Participant follow-up is to occur every 6 months based on the date of randomization, as indicated by the participant case calendar. The purpose of the Follow-up Coversheet is to report the vital status of the participant (deceased/alive) and to document how the vital status and follow-up information (F2) was obtained. The Coversheets are now time-point-specific; XB represents the 1-year follow-up, XC represents the 1.5-year follow-up, XD represents the 2-year follow-up and so on down to the XP, which represents the 8-year follow-up. The Coversheet is completed by the RA and is NOT given to the participant as part of the F2.

1. **Participant vital status:** Report the vital status of the participant (Alive, Deceased, Unknown) by placing a check mark in the appropriate response box.
   - **Mark Alive:** If the participant is known to be alive by any means (self-report, family member or other proxy, health care provider, or NLST staff). Note: Participant status cannot be recorded as “Alive” if the participant is later described as “Lost” on this form (see below, 2b, and example).
   - **Mark Deceased:** If the participant is known to be deceased by any means.
   - **Mark Unknown:** If participant vital status cannot be determined.

1a. **Date of Death:** If the participant is deceased, record the date of death in the space provided. The date must be recorded as MM/DD/YYYY. If unable to obtain any portion of the date, record ‘99’. For example, if the contact is unable to provide the day and provides only 10/2003, the RA should record the day as ‘99’. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use ‘99’ as directed.

1b. **Indicate source of information:** Check all that apply. Check the appropriate box or boxes to indicate how you obtained the death information. If the reason cannot be found use the “other, specify” option. WEB: data field is limited to 100 characters.
   - **Participant family member or friend:** Select this if information regarding the participant’s vital status is obtained directly from the participant or through a reliable proxy. The reliability of sources is a site decision.
   - **Participant’s health care provider or other health care source:** Select this if a provider or NLST staff are aware of the vital status, in the absence of direct contact with the participant. This may occur if the participant is observed outside the setting of the NLST.
   - **Medical document or Death Certificate:** Medical documentation or a death certificate serves to document participant death. In the case of the former, the site should initiate efforts to secure the death certificate of the decedent within 6-9 months of the reported date of death.
   - **Mailing returned as “Deceased”:** The site should initiate efforts to secure the death certificate of the decedent within 6-9 months of the reported date of death.
   - **Other, specify:** Record any other mechanism through which the site is aware of the vital status of the participant.

2. **Was the Follow-up Form for this reporting period completed?**
   - If NO, complete the follow-up time interval and Q2b to indicate the reason the F2 Form was not completed.
   - If YES, complete the follow-up time interval and Q2a to indicate the method of completion of the F2 Form.

Follow-up time interval collected: Record the current follow-up interval (previous F1/F2 to current F2).
   - **Start date:** Date participant completed the last F1/F2 Form. If the participant did not complete the previous F2 Form, use the completion date from the most recent F2 Form completed. If the participant never completed an F2 Form, then the randomization date should be used.
   - **End date:** Date the participant completed the current F2 Form. If the F2 Form was not completed/returned, then this date should be the date that the vital status was confirmed or able to be determined.
Both date fields are required data elements. The date fields must be completed as MM/DD/YYYY.

2a. Method(s) the Follow-up Form was completed: Select each appropriate response from the list provided indicating all sources of follow-up information.

- **In-person interview**: Select this response if all or part of the follow-up data (vital status, F2) was collected during an in-person interview. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Telephone interview**: Select this response if all or part of the follow-up data (vital status, F2) was collected during a phone interview. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Mailing**: Select this response if all or part of the follow-up data (vital status, F2) was collected via the mail (i.e., return of completed F2). An unreturned F2 Form is not considered a direct contact. Unreturned F2 Forms should be followed up on, as described in the F2 Form instructions. This response signifies direct contact with the participant and expectation of F2 Form submission.
- **Proxy**: Select this response if the participant is incapacitated or unavailable and the information was obtained from another person or representative of the participant.

