

Draft 18.0 version 1.0 MIGPROD 10FEB2020 - All Forms

Generated By: Lindsey Dymond

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Enrollment Forms

Form: Demography

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| | |
|--|---|
| FORM_OID | PID3302204_V1_0 |
| Patient Initials (LFM) | |
| Patient's Date of Birth | |
| Ethnicity | Hispanic or Latino <input type="checkbox"/> |
| | Not Hispanic or Latino <input type="checkbox"/> |
| | Not Reported <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Gender of a Person | Female Gender <input type="checkbox"/> |
| | Male Gender <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Country of Residence | |
| ZIP Code | |
| Method of Payment | PRIVATE INSURANCE <input type="checkbox"/> |
| | MEDICARE <input type="checkbox"/> |
| | MEDICARE AND PRIVATE INSURANCE <input type="checkbox"/> |
| | MEDICAID <input type="checkbox"/> |
| | MEDICAID AND MEDICARE <input type="checkbox"/> |
| | MILITARY OR VETERANS SPONSORED NOS <input type="checkbox"/> |
| | MILITARY SPONSORED (INCLUDING CHAMPUS & TRICARE) <input type="checkbox"/> |
| | VETERANS SPONSORED <input type="checkbox"/> |
| | SELF PAY (NO INSURANCE) <input type="checkbox"/> |
| | NO MEANS OF PAYMENT (NO INSURANCE) <input type="checkbox"/> |
| | OTHER <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| | Race |
| Asian <input type="checkbox"/> | |
| Black or African American <input type="checkbox"/> | |
| Native Hawaiian or Other Pacific Islander <input type="checkbox"/> | |
| White <input type="checkbox"/> | |
| | |

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Not Reported

Unknown

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Folder: Enrollment Forms

Form: Step Information

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| | |
|------------------------|------------------------------|
| FORM_OID | PID3285392_V1_0 |
| Registration Step | |
| Event Description | |
| Tracking Number | |
| Treating Investigator | |
| Site Registrar | |
| Crediting Group | |
| Crediting Investigator | |
| Arm Name | |
| Event Date | |
| Event Time | EST <input type="checkbox"/> |
| | CST <input type="checkbox"/> |
| | MST <input type="checkbox"/> |
| | PST <input type="checkbox"/> |
| | EDT <input type="checkbox"/> |
| | CDT <input type="checkbox"/> |
| | MDT <input type="checkbox"/> |
| | PDT <input type="checkbox"/> |

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Folder: Enrollment Forms

Form: Treatment Assignment

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| | |
|---|--|
| FORM_OID | PID3285336_V1_0 |
| Arm Name | |
| Step No | |
| Event description | |
| Date of Intervention/Treatment Assignment | |
| Event Time | <input type="radio"/> EST <input type="radio"/> CST <input type="radio"/> MST <input type="radio"/> PST <input type="radio"/> EDT <input type="radio"/> CDT <input type="radio"/> MDT <input type="radio"/> PDT |

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Folder: Enrollment Forms

Form: Eligibility Checklist

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Demography: Age and Birth Year

26. - Year of Birth _____

27. - Age _____

Inclusion Criteria

30. - Is the patient willing and able to provide written informed consent? No
Yes

4. - Date Informed Consent Signed _____

31. - Is the patient 50-79 years old? No
Yes

32. - Is the patient able to fill out the Patient Lung History questionnaire? No
Yes

33. - Is the patient able to tolerate all biospecimen collection as required by protocol? No
Yes

42. - Does the patient have a history of Chronic Obstructive Pulmonary Disease (COPD) or emphysema? No
Yes

43. - Does the participant have at least one first-degree relative with a diagnosis of lung cancer? No
Yes

45. - Indicate the patients smoking status Current Smoker
Former Smoker

Current Smokers Only

54. - Has the patient smoked >10 cigarettes per day for at least 25 years? No
Yes

46. - Provide the number of cigarettes smoked per day _____

Former Smokers Only

55. - Does the patient have at least ≥ 20 pack years history and quit 20 years ago or less? No
Yes

47. - Provide the pack years _____

48. - Is the patient willing to undergo fiberoptic bronchoscopy? No
Yes

49. - Is the patient able to comply with standard-of-care follow-up visits, including clinical exams, diagnostic work-ups, and imaging for a maximum of four years or until diagnosis of lung cancer? No
Yes

Exclusion Criteria

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Form: Eligibility Checklist

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| | |
|---|------------------------------|
| 50. - Does the patient have a diagnosis of lung cancer prior to the current assessment? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| 51. - Does the patient have any contraindications to nasal brushing or fiberoptic bronchoscopy? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| 52. - Does the patient have allergies to any local anesthetic that may be used to obtain biosamples in the study? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| 53. - Does the patient weigh more than allowable by the CT scanner? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |

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Folder: Eligibility/Registration Visit

Form: Registration Visit

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Date of Registration Visit _____

Was the patient lung history questionnaire completed? No
Yes
Unknown

Reason patient lung questionnaire was not completed Patient Refused
Questionnaire Not Distributed to Patient
Site Error
Questionnaire Lost
Unknown
Other, specify

Was the patients medical history obtained? No
Yes
Unknown

Reason medical history not obtained Patient Refused
Site error
Unknown
Other, specify

Was the SOC Diagnostic Imaging reviewed? No
Yes
Unknown

Primary reason SOC Diagnostic Imaging not reviewed Images Lost
Site error
Unknown
Other, specify

If yes, check the SOC diagnostic imaging performed prior to enrollment(check all that apply)

CT _____
PET _____
MRI _____
X-ray _____
Other, specify _____
Dynamic contrast-enhanced CT _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Medical History- Log

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Instructions: Provide the medical history for the patient as assessed during registration. If the date of diagnosis is unknown, enter days as UN, months as UNK, and years as 0000.

Has the patient been diagnosed with any other aerodigestive conditions not listed in the table below? *Note: This may include additional conditions/events of those conditions listed*

No

Yes

Unknown

| Medical Condition | |
|--|-------------------------------------|
| Asbestosis | <input checked="" type="checkbox"/> |
| Barrett's esophagus | <input type="checkbox"/> |
| Bronchiectasis | <input type="checkbox"/> |
| Central Airway Obstruction/Extrinsic Compression | <input type="checkbox"/> |
| Chronic Bronchitis | <input type="checkbox"/> |
| COPD | <input type="checkbox"/> |
| Cystic Fibrosis | <input type="checkbox"/> |
| Emphysema | <input type="checkbox"/> |
| GERD | <input type="checkbox"/> |
| Heart Disease - Heart Attack | <input type="checkbox"/> |
| Hypertension - High Blood Pressure | <input type="checkbox"/> |
| Interstitial Lung Disease | <input type="checkbox"/> |
| Lung Infection | <input type="checkbox"/> |
| Obliterative Bronchiolitis | <input type="checkbox"/> |
| Occupational Lung Diseases | <input type="checkbox"/> |
| Pulmonary Fibrosis | <input type="checkbox"/> |
| Sleep Apnea | <input type="checkbox"/> |
| Stroke - Cerebrovascular Disease | <input type="checkbox"/> |
| TB or active Pneumonia | <input type="checkbox"/> |
| Thyroid disorders | <input type="checkbox"/> |
| Other aerodigestive conditions | <input type="checkbox"/> |

Has patient ever been diagnosed with this condition?

No

Yes

Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

| | | |
|-------------------|----------------------------------|-------------------------------------|
| Medical Condition | Asbestosis | <input type="checkbox"/> |
| | Barrett's esophagus | <input type="checkbox"/> |
| | Bronchiectasis | <input type="checkbox"/> |
| | Central Airway | <input type="checkbox"/> |
| | Obstruction/Extrinsic | <input type="checkbox"/> |
| | Compression | <input type="checkbox"/> |
| | Chronic Bronchitis | <input type="checkbox"/> |
| | COPD | <input checked="" type="checkbox"/> |
| | Cystic Fibrosis | <input type="checkbox"/> |
| | Emphysema | <input type="checkbox"/> |
| | GERD | <input type="checkbox"/> |
| | Heart Disease - Heart Attack | <input type="checkbox"/> |
| | Hypertension - High Blood | <input type="checkbox"/> |
| | Pressure | <input type="checkbox"/> |
| | Interstitial Lung Disease | <input type="checkbox"/> |
| | Lung Infection | <input type="checkbox"/> |
| | Obliterative Bronchiolitis | <input type="checkbox"/> |
| | Occupational Lung Diseases | <input type="checkbox"/> |
| | Pulmonary Fibrosis | <input type="checkbox"/> |
| | Sleep Apnea | <input type="checkbox"/> |
| | Stroke - Cerebrovascular Disease | <input type="checkbox"/> |
| | TB or active Pneumonia | <input type="checkbox"/> |
| | Thyroid disorders | <input type="checkbox"/> |
| | Other aerodigestive conditions | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Has patient ever been diagnosed with this condition? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | |
|--|-------|
| Date diagnosed | _____ |
| If yes, provide a description of medical condition | _____ |

| | | |
|-------------------|-----------------------|--------------------------|
| Medical Condition | Asbestosis | <input type="checkbox"/> |
| | Barrett's esophagus | <input type="checkbox"/> |
| | Bronchiectasis | <input type="checkbox"/> |
| | Central Airway | <input type="checkbox"/> |
| | Obstruction/Extrinsic | <input type="checkbox"/> |
| | Compression | <input type="checkbox"/> |

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Chronic Bronchitis

COPD

Cystic Fibrosis

Emphysema

GERD

Heart Disease - Heart Attack

Hypertension - High Blood Pressure

Interstitial Lung Disease

Lung Infection

Obliterative Bronchiolitis

Occupational Lung Diseases

Pulmonary Fibrosis

Sleep Apnea

Stroke - Cerebrovascular Disease

TB or active Pneumonia

Thyroid disorders

Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No

Yes

Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition _____

Asbestosis

Barrett's esophagus

Bronchiectasis

Central Airway

Obstruction/Extrinsic

Compression

Chronic Bronchitis

COPD

Cystic Fibrosis

Emphysema

GERD

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- Heart Disease - Heart Attack
- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway Obstruction/Extrinsic Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack
 - Hypertension - High Blood Pressure
 - Interstitial Lung Disease
 - Lung Infection
 - Obliterative Bronchiolitis

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- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition?

No

Yes

Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition

- Asbestosis
- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood
- Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia

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Thyroid disorders
Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
Yes
Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition _____

- Asbestosis
- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood
- Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
Yes
Unknown

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Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition _____

- Asbestosis
- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No

Yes

Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition _____

- Asbestosis
- Barrett's esophagus
- Bronchiectasis

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- Central Airway Obstruction/Extrinsic Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway Obstruction/Extrinsic Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis

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- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway
 - Obstruction/Extrinsic Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack
 - Hypertension - High Blood Pressure
 - Interstitial Lung Disease

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- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway
 - Obstruction/Extrinsic
 - Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack
 - Hypertension - High Blood
 - Pressure
 - Interstitial Lung Disease
 - Lung Infection
 - Obliterative Bronchiolitis
 - Occupational Lung Diseases
 - Pulmonary Fibrosis
 - Sleep Apnea

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- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition

- Asbestosis
- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood
- Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No

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Folder: Eligibility/Registration Visit

Form: Medical History- Log

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Yes
Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition

- Asbestosis
- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood
- Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
Yes
Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition

Asbestosis

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- Barrett's esophagus
- Bronchiectasis
- Central Airway
- Obstruction/Extrinsic
- Compression
- Chronic Bronchitis
- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood
- Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
Yes
Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway
 - Obstruction/Extrinsic
 - Compression
 - Chronic Bronchitis

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- COPD
- Cystic Fibrosis
- Emphysema
- GERD
- Heart Disease - Heart Attack
- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway Obstruction/Extrinsic Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack

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- Hypertension - High Blood Pressure
- Interstitial Lung Disease
- Lung Infection
- Obliterative Bronchiolitis
- Occupational Lung Diseases
- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No
 Yes
 Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway
 - Obstruction/Extrinsic
 - Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack
 - Hypertension - High Blood Pressure
 - Interstitial Lung Disease
 - Lung Infection
 - Obliterative Bronchiolitis
 - Occupational Lung Diseases

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- Pulmonary Fibrosis
- Sleep Apnea
- Stroke - Cerebrovascular Disease
- TB or active Pneumonia
- Thyroid disorders
- Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No Yes Unknown

Date diagnosed _____
If yes, provide a description of medical condition _____

- Medical Condition
- Asbestosis
 - Barrett's esophagus
 - Bronchiectasis
 - Central Airway Obstruction/Extrinsic Compression
 - Chronic Bronchitis
 - COPD
 - Cystic Fibrosis
 - Emphysema
 - GERD
 - Heart Disease - Heart Attack
 - Hypertension - High Blood Pressure
 - Interstitial Lung Disease
 - Lung Infection
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 - Occupational Lung Diseases
 - Pulmonary Fibrosis
 - Sleep Apnea
 - Stroke - Cerebrovascular Disease
 - TB or active Pneumonia
 - Thyroid disorders

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Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No

Yes

Unknown

Date diagnosed _____

If yes, provide a description of medical condition _____

Medical Condition _____

Asbestosis

Barrett's esophagus

Bronchiectasis

Central Airway

Obstruction/Extrinsic

Compression

Chronic Bronchitis

COPD

Cystic Fibrosis

Emphysema

GERD

Heart Disease - Heart Attack

Hypertension - High Blood

Pressure

Interstitial Lung Disease

Lung Infection

Obliterative Bronchiolitis

Occupational Lung Diseases

Pulmonary Fibrosis

Sleep Apnea

Stroke - Cerebrovascular Disease

TB or active Pneumonia

Thyroid disorders

Other aerodigestive conditions

Has patient ever been diagnosed with this condition? No

Yes

Unknown

Date diagnosed _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Medical History- Log

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If yes, provide a description of medical condition

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Folder: Eligibility/Registration Visit

Form: Medical History- Other

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| | |
|---------------------------|----------------------------------|
| History/Condition/Allergy | |
| Date of Diagnosis | |
| Active/Ongoing | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |

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Has the patient had any prior thoracic surgery? No
 Yes
 Unknown

Instructions: If any of the above question is answered yes, provide the details of the thoracic surgery in the table below. A brief description of the procedure and date are required. If multiple types apply to one date, provide each in a separate row.

| | | |
|-------------------------|--|--------------------------|
| Surgical Procedure Type | Excision of lung, bronchus | <input type="checkbox"/> |
| | Operations of chest wall, pleura, mediastinum, diaphragm | <input type="checkbox"/> |
| | Operations of pharynx, hypopharynx, oropharynx | <input type="checkbox"/> |
| | Operations of larynx, trachea | <input type="checkbox"/> |
| | Operations of thyroid, parathyroid glands | <input type="checkbox"/> |
| | Operations of esophagus | <input type="checkbox"/> |
| | Operations of lymph nodes | <input type="checkbox"/> |
| | Other thoracic surgery | <input type="checkbox"/> |

| | |
|-----------------------------------|-------|
| Description of surgical procedure | _____ |
| Date of surgery | _____ |

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Folder: Eligibility/Registration Visit

Form: Concomitant Medications Yes/No

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Has the participant taken any *inhaled* medications within the last two weeks? No

Yes

Unknown

Has the participant taken any *intranasal* medications within the last two weeks? No

Yes

Unknown

Has the participant taken any *statins* within the last two weeks? No

Yes

Unknown

Has the participant taken any other medications within the last two weeks? No

Yes

Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Inhaled Medications

Generated On: 09 Apr 2020 15:26:54

Provide the details of the inhaled medication taken in the past 2 weeks

Medication

(Generic Name only)

Start Date

End Date

Check If Ongoing

Indication

(Reason for use)

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Intranasal Medications

Generated On: 09 Apr 2020 15:26:54

Provide the details of the intranasal medication taken in the past 2 weeks

Medication

(Generic Name only)

Start Date

End Date

Check If Ongoing

Indication

(Reason for use)

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Statin Medications

Generated On: 09 Apr 2020 15:26:54

Provide the details of the statin medication taken in the past 2 weeks

Medication

(Generic Name only)

Start Date

End Date

Check If Ongoing

Indication

(Reason for use)

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Eligibility/Registration Visit

Form: Other Medications

Generated On: 09 Apr 2020 15:26:54

Provide the details of the other medication taken in the past 2 weeks

Medication

(Generic Name only)

Start Date

End Date

Check If Ongoing

Indication

(Reason for use)

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Timepoint

Generated On: 09 Apr 2020 15:26:54

Indicate the timepoint the patient questionnaire was completed/returned

Eligibility/Registration

Baseline Visit

Surgery

Other, specify

Indicate the timepoint the patient questionnaire was completed/returned

Eligibility/Registration

Baseline Visit

Other, specify

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1. - **Indicate your current military status**

| | |
|--------------------------------------|-------|
| Active Duty Military | _____ |
| Retired Military | _____ |
| Veteran | _____ |
| Family member of Active Duty/Veteran | _____ |
| Check if patient left Q1 blank | _____ |

2. - **Have you ever been deployed?**

No

Yes

Pt Left Field Blank

3. - **If you have been deployed, please provide the location of deployment(s)**

| | |
|--|--------------------------|
| Check if patient left Q3 blank | _____ |
| Deployment Country | _____ |
| Length of Deployment | _____ Fixed Unit: weeks |
| Length of Deployment | _____ Fixed Unit: months |
| Length of Deployment | _____ Fixed Unit: years |
| Check if pt left deployment length blank | _____ |

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4. - Please check the occupations that you have ever worked

Check if patient left Q4 blank

Occupation

Airline Industry (pilot, flight attendant, and/or flight crew)

Baking

Butchering/Meat Packing

Chemical or plastics

Manufacturing

Coal Mining

Cotton or jute processing

Duty involving exposure to

ionizing radiation

Farming

Fire Fighting

Flour, feed, or grain milling

Foundry or steel milling

Hard Rock Mining

Painting

Sandblasting

Welding

Wood Working

Other, specify

None of the above

If other, specify

Total Number of Months Worked

Fixed Unit: months

Total Number of Years Worked

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

No

Yes

Unknown

Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify

Total Number of Months Worked

Fixed Unit: months

Total Number of Years Worked

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No
- Yes
- Unknown
- Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)

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- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____

Fixed Unit: months

Total Number of Years Worked _____

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

No

Yes

Unknown

Pt Left Field Blank

Occupation _____

Airline Industry (pilot, flight attendant, and/or flight crew)

Baking

Butchering/Meat Packing

- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank

- Did you wear a respirator?
- No
 - Yes
 - Unknown
 - Pt Left Field Blank

- Occupation _____
- Airline Industry (pilot, flight attendant, and/or flight crew)
 - Baking
 - Butchering/Meat Packing
 - Chemical or plastics manufacturing
 - Coal Mining

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- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank

- Did you wear a respirator?
- No
 - Yes
 - Unknown
 - Pt Left Field Blank

- Occupation _____
- Airline Industry (pilot, flight attendant, and/or flight crew)
 - Baking
 - Butchering/Meat Packing
 - Chemical or plastics manufacturing
 - Coal Mining
 - Cotton or jute processing
 - Duty involving exposure to ionizing radiation

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- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____

Fixed Unit: months

Total Number of Years Worked _____

Fixed Unit: years

Check if the pt left the total number of months/years blank _____

Did you wear a respirator? _____

- No
- Yes
- Unknown
- Pt Left Field Blank

Occupation _____

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____

Fixed Unit: months

Total Number of Years Worked _____

Fixed Unit: years

Check if the pt left the total number of months/years blank _____

Did you wear a respirator? _____

- No
- Yes
- Unknown
- Pt Left Field Blank

Occupation _____

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling

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- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify _____

Total Number of Months Worked _____

Fixed Unit: months

Total Number of Years Worked _____

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No
- Yes
- Unknown
- Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting

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| | | |
|--|-------------------|--------------------------|
| | Sandblasting | <input type="checkbox"/> |
| | Welding | <input type="checkbox"/> |
| | Wood Working | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | None of the above | <input type="checkbox"/> |

If other, specify _____

| | |
|-------------------------------|--------------------|
| Total Number of Months Worked | Fixed Unit: months |
|-------------------------------|--------------------|

| | |
|------------------------------|-------------------|
| Total Number of Years Worked | Fixed Unit: years |
|------------------------------|-------------------|

Check if the pt left the total number of months/years blank

| | | |
|----------------------------|---------------------|--------------------------|
| Did you wear a respirator? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | | |
|------------|--|-------------------------------------|
| Occupation | Airline Industry (pilot, flight attendant, and/or flight crew) | <input type="checkbox"/> |
| | Baking | <input type="checkbox"/> |
| | Butchering/Meat Packing | <input type="checkbox"/> |
| | Chemical or plastics manufacturing | <input type="checkbox"/> |
| | Coal Mining | <input type="checkbox"/> |
| | Cotton or jute processing | <input type="checkbox"/> |
| | Duty involving exposure to ionizing radiation | <input type="checkbox"/> |
| | Farming | <input type="checkbox"/> |
| | Fire Fighting | <input type="checkbox"/> |
| | Flour, feed, or grain milling | <input checked="" type="checkbox"/> |
| | Foundry or steel milling | <input type="checkbox"/> |
| | Hard Rock Mining | <input type="checkbox"/> |
| | Painting | <input type="checkbox"/> |
| | Sandblasting | <input type="checkbox"/> |
| | Welding | <input type="checkbox"/> |

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Wood Working
Other, specify
None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator? No
Yes
Unknown
Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify

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None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator? No

Yes

Unknown

Pt Left Field Blank

Occupation

Airline Industry (pilot, flight attendant, and/or flight crew)

Baking

Butchering/Meat Packing

Chemical or plastics manufacturing

Coal Mining

Cotton or jute processing

Duty involving exposure to ionizing radiation

Farming

Fire Fighting

Flour, feed, or grain milling

Foundry or steel milling

Hard Rock Mining

Painting

Sandblasting

Welding

Wood Working

Other, specify

None of the above

If other, specify _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational History

Generated On: 09 Apr 2020 15:26:54

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator? _____ No

Yes

Unknown

Pt Left Field Blank

Occupation _____

Airline Industry (pilot, flight attendant, and/or flight crew)

Baking

Butchering/Meat Packing

Chemical or plastics manufacturing

Coal Mining

Cotton or jute processing

Duty involving exposure to ionizing radiation

Farming

Fire Fighting

Flour, feed, or grain milling

Foundry or steel milling

Hard Rock Mining

Painting

Sandblasting

Welding

Wood Working

Other, specify

None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational History

Generated On: 09 Apr 2020 15:26:54

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank _____

Did you wear a respirator? _____
No
Yes
Unknown
Pt Left Field Blank

Occupation _____
Airline Industry (pilot, flight attendant, and/or flight crew)
Baking
Butchering/Meat Packing
Chemical or plastics manufacturing
Coal Mining
Cotton or jute processing
Duty involving exposure to ionizing radiation
Farming
Fire Fighting
Flour, feed, or grain milling
Foundry or steel milling
Hard Rock Mining
Painting
Sandblasting
Welding
Wood Working
Other, specify
None of the above

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational History

Generated On: 09 Apr 2020 15:26:54

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No
- Yes
- Unknown
- Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify

Total Number of Months Worked

Fixed Unit: months

Total Number of Years Worked

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No

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- Yes
- Unknown
- Pt Left Field Blank

Occupation

- Airline Industry (pilot, flight attendant, and/or flight crew)
- Baking
- Butchering/Meat Packing
- Chemical or plastics manufacturing
- Coal Mining
- Cotton or jute processing
- Duty involving exposure to ionizing radiation
- Farming
- Fire Fighting
- Flour, feed, or grain milling
- Foundry or steel milling
- Hard Rock Mining
- Painting
- Sandblasting
- Welding
- Wood Working
- Other, specify
- None of the above

If other, specify

Total Number of Months Worked

Fixed Unit: months

Total Number of Years Worked

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No
- Yes
- Unknown

Pt Left Field Blank

Occupation

Airline Industry (pilot, flight attendant, and/or flight crew)

Baking

Butchering/Meat Packing

Chemical or plastics manufacturing

Coal Mining

Cotton or jute processing

Duty involving exposure to ionizing radiation

Farming

Fire Fighting

Flour, feed, or grain milling

Foundry or steel milling

Hard Rock Mining

Painting

Sandblasting

Welding

Wood Working

Other, specify

None of the above

If other, specify

Total Number of Months Worked

Fixed Unit: months

Total Number of Years Worked

Fixed Unit: years

Check if the pt left the total number of months/years blank

Did you wear a respirator?

