INSTRUCTIONS FOR BRONCHOSCOPY SPECIMEN COLLECTION WORKSHEET BCW, VERSION 4.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Bronchoscopy Specimen Collection Worksheet (BCW) is to be completed during the participant's Bronchoscopy Substudy Visit 2.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected or abstracted. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data, please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Please answer every question on this form.

Item 1. **Oxygen saturation of room air:** Record the participant's pre-bronchoscopy O_2 saturation percentage of room air.

MEDICAL HISTORY AND PHYSICAL

Item 2. **Lab work requirement:** Select only one option among the two possible choices.
- Select No if your center does not require lab work prior to bronchoscopy. [Go to Q3]
- Select Yes if your center does require lab work prior to bronchoscopy.

Item 2a. If yes, describe the required lab work.

Item 2b. **Lab work results:** Select only one option among the two possible choices.
- Select No if the lab work results were normal.
- Select Yes if the lab work results were abnormal.

Item 2c. **Lab results described in 2a and 2b:** Select only one option among the two possible choices.
- Select No if the results of blood work described in 2a and 2b do not make the participant ineligible to proceed with a bronchoscopy.
- Select Yes if the results of blood work described in 2a and 2b make the participant ineligible to proceed with a bronchoscopy. [Go to END]

Item 3. **Limited physical exam:** Select only one option among the two possible choices.
- Select No if the doctor did not perform a limited physical exam. [Go to Q4]
- Select Yes if the doctor did perform a limited physical exam.

Item 3a. **Exam results:** Select only one option among the two possible choices.

- Select No if the doctor's opinion is that there are no other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy study. [Go to Q3b]
- Select Yes if the doctor's opinion is that there are other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy study. [End form after completing Q3a1]

Item 3a1. If yes, describe the physical symptoms or conditions.

Item 3b. **Participant report:** Select only one option among the two possible choices.
- Select No if the participant does not report any new physical symptoms or conditions that would make this participant ineligible for participation in the bronchoscopy study. [Go to Q4]
- Select Yes if the participant does report any new physical symptoms or conditions that would make this participant ineligible for participation in the bronchoscopy study. [End form after completing Q3b1]

Item 3b1. If yes, describe the participant's reported physical symptoms or conditions.

Item 4. **Participant gender:** Select only one option among the two possible choices.
- Select No if the participant is not female. [Go to Q5]
- Select Yes if the participant is female.

Item 4a. **Child-bearing potential:** Select only one option among the two possible choices.
- Select No if the participant's is not of child-bearing potential. [Go to Q5]
- Select Yes if the participant's is of child-bearing potential.

Item 4b. **Pregnancy test results:** Select only one option among the two possible choices.
- Select Negative if the pregnancy test result was negative.
- Select Positive if the pregnancy test result was positive.

PRE-BRONCHOSCOPY STATUS

Item 5. **Medications:** Select only one option among the two possible choices.
- Select No if the participant has not taken any medications within the past 7 days. [Go to Q6]
- Select Yes if the participant has taken any medications within the past 7 days.

Item 5a. **Inhaled Steroids:** Select only one option among the two possible choices.
- Select No if the participant has not taken inhaled steroids within the past 7 days.
- Select Yes if the participant has taken inhaled steroids within the past 7 days.

Item 5b. **Nasal Steroids:** Select only one option among the two possible choices.
- Select No if the participant has not taken nasal steroids within the past 7 days.
- Select Yes if the participant has taken nasal steroids within the past 7 days.

Item 5c. **Oral Steroids:** Select only one option among the two possible choices.
- Select No if the participant has not taken oral steroids within the past 7 days.
- Select Yes if the participant has taken oral steroids within the past 7 days.

Item 5d. **Antibiotics:** Select only one option among the two possible choices.
- Select No if the participant has not taken antibiotics within the past 7 days.
- Select Yes if the participant has taken antibiotics within the past 7 days.

Item 5e. **Mucolytics:** Select only one option among the two possible choices.
- Select No if the participant has not taken mucolytics within the past 7 days.
- Select Yes if the participant has taken mucolytics within the past 7 days.

Item 6. **Acute exacerbation:** Select only one option among the two possible choices.
- Select No if the participant did not have an acute exacerbation of COPD (requiring antibiotics and/or steroids) in the past 3 months. [Go to Q7]
- Select Yes if the participant did have an acute exacerbation of COPD (requiring antibiotics and/or steroids) in the past 3 months.

Item 6a. If yes, record the date of onset of the acute exacerbation in mm/dd/yyyy format.

Item 7. **Spirometry:** Select only one option among the two possible choices.
- Select No if spirometry was not done today.
- Select Yes if spirometry was done today. [Go to Q8]

Item 7a. If no, record the date of the most recent spirometry completed in mm/dd/yyyy format.

Item 8. **Pre-bronchodilator FEV_1:** Record the best pre-bronchodilator result from today or from the date entered in 7a.

Item 9. **Additional albuterol:** Select only one option among the two possible choices.
- Select No if additional albuterol was not administered today. [Go to Q10]
- Select Yes if additional albuterol was administered today.

Item 9a. If yes, record how many micrograms of additional albuterol were administered today.

Item 10. **Post-bronchodilator FEV_1:** Record the best post-bronchodilator result from today or from the date entered in 7a.

BLOOD COLLECTION

Item 11. **Date of blood collection:** Record the date of blood collection in mm/dd/yyyy format.

