

BRONCHOSCOPY SUB-STUDY SPECIMEN COLLECTION WORKSHEET

ID NUMBER:

FORM CODE: BCW
VERSION: 2.0 05/09/2023

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) O₂ saturation of room air:

%

MEDICAL HISTORY AND PHYSICAL

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

- No₀ → **Go to 3**
 Yes₁

2a) If Yes, please describe: _____

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

- No₀
 Yes₁

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

- No₀
 Yes₁ → **Go to End**

3) Did the doctor perform a limited physical exam?

- No₀ → **Go to 4**
 Yes₁

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?

- No₀ → **Go to 3b**
 Yes₁ → **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?

- No₀ → **Go to 4**
- Yes₁ → **Go to End after completing 3b1**

3b1) If Yes, please describe: _____

4) Is the participant female?

- No₀ → **Go to 5**
- Yes₁

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

- No₀ → **Go to 5**
- Yes₁

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

- Negative₀
- Positive₁

PRE-BRONCHOSCOPY STATUS

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

- No₀ → **Go to 6**
- Yes₁

5a) Inhaled steroids?

- No₀
- Yes₁

5b) Nasal steroids?

- No₀
- Yes₁

5c) Oral steroids?

- No₀
- Yes₁

5d) Antibiotics?

- No₀
- Yes₁

5e) Mucolytics?

- No₀
- Yes₁

ID NUMBER:

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

- No₀ → **Go to 7**
- Yes₁

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

/ /

7) Was spirometry done today?

- No₀
- Yes₁ → **Go to 8**

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

/ /

8) Pre-bronchodilator FEV₁ (reported/best; today or most recent):

. L-BTPS

9) Did you administer albuterol?

- No₀ → **Go to 10**
- Yes₁

9a) If Yes, how many micrograms?

μg

10) Post-bronchodilator FEV₁ (reported/best; today or most recent):

. L-BTPS

BLOOD COLLECTION

11) Date of blood collection:

/ /

12) Blood collection time:

: AM₁ / PM₂

13) Number of venipuncture attempts:

sticks

14) Any blood drawing incidents or problems?

- No₀ → **Go to 16**
- Yes₁

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?

- No₀ → **Go to 14b**
 Yes₁

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

14b) Partial sample drawn?

- No₀ → **Go to 14c**
 Yes₁

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

14c) Tourniquet reapplied?

- No₀ → **Go to 14d**
 Yes₁

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

14d) Fist clenching?

- No₀ → **Go to 14e**
 Yes₁

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

14e) Needle movement?

- No₀ → **Go to 14f**
 Yes₁

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

14f) Participant reclining?

- No₀ → **Go to 14g**
 Yes₁

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

14g) Sample re-drawn?

- No₀ → **Go to 15**
 Yes₁

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:

16) Phlebotomist's staff code:

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NASAL SWAB

17) Was the nasal swab biospecimen collected?

No₀ → **Go to 19**
 Yes₁

18) Nasal specimen source:

18a) Number of swabs completed in right naris:

18b) Number of swabs completed in left naris:

18c) Nasal swab collection time:

		:			AM ₁ / PM ₂
--	--	---	--	--	-----------------------------------

ORAL RINSE

19) Was the tongue scraping collected?

No₀ → **Go to 20**
 Yes₁

19a) Tongue scrape collection time:

		:			AM ₁ / PM ₂
--	--	---	--	--	-----------------------------------

20) Was the oral rinse collected?

No₀ → **Go to 21**
 Yes₁

20a) Oral rinse collection time:

		:			AM ₁ / PM ₂
--	--	---	--	--	-----------------------------------

20b) Was the time between oral rinse and bronchoscopy more than 60 minutes?

No₀ → **Go to 21**
 Yes₁

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

- No₀
 Yes₁

BRONCHOSCOPY PROCEDURES

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

- No₀
 Yes₁

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

- No₀ → **Go to 23**
 Yes₁

22a) Lobe: _____

22b) Segment: _____

22c) Number collected:

22d) Collection time: : AM₁ / PM₂

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

- No₀ → **Go to 24**
 Yes₁

23a) Lobe(s): _____

23b) Segment(s): _____

23c) Infused: mL

23d) Return: . mL

23e) Collection time: : AM₁ / PM₂

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?

- No₀
- Yes₁

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

- No₀ → **Go to 25**
- Yes₁

24a) Lobe: _____

24b) Segment: _____

24c) Number of brushes collected:

24d) Collection time: : AM₁ / PM₂

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

- No₀ → **Go to 26**
- Yes₁

25a) Lobe: _____

25b) Segment: _____

25c) Number of brushes collected:

25d) Collection time: : AM₁ / PM₂

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

- No₀ → **Go to 27**
- Yes₁

26a) Lobe: _____

26b) Segment: _____

26c) Number of brushes collected:

ID NUMBER:

Event: _____

26d) Collection time:

: AM₁ / PM₂

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

- No₀ → **Go to 28**
 Yes₁

27a) Lobe(s): _____

27b) Segment(s): _____

27c) Number of brushes collected:

27d) Collection time: : AM₁ / PM₂

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

- No₀ → **Go to 28**
 Yes₁

27e1) Put into culture time: : AM₁ / PM₂

27e2) Passaged and frozen time: : AM₁ / PM₂

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?

- No₀ → **Go to 33**
 Yes₁

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Event: _____

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

33) Was post-bronchoscopy pulmonary function testing done?

- No₀ → **Go to 39**
 Yes₁

34) Pre-bronchodilator FEV₁ (reported/best):

. L-BTPS

35) Did you administer albuterol?

- No₀ → **Go to 36**
 Yes₁

35a) If Yes, how many micrograms?

μg

36) Post-bronchodilator FEV₁ (reported/best):

. L-BTPS

37) Did you administer additional albuterol?

- No₀ → **Go to 39**
 Yes₁

37a) If Yes, how many micrograms?

μg

38) Post-additional bronchodilator FEV₁ (reported/best):

. L-BTPS

POST-BRONCHOSCOPY PROCEDURES STATUS

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

- No₀ → **Go to 40**
 Yes₁

39a) Please list relevant adverse events:

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

- No₀ → **Go to 43**
 Yes₁

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, FEV₁ > 90% of the pre-BD baseline FEV₁
41g) no complaints of chest discomfort

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

POST-DISCHARGE FOLLOW-UP

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

- No₀ → **Go to 44**
 Yes₁

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?

- No₀ → **Go to 44**
 Yes₁

43c1) If Yes, please describe: _____

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

No₀ → **Go to End**

Yes₁

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

--	--	--

44b) Date of contact:

		/			/				
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44c) Were there any problems?

No₀ → **Go to End**

Yes₁

44c1) If Yes, please describe: _____

END OF FORM