (as outlined by NLST guidelines), but did not respond to site requests and/or contact.

12 = Incorrect exam/study activity performed:
The site performed the wrong (per randomization) imaging exam or study activity so the calendared data form will not be submitted.

13 = Participant refused randomized arm:
The participant refused the imaging exam or study activity to which they were assigned.

14 = Refused repeat study activity - technical factors:
Study activity WAS performed but needs to be repeated due to technical factors (incorrect imaging protocol, non-diagnostic exam, inadequate test). Participant refuses the repeat study activity.

15 = Refused to re-schedule study activity - study site factors:
Participant refuses to re-schedule a study activity that was NOT performed, as originally scheduled, due to study site factors (equipment malfunction, lengthy wait, etc.).

16 = Images Lost:
Images will not be submitted to ACRIN because the study site lost the images and is unable to recreate the study exam.

17 = Transportation problems:
The participant refuses to schedule a study visit because s/he does not have transportation to/from the screening center.

18 = Concerned about privacy:
The participant refuses to complete a data collection form or schedule a study activity because s/he is concerned about privacy.

19 = Family responsibilities:
The participant refuses to complete a data collection form or schedule a study activity because s/he has family responsibilities that preclude participation.

20 = Work demands:
The participant refuses to complete a data collection form or schedule a study activity because s/he has work demands that preclude participation.

21 = Concerned about medical cost responsibility:
The participant refuses to schedule a study activity because s/he is concerned about associated medical costs (additional exams, f/u procedures).

22 = Concerned about health effects of participation:
The participant refuses to schedule a study activity because s/he is concerned about negative health effects of participant.

23 = Participating in other research study:
The participant refuses to complete a data collection form or schedule a study activity because s/he is currently participating in another research study.

24 = Loss of interest in study:
The participant refuses to complete a data collection form or schedule a study activity because s/he has lost interest in the study.

25 = Dissatisfied with study:
The participant refuses to complete a data collection form or schedule a study activity because s/he is dissatisfied with the study.

26 = Out of area:
The participant was contacted but is unable or unwilling to complete a data collection form or schedule a study activity because s/he is out of the area.

27 = Refuses to release medical records:
The medical records necessary for completion of study form(s) cannot be obtained because the participant, family or provider/facility refuses to release the records/reports.

28 = No response to record requests:
The medical record(s) necessary for completion of the study form(s) and/or submission to ACRIN cannot be obtained because the health care provider/facility does not respond to study site requests for records.

Explanation / Comments: Optional element, provide comments as appropriate (this is not entered into database).

If GCM is in reference to a Forms Due Report, date of report: Required data field if GCM is in response to FDR; report date of FDR as month, day, year.

Additional Comments / Reporting Other Case Specific Information: Optional element, provide comments, as appropriate, in support of the information reported above (this is not entered into the database).

Person responsible for GCM data: Required element. Legible signature of the study staff responsible for the interview data or for reviewing the completeness of the participant completed data.

Date GCM completed: Record the date that the GCM was completed; record date as month, day, year.

RT

ACRIN 6654
Remnant Tissue Transmittal Form

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: The RT form is to be completed for all participants with a diagnosis of lung cancer. If remnant tissue (non-damaged requested blocks see remnant tissue MOP section 4.1.3) is obtained, complete as directed. Please submit this form, pathology report, and tissue to UCLA (see address on page 2) and fax a copy of the pathology report to ACRIN Data Management @ 215-717-0936. Please submit the RT form via the ACRIN website on your site's shipping day. Follow the instructions for mailing and labeling as detailed in the Remnant Tissue MOP, Sections 4.2 and Section 5.1-5.4.

Part A: Complete Part A for all lung cancer cases. If remnant tissue is not obtained, complete Part A only, sign and date this form and submit to ACRIN via fax (215-717-0936).

Section 1 – Admin/Eligibility

1. Source of information used to determine lung cancer status *(check all that apply)*

- ☐ CC form
- ☐ F1/F2 form
- ☐ EVP
- ☐ Other, specify _____

2. Was lung tissue resected?

- O No (sign and date form)
- O Yes

3. Are pathology or operative reports available?

- O No (sign and date form)
- O Yes

4. Has the participant signed a remnant tissue consent form, or has a waiver of consent been obtained?

- O No (sign and date form)
- O Yes, provide date _____-_____-_____ *(mm-dd-yyyy)*

5. Has the participant signed the authorization to release surgical material and related health information for local pathology lab release of blocks?

- O No (sign and date form)
- O Yes, provide date _____-_____-_____ *(mm-dd-yyyy)*
- O Not required by local pathology lab

Section 2 - Site Receipt of block(s) from Pathology Lab

6. Did the site receive the requested blocks from the Pathology Lab(s)?

- O No (sign and date form)
- O Yes (Complete 6a and 6b)

6a. ☐☐ Number of blocks received for this participant

6b. Date blocks were received _____-_____-_____
(mm-dd-yyyy)

7. Did the site receive damaged blocks from the Pathology Lab(s)? (Damaged blocks should be returned to the Pathology Lab)

- O No
- O Yes (Complete 7a and 7b, **then skip Part B and sign and date form**)

7a. ☐☐ Number of damaged blocks received

7b. Date blocks were returned to path lab _____-_____-_____
(mm-dd-yyyy)

RT

ACRIN 6654
Remnant Tissue Transmittal Form

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part B: Complete Part B for all cases for which remnant tissue blocks are obtained. Follow the instructions for labeling and shipping as detailed in the RT MOP section 4.1 and 5.1-5.4. Block ID number should be physically placed on the block, using site number, case number, and sequence number. For example, for the first block: 4202-1234-01, the second block: 4202-1234-02, etc.

Answer the following questions for EACH block:

Tissue blocks are sent from: (check one)

☐ UCHSC

☐ Site number _____

ACRIN NLST Block ID (IIII-CCCC-SS)	**Date of Surgical Procedure (mm-dd-yyyy)**	**Original Pathology Block ID**	**Fixative Type** 1 Formalin (buffered) 2 Formalin (unbuffered) 3 Gluteraldehyde 4 Ethanol 5 Methanol 6 B5 7 Bouin's 8 Zenker's 99 Unknown	**Return Block to Pathology Lab (Y/N)**	**Loan Period (minimum 3 months)** 1 < 3 months 2 3-6 months 3 6-9 months 4 9-12 months 5 >12 months	**Maximum # of Cores allowed to be taken per block**	**Date Block Sent to UCLA (mm-dd-yyyy)**
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____
	_____ - _____ - _____						_____ - _____ - _____

Completed By: _____

Date: _____ - _____ - _____ *(mm-dd-yyyy)*

Primary Contact: _____

Telephone No: (_____) _____

Send this form, pathology report, and tissue to:

Sheila Tze, Laboratory Manager
David Geffen School of Medicine at UCLA
UCLA Tissue Array Core Facility
Reed Neurological Research Center, Room 3243
650 Charles E. Young Drive South
Los Angeles, California 90095
310-267-2468

Fax a copy of the pathology report to ACRIN Data Management @ 215-717-0936

RT Completion Instructions

Instructions: The RT form is to be completed for all participants with a diagnosis of lung cancer. If remnant tissue (non-damaged requested blocks see remnant tissue MOP section 4.1.3) is obtained, complete as directed. Please submit this form, pathology report, and tissue to UCLA (see address on page 2) and fax a copy of the pathology report to ACRIN Data Management @ 215-717-0936. Please submit the RT form via the ACRIN website on your site's shipping day. Follow the instructions for mailing and labeling as detailed in the Remnant Tissue MOP, Sections 4.2 and Section 5.1-5.4.

Part A: Complete Part A for all lung cancer cases. If remnant tissue is not obtained, complete Part A only, sign, and date this form and submit to ACRIN via fax (215-717-0936).

Section 1- Admin/Eligibility

1. **Source of information used to determine lung cancer status:** Please select the source of information used to determine the participant's lung cancer status (CC form, F1/F2 form, EVP, other). Check all that apply.

2. **Was lung tissue resected:** If tissue was unable to be resected, please select 'no' and sign and date the form at the bottom of page two. In addition to lung tissue, UCLA will also accept normal and other tissue types. Please contact the NLST Remnant Tissue Project Manager to determine other acceptable types of tissue.

3. **Are pathology or operative reports available:** If pathology/operative reports are unavailable, please select 'no' and sign and date the form at the bottom of page two.

4. **Has the participant signed a remnant tissue consent form, or has a waiver of consent been obtained:** If consent/waiver of consent for remnant tissue has not been obtained, please select 'no' and sign and date the form at the bottom of page two. The original remnant tissue consent or IRB waiver of consent should be stored in the participant's ACRIN-NLST file.

5. **Has the participant signed the authorization to release surgical material and related health information for local pathology lab release of blocks:** If authorization has not been signed, please select 'no' and sign and date the form at the bottom of page two. If the authorization is not required by the local pathology lab, please continue on with the form.

6. **Did the site receive the requested blocks from the Pathology Lab(s):** If the requested blocks have not been received, please select 'no' and sign and date the form at the bottom of page two. If the requested blocks have been received, please enter the number of blocks and the date received.

7. **Did the site receive damaged blocks from the Pathology Lab(s):** Damaged blocks should be returned to the pathology lab. If damaged blocks are received, please select 'yes' and enter the number of damaged blocks and the date returned, then sign and date the form at the bottom of page two. If a block is damaged, contact the pathology department to report the damage and to request a replacement block, if needed and available. If you are uncertain about the viability of a block, forward the specimen to UCLA and they will determine if the block can be processed. Types of damage to look for include: melting, significant dents or punctures, excessively used paraffin blocks, etc.

Part B: Complete Part B for all cases for which remnant tissue blocks are obtained. Follow the instructions for labeling and shipping as detailed in the RT MOP section 4.1 and 5.1-5.4. Block ID number should be physically placed on the block, using site number, case number, and sequence number. Labels will be provided by ACRIN. The duplicate label should be placed in the first column of part B, in sequential order. For example, for the first block: 4202-1234-01, the second block: 4202-1234-02, etc.

Answer the following questions for each block:

- **ACRIN NLST Block ID:** (ex: 4202-1234-01) 10 digits, do not enter dashes on web

- **Date of Surgical Procedure** (mm-dd-yyyy)
- **Original Pathology Block ID:** Enter the site's original pathology block ID
- **Fixative Type:** Enter the fixative type according to the code table. If the fixative type is not known enter 'unknown'.
- **Return Block to Pathology Lab:** Enter 'no' and skip the next column if the specimen is to be obtained for permanent retention (all specimens obtained for permanent retention will be stored at the UCLA Tissue Array Core Facility after processing). Enter 'yes' if the specimen is to be returned after processing and specify the loan period in the next column by selecting the number on the loan period code table.
- **Loan Period:** Select the number on the loan period code table that corresponds with the period that the specimen will be obtained. The minimum loan period is 3 months. All loaned specimens will be returned to the original pathology laboratory within the loan period.
- **Maximum # of Cores allowed to be taken per block**
- **Date Block Sent to UCLA** (mm-dd-yyyy)

Completed By: Legible signature of staff member completing the form.

Date: Date the form was completed (mm-dd-yyyy)

Primary Contact: Enter the primary contact person at the site (lead RA)

Telephone Number: Enter the telephone number of the primary contact

Tissue blocks are sent from: (Check one) Please select whether the tissue blocks were sent from UCHSC or the Site. If the blocks came from a site then please enter the 4-digit NLST site number.

CO

ACRIN 6654 NLST Colorado Tumor Slide Annotation

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: Complete this form for each **individual** slide received from UCLA. For each question, select only one response.

Case Demographics

1. **ACRIN NLST Block ID** ☐☐☐☐ - ☐☐☐☐☐ - ☐☐ [1]

2. **Slide label: S** ☐ (Slide # 1, 2, 3, ...9) [2]

3. **How many targets (regions of interest or ROI) were drawn by the pathologist?** [3]

- ☐ 01 (Continue to Q5)
- ☐ 02 (Continue to Q5)
- ☐ 03 (Continue to Q5)
- ☐ 04 (Continue to Q5)
- ☐ 05 = None (Continue to Q4 and then skip to comments/signature)

4. **For what reason was the slide NOT annotated?** [4]

- ☐ 220 Insufficient target tissue: Volume
- ☐ 221 Insufficient target tissue: Histologic type
- ☐ 222 Insufficient target tissue: Histologic grade
- ☐ 223 Poor fixation seen histologically
- ☐ 224 Autolysis seen histologically
- ☐ 225 Extra tissue not needed for arrays
- ☐ 227 Slide broken
- ☐ 228 Slide stain poor
- ☐ 229 Slide not labeled
- ☐ 230 Slide other, specify _____ [5]

Slide Digitization

5. **Date of slide annotated:** _____-_____-_____ **(mm-dd-yyyy)** [6]

6. **Was the slide digitized?** [7]

- ☐ No
- ☐ Yes

7. **Colorado slide digitization ID: LAS** ☐☐☐☐☐☐☐☐☐ [8]

Section 1 - Tumor Slide Characterization

8a. **Is there any tumor tissue on the slide?** [9]

- ☐ No (Complete Section 2 Non-Tumor Slide Characterization)
- ☐ Yes

CO

ACRIN 6654 NLST Colorado Tumor Slide Annotation

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

8b. Characterize the most representative topography of this tumor based on the accompanying Surgical Pathology Report. [10]

- ☐ C34.0 = Main Bronchus | Malignant neoplasm of bronchus and lung
- ☐ C34.1 = Upper Lobe | Malignant neoplasm of bronchus and lung
- ☐ C34.2 = Middle Lobe | Malignant neoplasm of bronchus and lung
- ☐ C34.3 = Lower Lobe | Malignant neoplasm of bronchus and lung
- ☐ C34.8 = Overlapping lesion of bronchus and lung| Malignant neoplasm of bronchus and lung
- ☐ C34.9 = Not Otherwise Specified | Malignant neoplasm of bronchus and lung
- ☐ C33 = Malignant Neoplasm of Trachea
- ☐ 88 = Other, Specify _____ [11]
- ☐ 99 = Not Applicable

9. On which side of the body was the tissue located? (Refer to the accompanying Surgical Pathology report from the originating Pathology Department.) [12]

- ☐ RT = Right side
- ☐ LT = Left side
- ☐ NS = Not-specified

10. Please record the predominant histology on the slide using the WHO Classification of Tumours of the Lung 2004 (Appendix A).

☐☐☐☐ / ☐ [13]

11. Record the highest grade of the neoplasm visible on the slide. [14]

- ☐ G1 Well differentiated
- ☐ G2 Moderately differentiated
- ☐ G3 Poorly differentiated
- ☐ G4 Undifferentiated
- ☐ 88 Other, specify _____ [15]

12. Record the percentage of cellular material that is tumor cells on the slide.

☐☐☐ **%** (001-100%) [16]

13. Record the percentage of the tumor that shows invasion on the slide.

☐☐☐ **%** (001-100%) [17]

14. Record whether lymphatic vessel invasion is present. [18]

- ☐ No
- ☐ Yes

15. Record whether blood vessel invasion is present [19]

- ☐ No
- ☐ Yes

16. Provide a visual estimate of the percentage of <u>inflammatory cells</u> on the slide.

☐☐☐ **%** (001-100%) [20]

17. Record the likelihood of metastases from a NON-lung primary neoplasm on the slide. [21]

- ☐ NONE
- ☐ Unlikely
- ☐ Probable
- ☐ Can't determine

Section 2 - Non-Tumor Slide Characterization

18a. Is there any Non-tumor tissue on the slide? [22]

- ☐ No (skip Q18b and Q19)
- ☐ Yes

18b. Characterize the most representative (predominant) <u>NON-tumor histology</u> on this <u>slide</u>. [23]

- ☐ 01 = Normal lung parenchyma
- ☐ 02 = Granuloma
- ☐ 03 = Pneumonia
- ☐ 04 = Hemorrhage
- ☐ 05 = Necrosis
- ☐ 06 = Infarction
- ☐ 07 = Emphysema
- ☐ 08 = Fibrosis
- ☐ 09 = Pre-neoplastic tissue (Complete Q19)
- ☐ 88 = Other, Specify _____ [24]

19. Characterize the most representative (predominant) <u>pre-malignant histology</u> observed on this <u>slide</u>. [25]

- ☐ 01 = (8070/2) Squamous carcinoma *in situ*
- ☐ 02 = Squamous dysplasia, MILD
- ☐ 03 = Squamous dysplasia, MODERATE
- ☐ 04 = Squamous dysplasia, SEVERE
- ☐ 05 = (AAH) Atypical adenomatous hyperplasia
- ☐ 06 = (DIPNECH) Diffuse idiopathic neuroendocrine cell hyperplasia
- ☐ 88 = Other, Specify _____ [26]

COMMENTS: _____

_____

_____ **[27]**

_____ **[28]**
Interpreting Pathologist's initials

_____-_____-**20**_____ **[30]**
Date form completed (mm-dd-yyyy)

_____ **[29]**
Initials of person(s) completing the form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Appendix A: WHO Classification of Tumours of the Lung

Code	Description
	Malignant Epithelial Tumors
8070/3	Squamous cell carcinoma
8052/3	Papillary
8084/3	Clear cell
8073/3	Small cell
8083/3	Basaloid
8041/3	**Small cell carcinoma**
8045/3	Combined small cell carcinoma
8140/3	**Adenocarcinoma**
8225/3	Adenocarcinoma, mixed subtype
8550/3	Acinar adenocarcinoma
8260/3	Papillary adenocarcinoma
8269/3	Micropapillary adenocarcinoma
8250/3	Bronchioloalveolar carcinoma
8252/3	Nonmucinous
8253/3	Mucinous
8254/3	Mixed nonmucinous and mucinous *or* indeterminate
8230/3	Solid adenocarcinoma with mucin production
8333/3	Fetal adenocarcinoma
8480/3	Mucinous ("colloid") carcinoma
8470/3	Mucinous cystadenocarcinoma
8490/3	Signet ring adenocarcinoma
8310/3	Clear cell adenocarcinoma
8012/3	**Large cell carcinoma**
8013/3	Large cell neuroendocrine carcinoma
8013/3	Combined large cell Neuroendocrine carcinoma
8123/3	Basaloid carcinoma
8082/3	Lymphoepithelioma-like carcinoma
8310/3	Clear cell carcinoma
8014/3	Large cell carcinoma with rhabdoid phenotype
8560/3	Adenosquamous carcinoma

Code	Description
8033/3	**Sarcomatoid carcinoma**
8022/3	Pleomorphic carcinoma
8032/3	Sindle cell carcinoma
8031/3	Giant cell carcinoma
8980/3	Carcinomsarcoma
8972/3	Pulmonary blastoma
8240/3	**Carcinoid tumor**
8240/3	Typical carcinoid
8249/3	Atypical carcinoid
	Salivary gland tumours
8430/3	Mucoepidermoid carcinoma
8200/3	Adenoid cystic carcinoma
8562/3	Epithelial-myoepithelial carcinoma
	Lymphoproliferative tumours
9699/3	Marginal zone B-cell lymphoma of the MALT type
9680/3	Diffuse large B-cell lymphoma
9766/1	Lymphomatoid granulomatosis
9751/1	Langerhans cell histiocytosis
	Mesenchymal tumours
9133/1	Epithelioid haemangioendothelioma
9120/3	Angiosarcoma
8973/3	Pleuropulmonary blastoma
9220/0	Chondroma
8827/1	Congenital peribronchial myofibroblastic tumour
8825/1	Inflammatory myofibroblastic tumour
9174/1	Lymphangioleiomyomatosis
9040/3	Synovial sarcoma
9041/3	Monophasic
9043/3	Biphasic
8800/3	Pulmonary artery sarcoma
8800/3	Pulmonary vein sarcoma

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Appendix A: WHO Classification of Tumours of the Lung

Code	Description
	Benign Epithelial Tumors
	Papillomas
8052/0	Squamous cell papilloma
8052/0	Exophytic
8053/0	Inverted
8260/0	Glandular papilloma
8560/0	Mixed squamous cell and glandular
	Adenomas
8251/0	Alveolar adenoma
8260/0	Papillary adenoma
	Adenomas of the salivary gland type
8140/0	Mucous gland adenoma
8940/0	Pleomorphic adenoma
N/A	Others
8470/0	Mucinous cystadenoma

Code	Description
	Miscellaneous Tumours
	Harmatoma
8832/0	Sclerosing hemangioma
8005/0	Clear cell tumour
	Germ cell tumours
9080/0	Teratoma, mature
9080/3	Immature
N/A	**Other germ cell tumours**
8580/1	Intrapulmonary thymoma
8720/3	Melanoma
	Pre-invasive lesions
8070/2	Squamous carcinoma *in situ*
AAH	Atypical adenomatous hyperplasia
DIPNECH	DIPNECH
Mets	Metastatic tumours

TA

ACRIN 6654 NLST
Colorado Target (Region of Interest) Annotation

ACRIN Study **6654**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: Complete one form for each specific Target | Region of Interest (ROI) you annotate on a slide. These targets will define the locations for punches to create tissue microarray blocks. For each Target, complete only the Tumor or NON-Tumor sections of the case report form. For each question, select only one response. When annotating the slide use the following color coding: BLUE = Target 1, GREEN = Target 2, BLACK = Target 3, RED = Target 4.