2b. Reason the Follow-up Form was not completed. If the F2 Form is not completed please check the appropriate box indicating the reason. **Check only one selection.**

- **Participant deceased**: Choose this option if the participant is deceased as indicated in question 1.
- **No response, multiple contact attempts made but participant has not replied**: Record this option should a participant fail to return a completed F2 Form after repeated mailings and attempted telephone contacts. All attempts (and dates) to contact the participant should be documented in the participant chart. A time frame of 3 months is generally considered ample time to contact a participant. If a participant has not been contacted by that time, submit the F2 coversheet for that time point using this response. Continued attempts should be made to contact the participant. This option is appropriate if the participant vital status is “Alive” or “Unknown”.
- **Participant or Proxy refused completion of the Follow-Up Form**: If the participant responds to contact but refuses to complete the follow-up Form please select this option.
- **Participant or Proxy failed to return Follow-Up Form**: If receipt of the F2 Form is confirmed, by registered mail, phone or other method, and the participant fails to return the form please select this option.
- **Lost participant, unable to locate participant (phone, address, contacts attempted: begin tracing activities)**: Choose this selection if you are unable to contact the participant after exhausting all methods available. NOTE: This option cannot be recorded if participant vital status is listed as “Alive”. Similarly, although a participant may refuse to complete F2 Forms, they are not “Lost”. Choose this option only if the participant is lost (site cannot locate the participant, and therefore cannot determine vital status).
- **Lost to follow-up, unable to establish contact for a consecutive 18 month period (3 follow-up time points)**: Participants will be considered lost to follow-up if no contact of any kind can be established for a period of 18 consecutive months. NOTE: This option cannot be recorded if participant vital status is listed as “Alive”. Choose this option only if the participant is lost to follow-up with vital status unknown for a consecutive 18 month period. This will prompt a suppression of the F2 Coversheet collection from every 6 months to yearly completion. As such, efforts to locate the participant should continue on at least an annual basis. If a participant is successfully relocated, then enter the appropriate X Form data and F2 data into the database (Data Management may need to be contacted to add these forms on the calendar).
- **No attempt made to administer Follow-Up Form**: Choose this option if your site inadvertently forgot to administer a Follow-Up Form or if the participant is an NP level 3 (annual X Forms still required for vital status).
- **Physical illness / cognitive impairment**: Choose this option if the participant is too ill to complete the form.
- **Other, specify: _________________________** Choose this option if a reason other than one that appears in the list is the cause for not completing the form.
Example 1: A participant may not complete the F2 Form and may not respond to repeated telephone calls; however, the NLST staff knows their vital status is “alive” based on the fact that the participant has been seen in the institution, newspaper, etc. The participant is not lost. The option “No response, multiple contacts made but participant has not replied” would be appropriate. The start date should correspond to the end date of the last F1/F2 form or coversheet. The end date should be the actual date that the NLST staff member saw the participant in the institution. Ultimately: If you know their vital status, they are not lost!

Example 2: When the previous interval ends without an F2 Form being completed, the start date of the next interval will still be the last date an F2 Form was completed. If the participant completed a F2 Form for year 3 and has not completed one since, then the start date for all subsequent intervals is the date the year 3 F2 Form was completed. If the participant has never completed an F2, then the start date should be the randomization date (WEB: Enter 7/1/03 as the start date for any randomization before this date). The purpose is to limit any gaps in intervals for recording care.

NOTE: Regardless of the method of administration, it is expected that you make multiple attempts to contact the participant for completion of the F2 Form (refer to MOP, Appendix 8-3). At a minimum, obtaining the participant's vital status (dead or alive) at each time point is important, as this relates to the primary endpoint. If at the end of the follow-up window the F2 Form is not completed, then submit the appropriate Coversheet. For each time point, a Coversheet should be completed, whether the F2 is completed or not.

3. Was there any change in the participant contact information since last contact or study follow-up?
   - Check NO if the participant reported no change in her/his contact information.
   - Check YES if the participant reported a change in her/his contact information. Both Group 1 and Group 2 sites should update their local database/records. Group 1 sites are required to fax/mail the annual contact sheet to the Biostatistical Center.
   - Check Not Applicable if the participant did not complete an annual contact worksheet associated with this reporting period (e.g. interim time point, no contact made).

Signature of person responsible for data: Legible signature of the RA responsible for the follow-up data recorded on the form.

Date of form completion: Date the Coversheet was completed by the RA responsible for the follow-up data.

Person entering data onto web: Legible signature of staff member web entering the data from this form. Signature should be done at web entry.