#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 interpreting 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

6-10-04
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 interpreting 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 interpreting 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 interpreting 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.
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Pending: DE, TF, CX, PQ