Follow up and Surgery eCRF Completion Instructions

Follow up should be assessed per institutional SOC, and the SOC follow up folder should be added to the participants homepage every time the patient has a lung related SOC follow up. At 2 years post registration, the 2 year follow up folder should be completed.

8.3 Follow Up, as per institutional SOC
   8.3.1 Standard of care clinical exams and diagnostic work-ups, as per institutional standards;
   8.3.2 Standard of care follow-up imaging, as per institutional standards;
   8.3.3 Completion of Study Evaluation and Diagnosis Form by treating physician.

8.4 Surgery
   8.4.1 Surgery, if prescribed;
   8.4.2 Collect surgical tissue samples (paraffin and frozen, if available)
   8.4.3 Completion of Study Evaluation and Diagnosis form by treating physician.

Note: Surgery related forms can be found within the follow up folders.

These instructions include guidance on the entry of the Follow up and Surgery related forms. Some queries are included in this document, however it is not a comprehensive reference for queries- all queries reasons should be clear in the query text. If there is any issue or question regarding a query, please contact the lead data manager on this trial for clarification.
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Lung Specimens- Formalin Fixed</td>
<td>17</td>
</tr>
<tr>
<td>General Instructions</td>
<td>18</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>18</td>
</tr>
<tr>
<td>Surgical Lung Specimens- Fresh Frozen</td>
<td>19</td>
</tr>
<tr>
<td>General Instructions</td>
<td>19</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>20</td>
</tr>
<tr>
<td>Follow up-2 Year Folder- Instructions</td>
<td>21</td>
</tr>
<tr>
<td>General Follow up- 2 Year Folder Instructions</td>
<td>21</td>
</tr>
<tr>
<td>SOC Follow up</td>
<td>22</td>
</tr>
<tr>
<td>General Instructions</td>
<td>22</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>22</td>
</tr>
<tr>
<td>Study Evaluation and Diagnosis- Pt I, II, III</td>
<td>24</td>
</tr>
<tr>
<td>General Instructions</td>
<td>24</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>27</td>
</tr>
<tr>
<td>Study Evaluation and Diagnosis- Pt IV</td>
<td>32</td>
</tr>
<tr>
<td>General Instructions</td>
<td>32</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>34</td>
</tr>
<tr>
<td>Surgical Lung Specimens- Formalin Fixed</td>
<td>35</td>
</tr>
<tr>
<td>General Instructions</td>
<td>35</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>35</td>
</tr>
<tr>
<td>Surgical Lung Specimens- Fresh Frozen</td>
<td>36</td>
</tr>
<tr>
<td>General Instructions</td>
<td>36</td>
</tr>
<tr>
<td>Question Specific Instructions</td>
<td>37</td>
</tr>
</tbody>
</table>
SOC Follow up Visits Folder- Instructions

Aim: The aim of the SOC Follow up Visits Folder is to record the SOC lung related follow up the participant has after registration.

Completion: The SOC Follow up Visits Folder must be completed each time the participant has lung related follow up visits after registration.

Forms:
- SOC Follow up
- Study Evaluation and Diagnosis- Part I, II, III
- Study Evaluation and Diagnosis- Part IV  *This form only appears if the Study Evaluation and Diagnosis worksheet was completed (Q1 on the Study Evaluation and Diagnosis-Part I, II, III =yes)*
- Surgical Lung Specimens- Formalin Fixed  *This form only appears if it is indicated on the SOC Follow up form that surgery was performed and specimens were collected*
- Surgical Lung Specimens- Fresh Frozen  *This form only appears if it is indicated on the SOC Follow up form that surgery was performed and specimens were collected*

General SOC Follow up Visits Folder Instructions

All lung related SOC follow up the participant has after registration should be recorded in the Follow up folder, with the exception of the 2 year follow up. A Study Evaluation and Diagnosis form should be completed by the treating physician at each of these follow up visits.

In the event the participant has surgery, it should be considered part of the participants SOC follow up and recorded in the Follow up Folder.

The Follow up folder is added in Rave via the Add Event feature on the subject’s homepage. Each time you select the Follow up folder and click ‘add’, a new Follow up folder will be added to the subject’s homepage. There is no limit on the number of times the folder can be added, so please ensure that the specific follow up has not already been recorded (reference the follow up date available next to the folder name).

A response of “Yes” to Question #4 (either during the course of follow up or at the completion of the two-year follow up timeline for the study without a definitive diagnosis) completes the participant’s involvement in the study. The Off Study form should be completed at this point.

Add Event:
**SOC Follow up**

**General Instructions**

The SOC Follow up Form should be completed for each SOC follow up visit that the participant has after registration. All questions on the form are required.

The folder name will be updated with the date of follow up visit after the form is saved.

**Initial View**

![Form Preview Image]

**Question Specific Instructions**

**Was the SOC follow up completed?**

- No
- Yes
- Unknown
ACRIN 4703: Detection of Early lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Follow up and Surgery eCRF Completion Instructions

Indicate if the SOC follow up was completed. This question should always be answered ‘yes’ since the form/folder is added only when SOC follow up is completed.

