ACRIN – NLST Decision Log # 2

July 25, 2005

The scope and format of the ACRIN-NLST Decision Log was revised March, 2005. The Decision Log will continue to document study related changes and updates but will now incorporate the Forms Revision Notice. Future study form revisions will be detailed within the Decision Log; a separate Forms Revision Notice will not be created. The format of the Decision Log has been revised so that each document is independent. Decision Log # 1 lists Form Revision Notices and study-related updates through March, 2005. Study sites are responsible for keeping Decision Log # 1-2, all future Decision Logs, and all previous Forms Revisions Notices in the front section of the ACRIN-NLST Manual of Operations and for implementing the study forms and/or decisions documented in the Decision Logs.

Enclosed please find the supporting documents for ACRIN-NLST Decision Log # 2. All revisions are highlighted in yellow. Decision Log # 2 includes:

- **Revised NP Form (v2, new version date 7-13-2005)**
  The text for Q2b code table (2-4) has been revised. Q2b, response codes 2 and 3, now requires the study site to document whether the participant will permit medical records collection to continue. Q2b, response code 4, now requires the study site to document whether the participant can be included in the NDI search as part of the EVP.

  Previously reported withdrawals will require submission of the revised NP(v2) to ACRIN HQs. A report identifying these cases and any relevant queries will be sent by Deb Harbison to each of the study sites. The details for each case may vary so resolutions will need to be considered/reviewed case by case. Questions related to withdrawals and the NP should be directed to Deb Harbison.

- **Revised NP Instructions (v2, new version date 7-13-2005)**
  Additional details have been added to the introductory discussion regarding the withdrawal process and the purpose of the NP Form and documentation. Q2b, response codes 2-3, additional details have been added to help illustrate the differences between the two categories, as well as, added information pertaining to the reason and documentation for obtaining participant permission for continued medical records collection. Q2b, response code 4, information has been added pertaining to the reason and documentation for obtaining participant permission for inclusion in the NDI searches.

- **NP Instructions, Appendix A – Flowchart and Guidelines (new document, version date 7-13-2005)**
  Appendix A contains (1) a flowchart of the withdrawal process and decision tree; (2) an explanation of the reason for continued medical records collection and guidelines for determining which participants will require additional medical records collection; and (3) an explanation on when to use template withdrawal documents, Letter A and B, within the withdrawal process.

- **NP Instructions, Appendix B – Withdrawal Worksheet (new document, version date 7-13-2005)**
  The Withdrawal Worksheet is an optional tool which can be used to help guide the RA through a discussion with the participant, once the participant indicates a desire to alter her/his study participation/adherence. This discussion will help determine the participant’s true intention regarding her/his altered participation so that the study staff is not left to interpret the participant’s request.

  Letter A is a template letter which can be sent to those participants requesting to drop out of the study whom you were unable to have a direct discussion with. The letter serves as confirmation of the participant’s altered study status and also seeks to gain permission for continue medical records collection.

  Letter B is a template letter which can be sent to those participants withdrawing/rescinding study consent/authorizations. The letter serves as confirmation of the participant’s altered study status and also seeks to gain permission for continue medical records collection.
• F2 Follow-Up Form and Instructions (version date 3-7-2005, will replace F1 as of 8-1-2005)
• Follow-up Coversheets and Instructions (version date 3-7-2005, will replace FC as of 8-1-2005)

The F2 is the revised 6-month follow-up form to replace the F1. These forms were previously distributed in March, 2005; the forms will also be available on the ACRIN web site. Only the revised Follow-up Coversheets (XB-XP) will be added to the case calendars. The F2 Form will be generated by responses provided on the Coversheet. The Supplemental Follow-up Forms (FH, FE, FP) will be generated by responses provided on the F2 Form.

As of 8-1-2005, only F2 Forms should be sent to participants. As the outstanding F1 Forms are returned, they should be applied to the appropriate calendar due date. F1 and FC Forms will stay on the calendars for approximately 6 months to allow for transition time and late-returned F1 Forms to be submitted, they will then be deleted from the case calendars.