1. **ACRIN NLST Block ID** ☐☐☐☐ - ☐☐☐☐☐ - ☐☐ [1]

2. **Slide label: S** ☐ (Slide # 1, 2, 3, ...9) [2]

3. **Date of Pathologist's Interpretation:** _____-_____-_____ *(mm-dd-yyyy)* [3]

ROI General Data

4. **Provide the target label color code (ROI #): R** ☐ **(Region # 1, 2, 3, 4) Entered by interpreting pathologist** [4]

1 Blue
2 Green
3 Black
4 Red

ROI Tissue Type

5. **What is the representative histology of this specific target (ROI) on the slide?** [5]

☐ 1 Tumor (Complete section 1 - Tumor ROI Annotation)
☐ 2 Non-Tumor (Complete section 2 - Non-Tumor ROI Annotation)

Section 1 - Tumor ROI Annotation (Complete for the Tumor ROI annotation)

6. **Record the predominant histology in the Target (ROI) using the WHO Classification of Tumors of the Lung 2004 (Appendix A)** [6]

☐☐☐☐ / ☐

7. **Record the highest grade of the neoplasm visible in the Target (ROI).** [7]

☐ G1 Well differentiated
☐ G2 Moderately differentiated
☐ G3 Poorly differentiated
☐ G4 Undifferentiated
☐ 88 Other, specify _____ [8]

8. **Record the percentage of cellular material in the Target (ROI) that is tumor cells.**

☐☐☐ **%** (001-100%) [9]

9. Record the percentage of the tumor in the Target (ROI) that shows invasion.

☐☐☐ **%** (001-100%) [10]

10. Record whether lymphatic vessel invasion is present in the Target (ROI). [11]

☐ No
☐ Yes

11. Record whether blood vessel invasion is present in the Target (ROI). [12]

☐ No
☐ Yes

12. Provide a visual estimate of the percentage of the Target (ROI) that consists of inflammatory cells.

☐☐☐ **%** (001-100%) [13]

13. Record the likelihood of metastases from a NON-lung primary neoplasm in the Target (ROI). [14]

☐ None
☐ Unlikely
☐ Probable
☐ Can't determine

TA

ACRIN 6654 NLST
Colorado Target (Region of Interest) Annotation

If this is a revised or corrected form, please √ box. ☐

ACRIN Study **6654**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Section 2 - Non-Tumor ROI Annotation (Complete for the NON-Tumor Annotation)

14. Characterize the most representative (predominant) NON-tumor histology in this Target (ROI) [15]

- ☐ 1 Normal lung parenchyma
- ☐ 2 Granuloma
- ☐ 3 Pneumonia
- ☐ 4 Hemorrhage
- ☐ 5 Necrosis
- ☐ 6 Infarction
- ☐ 7 Emphysema
- ☐ 8 Fibrosis
- ☐ 9 Pre-neoplastic tissue (complete Q15)
- ☐ 88 Other, specify _____ [16]

15. Characterize the most representative (predominant) pre-malignant histology observed in this Target (ROI) [17]

- ☐ 1 (8070/2) Squamous carcinoma *in situ*
- ☐ 2 Squamous dysplasia, MILD
- ☐ 3 Squamous dysplasia, MODERATE
- ☐ 4 Squamous dysplasia, SEVERE
- ☐ 5 (AAH) Atypical adenomatous hyperplasia
- ☐ 6 (DIPNECH) Diffuse idiopathic neuroendocrine cell hyperplasia
- ☐ 88 Other, specify _____ [18]

Section 3 - Conclusion

16. Was the data assessed, reviewed and approved by the pathologist? [19]

- ☐ No
- ☐ Yes

COMMENTS: _____

_____

_____

_____ **[20]**

_____ **[21]**
Interpreting Pathologist's initials

_____-_____-_____ **[23]**
Date form completed (mm-dd-yyyy)

_____ **[22]**
Initials of person(s) completing the form

Appendix A: WHO Classification of Tumours of the Lung

Code	Description
	Malignant Epithelial Tumors
8070/3	Squamous cell carcinoma
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8045/3	Combined small cell carcinoma
8140/3	**Adenocarcinoma**
8225/3	Adenocarcinoma, mixed subtype
8550/3	Acinar adenocarcinoma
8260/3	Papillary adenocarcinoma
8269/3	Micropapillary adenocarcinoma
8250/3	Bronchioloalveolar carcinoma
8252/3	Nonmucinous
8253/3	Mucinous
8254/3	Mixed nonmucinous and mucinous *or* indeterminate
8230/3	Solid adenocarcinoma with mucin production
8333/3	Fetal adenocarcinoma
8480/3	Mucinous ("colloid") carcinoma
8470/3	Mucinous cystadenocarcinoma
8490/3	Signet ring adenocarcinoma
8310/3	Clear cell adenocarcinoma
8012/3	**Large cell carcinoma**
8013/3	Large cell neuroendocrine carcinoma
8013/3	Combined large cell Neuroendocrine carcinoma
8123/3	Basaloid carcinoma
8082/3	Lymphoepithelioma-like carcinoma
8310/3	Clear cell carcinoma
8014/3	Large cell carcinoma with rhabdoid phenotype
8560/3	Adenosquamous carcinoma

Code	Description
8033/3	**Sarcomatoid carcinoma**
8022/3	Pleomorphic carcinoma
8032/3	Sindle cell carcinoma
8031/3	Giant cell carcinoma
8980/3	Carcinomsarcoma
8972/3	Pulmonary blastoma
8240/3	**Carcinoid tumor**
8240/3	Typical carcinoid
8249/3	Atypical carcinoid
	Salivary gland tumours
8430/3	Mucoepidermoid carcinoma
8200/3	Adenoid cystic carcinoma
8562/3	Epithelial-myoepithelial carcinoma
	Lymphoproliferative tumours
9699/3	Marginal zone B-cell lymphoma of the MALT type
9680/3	Diffuse large B-cell lymphoma
9766/1	Lymphomatoid granulomatosis
9751/1	Langerhans cell histiocytosis
	Mesenchymal tumours
9133/1	Epithelioid haemangioendothelioma
9120/3	Angiosarcoma
8973/3	Pleuropulmonary blastoma
9220/0	Chondroma
8827/1	Congenital peribronchial myofibroblastic tumour
8825/1	Inflammatory myofibroblastic tumour
9174/1	Lymphangioleiomyomatosis
9040/3	Synovial sarcoma
9041/3	Monophasic
9043/3	Biphasic
8800/3	Pulmonary artery sarcoma
8800/3	Pulmonary vein sarcoma

Appendix A: WHO Classification of Tumours of the Lung

Code	Description
	Benign Epithelial Tumors
	Papillomas
8052/0	Squamous cell papilloma
8052/0	Exophytic
8053/0	Inverted
8260/0	Glandular papilloma
8560/0	Mixed squamous cell and glandular
	Adenomas
8251/0	Alveolar adenoma
8260/0	Papillary adenoma
	Adenomas of the salivary gland type
8140/0	Mucous gland adenoma
8940/0	Pleomorphic adenoma
N/A	Others
8470/0	Mucinous cystadenoma

Code	Description
	Miscellaneous Tumours
	Harmatoma
8832/0	Sclerosing hemangioma
8005/0	Clear cell tumour
	Germ cell tumours
9080/0	Teratoma, mature
9080/3	Immature
N/A	**Other germ cell tumours**
8580/1	Intrapulmonary thymoma
8720/3	Melanoma
	Pre-invasive lesions
8070/2	Squamous carcinoma *in situ*
AAH	Atypical adenomatous hyperplasia
DIPNECH	DIPNECH
Mets	Metastatic tumours

RM

ACRIN NLST 6654
Remnant Tissue Collection Form

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

This form is used to document the collection of all remnant pathologic tissue specimens obtained on NLST participant. Site RA: complete section A, retain copy for study file, mail copy to ACRIN, and send original with specimens to Colorado Specimen Bank. CSB: To track specimens, complete Section B upon receipt of specimens and send copy of RM to ACRIN.

Section A: Remnant Tissue Specimens (completed by research associate)

1. Has the participant signed consent for remnant tissue collection?
- ☐ No
- ☐ Yes (consent must be retained in study case file)

2. Type of remnant tissue submitted: (check all that apply)
- ☐ Frozen tissue, number of samples: |___| (integer 1-5)
- ☐ Paraffin blocks, number of blocks: |___| (integer 1-5)
- ☐ Slides, number of slides: |___|___| (integer 1-10)

3. Specimen Accession Number: |___|___|___|___|

4. Date specimens obtained: |___|___| -|___|___| - 20|___|___| (mm-dd-yyyy)

5. Were specimens processed on the day obtained?
- ☐ No
- ☐ Yes

6. Have all specimens been correctly labeled with the patient's Specimen Accession Number
- ☐ No
- ☐ Yes

7. Date of mailing of specimens to Central Archive: |___|___| -|___|___| - 20|___|___| (mm-dd-yyyy)

_____ |___|___| -|___|___| - 20|___|___| (mm-dd-yyyy)

Person responsible for data (NLST study staff) Date of form completion

Section B: Remnant Tissue Specimen Tracking (completed by Colorado Specimen Bank)

8. Date specimen received at Colorado: |___|___| -|___|___| - 20|___|___|

9. Are the specimen(s) in acceptable condition?
- ☐ No
- ☐ Yes

Comments: _____

_____

Person completing form (Colorado Specimen Bank)

ACRIN NLST 6654 – NF

Place Label Here

Institution _____Institution No. _____

Participant Initials _____ Case No.

Abstraction Worksheet
Positive Screen – No Diagnostic Follow-up Reported

Instructions: Study sites will be provided with a list of positive screen participants with no reported diagnostic follow-up. Investigate each case to confirm, as best as possible, whether or not diagnostic follow-up of the positive screen occurred. Document the results of the investigation using this worksheet and file in the participant's Outcomes Chart. This worksheet must be completed for each positive screen participant with no reported diagnostic follow-up (per the case list), including those on whom follow-up is found to have occurred. CARE Communications will collect this data as part of the abstraction process. **This form is not data entered by site RA.**

Interval Start Date: _____ - _____ - 20_____ (mm-dd-yyyy)

Interval End Date: _____ - _____ - 20_____ (mm-dd-yyyy)

Report whether diagnostic follow-up of the positive screen occurred during this interval (check only one):

a. ☐ **Unable to determine whether diagnostic follow-up occurred**
(This may occur when providers are unknown, participants are lost to follow-up, or NP-level 2 or 3)

b. ☐ **Diagnostic follow-up did occur**
Obtain medical records for requested interval(s) for abstraction. If unable to locate or obtain interval medical records (from any provider / facility), complete the NR Worksheet. CARE abstractors will use the NR worksheet to document the reason records abstraction cannot be performed.

c. ☐ **Diagnostic follow-up did <u>not</u> occur, indicate why (check only one)**
1 ☐ Provider was not aware of screening results or recommendations
2 ☐ Provider was aware of screening results and recommendations but chose not to follow-up
3 ☐ Participant declined to undergo follow-up for primarily financial reasons
4 ☐ Participant declined to undergo follow-up for other reasons (not primarily financial)
5 ☐ Provider and/or radiologist recommended repeat exam in one year / next annual NLST screen
6 ☐ Provider and/or radiologist recommended diagnostic follow-up to be done at future date (outside the expected time interval)
7 ☐ Radiologist did not recommend diagnostic follow-up
8 ☐ Other, specify _____

Identify source of information for above responses (check all that apply):
1 ☐ Provider
2 ☐ Participant
3 ☐ Other, specify _____

_____ Signature of person responsible for data

____ - ____ - 20____ Date worksheet completed (mm-dd-yyyy)

Notes:

ACRIN NLST 6654
Abstraction Worksheet
No Medical Records (NR)

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Complete this worksheet when there is at least one indication for requesting medical records for which no records will be obtained. Place this worksheet in the participant's Outcomes Chart. The abstractors will use this worksheet to document why medical abstraction for the indication cannot be performed. Sites utilizing central abstraction should also mail a copy to CARE Communications. **This worksheet is not data entered by the site RA.**

Interval Start Date: _____ - _____ - 20_____ (mm-dd-yyyy)

Interval End Date: _____ - _____ - 20_____ (mm-dd-yyyy)

Reason medical records are not available / procured for this abstraction interval:

Check the specific indications for which medical records are requested for this interval (this can be obtained from the Abstraction List). If the records relevant to that specific indication are NOT available, record the reason why the records are not available using the **Reason Codes** below. Note: participants may have records requested for more than one indication for the same time interval. For example, medical records may be requested in one interval for both a positive screen and as part of the 5% sample. Records for the positive screen follow-up may be unavailable, while those for the 5% random sample are available. In this instance, record both of the indications for abstraction AND the reason why records relevant to the positive screen are not available.

Indication(s) for Medical Outcomes Collection	Check the applicable indication(s) for records collection request	If absolutely NO records are available for the indication listed, record the reason (Reason Code)
[+] Screen	☐	
5% Sample	☐	
Code 3 Screen	☐	
Lung Cancer	☐	
Other Cancer	☐	
Other (_____)	☐	

Reason Codes:

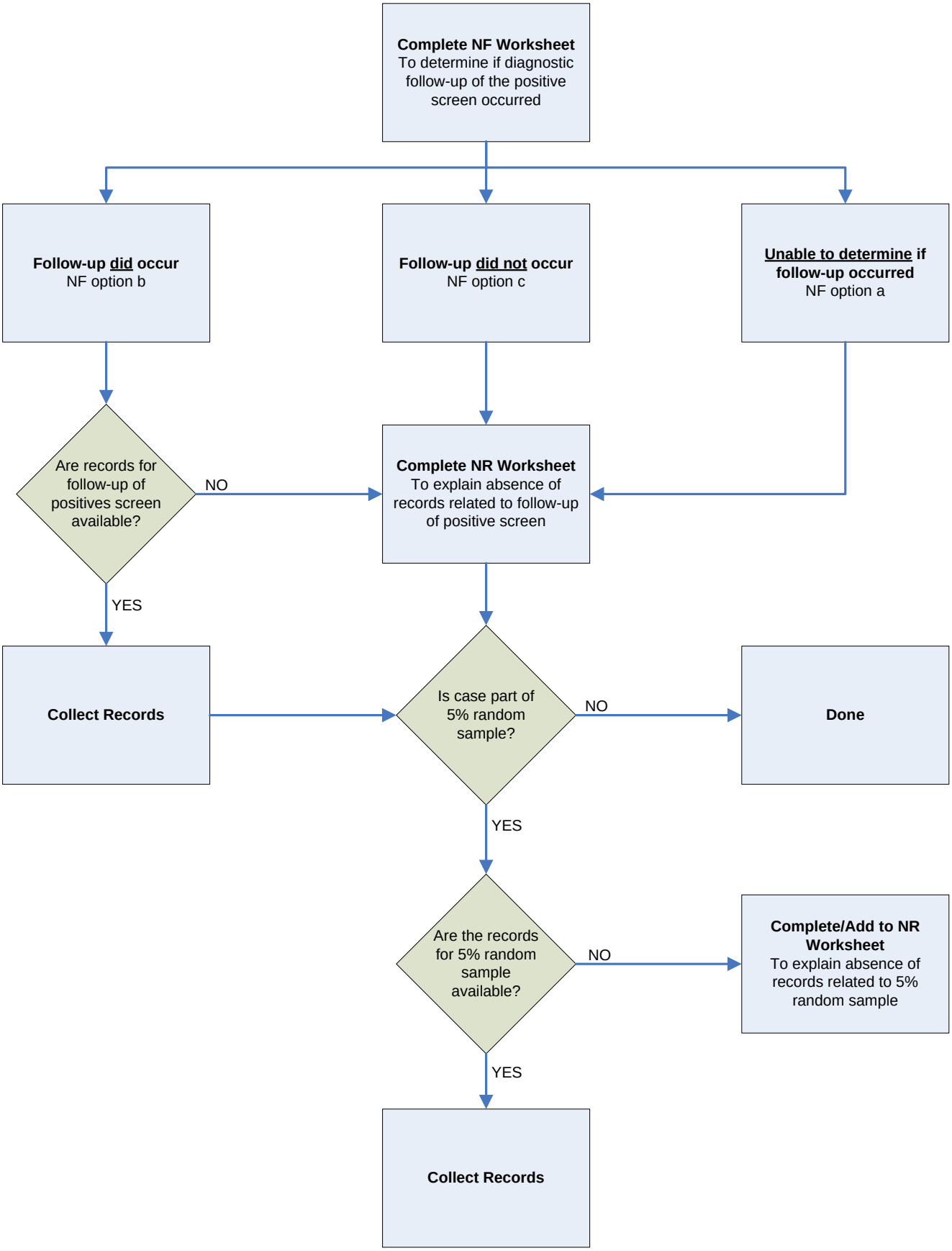
1. **Abstraction for this interval was triggered in error:** For example, this may occur due to [1] a follow-up form reporting, in error, a lung-related visit or procedure; [2] a data entry error on a screening form reporting a negative screen as a positive screen (submit the data entry correction to data management); [3] CC Form submitted in error.
2. **Participant withdrew consent for records collection**
3. **Records request refused by provider / facility:** Attempts should be made to meet provider / facility requirements to obtain records, including educating provider / facility of HIPAA regulations regarding research participants. Sites can contact CARE or ACRIN for assistance, if needed.
4. **Provider(s) or provider contact information unknown:** The participant did not withdraw consent for records collection but provider(s) is unknown and site is unable to contact participant for provider information; this may occur when a participant is lost to follow-up or NP-level 2 or 3. Unknown provider contact information may occur when sites are unable to contact participant for additional provider information or provider cannot be located using local resources or participant was re-contacted and is unable to give adequate information to locate the provider.
5. **No records to obtain:** Site RA has verified that no medical care occurred during this interval
6. **Other, specify:** _____

_____ Signature of person responsible for data

____ - ____ - 20____ Date worksheet completed (mm-dd-yyyy)

Notes:
.

ACRIN NLST 6654 -- Positive Screen Participants With No Reported Diagnostic Follow-Up



Procedures to be Followed in Reporting Follow-up of Positive Screening Exams:

Investigate case:

- Review interval F1/F2 (if completed) to confirm the participant did not report diagnostic follow-up.
- Review study chart / case notes which may document information relevant to diagnostic follow-up.
- If no F1/F2 was completed for the given interval, contact the participant.
- Contact participant's PCP and the provider to whom the Results Letter was sent (if different than PCP).

[a] If participants specified that their provider could not be sent the NLST Results Letters, follow local IRB guidelines with respect to contacting providers. Recommendations: (1) Contact provider if this is consistent with local IRB guidelines -OR- (2) contact participant to obtain permission to contact local provider -OR- (3) contact participant to CONFIRM that no follow-up of any kind was performed.

[b] If abstraction determines that the reported follow-up care was performed for clinical reasons and NOT as follow-up of the positive screen, a data correction for the NF Worksheet will be triggered.

[c] If participant was chosen as part of the 5% sample, attempt to collect medical records from all known providers.

Frequently Asked Questions Regarding the NF/NR Process

1. The participant listed on the NF list has received follow-up of his positive test, but the follow-up o occurred right after the screening exam. I have already obtained these medical records, and the interval has been abstracted. The interval on this list follows the interval in which the positive follow-up occurred.

According to our criteria for following up a positive screening examination, we require that we continue to follow a participant until:

- A definitive diagnosis is reached
- The next screening examination
- If there is no subsequent screening examination, two years from the positive screening result

In order to accurately report all follow-up care, we need to confirm that no care occurred during this entire time interval. In order to help us do this, we ask that RAs complete the NF and NR forms for these cases in the following manner to tell us that no care occurred during this (requested) interval.

- NF Form, option "C" number "8 Other Specify." In the blank space, please write, follow-up care occurred in another time interval.
- NR Form, check the box next to [+] screen, place code "5" in the column to indicate that there are "no records to obtain," for this interval.

2. Some of these intervals are really short.

As indicated above, we are responsible for reporting all follow-up care. Short intervals are on this list so that site RAs can confirm that no care occurred during these intervals. If no care occurred during these intervals, but follow-up care occurred during another interval, please complete the NF and NR as follows:

- NF Form, option "C" number "8 Other Specify." In the blank space, please write: follow-up care occurred in another time interval.
- NR Form, check the box next to [+] screen, place code "5" in the column to indicate that there are "no records to obtain," for this interval.

3. One of our participants has a very long interval that covers more than one screening test for which the results were positive. How do I indicate that the participant had follow-up for the T0 screen, but not for the T1 screen?

Fortunately, this situation occurs only rarely. For this case, a separate NF and NR should be completed for each screening examination. Write the screening examination for which the information is relevant (T0, T1, T2) on the forms next to the interval dates. Then complete the forms for each screening exam. The abstractors will be able to abstract the information correctly onto the laptop system.