If the SOC follow up was not completed, please provide the primary reason it was not done

- Patient Refused
- Patient Lost to Follow up
- Site error
- Other, specify

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘no’.

Provide the primary reason SOC follow up was not completed.

Date of Standard of Care Follow up

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Provide the date of SOC follow-up. If follow up occurred over more than one day, provide the last day of follow-up.

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

- No
- Yes
- Unknown

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if any adverse events occurred that meet the reporting requirements related to the biospecimen collection

If yes, the comment ‘An Adverse Event Form must be completed for each adverse event that occurs. Note: The adverse event form is added using the ‘Add Event’ feature’ will be added below the question as a reminder to complete an adverse event form

Refer to the Adverse Event eCRF Completion Instructions for more details on the AE/SAE forms

Did the patient have any imaging performed as part of follow up?

- No
- Yes
- Unknown
ACRIN 4703: Detection of Early lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Follow up and Surgery eCRF Completion Instructions

This question only appears is ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if the participant had any imaging performed as part of follow-up, not previously recorded on a SOC Follow up form.

If yes, the below question will appear

<table>
<thead>
<tr>
<th>#</th>
<th>Provide the date(s) of imaging the patient had as part of follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>...</td>
</tr>
</tbody>
</table>

This table only appears is ‘Was the SOC follow up completed?’ is answered ‘yes’ and if ‘Did the patient have any imaging performed as part of follow up?’ is answered yes.

Provide the date(s) of imaging the patient had as part of follow up. To add additional rows, click on the ‘Add new log line’ link.

Did the patient have any surgery performed as part of follow up?

- No
- Yes
- Unknown

This question only appears is ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if the participant had any lung related surgery as part of follow up.

If yes, the date of surgery and collection of sample questions below will appear.

Date of Surgery

This question only appears is ‘Was the SOC follow up completed?’ is answered ‘yes’ and ‘Did the patient have any surgery performed as part of follow-up?’ is answered ‘yes’

Provide the date of surgery

Were surgical tissue samples collected?

- No
- Yes
- Unknown
Indicate if surgical lung tissue samples were collected.

If yes, the Surgical Lung Specimens- Formalin Fixed and Surgical Lung Specimens- Fresh Frozen forms will be added to the folder.

Note: Surgical samples are required per protocol. If the surgical lung specimens were not collected, a protocol variation form will be required.

**Study Evaluation and Diagnosis- Pt I, II, III**

General Instructions

The Study Evaluation and Diagnosis eCRF’s are split into 2 forms, one that contains the questions from Part I, II, and III, the other covers the questions found in Part IV of the paper form.

Please ensure the instructions for completion of questions is followed on the paper form- queries will appear if the instructions are not followed.
### Instructions

The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician at each SOC follow up visit. Malignancy identified during the two-year follow up time period will need to be reported on the Study Evaluation and Diagnosis Form. If a definitive diagnosis of the lesion identified for eligibility has not yet been diagnosed, then Question #4 should be reported as "Yes" and a determination of "Benign" as the diagnosis. A response of "Yes" to Question #4 (either during the course of follow up or at the time of the two-year follow-up timeline for the study without a definitive diagnosis) completes the participant’s involvement in the study.

1. Was the Study Evaluation and Diagnosis Form completed by the treating physician?  
   - No  
   - Yes  
   - Unknown

1a. If no, provide primary reason  
   - Patient Refused Follow up  
   - Patient Lost to Follow up  
   - Treating physician did not complete form  
   - Other, specify

2. Date study evaluation and diagnosis completed

3. Is there malignancy in the lung not related to the lesion used as eligibility for this trial?  
   - No  
   - Yes  
   - Uncertain

3a. If yes, the malignancy is
   - Primary Lung  
   - Metastatic to the Lung  
   - Uncertain  
   - Other, specify

3a1. If metastatic, provide the site of primary origin

4. Indicate the status of the lesion used as eligibility for this trial  
   - Resolved  
   - Stable  
   - Progressive  
   - Uncertain

5. Was a diagnosis established for this lesion used as eligibility for this trial?  
   - No  
   - Yes  
   - Uncertain
### Part II. Lung Malignancy

**complete this section only if Q5b=malignant, primary**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Has the lung malignancy been reported on a previous Study Evaluation</td>
<td>- No</td>
</tr>
<tr>
<td>and Diagnosis form?</td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- Not Applicable</td>
</tr>
<tr>
<td></td>
<td>- Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a. Has the patient developed progressive disease following treatment for</td>
<td>- No</td>
</tr>
<tr>
<td>lung cancer?</td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a.1. If yes, date of first documentation of progressive lung cancer</td>
<td>- ...</td>
</tr>
</tbody>
</table>

