

## BRONCHOSCOPY SUB-STUDY SPECIMEN COLLECTION WORKSHEET

ID NUMBER:										
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FORM CODE: BCW  
VERSION: 1.0 08/03/2022

Event: \_\_\_\_\_

0a) Date of Collection:   /   /

0b) Staff Code:

**Instructions:** This form should be completed during the participant's Bronchoscopy Visit 2.

**OXYGEN SATURATION (OF ROOM AIR) (PRE-BRONCHOSCOPY)**

1) O<sub>2</sub> saturation of room air:    %

**MEDICAL HISTORY AND PHYSICAL**

2) Does your center require lab work prior to bronchoscopy?

- No<sub>0</sub> → **Go to 3**  
 Yes<sub>1</sub>

2a) If Yes, please describe: \_\_\_\_\_

2b) Were the results of the lab work abnormal?

- No<sub>0</sub>  
 Yes<sub>1</sub>

2c) Do the results of the lab blood work described in 2a and 2b make the participant ineligible to proceed with a bronchoscopy?

- No<sub>0</sub>  
 Yes<sub>1</sub> → **Go to End**

3) Did the doctor perform a limited physical exam?

- No<sub>0</sub> → **Go to 4**  
 Yes<sub>1</sub>

3a) In the opinion of the doctor, are there any other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy sub-study?

- No<sub>0</sub> → **Go to 3b**  
 Yes<sub>1</sub> → **Go to End after completing 3a1**

3a1) If Yes, please describe: \_\_\_\_\_

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3b) Does the participant report any new physical symptoms or conditions that would make the participant ineligible for participation in the bronchoscopy sub-study?

- No<sub>0</sub> → **Go to 4**
- Yes<sub>1</sub> → **Go to End after completing 3b1**

3b1) If Yes, please describe: \_\_\_\_\_

4) Is the participant female?

- No<sub>0</sub> → **Go to 5**
- Yes<sub>1</sub>

4a) Is the participant of child-bearing potential?

- No<sub>0</sub> → **Go to 5**
- Yes<sub>1</sub>

4b) If Yes, what was the result of the pregnancy test?

- Negative<sub>0</sub>
- Positive<sub>1</sub>

### **PRE-BRONCHOSCOPY STATUS**

5) Has the participant taken any medications within the past 7 days?

- No<sub>0</sub> → **Go to 6**
- Yes<sub>1</sub>

5a) Inhaled steroids?

- No<sub>0</sub>
- Yes<sub>1</sub>

5b) Nasal steroids?

- No<sub>0</sub>
- Yes<sub>1</sub>

5c) Oral steroids?

- No<sub>0</sub>
- Yes<sub>1</sub>

5d) Antibiotics?

- No<sub>0</sub>
- Yes<sub>1</sub>

5e) Mucolytics?

- No<sub>0</sub>
- Yes<sub>1</sub>

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6) Did the participant have an acute exacerbation of COPD (requiring antibiotics and/or steroids) in the past 3 months?

- No<sub>0</sub> → **Go to 7**  
 Yes<sub>1</sub>

6a) Record the date of onset of the acute exacerbation:

/   /

7) Was spirometry done today?

- No<sub>0</sub>  
 Yes<sub>1</sub> → **Go to 8**

7a) If No, record most recent date completed:

/   /

8) Pre-bronchodilator FEV<sub>1</sub> (reported/best; today or most recent):

.   L-BTPS

9) Did you administer albuterol?

- No<sub>0</sub> → **Go to 10**  
 Yes<sub>1</sub>

9a) If Yes, how many micrograms?

μg

10) Post-bronchodilator FEV<sub>1</sub> (reported/best; today or most recent):

.   L-BTPS

### **BLOOD COLLECTION**

11) Date of blood collection:

/   /

12) Blood collection time:

:   AM<sub>1</sub> / PM<sub>2</sub>

13) Number of venipuncture attempts:

sticks

14) Any blood drawing incidents or problems?

- No<sub>0</sub> → **Go to 16**  
 Yes<sub>1</sub>

*Document problems with blood drawing below. If a problem other than those listed occurred, use Item 15.*

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14a) Sample not drawn?

- No<sub>0</sub> → **Go to 14b**
- Yes<sub>1</sub>

14a1) If Yes, please specify which tube(s): \_\_\_\_\_

14b) Partial sample drawn?

- No<sub>0</sub> → **Go to 14c**
- Yes<sub>1</sub>

14b1) If Yes, please specify which tube(s): \_\_\_\_\_

14c) Tourniquet reapplied?

