The F3 Follow-Up Questionnaire is a participant-completed form designed to collect information about the diagnosis and/or treatment of lung cancer and the diagnosis of other cancers. The F3 is to be completed every six months for all participants for the remainder of the trial. The F3 may be completed by the participant during a visit to the site, as a telephone interview, or administered via mail. NOTE: The F3 has replaced the F2 and F1 as the participant completed follow-up form.

If the F3 questionnaire is administered by mail:

- Prior to mailing, each page of the F3 Form must be labeled with the participant identifiers (at minimum, the case number and participant initials). If the participant identifiers do not appear, there may be no reliable way to identify who completed the form.
- Include a self-addressed, stamped envelope for the return of the form.
- Provide the NLST site contact information in the space provided on page 1.
- If the questionnaire has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received and completed.
- Once received, the RA should review the questionnaire for completeness and an attempt should be made to collect any outstanding information and correct all errors or discrepant data (by telephone or in-person), particularly for the critical data elements. **If a blank data element cannot be completed (data not obtained) it should remain blank.** Document this on the F3 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the “Unknown” response indicating that the data was not obtained. **If discrepancies in data cannot be resolved they should remain as recorded by the participant and not changed.** All original responses, edits, corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).
- Unsuccessful attempts to contact participants for further information should be recorded in the chart.

If the F3 questionnaire is administered by in-person or telephone interview:

- The RA should review the questionnaire for completeness. An attempt should be made to collect any outstanding information and correct all errors or discrepant data before the interview is concluded, particularly for the critical data elements. **If a data element cannot be completed (data not obtained) it should remain blank.** Document this on the F3 adjacent to the appropriate question in explanation of the missing/blank data. At web entry, select the “Unknown” response indicating that the data was not obtained. All original responses, edits/corrections, and data recording must be clearly documented on the questionnaire (i.e. follow the rules of Good Clinical Practice).

If the F3 questionnaire is completed by in-person interview:

- Instruct the participant to sign her/his name on the line provided. WEB: not submitted to ACRIN.
- Instruct the participant to record the date the questionnaire is completed (mm/dd/yyyy). WEB: submitted to ACRIN.

If the participant indicates s/he has questions regarding the questionnaire and/or study, follow-up by the site is required.

**Interval Follow-Up Form**

**Participant Label:** Affix a Case Specific Label to each page in the box provided at the top right corner of the form. These labels are supplied by ACRIN once a participant has been randomized and contain all the participant identifiers (case number, participant initials, and institution name/number). To receive additional labels, submit a Request for Case Specific Labels to ACRIN HQ. You can also print case labels yourself by going to the ACRIN Web site in the Data Login Center. Type in your user name and password, select your institution and select extra labels. In lieu of a Case Specific Label, record the Institution, Institution Number, Participant Initials, and Case Number in the box provided at the top right corner of the form.

**F3 data collection interval:** _____ / _____ / ______ to TODAY
Prior to mailing or administering this form, the time interval for participant F3 form completion must be indicated on page 1. The interval extends from the date that the participant last completed (i.e. dated) an F1/F2/F3 Form (Part D, Date you completed this form) to the present. If this is the first follow-up form, the interval extends from the date of randomization. For example: if the participant recorded 4/28/04 as the form completion date of their last F1/F2/F3 Form, the interval for the current follow-up period extends from 4/28/04 until the present.

**NLST Site-Specific Contact Info:** Provide appropriate site contact information in the space provided on page 1.

**NLST Staff Only: Follow-up Time Period:** Site Staff should check the appropriate box to indicate the time point for the form. The F3 time point should match the F2/F3 Coversheet time point.

**Part A: Lung Cancer Diagnosis and Treatment:**
This section documents diagnosis or treatment of lung cancer since the date on the front of this form. All information should be provided to the best of the participant’s recollection. A medical diary can be provided to participants in advance to record visits rather than relying on recall for completion of the F3 form.

**Q1. Since the date on the front of this form, have you received a diagnosis or treatment of lung cancer by any health provider?**
Document any diagnosis or treatment of lung cancer not previously reported. This is a critical data element; attempts should be made to collect this data.

If the response is “no”, skip to Part B, Question 1.

If the response is “not sure”, skip Question 2, but do list any providers seen during this time period in boxes I-III below.

- If ‘not sure’ is checked and no other providers are listed, the RA should contact the participant to review this element. Please verify that the participant is not sure about the diagnosis of cancer & collect ANY providers seen during the interval to verify with those providers if a diagnosis of cancer was made.

If the response is “yes,” the participant should provide:

- **Q2:** The date of diagnosis of lung cancer (mm/dd/yyyy). Use 99 if month, day, or year is unknown.
- **Boxes I- III:** The name, address, phone number of any health care provider/hospital that was associated with the diagnosis and/or treatment of lung cancer. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval. Please specify the type of care received (check all that apply).
- **Q3:** If additional providers/hospitals were involved in the participant’s diagnosis and/or treatment please check yes. Follow up with the participant to record the names for medical records retrieval.

**Part B: Other Cancer Diagnosis:**
This section documents diagnosis of any other cancer, besides lung cancer, since the date on the front of this form. All information should be provided to the best of the participant’s recollection. Do not record diagnoses of squamous cell skin cancer or basal cell skin cancers.