### Part III. No Malignancy

**complete this section only if Q5b=Benign/Non-cancerous lesion**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Provide the reasoning for the no malignancy diagnosis</td>
<td>- Alternate Diagnosis</td>
</tr>
<tr>
<td></td>
<td>- Resolution of Abnormality</td>
</tr>
<tr>
<td></td>
<td>- Stable mass, no additional FU</td>
</tr>
<tr>
<td></td>
<td>- Stable mass, additional FU required</td>
</tr>
<tr>
<td></td>
<td>- Other, specify</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. If alternative diagnosis, what is the alternate diagnosis?</td>
<td>- Sarcoid</td>
</tr>
<tr>
<td></td>
<td>- Atelectasis</td>
</tr>
<tr>
<td></td>
<td>- Carcinoid</td>
</tr>
<tr>
<td></td>
<td>- Infection</td>
</tr>
<tr>
<td></td>
<td>- Other, specify</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>12a. If the alternative diagnosis is infection, provide the type</td>
<td>- TB</td>
</tr>
<tr>
<td></td>
<td>- Bacterial Pneumonia</td>
</tr>
<tr>
<td></td>
<td>- Fungus</td>
</tr>
<tr>
<td></td>
<td>- Viral Pneumonia</td>
</tr>
<tr>
<td></td>
<td>- Other, specify</td>
</tr>
</tbody>
</table>
ACRIN 4703: Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules
Follow up and Surgery eCRF Completion Instructions

Question Specific Instructions

1. Was the Study Evaluation and Diagnosis Form completed by the treating physician?
   - No
   - Yes
   - Unknown

Indicate if the Study Evaluation and Diagnosis Form was completed by the treating physician.

If no, answer Q1a, leave the rest of the form blank, and select ‘save’

If yes, the Study Evaluation and Diagnosis- Pt IV will appear in the folder

1a. If no, provide primary reason
   - Patient Refused Follow up
   - Patient Lost to Follow up
   - Treating physician did not complete form
   - Other, specify

This question is required if Q1 is answered ‘no’.

Provide the primary reason the Study Evaluation and Diagnosis form was not completed. If other is selected, specify the reason in the specify field.

Date study evaluation and diagnosis completed

This question is required if Q1 is answered ‘yes’.

Provide the date the treating physician completed the Study Evaluation and Diagnosis form.

3. Is there malignancy in the lung not related to the lesion used as eligibility for this trial?
   - No
   - Yes
   - Uncertain

This question is required if Q1 is answered ‘yes’.

Indicate if there is malignancy in the lung not related to the lesion used as eligibility for this trial. This is the lesion that the measurements were taken from as part of the eligibility assessment.

If no, skip to Q4 (questions 3a and 3a1 must be blank)

If yes or unknown, Q3a is required
This question is required if Q3 is answered ‘yes’.

Indicate if the malignancy is primary or metastatic to the lung.

If primary, skip to Q4

If metastatic to the lung, Q3a1 is required

If uncertain or other, skip to Q4

This question is required if Q3a is answered ‘metastatic to the lung’.

Provide the primary site of origin. If other, specify in the specify field.

This question is required if Q1=yes

Indicate the status of the lesion used as eligibility for this trial as determined during the SOC follow up. This is the lesion that the measurements were taken from as part of the eligibility assessment.

This question is required for the lesion used as eligibility for this trial?
This question is required if Q1=yes

Indicate if a diagnosis was established for the lesion used as eligibility for the trial. This is the lesion that the measurements were taken from as part of the eligibility assessment.

If no or unknown, skip the rest of the questions on the form and save. Continue to Part IV eCRF

If yes, Q5a and 5b are required

A response of “Yes” to Question #5 completes the participant’s involvement in the study.

This question is required if Q5=yes

Provide the date the diagnosis was established

This question is required if Q5=yes

Provide the diagnosis of the lesion

If ‘benign/non-cancerous lesion’, skip 5b1 and Part II questions and continue to Part III. Part IV is required.

If ‘malignant, primary’, skip Q5b1 and continue to Part II. Part III should be skipped, Part IV is required.

If ‘malignant, metastatic’, complete Q5b1, skip Part II and III, and save the form. Part IV is required.

This question is required if Q5b=malignant, metastatic

Provide the primary site of origin
6. Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form?

This question is required if Q5b=malignant, primary

Indicate if the lung malignancy has been reported on a previous Study Evaluation and Diagnosis form

If no, unknown, or not applicable, skip to Q7

If yes, continue to Q6a

6a. Has the patient developed progressive disease following treatment for lung cancer?

This question is required if Q5b=malignant, primary and Q6=yes

Indicate if the lung malignancy has been reported on a previous Study Evaluation and Diagnosis form

If no or unknown, skip the rest of the questions on the eCRF and save the form. Part IV is required

If yes, complete Q6a1 and Q6a2, then skip the rest of the questions on the eCRF and save the form. Part IV is required.