No

Yes

Unknown

Pt Left Field Blank

| | | |
|------------|--|-------------------------------------|
| Occupation | Airline Industry (pilot, flight attendant, and/or flight crew) | <input type="checkbox"/> |
| | Baking | <input type="checkbox"/> |
| | Butchering/Meat Packing | <input type="checkbox"/> |
| | Chemical or plastics manufacturing | <input type="checkbox"/> |
| | Coal Mining | <input type="checkbox"/> |
| | Cotton or jute processing | <input type="checkbox"/> |
| | Duty involving exposure to ionizing radiation | <input type="checkbox"/> |
| | Farming | <input type="checkbox"/> |
| | Fire Fighting | <input type="checkbox"/> |
| | Flour, feed, or grain milling | <input type="checkbox"/> |
| | Foundry or steel milling | <input type="checkbox"/> |
| | Hard Rock Mining | <input type="checkbox"/> |
| | Painting | <input type="checkbox"/> |
| | Sandblasting | <input type="checkbox"/> |
| | Welding | <input type="checkbox"/> |
| | Wood Working | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | None of the above | <input checked="" type="checkbox"/> |

If other, specify _____

Total Number of Months Worked _____ Fixed Unit: months

Total Number of Years Worked _____ Fixed Unit: years

Check if the pt left the total number of months/years blank _____

Did you wear a respirator? No

Yes

Unknown

Pt Left Field Blank

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5. - Please any occupational exposure that you may have had

Check if patient left Q5 blank

Occupation _____

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational Exposure History

Generated On: 09 Apr 2020 15:26:54

Indicate the effect of the exposure

| | |
|---------------------|--------------------------|
| Not Noticeable | <input type="checkbox"/> |
| Mild | <input type="checkbox"/> |
| Moderate | <input type="checkbox"/> |
| Severe | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> |

Occupation

| | |
|--------------------------------------|-------------------------------------|
| Asbestos | <input type="checkbox"/> |
| Burn Pits | <input checked="" type="checkbox"/> |
| Chemicals/Acids/Solvents | <input type="checkbox"/> |
| Coal Tar/Asphalt | <input type="checkbox"/> |
| Diesel Engine Exhaust | <input type="checkbox"/> |
| Dyes | <input type="checkbox"/> |
| Explosives | <input type="checkbox"/> |
| Formaldehyde | <input type="checkbox"/> |
| Gasoline Exhaust | <input type="checkbox"/> |
| Jet Fuel | <input type="checkbox"/> |
| Pesticides/Herbicides (agent orange) | <input type="checkbox"/> |
| Radioactive Materials | <input type="checkbox"/> |
| Sandstorms | <input type="checkbox"/> |
| Smoke | <input type="checkbox"/> |
| Textile Fibers/Dust | <input type="checkbox"/> |
| Well Water | <input type="checkbox"/> |
| Wood Dust | <input type="checkbox"/> |
| Other, specify | <input type="checkbox"/> |
| None of the above | <input type="checkbox"/> |

If other, specify _____

Number of Months Exposed _____ Fixed Unit: months

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____ Continuously

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Form: Pt Questionnaire: Occupational Exposure History

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| | | |
|-------------------------------------|---------------------|--------------------------|
| | Regularly | <input type="checkbox"/> |
| | Occasionally | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| <hr/> | | |
| Indicate the effect of the exposure | Not Noticeable | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | | |
|------------|---|-------------------------------------|
| Occupation | Asbestos | <input type="checkbox"/> |
| | Burn Pits | <input type="checkbox"/> |
| | Chemicals/Acids/Solvents | <input checked="" type="checkbox"/> |
| | Coal Tar/Asphalt | <input type="checkbox"/> |
| | Diesel Engine Exhaust | <input type="checkbox"/> |
| | Dyes | <input type="checkbox"/> |
| | Explosives | <input type="checkbox"/> |
| | Formaldehyde | <input type="checkbox"/> |
| | Gasoline Exhaust | <input type="checkbox"/> |
| | Jet Fuel | <input type="checkbox"/> |
| | Pesticides/Herbicides (agent orange) | <input type="checkbox"/> |
| | Radioactive Materials | <input type="checkbox"/> |
| | Sandstorms | <input type="checkbox"/> |
| | Smoke | <input type="checkbox"/> |
| | Textile Fibers/Dust | <input type="checkbox"/> |
| | Well Water | <input type="checkbox"/> |
| | Wood Dust | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | None of the above | <input type="checkbox"/> |

| | |
|--------------------------|--------------------|
| If other, specify | |
| Number of Months Exposed | Fixed Unit: months |

| | |
|-------------------------|-------------------|
| Number of Years Exposed | Fixed Unit: years |
|-------------------------|-------------------|

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational Exposure History

Generated On: 09 Apr 2020 15:26:54

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify

Number of Months Exposed

Fixed Unit: months

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational Exposure History

Generated On: 09 Apr 2020 15:26:54

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

Continuously

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable

Mild

Moderate

Severe

Pt Left Field Blank

Occupation _____

Asbestos

Burn Pits

Chemicals/Acids/Solvents

Coal Tar/Asphalt

Diesel Engine Exhaust

Dyes

Explosives

Formaldehyde

Gasoline Exhaust

Jet Fuel

Pesticides/Herbicides (agent orange)

Radioactive Materials

Sandstorms

Smoke

Textile Fibers/Dust

Well Water

Wood Dust

Other, specify

None of the above

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational Exposure History

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If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

Continuously

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable

Mild

Moderate

Severe

Pt Left Field Blank

Occupation _____

Asbestos

Burn Pits

Chemicals/Acids/Solvents

Coal Tar/Asphalt

Diesel Engine Exhaust

Dyes

Explosives

Formaldehyde

Gasoline Exhaust

Jet Fuel

Pesticides/Herbicides (agent

orange)

Radioactive Materials

Sandstorms

Smoke

Textile Fibers/Dust

Well Water

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Occupational Exposure History

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Wood Dust
Other, specify
None of the above

If other, specify _____

Number of Months Exposed _____ Fixed Unit: months

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had

Continuously
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable
Mild
Moderate
Severe
Pt Left Field Blank

Occupation

Asbestos
Burn Pits
Chemicals/Acids/Solvents
Coal Tar/Asphalt
Diesel Engine Exhaust
Dyes
Explosives
Formaldehyde
Gasoline Exhaust
Jet Fuel
Pesticides/Herbicides (agent orange)
Radioactive Materials
Sandstorms

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- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation _____

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel

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- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation _____

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives

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| | | |
|--|---|-------------------------------------|
| | Formaldehyde | <input type="checkbox"/> |
| | Gasoline Exhaust | <input checked="" type="checkbox"/> |
| | Jet Fuel | <input type="checkbox"/> |
| | Pesticides/Herbicides (agent orange) | <input type="checkbox"/> |
| | Radioactive Materials | <input type="checkbox"/> |
| | Sandstorms | <input type="checkbox"/> |
| | Smoke | <input type="checkbox"/> |
| | Textile Fibers/Dust | <input type="checkbox"/> |
| | Well Water | <input type="checkbox"/> |
| | Wood Dust | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | None of the above | <input type="checkbox"/> |

If other, specify

Number of Months Exposed

Fixed Unit: months

Number of Years Exposed

Fixed Unit: years

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt

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- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent or orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation _____

Asbestos

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- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____ Fixed Unit: months

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable
- Mild
- Moderate
- Severe

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Pt Left Field Blank

Occupation

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify

Number of Months Exposed

Fixed Unit: months

Number of Years Exposed

Fixed Unit: years

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable

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- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify

Number of Months Exposed

Fixed Unit: months

Number of Years Exposed

Fixed Unit: years

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

- Continuously
- Regularly

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| | | |
|-------------------------------------|---------------------|--------------------------|
| | Occasionally | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| <hr/> | | |
| Indicate the effect of the exposure | Not Noticeable | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | | |
|------------|--------------------------------------|-------------------------------------|
| Occupation | Asbestos | <input type="checkbox"/> |
| | Burn Pits | <input type="checkbox"/> |
| | Chemicals/Acids/Solvents | <input type="checkbox"/> |
| | Coal Tar/Asphalt | <input type="checkbox"/> |
| | Diesel Engine Exhaust | <input type="checkbox"/> |
| | Dyes | <input type="checkbox"/> |
| | Explosives | <input type="checkbox"/> |
| | Formaldehyde | <input type="checkbox"/> |
| | Gasoline Exhaust | <input type="checkbox"/> |
| | Jet Fuel | <input type="checkbox"/> |
| | Pesticides/Herbicides (agent orange) | <input type="checkbox"/> |
| | Radioactive Materials | <input type="checkbox"/> |
| | Sandstorms | <input type="checkbox"/> |
| | Smoke | <input checked="" type="checkbox"/> |
| | Textile Fibers/Dust | <input type="checkbox"/> |
| | Well Water | <input type="checkbox"/> |
| | Wood Dust | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | None of the above | <input type="checkbox"/> |

| | |
|--------------------------|--------------------|
| If other, specify | <hr/> |
| Number of Months Exposed | Fixed Unit: months |
| <hr/> | <hr/> |
| Number of Years Exposed | Fixed Unit: years |

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Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation _____

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel
- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

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Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

Continuously

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable

Mild

Moderate

Severe

Pt Left Field Blank

Occupation _____

Asbestos

Burn Pits

Chemicals/Acids/Solvents

Coal Tar/Asphalt

Diesel Engine Exhaust

Dyes

Explosives

Formaldehyde

Gasoline Exhaust

Jet Fuel

Pesticides/Herbicides (agent
orange)

Radioactive Materials

Sandstorms

Smoke

Textile Fibers/Dust

Well Water

Wood Dust

Other, specify

None of the above

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If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

Continuously

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable

Mild

Moderate

Severe

Pt Left Field Blank

Occupation _____

Asbestos

Burn Pits

Chemicals/Acids/Solvents

Coal Tar/Asphalt

Diesel Engine Exhaust

Dyes

Explosives

Formaldehyde

Gasoline Exhaust

Jet Fuel

Pesticides/Herbicides (agent

orange)

Radioactive Materials

Sandstorms

Smoke

Textile Fibers/Dust

Well Water

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Wood Dust
Other, specify
None of the above

If other, specify _____

Number of Months Exposed _____ Fixed Unit: months

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had

Continuously
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable
Mild
Moderate
Severe
Pt Left Field Blank

Occupation

Asbestos
Burn Pits
Chemicals/Acids/Solvents
Coal Tar/Asphalt
Diesel Engine Exhaust
Dyes
Explosives
Formaldehyde
Gasoline Exhaust
Jet Fuel
Pesticides/Herbicides (agent
orange)
Radioactive Materials
Sandstorms

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- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation _____

- Asbestos
- Burn Pits
- Chemicals/Acids/Solvents
- Coal Tar/Asphalt
- Diesel Engine Exhaust
- Dyes
- Explosives
- Formaldehyde
- Gasoline Exhaust
- Jet Fuel

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- Pesticides/Herbicides (agent orange)
- Radioactive Materials
- Sandstorms
- Smoke
- Textile Fibers/Dust
- Well Water
- Wood Dust
- Other, specify
- None of the above

If other, specify _____

Number of Months Exposed _____

Fixed Unit: months

Number of Years Exposed _____

Fixed Unit: years

Check if the pt left the total number of months/ years blank _____

Indicate the amount of exposure you had _____

- Continuously
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure _____

- Not Noticeable
- Mild
- Moderate
- Severe
- Pt Left Field Blank

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6. - What is your current weight? Fixed Unit: lbs

Check if pt left Q6 blank

7. - How tall are you? Fixed Unit: feet

Fixed Unit: inches

Check if pt left Q7 blank

8. - Please check if your doctor has every told you that you have the listed conditions or illnesses

Check if pt left Q8 blank

Conditions, Illnesses Asbestosis

Asthma - first diagnosed as a child

Asthma - first diagnosed as an adult

Bronchiectasis

Chronic Bronchitis

Chronic Obstructive Pulmonary Disease

Diabetes

Emphysema

Fibrosis of the Lung

Heart Disease or Heart Attack

High Blood Pressure

(Hypertension)

HIV infection

Hodgkins Disease

Pneumonia

Sarcoidosis

Silicosis

Stroke

Tuberculosis (TB)

None of the above

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Form: Pt Questionnaire: Medical History- Conditions and Illnesses

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If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child

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- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema

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- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis

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- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

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Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack

FOR SITE IRB SUBMISSION ONLY
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- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

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Tuberculosis (TB)

None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

Asbestosis

Asthma - first diagnosed as a child

Asthma - first diagnosed as an adult

Bronchiectasis

Chronic Bronchitis

Chronic Obstructive Pulmonary Disease

Diabetes

Emphysema

Fibrosis of the Lung

Heart Disease or Heart Attack

High Blood Pressure (Hypertension)

HIV infection

Hodgkins Disease

Pneumonia

Sarcoidosis

Silicosis

Stroke

Tuberculosis (TB)

None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

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Form: Pt Questionnaire: Medical History- Conditions and Illnesses

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Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease

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- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestos
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

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Form: Pt Questionnaire: Medical History- Conditions and Illnesses

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If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child

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- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema

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Form: Pt Questionnaire: Medical History- Conditions and Illnesses

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- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis
- Silicosis
- Stroke
- Tuberculosis (TB)
- None of the above

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

Conditions, Illnesses

- Asbestosis
- Asthma - first diagnosed as a child
- Asthma - first diagnosed as an adult
- Bronchiectasis
- Chronic Bronchitis
- Chronic Obstructive Pulmonary Disease
- Diabetes
- Emphysema
- Fibrosis of the Lung
- Heart Disease or Heart Attack
- High Blood Pressure (Hypertension)
- HIV infection
- Hodgkins Disease
- Pneumonia
- Sarcoidosis

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Form: Pt Questionnaire: Medical History- Conditions and Illnesses

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| | | |
|--|-------------------|--------------------------|
| | Silicosis | <input type="checkbox"/> |
| | Stroke | <input type="checkbox"/> |
| | Tuberculosis (TB) | <input type="checkbox"/> |
| | None of the above | <input type="checkbox"/> |

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

Check if the pt left the age blank

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9. - Have any of the following blood relatives ever had lung cancer?

| | | |
|-------------------------------------|---------------------|--------------------------|
| Father | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Not Applicable | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| Mother | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Not Applicable | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| Brother(s), including half brothers | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Not Applicable | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| Sister(s), including half sisters | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Not Applicable | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| Children (biological) | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Not Applicable | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

10. - Please check if your doctor has every told you that you have any of the cancers listed below

Check if pt left Q10 blank _____

| | | |
|--------|-----------------|-------------------------------------|
| Cancer | Bladder Cancer | <input checked="" type="checkbox"/> |
| | Breast Cancer | <input type="checkbox"/> |
| | Cervical cancer | <input type="checkbox"/> |

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Medical History- Cancer

Generated On: 09 Apr 2020 15:26:54

- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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Form: Pt Questionnaire: Medical History- Cancer

Generated On: 09 Apr 2020 15:26:54

- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer

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- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Medical History- Cancer

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- Colon-Rectal Cancer
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- Nasal Cancer
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- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Colon-Rectal Cancer
- Esophageal Cancer
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- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer

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Form: Pt Questionnaire: Medical History- Cancer

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- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer
- Transition Cell Cancer
- Other Cancer, Specify
- Never diagnosed with cancer

If other, specify _____

If checked, provide age at first diagnosis _____

Fixed Unit: years old

Check if the pt left the age blank _____

Cancer

- Bladder Cancer
- Breast Cancer
- Cervical cancer
- Colon-Rectal Cancer
- Esophageal Cancer
- Kidney Cancer
- Larynx Cancer
- Lung cancer
- Mouth (Oral) Cancer
- Nasal Cancer
- Pancreatic Cancer
- Pharynx Cancer
- Stomach (Gastric) Cancer
- Thyroid Cancer

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Form: Pt Questionnaire: Medical History- Cancer

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| | | |
|--|-----------------------------|-------------------------------------|
| | Transition Cell Cancer | <input type="checkbox"/> |
| | Other Cancer, Specify | <input type="checkbox"/> |
| | Never diagnosed with cancer | <input checked="" type="checkbox"/> |
| If other, specify | | |
| If checked, provide age at first diagnosis | | Fixed Unit: years old |
| Check if the pt left the age blank | | |

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Symptom History: Cough

11. - Do you usually have a cough? No
Yes
Unknown
Pt Left Field Blank

12. - Do you usually cough as much as 4-6 times a day, 4 or more days out of the week? No
Yes
Unknown
Pt Left Field Blank

13. - Do you usually cough at all upon getting up, or first thing in the morning? No
Yes
Unknown
Pt Left Field Blank

14. - Do you usually cough at all during the rest of the day or night? No
Yes
Unknown
Pt Left Field Blank

15. - Do you usually cough like this on most days for 3 consecutive months or more during the year? No
Yes
Unknown
Pt Left Field Blank

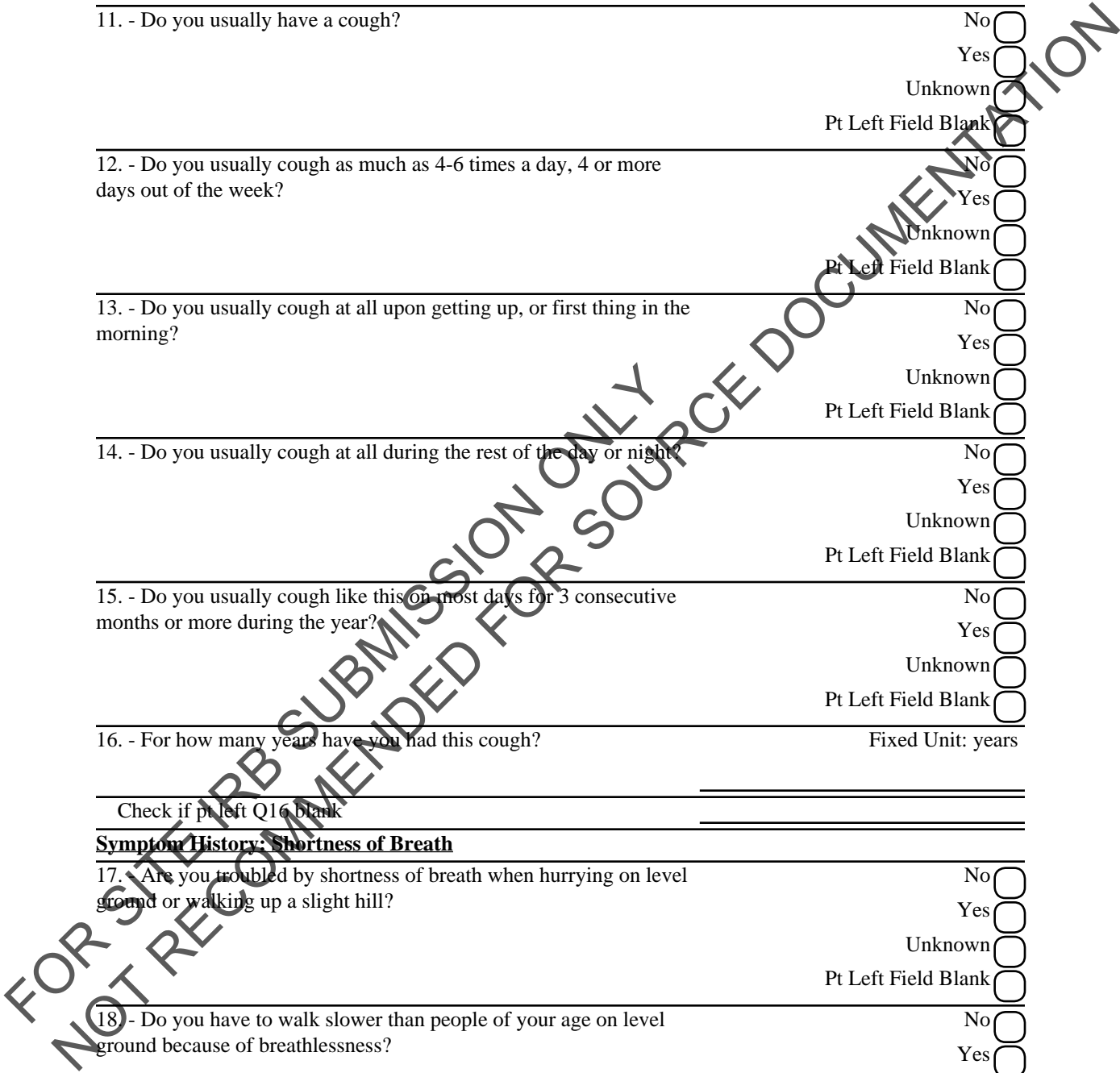
16. - For how many years have you had this cough? Fixed Unit: years

Check if pt left Q16 blank

Symptom History: Shortness of Breath

17. - Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? No
Yes
Unknown
Pt Left Field Blank

18. - Do you have to walk slower than people of your age on level ground because of breathlessness? No
Yes
Unknown



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Form: Pt Questionnaire: Symptom History: Cough, Shortness of Breath, Exacerbations

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Pt Left Field Blank

19. - Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on level ground? No
Yes
Unknown

Pt Left Field Blank

20. - Are you too breathless to leave the house or do you get breathless upon dressing or undressing? No
Yes
Unknown

Pt Left Field Blank

21. - For how many years have you experienced shortness of breath? Fixed Unit: years

Check if pt left Q21 blank

Symptom History: Exacerbations

22. - Over the past year, how many times did you require treatment with oral steroids and/or antibiotics for a COPD exacerbation (defined as an increase in dyspnea, sputum production or sputum purulence)? Fixed Unit: times

Check if pt left Q22 blank

23. - Over the past year, how many of these COPD exacerbations required admission to the hospital? Fixed Unit: admissions to hospital caused by COPD exacerbations

Check if pt left Q23 blank

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Symptom History: Phlegm

24. - Do you usually bring up phlegm from your chest

No
Yes
Unknown
Pt Left Field Blank

24a. - Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week?

No
Yes
Unknown
Pt Left Field Blank

25. - Do you usually bring up phlegm at all on getting up, or first thing in the morning?

No
Yes
Unknown
Pt Left Field Blank

26. - Do you usually bring up phlegm at all during the rest of the day or at night?

No
Yes
Unknown
Pt Left Field Blank

If yes to any of the above (Q24, Q24a, Q25, Q26), answer the following two questions; if no to all, skip to the next section

27. - Do you bring up phlegm like this on most days for 3 consecutive months or more during the year?

No
Yes
Unknown
Pt Left Field Blank

28. - For how many years have you had trouble with phlegm? Fixed Unit: years

Check if pt left Q28 blank

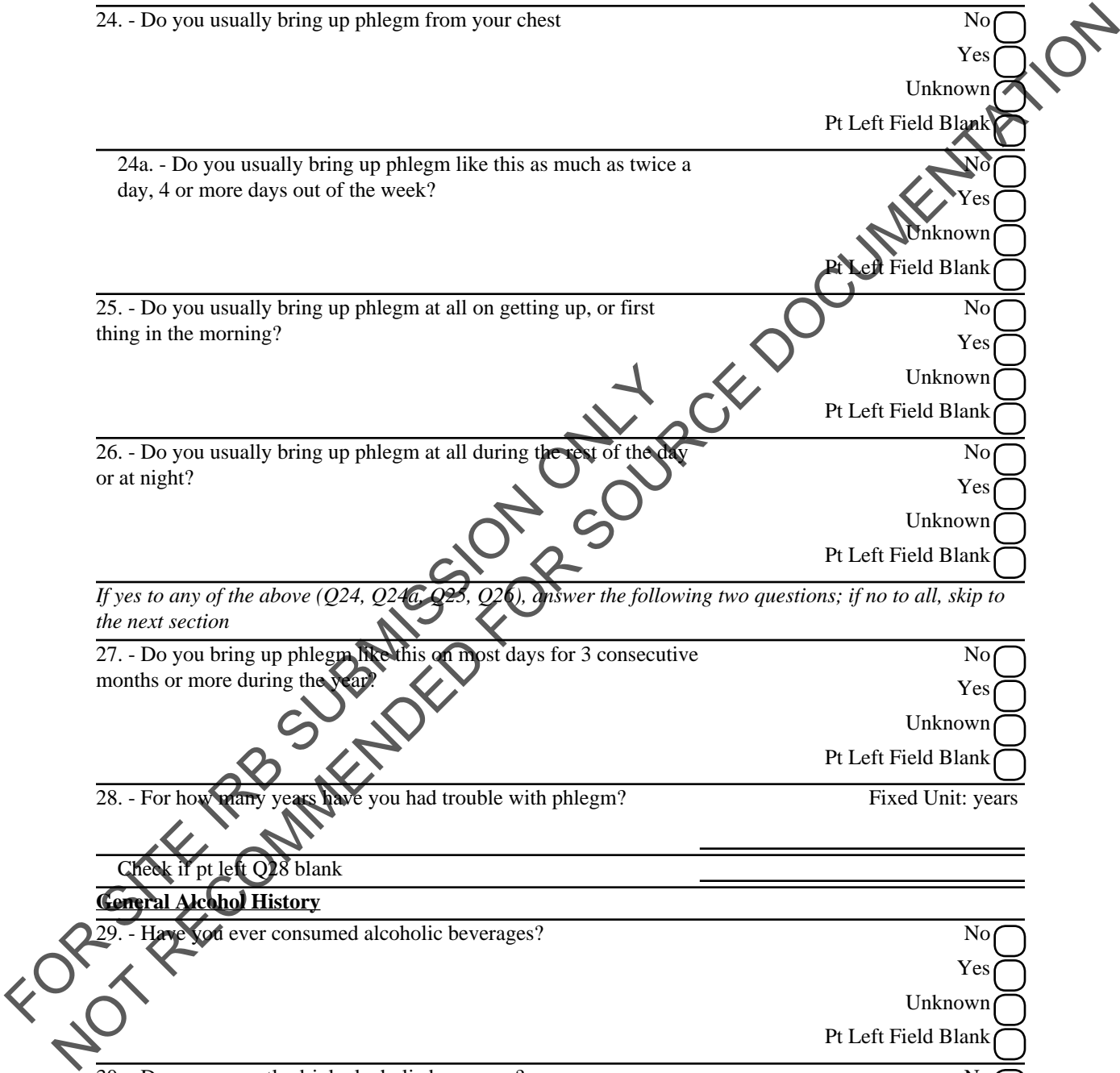
General Alcohol History

29. - Have you ever consumed alcoholic beverages?