- No<sub>0</sub> → **Go to 14d**
- Yes<sub>1</sub>

14c1) If Yes, please specify which tube(s): \_\_\_\_\_

14d) Fist clenching?

- No<sub>0</sub> → **Go to 14e**
- Yes<sub>1</sub>

14d1) If Yes, please specify which tube(s): \_\_\_\_\_

14e) Needle movement?

- No<sub>0</sub> → **Go to 14f**
- Yes<sub>1</sub>

14e1) If Yes, please specify which tube(s): \_\_\_\_\_

14f) Participant reclining?

- No<sub>0</sub> → **Go to 14g**
- Yes<sub>1</sub>

14f1) If Yes, please specify which tube(s): \_\_\_\_\_

14g) Sample re-drawn?

- No<sub>0</sub> → **Go to 15**
- Yes<sub>1</sub>

14g1) If Yes, please specify which tube(s): \_\_\_\_\_

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15) If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here:

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16) Phlebotomist's staff code:

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**NASAL EPITHELIAL BRUSHINGS**

17) Were nasal brushings done?

No<sub>0</sub> → **Go to 19**  
 Yes<sub>1</sub>

18) Nasal specimen source:

18a) Number of brushings completed in right naris:

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18b) Number of brushings completed in left naris:

--	--

18c) Nasal brushing collection time:

		:			AM <sub>1</sub> / PM <sub>2</sub>
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**ORAL RINSE**

19) Was the tongue scraping collected?

No<sub>0</sub> → **Go to 20**  
 Yes<sub>1</sub>

19a) Tongue scrape collection time:

		:			AM <sub>1</sub> / PM <sub>2</sub>
--	--	---	--	--	-----------------------------------

20) Was the oral rinse collected?

No<sub>0</sub> → **Go to 21**  
 Yes<sub>1</sub>

20a) Oral rinse collection time:

		:			AM <sub>1</sub> / PM <sub>2</sub>
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20b) Was the time between oral rinse and bronchoscopy more than 60 minutes?

No<sub>0</sub> → **Go to 21**  
 Yes<sub>1</sub>

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20b1) If Yes, was an additional tongue scraping collected?

- No<sub>0</sub>  
 Yes<sub>1</sub>

### **BRONCHOSCOPY PROCEDURES**

21) Was the **Saline through the Scope** sample collected?

- No<sub>0</sub>  
 Yes<sub>1</sub>

22) Were the **Protected Brush** specimens collected? (3x in lower lobe)

- No<sub>0</sub> → **Go to 23**  
 Yes<sub>1</sub>

22a) Lobe: \_\_\_\_\_

22b) Segment: \_\_\_\_\_

22c) Number collected:

22d) Collection time:   :   AM<sub>1</sub> / PM<sub>2</sub>

23) Were the **Bronchial Alveolar Lavage (BAL)** specimens collected? (data from both BALs combined)

- No<sub>0</sub> → **Go to 24**  
 Yes<sub>1</sub>

23a) Lobe(s): \_\_\_\_\_

23b) Segment(s): \_\_\_\_\_

23c) Infused:    mL

23d) Return:    .  mL

23e) Collection time:   :   AM<sub>1</sub> / PM<sub>2</sub>

*Note: If less than 15 cc of fluid is returned from the combined volume of the 20 cc wash and the 2 x 40 cc lavage, then the 1 x 50 cc lavage should not be performed.*

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23f) Was BAL stopped because of poor fluid return?

- No<sub>0</sub>
- Yes<sub>1</sub>

24) Were the **Cytological Brushings** collected for **RNA**? (3x for RNA in ipsilateral lower lobe)

- No<sub>0</sub> → **Go to 25**
- Yes<sub>1</sub>

24a) Lobe: \_\_\_\_\_

24b) Segment: \_\_\_\_\_

24c) Number of brushes collected:

24d) Collection time:   :   AM<sub>1</sub> / PM<sub>2</sub>

25) Were the **Cytological Brushings** collected for **DNA**? (2x for DNA in ipsilateral lower lobe)

- No<sub>0</sub> → **Go to 26**
- Yes<sub>1</sub>

25a) Lobe: \_\_\_\_\_

25b) Segment: \_\_\_\_\_

25c) Number of brushes collected:

25d) Collection time:   :   AM<sub>1</sub> / PM<sub>2</sub>

26) Were the **Microcytological Brushings** collected for **Mucin**? (2x in ipsilateral upper lobe bronchi)

- No<sub>0</sub> → **Go to 27**
- Yes<sub>1</sub>

26a) Lobe: \_\_\_\_\_

26b) Segment: \_\_\_\_\_

26c) Number of brushes collected:

ID NUMBER:

Event: \_\_\_\_\_

26d) Collection time:

:   AM<sub>1</sub> / PM<sub>2</sub>

27) Were the **Small Airway Epithelial Brushings** collected?