6a1. Date of first documentation of progressive lung cancer

This question is required if Q5b=malignant, primary, Q6=yes, and Q6a=yes

Indicate the date of the first documentation of progressive lung cancer

6a2. List the site(s) of progression of cancer

This question is required if Q5b=malignant, primary, Q6=yes, and Q6a=yes

Indicate the site(s) of progression of cancer. Use the 'Add a new Log Line' link to add additional rows to the question
ACRIN 4703: Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Follow up and Surgery eCRF Completion Instructions

7. Lung Cancer Type

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Indicate the type of lung cancer

8. Histologic Class

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Select the histologic class of lung cancer from the drop down menu

9. Histologic Subtype

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Select the histologic subtype of lung cancer from the drop down menu

10. Cancer Stage

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Select the cancer stage from the drop down menu

11. Provide the reasoning for the no malignancy diagnosis

This question is required if Q5b=benign/non-cancerous lesion

Select the reason for the diagnosis provided in Q5b.
This question is required if Q5b=benign/non-cancerous lesion and Q11=alternate diagnosis

Provide the alternate diagnosis for the lesion

This question is required if Q5b=benign/non-cancerous lesion and Q12=infection

Provide the infection type

**Study Evaluation and Diagnosis- Pt IV**

**General Instructions**

The Study Evaluation and Diagnosis eCRF’s are split into 2 forms, one that contains the questions from Part I, II, and III, the other covers the questions found in Part IV of the paper form.

Please ensure the instructions for completion of questions is followed on the paper form-queries will appear if the instructions are not followed.

This form appears if Q1 on the Study Evaluation and Diagnosis- Part I, II, III is answered ‘yes’. All diagnostic tests require a deidentified copy uploaded into the form.

Initial View
<table>
<thead>
<tr>
<th>#</th>
<th>Diagnostic Test Type</th>
<th>Was test performed since last Study Evaluation and Diagnosis Form was completed?</th>
<th>Date of test</th>
<th>Was test used to establish diagnosis described above?</th>
<th>Upload Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Biopsy</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>2</td>
<td>Bone Scan</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>3</td>
<td>Bronchoscopy</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>4</td>
<td>Chest X Ray</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>5</td>
<td>CT Scan</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>6</td>
<td>Mediastinoscopy</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>7</td>
<td>MRI</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>8</td>
<td>PET</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>9</td>
<td>Sputum</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>10</td>
<td>Surgical Pathology</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>11</td>
<td>TBNA</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>12</td>
<td>Thoracotomy</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>13</td>
<td>TINA</td>
<td>No Yes Unknown</td>
<td>...</td>
<td>No Yes</td>
<td>Choose File</td>
</tr>
</tbody>
</table>
### Question Specific Instructions

This form is required if Q1 on the Study Evaluation- Part I, II, and III is answered ‘yes’.

Indicate if the listed diagnostic test types were performed since the last Study Evaluation and Diagnosis Form was completed. All listed diagnostic test types must have this question answered.

If yes, provide the date of test and indicate if the test was used to diagnose the lesion in Q5b. Upload a copy of the deidentified report.

<table>
<thead>
<tr>
<th>#</th>
<th>Diagnostic Test Type</th>
<th>Was test performed since last Study Evaluation and Diagnosis form was completed?</th>
<th>Date of test</th>
<th>Was test used to establish diagnosis described above?</th>
<th>Upload Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Biopsy</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>2</td>
<td>Bone Scan</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>3</td>
<td>Bronchoscopy</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>4</td>
<td>Chest X Ray</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>5</td>
<td>CT Scan</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>6</td>
<td>Mediastinoscopy</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>7</td>
<td>MRI</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>8</td>
<td>PET</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>9</td>
<td>Sputum</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>10</td>
<td>Surgical Pathology</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>11</td>
<td>TBNA</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>12</td>
<td>Thoracotomy</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
<tr>
<td>13</td>
<td>TTNA</td>
<td>[No, Yes, Unknown]</td>
<td></td>
<td>[No, Yes]</td>
<td>Choose File</td>
</tr>
</tbody>
</table>
If no, leave the rest of the row blank.

If additional test were given that are not listed in the ‘Diagnostic Test Type’ column, use the ‘Add a new Log Line’ link to add additional rows.

**Surgical Lung Specimens- Formalin Fixed**

**General Instructions**

The Surgical Lung Specimens- Formalin fixed form appears if it is indicated surgical lung specimens were collected as part of SOC Follow up/Surgery.

**Initial View**

<table>
<thead>
<tr>
<th>Kit Barcode</th>
<th>Date Specimen Mailed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biospecimen Type</th>
<th>Barcode Sequence</th>
<th>Check if Specimen Included</th>
<th>Storage Temp</th>
<th>Did any freeze/thaw occur?</th>
<th>If yes to freeze/thaw- Total # of Times</th>
<th>If yes to freeze/thaw- length of each time</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Formalin Fixed Tumor Tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Formalin Fixed Normal Tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Add a new Log line Inactivate**

**Question Specific Instructions**

Provide the kit barcode number. The format should be XXXX-XXXX

This question is required
Check the specimens included in the shipment. If the specimen is included, ‘Storage Temp’ and ‘Did any freeze/thaw occur?’ are required.

If ‘Did any freeze/thaw occur?’ is answered yes, ‘If yes to freeze/thaw, total # of times’ and ‘If yes to freeze/thaw- length of each time’ are required.

If any additional formalin fixed surgical specimens, use the ‘Add a new log line’ link to add additional rows.