No
Yes
Unknown
Pt Left Field Blank

30. - Do you presently drink alcoholic beverages?

No
Yes



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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History:Phlegm and Alcohol History

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| | | |
|--|---------------------|--------------------------|
| | Unknown | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| 31. - How long has it been since you last had an alcoholic drink (wine, beer, liquor)? | Less than 1 year | <input type="checkbox"/> |
| | 1 year to 2 years | <input type="checkbox"/> |
| | More than 3 years | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | |
|---|-------------------|
| 32. - For how many years did you drink alcoholic beverages? | Fixed Unit: years |
|---|-------------------|

| | |
|----------------------------|--|
| Check if pt left Q32 blank | |
|----------------------------|--|

| | |
|---|----------------------|
| 33. - What was the usual number of drinks you had per week? (one drink means 1 beer or 1 glass or wine or 1 shot of liquor, record 0 if less than 1 drink per week) | Fixed Unit: per week |
|---|----------------------|

| | |
|----------------------------|--|
| Check if pt left Q33 blank | |
|----------------------------|--|

| | |
|---|----------------------------------|
| 34. - During the past 24 hours, how many drinks have you had? | Fixed Unit: within last 24 hours |
|---|----------------------------------|

| | |
|----------------------------|--|
| Check if pt left Q34 blank | |
|----------------------------|--|

| | |
|--|--|
| 35. - Provide your average alcohol consumption | |
|--|--|

| | |
|----------------------------|--|
| Check if pt left Q35 blank | |
|----------------------------|--|

| | |
|--|-----------------------------|
| | Fixed Unit: drinks per week |
|--|-----------------------------|

| | |
|--|-------------------------------------|
| | Fixed Unit: drinks in the last year |
|--|-------------------------------------|

| | |
|--|--|
| | Fixed Unit: drinks in the last 3 years |
|--|--|

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Smoking History Pt. 1

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36. - Current smoking status

Current Smoker (one puff in the last month)

Former Smoker (not smoking for > or = 1 month(not even a puff))

Never smoked

Pt Left Field Blank

37. - Please indicate your current smoking habit

Never Smoked

Former Smoker (not smoking for > or = 1 month(not even a puff))

Occasional smoker (< or = 6 cigarette per week)

Regular smoker (> or = 7 cigarettes per week)

Pt Left Field Blank

38. - Average # cigarettes per day

Fixed Unit: per day

Check if pt left Q38 blank

39. - Number of Years Smoking

Fixed Unit: years

Check if pt left Q39 blank

40. - How old were you the first time you EVER smoked even a puff of a cigarette?

Fixed Unit: years old

Check if pt left Q40 blank

41. - When you first started smoking a few cigarettes (between 2-10), how much did you feel dizzy?

Not at all

A slight amount

A moderate amount

An intense amount

Don't Know

Pt Left Field Blank

42. - When you first started smoking a few cigarettes (between 2-10), how much did you feel a pleasureable rush or buzz?

Not at all

A slight amount

A moderate amount

An intense amount

Don't Know

Pt Left Field Blank

43. - How old were you when you began smoking daily (at least one cigarette per day or more)? Fixed Unit: years old

Check if pt left Q43 blank

For the next questions, think about the time period when you smoked most

44. - Think about the time you smoked the most. How many cigarettes did you smoke per day? Fixed Unit: cigarettes

Check if pt left Q44 blank

45. - During the time that you smoked, how many different times in your life did you go without smoking for THREE MONTHS or longer? Fixed Unit: times

Check if pt left Q45 blank

46. - Do you find it difficult not to smoke in places where it is forbidden such as in church, at a library, or in a movie theater?
No
Yes
Unknown
Pt Left Field Blank

47. - Do you smoke MORE during the first hours after you woke up or during the rest of the day?
When I first woke up
During the rest of the day
Pt Left Field Blank

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48. - How soon after you woke up in the morning did you smoke the first cigarette?

| | |
|--|--------------------------|
| Within 5 minutes | <input type="checkbox"/> |
| Within 6 to 14 minutes | <input type="checkbox"/> |
| Within 15 to 29 minutes | <input type="checkbox"/> |
| Within 30 minutes but less than 1 hour | <input type="checkbox"/> |
| Within 1 hour but less than 2 hours | <input type="checkbox"/> |
| Within 2 hours but less than 8 hours | <input type="checkbox"/> |
| More than 7 hours | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> |

49. - Did you smoke even if you were so ill that you were in bed most of the day?

| | |
|---------------------|--------------------------|
| No | <input type="checkbox"/> |
| Yes | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> |

50. - When you smoked the most, how often did you inhale?

| | |
|---------------------|--------------------------|
| None of the Time | <input type="checkbox"/> |
| Some of the Time | <input type="checkbox"/> |
| All of the Time | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> |

51. - Which cigarette of the day did you hate to give up the most?

| | |
|--------------------------|--------------------------|
| First one in the morning | <input type="checkbox"/> |
| One later in the morning | <input type="checkbox"/> |
| One at mid day | <input type="checkbox"/> |
| One in the afternoon | <input type="checkbox"/> |
| One after work | <input type="checkbox"/> |
| One in the evening | <input type="checkbox"/> |
| One late at night | <input type="checkbox"/> |
| One before bedtime | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> |

52. - When you smoked the most, what was your usual brand of cigarettes?

The next questions are about your usual brand of cigarette when you were smoking the most

52a. - Was the type

| | |
|-------------|--------------------------|
| Regular | <input type="checkbox"/> |
| Lights | <input type="checkbox"/> |
| Ultralights | <input type="checkbox"/> |

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| | | |
|--|---------------------|--------------------------|
| | Pt Left Field Blank | <input type="checkbox"/> |
| 52b. - Was the flavor | Regular | <input type="checkbox"/> |
| | Menthol | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| 52c. - Was the packing | Hard | <input type="checkbox"/> |
| | Soft | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| 52d. - Were the cigarettes | Filtered | <input type="checkbox"/> |
| | Unfiltered | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |
| 53. - Have you ever switched to a low tar, low nicotine or ultralight cigarette? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

Complete the following 3 questions only if you answered yes to the having switched to a low tar, low nicotine, or ultralight cigarette

54. - How old were you when you switched? Fixed Unit: years old

Check if pt left Q54 blank

55. - During the time that you were smoking low tar, low nicotine, or ultralight cigarettes, about how many cigarettes did you usually smoke per day? Fixed Unit: per day

Check if pt left Q55 blank

56. - How many years TOTAL did you smoke low tar, low nicotine, or ultralight cigarettes? Fixed Unit: years

Check if pt left Q56 blank

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The next question contains statements that smokers have said about quitting.

57. - Please indicate which statement best represents what you think right now
- I enjoy smoking so much I will never consider quitting no matter what happens
 - I never think about quitting but I might someday
 - I rarely think about quitting and have no specific plans to quit
 - I sometimes think about quitting but have no specific plans to quit
 - I often think about quitting but have no specific plans to quit
 - I plan to quit in the next 6 months
 - I plan to quit in the next 30 days
 - I have already begun to cut down and I have set a quit date
 - I have already quit and but I worry about slipping back or relapsing
 - I have quit and I am 100% confident that I will never smoke again
 - I decline to answer
 - Pt left field blank

- 57a. - If you are planning to quit someday, did previous screenings with positive results play a role in your decision?
- No
 - Yes
 - Unknown
 - Not Applicable
 - Pt Left Field Blank

Former Smokers Only

58. - How old were you when you stopped smoking for good? Fixed Unit: years old

Check if pt left Q58 blank

59. - When was your last cigarette?
- Less than 6 months ago
 - 6 months to 1 year ago
 - 1 year to 4 years ago
 - 4 years to 10 years ago

10 years to 15 years ago
More than 15 years ago
Pt Left Field Blank

Current Smokers Only

60. - How many time in the PAST YEAR have you quit smoking for 24 hours or longer? Fixed Unit: times

Check if pt left Q60 blank

61. - Since you started smoking, what was the LONGEST period of time that you were able not to smoke cigarettes at all?

Check if pt left Q61 blank

Fixed Unit: hours

Fixed Unit: days

Fixed Unit: weeks

Fixed Unit: years

All Participants

62. - Have you EVER smoked any other forms of tobacco? No
Yes
Unknown
Pt Left Field Blank

63. - Do you currently smoke any other forms of tobacco? No
Yes
Pt Left Field Blank

64. Check the form(s) of tobacco you did/do smoke

Check if pt left Q64 blank

Forms of Tobacco Pipe
Cigar
Tiparillos
Other

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Smoking Cessation

Generated On: 09 Apr 2020 15:26:54

If other, specify _____

Forms of Tobacco

- Pipe
- Cigar
- Tiparillos
- Other

If other, specify _____

Forms of Tobacco

- Pipe
- Cigar
- Tiparillos
- Other

If other, specify _____

Forms of Tobacco

- Pipe
- Cigar
- Tiparillos
- Other

If other, specify _____

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The following questions are about exposure to other people's smoking, otherwise known as second hand smoke

65. - Have you EVER lived with someone who smoked in your home? No
Yes
Unknown
Pt Left Field Blank

66. - Do you currently live with someone who smokes in your home? No
Yes
Unknown
Pt Left Field Blank

67. - Not including yourself, how many people smoke(d) in your home? Fixed Unit: people

Check if pt left Q67 blank

68. - Have you EVER worked in a place where you were exposed to other people's smoking? No
Yes
Unknown
Pt Left Field Blank

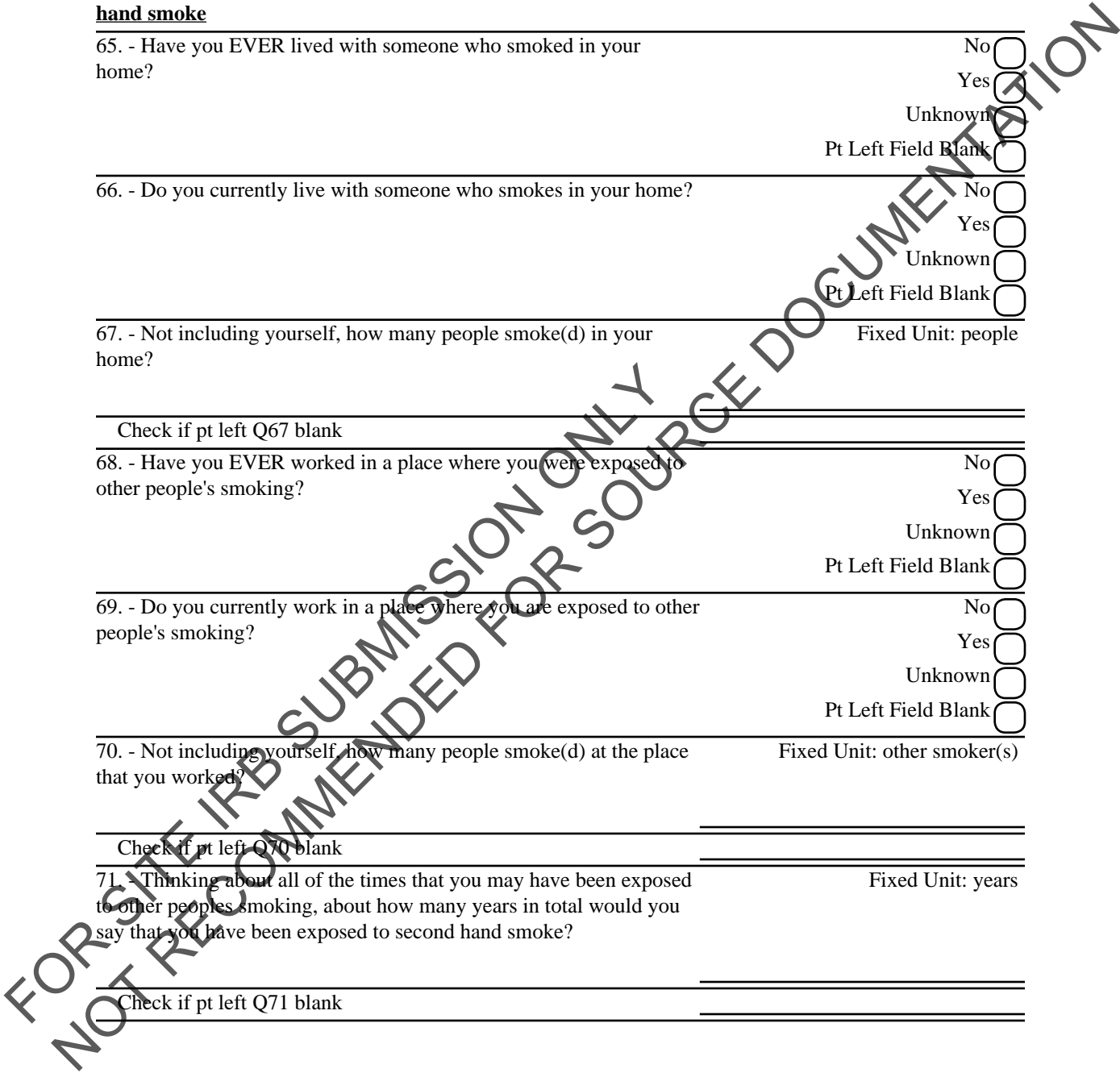
69. - Do you currently work in a place where you are exposed to other people's smoking? No
Yes
Unknown
Pt Left Field Blank

70. - Not including yourself, how many people smoke(d) at the place that you worked? Fixed Unit: other smoker(s)

Check if pt left Q70 blank

71. - Thinking about all of the times that you may have been exposed to other peoples smoking, about how many years in total would you say that you have been exposed to second hand smoke? Fixed Unit: years

Check if pt left Q71 blank



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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Demography

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| | | |
|--|--|--------------------------|
| 72. - Indicate the highest grade or level of schooling completed | 8th grade or less | <input type="checkbox"/> |
| | 9-11th grade | <input type="checkbox"/> |
| | High school graduate or high school equivalency | <input type="checkbox"/> |
| | Post high school training, other than college (for example, Vocational/technical school) | <input type="checkbox"/> |
| | Associate degree/some college | <input type="checkbox"/> |
| | Bachelors degree | <input type="checkbox"/> |
| | Graduate or Professional School | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |
| | Unknown/I prefer not to answer | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | | |
|------------------------------------|--------------------------------|--------------------------|
| 73. - Indicate your marital status | Never Married | <input type="checkbox"/> |
| | Married or living as married | <input type="checkbox"/> |
| | Widowed | <input type="checkbox"/> |
| | Separated | <input type="checkbox"/> |
| | Divorced | <input type="checkbox"/> |
| | Unknown/I prefer not to answer | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

| | | |
|--|--------------------------------|--------------------------|
| 74. - Indicate household income (select one which most closely describes the TOTAL average yearly gross income for your household) | Less than \$8,000 per year | <input type="checkbox"/> |
| | \$8,000 to 14,999 per year | <input type="checkbox"/> |
| | \$15,000 to \$24,999 per year | <input type="checkbox"/> |
| | \$25,000 to \$34,999 per year | <input type="checkbox"/> |
| | \$35,000 to \$49,999 per year | <input type="checkbox"/> |
| | \$50,000 to \$64,999 per year | <input type="checkbox"/> |
| | \$65,000 to \$79,999 per year | <input type="checkbox"/> |
| | \$80,000 to \$100,000 per year | <input type="checkbox"/> |
| | >\$100,000 per year | <input type="checkbox"/> |
| | Unknown/I prefer not to answer | <input type="checkbox"/> |
| Pt Left Field Blank | <input type="checkbox"/> | |

| | |
|---|-------|
| 75. - Including yourself, how many people are supported by the income listed above? | _____ |
| Check if pt left Q75 blank | _____ |

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Conclusion

Generated On: 09 Apr 2020 15:26:54

76. - Did you require any assistance completing this questionnaire? No
Yes
Pt Left Field Blank

76a. - Indicate the person who assisted you ACRIN-DECAMP Staff Member
Family
Unknown/I prefer not to answer
Pt Left Field Blank
Other

77. - Specify the method used to complete this questionnaire At my appointment
By mail
By telephone
Unknown/I prefer not to answer
Other
Pt Left Field Blank

78. - Comments _____
Date Participant Completed Questionnaire Fixed Unit: MMM dd yyyy

Scanned copy of the completed Patient Questionnaire _____

76b. - Extent of Assistance Read items to me
Marked items as I responded
Other
Unknown/I prefer not to answer
Pt Left Field Blank

If other, specify _____
Check all that apply _____

76b. - Extent of Assistance Read items to me
Marked items as I responded
Other
Unknown/I prefer not to answer
Pt Left Field Blank

If other, specify _____
Check all that apply _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Conclusion

Generated On: 09 Apr 2020 15:26:54

| | | |
|-----------------------------|--------------------------------|--------------------------|
| 76b. - Extent of Assistance | Read items to me | <input type="checkbox"/> |
| | Marked items as I responded | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| | Unknown/I prefer not to answer | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

If other, specify _____

Check all that apply _____

| | | |
|-----------------------------|--------------------------------|-------------------------------------|
| 76b. - Extent of Assistance | Read items to me | <input type="checkbox"/> |
| | Marked items as I responded | <input type="checkbox"/> |
| | Other | <input checked="" type="checkbox"/> |
| | Unknown/I prefer not to answer | <input type="checkbox"/> |
| | Pt Left Field Blank | <input type="checkbox"/> |

If other, specify _____

Check all that apply _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit

Form: Baseline Visit

Generated On: 09 Apr 2020 15:26:54

Date of Baseline Visit _____

Was the patient lung history questionnaire completed? No
Yes
Unknown

Reason patient lung questionnaire was not completed Patient Refused
Questionnaire Not Distributed to Patient
Site Error
Questionnaire Lost
Unknown
Other, specify

Was physical exam performed? No
Yes
Unknown

Reason physical exam not performed Patient Refused
Site error
Unknown
Other, specify

Was the sputum instructions and sample collection kit distributed to the patient? No
Yes
Unknown

Reason sputum instructions and sample collection kit not distributed to patient Patient Refused
Site error
Unknown
Other, specify

Date distributed to patient _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit

Form: Physical Exam

Generated On: 09 Apr 2020 15:26:54

Examination Date Fixed Unit: MMM dd yyyy

Weight kg

lbs

Height cm

in

Pulse Fixed Unit: bpm

Blood pressure

Systolic Fixed Unit: mmHg

Diastolic Fixed Unit: mmHg

Temperature C

F

Respiratory Rate Fixed Unit: breaths per minute

Body System/Site Head

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify Abnormal

Body System Normal

Not Examined

If abnormal, describe

Body System/Site Head

Neck

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| | | |
|--|-----------------|--------------------------|
| | Chest | <input type="checkbox"/> |
| | Heart | <input type="checkbox"/> |
| | Abdomen | <input type="checkbox"/> |
| | Musculoskeletal | <input type="checkbox"/> |
| | Neurologic | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

If other, specify _____

| | | |
|-------------|--------------|--------------------------|
| Body System | Abnormal | <input type="checkbox"/> |
| | Normal | <input type="checkbox"/> |
| | Not Examined | <input type="checkbox"/> |

If abnormal, describe _____

| | | |
|------------------|-----------------|-------------------------------------|
| Body System/Site | Head | <input type="checkbox"/> |
| | Neck | <input type="checkbox"/> |
| | Chest | <input checked="" type="checkbox"/> |
| | Heart | <input type="checkbox"/> |
| | Abdomen | <input type="checkbox"/> |
| | Musculoskeletal | <input type="checkbox"/> |
| | Neurologic | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

If other, specify _____

| | | |
|-------------|--------------|--------------------------|
| Body System | Abnormal | <input type="checkbox"/> |
| | Normal | <input type="checkbox"/> |
| | Not Examined | <input type="checkbox"/> |

If abnormal, describe _____

| | | |
|------------------|-----------------|-------------------------------------|
| Body System/Site | Head | <input type="checkbox"/> |
| | Neck | <input type="checkbox"/> |
| | Chest | <input type="checkbox"/> |
| | Heart | <input checked="" type="checkbox"/> |
| | Abdomen | <input type="checkbox"/> |
| | Musculoskeletal | <input type="checkbox"/> |
| | Neurologic | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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If other, specify _____

Body System _____

Abnormal

Normal

Not Examined

If abnormal, describe _____

Body System/Site _____

Head

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify _____

Body System _____

Abnormal

Normal

Not Examined

If abnormal, describe _____

Body System/Site _____

Head

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify _____

Body System _____

Abnormal

Normal

Not Examined

If abnormal, describe _____

Body System/Site _____

Head

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- Neck
- Chest
- Heart
- Abdomen
- Musculoskeletal
- Neurologic
- Other, specify

If other, specify _____

- Body System
- Abnormal
 - Normal
 - Not Examined

If abnormal, describe _____

- Body System/Site
- Head
 - Neck
 - Chest
 - Heart
 - Abdomen
 - Musculoskeletal
 - Neurologic
 - Other, specify

If other, specify _____

- Body System
- Abnormal
 - Normal
 - Not Examined

If abnormal, describe _____

- Body System/Site
- Head
 - Neck
 - Chest
 - Heart
 - Abdomen
 - Musculoskeletal
 - Neurologic

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Other, specify

If other, specify _____

Body System _____
Abnormal
Normal
Not Examined

If abnormal, describe _____

Body System/Site _____
Head
Neck
Chest
Heart
Abdomen
Musculoskeletal
Neurologic
Other, specify

If other, specify _____

Body System _____
Abnormal
Normal
Not Examined

If abnormal, describe _____

Body System/Site _____
Head
Neck
Chest
Heart
Abdomen
Musculoskeletal
Neurologic
Other, specify

If other, specify _____

Body System _____
Abnormal
Normal
Not Examined

If abnormal, describe _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit

Form: Pulmonary Function Test/Spirometry

Generated On: 09 Apr 2020 15:26:54

Was pulmonary function test performed? No

Yes

Reason not performed Patient Refused

Site error

Equipment Unavailable

Unknown

Other, specify

Indicate the timing of the PFT values provided on this page Pre bronchodilator

Post bronchodilator (preferred)

Unknown

Date of Spirometry Fixed Unit: MMM dd yyyy

Upload a de-identified copy of the PFT

FVC (L-BTPS) Fixed Unit: actual

FVC Fixed Unit: % predicted

FEV₁ Fixed Unit: actual

FEV₁ Fixed Unit: % predicted

FEV₁/FVC Fixed Unit: actual

FEF 25-75% Fixed Unit: actual

FEF 25-75% Fixed Unit: predicted

Was full pulmonary function test performed? No

Yes

Unknown

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Folder: Baseline Visit

Form: Pulmonary Function Test/Spirometry

Generated On: 09 Apr 2020 15:26:54

If full pulmonary test was not done, the following questions are not required

If full pulmonary test was done, the following questions are required

| | |
|-----------------------------|----------------------------|
| Date of full pulmonary test | |
| Total Lung Capacity | Fixed Unit: actual |
| Total Lung Capacity | Fixed Unit: % predicted |
| Residual Lung Volume | Fixed Unit: actual |
| Residual Lung Volume | Fixed Unit: % predicted |
| D _{Lco} | Fixed Unit: actual |
| D _{Lco} | Fixed Unit: % of predicted |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit

Form: CT Imaging

Generated On: 09 Apr 2020 15:26:54

Did CT commence? No
Yes

Reason imaging did not commence Adverse Event
Claustrophobia
Equipment failure/error
Injection complication
Other (specify additional
information)
Participant refusal
Unknown

Date of Imaging

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Was bronchoscopy performed? No
Yes
Unknown

Primary reason bronchoscopy not performed Patient Refused
Site error
Missing equipment
Unknown
Other, specify

Indicate the timepoint the bronchoscopy was performed Baseline Visit
Surgery
Other, specify

Date of Bronchoscopy Fixed Unit: MMM dd yyyy

Was a sedative given? No
Yes
Unknown

Route of administration Intravenous
Intramuscular
Other, specify

Type used: _____

Was a local anesthetic used? No
Yes
Unknown

Type of local anesthetic _____

Was endobronchial tissue obtained as part of the bronchoscopy? No
Yes
Unknown

Primary reason endobronchial tissue was not obtained Site error
Missing equipment
Unknown
Adverse event
Other, specify

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Folder: Baseline Visit-Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed

Fresh-frozen

Check if collected

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed

Fresh-frozen

Check if collected

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? _____ No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site _____ right upper lobe (RUL)
subsegmental carinas _____
right middle lobe (RML)
subsegmental carinas _____
left upper lobe (LUL)
subsegmental carinas _____
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? _____ No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site _____ right upper lobe (RUL)
subsegmental carinas _____
right middle lobe (RML)
subsegmental carinas _____
left upper lobe (LUL)
subsegmental carinas _____
Formalin-fixed
Fresh-frozen

Check if collected _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

| | |
|--------------------------------------|-------------------------------|
| Fluorescence ratio at biopsy site | |
| Check if fluorescence ratio not done | |
| Date and Time Into Freezer | |
| Freezer Temp | Fixed Unit: °C |
| Did any freeze/thaw occur? | No <input type="radio"/> |
| | Yes <input type="radio"/> |
| | Unknown <input type="radio"/> |
| Freeze/Thaw Comments | |
| Other Comments | |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Was blood collection performed? No
Yes
Unknown

Reason blood collection not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Date of Blood Collection Fixed Unit: MMM dd yyyy

Time of blood collection Fixed Unit: HH:mm

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was plasma collection performed? No
Yes
Unknown

Were plasma samples processed and stored within 2 hours of blood collection? No
Yes
Unknown

Did plasma samples undergo centrifugation within 2 hours of blood collection? No
Yes
Unknown

Primary reason plasma collection was not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Was plasma collection performed per protocol? No

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

| | |
|---|---|
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Primary reason plasma collection was not performed per protocol | Collection Tube(s) broke <input type="checkbox"/> |
| | Missing Materials <input type="checkbox"/> |
| | Site error <input type="checkbox"/> |
| | Storage not per protocol <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |
| <i>Was buffy coat collection performed?</i> | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Primary reason buffy coat collection was not performed | Sample not collected <input type="checkbox"/> |
| | Collection tubes broken <input type="checkbox"/> |
| | Patient Refusal <input type="checkbox"/> |
| | Adverse Event <input type="checkbox"/> |
| | Site error <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |
| <i>Was buffy coat collection performed per protocol?</i> | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Primary reason buffy coat collection was not performed per protocol | Collection Tube(s) broke <input type="checkbox"/> |
| | Missing Materials <input type="checkbox"/> |
| | Site error <input type="checkbox"/> |
| | Storage not per protocol <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |
| <i>Was serum collection performed?</i> | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| Primary reason serum collection was not performed | Sample not collected <input type="checkbox"/> |
| | Collection tubes broken <input type="checkbox"/> |
| | Patient Refusal <input type="checkbox"/> |
| | Adverse Event <input type="checkbox"/> |
| | Site error <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Other, specify

Was serum collection performed per protocol? No

Yes

Unknown

Primary reason serum collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PAX gene collection performed? No

Yes

Unknown

Primary reason PAX gene collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

Adverse Event

Site error

Other, specify

Was PAX gene collection performed per protocol? No

Yes

Unknown

Primary reason PAX gene collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was streck collection performed? No

Yes

Unknown

Primary reason streck collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

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Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

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- Adverse Event
- Site error
- Other, specify

- Was Streck collection performed per protocol?*
- No
 - Yes
 - Unknown

- Primary reason Streck collection was not performed per protocol
- Collection Tube(s) broke
 - Missing Materials
 - Site error
 - Storage not per protocol
 - Other, specify

- Was PBMC collection performed?*
- No
 - Yes
 - Unknown

- Primary reason PBMC collection was not performed per protocol
- Collection Tube(s) broke
 - Missing Materials
 - Site error
 - Storage not per protocol
 - Other, specify

- Was PBMC collection performed per protocol?*
- No
 - Yes
 - Unknown

- Tube Type
- Purple Top Venous Blood Collection Tube
 - Red Top Venous Blood Collection Tube
 - PAXgene tube
 - Yellow Top Venous Blood Collection Tube
 - Streck Tube

- Check if tube collected
- Reason Tube Not Collected
- Patient Refused

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|----------------|--------------------------|
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|--------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|---|-------------------------------------|
| | PAXgene tube | <input checked="" type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

| | |
|---------------------------|--|
| Check if tube collected | <input type="checkbox"/> |
| Reason Tube Not Collected | Patient Refused <input type="checkbox"/> |
| | Adverse Event <input type="checkbox"/> |
| | Site Error <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | PAXgene tube | <input checked="" type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

| | |
|---------------------------|--|
| Check if tube collected | <input type="checkbox"/> |
| Reason Tube Not Collected | Patient Refused <input type="checkbox"/> |
| | Adverse Event <input type="checkbox"/> |
| | Site Error <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input checked="" type="checkbox"/> |

| | |
|---------------------------|--|
| Check if tube collected | <input type="checkbox"/> |
| Reason Tube Not Collected | Patient Refused <input type="checkbox"/> |
| | Adverse Event <input type="checkbox"/> |
| | Site Error <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Total # of Aliquots prepared from the Blood Collection _____

If yes

If **all** aliquots listed were put into the same freezer on the same day and same time, please provide that date/time and freezer temp in the fields below. Please leave these columns in the table blank

Did all of the listed aliquots go into the same freezer at the same date/time?

No

Yes

Unknown

Temperature of Freezer for All Aliquots _____

Date/Time into Freezer for All Aliquots _____

The below table is prefilled with the expected blood collection samples. All fields are editable and the table should reflect the actual samples processed/collected. The total number of items collected should equal the total number of rows in the table. **If PBMC preparation and/or Buffy Coat Preparation is performed, details of the aliquots should not be recorded on this form, but should be recorded on the PBMC Blood Collection Form and/or Buffy Coat Collection Form**

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

Amount of aliquot in vial/tube _____

Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur?

No

Yes

Unknown

Temperature of freezer _____

Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type

Plasma Collection

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|-----------------------|--------------------------|
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input checked="" type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

Unknown

FOR SITE IRB SUBMISSION ONLY
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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

_____ Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

_____ Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

_____ Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Collection Type

| | |
|-----------------------|-------------------------------------|
| Plasma Collection | <input type="checkbox"/> |
| Buffy Coat Collection | <input type="checkbox"/> |
| Serum Collection | <input checked="" type="checkbox"/> |
| PAX Gene | <input type="checkbox"/> |
| PBMC | <input type="checkbox"/> |
| Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type

| | |
|-----------------------|-------------------------------------|
| Plasma Collection | <input type="checkbox"/> |
| Buffy Coat Collection | <input type="checkbox"/> |
| Serum Collection | <input type="checkbox"/> |
| PAX Gene | <input checked="" type="checkbox"/> |
| PBMC | <input type="checkbox"/> |
| Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

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Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

PBMC
Streck

Check if collected _____
Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____
Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

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Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Other comments

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Vial/Tube Type

2mL cryovials

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No

Yes

Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Vial/Tube Type

2mL cryovials

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|------------------|--------------------------|
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

| | | |
|--|---------|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Comments regarding freeze- thaw

Other comment

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input checked="" type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

| | | |
|--|----|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
|--|----|--------------------------|

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Yes
Unknown

Comments regarding freeze- thaw

Other comment

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Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Date and Time of Start of PBMC Processing Fixed Unit: MMM dd yyy HH:MM

PBMC count Fixed Unit: 10⁶ cells/mL

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

Vial/Tube Type
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Number of Cells

LTGO volume

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comment

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

| | |
|----------------------------|----------------------|
| Number of Cells | _____ |
| LTGO volume | _____ |
| Date and Time into Freezer | _____ |
| Temperature of Freezer | _____ Fixed Unit: °C |

| | | |
|--|---------|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | |
|---------------------------------|-------|
| Comments regarding freeze- thaw | _____ |
| Other comment | _____ |

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input checked="" type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

| | |
|--------------------|-------|
| Check if collected | _____ |
|--------------------|-------|

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

| | |
|----------------------------|----------------------|
| Number of Cells | _____ |
| LTGO volume | _____ |
| Date and Time into Freezer | _____ |
| Temperature of Freezer | _____ Fixed Unit: °C |

| | | |
|--|---------|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial
 PAXgene Blood RNA tube

Number of Cells _____

LTGO volume _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
 Yes
 Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|------------------------|--------------------------|
| | PAXgene Blood RNA tube | <input type="checkbox"/> |
| Number of Cells | | |
| LTGO volume | | |
| Date and Time into Freezer | | |
| Temperature of Freezer | Fixed Unit: °C | |
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| Comments regarding freeze- thaw | | |
| Other comment | | |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

Was bronchial airway brushing performed? No
Yes
Unknown

Primary reason not performed Patient Refused
Missing Materials
Adverse Event
Unknown
Other, specify

Indicate the timepoint the bronchial airway brushing was performed Baseline Visit
Surgery
Other, specify

Was bronchial airway brushing performed per protocol? No
Yes
Unknown

Primary reason not performed per protocol Missing Materials
Site error
Adverse Event
Bronchoscopy not performed
Unknown
Other, specify

Date of bronchial airway Brushing Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Tube A
Tube B
Tube C
Tube D

Eppendorf tube containing 1mL of RNA protect Cell Reagent
1mL of 1X PBS solution for proteomic analysis

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Folder: Baseline Visit-Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

1mL of 1X PBS solution for DNA extraction
1mL of RNA protect Cell Reagent

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube A
Tube B
Tube C
Tube D

Eppendorf tube containing 1mL of RNA protect Cell Reagent
1mL of 1X PBS solution for proteomic analysis
1mL of 1X PBS solution for DNA extraction
1mL of RNA protect Cell Reagent

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube A

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Tube B
Tube C
Tube D

Eppendorf tube containing
1mL of RNA protect Cell Reagent
1mL of 1X PBS solution for proteomic analysis
1mL of 1X PBS solution for DNA extraction
1mL of RNA protect Cell Reagent

Check if collected _____
Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____
Other comments _____

Type Tube A
Tube B
Tube C
Tube D

Eppendorf tube containing
1mL of RNA protect Cell Reagent
1mL of 1X PBS solution for proteomic analysis
1mL of 1X PBS solution for DNA extraction
1mL of RNA protect Cell Reagent

Check if collected _____
Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

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Folder: Baseline Visit-Biospecimen Collection

Form: Bronchial Airway Brushing

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Did any freeze-thaw occur to the sample?

No
Yes
Unknown

Comments regarding freeze-thaw

Other comments

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Folder: Baseline Visit-Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Was urine sample collected? No
Yes
Unknown

Reason urine sample was not collected Patient Refused
Adverse Event
Unknown
Other, specify

Date of Urine Sample Collection Fixed Unit: MMM dd yyyy

Was urine collection performed per protocol? No
Yes
Unknown

Primary reason urine collection was not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Unknown
Other, specify

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Sterile Urine Collection Container
Cryovial

Check if collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comments

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No

Yes

Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No

Yes

Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No

Yes

Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Was nasal brushing performed? No
Yes
Unknown

Was nasal brushing additional optional collected. **(Optional nasal collection is only for the three participating sites, Water Reed, Boston University, and UCLA.)** No
Yes

Primary reason nasal brushing not performed Patient Refused
Adverse Event
Missing Materials
Site Error
Unknown
Other, specify

Was nasal brushing performed per protocol? No
Yes
Unknown

Primary reason nasal brushing not done per protocol Storage Not Per Protocol
Missing Materials
Site Error
Unknown
Other, specify

Date of Nasal Brushing Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

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Folder: Baseline Visit-Biospecimen Collection

Form: Nasal Brushing

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Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent

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Folder: Baseline Visit-Biospecimen Collection

Form: Nasal Brushing

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Single cell analysis (Optional)

Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: C

Did any freeze-thaw occur to the sample? No

Yes

Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Folder: Baseline Visit-Biospecimen Collection

Form: Buccal Scraping

Generated On: 09 Apr 2020 15:26:54

Was buccal scraping performed? No
Yes
Unknown

Primary reason buccal scraping not performed Patient Refused
Adverse Event
Unknown
Other, specify

Was buccal scraping performed per protocol? No
Yes
Unknown

Primary reason buccal scraping was not performed per protocol Missing Materials
Site error
Unknown
Other, specify

Date of Buccal Scraping Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Microtube
Microtube with Scraper

Check if Collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw

Other comments

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Folder: Baseline Visit-Biospecimen Collection

Form: Sputum Samples

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Was sputum sample collected by the patient and mailed to the core pathology lab? No

Yes

Unknown

Primary reason not collected and/or mailed

Lost kit

Sputum kit not distributed to pt

Patient refused

Other Pt related error

Other, specify

Date Sputum Sample Mailed

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No

Yes

Unknown

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Folder: Baseline Visit-Biospecimen Collection

Form: Urine Processing for Metabolomics Study

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Was the urine processing for metabolomics study performed? No
Yes
Unknown

If processing not done, provided primary reason Participant Refused
Site error
Missing or incomplete kit contents
Missing or incomplete material(s) or equipment
Optional biospecimen
Other, specify

Was the urine processing for metabolomics study performed per protocol? No
Yes
Unknown

Primary Reason not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Prepared Urine specimen cups not used
Unknown
Other, specify

Date Urine Processed at Site Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Total number of urine checks

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected

Date and Time Into Freezer

Freezer Temperature Fixed Unit: °C

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Folder: Baseline Visit-Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

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Folder: Baseline Visit-Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal (8 pages total) _____

Did all of the listed specimens go into the same freezer at the same date/time? No
Yes

Unknown

Did any freeze thaw occur? No

Yes

Were all specimens stored at the same temp? No

Yes

Provide storage temp for all specimens _____

If the Biospecimens collected have different storage temps record this in the provided comment box.

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

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Form: Biospecimen Transmittal-Required v2

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Barcode Sequence # 7

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 8

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 9

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|----------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="radio"/> |
| Blood Collection- Serum | <input type="radio"/> |
| Blood Collection-PAXgene | <input type="radio"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 10

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 11

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

Bronchial Airway Brushings-
Brush C

Bronchial Biopsy Collection-
RUL Fresh Frozen

Bronchial Biopsy Collection-
RML Fresh Frozen

Bronchial Biopsy Collection-
LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-
RUL Formalin Fixed

Bronchial Biopsy Collection-
RML Formalin Fixed

Bronchial Biopsy Collection-
LUL Formalin Fixed

Streck Collection

Barcode Sequence # 12

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 19

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input checked="" type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 20

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed
- Bronchial Biopsy Collection-
RML Formalin Fixed
- Bronchial Biopsy Collection-
LUL Formalin Fixed
- Streck Collection

Barcode Sequence # 21

Check if specimen **NOT** included

Check if freeze/thaw occurred

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Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-Brush A
- Bronchial Airway Brushings-Brush B
- Bronchial Airway Brushings-Brush C
- Bronchial Biopsy Collection-RUL Fresh Frozen
- Bronchial Biopsy Collection-RML Fresh Frozen
- Bronchial Biopsy Collection-LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-RUL Formalin Fixed
- Bronchial Biopsy Collection-RML Formalin Fixed
- Bronchial Biopsy Collection-LUL Formalin Fixed
- Streck Collection

Barcode Sequence #

25

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-Brush A
- Bronchial Airway Brushings-Brush B
- Bronchial Airway Brushings-Brush C

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 26

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 28

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 29

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

FOR SITE IRB SUBMISSION ONLY
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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 30

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|--------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

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| | | |
|--|--|-------------------------------------|
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 31

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |

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Bronchial Biopsy Collection-
LUL Formalin Fixed
Streck Collection

Barcode Sequence # 60

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

Barcode Sequence # 61

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

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Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 62

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input checked="" type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | |
|--|--------------------------|
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 68

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Streck Collection

Barcode Sequence # 70

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

Barcode Sequence # 72

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 51

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 54

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Barcode Sequence # 55

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 34

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 35

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

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| | | |
|--|--|-------------------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 36

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 37

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B
 - Bronchial Airway Brushings-Brush C
 - Bronchial Biopsy Collection-RUL Fresh Frozen
 - Bronchial Biopsy Collection-RML Fresh Frozen
 - Bronchial Biopsy Collection-LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection-RUL Formalin Fixed
 - Bronchial Biopsy Collection-RML Formalin Fixed
 - Bronchial Biopsy Collection-LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 38

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|---------------------------------------|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |
| Barcode Sequence # | | 39 |
| Check if specimen NOT included | | <input type="checkbox"/> |
| Check if freeze/thaw occurred | | <input type="checkbox"/> |
| Comments | | <input type="checkbox"/> |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal- Bronchial Biopsy Formalin Fixed _____

- Biospecimen Sample
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # _____ 67

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

| | | |
|--------------------|--|-------------------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 69

Check if Specimen Included

Storage Temp Fixed Unit: °C

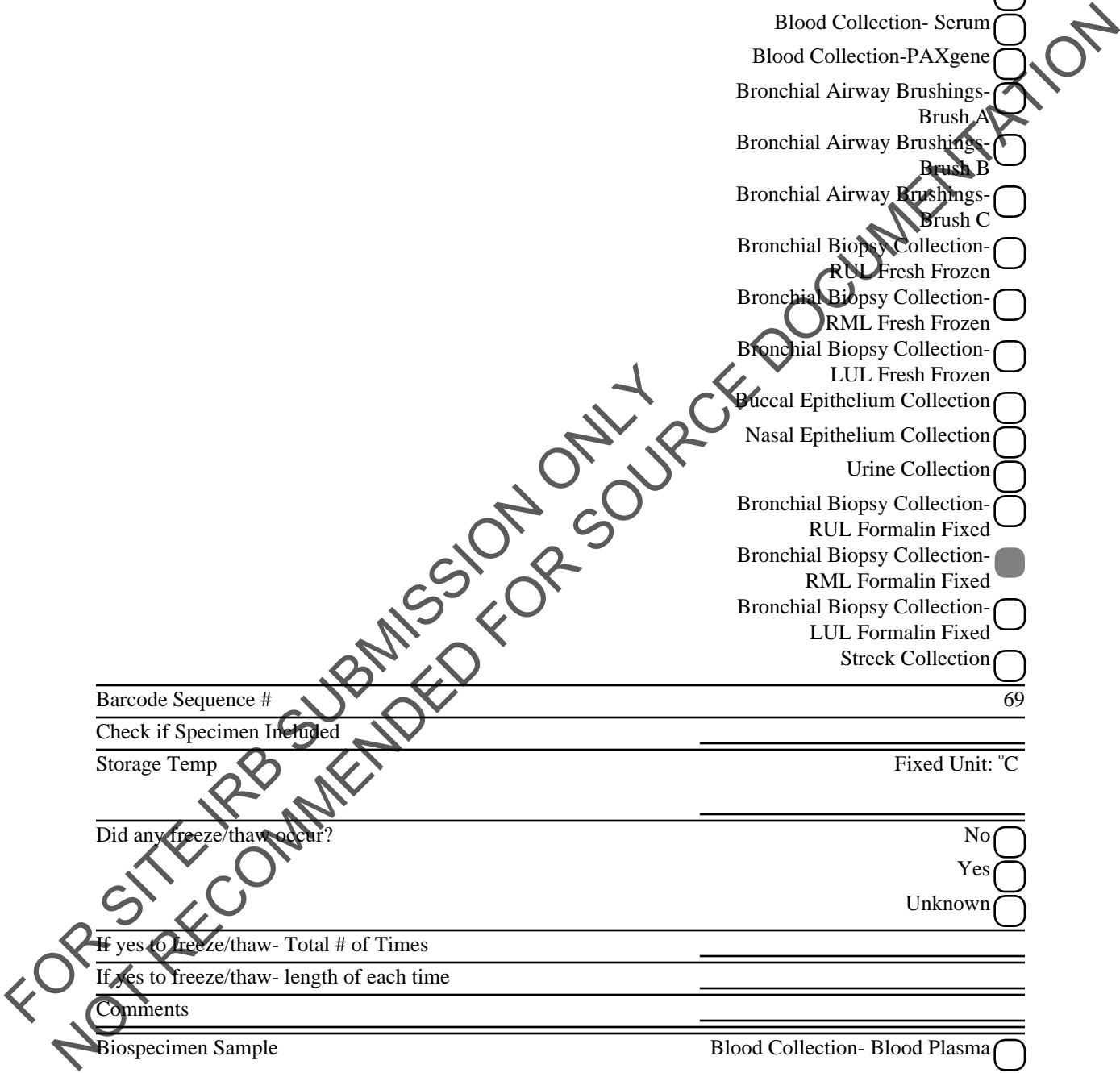
Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|--------------------|--------------------------------|--------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |



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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

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| | | |
|--|--|-------------------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input checked="" type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 71

Check if Specimen Included

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Were optional biospecimens sent to the core lab? No
Yes
Unknown

If no optional biospecimens were sent to the core lab, leave the table blank.

