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.

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**Pending:** F1, DE, TF, CX, PQ

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