4. The participant had a chest x-ray because he was hospitalized for pneumonia, does this count as follow-up of the positive screening exam?

If the participant was selected for abstraction as part of the 5% random sample, then records related to this chest x-ray should be collected and provided to the medical records abstractors. If not, then, because this imaging was not done to follow-up the positive screen, these records should not be obtained.

5. I have located medical records for care related to a positive screening examination that occurred outside of an interval requested for abstraction.

Please contact Ilana at igareen@stat.brown.edu to discuss these situations so that we can ensure that we don't miss triggering these records in the future. You should also provide these records to Care Communications abstractors for abstraction. We want to ensure that all care that has been obtained is abstracted.

FL ACRIN NLST 6654

Follow-up to Positive Screen With No Reported F/U

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please √box. ☐

Instructions: Please complete this form based on best knowledge of medical care obtained following a positive screening result. Assessment for follow-up should continue until next scheduled NLST screen or for up to 12 months from the [+] screen. If follow-up occurred, record the name(s) of the provider(s) on the Provider Summary ID sheet. All dates should be reported as mm-dd-yyyy. This paper form is completed by the Site and faxed (215-717-0936) or mailed directly to ACRIN Data Management for data entry. The form is **NOT** web entered.

1. **Screening:** ☐ **T0** ☐ **T1** ☐ **T2** (check only one) [1]

2. **Date of Exam:** _____ - _____ - 20_____ (mm-dd-yyyy) [2]

3. **Source of information for completion of FL Form** (check all that apply)

   - ☐ NLST chart notes [3]
   - ☐ Medical records [4]
   - ☐ Primary care provider [5]
   - ☐ Other provider(s) [6]
   - ☐ Participant [7]
   - ☐ Representative for participant (participant unable to provide information) [8]
   - ☐ Other source: [9] _____ [10]
   - ☐ No information available [11]

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 screen was at T2, was there any diagnostic follow-up within 12 months of the positive screen?** [12]

   - ☐ No
   - ☐ Yes (Skip Q5, request medical records from appropriate provider(s) on the provider summary ID sheet for medical chart abstraction)
   - ☐ Unable to determine (Skip Q5)

5. **Reason why diagnostic follow-up of the positive screen did not occur:** (check only one) [13]

   - ☐ Provider was not aware of screening results or recommendations
   - ☐ Provider was aware of screening results and recommendations but advised no follow-up
   - ☐ Participant declined to undergo follow-up for primarily financial reasons
   - ☐ Participant declined to undergo follow-up for other reasons (not primarily financial)
   - ☐ Provider recommended repeat exam in one year / next annual NLST screen
   - ☐ Provider recommended diagnostic follow-up to be done at future date (outside the expected time interval)
   - ☐ Unable to determine
   - ☐ Other, specify _____ [14]

_____ [15]
Signature of person responsible for data

_____ - _____ - 20_____ (mm-dd-yyyy) [16]
Date form completed

FL COMPLETION INSTRUCTIONS

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 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 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 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).

FL COMPLETION INSTRUCTIONS

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.

FL COMPLETION INSTRUCTIONS

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).

FL COMPLETION INSTRUCTIONS

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).

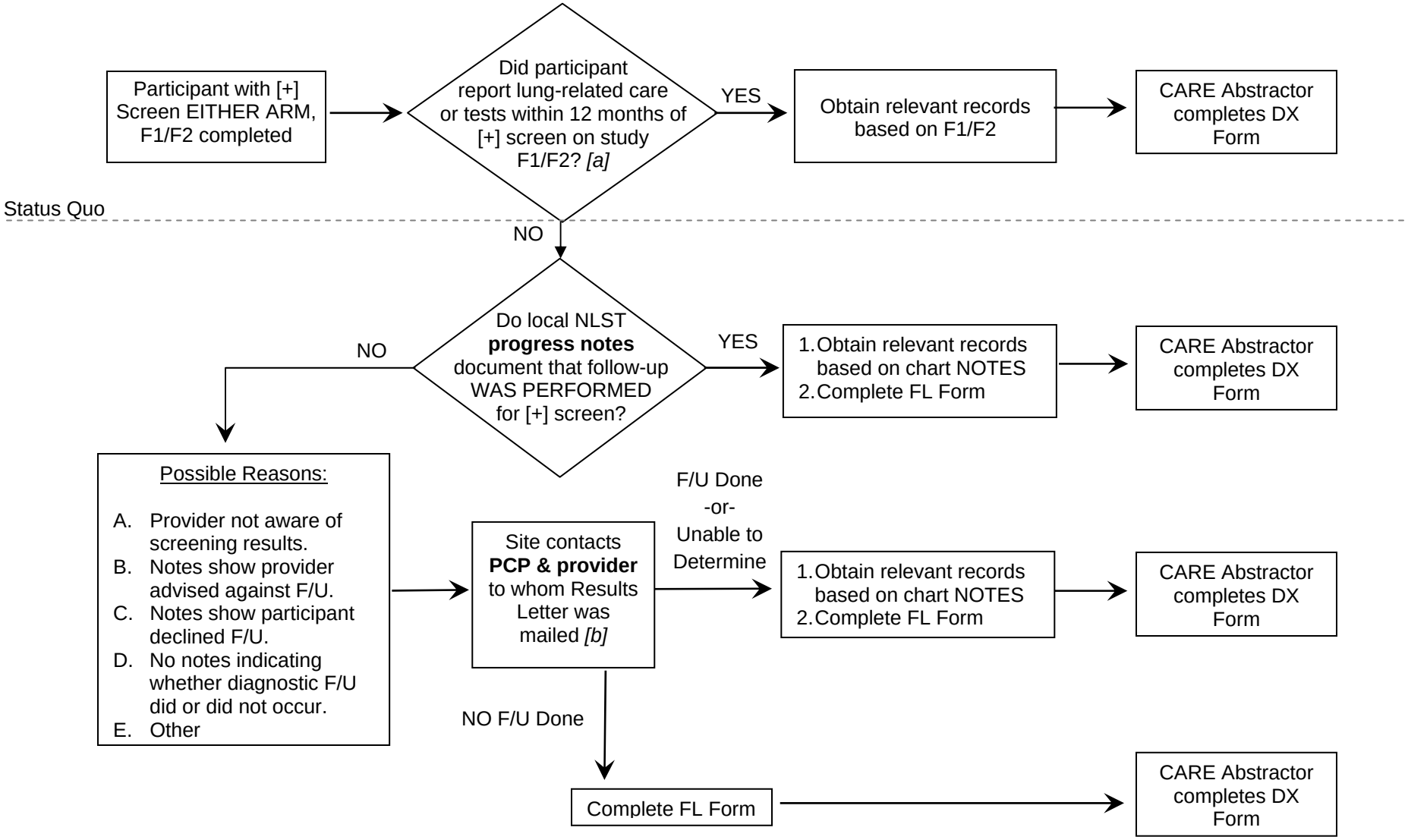
7 Unable to determine: Check this response if the FL investigation yields no explicit information as to why diagnostic follow-up was not performed. For example, [a] you were unable to contact the provider (due to waiver or no provider identified by participant) or [b] lack of documentation as to 'why'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

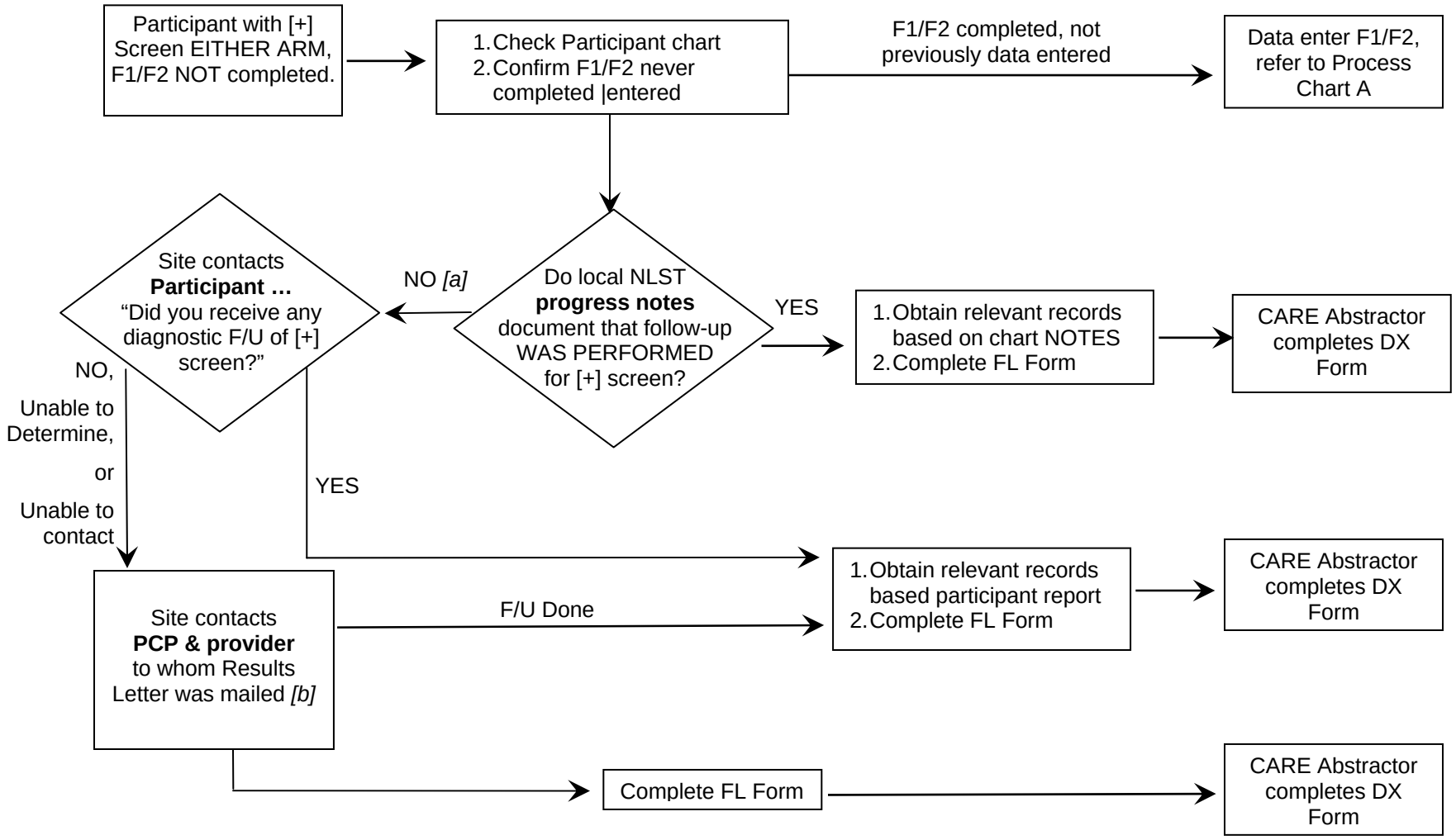
Date of form completion: Record the date the original CRF was completed (data recorded); record date as month, day, and year (mm-dd-yyyy).

A. Positive Screen Participants With No Documented Diagnostic Follow-Up (F1/F2 completed)



[a] Per established abstraction triggers, refer to Medical Records Selection document.
[b] If participants specified that their provider could not be sent the NLST Results Letters, follow local IRB guidelines with respect to contacting providers. Recommendations: (1) Contact provider if this is consistent with local IRB guidelines -OR- (2) contact participant to obtain permission to contact local provider -OR- (3) contact participant to CONFIRM that no follow-up of any kind was performed.

B. Positive Screen Participants With No Documented Diagnostic Follow-Up (F1/F2 not completed)



[a] Possible reasons: (1) Provider not aware of screening results; (2) Notes show provider advised against F/U; (3) Notes show participant declined F/U; (4) No notes indicating whether diagnostic F/U did or did not occur; (5) Other.

[b] If participants specified that their provider could not be sent the NLST Results Letters, follow local IRB guidelines with respect to contacting providers. Recommendations: (1) Contact provider if this is consistent with local IRB guidelines -OR- (2) obtain permission from participant to contact local provider.

8-29-06

ND

ACRIN 6654
NLST
National Death Index Results Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: Complete this form for all participants who met the NDI search request criteria as stated below.

NDI Search request criteria: The NDI will be used for known decedents on whom you were unable to obtain/locate a death certificate (after all local search possibilities were exhausted) or participants lost to follow-up (for 18 consecutive months).

1. Was the NDI used for the above criteria? [1]

- ☐ 1 No (go to Q1a, then sign and date form)
- ☐ 2 Yes (go to Q2)

1a. Reason why the NDI was not used (select the primary reason) [2]

- ☐ 1 Will submit via NDI in the future (example: death date is beyond the current NDI database cut-off)
- ☐ 2 Per local IRB mandate
- ☐ 3 Participant, next of kin, or family decision (per source records)
- ☐ 88 Other, specify _____ [3]

2. The NDI search results review was completed on ____-____-____ *(mm-dd-yyyy)* [4]

3. Indicate the results of the NDI search for this participant: [5]

- ☐ 1 Exact match (go to Q4)
- ☐ 2 Probable match (go to Q4)
- ☐ 3 No match (go to Q6)
- ☐ 4 Rejected (go to Q6)

4. Will you be requesting a Death Certificate? [6]

- ☐ 1 No (enter reason in comments)
- ☐ 2 Yes

5. Record results of NDI search:

Underlying cause of death: ICD-10 ☐☐☐☐☐ [7] Check if ICD-10 code is unknown ☐ [8]

Year of death ☐☐☐☐ [9] State of death ☐☐ [10]

6. NDI results completed by (Initials): _____ [11]

7. Initials of person who performed QC: _____ [12]

Comments: _____

_____ [13]

_____ [14], [15], [16], [17]

_____ [18]
Form completed by

____-____-____ [19]
Date Form Completed (mm-dd-yyyy)

ND Completion Instructions

The National Death Index Results Form should be completed for all cases that meet the NDI search request criteria.

Please refer to the "NDI Results Instructions" to assist in the interpretation of the NDI search output.

NDI search request criteria: The NDI will be used for known decedents on whom you were unable to obtain/locate a death certificate (after all local search possibilities were exhausted) or participants lost to follow-up (for 18 consecutive months as documented on an F2 coversheet).

1. Was the NDI used for the above criteria: Answer whether or not the NDI was used to search for the case.

If an NDI search was **not** performed, complete question 1a then sign and date the form.

Some examples of cases that met the NDI search request criteria but were not submitted through the NDI search are:

- ⇒ Known deaths where a death certificate could not be obtained after all local search possibilities were exhausted but did not go through the NDI search for reasons such as IRB mandate, participant or next of kin decision, or deaths that occurred after the NDI database cut-off date.
- ⇒ Lost to follow-up cases that could not be submitted through the NDI search for reasons such as IRB mandate, participant or next of kin decision (as documented on NP form), or last known alive date is after the NDI database cut-off date.

If the NDI search was used, go to question 2.

1a. Reason why the NDI was not used (Select the Primary Reason):

Select the most applicable reason why information was not submitted to the NDI to run a search. Reasons could be:

Will submit via NDI in the future. This option may be selected for cases where a known death occurred after the NDI database cut-off date (i.e. death records are added to the NDI file annually, approximately 12 months after the end of a particular calendar year – on December 31, 2007 deaths that occurred on or before December 31, 2005 will be listed in the NDI file). This option can be selected for lost to follow-up cases that could not be submitted to the NDI because the date last known alive follows the NDI database cut-off date.

Per local IRB mandate. This option may be marked for cases where there has not been IRB approval from the site IRB to run NDI searches on any participant enrolled at that site.

Participant, next of kin, or family decision (per source records). This option will be chosen for cases where a participant, next of kin, or family member refused the NDI search as noted in the participant 's source records.

Other, specify. Chose the "Other" option only if any of the above reasons are not applicable, then specify the reason why the NDI was not searched.

2. The NDI search results review was completed on: Provide the date of the current review of the NDI output**.**

3. Indicate the results of the NDI search for this participant (as determined by the site RA, using the NDI Results Instructions):

Exact Match: for records that produced an exact match from the NDI

Probable Match: for records that produced a probable match (as determined by the site RA, using the probable match criteria found in the NDI Results Instructions)

No Match: for records that did not produce a match from the NDI **OR** records that produced a possible match (as indicated on the Retrieval Report) but were not found to be a probable match

Rejected: for records that were submitted to the NDI; however, failed to satisfy the basic criteria of the NDI edit program and were rejected prior to the NDI database search (as identified on the Rejected File from the NDI output)

4. **Will you be requesting a Death Certificate?:** Select Yes or No as to whether you will be requesting a death certificate for a record that produced an exact or probable match. If "No" is chosen, enter a reason in the comments field.

5. **Record results of NDI search:**

   Provide the **ICD-10 code** for the cause of death (as found on the PRT cause file from the NDI output). The underlying cause of death may not have been provided by the NDI for reasons such as: specific states do not allow for the release of ICD-10 codes through the NDI or if more than one possible match is provided by the NDI only the highest ranked match will have a cause of death code. If the cause of death code is not supplied, check the **"Unknown"** box.

   Provide the **Year** in which the death occurred for the match.

   Provide the **State** in which the death occurred for the match.

6. **NDI results completed by:** The initials of the first reviewer should be provided here.

7. **Initials of person who performed QC:** The initials of the second reviewer will be provided here.

Form completed by: Legible signature of staff member web entering the data from this form

Date Form Completed: Date the form was completed (mm-dd-yyyy)

Endpoint Verification Process

ACRIN 6654– NLST Death Certificate Transmittal Log
Please complete this transmittal log for the death certificates that are currently being shipped. Please keep a copy of this log at the Study Site for your records and include a copy of the log in the shipment. Ship death certificates and the Transmittal Log to:
ACRIN EVP Coordinator American College of Radiology 1818 Market Street, Suite 1600 Philadelphia, PA 19103
Study Site #
Study Coordinator Name:
Date sent to ACRIN EVP Coordinator: _____ - _____ - **20** _____
Shipping Tracking Number:

ACRIN Case #
1.
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.
13.
14.
15.

DD

ACRIN 6654 - NLST
Death Documentation Worksheet - EVP

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part A. EVP Documentation

1. Participant date of death: _____ - _____ - 20_____

2. Data Management Tasks: (check each step as it is completed/confirmed)

- ☐ Participant death reported to ACRIN via Follow-up Coversheet
- ☐ All data forms due prior to date of death submitted to ACRIN or suppressed by PR/GCM (as appropriate)
- ☐ Death certificate submitted to ACRIN
- ☐ All outside reports of cancer documented on CC and submitted to ACRIN
- ☐ Medical records collected on all reported cancers (F1, F2, CC) for cancer confirmation and abstraction (DE)

3. Was this case selected for EVT review?

- ☐ No (end)
- ☐ Yes (complete Parts B and C)

Part B. Medical Documentation

	Document Type	Requested (√)	Received (√)	NA (√)	Comments
1.	Terminal events (Death Summary)				
2.	Hospital Admission History/Physical				
3.	Operative Procedures Reports				
4.	Pathology Reports				
5.	Chemotherapy Notes				
6.	Radiotherapy Notes				
7.	Management of co-existing cancers				
8.	Hospital Discharge Abstracts				
9.	Hospital Discharge Summary				
10.	Diagnostic Procedure Reports				
11.	Diagnostic Imaging Reports				
12.	Outpatient Notes				
13.	Autopsy Reports				
14.	Clinical Laboratory Data				
15.	Consultation Reports				
16.	Emergency Medicine Documents				
17.	Other Diagnostic Documents				
18.	Other Treatment Documents				

DD

ACRIN 6654 - NLST
Death Documentation Worksheet - EVP

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part C. Editing & Shipping EVP Documents

1. Editing of documentation: (check each step as it is completed)

- ☐ Identifiers removed
- ☐ References to ACRIN-NLST removed or NA
- ☐ References to arm (CT/CXR) removed or NA
- ☐ Method of cancer detection removed or NA
- ☐ Each page labeled with case label

2. Medical record documentation complete?

- ☐ No
- ☐ Yes

3. Shipping of materials: (check each step as it is completed)

- ☐ One copy of EVP folder
- ☐ Folders organized
- ☐ EVP Transmittal Log completed

Additional Comments:

ACRIN 6654 – NLST EVP Material Transmittal Log

Please complete this transmittal log documenting the EVP folders that are currently being shipped. Please print and keep a copy of the completed log at the Study Site for your records and include a copy of the log in the package of EVP folders to be shipped to:

ACRIN EVP Coordinator
American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103

Study Site #

Study Coordinator Name:

Date sent to ACRIN EVP Coordinator: _____ - _____ - **20** _____

Shipping Tracking Number:

	ACRIN Case #	**Participant Initials**
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

PL

ACRIN 6654 - NLST
Pathology Transmittal Log

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part A: Tracking
Study Coordinator Name:
Date slides sent: _____ - _____ - 20_____
Shipping Tracking Number:

Part B: Pathology Slide Information				
	Institution	Anatomic Location	Slide Number(s)	Return Requested? (Y/N)
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
Comments:				

HM

ACRIN 6654 - NLST
History of Malignancy Form - EVP

To: Dr.	Date: _____ - _____ - **20**_____
Re:	SSN:
Participant's Address:	
Date of Birth: _____ - _____ - **20**_____	Date of Death: _____ - _____ - **20**_____

Please answer the following questions regarding this patient. Check only one box, unless otherwise instructed.