If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 13

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 14

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 15

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 16

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 17

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 18

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 27

Check if Specimen Included

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 28

Check if Specimen Included

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | | |
|--|---|--------------------------|
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

Barcode Sequence # 29

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur?

| | |
|---------|--------------------------|
| No | <input type="checkbox"/> |
| Yes | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |
| | | |

Barcode Sequence # 30

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur?

| | |
|---------|--------------------------|
| No | <input type="checkbox"/> |
| Yes | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |
| | | |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Barcode Sequence # 31

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 63

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 40

Check if Specimen Included

Storage Temp Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 41

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 42

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 43

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 44

Check if Specimen Included _____

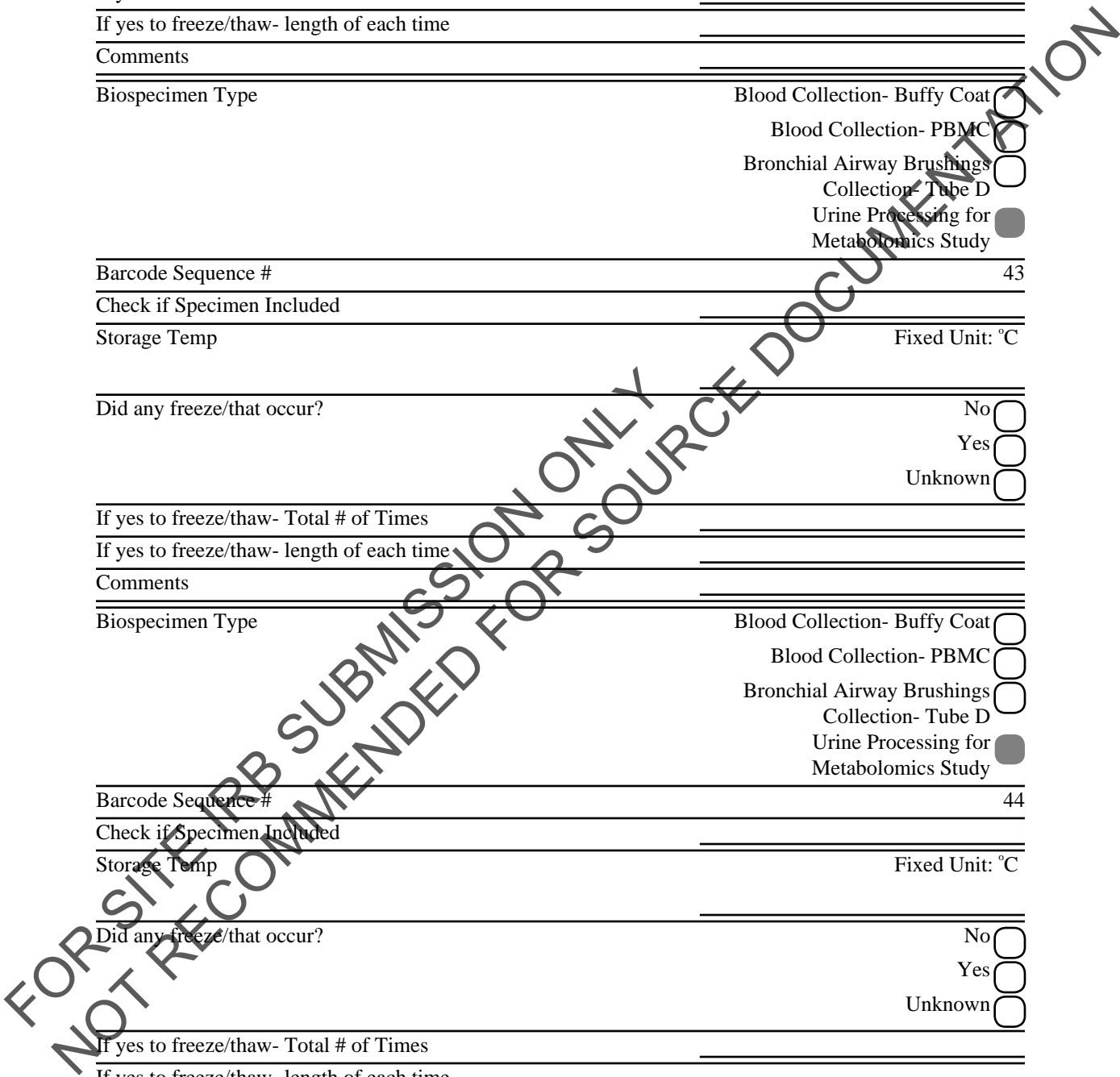
Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____



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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | |
|--|---|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |
| Barcode Sequence # | 45 |
| Check if Specimen Included | <input type="checkbox"/> |
| Storage Temp | Fixed Unit: °C |
| Did any freeze/thaw occur? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| If yes to freeze/thaw- Total # of Times | |
| If yes to freeze/thaw- length of each time | |
| Comments | |

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Folder: Baseline Visit-Biospecimen Collection

Form: Biospecimen Transmittal- Additional

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Were additional biospecimens sent to the core lab? No
Yes
Unknown

If no additional biospecimens were sent to the core lab, leave the table blank.

If additional specimens were sent, at least one row of the table must be completed.

| | | |
|------------------|--|--------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

Barcode Sequence # _____
Date Sent to Core Lab _____
Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____
If yes to freeze/thaw- length of each time _____
Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Follow up

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Was the follow up completed? No
Yes
Unknown

If the follow up was not completed, please provide the primary reason is was not done Patient Refused
Patient Lost to Follow up
Site error
Other, specify

Date of Follow up Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was pulmonary function test/spirometry performed? No
Yes

Reason pulmonary function test/spirometry not performed Patient Refused
Site error
Equipment Unavailable
Unknown
Other, specify

Was physical exam performed? No
Yes
Unknown

Reason physical exam not performed Patient Refused
Site error
Unknown
Other, specify

Did the patient have any imaging performed as part of follow up? No
Yes
Unknown

Image Type CT
Dynamic contrast-enhanced CT
PET

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Follow up

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| | | |
|--|-------|--------------------------|
| | MRI | <input type="checkbox"/> |
| | X-ray | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |

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

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

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of Surgery _____

Were surgical tissue samples collected?

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Primary reason surgical tissue samples were not collected

| | | |
|--|-------------------------------|--------------------------|
| | Site Error | <input type="checkbox"/> |
| | Patient Refused | <input type="checkbox"/> |
| | Pathology Lab Refused Request | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Instructions:

The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician annually until

lung cancer diagnosis or year 4 follow up. Any malignancy identified during the four-year follow-up time period will need to be

reported on the Study Evaluation and Diagnosis Form. A response of "Primary Lung" or "Metastatic to the Lung" to Question #4a

completes the participant's involvement in the follow up procedures.

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 _____

4. - Is there malignancy in the lung? No
Yes
Uncertain

4a. - If yes, the malignancy is Primary Lung
Metastatic to the Lung
Uncertain
Other, specify

4a1. - If metastatic, provide the site of primary organ Bladder
Bone
Brain
Breast
Cervical
Colon-Rectal
Esophageal
Gastric
Kidney
Larynx
Lymphoma

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- Melanoma
- Nasal
- Oral
- Pancreatic
- Pharynx
- Prostate
- Renal Cell
- Thyroid
- Transition Cell
- Uncertain
- Other Cancer, Specify

Part II. Lung Malignancy *complete this section only if Q4a=primary lung*

5. - Date of first diagnosis _____

6. - Has the lung cancer been reported on a previous Study Evaluation and Diagnosis form? No
Yes
Unknown

6a. - Has the patient developed progressive disease following treatment for lung cancer? No
Yes
Unknown

6a1. - If yes, date of first documentation of progressive lung cancer _____

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

- Original lung site
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt I, II

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Unknown
Other, specify

7. - Lung Cancer Type
Small Cell Lung Cancer
Non-Small Cell Lung Cancer
Unknown

8. - Histologic Class
Adenocarcinoma
Adenosquamous Carcinoma
Epidermoid Carcinoma
Bronchioloalveolar Carcinoma
Carcinoid
Large Cell Carcinoma
Small Cell Carcinoma
Squamous Cell Carcinoma
Other, specify
Unknown

9. - Histologic Subtype
Acinar
Bronchioalveola
Papillary
Solid carcinoma with mucus formation
Mixed
Pure small cell carcinoma
Combined small cell carcinoma
Large cell neuroendocrine
Basaloid
Lymphoepithelial-like
Large cell with rhabdoid phenotype
Unknown

10. - Cancer Stage
Occult
0
IA
IB

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt I, II

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IIA

IIB

IIIA

IIIB

IV

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

Generated On: 09 Apr 2020 15:26:54

Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed *required if Q1=yes*

Note: All diagnostic tests will need a de-identified copy of the report uploaded into Rave

NOW DERIVATION

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input checked="" type="radio"/> |
| | Bone Scan <input type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |
| | PET <input type="radio"/> |
| | Sputum <input type="radio"/> |
| | Surgical Pathology <input type="radio"/> |
| | TBNA <input type="radio"/> |
| | Thoracoscopy <input type="radio"/> |
| | Thoracotomy <input type="radio"/> |
| | TTNA <input type="radio"/> |
| | Other, specify <input type="radio"/> |

| | |
|--|-------------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No <input type="radio"/> |
| | Yes <input type="radio"/> |
| | Unknown <input type="radio"/> |

| | |
|---|---------------------------|
| Date of test | |
| Was test used to establish diagnosis described above? | No <input type="radio"/> |
| | Yes <input type="radio"/> |

Upload Report

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input type="radio"/> |
| | Bone Scan <input checked="" type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|--------------------------|
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of test _____

| | | |
|---|-----|--------------------------|
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

Upload Report _____

Diagnostic Test Type

| | | |
|--|--------------------|-------------------------------------|
| | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input checked="" type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|-----|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

Generated On: 09 Apr 2020 15:26:54

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No

Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--------------------|--------------------------|
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of test _____

| | | |
|---|-----|--------------------------|
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

Upload Report _____

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input checked="" type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type Biopsy
Bone Scan
Bronchoscopy
Chest X Ray
CT Scan
Mediastinoscopy
MRI
PET
Sputum
Surgical Pathology
TBNA
Thoracoscopy
Thoracotomy
TTNA
Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type Biopsy
Bone Scan
Bronchoscopy

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|-------------------------------------|
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input checked="" type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-------|--------------------------|
| Date of test | _____ | |
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

| | |
|---------------|-------|
| Upload Report | _____ |
|---------------|-------|

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input checked="" type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

Generated On: 09 Apr 2020 15:26:54

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

Biopsy

Bone Scan

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--------------------|-------------------------------------|
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input checked="" type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of test _____

| | | |
|---|-----|--------------------------|
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

Upload Report _____

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input checked="" type="checkbox"/> |

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Folder: 1 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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TTNA
Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____
Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____
Was test used to establish diagnosis described above? No
Yes

Upload Report _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 73

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 75

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 74

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 76

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up

Form: CT Imaging

Generated On: 09 Apr 2020 15:26:54

Did CT commence? No

Yes

Reason imaging did not commence Adverse Event

Claustrophobia

Equipment failure/error

Injection complication

Other (specify additional information)

Participant refusal

Unknown

Date of Imaging _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Was blood collection performed? No
Yes
Unknown

Reason blood collection not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Date of Blood Collection Fixed Unit: MMM dd yyyy

Time of blood collection Fixed Unit: HH:mm

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was plasma collection performed? No
Yes
Unknown

Were plasma samples processed and stored within 2 hours of blood collection? No
Yes
Unknown

Did plasma samples undergo centrifugation within 2 hours of blood collection? No
Yes
Unknown

Primary reason plasma collection was not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Was plasma collection performed per protocol? No

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|---------|--------------------------|
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|--------------------------|--------------------------|
| Primary reason plasma collection was not performed per protocol | Collection Tube(s) broke | <input type="checkbox"/> |
| | Missing Materials | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Storage not per protocol | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|---|---------|--------------------------|
| <i>Was buffy coat collection performed?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|--|-------------------------|--------------------------|
| Primary reason buffy coat collection was not performed | Sample not collected | <input type="checkbox"/> |
| | Collection tubes broken | <input type="checkbox"/> |
| | Patient Refusal | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| <i>Was buffy coat collection performed per protocol?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|--------------------------|--------------------------|
| Primary reason buffy coat collection was not performed per protocol | Collection Tube(s) broke | <input type="checkbox"/> |
| | Missing Materials | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Storage not per protocol | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| <i>Was serum collection performed?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-------------------------|--------------------------|
| Primary reason serum collection was not performed | Sample not collected | <input type="checkbox"/> |
| | Collection tubes broken | <input type="checkbox"/> |
| | Patient Refusal | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection

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Other, specify

Was serum collection performed per protocol? No

Yes

Unknown

Primary reason serum collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PAX gene collection performed? No

Yes

Unknown

Primary reason PAX gene collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

Adverse Event

Site error

Other, specify

Was PAX gene collection performed per protocol? No

Yes

Unknown

Primary reason PAX gene collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was streck collection performed? No

Yes

Unknown

Primary reason streck collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

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Form: Blood Collection

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Adverse Event

Site error

Other, specify

Was Streck collection performed per protocol? No

Yes

Unknown

Primary reason Streck collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PBMC collection performed? No

Yes

Unknown

Primary reason PBMC collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PBMC collection performed per protocol? No

Yes

Unknown

Tube Type Purple Top Venous Blood Collection Tube

Red Top Venous Blood Collection Tube

PAXgene tube

Yellow Top Venous Blood Collection Tube

Streck Tube

Check if tube collected

Reason Tube Not Collected Patient Refused

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection

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| | | |
|--|----------------|--------------------------|
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|--------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection

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- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected _____

Reason Tube Not Collected _____

- Patient Refused
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type _____

- Purple Top Venous Blood Collection Tube
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected _____

Reason Tube Not Collected _____

- Patient Refused
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type _____

- Purple Top Venous Blood Collection Tube
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected _____

Reason Tube Not Collected _____

- Patient Refused
- Adverse Event
- Site Error

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Form: Blood Collection

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Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Total # of Aliquots prepared from the Blood Collection _____

If yes

If **all** aliquots listed were put into the same freezer on the same day and same time, please provide that date/time and freezer temp in the fields below. Please leave these columns in the table blank

Did all of the listed aliquots go into the same freezer at the same date/time? No
Yes
Unknown

Temperature of Freezer for All Aliquots _____

Date/Time into Freezer for All Aliquots _____

The below table is prefilled with the expected blood collection samples. All fields are editable and the table should reflect the actual samples processed/collected. The total number of items collected should equal the total number of rows in the table. **If PBMC preparation and/or Buffy Coat Preparation is performed, details of the aliquots should not be recorded on this form, but should be recorded on the PBMC Blood Collection Form and/or Buffy Coat Collection Form**

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection

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Form: Blood Collection Aliquots- Required

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Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____
Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____
Temperature of Freezer _____
Data and Time into -80° Freezer _____
Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C
Comments regarding freeze-thaw _____
Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____
Amount of aliquot in vial/tube _____ Fixed Unit: mL
Date and Time into -20° Freezer _____
Temperature of Freezer _____
Data and Time into -80° Freezer _____
Did any freeze-thaw occur? No
Yes
Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

_____ Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

_____ Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

_____ Check if collected _____

_____ Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input checked="" type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input checked="" type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

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Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

PBMC
 Streck

Check if collected

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
 Yes
 Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
 Yes
 Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

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Other comments

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

| | |
|-----------------|---|
| Collection Type | Plasma Collection <input type="checkbox"/> |
| | Buffy Coat Collection <input checked="" type="checkbox"/> |
| | Serum Collection <input type="checkbox"/> |
| | PAX Gene <input type="checkbox"/> |
| | PBMC <input type="checkbox"/> |
| | Streck <input type="checkbox"/> |

| | |
|--------------------|---|
| Check if collected | |
| Vial/Tube Type | 2mL cryovials <input type="checkbox"/> |
| | 5mL cryovial <input type="checkbox"/> |
| | 15mL cryovial <input type="checkbox"/> |
| | PAXgene Blood RNA tube <input type="checkbox"/> |

| | |
|----------------------------|----------------|
| Date and Time into Freezer | |
| Temperature of Freezer | Fixed Unit: °C |

| | |
|--|----------------------------------|
| Did any freeze-thaw occur to the sample? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |

| | |
|---------------------------------|--|
| Comments regarding freeze- thaw | |
| Other comment | |

| | |
|-----------------|---|
| Collection Type | Plasma Collection <input type="checkbox"/> |
| | Buffy Coat Collection <input checked="" type="checkbox"/> |
| | Serum Collection <input type="checkbox"/> |
| | PAX Gene <input type="checkbox"/> |
| | PBMC <input type="checkbox"/> |
| | Streck <input type="checkbox"/> |

| | |
|--------------------|---|
| Check if collected | |
| Vial/Tube Type | 2mL cryovials <input type="checkbox"/> |
| | 5mL cryovial <input type="checkbox"/> |
| | 15mL cryovial <input type="checkbox"/> |
| | PAXgene Blood RNA tube <input type="checkbox"/> |

| | |
|----------------------------|----------------|
| Date and Time into Freezer | |
| Temperature of Freezer | Fixed Unit: °C |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

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5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____
Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____
Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____
Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type _____
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____
No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type _____
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type _____
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____ No

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Yes

Unknown

Comments regarding freeze- thaw _____

Other comment _____

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Date and Time of Start of PBMC Processing Fixed Unit: MMM dd yyy HH:MM

PBMC count Fixed Unit: 10⁶ cells/mL

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

Vial/Tube Type
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Number of Cells

LTGO volume

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comment

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

| | |
|----------------------------|----------------------|
| Number of Cells | _____ |
| LTGO volume | _____ |
| Date and Time into Freezer | _____ |
| Temperature of Freezer | _____ Fixed Unit: °C |

| | | |
|--|---------|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | |
|---------------------------------|-------|
| Comments regarding freeze- thaw | _____ |
| Other comment | _____ |

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input checked="" type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

| | |
|--------------------|-------|
| Check if collected | _____ |
|--------------------|-------|

| | | |
|----------------|------------------------|--------------------------|
| Vial/Tube Type | 2mL cryovials | <input type="checkbox"/> |
| | 5mL cryovial | <input type="checkbox"/> |
| | 15mL cryovial | <input type="checkbox"/> |
| | PAXgene Blood RNA tube | <input type="checkbox"/> |

| | |
|----------------------------|----------------------|
| Number of Cells | _____ |
| LTGO volume | _____ |
| Date and Time into Freezer | _____ |
| Temperature of Freezer | _____ Fixed Unit: °C |

| | | |
|--|---------|--------------------------|
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial
 PAXgene Blood RNA tube

Number of Cells _____

LTGO volume _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
 Yes
 Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial

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Folder: 1 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|------------------------|--------------------------|
| | PAXgene Blood RNA tube | <input type="checkbox"/> |
| Number of Cells | | |
| LTGO volume | | |
| Date and Time into Freezer | | |
| Temperature of Freezer | Fixed Unit: °C | |
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| Comments regarding freeze- thaw | | |
| Other comment | | |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Was urine sample collected? No
Yes
Unknown

Reason urine sample was not collected Patient Refused
Adverse Event
Unknown
Other, specify

Date of Urine Sample Collection Fixed Unit: MMM dd yyyy

Was urine collection performed per protocol? No
Yes
Unknown

Primary reason urine collection was not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Unknown
Other, specify

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Sterile Urine Collection Container
Cryovial

Check if collected

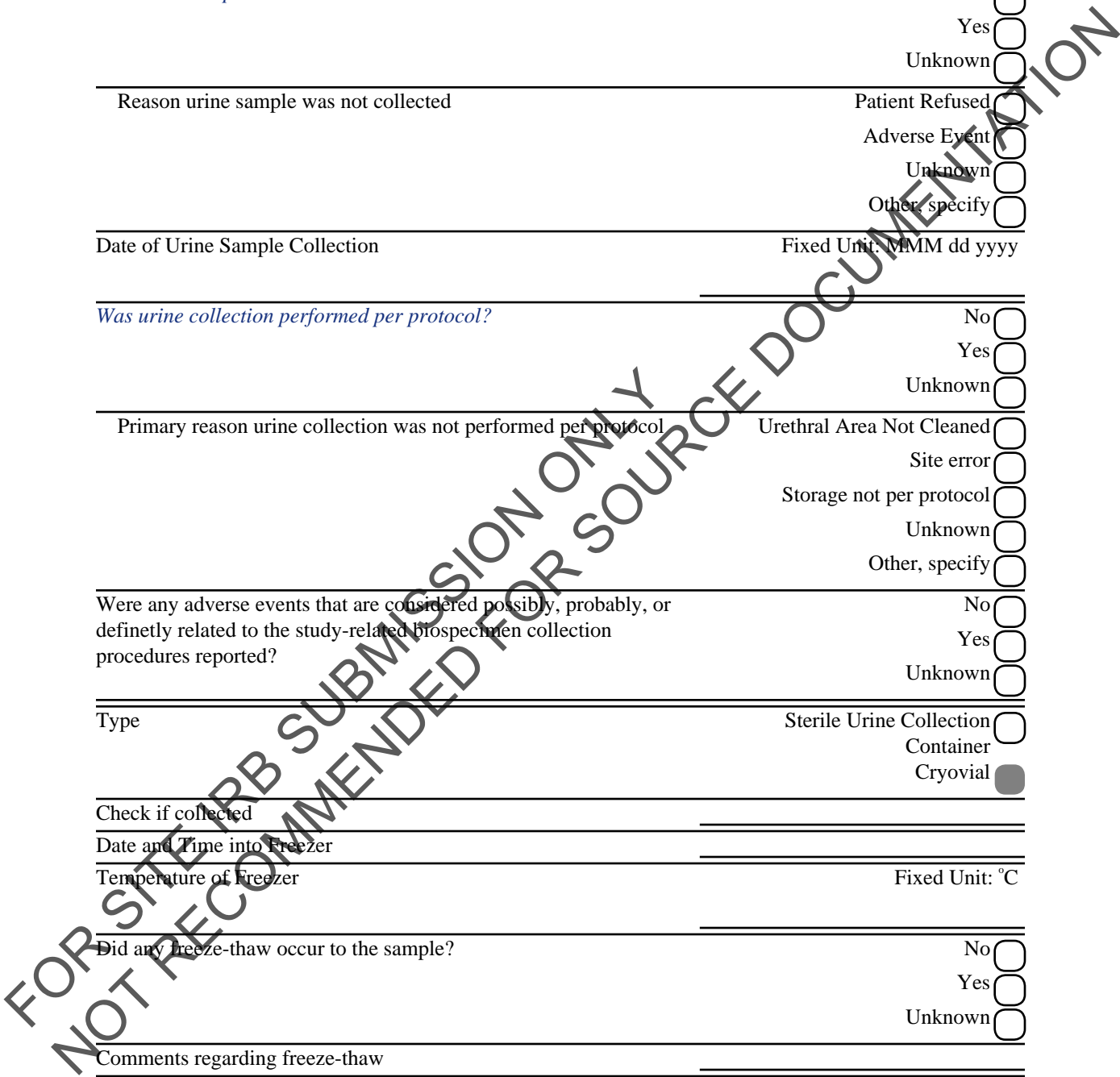
Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comments



Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Was nasal brushing performed? No
Yes
Unknown

Was nasal brushing additional optional collected. **(Optional nasal collection is only for the three participating sites, Water Reed, Boston University, and UCLA.** No
Yes

Primary reason nasal brushing not performed Patient Refused
Adverse Event
Missing Materials
Site Error
Unknown
Other, specify

Was nasal brushing performed per protocol? No
Yes
Unknown

Primary reason nasal brushing not done per protocol Storage Not Per Protocol
Missing Materials
Site Error
Unknown
Other, specify

Date of Nasal Brushing Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Single cell analysis (Optional)

Nasal Single Cell Plate
(Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Buccal Scraping

Generated On: 09 Apr 2020 15:26:54

Was buccal scraping performed? No
Yes
Unknown

Primary reason buccal scraping not performed Patient Refused
Adverse Event
Unknown
Other, specify

Was buccal scraping performed per protocol? No
Yes
Unknown

Primary reason buccal scraping was not performed per protocol Missing Materials
Site error
Unknown
Other, specify

Date of Buccal Scraping Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Microtube
Microtube with Scraper

Check if Collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw

Other comments

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Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Was the urine processing for metabolomics study performed? No
Yes
Unknown

If processing not done, provided primary reason Participant Refused
Site error
Missing or incomplete kit contents
Missing or incomplete material(s) or equipment
Optional biospecimen
Other, specify

Was the urine processing for metabolomics study performed per protocol? No
Yes
Unknown

Primary Reason not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Prepared Urine specimen cups not used
Unknown
Other, specify

Date Urine Processed at Site Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Total number of urine checks _____
Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature Fixed Unit: °C

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Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal (8 pages total) _____

Did all of the listed specimens go into the same freezer at the same date/time? No
Yes

Unknown

Did any freeze thaw occur? No

Yes

Were all specimens stored at the same temp? No

Yes

Provide storage temp for all specimens _____

If the Biospecimens collected have different storage temps record this in the provided comment box.

