March 10, 2008

To: ACRIN-NLST Principal Investigators  
ACRIN-NLST Study Coordinators

From: ACRIN Data Management

Enclosed please find the supporting documents for ACRIN-NLST Decision Log #4.

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.

This decision log 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.