1. On what date did you last see this patient? _____ - _____ - 20 _____

2. During which years was this patient seen at your facility? 19 _____ to 20 _____

3. Have you ever diagnosed cancer in this patient?

☐ No (go to question 4)
☐ Yes (complete 3a-c)*

a. On what date did you first make the diagnosis? _____ - _____ - 20 _____

b. At what institution(s) were the diagnostic tests performed?

1. Hospital/Clinic/Physician Office: _____

Address: _____

2. Hospital/Clinic/Physician Office: _____

Address: _____

c. Was it possible to determine the organ within which the tumor arose (primary site)?

☐ No
☐ Yes (site of cancer: _____)

**If more than one cancer diagnosis, provide this same information for the additional cancer(s) on the back of this form.*

4. If you have not diagnosed a malignancy in this patient, are you aware of a diagnosis of cancer made by another physician, health care provider, or health care clinic caring for your patient?

☐ No (end)
☐ Yes (site & type of cancer: _____)

a. Diagnosing physician, health care provider, or health care clinic's name and address:

1. Name: _____

Address:

Form Completed By:

Signature:	
Print Name:	Date Completed: _____ - _____ - 20 _____

Abstraction Forms

ZD ACRIN NLST 6654 Summary Sheet

ACRIN Study 6654 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

If this is a revised or corrected form, please √box. ☐

F1/F2 Interval: __ __ - __ __ - **20** __ __ [1] to __ __ - __ __ - **20** __ __ [2] (mm-dd-yy)

This interval has been replaced by another interval and therefore should be ignored [60]

☐ 1 No
☐ 2 Yes (complete replacement interval dates)

Start date of replacement 1 _____-_____-20_____ [61]

Stop date of replacement 1 _____-_____-20_____ [62]

Start date of replacement 2 _____-_____-20_____ [63]

Stop date of replacement 2 _____-_____-20_____ [64]

Section A: Reason for Chart Abstraction

1. Are there corrected ZD interval dates? [14]

☐ 1 No (skip to Q2)
☐ 2 Yes (change interval start date)
☐ 3 Yes (change interval end date)
☐ 4 Yes (change both interval dates)

1a. New/Corrected ZD start date: _____-_____-20_____ [15]

New/Corrected ZD end date: _____-_____-20_____ [16]

2. Reason for medical records abstraction *(check only one)* [17]

☐ 1 Abstraction List (Standard or NF)
☐ 2 CC
☐ 3 EVP
☐ 88 Other, specify: _____ [18]

3. Was the interval requested to obtain follow-up on one or more positive screens? [19]

☐ 1 No (Skip to Section C)
☐ 2 Yes (Complete Section B)

ZD

ACRIN NLST 6654
Summary Sheet

If this is a revised or corrected form, please √box. ☐

ACRIN Study **6654** Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Section B: NF Data

Instructions: The Abstractor will use information from the NF form(s) provided by the site RA for this interval, as well as the abstraction indication(s) noted on the NF list, to complete the following table. If an interval was not requested for a particular screen or if the NF form is not available for a particular screen, leave the row blank. For Columns A and B, please refer to the relevant reason code table below.

Positive Screen	A. Report whether diagnostic follow-up care of the positive screen occurred	B. Indicate why diagnostic follow-up did not occur	C. Identify source of information for responses 1 Provider 2 Participant 88 Other, specify _____
T0 +	_____ [20]	____ [21] _____ [22]	____ [23] _____ [24]
T1 +	_____ [25]	____ [26] _____ [27]	____ [28] _____ [29]
T2 +	_____ [30]	____ [31] _____ [32]	____ [33] _____ [34]

A. Report whether diagnostic follow-up of the positive screen occurred during this interval *(choose only one)*

1 Unable to determine whether diagnostic follow-up occurred (Skip to Column C)
2 Diagnostic Follow-up did occur (Skip to Column C)
3 Diagnostic follow-up did not occur (Complete Column B)

B. Diagnostic follow-up did <u>not</u> occur, indicate why *(choose only one)*

1 Provider was not aware of screening results or recommendations
2 Provider was aware of screening results and recommendations but chose not to follow-up
3 Participant declined to undergo follow-up for primarily financial reasons
4 Participant declined to undergo follow-up for other reasons (not primarily financial)
5 Provider and/or radiologist recommended repeat exam in one year / next annual NLST screen
6 Provider and/or radiologist recommended diagnostic follow-up to be done at future date (outside the expected time interval)
7 Radiologist did not recommend diagnostic follow-up
88 Other, specify: _____

ZD

ACRIN NLST 6654
Summary Sheet

If this is a revised or corrected form, please √box. ☐

ACRIN Study **6654** Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Section C: Availability of Records

4. Were medical records available? [3]

- ☐ 1 No (Skip to and complete Section D, then sign and date form)
- ☐ 2 Yes (Retired - kept for historical purposes)
- ☐ 3 Yes (Records available for all indications)
- ☐ 4 Yes (Some records available, but not for all indications) (Complete Q5, and Section D)

5. Were the medical records complete? [4]

- ☐ 1 No (Retired - kept for historical purposes)
- ☐ 2 Yes
- ☐ 3 No (Care gave site an MRR)
- ☐ 4 No (Site verified unable to obtain some records)

Section D: NR Data

Instructions: The Abstractor will use information from the NR form(s), as well as the abstraction indication(s) on the abstraction list, to complete the following table. If the interval was not requested for a particular indication then leave the row blank. For Column B, please refer to the relevant reason code table below.

Indication(s) for Medical Outcomes Collection	A. Check the applicable indication(s) for records collection request	B. If absolutely NO records are available for the indication listed, record the reason
T0 [+] screen	☐ [35]	___ [36] _____ [37]
T1 [+] screen	☐ [38]	___ [39] _____ [40]
T2 [+] screen	☐ [41]	___ [42] _____ [43]
5% Sample	☐ [44]	___ [45] _____ [46]
Code 3 screen	☐ [47]	___ [48] _____ [49]
Lung cancer	☐ [50]	___ [51] _____ [52]
Other cancer	☐ [53]	___ [54] _____ [55]
Other, specify _____ [59]	☐ [56]	___ [57] _____ [58]

Reason Codes for Column B:

1 Abstraction for this interval was triggered in error
2 Participant withdrew consent for records retention
3 Records request refused by provider / facility
4 Provider(s) or provider contact information unknown
5 No Records to Obtain
88 Other, specify: _____

ZD

ACRIN NLST 6654
Summary Sheet

If this is a revised or corrected form, please √ box. ☐

ACRIN Study **6654** Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant's Initials _____ **Case No.** _____

Section E: Summary of Chart Abstraction Data

6. Were there Outpatient Provider visits during this time interval? [5]

- ☐ 1 No
- ☐ 2 Yes (Records Complete)
- ☐ 3 Yes (Records Incomplete)
- ☐ 4 Yes (Records can not be obtained)

7. Were there Emergency Room visits during this time interval? [6]

- ☐ 1 No
- ☐ 2 Yes (Records Complete)
- ☐ 3 Yes (Records Incomplete)
- ☐ 4 Yes (Records can not be obtained)

8. Were there Hospitalizations during this time interval? [7]

- ☐ 1 No
- ☐ 2 Yes (Records Complete)
- ☐ 3 Yes (Records Incomplete)
- ☐ 4 Yes (Records can not be obtained)

9. Were cytology or pathology samples collected during this time interval? [8]

- ☐ 1 No
- ☐ 2 Yes (Records Complete)
- ☐ 3 Yes (Records Incomplete)
- ☐ 4 Yes (Records can not be obtained)

10. Was this participant diagnosed with a Primary Lung Cancer during this time interval? [9]

- ☐ 1 No
- ☐ 2 Yes (Records Complete)
- ☐ 3 Yes (Records Incomplete)
- ☐ 4 Yes (Records can not be obtained)

COMMENTS: _____ **[10]**

_____ **[11]**

_____ **[12]**
Abstractor ID

_____-_____-_____ **[13]**
Date form completed (mm-dd-yyyy)

_____
Abstractor signature

ZX ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

F1/F2 Interval: __-__-20__ to __-__-20__ *(mm-dd-20yy)*

1. Did the participant undergo diagnostic procedures?
- ☐ 1 No, medical records/physician report (Go to Q6)
- ☐ 2 No, participant self report (go to Q6)
- ☐ 3 No, medical records incomplete (go to Q6)
- ☐ 4 Yes

2. What was the reason for the initial visit for diagnostic evaluation? (mark all that apply)
- ☐ 1 Participant was symptomatic
- ☐ 2 Follow-up of a positive NLST screen: ☐ T0 ☐ T1 ☐ T2
- ☐ 3 Other, specify: _____

3. Diagnostic Evaluation Procedures: Enter all diagnostic procedures performed. For each procedure, enter the date of procedure and procedure code (see Procedure Code, Table 1, page 5). Do NOT record the T0, T1, or T2 NLST screening examinations as part of diagnostic evaluation.

Procedure #	Date of Procedure		Type of Procedure (Table 1, page 5)
1	____-____-20____	_____	Other, specify:
2	____-____-20____	_____	Other, specify:
3	____-____-20____	_____	Other, specify:
4	____-____-20____	_____	Other, specify:
5	____-____-20____	_____	Other, specify:
6	____-____-20____	_____	Other, specify:
7	____-____-20____	_____	Other, specify:
8	____-____-20____	_____	Other, specify:
9	____-____-20____	_____	Other, specify:
10	____-____-20____	_____	Other, specify:
11	____-____-20____	_____	Other, specify:
12	____-____-20____	_____	Other, specify:
13	____-____-20____	_____	Other, specify:
14	____-____-20____	_____	Other, specify:
15	____-____-20____	_____	Other, specify:

ZX ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

4. Were there any medical complications as a result of diagnostic evaluation and staging?

- ☐ 1 No (go to Q6)
- ☐ 2 Yes (complete Table 5 below)
- ☐ 3 Unknown

5. Table of Complications From Diagnostic Evaluation (use Complication Codes provided, Table 2, page 5)

Complication#	Date of Complication	Type of Complication (Table 2, page 5 - Complication Codes)	Related Diagnostic / Staging Procedure (Table 1, page 5 - Procedure Codes)
1	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
2	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
3	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
4	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
5	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
6	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
7	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
8	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
9	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:
10	____ - ____ - 20____	_____ Other, specify:	_____ Other, specify:

ZX ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

6. Result of Diagnostic Evaluation for Primary Lung Cancer

Please record the diagnosis resulting from the diagnostic procedures recorded above. List only one diagnosis.

- ☐ No malignancy, confirmed by histology or cytology
- ☐ No malignancy, confirmed by clinical evaluation only - no pathologic proof
- ☐ Primary lung malignancy, confirmed by histology
- ☐ Primary lung malignancy, confirmed by cytology
- ☐ Primary lung malignancy, diagnosed by clinical evaluation only - no pathologic proof
- ☐ Malignancy other than primary lung cancer, with or without lung metastases, confirmed by histology or cytology
- ☐ Malignancy other than primary lung cancer, with or without lung metastases, diagnosed by clinical evaluation only - no pathologic proof
- ☐ Diffuse idiopathic pulmonary neuroendocrine hyperplasia
- ☐ Neoplasm of uncertain behavior
- ☐ Carcinoma in situ
- ☐ Squamous dysplasia
- ☐ Atypical adenomatous hyperplasia
- ☐ Further follow-up required (please clarify in Q8: Comments)
- ☐ No information available (please clarify in Q8: Comments)

7. Date of Primary Lung Cancer Diagnosis _____ - _____ -20_____ (mm-dd-yyyy)

Diagnosis Information For Any Condition Other Than Primary Lung Cancer

8.	**Non-Cancer Diagnosis**	☐ **No** ☐ **Yes**		
	ICD-9-CM Classification:	**Date of Diagnosis: ____ - ____ - 20____**	**ICD-9-CM Classification:**	**Date of Diagnosis: ____ - ____ - 20____**

ZX ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

9. Comments Section: _____

_____

_____

_____

Is an additional ZX Form required to complete the abstraction of this F1/F2 interval?

- ☐ 1 No
- ☐ 2 Yes

Were the medical records required for the ZX Form for this F1/F2 Interval complete?

- ☐ 1 No *(Complete an Additional Records Request)*
- ☐ 2 Yes

☐ **This form was created in error and should be deleted and all information should be ignored**

☑ = marked, ☐ = not marked

Reason for form deletion: *(choose only one)*

- ☐ 01 Query response
- ☐ 02 Data entry error correction
- ☐ 03 Audit QC Finding correction
- ☐ 04 Site revision

_____ Abstractor ID

_____ Abstractor Signature

__ __ - __ __ - 2 0 __ __ (mm-dd-20yy) Date Form Completed

ZX ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

TABLE 1 - PROCEDURE CODES

01 = Biopsy - Endobronchial
04 = Biopsy - Lymph node, scalene/supraclavicular nodes
03 = Biopsy - Lymph node, other **(Specify)**
09 = Biopsy - Open surgical
52 = Biopsy - Percutaneous adrenal
02 = Biopsy - Percutaneous liver
53 = Biopsy - Percutaneous transthoracic yielding histology
50 = Biopsy - Thoracoscopic
10 = Biopsy - Transbronchial
08 = Biopsy - Other **(Specify)**
54 = Bronchoscopy without biopsy or cytology
14 = Clinical evaluation
55 = CT - Abdomen (or liver)
17 = CT - Abdomen and pelvis
18 = CT - Brain
56 = CT - Chest, plus contrast-enhanced nodule densitometry
57= CT - Diagnostic chest
23 = CT - Chest, limited thin section of nodule
80 = CT - Low dose screening CT exam
22 = CT - Other **(Specify)**
58 = Cytology - Bronchoscopic
59 = Cytology - Percutaneous transthoracic
25 = Cytology - Sputum
60 = Cytology - Other **(Specify)**
61 = Echocardiography
27 = Fluoroscopy
29 = Lymphadenectomy/lymph node sampling
30 = Mediastinoscopy/Mediastinotomy
62 = MRI - Abdomen (or liver)
31 = MRI - Bone
32 = MRI - Brain
33 = MRI - Chest
35 = MRI - Other **(Specify)**
39 = Pulmonary function tests/spirometry
11 = Radiograph - Bone
13 = Radiograph - Chest
15 = Radiograph - Comparison with historical images
37 = Radiograph - Other **(Specify)**
40 = Radionuclide scan - Bone
41 = Radionuclide scan - Brain
63 = Radionuclide scan - FDG-PET scan
68 = Radionuclide scan - Fusion PET/CT scan
64 = Radionuclide scan - Gallium
42 = Radionuclide scan - Liver
65 = Radionuclide scan - Somatostatin receptor
66 = Radionuclide scan - Ventilation/perfusion lung
67 = Radionuclide scan - Other **(Specify)**
43 = Resection
47 = Thoracentesis
49 = Thoracoscopy
46 = Thoracotomy
70 = CT-Chest limited thin section of entire lung
71 = CT-Chest and abdomen
72 = CT-Chest, abdomen, and pelvis
48 = Ultrasound **(Specify)**
36 = Other **(Specify)**
99 = Unknown

TABLE 2 - COMPLICATION CODES

01 = Acute respiratory failure
02 = Allergic reaction
03 = Anaphylaxis
05 = Blood loss requiring transfusion
06 = Bronchopulmonary fistula
29 = Bronchial stump leak requiring tube thoracostomy or other drainage for >4 days
07 = Bronchospasms
08 = Cardiac arrest
09 = Cardiac arrhythmia requiring medical intervention
10 = Cerebral vascular accident (CVA)/stroke
11 = Congestive heart failure (CHF)
12 = Death
30 = Empyema
14 = Fever requiring antibiotics
37 = Infection requiring antibiotics
16 = Hemothorax requiring tube placement
17 = Hospitalization post procedure
31 = Injury to vital organ or vessel
21 = Myocardial Infarction
22 = Pain requiring referral to a pain specialist
23 = Pneumothorax requiring tube placement
32 = Prolonged mechanical ventilation over 48 hours post-operatively
25 = Respiratory arrest
26 = Rib fracture (s)
33 = Thromboembolic complications requiring intervention
34 = Vaso-vagal reaction
27 = Vocal cord immobilitiy/paralysis
28 = Wound dehiscence
36 = Wound infection
35 = Other **(Specify)**
99 = Unknown

ZE ACRIN NLST 6654
Emergency Room Visits

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

F1/F2 Interval: __-__-20__ to __-__-20__ *(mm-dd-20yy)*

Facility Code: _____ **ER Admission Date:** __-__-20__ *(mm-dd-20yy)*

ICD-9-CM Reason for ER Visit										
ICD-9-CM Pre-existing (Comorbid)Conditions										
ICD-9-CM Discharge DX and Complication										
CPT Procedure Codes										
CPT Procedure Codes										

☐ More Codes
☐ More Visits
☐ No More Visits

☐ **This form was created in error and should be deleted and all information should be ignored**
☑ = marked, ☐ = not marked

Reason for form deletion: *(choose only one)*
- ☐ 01 Query response
- ☐ 02 Data entry error correction
- ☐ 03 Audit QC Finding correction
- ☐ 04 Site revision

Abstractor ID _____

Abstractor Signature _____

Date Form Completed (mm-dd-20yy) __-__-20__

ZH ACRIN NLST 6654 Hospital Admissions

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

F1/F2 Interval: __-__- 20__ **to** __-__- 20__ (mm-dd-20yy)

Facility Code: _____ **# ICU Days:** _____

Admission Date: __-__- 20__ (mm-dd-20yy) **Discharge Date:** __-__- 20__ (mm-dd-20yy)

ICD-9-CM Reason for Hospitalization										
ICD-9-CM Pre-existing Conditions										
ICD-9-CM Discharge DX & Complications										
Date of DX or Complication	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__
ICD-9-CM Procedure Codes										
ICD-9-CM Procedure Codes										
CPT Procedure Codes										
Date of Procedure	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__
CPT Procedure Codes										
Date of Procedure	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__	__ - __ - 20__

☐ More Codes

☐ More Hospital Admissions

☐ No More Hospital Admissions

☐ **This form was created in error and should be deleted and all information should be ignored**

☑ = marked, ☐ = not marked

Reason for form deletion: *(choose only one)*

☐ 01 Query response

☐ 02 Data entry error correction

☐ 03 Audit QC Finding correction

☐ 04 Site revision

Abstractor ID

Abstractor Signature

__-__- 20__ (mm-dd-20yy)

Date Form Completed

ZL

ACRIN NLST 6654
Primary Lung Cancer

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

F1/F2 Interval: __-__-20__ **to** __-__-20__ **(mm-dd-yyyy)**

1. Date of diagnosis: __-__-20__ **(mm-dd-yyyy)**

2. Samples recorded:

	ZP Number	S-Number
1)	_____	_____
2)	_____	_____
3)	_____	_____
4)	_____	_____

(Refer to Form PX, Column 1. In the rare instance of a diagnosis of lung cancer in the absence of any pathologic specimen, record **98 = Not Applicable**)

	Topography	Morphology	Behavior	Grade
2a.	C__.__	____	____	____

2b. Source of samples for ICD-0-3 code:

- ☐ 1 = Cytology
- ☐ 2 = Histology
- ☐ 3 = Combined

2c. Is this a synchronous primary cancer?

- ☐ 1 = No
- ☐ 2 = Yes

2d. If a synchronous primary, please designate this as Cancer A, B, or C ____

3. Primary Lung Cancer Chart

Anatomic Location (s) of Primary Lung Cancer	Maximum Diameter Primary Lesion	Basis of Lesion Size	Sites of Metastases	How Metastases Confirmed?
1 = RUL, **2** = RML, **3** = RLL, **4** = LUL, **5** = Lingula, **6** = LLL, **7** = R Hilum, **8** = L Hilum, **9** = RMSB, **10** = LMSB, **11** = Carina, **12** = Mediastinum, **13** = Other, specify, **99** = Unknown	___ mm **999** = Not available	**1** = Clinical **2** = Pathology **99** = No Size	**0** = No metastases, **1** = Brain, **2** = Pleura, **3** = Lung, not primary site, **4** = Liver, **5** = Adrenal, **6** = Bone, **7** = Other, specify, **99** = Unknown	**0** = None **1** = Clinical **2** = Pathology **3** = Cytology **99** = Unknown
Other, specify:				
Other, specify:			___ Other, specify:	
Other, specify:				
Other, specify:			___ Other, specify:	
Other, specify:				
Other, specify:			___ Other, specify:	
Other, specify:				
Other, specify:			___ Other, specify:	

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

4a. Is there evidence of nodal involvement by primary lung cancer?