- No<sub>0</sub> → **Go to 28**  
 Yes<sub>1</sub>

27a) Lobe(s): \_\_\_\_\_

27b) Segment(s): \_\_\_\_\_

27c) Number of brushes collected:

27d) Collection time:   :   AM<sub>1</sub> / PM<sub>2</sub>

27e) Were small airway epithelial cells acquired for basal cell culture?

- No<sub>0</sub> → **Go to 28**  
 Yes<sub>1</sub>

27e1) Put into culture time:   :   AM<sub>1</sub> / PM<sub>2</sub>

27e2) Passaged and frozen time:   :   AM<sub>1</sub> / PM<sub>2</sub>

**Anesthesia with lidocaine should be performed using local protocols with the following limit on lidocaine dose: 600 mg or 9 mg/kg, whichever is less. Some institutions may have a more stringent cutoff, which should be observed (if applicable). Alert the bronchoscopist when 300 mg of lidocaine has been delivered.**

28) Total amount of Lidocaine 1% used:    mg

29) Total amount of Lidocaine 2% used:    mg

30) Total amount of Lidocaine 4% used:    mg

31) Total amount of Lidocaine used:    mg

*NOTE: This value will be automatically calculated in the DMS.*

32) Were there any deviations from the planned bronchoscopy collection protocol?

- No<sub>0</sub> → **Go to 33**  
 Yes<sub>1</sub>



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Event: \_\_\_\_\_

32a) If Yes, please elaborate with detailed comments:

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33) Was post-bronchoscopy pulmonary function testing done?

- No<sub>0</sub> → **Go to 39**  
 Yes<sub>1</sub>

34) Pre-bronchodilator FEV<sub>1</sub> (reported/best):

.   L-BTPS

35) Did you administer albuterol?

- No<sub>0</sub> → **Go to 36**  
 Yes<sub>1</sub>

35a) If Yes, how many micrograms?

μg

36) Post-bronchodilator FEV<sub>1</sub> (reported/best):

.   L-BTPS

37) Did you administer additional albuterol?

- No<sub>0</sub> → **Go to 39**  
 Yes<sub>1</sub>

37a) If Yes, how many micrograms?

μg

38) Post-additional bronchodilator FEV<sub>1</sub> (reported/best):

.   L-BTPS

**POST-BRONCHOSCOPY PROCEDURES STATUS**

39) Did the participant experience any adverse events during the bronchoscopy?

- No<sub>0</sub> → **Go to 40**  
 Yes<sub>1</sub>

39a) Please list relevant adverse events:

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40) Did the participant need to be admitted for overnight observation post-bronchoscopy?

- No<sub>0</sub> → **Go to 43**  
 Yes<sub>1</sub>

41) Upon discharge was the participant or did the participant have any of the following? (check all that apply)

- 42b 41a)  alert / responsive  
42c 41b)  oriented to time, person, place  
42d 41c)  heart rate < 100/min  
42e 41d)  ambulate without difficulty  
42f 41e)  sips water without difficulty or cough  
42g 41f)  if done, FEV<sub>1</sub> > 90% of the pre-BD baseline FEV<sub>1</sub>  
41g)  no complaints of chest discomfort

42) Please enter any comments you have regarding the participant upon discharge:

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### **POST-DISCHARGE FOLLOW-UP**

43) Was the participant contacted the night of the bronchoscopy procedure?

- No<sub>0</sub> → **Go to 44**  
 Yes<sub>1</sub>

43a) Staff code of person who contacted the participant:

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43b) Date of contact:

		/			/				
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43c) Were there any problems?

- No<sub>0</sub> → **Go to 44**  
 Yes<sub>1</sub>

43c1) If Yes, please describe: \_\_\_\_\_

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44) Was the participant contacted 24 hours after the bronchoscopy procedure?

No<sub>0</sub> → **Go to End**

Yes<sub>1</sub>

44a) Staff code of person who contacted the participant:

--	--	--

44b) Date of contact:

		/			/				
--	--	---	--	--	---	--	--	--	--

44c) Were there any problems?

No<sub>0</sub> → **Go to End**

Yes<sub>1</sub>

44c1) If Yes, please describe: \_\_\_\_\_

**END OF FORM**