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Barcode Sequence # 7

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

Bronchial Airway Brushings-
Brush C

Bronchial Biopsy Collection-
RUL Fresh Frozen

Bronchial Biopsy Collection-
RML Fresh Frozen

Bronchial Biopsy Collection-
LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-
RUL Formalin Fixed

Bronchial Biopsy Collection-
RML Formalin Fixed

Bronchial Biopsy Collection-
LUL Formalin Fixed

Streck Collection

Barcode Sequence # 8

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 9

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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| | | |
|--|--|--------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 10

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 11

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Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

Bronchial Airway Brushings-
Brush C

Bronchial Biopsy Collection-
RUL Fresh Frozen

Bronchial Biopsy Collection-
RML Fresh Frozen

Bronchial Biopsy Collection-
LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-
RUL Formalin Fixed

Bronchial Biopsy Collection-
RML Formalin Fixed

Bronchial Biopsy Collection-
LUL Formalin Fixed

Streck Collection

Barcode Sequence # 12

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

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| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 19

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input checked="" type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 20

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed
- Bronchial Biopsy Collection-
RML Formalin Fixed
- Bronchial Biopsy Collection-
LUL Formalin Fixed
- Streck Collection

Barcode Sequence # 21

Check if specimen **NOT** included

Check if freeze/thaw occurred

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Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed
- Bronchial Biopsy Collection-
RML Formalin Fixed
- Bronchial Biopsy Collection-
LUL Formalin Fixed
- Streck Collection

Barcode Sequence #

25

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 26

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 28

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 29

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

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Form: Biospecimen Transmittal-Required v2

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| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 30

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|--------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |

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| | | |
|--|--|-------------------------------------|
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 31

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |

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Bronchial Biopsy Collection-
LUL Formalin Fixed
Streck Collection

Barcode Sequence # 60

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

Barcode Sequence # 61

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

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| | | |
|--|--|--------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 62

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input checked="" type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |

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| | | |
|---------------------------------------|--|-------------------------------------|
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |
| Barcode Sequence # | | 68 |
| Check if specimen NOT included | | <input type="checkbox"/> |
| Check if freeze/thaw occurred | | <input type="checkbox"/> |
| Comments | | <input type="checkbox"/> |
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |

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Streck Collection

Barcode Sequence # 70

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

Barcode Sequence # 72

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

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Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 51

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 54

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Barcode Sequence # 55

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed
- Bronchial Biopsy Collection-
RML Formalin Fixed
- Bronchial Biopsy Collection-
LUL Formalin Fixed
- Streck Collection

Barcode Sequence # 34

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 35

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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| | | |
|--|--|-------------------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 36

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 37

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B
 - Bronchial Airway Brushings-Brush C
 - Bronchial Biopsy Collection-RUL Fresh Frozen
 - Bronchial Biopsy Collection-RML Fresh Frozen
 - Bronchial Biopsy Collection-LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection-RUL Formalin Fixed
 - Bronchial Biopsy Collection-RML Formalin Fixed
 - Bronchial Biopsy Collection-LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 38

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed
- Bronchial Biopsy Collection-
RML Formalin Fixed
- Bronchial Biopsy Collection-
LUL Formalin Fixed
- Streck Collection

| | |
|---------------------------------------|--------------------------|
| Barcode Sequence # | 39 |
| Check if specimen NOT included | <input type="checkbox"/> |
| Check if freeze/thaw occurred | <input type="checkbox"/> |
| Comments | <input type="text"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

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Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal- Bronchial Biopsy Formalin Fixed _____

- Biospecimen Sample
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # _____ 67

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

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| | | |
|--------------------|--|-------------------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 69

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

| | | |
|--------------------|--------------------------------|--------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

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| | | |
|--|--|-------------------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input checked="" type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 71

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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Were optional biospecimens sent to the core lab? No
Yes
Unknown

If no optional biospecimens were sent to the core lab, leave the table blank.

If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 13

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 14

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 15

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 16

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 17

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 18

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 27

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 28

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | | |
|--|---|--------------------------|
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

Barcode Sequence # 29

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

Barcode Sequence # 30

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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Barcode Sequence # 31

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 63

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 40

Check if Specimen Included

Storage Temp Fixed Unit: °C

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 41

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 42

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 43

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 44

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | |
|--|---|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |
| Barcode Sequence # | 45 |
| Check if Specimen Included | <input type="checkbox"/> |
| Storage Temp | Fixed Unit: °C |
| Did any freeze/thaw occur? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| If yes to freeze/thaw- Total # of Times | |
| If yes to freeze/thaw- length of each time | |
| Comments | |

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Folder: 1 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Additional

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Were additional biospecimens sent to the core lab? No
Yes
Unknown

If no additional biospecimens were sent to the core lab, leave the table blank.

If additional specimens were sent, at least one row of the table must be completed.

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Blood Plasma <input type="checkbox"/> |
| | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input type="checkbox"/> |
| | Blood Collection- Serum <input type="checkbox"/> |
| | Blood Collection-PAXgene <input type="checkbox"/> |
| | Bronchial Airway Brushings Collection <input type="checkbox"/> |
| | Bronchial Biopsy Collection <input type="checkbox"/> |
| | Buccal Epithelium Collection <input type="checkbox"/> |
| | Nasal Epithelium Collection <input type="checkbox"/> |
| | Urine Collection <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |

Barcode Sequence # _____
Date Sent to Core Lab _____
Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____
If yes to freeze/thaw- length of each time _____
Comments _____

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Form: Follow up

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Was the follow up completed? No
Yes
Unknown

If the follow up was not completed, please provide the primary reason is was not done Patient Refused
Patient Lost to Follow up
Site error
Other, specify

Date of Follow up Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was pulmonary function test/spirometry performed? No
Yes

Reason pulmonary function test/spirometry not performed Patient Refused
Site error
Equipment Unavailable
Unknown
Other, specify

Was physical exam performed? No
Yes
Unknown

Reason physical exam not performed Patient Refused
Site error
Unknown
Other, specify

Did the patient have any imaging performed as part of follow up? No
Yes
Unknown

Image Type CT
Dynamic contrast-enhanced CT
PET

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Form: Follow up

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| | | |
|--|-------|--------------------------|
| | MRI | <input type="checkbox"/> |
| | X-ray | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |

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

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

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of Surgery _____

Were surgical tissue samples collected?

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Primary reason surgical tissue samples were not collected

| | | |
|--|-------------------------------|--------------------------|
| | Site Error | <input type="checkbox"/> |
| | Patient Refused | <input type="checkbox"/> |
| | Pathology Lab Refused Request | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Instructions:

The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician annually until

lung cancer diagnosis or year 4 follow up. Any malignancy identified during the four-year follow-up time period will need to be

reported on the Study Evaluation and Diagnosis Form. A response of "Primary Lung" or "Metastatic to the Lung" to Question #4a

completes the participant's involvement in the follow up procedures.

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 _____

4. - Is there malignancy in the lung? No

Yes

Uncertain

4a. - If yes, the malignancy is Primary Lung

Metastatic to the Lung

Uncertain

Other, specify

4a1. - If metastatic, provide the site of primary organ Bladder

Bone

Brain

Breast

Cervical

Colon-Rectal

Esophageal

Gastric

Kidney

Larynx

Lymphoma

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- Melanoma
- Nasal
- Oral
- Pancreatic
- Pharynx
- Prostate
- Renal Cell
- Thyroid
- Transition Cell
- Uncertain
- Other Cancer, Specify

Part II. Lung Malignancy complete this section only if Q4a=primary lung

5. - Date of first diagnosis _____

6. - Has the lung cancer been reported on a previous Study Evaluation and Diagnosis form? No
Yes
Unknown

6a. - Has the patient developed progressive disease following treatment for lung cancer? No
Yes
Unknown

6a1. - If yes, date of first documentation of progressive lung cancer _____

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

- Original lung site
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)

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Unknown
Other, specify

7. - Lung Cancer Type
Small Cell Lung Cancer
Non-Small Cell Lung Cancer
Unknown

8. - Histologic Class
Adenocarcinoma
Adenosquamous Carcinoma
Epidermoid Carcinoma
Bronchioloalveolar Carcinoma
Carcinoid
Large Cell Carcinoma
Small Cell Carcinoma
Squamous Cell Carcinoma
Other, specify
Unknown

9. - Histologic Subtype
Acinar
Bronchioalveola
Papillary
Solid carcinoma with mucus formation
Mixed
Pure small cell carcinoma
Combined small cell carcinoma
Large cell neuroendocrine
Basaloid
Lymphoepithelial-like
Large cell with rhabdoid phenotype
Unknown

10. - Cancer Stage
Occult
0
IA
IB

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IIA
IIB
IIIA
IIIB
IV

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Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed *required if Q1=yes*

Note: All diagnostic tests will need a de-identified copy of the report uploaded into Rave

NOW DERIVATION

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input checked="" type="radio"/> |
| | Bone Scan <input type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |
| | PET <input type="radio"/> |
| | Sputum <input type="radio"/> |
| | Surgical Pathology <input type="radio"/> |
| | TBNA <input type="radio"/> |
| | Thoracoscopy <input type="radio"/> |
| | Thoracotomy <input type="radio"/> |
| | TTNA <input type="radio"/> |
| | Other, specify <input type="radio"/> |

| | |
|--|-------------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No <input type="radio"/> |
| | Yes <input type="radio"/> |
| | Unknown <input type="radio"/> |

| | |
|---|---------------------------|
| Date of test | _____ |
| Was test used to establish diagnosis described above? | No <input type="radio"/> |
| | Yes <input type="radio"/> |

Upload Report _____

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input type="radio"/> |
| | Bone Scan <input checked="" type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |

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| | | |
|--|--------------------|--------------------------|
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of test _____

| | | |
|---|-----|--------------------------|
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

| | | |
|--|-----|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

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Form: Study Evaluation and Diagnosis- Pt III

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Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No

Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

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| | | |
|--|--------------------|--------------------------|
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of test _____

| | | |
|---|-----|--------------------------|
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

Upload Report _____

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input checked="" type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy

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Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|-------------------------------------|
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input checked="" type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-------|--------------------------|
| Date of test | _____ | |
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

| | |
|---------------|-------|
| Upload Report | _____ |
|---------------|-------|

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input checked="" type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |

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Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan

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Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|-------------------------------------|
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input checked="" type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-----|--------------------------|
| Date of test | | |
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

| | | |
|----------------------|--|--|
| Upload Report | | |
| Diagnostic Test Type | | |

| | | |
|--|--------------------|-------------------------------------|
| | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input checked="" type="checkbox"/> |

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Form: Study Evaluation and Diagnosis- Pt III

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TTNA
Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

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Folder: 2 year Follow up

Form: Surgical Lung Specimens- Formalin Fixed

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Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 73

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 75

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up

Form: Surgical Lung Specimens- Fresh Frozen

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Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 74

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 76

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up

Form: CT Imaging

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Did CT commence? No
Yes

Reason imaging did not commence Adverse Event
Claustrophobia
Equipment failure/error
Injection complication
Other (specify additional
information)
Participant refusal
Unknown

Date of Imaging

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Was bronchoscopy performed? No
Yes
Unknown

Primary reason bronchoscopy not performed Patient Refused
Site error
Missing equipment
Unknown
Other, specify

Indicate the timepoint the bronchoscopy was performed Baseline Visit
Surgery
Other, specify

Date of Bronchoscopy Fixed Unit: MMM dd yyyy

Was a sedative given? No
Yes
Unknown

Route of administration Intravenous
Intramuscular
Other, specify

Type used: _____

Was a local anesthetic used? No
Yes
Unknown

Type of local anesthetic _____

Was endobronchial tissue obtained as part of the bronchoscopy? No
Yes
Unknown

Primary reason endobronchial tissue was not obtained Site error
Missing equipment
Unknown
Adverse event
Other, specify

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchoscopy

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Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed
Fresh-frozen

Check if collected

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed
Fresh-frozen

Check if collected

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site right upper lobe (RUL)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchoscopy

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Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? _____ No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site _____ right upper lobe (RUL)
subsegmental carinas _____
right middle lobe (RML)
subsegmental carinas _____
left upper lobe (LUL)
subsegmental carinas _____
Formalin-fixed
Fresh-frozen

Check if collected _____

Fluorescence ratio at biopsy site _____

Check if fluorescence ratio not done _____

Date and Time Into Freezer _____

Freezer Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? _____ No
Yes
Unknown

Freeze/Thaw Comments _____

Other Comments _____

Site _____ right upper lobe (RUL)
subsegmental carinas _____
right middle lobe (RML)
subsegmental carinas _____
left upper lobe (LUL)
subsegmental carinas _____
Formalin-fixed
Fresh-frozen

Check if collected _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchoscopy

Generated On: 09 Apr 2020 15:26:54

| | |
|--------------------------------------|-------------------------------|
| Fluorescence ratio at biopsy site | |
| Check if fluorescence ratio not done | |
| Date and Time Into Freezer | |
| Freezer Temp | Fixed Unit: °C |
| Did any freeze/thaw occur? | No <input type="radio"/> |
| | Yes <input type="radio"/> |
| | Unknown <input type="radio"/> |
| Freeze/Thaw Comments | |
| Other Comments | |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Was blood collection performed? No
Yes
Unknown

Reason blood collection not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Date of Blood Collection Fixed Unit: MMM dd yyyy

Time of blood collection Fixed Unit: HH:mm

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was plasma collection performed? No
Yes
Unknown

Were plasma samples processed and stored within 2 hours of blood collection? No
Yes
Unknown

Did plasma samples undergo centrifugation within 2 hours of blood collection? No
Yes
Unknown

Primary reason plasma collection was not performed Sample not collected
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Was plasma collection performed per protocol? No

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|---------|--------------------------|
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|--------------------------|--------------------------|
| Primary reason plasma collection was not performed per protocol | Collection Tube(s) broke | <input type="checkbox"/> |
| | Missing Materials | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Storage not per protocol | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|---|---------|--------------------------|
| <i>Was buffy coat collection performed?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|--|-------------------------|--------------------------|
| Primary reason buffy coat collection was not performed | Sample not collected | <input type="checkbox"/> |
| | Collection tubes broken | <input type="checkbox"/> |
| | Patient Refusal | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| <i>Was buffy coat collection performed per protocol?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|--------------------------|--------------------------|
| Primary reason buffy coat collection was not performed per protocol | Collection Tube(s) broke | <input type="checkbox"/> |
| | Missing Materials | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |
| | Storage not per protocol | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| <i>Was serum collection performed?</i> | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-------------------------|--------------------------|
| Primary reason serum collection was not performed | Sample not collected | <input type="checkbox"/> |
| | Collection tubes broken | <input type="checkbox"/> |
| | Patient Refusal | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site error | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

Other, specify

Was serum collection performed per protocol? No

Yes

Unknown

Primary reason serum collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PAX gene collection performed? No

Yes

Unknown

Primary reason PAX gene collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

Adverse Event

Site error

Other, specify

Was PAX gene collection performed per protocol? No

Yes

Unknown

Primary reason PAX gene collection was not performed per protocol Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was streck collection performed? No

Yes

Unknown

Primary reason streck collection was not performed Sample not collected

Collection tubes broken

Patient Refusal

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Form: Blood Collection

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Adverse Event

Site error

Other, specify

Was Streck collection performed per protocol?

No

Yes

Unknown

Primary reason Streck collection was not performed per protocol

Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PBMC collection performed?

No

Yes

Unknown

Primary reason PBMC collection was not performed per protocol

Collection Tube(s) broke

Missing Materials

Site error

Storage not per protocol

Other, specify

Was PBMC collection performed per protocol?

No

Yes

Unknown

Tube Type

Purple Top Venous Blood

Collection Tube

Red Top Venous Blood

Collection Tube

PAXgene tube

Yellow Top Venous Blood

Collection Tube

Streck Tube

Check if tube collected

Reason Tube Not Collected

Patient Refused

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|----------------|--------------------------|
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|-------------------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input checked="" type="checkbox"/> |
| | PAXgene tube | <input type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

| | | |
|---------------------------|-----------------|--------------------------|
| Reason Tube Not Collected | Patient Refused | <input type="checkbox"/> |
| | Adverse Event | <input type="checkbox"/> |
| | Site Error | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|-----------|---|--------------------------|
| Tube Type | Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Red Top Venous Blood Collection Tube | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|---|-------------------------------------|
| | PAXgene tube | <input checked="" type="checkbox"/> |
| | Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| | Streck Tube | <input type="checkbox"/> |

Check if tube collected

Reason Tube Not Collected

| | |
|-----------------|--------------------------|
| Patient Refused | <input type="checkbox"/> |
| Adverse Event | <input type="checkbox"/> |
| Site Error | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
| Other, specify | <input type="checkbox"/> |

Tube Type

| | |
|---|-------------------------------------|
| Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| PAXgene tube | <input checked="" type="checkbox"/> |
| Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| Streck Tube | <input type="checkbox"/> |

Check if tube collected

Reason Tube Not Collected

| | |
|-----------------|--------------------------|
| Patient Refused | <input type="checkbox"/> |
| Adverse Event | <input type="checkbox"/> |
| Site Error | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
| Other, specify | <input type="checkbox"/> |

Tube Type

| | |
|---|-------------------------------------|
| Purple Top Venous Blood Collection Tube | <input type="checkbox"/> |
| Red Top Venous Blood Collection Tube | <input type="checkbox"/> |
| PAXgene tube | <input type="checkbox"/> |
| Yellow Top Venous Blood Collection Tube | <input type="checkbox"/> |
| Streck Tube | <input checked="" type="checkbox"/> |

Check if tube collected

Reason Tube Not Collected

| | |
|-----------------|--------------------------|
| Patient Refused | <input type="checkbox"/> |
| Adverse Event | <input type="checkbox"/> |
| Site Error | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection

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Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

Tube Type
Purple Top Venous Blood Collection Tube
Red Top Venous Blood Collection Tube
PAXgene tube
Yellow Top Venous Blood Collection Tube
Streck Tube

Check if tube collected

Reason Tube Not Collected
Patient Refused
Adverse Event
Site Error
Unknown
Other, specify

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Total # of Aliquots prepared from the Blood Collection _____

If yes

If **all** aliquots listed were put into the same freezer on the same day and same time, please provide that date/time and freezer temp in the fields below. Please leave these columns in the table blank

Did all of the listed aliquots go into the same freezer at the same date/time?

No

Yes

Unknown

Temperature of Freezer for All Aliquots _____

Date/Time into Freezer for All Aliquots _____

The below table is prefilled with the expected blood collection samples. All fields are editable and the table should reflect the actual samples processed/collected. The total number of items collected should equal the total number of rows in the table. **If PBMC preparation and/or Buffy Coat Preparation is performed, details of the aliquots should not be recorded on this form, but should be recorded on the PBMC Blood Collection Form and/or Buffy Coat Collection Form**

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

Amount of aliquot in vial/tube _____

Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur?

No

Yes

Unknown

Temperature of freezer _____

Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type

Plasma Collection

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|-----------------------|--------------------------|
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input checked="" type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

- Plasma Collection
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
Yes
Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

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_____ Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

_____ Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

_____ Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

_____ Date and Time into -20° Freezer

_____ Temperature of Freezer

_____ Data and Time into -80° Freezer

Did any freeze-thaw occur? _____ No

Yes

Unknown

_____ Temperature of freezer _____ Fixed Unit: °C

_____ Comments regarding freeze-thaw

_____ Other comments

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input checked="" type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input checked="" type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No

Yes

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

Generated On: 09 Apr 2020 15:26:54

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

Date and Time into -20° Freezer

Temperature of Freezer

Date and Time into -80° Freezer

Did any freeze-thaw occur? No

Yes

Unknown

Temperature of freezer Fixed Unit: °C

Comments regarding freeze-thaw

Other comments

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Amount of aliquot in vial/tube Fixed Unit: mL

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

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Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Date and Time into -80° Freezer _____

Did any freeze-thaw occur? _____

No

Yes

Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type _____

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Required

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PBMC
 Streck

Check if collected

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
 Yes
 Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

Other comments _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected

Amount of aliquot in vial/tube _____ Fixed Unit: mL

Date and Time into -20° Freezer _____

Temperature of Freezer _____

Data and Time into -80° Freezer _____

Did any freeze-thaw occur? No
 Yes
 Unknown

Temperature of freezer _____ Fixed Unit: °C

Comments regarding freeze-thaw _____

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Form: Blood Collection Aliquots- Required

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Other comments

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input checked="" type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

| | |
|--------------------|---|
| Check if collected | |
| Vial/Tube Type | 2mL cryovials <input type="checkbox"/> |
| | 5mL cryovial <input type="checkbox"/> |
| | 15mL cryovial <input type="checkbox"/> |
| | PAXgene Blood RNA tube <input type="checkbox"/> |

| | |
|----------------------------|----------------|
| Date and Time into Freezer | |
| Temperature of Freezer | Fixed Unit: °C |

| | |
|--|----------------------------------|
| Did any freeze-thaw occur to the sample? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |

| | |
|---------------------------------|--|
| Comments regarding freeze- thaw | |
| Other comment | |

| | | |
|-----------------|-----------------------|-------------------------------------|
| Collection Type | Plasma Collection | <input type="checkbox"/> |
| | Buffy Coat Collection | <input checked="" type="checkbox"/> |
| | Serum Collection | <input type="checkbox"/> |
| | PAX Gene | <input type="checkbox"/> |
| | PBMC | <input type="checkbox"/> |
| | Streck | <input type="checkbox"/> |

| | |
|--------------------|---|
| Check if collected | |
| Vial/Tube Type | 2mL cryovials <input type="checkbox"/> |
| | 5mL cryovial <input type="checkbox"/> |
| | 15mL cryovial <input type="checkbox"/> |
| | PAXgene Blood RNA tube <input type="checkbox"/> |

| | |
|----------------------------|----------------|
| Date and Time into Freezer | |
| Temperature of Freezer | Fixed Unit: °C |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

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Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type 2mL cryovials

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Form: Blood Collection Aliquots- Buffy Coat

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5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____
Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____
Vial/Tube Type 2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze- thaw _____
Other comment _____

Collection Type Plasma Collection
Buffy Coat Collection

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

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Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type _____
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____
No
Yes
Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type _____
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____

Vial/Tube Type _____
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____ No

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 09 Apr 2020 15:26:54

Yes

Unknown

Comments regarding freeze- thaw _____

Other comment _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Date and Time of Start of PBMC Processing Fixed Unit: MMM dd yyyy HH:MM

PBMC count Fixed Unit: 10⁶ cells/mL

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

Vial/Tube Type
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Number of Cells

LTGO volume

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comment

Collection Type
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected

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Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial
 PAXgene Blood RNA tube

Number of Cells _____

LTGO volume _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
 Yes
 Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial
 PAXgene Blood RNA tube

Number of Cells _____

LTGO volume _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
 Yes
 Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial
 PAXgene Blood RNA tube

Number of Cells _____

LTGO volume _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
 Yes
 Unknown

Comments regarding freeze- thaw _____

Other comment _____

Collection Type Plasma Collection
 Buffy Coat Collection
 Serum Collection
 PAX Gene
 PBMC
 Streck

Check if collected _____

Vial/Tube Type 2mL cryovials
 5mL cryovial
 15mL cryovial

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|------------------------|--------------------------|
| | PAXgene Blood RNA tube | <input type="checkbox"/> |
| Number of Cells | | |
| LTGO volume | | |
| Date and Time into Freezer | | |
| Temperature of Freezer | Fixed Unit: °C | |
| Did any freeze-thaw occur to the sample? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| Comments regarding freeze- thaw | | |
| Other comment | | |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

Was bronchial airway brushing performed? No
Yes
Unknown

Primary reason not performed Patient Refused
Missing Materials
Adverse Event
Unknown
Other, specify

Indicate the timepoint the bronchial airway brushing was performed Baseline Visit
Surgery
Other, specify

Was bronchial airway brushing performed per protocol? No
Yes
Unknown

Primary reason not performed per protocol Missing Materials
Site error
Adverse Event
Bronchoscopy not performed
Unknown
Other, specify

Date of bronchial airway Brushing Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Tube A
Tube B
Tube C
Tube D

Eppendorf tube containing 1mL of RNA protect Cell Reagent
1mL of 1X PBS solution for proteomic analysis

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

1mL of 1X PBS solution for DNA extraction
1mL of RNA protect Cell Reagent

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____

Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____

No

Yes

Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type _____

Tube A

Tube B

Tube C

Tube D

Eppendorf tube containing _____

1mL of RNA protect Cell Reagent

1mL of 1X PBS solution for proteomic analysis

1mL of 1X PBS solution for DNA extraction

1mL of RNA protect Cell Reagent

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____

Fixed Unit: °C

Did any freeze-thaw occur to the sample? _____

No

Yes

Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type _____

Tube A

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Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

Tube B
Tube C
Tube D

Eppendorf tube containing _____ 1mL of RNA protect Cell
Reagent
1mL of 1X PBS solution for
proteomic analysis
1mL of 1X PBS solution for
DNA extraction
1mL of RNA protect Cell
Reagent

Check if collected _____
Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____
Other comments _____

Type _____ Tube A
Tube B
Tube C
Tube D

Eppendorf tube containing _____ 1mL of RNA protect Cell
Reagent
1mL of 1X PBS solution for
proteomic analysis
1mL of 1X PBS solution for
DNA extraction
1mL of RNA protect Cell
Reagent

Check if collected _____
Date and Time into Freezer _____
Temperature of Freezer _____ Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample?