☐ 1 No (skip to Q6. Nodal status for staging purposes = N0)

☐ 2 Yes (Complete Q4b and Q4c)

☐ 99 Not available (skip to Q6. Nodal status for staging purposes = NX)

4b. Was nodal involvement documented by clinical means? The following responses apply:

☐ 1 No = There is no documentation of clinical nodal involvement.

(Do not complete Q5 Tables 5A or 5B: Clinical Diagnosis)

☐ 2 Yes = There is documentation of clinical nodal involvement by ATS nodal mapping.

(Complete Table 5A: Clinical Diagnosis)

☐ 3 Yes = There is documentation of clinical nodal involvement by TNM description only.

(Complete Table 5B: Clinical Diagnosis)

4c. Was nodal involvement documented by pathologic means? The following responses apply:

☐ 1 No = There is no documentation of pathologic nodal involvement.

(Do not complete Q5 Tables 5A or 5B: Pathologic Diagnosis)

☐ 2 Yes = There is documentation of pathologic nodal involvement by ATS nodal mapping.

(Complete Table 5A: Pathologic Diagnosis)

☐ 3 Yes = There is documentation of pathologic nodal involvement by TNM description only.

(Complete Table 5B: Pathologic Diagnosis)

ZL **ACRIN NLST 6654**
Primary Lung Cancer

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

5. For each lymph node station, record the presence or absence of involvement by lung cancer based upon both clinical and pathological methods of determination separately. If there is no data to base a determination for a given lymph region, record "99" No data available (# nodes) and "0" (Mode of diagnosis). Complete the tables according to responses provided in Q4B (clinical means) and Q4C (pathological means).

Table 5A
Lymph Node Chain

	Clinical Diagnosis					Pathologic Diagnosis
	# Nodes	**Mode of Diagnosis**				**# Nodes**
	0 = 0 nodes involved **1** = 1 node involved **2** = ≥ 2 nodes involved **3** = Involved nodes; # not known **99** = No data available	**0** = No clinical information **1** = CXR **4** = PET/CT **2** = CT **5** = MRI **3** = PET **6** = Other, specify *Insert codes in the columns below;*			*for Other, specify fill in here*	**0** = 0 nodes involved **1** = 1 node involved **2** = ≥ 2 nodes involved **3** = Involved nodes; # not known **99** = No data available
1 Supraclavicular						
2R Right upper paratracheal						
2L Left upper paratracheal						
3 Prevascular and Retrotracheal						
4R Right lower paratracheal						
4L Left lower paratracheal						
5 AP window/Subaortic						
6 Para-aortic, ascending aorta or phrenic						
7 Subcarinal						
8 Paraesophageal						
9 Pulmonary Ligament						
10R Right hilar						
10L Left hilar						
11R Right interlobar						
11L Left interlobar						
12R Right lobar						
12L Left lobar						
13R Right segmental						
13L Left segmental						
14R Right subsegmental						
14L Left subsegmental						

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

Complete Table B for clinical or pathologic staging only if medical records indicate nodal involvement without reference to specific regions.

Table 5B
Lymph Node Chain

	Clinical Diagnosis			Pathologic Diagnosis
	# Nodes	Mode of Diagnosis		# Nodes
	0 = 0 nodes involved **1** = 1 node involved **2** = ≥ 2 nodes involved **3** = Involved nodes; # not known **99** = No data available	**0** = No clinical information **1** = CXR **4** = PET/CT **2** = CT **5** = MRI **3** = PET **6** = Other, specify *Insert codes in the columns below;* *for Other, specify fill in here*		**0** = 0 nodes involved **1** = 1 node involved **2** = ≥ 2 nodes involved **3** = Involved nodes; # not known **99** = No data available
N1 = Ipsilateral hilar or more distal nodes				
N2 = Ipsilateral mediastinal nodes				
N3 = Contralateral hilar, mediastinal, or scalene nodes				

Record the staging for primary lung cancer.

6. TNM Clinical Stage:

T Codes	N Codes	M Codes
☐ TX	☐ NX	☐ MX
☐ T0	☐ N0	☐ M0
☐ T1	☐ N1	☐ M1
☐ T2	☐ N2	☐ Not Available
☐ T3	☐ N3	
☐ T4	☐ Not Available	
☐ Not Available		

7. TNM Pathologic Stage:

T Codes	N Codes	M Codes
☐ TX	☐ NX	☐ MX
☐ T1	☐ N0	☐ M0
☐ T2	☐ N1	☐ M1
☐ T3	☐ N2	☐ Not Available
☐ T4	☐ N3	
☐ Not Available	☐ Not Available	

ZL

ACRIN NLST 6654
Primary Lung Cancer

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

8. Record Stage: Enter the stage of primary lung cancer based upon the data elements.

Stage Only (Non-Small Cell and Small Cell Histology)	VALCSG (Small Cell only)	Summary Staging	
☐ Occult ☐ IIA ☐ IIIB ☐ IA ☐ IIB ☐ IV ☐ IB ☐ IIIA ☐ Not Available	☐ Limited ☐ Extensive ☐ Not Available	☐ Localized ☐ Regional ☐ Distant	☐ Not Available
Post-Neo-adjuvant therapy? ☐ No ☐ Yes	**Describe Treatment:**		

9. Was another primary lung cancer diagnosed during this same interval?

- ☐ No
- ☐ Yes (complete an additional ZL Form for each individual primary lung cancer diagnosed during this time interval)

10. Were the medical records required for the ZL Form for this F1/F2 Interval complete?

- ☐ No (complete an additional records request)
- ☐ Yes

11. ☐ **This form was created in error and should be deleted and all information should be ignored**

☑ = marked, ☐ = not marked

11a. Reason for form deletion: *(choose only one)*

- ☐ 01 Query response
- ☐ 02 Data entry error correction
- ☐ 03 Audit QC Finding correction
- ☐ 04 Site revision

12. Comments: _____

CTR Coder ID:	CTR Coder Signature:	Date Form Completed: (mm-dd-yyyy)

ZO

ACRIN NLST 6654
Outpatient Provider Visits

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

F1/F2 Interval: __-__-20__ to __-__-20__ (mm-dd-20yy)

Provider Code: _____ **Outpatient Date of Care:** __-__-20__ (mm-dd-20yy)

☐ **Type of Visit**

1 = Office Visit *(may include procedures)*

2 = Invasive Procedure *(no office visit)*

3 = Non-Invasive Procedure *(no office visit)*

4 = Other, specify: _____

ICD-9-CM Reason for Visit										
ICD-9-CM Pre-existing Condition										
ICD-9-CM Final DX & Complications										
CPT Code										

☐ **More Codes**

☐ **More Visits**

☐ **No More Visits**

☐ **This form was created in error and should be deleted and all information should be ignored**

☑ = marked, ☐ = not marked

Reason for form deletion: *(choose only one)*

- ☐ 01 Query response
- ☐ 02 Data entry error correction
- ☐ 03 Audit QC Finding correction
- ☐ 04 Site revision

Abstractor ID

Abstractor Signature

__-__-20__
Date Form Completed (mm-dd-20yy)

ZP

ACRIN NLST 6654
ZP - Pathology Samples

ACRIN Study **6654**
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

F1/F2 Interval Start Date: __ __ - __ __ - 20__ __ **F1/F2 Interval End Date:** __ __ - __ __ - 20__ __ (mm-dd-20yy) **ZP Form #** _____

Complete Table below for each sample obtained.

S#	Site of Specimen Collection		Laterality [Paired Organs]	Type of Sample	Date of Specimen Procurement	ICD-0-3				SNOMED Code for Non-Malignant Lesions	Define Organ Site of 1° Malignancy		Is This Cancer Metastatic to Lung?
	1 = Lung 5 = Kidney 2 = Breast 6 = Colon 3 = Liver 7 = Prostate 4 = Adrenal 8 = Lymph 9 = Other, specify *Insert codes in the columns below;*	*for Other, specify fill in here*	1 = Right 2 = Left 3 = Bilateral 98 = Not applicable 99 = Unknown	1 = Cytology 2 = Histology 3 = Combined	MM-DD-YYYY	Topography C__.__	Morphology ____	Behavior __	Grade __	99999 = Non-diagnostic Tissue specimen	1 = Lung 6 = Colon 2 = Breast 7 = Prostate 3 = Liver 8 = Lymph 4 = Adrenal 9 = Other, specify 5 = Kidney 98 = Not applicable 99 = Unknown *Insert codes in the columns below;*	*for Other, specify fill in here*	1 = No 2 = Yes 98 = Not Applicable 99 = Not Available
S1					____-____-____	C .							
S2					____-____-____	C .							
S3					____-____-____	C .							
S4					____-____-____	C .							
S5					____-____-____	C .							
S6					____-____-____	C .							
S7					____-____-____	C .							
S8					____-____-____	C .							
S9					____-____-____	C .							
S10					____-____-____	C .							

ZP

ACRIN NLST 6654
ZP - Pathology Samples

ACRIN Study **6654**
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____

_____

Are there additional pathology samples for this F1/F2 Interval?

- ☐ 1 No
- ☐ 2 Yes (Complete an Additional ZP Form)

Were the pathology records complete for this F1/F2 Interval?

- ☐ 1 No (Complete an Additional Records Request)
- ☐ 2 Yes (Complete an Additional ZP Form)

☐ **This form was created in error and should be deleted and all information should be ignored**

☑ = marked, ☐ = not marked

Reason for form deletion: *(choose only one)*

- ☐ 01 Query response
- ☐ 02 Data entry error correction
- ☐ 03 Audit QC Finding correction
- ☐ 04 Site revision

CTR Coder ID

CTR Coder Signature

__ __ - __ __ - **20** __ __ (mm-dd-20yy)
Date Form Completed

ZY ACRIN NLST 6654 Diagnostic Evaluation Form

ACRIN Study 6654
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

F1/F2 Interval: __-__-20__ to __-__-20__ (mm-dd-20yy)

1.	Cancer Diagnosis, NON-Lung Primary	☐ No ☐ Yes	Topography C__.__ Morphology ____ Behavior __ Grade __	Date of Diagnosis: __-__-20__
2.	Is this cancer metastatic to lung?	☐ No ☐ Yes		

3. **Was there an additional non-lung primary cancer diagnosis during this F1/F2 Interval?**
   - ☐ No
   - ☐ Yes (Complete an additional ZY)

4. **Were the medical records for the ZY Form for this F1/F2 Interval complete?**
   - ☐ No(Complete an additional records request)
   - ☐ Yes

5. ☐ **This form was created in error and should be deleted and all information should be ignored?**
   ☑ = marked, ☐ = not marked

   5a. Reason for form deletion: *(choose only one)*
   - ☐ 01 Query response
   - ☐ 02 Data entry error correction
   - ☐ 03 Audit QC Finding correction
   - ☐ 04 Site revision

Comments: _____

CTR Coder ID _____

CTR Coder Signature _____

Date Form Completed (mm-dd-20yy) __-__-20__

CX ACRIN 6654 NLST Cancer Progression Form

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please √ box. ☐

Instructions: For all NLST participants with lung cancer, complete this form on an annual basis to document the presence or absence of progression of lung cancer or the development of a second primary lung cancer.

F1/F2 Follow-Up Interval: __-__-20__ [1] **to** __-__-20__ [2] *(mm-dd-20yy)*

Part A. Progressive Disease Following Treatment of First Primary Lung Cancer

1. __ During this interval, did the participant develop progressive disease (e.g., progression at primary site, metastases, other recurrence) following treatment for lung cancer? [3]

01 No (skip to part B)
02 Yes (continue below)
99 Unknown (skip to part B)

2. Date of first documentation of progressive lung cancer: __-__-20__ ***(mm-dd-20yy)*** [4]

3. Site(s) of progression of lung cancer (record all that apply, using Table 1 codes):

a. __ [5] Other, specify: _____ [6]

b. __ [7] Other, specify: _____ [8]

c. __ [9] Other, specify: _____ [10]

d. __ [11] Other, specify: _____ [12]

e. __ [13] Other, specify: _____ [14]

Table 1: Anatomic Site(s) of Progression

01	Original lung site	**11**	N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
02	Other lung site(s)	**12**	N2 Ipsilateral mediastinal lymph nodes
03	Pleura	**13**	N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
04	XXXXXXXXX	**99**	Unknown site
05	Brain		
06	Bone		
07	Liver		
08	Adrenal		
09	Other, specify		
10	Skin/subcutaneous tissue		

CX

ACRIN 6654
NLST Cancer Progression Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part B. Development of Second Primary Lung Cancer

4. ☐☐ **During this interval, did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer?** [18]

01 No (skip to comments)
02 Yes (complete Q5, please complete LX and PX abstraction forms)
99 Unknown (skip to Q6)

5. Date of diagnosis of second primary lung cancer: ☐☐-☐☐-**20**☐☐ *(mm-dd-20yy)* **[19]**

6. Is an additional form required for this interval? **[24]**

01 No
02 Yes

7. ☐ **This form was created in error and should be deleted and all information should be ignored**
☑ = marked, ☐ = not marked **[25]**

7a. Reason for form deletion: *(choose only one)* [26]

☐ 01 Query response
☐ 02 Data entry error correction
☐ 03 Audit QC Finding correction
☐ 04 Site revision

COMMENTS: _____

_____

_____

_____ [20] / [21]

_____ **Abstractor ID** [22]

_____ **Abstractor Signature**

☐☐-☐☐-**20**☐☐ (mm-dd-20yy) **Date of Completion** [23]

TF

ACRIN 6654
NLST
Treatment Form - Initial

ACRIN Study 6654
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: Complete the **TF-Initial Treatment Form** for all inital treatments of primary lung cancer. Additional treatment(s) administered for progression, relapse, or second primary lung cancers should be recorded on the **TS-Subsequent Treatment Form.**

F1/F2 Interval: __ __ - __ __ - **20** __ __ [1] to __ __ - __ __ - **20** __ __ [2] (mm-dd-yy)

Initial Treatment of Primary Invasive Lung Cancer

1. __ __ **Did the participant undergo radiation treatment(s) for the initial treatment of primary lung cancer during this follow-up interval?** [46]

01 No (skip to Q2)
02 Yes (continue below)
99 Unknown (skip to Q2)

1a. Record the sequence of radiotherapy relative to surgery *(check all that apply)*

☐ 01 Pre-operative [85]
☐ 02 Post-operative [86]
☐ 03 Definitive [87]
☐ 99 Unknown [88]

1b. Complete the following for each site receiving radiotherapy treatment:

Radiotherapy Site	Start Date (mm-dd-20yy)	End Date (mm-dd-20yy)	Total Dose (cGy)
Chest Primary Tumor Volume	[47] __ __ - __ __ 20 __ __	[48] __ __ - __ __ 20 __ __	[49] __ __ __ __ . __
Hilar/Mediastinal Lymph Nodes	[50] __ __ - __ __ 20 __ __	[51] __ __ - __ __ 20 __ __	[52] __ __ __ __ . __
Prophylactic Brain	[53] __ __ - __ __ 20 __ __	[54] __ __ - __ __ 20 __ __	[55] __ __ __ __ . __
Therapeutic Brain	[89] __ __ - __ __ 20 __ __	[90] __ __ - __ __ 20 __ __	[91] __ __ __ __ . __
Other, specify _____ [82]	[56] __ __ - __ __ 20 __ __	[57] __ __ - __ __ 20 __ __	[58] __ __ __ __ . __
Unknown	[59] __ __ - __ __ 20 __ __	[60] __ __ - __ __ 20 __ __	[61] __ __ __ __ . __

2. ☐☐ **Did the participant have surgical treatment(s) for the initial primary lung cancer during this follow-up interval?** [29]

01 No (skip to Q4)
02 Yes (continue below)
99 Unknown (skip to Q4)

2a. Record the surgical procedure(s) AND approach(es) below using Table 1 codes:

Surgical Procedure / Approach Code	Date of Procedure / Approach *(mm-dd-20yy)*
☐☐ [30] _____ [31]	[32] ☐☐ - ☐☐ - 20☐☐
☐☐ [33] _____ [34]	[35] ☐☐ - ☐☐ - 20☐☐
☐☐ [36] _____ [37]	[38] ☐☐ - ☐☐ - 20☐☐
☐☐ [39] _____ [40]	[41] ☐☐ - ☐☐ - 20☐☐
☐☐ [42] _____ [43]	[44] ☐☐ - ☐☐ - 20☐☐

Table 1: Surgical Procedure and Approach (Small Box) Codes

01 Exploratory thoracotomy without resection
02 Median Sternotomy
14 Thoracotomy
15 Thoracoscopy | Video-assisted (VATS)
16 Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
88 Other surgical approach (specify): _____
98 Unknown surgical approach

03 Lobectomy
04 Bilobectomy
05 Pneumonectomy
06 Wedge resection
07 Segmentectomy | segmental resection
08 Lymphadenectomy | lymph node sampling
09 Chest wall resection
10 Thoracentesis
11 Partial pleurectomy
12 Multiple wedge resections
13 Multiple segmental resections
89 Other surgical procedure (specify): _____
99 Unknown surgical procedure

3. ☐☐ **Record the extent of local or residual disease (margins of surgical resection) after surgery:** [45]

01 R0 = none, all margins pathologically negative
02 R1 = microscopically positive margins or microscopic residual disease
03 R2 = macroscopically positive margins or gross residual disease
99 Unknown

TF If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. ☐☐ **Did the participant receive systemic chemotherapy as initial treatment for primary lung cancer during this follow-up interval?** [3]

01 No (skip to Q5)
02 Yes (complete Q4a)
99 Unknown (skip to Q5)

4a. Indicate all chemotherapeutic agents given, along with date first administered, to treat primary lung cancer using Table 2 below:

Chemotherapeutic Agent (specify)	Date Chemotherapy First Administered
☐☐ [5] _____ [6]	[7] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [8] _____ [9]	[10] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [11] _____ [12]	[13] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [14] _____ [15]	[16] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [17] _____ [18]	[19] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [20] _____ [21]	[22] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [23] _____ [24]	[25] ☐☐ - ☐☐ - 20 ☐☐
☐☐ [26] _____ [27]	[28] ☐☐ - ☐☐ - 20 ☐☐

TABLE 2: Codes for Chemotherapeutic Agents and Targeted Molecular Agents

Generic	Brand	Generic	Brand
01 Adriamycin	*(Doxorubicin HCL / Rubex)*	**16** Irinotecan HCL	*(Camptosar | CPT-11 | Camptothecin)*
02 Bevacizumab	*(Avastin)*	**17** Lomustin	*(CeeNu | CCNU)*
03 Bortezomib	*(Velcade)*	**18** Mesna	*(Often used with Ifosamide /* Mesnex
04 Carboplatin	*(Paraplatin)*	**19** Methotrexate	*(MTX | Trexall | Rheumatrex | Amethopterin | Methotrexate sodium)*
05 Celecoxib	*(Celebrex)*		
06 Cisplatin	*(COPP / Plational / Platinol - AQ)*	**20** Mitomycin	*(Mutamycin)*
07 Cyclophosphamide	*(Cytoxan | Neosar)*	**21** Paclitaxel	*(Taxol | Onxal | Abraxane)*
08 Docetaxel	*(Taxotere)*	**22** Pemetrexed	*(Alimta)*
09 Doxorubicin	*(Adriamycin / Doxil / Rubex)*	**23** Topotecan HCL	*(Hycamtim)*
10 Epirubicin	*(Ellence)*	**24** Trastuzumab	*(Herceptin)*
11 Erlotinib	*(Tarceva)*	**25** Vinblastine	*(Velban | Velbe | Sensipar | Alkaban-AQ | VLB | Vinblastin Sulfate Vincalewkoblastine)*
12 Etopicide	*(VP-16 | VE-Pesid | Toposar | Etopophos | Etoposide Phosphate)*		
13 Gefitinib	*(Iressa)*	**26** Vincristine	*Oncovin | Vincasar | Vincrex*
14 Gemcitibine HCL	*(Gemzar)*	**27** Vindesine	*Eldisine*
15 Ifosamide	*(IFEX)*	**28** Vinorelbine	*Navelbine | Vinorelbine*
		88 Other, specify _____	

TF If this is a revised or corrected form, please √box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

5. ☐☐ **Did the participant undergo any other initial treatment(s) administered by a physician for primary lung cancer during this follow-up interval?** [62]

01 No (skip to Q6)
02 Yes (continue below)
99 Unknown (skip to Q6)

5a. Specify initial other treatment type and date treatment began:

Type of Treatment	Treatment Start Date *(mm-dd-20yy)*	Treatment Codes
☐☐ [63] _____ [64]	[65] ☐☐ - ☐☐ - 20 ☐☐	**01** Immune Therapy **02** Radio Frequency Ablation **03** Thermal Ablation **04** Chemical Ablation **05** Other(specify): _____ **06** Brachytherapy **99** Unknown treatment
☐☐ [66] _____ [67]	[68] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [69] _____ [70]	[71] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [72] _____ [73]	[74] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [75] _____ [76]	[77] ☐☐ - ☐☐ - 20 ☐☐	

6. Is an additional TF form required for this this interval? [84]

O No
O Yes

7. ☐ **This form was created in error and should be deleted and all information should be ignored**
☑ = marked, ☐ = not marked [92]

7a. Reason for form deletion: *(choose only one)* [93]

☐ 01 Query response
☐ 02 Data entry error correction
☐ 03 Audit QC Finding correction
☐ 04 Site revision

COMMENTS: _____ [78]

_____ [79]

_____ [80]
Abstractor ID

_____-_____-_____ [81]
Date form completed (mm-dd-yyyy)

_____
Abstractor signature

TS

ACRIN 6654
NLST
Treatment Form - Subsequent

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Instructions: Complete the **TS-Subsequent Treatment Form** for all lung cancer treatments **after the initial treatment**. Any treatment(s) administered for lung cancer progression, relapse, or second primary lung cancers should be recorded on this form. Any treatment(s) administered as part of **initial treatment for primary lung cancer** should be recorded on the **TF-Initial Treatment Form**.