**Surgical Lung Specimens- Fresh Frozen**

**General Instructions**

The Surgical Lung Specimens- Formalin fixed form appears if it is indicated surgical lung specimens were collected as part of SOC Follow up/Surgery.

**Initial View**
## Question Specific Instructions

**Kit Barcode**

Provide the kit barcode number. The format should be XXXX-XXXX

This question is required

**Date Specimen Mailed**

Provide the date the specimen was mailed.

This question is required
Check the specimens included in the shipment. If the specimen is included, ‘Storage Temp’ and ‘Did any freeze/thaw occur?’ are required.

If ‘Did any freeze/thaw occur?’ is answered yes, ‘If yes to freeze/thaw, total # of times’ and ‘If yes to freeze/thaw- length of each time’ are required.

If any additional formalin fixed surgical specimens, use the ‘Add a new log line’ link to add additional rows.

---

### Follow up-2 Year Folder - Instructions

**Aim:** The aim of the Follow up-2 Year Folder is to record the status of the lesion used for eligibility at the 2 year time point.

**Completion:** The Follow up-2 Year folder should be completed 2 years after registration, as indicated by the target date in Rave. The folder will not be available for entry until 6 months prior to this date.

**Forms:**
- SOC Follow up
- Study Evaluation and Diagnosis- Part I, II, III
- Study Evaluation and Diagnosis- Part IV  *This form only appears if the Study Evaluation and Diagnosis worksheet was completed (Q1 on the Study Evaluation and Diagnosis-Part I, II, III =yes)*
- Surgical Lung Specimens- Formalin Fixed *This form only appears if it is indicated on the SOC Follow up form that surgery was performed and specimens were collected*
- Surgical Lung Specimens- Fresh Frozen *This form only appears if it is indicated on the SOC Follow up form that surgery was performed and specimens were collected*

**General Follow up- 2 Year Folder Instructions**

All lung related SOC follow up the participant has after registration should be recorded in the Follow up folder, with the exception of the 2 year follow up. A Study Evaluation and Diagnosis form should be completed by the treating physician at each of these follow up visits.

At two years follow up, if a definitive diagnosis of the lesion identified for eligibility has not yet been diagnosed, then Question #5 should be reported as “Yes” with the date of follow up and a
determination of “Benign” as the diagnosis. A response of “Yes” to Question #5 completes the participant's involvement in the study. The Off Study form should be completed at this timepoint.

**SOC Follow up**

**General Instructions**

The SOC Follow up Form should be completed for the 2 years after registration (+/-6 months). All questions on the form are required.

The folder name will be updated with the date of follow up visit after the form is saved.

**Initial View**

<table>
<thead>
<tr>
<th>Was the SOC follow up completed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

**Question Specific Instructions**

<table>
<thead>
<tr>
<th>Was the SOC follow up completed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

Indicate if the SOC follow up was completed. This question should always be answered ‘yes’ since the form/folder is added only when SOC follow up is completed.

<table>
<thead>
<tr>
<th>If the SOC follow up was not completed, please provide the primary reason it was not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Refused</td>
</tr>
<tr>
<td>Patient Lost to Follow up</td>
</tr>
<tr>
<td>Site error</td>
</tr>
<tr>
<td>Other, specify</td>
</tr>
</tbody>
</table>

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘no’.

Provide the primary reason SOC follow up was not completed.
This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Provide the date of SOC follow-up. If follow up occurred over more than one day, provide the last day of follow-up.

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if any adverse events occurred that meet the reporting requirements related to the biospecimen collection

If yes, the comment ‘An Adverse Event Form must be completed for each adverse event that occurs. Note: The adverse event form is added using the ‘Add Event’ feature’ will be added below the question as a reminder to complete an adverse event form

Refer to the Adverse Event eCRF Completion Instructions for more details on the AE/SAE forms

Did the patient have any imaging performed as part of follow up?

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if the participant had any imaging performed as part of follow-up, not previously recorded on a SOC Follow up form.

If yes, the below question will appear

Provide the date(s) of imaging the patient had as part of follow up

Add a new Log line
ACRIN 4703: Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Follow up and Surgery eCRF Completion Instructions

This table only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’ and if ‘Did the patient have any imaging performed as part of follow up?’ is answered ‘yes’.

Provide the date(s) of imaging the patient had as part of follow up. To add additional rows, click on the ‘Add new log line’ link.

Did the patient have any surgery performed as part of follow up?

- No
- Yes
- Unknown

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’.

Indicate if the participant had any lung related surgery as part of follow up.

If yes, the date of surgery and collection of sample questions below will appear.

Date of Surgery

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’ and ‘Did the patient have any surgery performed as part of follow up?’ is answered ‘yes’.

Provide the date of surgery.

Were surgical tissue samples collected?

- No
- Yes
- Unknown

This question only appears if ‘Was the SOC follow up completed?’ is answered ‘yes’ and ‘Did the patient have any surgery performed as part of follow up?’ is answered ‘yes’.

Indicate if surgical lung tissue samples were collected.

