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.

(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.