F1/F2 Interval: __ __ - __ __ - 20 __ __ [1] to __ __ - __ __ - 20 __ __ [2] (mm-dd-yy)

Subsequent Treatment of Lung Cancer

1. __ __ **Did the participant undergo radiation treatment(s) for lung cancer during this follow-up interval, excluding initial therapy?** [46]

01 No (skip to Q2)
02 Yes (continue below)
99 Unknown (skip to Q2)

1b. Complete the following for each site receiving radiotherapy treatment: (Radiotherapy administered as part of initial treatment for first primary lung cancer should be recorded on the TF-Initial Treatment Form)

Radiotherapy Site	Start Date (mm-dd-20yy)	End Date (mm-dd-20yy)	Total Dose (cGy)
Chest Primary Tumor Volume	[47] __ __ - __ __ 20 __ __	[48] __ __ - __ __ 20 __ __	[49] __ __ __ __ . __
Hilar/Mediastinal Lymph Nodes	[50] __ __ - __ __ 20 __ __	[51] __ __ - __ __ 20 __ __	[52] __ __ __ __ . __
Prophylactic Brain	[53] __ __ - __ __ 20 __ __	[54] __ __ - __ __ 20 __ __	[55] __ __ __ __ . __
Therapeutic Brain	[89] __ __ - __ __ 20 __ __	[90] __ __ - __ __ 20 __ __	[91] __ __ __ __ . __
Other, specify _____ [82]	[56] __ __ - __ __ 20 __ __	[57] __ __ - __ __ 20 __ __	[58] __ __ __ __ . __
Unknown	[59] __ __ - __ __ 20 __ __	[60] __ __ - __ __ 20 __ __	[61] __ __ __ __ . __

2. __ __ **Did the participant undergo surgical treatment(s) for lung cancer during this follow-up interval, excluding initial therapy?** [29]

01 No (skip to Q4)
02 Yes (complete Q2a)
99 Unknown (skip to Q4)

TS If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

2a. Record the surgical procedure(s) AND approach(es) below using Table 1 codes:

Surgical Procedure / Approach Code	Date of Procedure / Approach *(mm-dd-20yy)*
☐☐ [30] _____ [31]	[32] ☐☐ - ☐☐ - 20☐☐
☐☐ [33] _____ [34]	[35] ☐☐ - ☐☐ - 20☐☐
☐☐ [36] _____ [37]	[38] ☐☐ - ☐☐ - 20☐☐
☐☐ [39] _____ [40]	[41] ☐☐ - ☐☐ - 20☐☐
☐☐ [42] _____ [43]	[44] ☐☐ - ☐☐ - 20☐☐

Table 1: Surgical Procedure and Approach (Small Box) Codes

01 Exploratory thoracotomy without resection
02 Median Sternotomy
14 Thoracotomy
15 Thoracoscopy | Video-assisted (VATS)
16 Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
88 Other surgical approach (specify): _____
98 Unknown surgical approach

03 Lobectomy
04 Bilobectomy
05 Pneumonectomy
06 Wedge resection
07 Segmentectomy | segmental resection
08 Lymphadenectomy | lymph node sampling
09 Chest wall resection
10 Thoracentesis
11 Partial pleurectomy
12 Multiple wedge resections
13 Multiple segmental resections
89 Other surgical procedure (specify): _____
99 Unknown surgical procedure

3. ☐☐ **Record the extent of local or residual disease (margins of surgical resection) after surgery:** [45]

01 R0 = none, all margins pathologically negative
02 R1 = microscopically positive margins or microscopic residual disease
03 R2 = macroscopically positive margins or gross residual disease
99 Unknown

4. ☐☐ **Did the participant receive systemic chemotherapy for lung cancer progression or second primary lung cancer during this follow-up interval, excluding initial therapy?** [3]

01 No (skip to Q5)
02 Yes (complete Q4a)
99 Unknown (skip to Q5)

TS If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4a. Record all chemotherapeutic agents given to treat lung cancer, subsequent to initial therapy, using Table 2 below: (Chemotherapy used for treatment at initial diagnosis of first primary lung cancer should be recorded on the TF-Initial Treatment Form).

Chemotherapeutic Agent	Date Administered	Reason for administration **A.** Cancer progression **B.** 2nd primary lung cancer **C.** Unknown
☐☐ [5] _____ [6]	☐☐ - ☐☐ - 20 ☐☐ [7]	☐ [92]
☐☐ [8] _____ [9]	☐☐ - ☐☐ - 20 ☐☐ [10]	☐ [93]
☐☐ [11] _____ [12]	☐☐ - ☐☐ - 20 ☐☐ [13]	☐ [94]
☐☐ [14] _____ [15]	☐☐ - ☐☐ - 20 ☐☐ [16]	☐ [95]
☐☐ [17] _____ [18]	☐☐ - ☐☐ - 20 ☐☐ [19]	☐ [96]
☐☐ [20] _____ [21]	☐☐ - ☐☐ - 20 ☐☐ [22]	☐ [97]
☐☐ [23] _____ [24]	☐☐ - ☐☐ - 20 ☐☐ [25]	☐ [98]
☐☐ [26] _____ [27]	☐☐ - ☐☐ - 20 ☐☐ [28]	☐ [99]

TABLE 2: Codes for Chemotherapeutic Agents and Targeted Molecular Agents

Generic	Brand	Generic	Brand
01 Adriamycin	*(Doxorubicin HCL / Rubex)*	**16** Irinotecan HCL	*(Camptosar | CPT-11 | Camptothecin)*
02 Bevacizumab	*(Avastin)*	**17** Lomustin	*(CeeNu | CCNU)*
03 Bortezomib	*(Velcade)*	**18** Mesna	*(Often used with Ifosamide /* Mesnex
04 Carboplatin	*(Paraplatin)*	**19** Methotrexate	*(MTX | Trexall | Rheumatrex | Amethopterin | Methotrexate sodium)*
05 Celecoxib	*(Celebrex)*	**20** Mitomycin	*(Mutamycin)*
06 Cisplatin	*(COPP / Plational / Platinol - AQ)*	**21** Paclitaxel	*(Taxol | Onxal | Abraxane)*
07 Cyclophosphamide	*(Cytoxan | Neosar)*	**22** Pemetrexed	*(Alimta)*
08 Docetaxel	*(Taxotere)*	**23** Topotecan HCL	*(Hycamtim)*
09 Doxorubicin	*(Adriamycin / Doxil / Rubex)*	**24** Trastuzumab	*(Herceptin)*
10 Epirubicin	*(Ellence)*	**25** Vinblastine	*(Velban | Velbe | Sensipar | Alkaban-AQ | VLB | Vinblastin Sulfate Vincalewkoblastine)*
11 Erlotinib	*(Tarceva)*	**26** Vincristine	*Oncovin | Vincasar | Vincrex*
12 Etopicide	*(VP-16 | VE-Pesid | Toposar | Etopophos | Etoposide Phosphate)*	**27** Vindesine	*Eldisine*
13 Gefitinib	*(Iressa)*	**28** Vinorelbine	*Navelbine | Vinorelbine*
14 Gemcitibine HCL	*(Gemzar)*	**88** Other, specify _____	
15 Ifosamide	*(IFEX)*		

TS If this is a revised or corrected form, please √box. ☐

ACRIN Study 6654

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

5. ☐☐ **Did the participant undergo any other treatment(s) administered by a physician for lung cancer during this follow-up interval, excluding initial treatments?** [62]

01 No (skip to Q6)
02 Yes (continue below)
99 Unknown (skip to Q6)

5a. Specify other treatment type and start date.

Type of Treatment	Treatment Start Date *(mm-dd-20yy)*	Treatment Codes
☐☐ [63] _____ [64]	[65] ☐☐ - ☐☐ - 20 ☐☐	**01** Immune Therapy **02** Radio Frequency Ablation **03** Thermal Ablation **04** Chemical Ablation **05** Other(specify): _____ **06** Brachytherapy **99** Unknown treatment
☐☐ [66] _____ [67]	[68] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [69] _____ [70]	[71] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [72] _____ [73]	[74] ☐☐ - ☐☐ - 20 ☐☐	
☐☐ [75] _____ [76]	[77] ☐☐ - ☐☐ - 20 ☐☐	

6. Is an additional TS form required for this interval? [84]

O No
O Yes

7. ☐ **This form was created in error and should be deleted and all information should be ignored**
☑ = marked, ☐ = not marked [100]

7a. Reason for form deletion: *(choose only one)* [101]

☐ 01 Query response
☐ 02 Data entry error correction
☐ 03 Audit QC Finding correction
☐ 04 Site revision

COMMENTS: _____ [78]

_____ [79]

_____ [80]
Abstractor ID

_____-_____-_____ [81]
Date form completed (mm-dd-yyyy)

_____
Abstractor signature

Spanish Versions

E1 ACRIN 6654 NLST Requisitos de preinscripción Hoja de trabajo

Centro # _____

Caso # _____

INSTRUCCIONES: Los datos a continuación determinan los requisitos para la inscripción en el Estudio Nacional para el Examen de Pulmón (NLST, por sus siglas en inglés), ACRIN 6654. ES NECESARIO completar este documento ANTES de inscribir al participante. Para que el participante sea registrado como un caso ELEGIBLE, las respuestas codificadas deben reflejar las indicadas en la hoja de instrucciones para el investigador que se adjunta (página 3), que confirman la elegibilidad.

El participante debe firmar y fechar este formulario en el momento de la inscripción. Este formulario se debe mantener en el archivo del estudio como verificación de elegibilidad y no se debe mandar a la oficina principal de ACRIN.

Información de contacto del posible participante:

_____ Nombre (o iniciales) del posible participante

_____ Teléfono 1 (casa)

_____ Teléfono 2 (trabajo / otro, especifique____)*

_____ E-mail *

_____ Dirección *

_____

_____

_____ Otra información de contacto *

_____ ** Información opcional*

A. Edad:

1. ¿Fecha de nacimiento? |__|__|-|__|__|-|__|__|__|__| **(mm-yyyy)**

2. ¿Cuántos años cumplidos tiene? |__|__| años de edad

B. Historia de tabaquismo:

3. |__| **¿Ha fumado cigarrillo alguna vez?**
1 No
2 Sí

4. |__|__| **¿A qué edad empezó a fumar cigarrillo?**

5. |__| **5. ¿Fuma cigarrillo ahora?**
1 No
2 Sí (pase a la pregunta 7)

6. |__| **6. ¿Cuándo se fumo el último cigarrillo?**
1 hace menos de 6 meses
2 hace entre 6 meses y 3.9 años
3 hace entre 4 y 9.9 años
4 hace entre 10 y 15 años
5 hace más de 15 años

7. |__|__| **¿Por cuántos años en total ha fumado cigarrillos?**

8. |__|__|__| **¿Cuántos cigarrillos fuma al día (en promedio)?**

C. Factores / condición médica que puede afectar la participación en este estudio:

Por favor conteste **1 No** o **2 Sí** a las siguientes preguntas.

9. ___ **¿Puede acostarse boca arriba con los brazos apoyados encima de la cabeza?**

10. ___ **10. ¿Tiene algún implante metálico en el pecho o en la espalda?** (por ejemplo barras de Harrington o marcapasos)

11. ___ **¿Le han diagnosticado alguna vez cáncer de pulmón o ha recibido tratamiento para este tipo de cáncer?**

12. ___ **En los últimos (5) años, ha recibido tratamiento para el cáncer o su médico le ha dicho que tiene evidencia de cáncer?** (excluyendo el cáncer de la piel no-melanoma o los cánceres in situ, diferente de los cánceres in situ de la célula de transición o de la vejiga)

13. ___ **¿Le han extraído alguna parte de los pulmones, excepto una biopsia con aguja?**

14. ___ **¿Recibe suplemento de oxígeno en el hogar?**

15. ___ **En este momento, ¿está participando en algún estudio para la detección del cáncer** (como el ELCAP o el PLCO)**?**

16. ___ **En este momento, ¿está participando en algún estudio para la prevención del cáncer, diferente al programa para dejar de fumar?**

17. ___ **En el último año, ¿ha perdido más de 15 libras, sin una causa justificada, o ha experimentado recientemente hemoptisis** (sangre en el esputo o gargajo)?

18. ___ **En las últimas 12 semanas, ¿ha tenido neumonía o una infección respiratoria aguda que se trato con antibióticos bajo supervisión médica?**

19. ___ **En los últimos seis meses, ¿ha sido tratado con agentes citotóxicos por alguna enfermedad?**

20. ___ **En los últimos 18 meses, ¿le han hecho una tomografía computarizada del pecho** (CT scan)**?**

21. ___ ___ ___ **Paquete-años** (para el cálculo, mire la hoja de referencia del investigador, página 3)

Comentarios: _____

_____

_____

Firma del participante

___ ___ - ___ ___ - ___ ___ ___ ___

Fecha en que se lleno el formulario (mes-día-año)

_____

Investigador

E1

Centro # _____

Caso # _____

Las respuestas que se proveen en esta hoja son para referencia del investigador SOLAMENTE. Estas respuestas no se deben dar al participante.

Instrucciones para el investigador: A continuación están las respuestas elegibles a las preguntas de la hoja de trabajo E1 del ACRIN 6654, NLST. Para poder inscribir al participante, las respuestas del participante a las preguntas deben coincidir con las respuestas aquí indicadas. Los posibles participantes deben contestar las páginas 1 y 2. Esta página da las respuestas que cumplen con los requisitos para cuando el investigador revise las respuestas de las páginas 1 y 2.

Pregunta	**Respuesta que cumple con los requisitos**
2.	Entre 55 y 74 años + 364 días
3.	2 - Sí
5.	2 – Sí o 1 No
6.	Códigos 1-4 solamente
9.	2 – Sí / se permite acostarse boca arriba con una o dos almohadas, los brazos apoyados en las almohadas /o con soportes y las piernas/rodillas con soportes
10.	1 – No / objetos de metal aceptables: injerto de derivación de la arteria coronaria, esternotomía, suturas, válvulas metálicas en el corazón, endoprótesis vascular, endoprótesis con angioplastía o posibles cantidades pequeñas de fragmentos de metralla o bala
11.	1 - No
12.	1 – No / llena los requisitos: cáncer de la piel no-melanoma o los cánceres in situ (excepto los cánceres in situ de la célula de transición o de la vejiga que no llenan los requisitos)
13.	1 – No / con excepción de la biopsia simple y la biopsia con aguja a través de la piel; pregunte sobre cualquier cirugía relacionada con el pulmón
14.	1 – No / se acepta la terapia de presión continua positiva de la vía aérea (CPAP, por sus siglas en inglés)
15.	1 – No / como el programa para la Detección Precoz del Cáncer de Pulmón (ELCAP), el Estudio para la Detección del Cáncer de Próstata, Pulmón, Colorrectal y Ovárico (PLCO), el Estudio para la Salud del Pulmón, etc
16.	1 –No / se acepta el programa para dejar de fumar
17.	1 - No
18.	1 – No / si la respuesta es sí, posponga la elegibilidad para participar en el NLST 12 semanas desde la fecha de la primera dosis de antibióticos
19.	1 – No / si la respuesta es sí, posponga la elegibilidad para participar en el NLST por 6 meses desde la última dosis del medicamento del último ciclo
20.	1 – No / si la respuesta es sí, posponga la elegibilidad para participar en el NLST por 18 meses desde la fecha de la última tomografía computarizada del pecho
21.	Cálculo para determinar el número de paquete-años

$$\frac{\text{Total de años que ha fumado (P.7) x número de cigarrillos por día (P.8)}}{20} = \text{paquete-años}$$

$$\frac{\quad}{20} \times = \_\_\_\_\_$$ Para que llene los requisitos de participación, el número de paquete-años debe ser = >30

DP

ACRIN 6654 NLST
Cuestionario de datos demográficos/ Estado de Salud/ Hábitos relacionados con la salud /Síntomas

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

Instrucciones para el participante: como parte del estudio, nos interesa recabar información general sobre datos demográficos y de salud. Sus respuestas son importantes para nosotros, así que trate de contestar todas las preguntas. Si no está seguro de cómo contestar una pregunta, trate de dar la mejor respuesta que pueda. Entregue este cuestionario al auxiliar del estudio cuando termine de llenarlo.

Historia clínica

1. **¿Cuál es su peso actual?** ☐☐☐ lbs.

2. **¿Cuál es su estatura?** ☐ pies ☐☐ pulgadas

3. **¿Le ha dicho alguna vez un médico que usted tiene una de las enfermedades o afecciones que se enumeran a continuación?**

   Conteste **SÍ** o **NO** a las preguntas siguientes; si la respuesta es **SÍ**, indique la edad cuando se hizo el diagnostico. Si prefiere no contestar o no sabe la respuesta, use el código 99

   1. No **2. Sí** **99 No sé / Prefiero no contestar**

			Si contestó SÍ, edad al diagnóstico:
3a.	☐	Asbestosis	☐☐
3b.	☐	Asma - diagnosticada en la infancia	☐☐
3c.	☐	Asma - diagnosticada en la adultez	☐☐
3d.	☐	Bronquiectasia	☐☐
3e.	☐	Bronquitis crónica	☐☐
3f.	☐	Enfermedad pulmonar obstructiva crónica (EPOC)	☐☐
3g.	☐	Enfisema	☐☐
3h.	☐	Diabetes	☐☐
3i.	☐	Cardiopatía o infarto	☐☐
3j.	☐	Fibrosis pulmonar	☐☐
3k.	☐	Neumonía	☐☐
3l.	☐	Sarcoidosis	☐☐
3m.	☐	Silicosis	☐☐
3n.	☐	Tuberculosis (TB)	☐☐
3o.	☐	Hipertensión arterial	☐☐
3p.	☐	Accidente cerebrovascular (Ataque cerebral)	☐☐

DP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

4. ¿Le ha dicho alguna vez un médico que usted tiene cualquiera de los cánceres de la lista de abajo?
Conteste **SÍ** o **NO** a las preguntas siguientes; si la respuesta es **SÍ**, indique la edad cuando se hizo el diagnostico. Si prefiere no contestar o no sabe la respuesta, use el código 99

1. No **2. Sí** **99 No sé / Prefiero no contestar**

			Si contestó SÍ, edad al diagnóstico:
4a.	☐	Cáncer de pulmón	☐☐
4b.	☐	Cáncer de vejiga	☐☐
4c.	☐	Cáncer de células transicionales	☐☐
4d.	☐	Cáncer cervical	☐☐
4e.	☐	Cáncer de boca	☐☐
4f.	☐	Cáncer de faringe	☐☐
4g.	☐	Cáncer de laringe	☐☐
4h.	☐	Cáncer de nariz	☐☐
4i.	☐	Cáncer de esófago	☐☐
4j.	☐	Cáncer de estómago (gástrico)	☐☐
4k.	☐	Cáncer pancreático	☐☐
4l.	☐	Cáncer de riñón (renal)	☐☐
4m.	☐	Cáncer colorrectal	☐☐
4n.	☐	Cáncer de mama (seno)	☐☐
4o.	☐	Cáncer tiroideo	☐☐
4p.	☐	Otro, especifique _____	☐☐

5. ¿Ha tenido alguna vez cáncer de pulmón uno de los familiares consanguíneos siguientes?