If yes, the Surgical Lung Specimens- Formalin Fixed and Surgical Lung Specimens- Fresh Frozen forms will be added to the folder.

Study Evaluation and Diagnosis- Pt I, II, III

General Instructions

The Study Evaluation and Diagnosis eCRF’s are split into 2 forms, one that contains the questions from Part I, II, and III, the other covers the questions found in Part IV of the paper form.
Please ensure the instructions for completion of questions is followed on the paper form. Queries will appear if the instructions are not followed.

This form is required at the 2 year follow up timepoint. If it is not completed, a protocol variation form will be required.

Initial View

<table>
<thead>
<tr>
<th>Page: Study Evaluation and Diagnosis - Pt I, II, III - SOC Follow up Visits (1)</th>
</tr>
</thead>
</table>
| **Instructions:** The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician at each SOC follow up. Malignancy identified during the two-year follow-up time period will need to be reported on the Study Evaluation and Diagnosis Form. If a definitive diagnosis of the lesion identified for eligibility has not yet been diagnosed, then Question #4 should be reported as “Yes” up and a determination of “Benign” as the diagnosis. A response of “Yes” to Question #4 (either during the course of follow up or at the two year follow-up timeline for the study without a definitive diagnosis) completes the participant’s involvement in the study.

1. Was the Study Evaluation and Diagnosis Form completed by the treating physician?
   - No
   - Yes
   - Unknown

1a. If no, provide primary reason
   - Patient Refused Follow up
   - Patient Lost to Follow up
   - Treating physician did not complete form
   - Other, specify

2. Date study evaluation and diagnosis completed

3. Is there malignancy in the lung not related to the lesion used as eligibility for this trial?
   - No
   - Yes
   - Uncertain

3a. If yes, the malignancy is
   - Primary Lung
   - Metastatic to the Lung
   - Uncertain
   - Other, specify

3a1. If metastatic, provide the site of primary origin

4. Indicate the status of the lesion used as eligibility for this trial
   - Resolved
   - Stable
   - Progressive
   - Uncertain

5. Was a diagnosis established for for the lesion used as eligibility for this trial?
   - No
   - Yes
   - Uncertain
## Part II. Lung Malignancy

**complete this section only if Q5b=malignant, primary**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form?</td>
<td>No, Yes, Not Applicable, Unknown</td>
</tr>
<tr>
<td>6a. Has the patient developed progressive disease following treatment for lung cancer?</td>
<td>No, Yes, Unknown</td>
</tr>
<tr>
<td>6a1. If yes, date of first documentation of progressive lung cancer</td>
<td>...</td>
</tr>
</tbody>
</table>

### #6a2 List the site(s) of progression of cancer

<table>
<thead>
<tr>
<th>Site</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small Cell Lung Cancer, Non-Small Cell Lung Cancer, Unknown</td>
</tr>
</tbody>
</table>

## Part III. No Malignancy

**complete this section only if Q5b=Benign/Non-cancerous lesion**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Provide the reasoning for the no malignancy diagnosis</td>
<td>Alternate Diagnosis, Resolution of Abnormality, Stable mass, no additional FU, Stable mass, additional FU required, Other, specify</td>
</tr>
<tr>
<td>12. If alternative diagnosis, what is the alternate diagnosis?</td>
<td>Sarcoi, Atelectasis, Carcinoid, Infection, Other, specify</td>
</tr>
<tr>
<td>12a. If the alternative diagnosis is infection, provide the type</td>
<td>TB, Bacterial Pneumonia, Fungus, Viral Pneumonia, Other, specify</td>
</tr>
</tbody>
</table>
ACRIN 4703: Detection of Early lung Cancer Among Military Personnel Study 1
(DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules
Follow up and Surgery eCRF Completion Instructions

Question Specific Instructions

1. Was the Study Evaluation and Diagnosis Form completed by the treating physician?
   - ☐ No
   - ☐ Yes
   - ☐ Unknown

Indicate if the Study Evaluation and Diagnosis Form was completed by the treating physician.

If no, answer Q1a, leave the rest of the form blank, and select ‘save’

If yes, the Study Evaluation and Diagnosis- Pt IV will appear in the folder

Note: This form is required at the 2 year time point. If it is not completed a protocol variation form will be required.

1a. If no, provide primary reason
   - ☐ Patient Refused Follow up
   - ☐ Patient Lost to Follow up
   - ☐ Treating physician did not complete form
   - ☐ Other, specify

This question is required if Q1 is answered ‘no’.

Provide the primary reason the Study Evaluation and Diagnosis form was not completed. If other is selected, specify the reason in the specify field.

Date study evaluation and diagnosis completed

This question is required if Q1 is answered ‘yes’.

Provide the date the treating physician completed the Study Evaluation and Diagnosis form.

3. Is there malignancy in the lung not related to the lesion used as eligibility for this trial?
   - ☐ No
   - ☐ Yes
   - ☐ Uncertain

This question is required if Q1 is answered ‘yes’.

Indicate if there is malignancy in the lung not related to the lesion used as eligibility for this trial. This is the lesion that the measurements were taken from as part of the eligibility assessment.