No
Yes
Unknown

Comments regarding freeze-thaw

Other comments

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Was urine sample collected? No
Yes
Unknown

Reason urine sample was not collected Patient Refused
Adverse Event
Unknown
Other, specify

Date of Urine Sample Collection Fixed Unit: MMM dd yyyy

Was urine collection performed per protocol? No
Yes
Unknown

Primary reason urine collection was not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Unknown
Other, specify

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Sterile Urine Collection Container
Cryovial

Check if collected

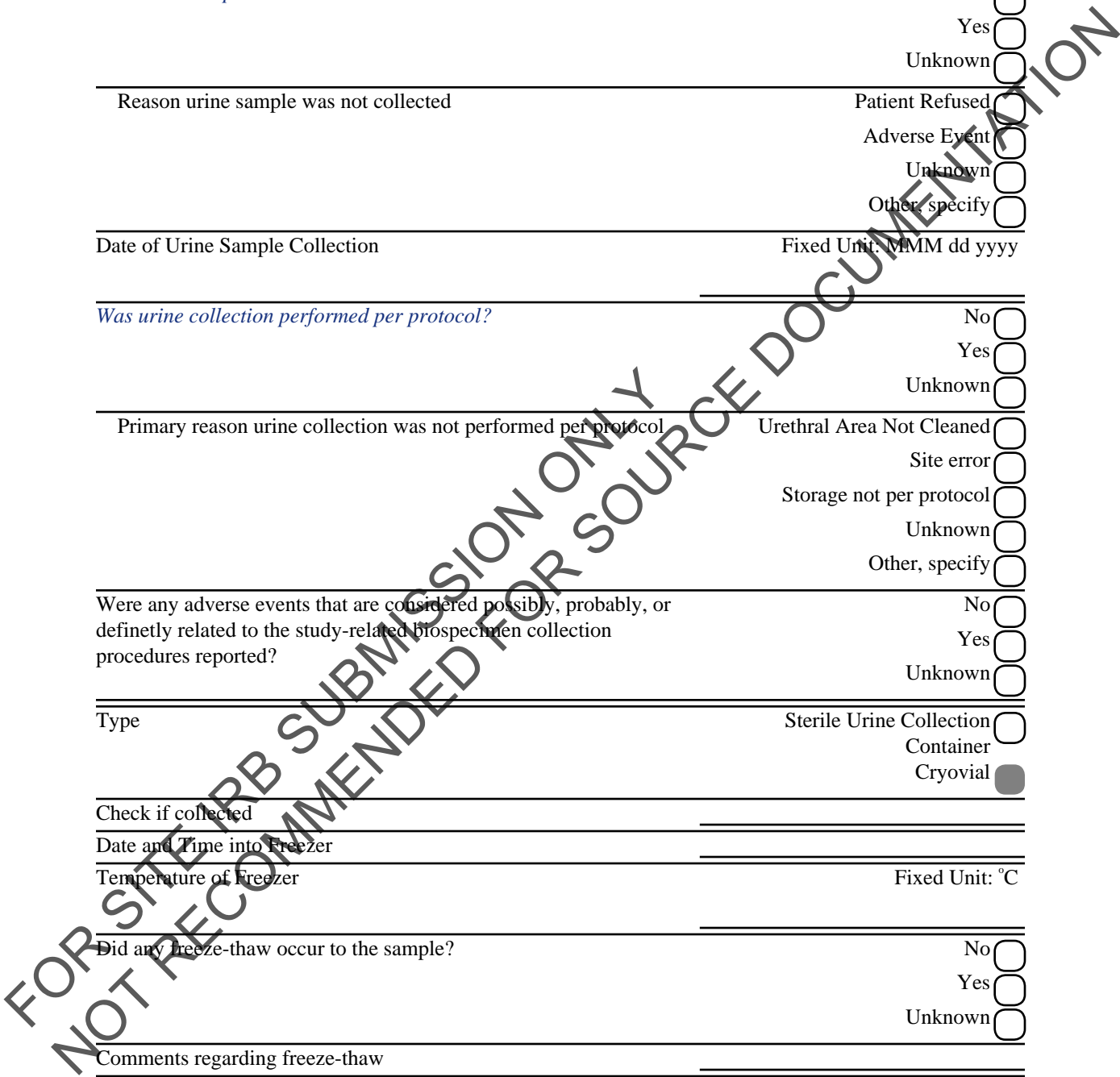
Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw

Other comments



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Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Sterile Urine Collection
Container
Cryovial

Check if collected

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 09 Apr 2020 15:26:54

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type _____ Sterile Urine Collection
Container
Cryovial

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Was nasal brushing performed? No
Yes
Unknown

Was nasal brushing additional optional collected. **(Optional nasal collection is only for the three participating sites, Water Reed, Boston University, and UCLA.** No
Yes

Primary reason nasal brushing not performed Patient Refused
Adverse Event
Missing Materials
Site Error
Unknown
Other, specify

Was nasal brushing performed per protocol? No
Yes
Unknown

Primary reason nasal brushing not done per protocol Storage Not Per Protocol
Missing Materials
Site Error
Unknown
Other, specify

Date of Nasal Brushing Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent
Single cell analysis (Optional)
Nasal Single Cell Plate (Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

Type Tube with RNAprotect Cell Reagent

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Folder: 2 year Follow up- Biospecimen Collection

Form: Nasal Brushing

Generated On: 09 Apr 2020 15:26:54

Single cell analysis (Optional)

Nasal Single Cell Plate
(Optional)

Check if collected _____

Date and Time into Freezer _____

Temperature of Freezer _____ Fixed Unit: C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze-thaw _____

Other comments _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Buccal Scraping

Generated On: 09 Apr 2020 15:26:54

Was buccal scraping performed? No
Yes
Unknown

Primary reason buccal scraping not performed Patient Refused
Adverse Event
Unknown
Other, specify

Was buccal scraping performed per protocol? No
Yes
Unknown

Primary reason buccal scraping was not performed per protocol Missing Materials
Site error
Unknown
Other, specify

Date of Buccal Scraping Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Type Microtube
Microtube with Scraper

Check if Collected

Date and Time into Freezer

Temperature of Freezer Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw

Other comments

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Folder: 2 year Follow up- Biospecimen Collection

Form: Sputum Samples

Generated On: 09 Apr 2020 15:26:54

Was sputum sample collected by the patient and mailed to the core pathology lab? No

Yes

Unknown

Primary reason not collected and/or mailed Lost kit

Sputum kit not distributed to pt

Patient refused

Other Pt related error

Other, specify

Date Sputum Sample Mailed _____

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No

Yes

Unknown

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Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Was the urine processing for metabolomics study performed? No
Yes
Unknown

If processing not done, provided primary reason Participant Refused
Site error
Missing or incomplete kit contents
Missing or incomplete material(s) or equipment
Optional biospecimen
Other, specify

Was the urine processing for metabolomics study performed per protocol? No
Yes
Unknown

Primary Reason not performed per protocol Urethral Area Not Cleaned
Site error
Storage not per protocol
Prepared Urine specimen cups not used
Unknown
Other, specify

Date Urine Processed at Site Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Total number of urine checks

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected

Date and Time Into Freezer

Freezer Temperature Fixed Unit: °C

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Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

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Folder: 2 year Follow up- Biospecimen Collection

Form: Urine Processing for Metabolomics Study

Generated On: 09 Apr 2020 15:26:54

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

Type Sterile Conical Tube
Eppendorf Tube

Check if Collected _____

Date and Time Into Freezer _____

Freezer Temperature _____ Fixed Unit: °C

Did any freeze-thaw occur to the sample? No
Yes
Unknown

Comments regarding freeze thaw _____

Other comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal (8 pages total) _____

Did all of the listed specimens go into the same freezer at the same date/time? No
Yes

Unknown

Did any freeze thaw occur? No

Yes

Were all specimens stored at the same temp? No

Yes

Provide storage temp for all specimens _____

If the Biospecimens collected have different storage temps record this in the provided comment box.

Biospecimen Type

Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Barcode Sequence # 7

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 8

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 9

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|----------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="radio"/> |
| Blood Collection- Serum | <input type="radio"/> |
| Blood Collection-PAXgene | <input type="radio"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|--------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 10

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input checked="" type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 11

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

Bronchial Airway Brushings-
Brush C

Bronchial Biopsy Collection-
RUL Fresh Frozen

Bronchial Biopsy Collection-
RML Fresh Frozen

Bronchial Biopsy Collection-
LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-
RUL Formalin Fixed

Bronchial Biopsy Collection-
RML Formalin Fixed

Bronchial Biopsy Collection-
LUL Formalin Fixed

Streck Collection

Barcode Sequence # 12

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-
Brush A

Bronchial Airway Brushings-
Brush B

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|--------------------------|
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 19

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input checked="" type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--------------------|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |
| Barcode Sequence # | | 20 |

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input checked="" type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # _____ 21

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-Brush A
- Bronchial Airway Brushings-Brush B
- Bronchial Airway Brushings-Brush C
- Bronchial Biopsy Collection-RUL Fresh Frozen
- Bronchial Biopsy Collection-RML Fresh Frozen
- Bronchial Biopsy Collection-LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-RUL Formalin Fixed
- Bronchial Biopsy Collection-RML Formalin Fixed
- Bronchial Biopsy Collection-LUL Formalin Fixed
- Streck Collection

Barcode Sequence #

25

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-Brush A
- Bronchial Airway Brushings-Brush B
- Bronchial Airway Brushings-Brush C

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 26

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

- Blood Collection- Blood Plasma
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings-
Brush A
- Bronchial Airway Brushings-
Brush B
- Bronchial Airway Brushings-
Brush C
- Bronchial Biopsy Collection-
RUL Fresh Frozen
- Bronchial Biopsy Collection-
RML Fresh Frozen
- Bronchial Biopsy Collection-
LUL Fresh Frozen
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Bronchial Biopsy Collection-
RUL Formalin Fixed

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Folder: 2 year Follow up- Biospecimen Collection

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 28

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 29

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

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Form: Biospecimen Transmittal-Required v2

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| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 30

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|--------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |

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| | | |
|--|--|-------------------------------------|
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input checked="" type="checkbox"/> |

Barcode Sequence # 31

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |

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| | | |
|--|--|--------------------------|
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 60

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 61

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--------------------------------|--------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|--------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 62

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input checked="" type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|---------------------------------------|--|-------------------------------------|
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |
| Barcode Sequence # | | 68 |
| Check if specimen NOT included | | <input type="checkbox"/> |
| Check if freeze/thaw occurred | | <input type="checkbox"/> |
| Comments | | <input type="checkbox"/> |
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |

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Streck Collection

Barcode Sequence # 70

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

Bronchial Airway Brushings-

Brush A

Bronchial Airway Brushings-

Brush B

Bronchial Airway Brushings-

Brush C

Bronchial Biopsy Collection-

RUL Fresh Frozen

Bronchial Biopsy Collection-

RML Fresh Frozen

Bronchial Biopsy Collection-

LUL Fresh Frozen

Buccal Epithelium Collection

Nasal Epithelium Collection

Urine Collection

Bronchial Biopsy Collection-

RUL Formalin Fixed

Bronchial Biopsy Collection-

RML Formalin Fixed

Bronchial Biopsy Collection-

LUL Formalin Fixed

Streck Collection

Barcode Sequence # 72

Check if specimen **NOT** included _____

Check if freeze/thaw occurred _____

Comments _____

Biospecimen Type Blood Collection- Blood Plasma

Blood Collection- Serum

Blood Collection-PAXgene

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 51

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 54

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|-------------------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |
| Nasal Epithelium Collection | <input checked="" type="checkbox"/> |
| Urine Collection | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| Streck Collection | <input type="checkbox"/> |

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Barcode Sequence # 55

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 34

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|--|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 35

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

Biospecimen Type

| | |
|--|--------------------------|
| Blood Collection- Blood Plasma | <input type="checkbox"/> |
| Blood Collection- Serum | <input type="checkbox"/> |
| Blood Collection-PAXgene | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| Buccal Epithelium Collection | <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|-------------------------------------|
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 36

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

| | | |
|------------------|--|-------------------------------------|
| Biospecimen Type | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 37

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

Generated On: 09 Apr 2020 15:26:54

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B
 - Bronchial Airway Brushings-Brush C
 - Bronchial Biopsy Collection-RUL Fresh Frozen
 - Bronchial Biopsy Collection-RML Fresh Frozen
 - Bronchial Biopsy Collection-LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection-RUL Formalin Fixed
 - Bronchial Biopsy Collection-RML Formalin Fixed
 - Bronchial Biopsy Collection-LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # 38

Check if specimen **NOT** included

Check if freeze/thaw occurred

Comments

- Biospecimen Type
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings-Brush A
 - Bronchial Airway Brushings-Brush B

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal-Required v2

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| | | |
|---------------------------------------|--|-------------------------------------|
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |
| Barcode Sequence # | | 39 |
| Check if specimen NOT included | | <input type="checkbox"/> |
| Check if freeze/thaw occurred | | <input type="checkbox"/> |
| Comments | | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimens Mailed _____

Copy of Biospecimen Transmittal- Bronchial Biopsy Formalin Fixed _____

- Biospecimen Sample
- Blood Collection- Blood Plasma
 - Blood Collection- Serum
 - Blood Collection-PAXgene
 - Bronchial Airway Brushings- Brush A
 - Bronchial Airway Brushings- Brush B
 - Bronchial Airway Brushings- Brush C
 - Bronchial Biopsy Collection- RUL Fresh Frozen
 - Bronchial Biopsy Collection- RML Fresh Frozen
 - Bronchial Biopsy Collection- LUL Fresh Frozen
 - Buccal Epithelium Collection
 - Nasal Epithelium Collection
 - Urine Collection
 - Bronchial Biopsy Collection- RUL Formalin Fixed
 - Bronchial Biopsy Collection- RML Formalin Fixed
 - Bronchial Biopsy Collection- LUL Formalin Fixed
 - Streck Collection

Barcode Sequence # _____ 67

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

| | | |
|--------------------|--|-------------------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input checked="" type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 69

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|--------------------|--------------------------------|--------------------------|
| Biospecimen Sample | Blood Collection- Blood Plasma | <input type="checkbox"/> |
| | Blood Collection- Serum | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|--|-------------------------------------|
| | Blood Collection-PAXgene | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush A | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush B | <input type="checkbox"/> |
| | Bronchial Airway Brushings- Brush C | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Fresh Frozen | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Fresh Frozen | <input type="checkbox"/> |
| | Buccal Epithelium Collection | <input type="checkbox"/> |
| | Nasal Epithelium Collection | <input type="checkbox"/> |
| | Urine Collection | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RUL Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- RML Formalin Fixed | <input type="checkbox"/> |
| | Bronchial Biopsy Collection- LUL Formalin Fixed | <input checked="" type="checkbox"/> |
| | Streck Collection | <input type="checkbox"/> |

Barcode Sequence # 71

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Were optional biospecimens sent to the core lab? No
Yes
Unknown

If no optional biospecimens were sent to the core lab, leave the table blank.

If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 13

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 14

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 15

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 16

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 17

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for
Metabolomics Study

Barcode Sequence # 18

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 27

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |

Barcode Sequence # 28

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input checked="" type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|---|--------------------------|
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

Barcode Sequence # 29

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur?

No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

Barcode Sequence # 30

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur?

No
Yes
Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

| | | |
|------------------|---|-------------------------------------|
| Biospecimen Type | Blood Collection- Buffy Coat | <input type="checkbox"/> |
| | Blood Collection- PBMC | <input checked="" type="checkbox"/> |
| | Bronchial Airway Brushings Collection- Tube D | <input type="checkbox"/> |
| | Urine Processing for Metabolomics Study | <input type="checkbox"/> |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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Barcode Sequence # 31

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 63

Check if Specimen Included

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No

Yes

Unknown

If yes to freeze/thaw- Total # of Times

If yes to freeze/thaw- length of each time

Comments

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # 40

Check if Specimen Included

Storage Temp Fixed Unit: °C

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 41

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 42

Check if Specimen Included _____

Storage Temp Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 09 Apr 2020 15:26:54

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for Metabolomics Study

Barcode Sequence # 43

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Blood Collection- Buffy Coat
 Blood Collection- PBMC
 Bronchial Airway Brushings
 Collection- Tube D
 Urine Processing for Metabolomics Study

Barcode Sequence # 44

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Optional

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| | |
|--|---|
| Biospecimen Type | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input type="checkbox"/> |
| | Bronchial Airway Brushings <input type="checkbox"/> |
| | Collection- Tube D <input type="checkbox"/> |
| | Urine Processing for <input type="checkbox"/> |
| | Metabolomics Study <input type="checkbox"/> |
| Barcode Sequence # | 45 |
| Check if Specimen Included | <input type="checkbox"/> |
| Storage Temp | Fixed Unit: °C |
| Did any freeze/thaw occur? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| If yes to freeze/thaw- Total # of Times | |
| If yes to freeze/thaw- length of each time | |
| Comments | |

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Folder: 2 year Follow up- Biospecimen Collection

Form: Biospecimen Transmittal- Additional

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Were additional biospecimens sent to the core lab? No
Yes
Unknown

If no additional biospecimens were sent to the core lab, leave the table blank.

If additional specimens were sent, at least one row of the table must be completed.

| | |
|------------------|--|
| Biospecimen Type | Blood Collection- Blood Plasma <input type="checkbox"/> |
| | Blood Collection- Buffy Coat <input type="checkbox"/> |
| | Blood Collection- PBMC <input type="checkbox"/> |
| | Blood Collection- Serum <input type="checkbox"/> |
| | Blood Collection-PAXgene <input type="checkbox"/> |
| | Bronchial Airway Brushings Collection <input type="checkbox"/> |
| | Bronchial Biopsy Collection <input type="checkbox"/> |
| | Buccal Epithelium Collection <input type="checkbox"/> |
| | Nasal Epithelium Collection <input type="checkbox"/> |
| | Urine Collection <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |

Barcode Sequence # _____
Date Sent to Core Lab _____
Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____
If yes to freeze/thaw- length of each time _____
Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 3 year Follow up

Form: Follow up

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Was the follow up completed? No
Yes
Unknown

If the follow up was not completed, please provide the primary reason is was not done Patient Refused
Patient Lost to Follow up
Site error
Other, specify

Date of Follow up Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was pulmonary function test/spirometry performed? No
Yes

Reason pulmonary function test/spirometry not performed Patient Refused
Site error
Equipment Unavailable
Unknown
Other, specify

Was physical exam performed? No
Yes
Unknown

Reason physical exam not performed Patient Refused
Site error
Unknown
Other, specify

Did the patient have any imaging performed as part of follow up? No
Yes
Unknown

Image Type CT
Dynamic contrast-enhanced CT
PET

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Folder: 3 year Follow up

Form: Follow up

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|-------|--------------------------|
| | MRI | <input type="checkbox"/> |
| | X-ray | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |

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

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

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of Surgery _____

Were surgical tissue samples collected?

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Primary reason surgical tissue samples were not collected

| | | |
|--|-------------------------------|--------------------------|
| | Site Error | <input type="checkbox"/> |
| | Patient Refused | <input type="checkbox"/> |
| | Pathology Lab Refused Request | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Instructions:

The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician annually until lung cancer diagnosis or year 4 follow up. Any malignancy identified during the four-year follow-up time period will need to be reported on the Study Evaluation and Diagnosis Form. A response of "Primary Lung" or "Metastatic to the Lung" to Question #4a completes the participant's involvement in the follow up procedures.

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 _____

4. - Is there malignancy in the lung? No
Yes
Uncertain

4a. - If yes, the malignancy is Primary Lung
Metastatic to the Lung
Uncertain
Other, specify

4a1. - If metastatic, provide the site of primary organ Bladder
Bone
Brain
Breast
Cervical
Colon-Rectal
Esophageal
Gastric
Kidney
Larynx
Lymphoma

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- Melanoma
- Nasal
- Oral
- Pancreatic
- Pharynx
- Prostate
- Renal Cell
- Thyroid
- Transition Cell
- Uncertain
- Other Cancer, Specify

Part II. Lung Malignancy *complete this section only if Q4a=primary lung*

5. - Date of first diagnosis _____

6. - Has the lung cancer been reported on a previous Study Evaluation and Diagnosis form? No
Yes
Unknown

6a. - Has the patient developed progressive disease following treatment for lung cancer? No
Yes
Unknown

6a1. - If yes, date of first documentation of progressive lung cancer _____

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

- Original lung site
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt I, II

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Unknown
Other, specify

7. - Lung Cancer Type
Small Cell Lung Cancer
Non-Small Cell Lung Cancer
Unknown

8. - Histologic Class
Adenocarcinoma
Adenosquamous Carcinoma
Epidermoid Carcinoma
Bronchioloalveolar Carcinoma
Carcinoid
Large Cell Carcinoma
Small Cell Carcinoma
Squamous Cell Carcinoma
Other, specify
Unknown

9. - Histologic Subtype
Acinar
Bronchioalveola
Papillary
Solid carcinoma with mucus formation
Mixed
Pure small cell carcinoma
Combined small cell carcinoma
Large cell neuroendocrine
Basaloid
Lymphoepithelial-like
Large cell with rhabdoid phenotype
Unknown

10. - Cancer Stage
Occult
0
IA
IB

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IIA
IIB
IIIA
IIIB
IV

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Form: Study Evaluation and Diagnosis- Pt III

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Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed *required if Q1=yes*

Note: All diagnostic tests will need a de-identified copy of the report uploaded into Rave

NOW DERIVATION

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input checked="" type="radio"/> |
| | Bone Scan <input type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |
| | PET <input type="radio"/> |
| | Sputum <input type="radio"/> |
| | Surgical Pathology <input type="radio"/> |
| | TBNA <input type="radio"/> |
| | Thoracoscopy <input type="radio"/> |
| | Thoracotomy <input type="radio"/> |
| | TTNA <input type="radio"/> |
| | Other, specify <input type="radio"/> |

| | |
|--|-------------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No <input type="radio"/> |
| | Yes <input type="radio"/> |
| | Unknown <input type="radio"/> |

| | |
|---|---------------------------|
| Date of test | _____ |
| Was test used to establish diagnosis described above? | No <input type="radio"/> |
| | Yes <input type="radio"/> |

Upload Report _____

| | |
|----------------------|--|
| Diagnostic Test Type | Biopsy <input type="radio"/> |
| | Bone Scan <input checked="" type="radio"/> |
| | Bronchoscopy <input type="radio"/> |
| | Chest X Ray <input type="radio"/> |
| | CT Scan <input type="radio"/> |
| | Mediastinoscopy <input type="radio"/> |
| | MRI <input type="radio"/> |

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test

Was test used to establish diagnosis described above? No
Yes

Upload Report

- Diagnostic Test Type
- Biopsy
 - Bone Scan
 - Bronchoscopy
 - Chest X Ray
 - CT Scan
 - Mediastinoscopy
 - MRI
 - PET
 - Sputum
 - Surgical Pathology
 - TBNA
 - Thoracoscopy
 - Thoracotomy
 - TTNA
 - Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No

Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

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Form: Study Evaluation and Diagnosis- Pt III

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- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
 Yes
 Unknown

Date of test _____

Was test used to establish diagnosis described above? No
 Yes

Upload Report _____

- Diagnostic Test Type
- Biopsy
 - Bone Scan
 - Bronchoscopy
 - Chest X Ray
 - CT Scan
 - Mediastinoscopy
 - MRI
 - PET
 - Sputum
 - Surgical Pathology
 - TBNA
 - Thoracoscopy
 - Thoracotomy
 - TTNA
 - Other, specify

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Form: Study Evaluation and Diagnosis- Pt III

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Was test performed since last Study Evaluation and Diagnosis form was completed? No

Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No

Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No

Yes

Upload Report _____

Diagnostic Test Type Biopsy

Bone Scan

Bronchoscopy

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|-------------------------------------|
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input checked="" type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-------|--------------------------|
| Date of test | _____ | |
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

| | |
|---------------|-------|
| Upload Report | _____ |
|---------------|-------|

| | | |
|----------------------|--------------------|-------------------------------------|
| Diagnostic Test Type | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input checked="" type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |

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Form: Study Evaluation and Diagnosis- Pt III

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Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

Biopsy

Bone Scan

Bronchoscopy

Chest X Ray

CT Scan

Mediastinoscopy

MRI

PET

Sputum

Surgical Pathology

TBNA

Thoracoscopy

Thoracotomy

TTNA

Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes

Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

Biopsy

Bone Scan

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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| | | |
|--|--------------------|-------------------------------------|
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input checked="" type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input type="checkbox"/> |
| | TTNA | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

| | | |
|--|---------|--------------------------|
| Was test performed since last Study Evaluation and Diagnosis form was completed? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

| | | |
|---|-----|--------------------------|
| Date of test | | |
| Was test used to establish diagnosis described above? | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |

| | | |
|----------------------|--|--|
| Upload Report | | |
| Diagnostic Test Type | | |

| | | |
|--|--------------------|-------------------------------------|
| | Biopsy | <input type="checkbox"/> |
| | Bone Scan | <input type="checkbox"/> |
| | Bronchoscopy | <input type="checkbox"/> |
| | Chest X Ray | <input type="checkbox"/> |
| | CT Scan | <input type="checkbox"/> |
| | Mediastinoscopy | <input type="checkbox"/> |
| | MRI | <input type="checkbox"/> |
| | PET | <input type="checkbox"/> |
| | Sputum | <input type="checkbox"/> |
| | Surgical Pathology | <input type="checkbox"/> |
| | TBNA | <input type="checkbox"/> |
| | Thoracoscopy | <input type="checkbox"/> |
| | Thoracotomy | <input checked="" type="checkbox"/> |

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Folder: 3 year Follow up

Form: Study Evaluation and Diagnosis- Pt III

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TTNA
Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

Diagnostic Test Type

- Biopsy
- Bone Scan
- Bronchoscopy
- Chest X Ray
- CT Scan
- Mediastinoscopy
- MRI
- PET
- Sputum
- Surgical Pathology
- TBNA
- Thoracoscopy
- Thoracotomy
- TTNA
- Other, specify

Was test performed since last Study Evaluation and Diagnosis form was completed? No
Yes
Unknown

Date of test _____

Was test used to establish diagnosis described above? No
Yes

Upload Report _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 3 year Follow up

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 73

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 75

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 3 year Follow up

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 74

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 76

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Follow up

Generated On: 09 Apr 2020 15:26:54

Was the follow up completed? No
Yes
Unknown

If the follow up was not completed, please provide the primary reason is was not done Patient Refused
Patient Lost to Follow up
Site error
Other, specify

Date of Follow up Fixed Unit: MMM dd yyyy

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported? No
Yes
Unknown

Was pulmonary function test/spirometry performed? No
Yes

Reason pulmonary function test/spirometry not performed Patient Refused
Site error
Equipment Unavailable
Unknown
Other, specify

Was physical exam performed? No
Yes
Unknown

Reason physical exam not performed Patient Refused
Site error
Unknown
Other, specify

Did the patient have any imaging performed as part of follow up? No
Yes
Unknown

Image Type CT
Dynamic contrast-enhanced CT
PET

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Follow up

Generated On: 09 Apr 2020 15:26:54

| | | |
|--|-------|--------------------------|
| | MRI | <input type="checkbox"/> |
| | X-ray | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |

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

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

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Date of Surgery _____

Were surgical tissue samples collected?

| | | |
|--|---------|--------------------------|
| | No | <input type="checkbox"/> |
| | Yes | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |

Primary reason surgical tissue samples were not collected

| | | |
|--|-------------------------------|--------------------------|
| | Site Error | <input type="checkbox"/> |
| | Patient Refused | <input type="checkbox"/> |
| | Pathology Lab Refused Request | <input type="checkbox"/> |
| | Unknown | <input type="checkbox"/> |
| | Other, specify | <input type="checkbox"/> |

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Instructions:

The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician annually until

lung cancer diagnosis or year 4 follow up. Any malignancy identified during the four-year follow-up time period will need to be

reported on the Study Evaluation and Diagnosis Form. A response of "Primary Lung" or "Metastatic to the Lung" to Question #4a

completes the participant's involvement in the follow up procedures.