1 No
2. Sí
98 No aplica
99 No sé / Prefiero no contestar

☐ Padre
☐ Madre
☐ Hermanos, incluidos los medio hermanos (hermanastros)
☐ Hermanas, incluidas las medio hermanas (hermanastras)
☐ Hijos (biológicos)

DP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

Información demográfica

6. ☐ **Indique el máximo grado o nivel educativo que tiene (seleccione uno)**

1. 8º grado o menos
2. De 9º a 11º grado
3. Educación secundaria (high school) o equivalente
4. Capacitación después de la secundaria (high school), que no sea universitaria (por ejemplo, escuela vocacional o técnica)
5. Título de colegio comunitario / algo de educación universitaria
6. Título de bachiller (4 años de universidad)
7. Título profesional
8. Otro, especifique _____
99. No sé / Prefiero no contestar

7. ☐ **Estado civil**

1. Nunca casado(a)
2. Casado(a) o vivir en pareja
3. Viudo(a)
4. Separado(a)
5. Divorciado(a)
99. No sé / Prefiero no contestar

8. ☐ **Indique el ingreso familiar** (seleccione el que se acerque más al promedio total del ingreso anual bruto de su familia)

1. Menos de $8.000 al año
2. de $8.000 a $14.999 al año
3. de $15.000 a $24.999 al año
4. de $25.000 a $34.999 al año
5. de $35.000 a $49.999 al año
6. de $50.000 a $64.999 al año
7. de $65.000 a $79.999 al año
8. de $80.000 a $100.000
10. más de $100.000 al año
99. No sé / Prefiero no contestar

9. ☐ **Incluido usted, ¿cuántas personas se mantienen con el ingreso indicado arriba?**

99. No sé / Prefiero no contestar

10. ☐ **¿En qué país nació?**

1. Estados Unidos de América (pase a la pregunta 10a)
2. Otro país (pase a la pregunta 10b)
99. No sé / Prefiero no contestar

10a. ☐☐ **Si nació en los EE UU, escriba el código de dos números que corresponde al estado en que nació**
(vea la lista en la página 8)

10b. ☐ **Si nació en otro país, especifique el continente en donde está ese país**.

1. Norteamérica
2. Suramérica
3. Europa
4. África
5. Asia
6. Australia
99. No sé / Prefiero no contestar

DP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

11. ☐ **¿En qué país ha vivido usted más tiempo?**

1. Estados Unidos de América (pase a la pregunta 11a)
2. Otro país (pase a la pregunta 11b)
99. No sé / Prefiero no contestar

11a. ☐☐ Si ha vivido por más tiempo en los EE UU, escriba el código de dos números que corresponde al estado en el cuál usted ha vivido más tiempo (vea la lista en la página 8)

11b. ☐ Si ha vivido más tiempo en otro país, especifique el continente en que está ese país.

1. Norteamérica
2. Suramérica
3. Europa
4. África
5. Asia
6. Australia
99. No sé / Prefiero no contestar

Historia laboral

12. ¿Ha trabajado usted alguna vez durante más de un año en cualquiera de las ocupaciones enumeradas a continuación? Conteste **SÍ** o **NO** en cada una. Si su respuesta es **SÍ**, escriba el número de años que trabajó en esa ocupación e indique si usaba mascarilla o respirador la mayor parte del tiempo que pasaba en el trabajo. Si no sabe la respuesta o prefiere no contestar, escriba el código 99.

1. No 2. Sí 99 No sé / Prefiero no contestar

		N° de años trabajados	¿Usó mascarilla o respirador?
12a. ☐	Panadería	☐☐	☐
12b. ☐	Carnicería / empacadora de carne	☐☐	☐
12c. ☐	Fábrica de plásticos o productos químicos	☐☐	☐
12d. ☐	Mina de carbón	☐☐	☐
12e. ☐	Procesamiento de algodón o yute	☐☐	☐
12f. ☐	Agricultura	☐☐	☐
12g. ☐	Cuerpo de bomberos	☐☐	☐
12h. ☐	Molinos de harina, de alimentos o granos	☐☐	☐
12i. ☐	Fundición o fábrica de acero	☐☐	☐
12j. ☐	Minería de cantera	☐☐	☐
12k. ☐	Pintura	☐☐	☐
12l. ☐	Pulir con chorro de arena (sandblasting)	☐☐	☐
12m. ☐	Soldadura	☐☐	☐
12n. ☐	Trabajos con asbestos	☐☐	☐

DP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

Historia de síntomas: Tos

Conteste **SÍ** o **NO** a las preguntas siguientes. Si tiene dudas de su respuesta, conteste **NO**.
Incluya tos con el primer cigarrillo o recién que sale al aire libre. No cuente las veces que carraspea para despejar la garganta.

1. No 2. Sí 99 No sé / Prefiero no contestar

13. ☐ **¿**Tiene usted tos con frecuencia? Si contestó **NO**, pase a la pregunta 19.

14. ☐ Por lo general, ¿de cuatro o más días en una semana, tose usted de 4 a 6 veces al día?

15. ☐ ¿Tose por lo regular al levantarse, o es lo primero que hace en la mañana?

16. ☐ ¿Es habitual que tosa durante el resto del día o de la noche?

Si contestó **SÍ** a cualquiera de las anteriores, pase a las preguntas 17 y 18

17. ☐ ¿Es normal que tosa de esa manera la mayoría de los días por 3 meses consecutivos o que tosa más durante el año?

18. ☐☐ ¿Hace cuántos años que tiene esa tos?

Historia de síntomas: Falta de aliento

Conteste **SÍ** o **NO** a las preguntas siguientes. Si tiene dudas de su respuesta, conteste **NO**.

1. No 2. Sí 99 No sé / Prefiero no contestar

19. ☐ ¿Le falta el aliento cuando camina aprisa por un terreno plano o cuando sube una cuesta?

20. ☐ ¿Tiene que caminar más despacio que otras personas de su edad por un terreno plano debido a la falta de aliento?

21. ☐ ¿Tiene que detenerse con frecuencia para recuperar el aliento cuando camina una cuadra (o después de algunos minutos) por terreno plano?

22. ☐ ¿Le falta tanto el aliento que no puede salir de su casa o se queda sin aliento al vestirse o desvestirse?

23. ☐☐ ¿Cuántos años hace que tiene esa falta de aliento?

DP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

Historia general de alcohol

24. ☐ ¿Ha consumido alguna vez bebidas alcohólicas? Si contestó NO, pase a la pregunta 32.

1 No
2. Sí
99. No sé / Prefiero no contestar

25. ☐ ¿Consume en la actualidad bebidas alcohólicas? Si contestó NO, responda la parte A. Si contestó SÍ, pase a la parte B.

1 No
2. Sí
99. No sé / Prefiero no contestar

Parte A. Historia previa de alcohol (si prefiere no contestar, use el código 99).

26. ☐ ¿Cuánto hace que consumió por última vez una bebida alcohólica? (vino, cerveza, licor)

1. Menos de un año
2. De uno a dos años
3. Más de dos años

27. ☐☐ ¿Durante cuántos años consumió bebidas alcohólicas?

28. ☐☐. ¿Cuál era el número habitual de bebidas que tomaba usted a la semana antes de dejar las bebidas alcohólicas? (una bebida significa una cerveza o un vaso de vino o una medida de licor, anote 0 si tomaba menos de una bebida a la semana)

Parte B. Historia actual de alcohol (si prefiere no contestar, use el código 99).

29. ☐☐ ¿Durante cuántos años ha consumido usted bebidas alcohólicas?

30. ☐☐ ¿Cuál es el número de bebidas que acostumbra tomar a la semana? (una bebida significa una cerveza o un vaso de vino o una medida de licor, anote 0 si es menos de una bebida a la semana)

31. ☐☐ En las últimas 24 horas, ¿cuántas bebidas alcohólicas ha tomado?

Número de Seguro Social (SSN)

Preguntamos su SSN porque los datos de este estudio se van a enlazar con los datos suministrados por el Centro Nacional de Estadísticas de Salud (National Center for Health Statistics).
Se mantendrán en confidencia de acuerdo con la Ley de Privacidad de 1974 y se usarán sólo para fines de investigación. El suministro de esta información es sumamente importante para propósitos de este estudio, pero es totalmente **voluntario** de su parte.
Si prefiere no divulgar su SSN, escriba 9 en todas las casillas.

32. ¿Cuál es su número de Seguro Social (SSN)? ☐☐☐-☐☐-☐☐☐☐

DP

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COLOQUE LA ETIQUETA AQUÍ
Institución_____ Institución N°_____
Iniciales del participante_____ Caso N°_____

En ocasiones, quienes dependen de uno o los cónyuges pueden solicitar los beneficios de Medicare usando el número de Seguro Social de otro miembro de la familia.

33. ☐ . ¿Alguna vez ha recibido beneficios de Medicare usando un número de Seguro Social (SSN) distinto al propio? Si prefiere no divulgar el número de seguro social, escriba 9 en todas las casillas.

1 No
2. Sí*
99. No sé / Prefiero no contestar

*Si la respuesta es afirmativa, ¿cuál es ese número de Seguro Social?

☐☐☐-☐☐-☐☐☐☐

Conclusión

34. ☐ ¿Necesitó algún tipo de asistencia para completar este cuestionario?

1 No (pase a la pregunta 37).
2. Sí*
99. No sé / Prefiero no contestar

35. ☐ Especifique quién le atendió

1 Miembro del personal de ACRIN-NLST
2. Familiar
3. Otro, especifique:
99 No sé / Prefiero no contestar

36. Especifique el tipo de asistencia prestada (marque lo necesario)
1. Me leyó las preguntas
2. Marcó las respuestas que le di
3. Otro, especifique:
99. No sé / Prefiero no contestar

37. ☐ Especifique el método utilizado para completar este cuestionario.

1. Durante mi cita
2. Por correo (incluso que le hayan enviado el cuestionario por correo y que usted lo haya llevado a la institución ya completo)
3. Por teléfono
99 No sé / Prefiero no contestar

Comentarios: _____-

Verifique por favor que usted haya contestado todas las preguntas. Cuando devuelva este cuestionario, firme y escriba la fecha a continuación.

_____
Firma del participante

☐☐-☐☐-2 0 0☐
Fecha en que completó el formulario (mes, día, año)

_____
Auxiliar del estudio

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2. Códigos de dos números de los estados

01 Alabama AL
02 Alaska A
03 Arizona AZ
04 Arkansas
05 California CA
06 Colorado CO
07 Connecticut CT
08 Delaware DE
09 Florida FL
10 Georgia GA
11 Hawaii HI
12 Idaho ID
13 Illinois IL
14 Indiana IN
15 Iowa IA
16 Kansas KA
17 Kentucky KY
18 Louisiana LA
19 Maine ME
20 Maryland MD
21 Massachusetts MA
22 Michigan MI
23 Minnesota MN
24 Mississippi MS
25 Missouri MI
26 Montana MO
27 Nebraska NE
28 Nevada NV
29 New Hampshire NH
30 New Jersey NJ
31 New Mexico NM
32 New York NY
33 North Carolina NC
34 North Dakota ND
35 Ohio OH
36 Oklahoma OK
37 Oregon OR
38 Pennsylvania PA
39 Rhode Island RI
40 South Carolina SC
41 South Dakota SD
42 Tennessee TN
43 Texas TX
44 Utah UT
45 Vermont VT
46 Virginia VA
47 Washington WA
48 West Virginia WV
49 Wisconsin WI
50 Wyoming WY
51 District of Columbia DC

SS

ACRIN 6654 NLST

Cuestionario sobre su hábito de fumar

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUI

Institución_____ Institución N°_____

Iniciales del participante_____ Caso N°_____

Instrucciones para el participante: como parte del estudio, nos interesa saber acerca de los hábitos de fumar. Sus respuestas son importantes para nosotros, así que trate de contestar todas las preguntas. Si no está seguro de cómo contestar una pregunta, trate de dar la mejor respuesta que pueda. Entregue este cuestionario a algún miembro del equipo de investigación cuando termine de llenarlo.

Historia de tabaquismo:

1. ☐☐ ¿Qué edad tenía usted cuando dio su primera fumada a un cigarrillo?

Cuando comenzó a fumar (entre dos y 10 cigarrillos), ¿se mareaba usted?

2a. ☐

Nada	Un poco	En forma moderada	Bastante	No sé
1	2	3	4	9

Cuando comenzó a fumar (entre dos y 10 cigarrillos), ¿sentía usted una oleada de energía o zumbido agradables?

2b. ☐

Nada	Un poco	En forma moderada	Bastante	No sé
1	2	3	4	9

3. ☐☐ ¿Qué edad tenía usted cuando empezó a fumar todos los días (aunque fuera un cigarrillo al día o más)?

Para las siguientes preguntas, piense en la época en que fumaba más

4. ☐☐☐ En la época en que fumaba más ¿cuántos cigarrillos fumaba al día?

5. ☐☐ Durante la época en que fumaba, ¿cuántas veces dejó de fumar por TRES MESES o más?

6. ☐ ¿Se le hacía muy difícil no fumar en sitios donde estaba prohibido, como en la iglesia, en una biblioteca o en una sala de cine?
   1 No
   2 Si

7. ☐ ¿Fumaba MÁS durante las primeras horas del día, al despertar, o durante el resto del día?
   1 Al despertar
   2 Durante el resto del día

8. ☐ Después de despertar, ¿qué tan pronto se fumaba el primer cigarrillo?
   1 A los cinco minutos
   2 Entre 6 y 14 minutos
   3 Entre 15 y 29 minutos
   4 Después de 30 minutos, pero antes de una hora
   5 Después de una hora, pero antes de dos horas
   6 Después de 2 horas, pero antes de ocho horas
   7 Más de 8 horas

9. ☐ ¿Fumaba usted aun cuando estuviera tan enfermo que se pasara la mayor parte del día en cama?
   1 No
   2 Sí

SS

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10. ☐ Cuando fumaba más, ¿con qué frecuencia inhalaba?
1 Siempre
2 A veces
3 Nunca

11. ☐ ¿Cuál cigarrillo del día le costaba más trabajo dejar?
1 El primero de la mañana
2 Uno a media mañana
3 Uno al mediodía
4 Uno en la tarde
5 Uno después del trabajo
6 Uno en la noche
7 Uno tarde en la noche
8 Uno a la hora de acostarse

12a. ☐☐☐ Cuando fumaba más, ¿cuál era su marca de cigarrillos preferida? **Vea la lista de marcas de cigarrillos en las páginas 6-8 de este formulario**

12b. Si su marca favorita no aparece, escriba aquí el nombre:_____

Las siguientes preguntas se refieren a la marca habitual de cigarrillos cuando usted fumaba más.

13. ☐ Era del tipo...
1 Regular
2 Ligero (light)
3 Ultralight

14. ☐ ¿De sabor
1 Regular
2 Mentolado

15. ☐ De cajetilla
1 Dura
2 Blanda

16. ☐ Los cigarrillos eran
1 Con filtro
2 Sin filtro

17. ☐ ¿Ha cambiado alguna vez a cigarrillos bajos en alquitrán o en nicotina o ultralight?
1 No (pase a la pregunta 21)
2 SÍ

18. ☐☐ ¿Qué edad tenía cuando cambió de marca? (solo si respondió SÍ a la pregunta 17)

19. ☐☐☐ Durante el tiempo que fumó cigarrillos bajos en alquitrán o nicotina o ultralight, ¿más o menos cuántos fumaba al día? (solo si respondió SÍ a la pregunta 17)

20. ☐☐ ¿Cuántos años en TOTAL fumó usted cigarrillos bajos en alquitrán o en nicotina o ultralight?

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Preguntas relacionadas con dejar de fumar

Las siguientes son declaraciones hechas por fumadores acerca de dejar de fumar. Diga cuál declaración describe mejor lo que usted piensa en este momento.

21. ☐☐
1 Me gusta tanto fumar que nunca voy a considerar la posibilidad de dejar de hacerlo, no importa lo que pase (vaya a la pregunta 24)
2 Nunca pienso en dejar de fumar, pero podría cambiar de opinión algún día (vaya a la pregunta 24)
3 Rara vez pienso en dejar de fumar y no tengo un plan específico para hacerlo (pase a la pregunta 23)
4 A veces pienso en dejar de fumar pero no tengo un plan específico para hacerlo (pase a la pregunta 23)
5 A menudo pienso en dejar de fumar pero no tengo un plan específico para hacerlo (pase a la pregunta 23)
6 Pienso dejar de fumar en los próximos 6 meses (pase a la pregunta 23)
7 Pienso dejar de fumar en los próximos 30 días (pase a la pregunta 23)
8 Ya empecé a fumar menos y me fijé una fecha para dejarlo por completo (pase a la pregunta 23)
9 Ya dejé de fumar pero me preocupa volver a empezar o recaer (conteste la pregunta 22 y luego pase a la 25)
10 Ya dejé de fumar y tengo un cien por ciento de confianza que nunca volveré a fumar jamás (conteste la pregunta 22 y luego pase a la 25)
99 Prefiero no contestar

Solo para exfumadores:

22. ☐☐ ¿Qué edad tenía cuando dejó de fumar cigarrillos para siempre?

Solo para fumadores actuales:

23. ☐☐ ¿Cuántas veces durante el AÑO PASADO dejó de fumar por 24 horas o más?

24. Desde que usted comenzó a fumar, ¿cuál ha sido el periodo más largo en el que pudo dejar de fumar cigarrillos del todo? (conteste solo uno)

☐☐ horas
☐☐ días
☐☐ semanas
☐☐ años

Para todos los participantes:

25. ☐ ¿Ha fumado usted ALGUNA VEZ tabaco en cualquier otra forma?
1 No (pase a la pregunta 28)
2 Sí

26. ☐ ¿Actualmente fuma usted tabaco en cualquier otra forma?
1 No
2 Sí

27. ☐ ¿Qué tipos de tabaco fuma o fumó usted? (Marque todo lo necesario).
1 Pipa
2 Cigarros (puros)
3 Tiparillos (cigarros delgados)
4 Marihuana

SS

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COLOQUE LA ETIQUETA AQUI
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Iniciales del participante_____ Caso N°_____

Fumador pasivo (de segunda mano):

Las siguientes preguntas se refieren a la exposición al humo del cigarrillo de otras personas, conocido como de segunda mano.

28. ☐ ¿Ha vivido alguna vez con alguien que fumaba en su casa?
1 No (pase a la pregunta 31)
2 SÍ

29. ☐ ¿Vive usted actualmente con alguien que fuma en su casa? (solo si respondió SÍ a la pregunta 28)
1 No
2 SÍ

30. ☐ Sin incluirlo a usted, ¿cuántas personas fuman o fumaban en su casa? (solo si respondió SÍ a la pregunta 28)
1 Otro fumador en casa
2 Otros dos fumadores en casa
3 Más de otros dos fumadores en la casa

31. ☐ ¿Ha trabajado ALGUNA VEZ en un lugar donde haya estado expuesto al humo del cigarrillo de otros?
1 No (pase a la pregunta 34).
2 SÍ

32. ☐ ¿Trabaja actualmente en un lugar donde está expuesto al humo del cigarrillo de otros? (solo si respondió SÍ a la pregunta 31)
1 No
2 Sí

33. ☐ Sin incluirlo a usted, ¿cuántas personas fuman o fumaban en el lugar en donde usted trabaja o trabajaba?
1 Otro fumador
2 Otros dos fumadores
3 Más de otros dos fumadores

34. ☐☐ Si piensa en todas las veces que usted ha estado expuesto al humo del cigarrillo de otras personas, ¿aproximadamente cuántos años en total diría usted que ha estado expuesto al humo de segunda mano?

Conclusión:

35. ☐ ¿Necesitó alguna asistencia para completar este cuestionario?
1 No (pase a la pregunta 38).
2 Sí
99 No sabe

36. ☐ Especifique quién le atendió:
1 Miembro del personal de ACRIN-NLST
2 Familiar
3 Otro, especifique: _____
99 No sabe

SS

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUI
Institución_____ Institución N°_____

Iniciales del participante_____ Caso N°_____

37. Especifique qué tipo de asistencia necesitó: (Marque todo lo necesario).
- ☐ Me leyó las preguntas
- ☐ Marcó las respuestas que le di
- ☐ Otro, especifique:_____
- ☐ No sé

38. ___ Especifique el método utilizado para completar este cuestionario:
1 Durante mi cita
2 Por correo (incluye que le hayan enviado el cuestionario por correo y usted lo haya llevado a la institución)
3 Por teléfono
99 No sabe

Comentarios:

_____

_____

_____

Revise por favor que usted haya contestado todas las preguntas. Cuando devuelva este cuestionario, firme y escriba la fecha a continuación.