If no, skip to Q4 (questions 3a and 3a1 must be blank)
ACRIN 4703: Detection of Early lung Cancer Among Military Personnel Study 1
(DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules
Follow up and Surgery eCRF Completion Instructions

If yes or unknown, Q3a is required

3a. If yes, the malignancy is

This question is required if Q3 is answered ‘yes’.

Indicate if the malignancy is primary or metastatic to the lung.

If primary, skip to Q4

If metastatic to the lung, Q3a1 is required

If uncertain or other, skip to Q4

3a1. If metastatic, provide the site of primary origin

This question is required if Q3a is answered ‘metastatic to the lung’.

Provide the primary site of origin. If other, specify in the specify field.

4. Indicate the status of the lesion used as eligibility for this trial

This question is required if Q1=yes

Indicate the status of the lesion used as eligibility for this trial as determined at 2 years. This is the lesion that the measurements were taken from as part of the eligibility assessment.

5. Was a diagnosis established for the lesion used as eligibility for this trial?

ACRIN 4703 Follow up and Surgery eCRF Instructions v1.0 1.14.13
ACRIN 4703: Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Follow up and Surgery eCRF Completion Instructions

This question is required if Q1=yes

Indicate if a diagnosis was established for the lesion used as eligibility for the trial. This is the lesion that the measurements were taken from as part of the eligibility assessment. If a definitive diagnosis of the lesion identified for eligibility has not yet been diagnosed, then Q5 should be reported as ‘Yes’ with the date of follow up and a determination of ‘Benign’ as the diagnosis.

If no or unknown, skip the rest of the questions on the form and save. Continue to Part IV eCRF

If yes, Q5a and 5b are required

5a. If yes, provide date established

This question is required if Q5=yes

Provide the date the diagnosis was established

5b. What was the diagnosis?

- Benign/Non-cancerous lesion
- Malignant, primary
- Malignant, metastatic

This question is required if Q5=yes

Provide the diagnosis of the lesion

If ‘benign/non-cancerous lesion’, skip 5b1 and Part II questions and continue to Part III. Part IV is required.

If ‘malignant, primary’, skip Q5b1 and continue to Part II. Part III should be skipped, Part IV is required.

If ‘malignant, metastatic’, complete Q5b1, skip Part II and III, and save the form. Part IV is required.

5b1. If metastatic, provide the primary site of origin:

This question is required if Q5b=malignant, metastatic

Provide the primary site of origin
This question is required if Q5b= malignant, primary
Indicate if the lung malignancy has been reported on a previous Study Evaluation and Diagnosis form
If no, unknown, or not applicable, skip to Q7
If yes, continue to Q6a

This question is required if Q5b= malignant, primary and Q6= yes
Indicate if the lung malignancy has been reported on a previous Study Evaluation and Diagnosis form
If no or unknown, skip the rest of the questions on the eCRF and save the form. Part IV is required
If yes, complete Q6a1 and Q6a2, then skip the rest of the questions on the eCRF and save the form. Part IV is required.

This question is required if Q5b= malignant, primary, Q6= yes, and Q6a= yes
Indicate the site(s) of progression of cancer. Use the 'Add a new Log Line' link to add additional rows to the question
This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Indicate the type of lung cancer

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Select the histologic class of lung cancer from the drop down menu

This question is required if Q5b=malignant, primary and Q6=No, Unknown, or Not Applicable.

Select the histologic subtype of lung cancer from the drop down menu

This question is required if Q5b=benign/non-cancerous lesion

Select the reason for the diagnosis provided in Q5b.
12. If alternative diagnosis, what is the alternate diagnosis?

- Sarcoid
- Allelectasis
- Carcinoid
- Infection
- Other, specify

This question is required if Q5b=benign/non-cancerous lesion and Q11=alternate diagnosis

Provide the alternate diagnosis for the lesion

12a. If the alternative diagnosis is infection, provide the type

- TB
- Bacterial Pneumonia
- Fungus
- Viral Pneumonia
- Other, specify

This question is required if Q5b=benign/non-cancerous lesion and Q12=infection

Provide the infection type

**Study Evaluation and Diagnosis- Pt IV**

General Instructions

The Study Evaluation and Diagnosis eCRF’s are split into 2 forms, one that contains the questions from Part I, II, and III, the other covers the questions found in Part IV of the paper form.

Please ensure the instructions for completion of questions is followed on the paper form-queries will appear if the instructions are not followed.

This form appears if Q1 on the Study Evaluation and Diagnosis- Part I, II, III is answered ‘yes’. All diagnostic tests require a deidentified copy uploaded into the form.