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 _____

4. - Is there malignancy in the lung? No

Yes

Uncertain

4a. - If yes, the malignancy is Primary Lung

Metastatic to the Lung

Uncertain

Other, specify

4a1. - If metastatic, provide the site of primary organ Bladder

Bone

Brain

Breast

Cervical

Colon-Rectal

Esophageal

Gastric

Kidney

Larynx

Lymphoma

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- Melanoma
- Nasal
- Oral
- Pancreatic
- Pharynx
- Prostate
- Renal Cell
- Thyroid
- Transition Cell
- Uncertain
- Other Cancer, Specify

Part II. Lung Malignancy *complete this section only if Q4a=primary lung*

5. - Date of first diagnosis _____

6. - Has the lung cancer been reported on a previous Study Evaluation and Diagnosis form? No
Yes
Unknown

6a. - Has the patient developed progressive disease following treatment for lung cancer? No
Yes
Unknown

6a1. - If yes, date of first documentation of progressive lung cancer _____

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

- Original lung site
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Study Evaluation and Diagnosis- Pt I, II

Generated On: 09 Apr 2020 15:26:54

Unknown
Other, specify

7. - Lung Cancer Type
Small Cell Lung Cancer
Non-Small Cell Lung Cancer
Unknown

8. - Histologic Class
Adenocarcinoma
Adenosquamous Carcinoma
Epidermoid Carcinoma
Bronchioloalveolar Carcinoma
Carcinoid
Large Cell Carcinoma
Small Cell Carcinoma
Squamous Cell Carcinoma
Other, specify
Unknown

9. - Histologic Subtype
Acinar
Bronchioalveola
Papillary
Solid carcinoma with mucus formation
Mixed
Pure small cell carcinoma
Combined small cell carcinoma
Large cell neuroendocrine
Basaloid
Lymphoepithelial-like
Large cell with rhabdoid phenotype
Unknown

10. - Cancer Stage
Occult
0
IA
IB

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Study Evaluation and Diagnosis- Pt I, II

Generated On: 09 Apr 2020 15:26:54

IIA
IIB
IIIA
IIIB
IV

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 73

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Formalin Fixed Tumor Tissue
 Formalin Fixed Normal Tissue

Barcode Sequence # _____ 75

Check if Specimen Included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 09 Apr 2020 15:26:54

Kit Barcode _____

Date Specimen Mailed _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 74

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type Fresh Frozen Tumor Tissue
 Fresh Frozen Normal Tissue

Barcode Sequence # _____ 76

Check if specimen included _____

Storage Temp _____ Fixed Unit: °C

Did any freeze/thaw occur? No
 Yes
 Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: 4 year Follow up

Form: CT Imaging

Generated On: 09 Apr 2020 15:26:54

Did CT commence? No
Yes

Reason imaging did not commence Adverse Event
Claustrophobia
Equipment failure/error
Injection complication
Other (specify additional
information)
Participant refusal
Unknown

Date of Imaging

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: 4 year Follow up

Form: Vital Status and Treatment Response

Generated On: 09 Apr 2020 15:26:54

Instruction: The Vital Status and Treatment/Response Worksheet should be completed by the Treating Physician at year 4 for all Group B participants who had a lung cancer diagnosis and/or were taken off study.

1. - Was the Vital Status and Treatment/Response form completed by the treating physician? No
Yes

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 vital status and treatment/response form completed _____

3. - Participant Vital Status

Alive
Dead
Unknown

3a. - Date of Death _____

3b. - Cause of death

Lung Cancer
Other, specify

Part II. Participants Taken Off Study Complete this section only for participants taken off study

4. - Did the participant have a diagnosis of malignancy in the lung since they were taken off study? No
Yes
Uncertain

4a. - If yes, the malignancy is/was:

Primary Lung
Metastatic to the Lung
Uncertain
Other, specify

4a1. - If metastatic, provide the primary site of origin

Bladder
Bone
Brain
Breast
Cervical
Colon-Rectal
Esophageal
Gastric

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

- Kidney
- Larynx
- Lymphoma
- Melanoma
- Nasal
- Oral
- Pancreatic
- Pharynx
- Prostate
- Renal Cell
- Thyroid
- Transition Cell
- Uncertain
- Other Cancer, Specify

Part III. Participants with Lung Cancer Diagnosis Complete this section for all patients with lung cancer diagnosis

5. - Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form? No
Yes
Unknown

5a. - Date of first diagnosis of lung cancer _____

- 5b. - Lung Cancer Type Small Cell Lung Cancer
Non-Small Cell Lung Cancer
Unknown

- 5c. - Histologic Class Adenocarcinoma
Adenosquamous Carcinoma
Epidermoid Carcinoma
Bronchioloalveolar Carcinoma
Carcinoid
Large Cell Carcinoma
Small Cell Carcinoma
Squamous Cell Carcinoma
Other, specify
Unknown

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

5d. - Histologic Subtype

| | |
|--------------------------------------|--------------------------|
| Acinar | <input type="checkbox"/> |
| Bronchioalveola | <input type="checkbox"/> |
| Papillary | <input type="checkbox"/> |
| Solid carcinoma with mucus formation | <input type="checkbox"/> |
| Mixed | <input type="checkbox"/> |
| Pure small cell carcinoma | <input type="checkbox"/> |
| Combined small cell carcinoma | <input type="checkbox"/> |
| Large cell neuroendocrine | <input type="checkbox"/> |
| Basaloid | <input type="checkbox"/> |
| Lymphoepithelial-like | <input type="checkbox"/> |
| Large cell with rhabdoid phenotype | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

5e. - Cancer Stage

| | |
|--------|--------------------------|
| Occult | <input type="checkbox"/> |
| 0 | <input type="checkbox"/> |
| IA | <input type="checkbox"/> |
| IB | <input type="checkbox"/> |
| IIA | <input type="checkbox"/> |
| IIB | <input type="checkbox"/> |
| IIIA | <input type="checkbox"/> |
| IIIB | <input type="checkbox"/> |
| IV | <input type="checkbox"/> |

6. - Did the patient developed progressive disease (e.g., progression at primary site, metastases, other recurrence) following treatment for lung cancer?

| | |
|---------|--------------------------|
| No | <input type="checkbox"/> |
| Yes | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

6a. - If yes, date of first documentation of progressive lung cancer _____

6b. List the site(s) of progression of lung cancer

| | |
|--------------------|--------------------------|
| Original lung site | <input type="checkbox"/> |
| Other lung site(s) | <input type="checkbox"/> |
| Pleura | <input type="checkbox"/> |
| Brain | <input type="checkbox"/> |
| Bone | <input type="checkbox"/> |
| Liver | <input type="checkbox"/> |
| Adrenal | <input type="checkbox"/> |

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Folder: 4 year Follow up

Form: Vital Status and Treatment Response

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- Skin/subcutaneous tissue
- N1 regional lymph nodes
(ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph
nodes
- N3 distant lymph nodes
(contralateral mediastinal or
hilar/supraclavicular/scalene)
- Unknown
- Other, specify

7. - Response Status

- Complete Response
- Partial Response
- Stable Disease
- Progressive Disease
- Unknown

8. - Date the response status was determined _____

Part IV. Treatment

9. - *Did the participant undergo any treatment for the primary lung cancer?*

- No
- Yes
- Unknown

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Folder: 4 year Follow up

Form: Vital Status and Treatment Response- Treatment

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| | |
|--|--|
| Treatment | Chemotherapy <input type="checkbox"/> |
| | Radiation <input type="checkbox"/> |
| | Surgery <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |
| Treatment Name/Description | |
| Dose | |
| Dose Units | mg <input type="checkbox"/> |
| | mg/kg <input type="checkbox"/> |
| | mg/m ² <input type="checkbox"/> |
| | mcg <input type="checkbox"/> |
| | Gy <input type="checkbox"/> |
| | Other, specify <input type="checkbox"/> |
| Check if dose is not applicable or unknown | |
| Start Date | |
| End Date | |
| Check if ongoing | |
| Chemo Only Number of Cycles | |

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Folder: CT SOC Images Sent to Core Lab

Form: CT Image Transmittal Worksheet

Generated On: 09 Apr 2020 15:26:54

Sites must complete, print, and include this form when mailing images to ACRIN

Mail to:
ACRIN Imaging Core Lab
Protocol: ACRIN 4704- DECAMP 2
1818 Market St, Suite 1700
Philadelphia, PA 19103

| | |
|----------------------------|--|
| Date of imaging | _____ |
| Date of imaging submission | _____ |
| Mode of image submission | TRIAD <input type="checkbox"/> |
| | sFTP <input type="checkbox"/> |
| | Disk <input type="checkbox"/> |
| | Hard Drive <input type="checkbox"/> |
| CT data sets submitted | CRF data <input type="checkbox"/> |
| | Scout / Topogram / Surview <input type="checkbox"/> |
| | Axial Plane Step & Shoot <input type="checkbox"/> |
| | BRAIN Pre-Contrast <input type="checkbox"/> |
| | Axial Plane Step & Shoot <input type="checkbox"/> |
| | BRAIN Post Contrast <input type="checkbox"/> |
| | Axial Plane BRAIN Bone/Sharp <input type="checkbox"/> |
| | Algorithm <input type="checkbox"/> |
| | Axial Plane Step & Shoot <input type="checkbox"/> |
| | Angiography BRAIN <input type="checkbox"/> |
| | Axial Plane Step & Shoot CCTA <input type="checkbox"/> |
| | Angiography <input type="checkbox"/> |
| | Axial Plane Helical/Spiral CCTA <input type="checkbox"/> |
| | Angiography <input type="checkbox"/> |
| | Axial Plane Helical/Spiral <input type="checkbox"/> |
| | CHEST/THORAX Unenhanced <input type="checkbox"/> |
| | Soft Tissue Algorithm 1 <input type="checkbox"/> |
| | Axial Plane Helical/Spiral <input type="checkbox"/> |
| | CHEST/THORAX Enhanced <input type="checkbox"/> |
| | Standard/Soft Tissue Algorithm <input type="checkbox"/> |
| | Axial Plane Helical/Spiral <input type="checkbox"/> |
| | ABDOMEN Unenhanced <input type="checkbox"/> |
| | Standard/Soft Tissue Algorithm <input type="checkbox"/> |

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Folder: CT SOC Images Sent to Core Lab

Form: CT Image Transmittal Worksheet

Generated On: 09 Apr 2020 15:26:54

- Axial Plane Helical/Spiral ABDOMEN Enhanced
- Standard/Soft Tissue Algorithm
- Axial Plane Helical/Spiral PELVIS Unenhanced
- Standard/Soft Tissue Algorithm
- Axial Plane Helical/Spiral PELVIS Enhanced Standard/Soft Tissue Algorithm
- Axial Plane Step & Shoot ABDOMEN Angiography
- Axial Plane Helical/Spiral ABDOMEN Angiography
- Axial Plane Step & Shoot PELVIS Angiography
- Axial Plane Helical/Spiral PELVIS Angiography
- SAGITTAL Standard/Soft Tissue
- SAGITTAL Bone/Sharp
- CORONAL Standard/Soft Tissue
- CORONAL Bone/Sharp
- 3-D Standard/Soft
- 3-D Bone/Sharp
- MULTI-PHASE
- SAGITTAL Standard/Soft Tissue
- SAGITTAL Bone/Sharp
- CORONAL Standard/Soft Tissue
- CORONAL Bone/Sharp
- 3-D Standard/Soft
- 3-D Bone/Sharp
- Other, specify

Comments _____

COMMENTS _____

Name of Technologist _____

Technologist phone number _____

Technologist email _____

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Folder: PET SOC Images Sent to Core Lab

Form: PET Image Transmittal Worksheet

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Date of imaging _____

Date of imaging submission _____

Mode of image submission _____

TRIAD

sFTP

Disk

Hard Drive

PET data sets submitted _____

CRF data

Torso survey [skull-base to mid-thigh level]

Whole Body [skull vertex to toes]

Static brain

Dynamic body

Dynamic brain

Summed static

CT for attenuation correction

Transmission scan (for PET only scanner)

Diagnostic CT

MRI

Multi-bed Position Static

Other, specify

Comments _____

COMMENTS _____

Name of Technologist _____

Technologist phone number _____

Technologist email _____

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Folder: MRI SOC Images Sent to Core Lab

Form: MRI Image Transmittal Worksheet

Generated On: 09 Apr 2020 15:26:54

| | |
|----------------------------|---|
| Date of imaging | _____ |
| Date of imaging submission | _____ |
| Mode of image submission | TRIAD <input type="checkbox"/> sFTP <input type="checkbox"/> Disk <input type="checkbox"/> Hard Drive <input type="checkbox"/> |
| MRI data sets submitted | _____ |
| Comments | _____ |
| COMMENTS | _____ |
| Name of Technologist | _____ |
| Technologist phone number | _____ |
| Technologist email | _____ |

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Folder: Other Type- SOC Images Sent to Core Lab

Form: Other Image Transmittal Worksheet

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| | |
|----------------------------|-------------------------------------|
| Type of Other Imaging | _____ |
| Date of imaging | _____ |
| Date of imaging submission | _____ |
| Mode of image submission | TRIAD <input type="checkbox"/> |
| | sFTP <input type="checkbox"/> |
| | Disk <input type="checkbox"/> |
| | Hard Drive <input type="checkbox"/> |
| Data sets submitted | _____ |
| Comments | _____ |
| COMMENTS | _____ |
| Name of Technologist | _____ |
| Technologist phone number | _____ |
| Technologist email | _____ |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Adverse Events

Form: Adverse Events

Generated On: 09 Apr 2020 15:26:54

INSTRUCTION TEXT. Only AEs that are considered possibly, probably, or definitely related to the study-related biospecimens collection procedures require reporting to ACRIN. Please refer to your local IRB's policies and procedures regarding reporting of AEs.

Refer to Protocol Section 10.0 for more details

| | |
|--------------------------------------|--|
| AE Term | _____ |
| Adverse Event Text Name (CTCAE v4.0) | _____ |
| Adverse Event Grade | 1- Mild <input type="checkbox"/> 2- Moderate <input type="checkbox"/> 3- Severe <input type="checkbox"/> 4- Life-threatening or disabling <input type="checkbox"/> 5- Death <input type="checkbox"/> |
| CTC Adverse Event Attribution Scale | Unrelated <input type="checkbox"/> Unlikely <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Definite <input type="checkbox"/> |
| Serious AE? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Action Taken- Mark all that apply | |
| Action Taken- None | _____ |
| Action Taken- Medication Therapy | _____ |
| Action Taken- Procedure | _____ |
| Action Taken- Hospitalization | _____ |
| Action Taken- Other | _____ |
| Outcome | Recovered <input type="checkbox"/> Improved <input type="checkbox"/> Ongoing <input type="checkbox"/> Death <input type="checkbox"/> Unknown <input type="checkbox"/> |
| AE Start Date | _____ |
| AE End Date | _____ |
| Check if ongoing | _____ |
| Comments | _____ |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Adverse Events

Form: Adverse Events

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Expectedness

Expected

Unexpected

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Adverse Events

Form: Serious Adverse Event

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The Serious Adverse Event Form should only be completed for reportable serious adverse events

One Serious Adverse Event Form should be completed per SAE. Any updates to the SAE should be recorded on the original SAE report

Definition of an SAE= any untoward medical occurrence that:

- Results in death;
- Is life-threatening (at the time of the event);
- Requires inpatient hospitalization or prolongation of an existing hospitalization;
- Results in persistent or significant disability or incapacity;
- Is a congenital anomaly/birth defect;
- Is considered a medically-important event

Refer to the 4703 Protocol Section 10.0 for more details

The Site PI must electronically sign off on the eCRF before the form can be considered complete

| | |
|---|--|
| Check if Final Report (i.e., no additional data will be collected regarding this SAE) | |
| Date of Birth | |
| Patient Gender | Male <input type="checkbox"/> Female <input type="checkbox"/> |
| Describe the serious adverse event (SAE) | |
| Onset Date of Event | |
| Severity of Event | Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Life threatening <input type="checkbox"/> Fatal <input type="checkbox"/> |
| Relationship of the study to the SAE | Unrelated <input type="checkbox"/> Unlikely <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Definite <input type="checkbox"/> |
| Event Resolution | Recovered/Resolved <input type="checkbox"/> Ongoing <input type="checkbox"/> Recovered/Resolved with sequelae, specify sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> |

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Draft 18.0 version 1.0 MIGPROD 10FEB2020: All Forms

Folder: Adverse Events

Form: Serious Adverse Event

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Unknown

If recovered/resolved, please provide date _____

If fatal, please provide date of death _____

Seriousness Criteria for SAE

Death

Life threatening

Hospitalization

Prolongation of hospitalization

Congenital anomaly or birth defect

Persistent or significant disability/incapacity

Important medical event requiring medical or surgical

intervention to prevent serious outcome, please specify: _____

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Form: Subject Enrollment

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FORM_OID PID3284264_V1_0

Patient ID _____

Enrolling Site CTEP ID _____

Lead Organization _____

Current Site CTEP ID _____

Enrollment Date _____

Enrollment Time _____

- EST
- CST
- MST
- PST
- EDT
- CDT
- MDT
- PDT

Group Data _____

Source Application _____

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Select the protocol event being reported

- Inclusion / exclusion criteria not met at time of registration
- Imaging-related deviation
- Study activity performed prior to participant signing study consent form
- Visit or follow-up assessments/procedures not performed per protocol
- Case enrolled under expired IRB approval / FWA
- Biospecimen Collection not performed per protocol
- Patient Lung Questionnaire Not Completed
- Other

Provide Reason for Imaging Protocol Deviation

- Missing exam series. Study is incomplete per protocol
- Inconsistent subject identifier
- Image artifact - rendering series non-diagnostic
- Incorrect case number assigned to images
- Incomplete image transfer
- Body weight is incorrect or unknown
- Images lost / unavailable
- Other

Protocol Deviation Occurrence Date

Date the Protocol Deviation was Discovered

Describe the Protocol Deviation

What Was Done to Rectify the Situation and/or Prevent Future Occurrence

At what reporting period did this Study Deviation Occur

- Eligibility / Registration
- Biospecimen Transmittal
- Baseline
- Baseline Biospecimen Collection
- Follow up- 1 year
- Follow up- 1 year Biospecimen Collection

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-
- Follow up- 2 year
 - Follow up- 2 year Biospecimen Collection
 - Follow up- 3 year
 - Follow up- 4 year
 - Follow up Through Surgery and Diagnosis
 - Other, specify

If biospecimen deviation, indicate the type

- Bronchoscopy
 - Blood Collection
 - Bronchial Airway Brushings
 - Urine Collection (Midstream Clean Catch)
 - Nasal Brushing
 - Buccal Scraping
 - Sputum Samples
 - Urine Processing for Metabolomics Study
 - Surgical Tissue Collection
 - All Biospecimen Collection
-

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Provide reason for study disposition by selecting one of the following

- Protocol defined follow up completed
- Participant lost to follow up
- Participant refused follow up/withdrew
- Death
- Adverse Event/Side Effects/Complications
- Disease progression
- Study terminated by sponsor
- Protocol violation-did not meet eligibility
- Protocol violation-technical problems
- Protocol violation-related to study visits
- Protocol violation-related to imaging
- Protocol violation-related to biospecimen collection
- Other, specify

Date of Death

Fixed Unit: MMM dd yyyy

Cause of Death

Disease progression

Other, specify

Date of disposition

Fixed Unit: MMM dd yyyy

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Form: Withdrawal of Consent

Generated On: 09 Apr 2020 15:26:54

Instructions: The study site completes the WOC 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. 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 (biospecimen collection, imaging, 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. Furthermore, the issue of withdrawal should not be confused with participants considered Non-responders, Lost, or Lost to Followup; withdrawal involves an active, explicit request by the participant.

| | |
|--|-------|
| Date study participant withdrew consent | _____ |
| Please select the reason(s) for withdrawal <i>select all that apply</i> | _____ |
| Transportation problems | _____ |
| Concerned about privacy | _____ |
| Physical illness/cognitive impairment | _____ |
| Out of Area | _____ |
| Concerned about medical costs responsibility | _____ |
| Concerned about health care effects | _____ |
| Participating in other research study | _____ |
| Dissatisfied with study | _____ |
| Family responsibilities | _____ |
| Work demands | _____ |
| Loss of interest in Study | _____ |
| No reason given | _____ |
| Other reason | _____ |

Level of Participant Withdrawal

- (1) Participant elected to cease one or more study procedures
- (2) Participant refuses further active study participation, but will allow continued vital and disease status collection

(3) Participant explicitly withdraws study consent/authorization

For Level 1 Consent Withdrawals

Indicate the level of withdrawal for each:

| | |
|------------------------|---|
| Biospecimen Collection | Participant did not withdraw consent for biospecimen collection <input type="checkbox"/> |
| | Participant refuses upcoming biospecimen collection and would like to be contacted to decide on future collections <input type="checkbox"/> |
| | Participant agrees to only partial biospecimen collection <input type="checkbox"/> |
| | Participant refuses all future biospecimen collection <input type="checkbox"/> |
| PFT | Participant did not withdraw consent for PFT <input type="checkbox"/> |
| | Participant refuses upcoming PFT and would like to be contacted to decide on future collections <input type="checkbox"/> |
| | Participant refuses all future PFTs <input type="checkbox"/> |
| CT | Participant did not withdraw consent for CT Imaging exams <input type="checkbox"/> |
| | Participant refuses upcoming CT Imaging exams and would like to be contacted to decide on future collections <input type="checkbox"/> |
| | Participant refuses all future CT Imaging exams <input type="checkbox"/> |

For Level 2 withdrawals

Indicate if contact is allowed for vital status No
 Yes

If yes, indicate the timeframe Yearly
 Other, specify

Documentation of the WOC conversation (participant letter, chart notes, etc..) _____

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Form: Withdrawal of Consent

Generated On: 09 Apr 2020 15:26:54

Complete this section only if the patient re-consents to participate in study. Note: All inactivated forms will be re-activated and the target dates of the visits and follow up will re-trigger off the re-consent date

| | |
|--------------------|-------|
| Date of re-consent | _____ |
| Reason for change | _____ |

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