**Q1. Since the date on the front of this form, have you been diagnosed with any other type of cancer by a health care provider?**
Document any diagnosis of any other type of cancer not previously reported. This is a critical data element; attempts should be made to collect this data.

If the response is “no”, skip to Part C, Question 1.

If the response is “not sure”, skip Questions 2 and 3, but do list any providers seen during this time period in boxes I-III below.

- If ‘not sure’ is checked and no other providers are listed, the RA should contact the participant to review this element. Please verify that the participant is not sure about the diagnosis of cancer & collect ANY providers seen during the interval to verify with those providers if a diagnosis of cancer was made.
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If the response is “yes,” the participant should provide:

- **Q2:** The date of diagnosis of other cancer (mm/dd/yyyy). Use 99 if month, day, or year is unknown.
- **Q3:** The site or type of other cancer.
- **Boxes I-III:** The name, address, phone number of any health care provider/hospital that was associated with the diagnosis of other cancer. Do not provide the names of providers or clinics where treatment for this other cancer occurred. This information is not submitted to ACRIN, but is collected to assist in medical records retrieval.
- **B4:** If additional providers/hospitals were involved in the participant’s diagnosis please check yes. Follow up with the participant to record the names for medical records retrieval.

**Part C. Cigarette Smoking Questions**

These questions are concerned with overall changes in participant cigarette smoking habits. This section is intended to collect smoking information pertaining only to the preceding 6 months despite missed data time points. An attempt should be made to collect responses to each question. WEB ENTRY: If unable to collect responses for questions the participant left blank, document the blank data fields by selecting the “Blank/Unknown” response during web entry.

**C1. Do you now smoke cigarettes (one or more cigarettes per week)?**
Instruct the participant to answer “no” or “yes” to this question, indicating whether or not s/he is smoking at least one cigarette a week.

- If the response is “no,” skip to Part D.
- If the response is “yes,” continue to Part C, Question 2.
- If no response is provided, select “unknown” at web entry.

**C2. How many cigarettes do you usually smoke per day, on average?**
Instruct the participant to provide, to the best of her/his ability, a numeric response (whole number) based on their daily average of cigarettes. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4).

- If the response is less than 1 cigarette a day, mark this response on the CRF.
- If the response is greater than 1, record the numeric response on the line provided.
- If no response is provided, enter ‘99’ at web entry.

**C3. In the past six (6) months, how many times have you intentionally quit smoking cigarettes (not even a puff) for at least 24 hours?**
Instruct the participant to select the appropriate response. If the participant did try to quit, instruct the participant to provide, to the best of her/his ability, a numeric response indicating the number of times s/he purposely quit smoking for at least one day. Record the whole number response on the line provided. If the participant enters a fraction or decimal number, round up if >=0.5 (e.g., 4.5 = 5; 4.4 = 4). If no response is provided, enter ‘99’ at web entry.

**Part D. Conclusion**

**D1. Present Insurance Status: (check only one)**

The participant should indicate the type of insurance or payment method they use for Medical Care. Only one option should be selected. If no response is provided, please select “unknown” at web entry.
D2. Who completed this form?
The F3 was designed to be a participant completed form. Some study participants may require assistance with completion of the form. If the participant is unable to provide information the F3 form may also be completed by a family member or friend.

  a. Specify the person who assisted you (check all that apply)
  Participants may ask for assistance when completing the F3. Please select from the list provided or specify the person assisting the participant with the form. Please check all that apply.

Your signature (participant or proxy)
The participant should sign her/his name on the line provided, but this is not mandatory. This field does not require completion by the RA and is not submitted to ACRIN.

Date you completed this form: Record the date that the interview/questionnaire was completed and/or reviewed by the RA.

ADDENDUM:

Unreturned F3 Forms: If, after mailing the questionnaire, it has not been returned after 3 weeks, the RA should call the participant to ensure that the questionnaire was received. Urge/remind the participant to complete and return the questionnaire and offer to obtain a phone interview (either then, at the time of contact, or schedule a future interview). Document contact attempts.

If a participant refuses to complete the F3 Form: Due to the importance of the F3 data, and the lower than desired participant response rates for the full form, it is better we collect some (partial) data than no data. Therefore, if a participant refuses to complete the F3 Form, attempt to collect information via an abbreviated follow-up phone interview. Contact the participant stating that you understand s/he does not want to complete the form at this time but to enable the study site to follow her/him properly could s/he please participate in a shortened follow-up interview. If the participant is adamant about not participating in the follow-up questions tell her/him you understand and thank her/him for her/his time. If the participant is willing to participate in an “abbreviated” follow-up, attempt to collect the following information.

Part A and Part B: This information is critical to the trial. At a minimum, try to obtain the provider name and contact information so that medical records relating to the cancer can be requested. All F3 questions not asked/collected as part of the abbreviated F3 interview should remain blank on the F3 Form. Indicate this at the time of web entry by using the 'unknown' response option for the given question. For thorough documentation, it is suggested that you note, on either the F3 or the Coversheet, that an abbreviated interview was performed.