_____ __ __-__ __-2 0 0 __

Firma del participante — Fecha en que completó el formulario (mm-dd-aaaa)

_____

Auxiliar del estudio

SS

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COLOQUE LA ETIQUETA AQUI
Institución_____ Institución N°_____

Iniciales del participante_____ Caso N°_____

Cigarette Brands

(NF)=non-filter

1 1st Choice
2 Alpine
3 Alpine Lights
4 Always Save
5 American Filter
6 American Lights
7 Austin
8 Barclay
9 Bargain Buy
10 Bargain King
11 Basic
12 Basic (NF)
13 Basic Lights
14 Basic Ultra Lights
15 Beacon
16 Belair
17 Belair Lights LoPrice
18 Belair Lo Price
19 Benson & Hedges
20 Benson & Hedges Deluxe Ultralights
21 Benson & Hedges DeNic
22 Benson & Hedges Lights
23 Benson & Hedges Multi
24 Best Buy
25 Best Choice
26 Best Value
27 Big Money
28 Black & Yellow
29 Bonus Value
30 Bristol (NF)
31 Bristol Full Flavor
32 Bristol Lights
33 Bristol Lowest
34 Bristol UltraLights
35 Bucks
36 Bucks Lights
37 Bull Durham
38 Bull Durham Lights
39 Cambridge Full Flavor
40 Cambridge Lights
41 Cambridge Lowest
42 Cambridge UltraLights
43 Camel
44 Camel (NF)
45 Camel UltraLights
46 Camel Wides
47 Camel Wides Lights
48 Capri 100's
49 Capri 120's
50 Cardinal
51 Carlton 120's
52 Carlton Kings
53 Carlton Ultra
54 Cartier Vendome
55 Cavalier
56 Century 25 Lights
57 Century 25's
58 Chelsea
59 Chesterfield Full Flavor
60 Chesterfield Kings (NF)
61 Chesterfield Lights
62 Chesterfield Regular (NF)
63 Citation
64 Class A Deluxe Full Flavor
65 Class A Deluxe Lights
66 Class A Deluxe UltraLights
67 Class A Full Flavor
68 Class A King (NF)
69 Class A Kings (NF)
70 Class A Lights
71 Class A Regular (NF)
72 Class A UltraLights
73 Commander (NF)
74 Cost Cutter
75 Covington Full Flavor
76 Covington Lights
77 Covington UltraLights
78 Dakota Full Flavor
79 Dakota Lights
80 Director's Choice
81 Doral
82 Doral Full Flavor
83 Doral Lights
84 Doral Ultra Lights
85 Eagle 20's
86 Econo Buy
87 English Oval (NF)
88 Epic
89 Eve Light 120's
90 Eve Slim Light 100's
91 Eve Slim Lights
92 Eve Slim UltraLights
93 Eve UltraLights
94 Extra Value
95 F&L
96 Falcon Lights
97 Famous Value
98 Federated
99 Focus
100 Genco
101 Generic

SS

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUI
Institución_____ Institución N°_____

Iniciales del participante_____ Caso N°_____

102 Generic Lights
103 Generic Ultra Lights
104 Golden Lights
105 GPA
106 GPC
107 Gridlock
108 Harley Davidson
109 Harley Davidson Lights
110 Herbert Tareyton (NF)
111 Heritage Lights
112 Highway
113 HiLite
114 Horizon Lights
115 Jacks
116 Jasmine Slim Lights
117 Jasmine Slims
118 Kent
119 Kent III
120 Kingsport
121 Kool Deluxe Lights
122 Kool Deluxe Ultra Long
123 Kool Kings
124 Kool Lights
125 Kool Mild
126 Kool Regular (NF)
127 Kool Super Long
128 Kool Ultra Lights
129 L&M
130 Lark Full Flavor
131 Lark Lights
132 Lucky Strike
133 Lucky Strike Lights
134 Lucky Strike Regulars (NF)
135 Magna
136 Magna Lights
137 Malibu
138 Malibu Lights
139 Malibu UltraLights
140 Marker
141 Marlboro
142 Marlboro Lights
143 Marlboro Medium
144 Marlboro UltraLights
145 Max 120's
146 Meridian
147 Merit
148 Merit DeNic
149 Merit Ultima
150 Merit UltraLights
151 Misty Slims
152 Monarch
153 Money
154 Montclair
155 Montclair Lights
156 Montclair UltraLights
157 More 100 Lights
158 More 120 Lights
159 More 120's
160 More 120's White Lights
161 Newport
162 Newport Lights
163 Newport Stripe
164 Next DeNic
165 No Frills
166 Now
167 Old Gold
168 Old Gold Lights
169 Old Gold Straight (NF)
170 Omni
171 Pall Mall (NF)
172 Pall Mall Gold
173 Pall Mall Lights
174 Pall Mall Red
175 Parliament Lights
176 Philip Morris
177 Philip Morris International
178 Phillip Morris Regular (NF)
179 Picayune (NF)
180 Pilot
181 Players
182 Players (NF)
183 Players Lights
184 Price Breaker
185 Price Master
186 Price Saver
187 Pyramid (NF)
188 Pyramid Full Flavor
189 Pyramid Lights
190 Pyramid UltraLights
191 Quality Lights
192 Quality Smokes
193 Raleigh
194 Raleigh (NF)
195 Raleigh Extra
196 Raleigh Extra (NF)
197 Raleigh ExtraLights
198 Raleigh Extra UltraLights
199 Raleigh Lights
200 Ralph's
201 Richland 100's
202 Richland Kings
203 Richland Lights
204 Ritz
205 Riviera

SS

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUI
Institución_____ Institución N°_____

Iniciales del participante_____ Caso N°_____

206 Salem
207 Salem Lights
208 Salem Slim Lights
209 Salem UltraLights
210 Saratoga 120's
211 Satin
212 Savvy
213 Scotch Buy
214 Sebring
215 Shurfine
216 Silva Thins
217 Sincerely Yours
218 Slim Price
219 Spring
220 Spring Lights
221 Sterling Full Flavor
222 Sterling Lights
223 Sterling UltraLights
224 Style Lights
225 Style UltraLights
226 Sundance
227 Tall 120's
228 Tareyton
229 Tareyton Lights
230 Tourney
231 Tourney Slim Lights
232 Tri Brand
233 Triumph
234 True 100's
235 Turney Slims
236 Upland
237 Value & Quality
238 Value Buy
239 Value Price
240 Value Sense
241 Vantage
242 Vantage UltraLights
243 Viceroy
244 Viceroy Lights
245 Virginia Slim Light 100's
246 Virginia Slims 100's
247 Virginia Slims 100's UltraLights
248 Virginia Slims Light 120's
249 Virginia Super Slim 100s
250 Winston
251 Winston Lights
252 Winston UltraLights
253 Worth
254 Yours
255 Otra marca que no esta en la lista

QP

ACRIN 6654
NLST
ENCUESTA DEL ESTADO DE SALUD SF-36V2, EQ-5D

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

INSTRUCCIONES: Esta encuesta le pide sus opiniones acerca de su salud. Esta información permitirá saber cómo se siente y qué bien puede hacer usted sus actividades normales. Conteste cada pregunta marcando la respuesta como se le indica. Si no está seguro o segura de cómo responder a una pregunta, por favor dé la mejor respuesta posible.

1. En general, ¿diría que su salud es: [Marque con una "x" la casilla que mejor corresponda a su respuesta.]

Excelente	Muy buena	Buena	Pasable	Mala
O 1	O 2	O 3	O 4	O 5

2. <u>Comparando su salud con la de hace un año</u>, ¿cómo la calificaría en general <u>ahora</u>?

Mucho mejor ahora que hace un año	Algo mejor ahora que hace un año	Más o menos igual ahora que hace un año	Algo peor ahora que hace un año	Mucho peor ahora que hace un año
O 1	O 2	O 3	O 4	O 5

3. Las siguientes preguntas se refieren a actividades que usted podría hacer durante un día típico. ¿Su estado de salud actual lo limita para hacer estas actividades? Si es así, ¿cuánto? [Marque con una "x" una casilla para cada pregunta.]

		Sí, me limita mucho	Sí, me limita un poco	No, no me limita en absoluto
a.	**Actividades vigorosas**, tales como correr, levantar objetos pesados, participar en deportes intensos	O 1	O 2	O 3
b.	**Actividades moderadas**, tales como mover una mesa, empujar una aspiradora, jugar al bowling o al golf, o trabajar en el jardín	O 1	O 2	O 3
c.	Levantar o cargar las compras del mercado	O 1	O 2	O 3
d.	Subir **varios** pisos por la escalera	O 1	O 2	O 3
e.	Subir **un** piso por la escalera	O 1	O 2	O 3
f.	Doblarse, arrodillarse o agacharse	O 1	O 2	O 3
g.	Caminar **más de una milla**	O 1	O 2	O 3
h.	Caminar **varias cuadras (varios cientos de metros)**	O 1	O 2	O 3
i .	Caminar **una cuadra (unos cien metros)**	O 1	O 2	O 3
j.	Bañarse o vestirse	O 1	O 2	O 3

QP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

4. Durante las <u>últimas 4 semanas</u>, ¿cuánto tiempo ha tenido usted alguno de los siguientes problemas con el trabajo u otras actividades diarias regulares a causa <u>de su salud física</u>?

		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a.	Ha reducido el **tiempo** que dedicaba al trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
b.	**Ha logrado hacer menos** de lo que le hubiera gustado	O 1	O 2	O 3	O 4	O 5
c.	Ha tenido limitaciones en cuanto al **tipo** de trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
d.	Ha tenido **dificultades** en realizar el trabajo u otras actividades (por ejemplo, le ha costado más esfuerzo)	O 1	O 2	O 3	O 4	O 5

5. Durante las <u>últimas 4 semanas</u>, ¿cuánto tiempo ha tenido usted alguno de los siguientes problemas con el trabajo u otras actividades diarias regulares a causa <u>de algún problema emocional</u> (como sentirse deprimido o ansioso)?

		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a.	Ha reducido el **tiempo** que dedicaba al trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
b.	**Ha logrado hacer menos** de lo que le hubiera gustado	O 1	O 2	O 3	O 4	O 5
c.	Ha hecho el trabajo u otras actividades **con menos cuidado** de lo usual	O 1	O 2	O 3	O 4	O 5

6. Durante las <u>últimas 4 semanas</u>, ¿en qué medida su salud física o sus problemas emocionales han dificultado sus actividades sociales normales con la familia, amigos, vecinos o grupos?

Nada en absoluto	Ligeramente	Medianamente	Bastante	Extremadamente
O 1	O 2	O 3	O 4	O 5

7. ¿Cuánto dolor <u>físico</u> ha tenido usted durante las <u>últimas 4 semanas</u>?

Ningún dolor	Muy poco	Poco	Moderado	Severo	Muy severo
O 1	O 2	O 3	O 4	O 5	O 6

8. Durante las <u>últimas 4 semanas</u>, ¿cuánto ha dificultado el <u>dolor</u> su trabajo normal (incluyendo tanto el trabajo fuera de casa como los quehaceres domésticos)?

Nada en absoluto	Un poco	Medianamente	Bastante	Extremadamente
O 1	O 2	O 3	O 4	O 5

QP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

9. Estas preguntas se refieren a cómo se siente usted y a cómo le han ido las cosas durante las últimas 4 semanas. Por cada pregunta, por favor dé la respuesta que más se acerca a la manera como se ha sentido usted.

¿Cuánto tiempo durante las últimas 4 semanas...

	Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a. se ha sentido lleno de vida?	O 1	O 2	O 3	O 4	O 5
b. se ha sentido muy nervioso?	O 1	O 2	O 3	O 4	O 5
c. se ha sentido tan decaído de ánimo que nada podía alentarlo?	O 1	O 2	O 3	O 4	O 5
d. se ha sentido tranquilo y sosegado?	O 1	O 2	O 3	O 4	O 5
e. ha tenido mucha energía?	O 1	O 2	O 3	O 4	O 5
f. se ha sentido desanimado y triste?	O 1	O 2	O 3	O 4	O 5
g. se ha sentido agotado?	O 1	O 2	O 3	O 4	O 5
h. se ha sentido feliz?	O 1	O 2	O 3	O 4	O 5
i. se ha sentido cansado?	O 1	O 2	O 3	O 4	O 5

10. Durante las últimas 4 semanas, ¿cuánto tiempo su salud física o sus problemas emocionales han dificultado sus actividades sociales (como visitar amigos, parientes, etc.)?

Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
O 1	O 2	O 3	O 4	O 5

11. ¿Qué tan CIERTA o FALSA es cada una de las siguientes frases para usted?

	Claramente cierta	Mayormente cierta	No sé	Mayormente falsa	Claramente falsa
a. Parece que yo me enfermo un poco más fácilmente que otra gente	O 1	O 2	O 3	O 4	O 5
b. Tengo tan buena salud como cualquiera que conozco	O 1	O 2	O 3	O 4	O 5
c. Creo que mi salud va a empeorar	O 1	O 2	O 3	O 4	O 5
d. Mi salud es excelente	O 1	O 2	O 3	O 4	O 5

QP

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

Marque con una cruz como esta ! la afirmación en cada sección que describa mejor su estado de salud en el día de hoy.

1. Movilidad

☐ 1 No tengo problemas para caminar "
☐ 2 Tengo algunos problemas para caminar "
☐ 3 Tengo que estar en la cama "

2.Cuidado-Personal

☐ 1 No tengo problemas con el cuidado personal "
☐ 2 Tengo algunos problemas para lavarme o vestirme solo "
☐ 3 Soy incapaz de lavarme o vestirme solo "

3. Actividades de Todos los Días *(ej, trabajar, estudiar, hacer tareas domésticas, actividades familiares o realizadas durante el tiempo libre)*

☐ 1 No tengo problemas para realizar mis actividades de todos los días "
☐ 2 Tengo algunos problemas para realizar mis actividades de todos los días "
☐ 3 Soy incapaz de realizar mis actividades de todos los días "

4. Dolor/Malestar

☐ 1 No tengo dolor ni malestar "
☐ 2 Tengo moderado dolor o malestar "
☐ 3 Tengo mucho dolor o malestar "

5. Ansiedad/Depresión

☐ 1 No estoy ansioso/a ni deprimido/a "
☐ 2 Estoy moderadamente ansioso/a o deprimido/a "
☐ 3 Estoy muy ansioso/a o deprimido/a "

QL

ACRIN 6654 NLST ENCUESTA DEL ESTADO DE SALUD SF-36v2, EQ-5D

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

INSTRUCCIONES: Esta encuesta le pide sus opiniones acerca de su salud. Esta información permitirá saber cómo se siente y qué bien puede hacer usted sus actividades normales. Conteste cada pregunta marcando la respuesta como se le indica. Si no está seguro o segura de cómo responder a una pregunta, por favor dé la mejor respuesta posible.

1. En general, ¿diría que su salud es: [Marque con una "x" la casilla que mejor corresponda a su respuesta.]

Excelente	Muy buena	Buena	Pasable	Mala
O 1	O 2	O 3	O 4	O 5

2. <u>Comparando su salud con la de hace un año</u>, ¿cómo la calificaría en general <u>ahora</u>?

Mucho mejor ahora que hace un año	Algo mejor ahora que hace un año	Más o menos igual ahora que hace un año	Algo peor ahora que hace un año	Mucho peor ahora que hace un año
O 1	O 2	O 3	O 4	O 5

3. Las siguientes preguntas se refieren a actividades que usted podría hacer durante un día típico. ¿Su estado de salud actual lo limita para hacer estas actividades? Si es así, ¿cuánto? [Marque con una "x" una casilla para cada pregunta.]

		Sí, me limita mucho	Sí, me limita un poco	No, no me limita en absoluto
a.	**Actividades vigorosas**, tales como correr, levantar objetos pesados, participar en deportes intensos	O 1	O 2	O 3
b.	**Actividades moderadas**, tales como mover una mesa, empujar una aspiradora, jugar al bowling o al golf, o trabajar en el jardín	O 1	O 2	O 3
c.	Levantar o cargar las compras del mercado	O 1	O 2	O 3
d.	Subir **varios** pisos por la escalera	O 1	O 2	O 3
e.	Subir **un** piso por la escalera	O 1	O 2	O 3
f.	Doblarse, arrodillarse o agacharse	O 1	O 2	O 3
g.	Caminar **más de una milla**	O 1	O 2	O 3
h.	Caminar **varias cuadras (varios cientos de metros)**	O 1	O 2	O 3
i .	Caminar **una cuadra (unos cien metros)**	O 1	O 2	O 3
j.	Bañarse o vestirse	O 1	O 2	O 3

QL

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

4. Durante las <u>últimas 4 semanas</u>, ¿cuánto tiempo ha tenido usted alguno de los siguientes problemas con el trabajo u otras actividades diarias regulares a causa <u>de su salud física</u>?

		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a.	Ha reducido el **tiempo** que dedicaba al trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
b.	**Ha logrado hacer menos** de lo que le hubiera gustado	O 1	O 2	O 3	O 4	O 5
c.	Ha tenido limitaciones en cuanto al **tipo** de trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
d.	Ha tenido **dificultades** en realizar el trabajo u otras actividades (por ejemplo, le ha costado más esfuerzo)	O 1	O 2	O 3	O 4	O 5

5. Durante las <u>últimas 4 semanas</u>, ¿cuánto tiempo ha tenido usted alguno de los siguientes problemas con el trabajo u otras actividades diarias regulares a causa <u>de algún problema emocional</u> (como sentirse deprimido o ansioso)?

		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a.	Ha reducido el **tiempo** que dedicaba al trabajo u otras actividades	O 1	O 2	O 3	O 4	O 5
b.	**Ha logrado hacer menos** de lo que le hubiera gustado	O 1	O 2	O 3	O 4	O 5
c.	Ha hecho el trabajo u otras actividades **con menos cuidado** de lo usual	O 1	O 2	O 3	O 4	O 5

6. Durante las <u>últimas 4 semanas</u>, ¿en qué medida su salud física o sus problemas emocionales han dificultado sus actividades sociales normales con la familia, amigos, vecinos o grupos?

Nada en absoluto	Ligeramente	Medianamente	Bastante	Extremadamente
O 1	O 2	O 3	O 4	O 5

7. ¿Cuánto dolor <u>físico</u> ha tenido usted durante las <u>últimas 4 semanas</u>?

Ningún dolor	Muy poco	Poco	Moderado	Severo	Muy severo
O 1	O 2	O 3	O 4	O 5	O 6

8. Durante las <u>últimas 4 semanas</u>, ¿cuánto ha dificultado el <u>dolor</u> su trabajo normal (incluyendo tanto el trabajo fuera de casa como los quehaceres domésticos)?

Nada en absoluto	Un poco	Medianamente	Bastante	Extremadamente
O 1	O 2	O 3	O 4	O 5

QL

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

9. Estas preguntas se refieren a cómo se siente usted y a cómo le han ido las cosas durante las últimas 4 semanas. Por cada pregunta, por favor dé la respuesta que más se acerca a la manera como se ha sentido usted.

¿Cuánto tiempo durante las últimas 4 semanas...

	Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
a. se ha sentido lleno de vida?	O 1	O 2	O 3	O 4	O 5
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f. se ha sentido desanimado y triste?	O 1	O 2	O 3	O 4	O 5
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h. se ha sentido feliz?	O 1	O 2	O 3	O 4	O 5
i. se ha sentido cansado?	O 1	O 2	O 3	O 4	O 5

10. Durante las últimas 4 semanas, ¿cuánto tiempo su salud física o sus problemas emocionales han dificultado sus actividades sociales (como visitar amigos, parientes, etc.)?

Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
O 1	O 2	O 3	O 4	O 5

11. ¿Qué tan CIERTA o FALSA es cada una de las siguientes frases para usted?

	Claramente cierta	Mayormente cierta	No sé	Mayormente falsa	Claramente falsa
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b. Tengo tan buena salud como cualquiera que conozco	O 1	O 2	O 3	O 4	O 5
c. Creo que mi salud va a empeorar	O 1	O 2	O 3	O 4	O 5
d. Mi salud es excelente	O 1	O 2	O 3	O 4	O 5

QL

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

Marque con una cruz como esta ! la afirmación en cada sección que describa mejor su estado de salud en el día de hoy.

1. Movilidad

☐ 1 No tengo problemas para caminar "
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☐ 1 No estoy ansioso/a ni deprimido/a "
☐ 2 Estoy moderadamente ansioso/a o deprimido/a "
☐ 3 Estoy muy ansioso/a o deprimido/a "

QF

ACRIN 6654
NLST
ENCUESTA DEL ESTADO DE SALUD SF-36V2, EQ-5D, STAI Y-1

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

INSTRUCCIONES: Esta encuesta le pide sus opiniones acerca de su salud. Esta información permitirá saber cómo se siente y qué bien puede hacer usted sus actividades normales. Conteste cada pregunta marcando la respuesta como se le indica. Si no está seguro o segura de cómo responder a una pregunta, por favor dé la mejor respuesta posible.

1. En general, ¿diría que su salud es: [Marque con una "x" la casilla que mejor corresponda a su respuesta.]

Excelente	Muy buena	Buena	Pasable	Mala
O 1	O 2	O 3	O 4	O 5

2. <u>Comparando su salud con la de hace un año</u>, ¿cómo la calificaría en general <u>ahora</u>?

Mucho mejor ahora que hace un año	Algo mejor ahora que hace un año	Más o menos igual ahora que hace un año	Algo peor ahora que hace un año	Mucho peor ahora que hace un año
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QF

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
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4. Durante las <u>últimas 4 semanas</u>, ¿cuánto tiempo ha tenido usted alguno de los siguientes problemas con el trabajo u otras actividades diarias regulares a causa <u>de su salud física</u>?

		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
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		Siempre	Casi Siempre	Algunas veces	Casi Nunca	Nunca
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Nada en absoluto	Ligeramente	Medianamente	Bastante	Extremadamente
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QF

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
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d. Mi salud es excelente	O 1	O 2	O 3	O 4	O 5

QF

Estudio ACRIN 6654
COLOQUE LA ETIQUETA AQUÍ

Institución_____ Institución _____
Iniciales del participante_____ Caso N°_____

Marque con una cruz como esta ! la afirmación en cada sección que describa mejor su estado de salud en el día de hoy.

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