SOURCE
SPIROMICS Study of Early COPD Progression

BRONCHOSCOPY SUB-STUDY
SPECIMEN COLLECTION WORKSHEET

ID NUMBER:									

FORM CODE: BCW
VERSION: 3.0 05/16/2024

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_2 saturation of room air: ☐☐☐ %

MEDICAL HISTORY AND PHYSICAL

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

☐ No$_0$ → **Go to 3**
☐ Yes$_1$

2a) If Yes, please describe: _____

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

☐ No$_0$
☐ Yes$_1$

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

☐ No$_0$
☐ Yes$_1$ → **Go to End**

3) Did the doctor perform a limited physical exam?

☐ No$_0$ → **Go to 4**
☐ Yes$_1$

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$_0$ → **Go to 3b**
☐ Yes$_1$ → **Go to End after completing 3a1**

3a1) If Yes, please describe: _____

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$_0$ → **Go to 4**
☐ Yes$_1$ → **Go to End after completing 3b1**

3b1) If Yes, please describe: _____

4) Is the participant female?

☐ No$_0$ → **Go to 5**
☐ Yes$_1$

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

☐ No$_0$ → **Go to 5**
☐ Yes$_1$

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

☐ Negative$_0$
☐ Positive$_1$

PRE-BRONCHOSCOPY STATUS

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

☐ No$_0$ → **Go to 6**
☐ Yes$_1$

5a) Inhaled steroids?

☐ No$_0$
☐ Yes$_1$

5b) Nasal steroids?

☐ No$_0$
☐ Yes$_1$

5c) Oral steroids?

☐ No$_0$
☐ Yes$_1$

5d) Antibiotics?

☐ No$_0$
☐ Yes$_1$

5e) Mucolytics?

☐ No$_0$
☐ Yes$_1$

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

☐ No$_0$ → **Go to 7**
☐ Yes$_1$

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

7) Was spirometry done today?

☐ No$_0$
☐ Yes$_1$ → **Go to 8**

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

8) Pre-bronchodilator FEV_1 (reported/best; today or most recent): ☐☐.☐☐ L-BTPS

9) Did you administer albuterol?

☐ No$_0$ → **Go to 10**
☐ Yes$_1$

9a) If Yes, how many micrograms? ☐☐☐ µg

10) Post-bronchodilator FEV_1 (reported/best; today or most recent): ☐☐.☐☐ L-BTPS

BLOOD COLLECTION

11) Date of blood collection: ☐☐/☐☐/☐☐☐☐

12) Blood collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

13) Number of venipuncture attempts: ☐ sticks

14) Any blood drawing incidents or problems?

☐ No$_0$ → **Go to 16**
☐ Yes$_1$

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

14a) Sample not drawn?

☐ No$_0$ → **Go to 14b**
☐ Yes$_1$

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

14b) Partial sample drawn?

☐ No$_0$ → **Go to 14c**
☐ Yes$_1$

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

14c) Tourniquet reapplied?

☐ No$_0$ → **Go to 14d**
☐ Yes$_1$

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

14d) Fist clenching?

☐ No$_0$ → **Go to 14e**
☐ Yes$_1$

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

14e) Needle movement?

☐ No$_0$ → **Go to 14f**
☐ Yes$_1$

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

14f) Participant reclining?

☐ No$_0$ → **Go to 14g**
☐ Yes$_1$

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

14g) Sample re-drawn?

☐ No$_0$ → **Go to 15**
☐ Yes$_1$

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

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: ☐☐☐

NASAL SWAB

17) Was the nasal swab biospecimen collected?

☐ No$_0$ → **Go to 19**
☐ Yes$_1$

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?

☐ No$_0$ → **Go to 20**
☐ Yes$_1$

19a) Tongue scrape collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

20) Was the oral rinse collected?

☐ No$_0$ → **Go to 21**
☐ Yes$_1$

20a) Oral rinse collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 21**
☐ Yes$_1$

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

☐ No$_0$
☐ Yes$_1$

BRONCHOSCOPY PROCEDURES

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

☐ No$_0$
☐ Yes$_1$

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

☐ No$_0$ → **Go to 23**
☐ Yes$_1$

22a) Lobe: _____

22b) Segment: _____

22c) Number collected: ☐

22d) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 24**
☐ Yes$_1$

23a) Lobe(s): _____

23b) Segment(s): _____

23c) Infused: ☐☐☐ mL

23d) Return: ☐☐☐.☐ mL

23e) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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.

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

☐ No$_0$
☐ Yes$_1$

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

☐ No$_0$ → **Go to 25**
☐ Yes$_1$

24a) Lobe: _____

24b) Segment: _____

24c) Number of brushes collected: ☐

24d) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 26**
☐ Yes$_1$

25a) Lobe: _____

25b) Segment: _____

25c) Number of brushes collected: ☐

25d) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 27**
☐ Yes$_1$

26a) Lobe: _____

26b) Segment: _____

26c) Number of brushes collected: ☐

26d) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 28**
☐ Yes$_1$

27a) Lobe(s): _____

27b) Segment(s): _____

27c) Number of brushes collected: ☐☐

27d) Collection time: ☐☐:☐☐ AM$_1$ / PM$_2$

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

☐ No$_0$ → **Go to 28**
☐ Yes$_1$

27e1) Put into culture time: ☐☐:☐☐ AM$_1$ / PM$_2$

27e1a) Put into culture date: ☐☐/☐☐/☐☐☐☐

27e2) Passaged time: ☐☐:☐☐ AM$_1$ / PM$_2$

27e2a) Passaged date: ☐☐/☐☐/☐☐☐☐

27e3) Frozen time: ☐☐:☐☐ AM$_1$ / PM$_2$

27e3a) Frozen date: ☐☐/☐☐/☐☐☐☐

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$_0$ → **Go to 33**
☐ Yes$_1$

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

_____

_____

_____

_____

33) Was post-bronchoscopy pulmonary function testing done?

☐ No$_0$ → **Go to 39**
☐ Yes$_1$

34) Pre-bronchodilator FEV_1 (reported/best): ☐☐.☐☐ L-BTPS

35) Did you administer albuterol?

☐ No$_0$ → **Go to 36**
☐ Yes$_1$

35a) If Yes, how many micrograms? ☐☐☐ µg

36) Post-bronchodilator FEV_1 (reported/best): ☐☐.☐☐ L-BTPS

37) Did you administer additional albuterol?

☐ No$_0$ → **Go to 39**
☐ Yes$_1$

37a) If Yes, how many micrograms? ☐☐☐ µg

38) Post-additional bronchodilator FEV_1 (reported/best): ☐☐.☐☐ L-BTPS

POST-BRONCHOSCOPY PROCEDURES STATUS

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

☐ No$_0$ → **Go to 40**
☐ Yes$_1$

39a) Please list relevant adverse events:

_____

_____

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

☐ No$_0$ → **Go to 43**
☐ Yes$_1$

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_1 > 90% of the pre-BD baseline FEV_1

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?

☐ No$_0$ → **Go to 44**
☐ Yes$_1$

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

43b) Date of contact: ☐☐ / ☐☐ / ☐☐☐☐

43c) Were there any problems?

☐ No$_0$ → **Go to 44**
☐ Yes$_1$

43c1) If Yes, please describe: _____

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

☐ No$_0$ → **Go to End**
☐ Yes$_1$

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

44b) Date of contact: ☐☐/☐☐/☐☐☐☐

44c) Were there any problems?

☐ No$_0$ → **Go to End**
☐ Yes$_1$

44c1) If Yes, please describe: _____

END OF FORM