Initial View
<table>
<thead>
<tr>
<th>#</th>
<th>Diagnostic Test Type</th>
<th>Was test performed since last Study Evaluation and Diagnosis Form was completed?</th>
<th>Date of test</th>
<th>Was test used to establish diagnosis described above?</th>
<th>Upload Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Biopsy</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>2</td>
<td>Bone Scan</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>3</td>
<td>Bronchoscopy</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>4</td>
<td>Chest X Ray</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>5</td>
<td>CT Scan</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>6</td>
<td>Mediastinoscopy</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>7</td>
<td>MRI</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>8</td>
<td>PET</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>9</td>
<td>Sputum</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>10</td>
<td>Surgical Pathology</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>11</td>
<td>TBNA</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>12</td>
<td>Thoracotomy</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
<tr>
<td>13</td>
<td>TTNA</td>
<td>☐ No ☐ Yes ☐ Unknown</td>
<td>...</td>
<td>☐ No ☐ Yes</td>
<td>Choose File No file chosen</td>
</tr>
</tbody>
</table>
### Question Specific Instructions

This form is required if Q1 on the Study Evaluation- Part I, II, and III is answered ‘yes’.

Indicate if the listed diagnostic test types were performed since the last Study Evaluation and Diagnosis Form was completed. All listed diagnostic test types must have this question answered.

If yes, provide the date of test and indicate if the test was used to diagnose the lesion in Q5b. Upload a copy of the deidentified report.

<table>
<thead>
<tr>
<th>#</th>
<th>Diagnostic Test Type</th>
<th>Was test performed since last Study Evaluation and Diagnosis form was completed?</th>
<th>Date of test</th>
<th>Was test used to establish diagnosis described above?</th>
<th>Upload Report</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Biopsy</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>1</td>
<td>Bone Scan</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>2</td>
<td>Bronchoscopy</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>3</td>
<td>Chest X Ray</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>4</td>
<td>CT Scan</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>5</td>
<td>Mediastinoscopy</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>6</td>
<td>MRI</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>7</td>
<td>PET</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>8</td>
<td>Sputum</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>9</td>
<td>Surgical Pathology</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>10</td>
<td>TBA (Transbronchial Aspirate)</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>11</td>
<td>Thoracotomy</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
<tr>
<td>12</td>
<td>TTNA (Thoracoscopy)</td>
<td>□ No □ Yes □ Unknown</td>
<td></td>
<td>□ No □ Yes</td>
<td>Choose File</td>
</tr>
</tbody>
</table>
If no, leave the rest of the row blank.

If additional test were given that are not listed in the ‘Diagnostic Test Type’ column, use the ‘Add a new Log Line’ link to add additional rows.

**Surgical Lung Specimens- Formalin Fixed**

General Instructions

The Surgical Lung Specimens- Formalin fixed form appears if it is indicated surgical lung specimens were collected as part of SOC Follow up/Surgery.

Initial View

<table>
<thead>
<tr>
<th>Kit Barcode</th>
<th>Date Specimen Mailed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>#</th>
<th>Biospecimen Type</th>
<th>Barcode Sequence #</th>
<th>Check if Specimen Included</th>
<th>Storage Temp</th>
<th>Did any freeze/thaw occur?</th>
<th>If yes to freeze/thaw- Total # of Times</th>
<th>If yes to freeze/thaw- length of each time</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Formalin Fixed Tumor Tissue</td>
<td></td>
<td></td>
<td>°C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Formalin Fixed Normal Tissue</td>
<td></td>
<td></td>
<td>°C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add a new Log line Inactivate

**Question Specific Instructions**

<table>
<thead>
<tr>
<th>Kit Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Provide the kit barcode number. The format should be XXXX-XXXX

This question is required

<table>
<thead>
<tr>
<th>Date Specimen Mailed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Provide the date the specimen was mailed.
This question is required.

<table>
<thead>
<tr>
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</thead>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Formalin Fixed Normal Tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Check the specimens included in the shipment. If the specimen is included, ‘Storage Temp’ and ‘Did any freeze/thaw occur?’ are required.

If ‘Did any freeze/thaw occur?’ is answered yes, ‘If yes to freeze/thaw, total # of times’ and ‘If yes to freeze/thaw- length of each time’ are required.

If any additional formalin fixed surgical specimens, use the ‘Add a new log line’ link to add additional rows.

**Surgical Lung Specimens- Fresh Frozen**

**General Instructions**

The Surgical Lung Specimens- Formalin fixed form appears if it is indicated surgical lung specimens were collected as part of SOC Follow up/Surgery.
### Question Specific Instructions

**Kit Barcode**

Provide the kit barcode number. The format should be XXXX-XXXX

This question is required

**Date Specimen Mailed**

Provide the date the specimen was mailed.

This question is required
Check the specimens included in the shipment. If the specimen is included, ‘Storage Temp’ and ‘Did any freeze/thaw occur?’ are required.

If ‘Did any freeze/thaw occur?’ is answered yes, ‘If yes to freeze/thaw, total # of times’ and ‘If yes to freeze/thaw- length of each time’ are required.

If any additional formalin fixed surgical specimens, use the ‘Add a new log line’ link to add additional rows.

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</thead>
<tbody>
<tr>
<td>1</td>
<td>Fresh Frozen Tumor Tissue</td>
<td></td>
<td></td>
<td>-50°C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Fresh Frozen Normal Tissue</td>
<td></td>
<td></td>
<td>-50°C</td>
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<td></td>
<td></td>
<td></td>
</tr>
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