Item 12. **Time of blood collection:** Record the time of blood collection.

Item 13. **Venipuncture attempts:** Record the number of venipuncture attempts.

Item 14. **Blood drawing incidents or problems:** Select only one option among the two possible choices.
- Select No if there were no blood drawing incidents or problems. [Go to Q16]
- Select Yes if there were blood drawing incidents or problems.

NOTE: If there was a blood drawing problem or incident other than those listed in 14a-14g, describe in Q15.

Item 14a. **Sample not drawn:** Select only one option among the two possible choices.
- Select No if the sample was drawn. [Go to 14b]
- Select Yes if the sample was not drawn.

Item 14a1. If yes, specify which tube(s) were not drawn.

Item 14b. **Partial sample drawn:** Select only one option among the two possible choices.
- Select No if a complete sample was drawn. [Go to 14c]
- Select Yes if a partial sample was drawn.

Item 14b1. If yes, specify which tube(s) were partially drawn.

Item 14c. **Tourniquet reapplied:** Select only one option among the two possible choices.
- Select No if the tourniquet was not reapplied. [Go to 14d]
- Select Yes if the tourniquet was reapplied.

Item 14c1. If yes, specify which tube(s) were affected.

Item 14d. **Fist clenching:** Select only one option among the two possible choices.
- Select No if there was no fist clenching. [Go to 14e]
- Select Yes if there was fist clenching.

Item 14d1. If yes, specify which tubes were affected by fist clenching.

Item 14e. **Needle movement:** Select only one option among the two possible choices.
- Select No if there was no needle movement. [Go to 14f]
- Select Yes if there was needle movement.

Item 14e1. If yes, specify which tube(s) were affected by needle movement.

Item 14f. **Participant reclining:** Select only one option among the two possible choices.
- Select No if the participant was not reclining. [Go to 14g]
- Select Yes if the participant was reclining.

Item 14f1. If yes, specify which tube(s) were affected by the participant reclining.

Item 14g. **Sample re-drawn:** Select only one option among the two possible choices.
- Select No if the sample was not re-drawn. [Go to 15]
- Select Yes if the sample was re-drawn.

Item 14g1. If yes, specify which tube(s) were re-drawn.

Item 15. **Blood drawing problems not listed:** Describe any blood drawing incidents or problems (such as fasting status, etc.) not listed in 14a-14g.

Item 16. **Phlebotomist's staff code:** Enter the phlebotomist's staff code.

NASAL EPTHELIAL SWABS

Item 17. **Nasal swabs:** Select only one option among the two possible choices.
- Select No if nasal swabs were not done. [Go to Q19]
- Select Yes if nasal swabs were done.

Item 18. **Nasal specimen source:**

Item 18a. **Right nare:** Record the number of swabs completed in right nare.

Item 18b. **Left nare:** Record the number of swabs completed in left nare.

Item 18c. **Nasal swab collection time:** Record the time of nasal swab collection.

ORAL RINSE

Item 19. **Tongue scraping:** Select only one option among the two possible choices.
- Select No if the tongue scraping was not collected. [Go to Q20]
- Select Yes if the tongue scraping was collected.

Item 19a. If yes, record the time of tongue scraping collection.

Item 20. **Oral Rinse:** Select only one option among the two possible choices.
- Select No if the oral rinse was not collected. [Go to Q21]
- Select Yes if the oral rinse was collected.

Item 20a. **Oral rinse collection time:** Record the time of oral rinse collection.

Item 20b. **Time between oral rinse and bronchoscopy:** Select only one option among the two possible choices.
- Select No if the time between oral rinse and bronchoscopy was 60 minutes or less. [Go to Q21]
- Select Yes if the time between oral rinse and bronchoscopy was more than 60 minutes.

Item 20b1. **Additional tongue scraping**: Select only one option among the two possible choices.
- Select No if an additional tongue scraping was not collected. [Go to Q21]
- Select Yes if an additional tongue scraping was collected.

BRONCHOSCOPY PROCEDURES

Item 21. **Saline Alone sample:** Select only one option among the two possible choices.
- Select No if the Saline Alone sample was not collected.
- Select Yes if the Saline Alone sample was collected.

Item 22. **Saline through the scope sample:** Select only one option among the two possible choices.
- Select No if the Saline through the Scope sample was not collected.
- Select Yes if the Saline through the Scope sample was collected.

Item 23. **Protected Brush specimens:** Select only one option among the two possible choices.
- Select No if the Protected Brush specimens (x3 in the lower lob) were not collected. [Go to Q24]
- Select Yes if the Protected Brush specimens (x3 in the lower lob) were collected.

Item 23a. If yes, indicate which lobe.

Item 23b. If yes, indicate which segment.

Item 23c. If yes, record the number of specimens collected.

Item 23d. If yes, record the collection time.

Item 24. **Airway Wash specimens:** Select only one option among the two possible choices.

- Select No if the Airway Wash specimens (data from first and second wash combined) were not collected. [Go to Q25]
- Select Yes if the Airway Wash specimens (data from first and second wash combined) were collected.

Item 24a. If yes, indicate which lobe.

Item 24b. If yes, indicate which segment.

Item 24c. If yes, record amount infused.

Item 24d. If yes, record amount returned.

Item 24e. If yes, record the collection time.

Item 25. **Bronchial Alveolar Lavage (BAL) specimens:** Select only one option among the two possible choices.

- Select No if the Bronchial Alveolar Lavage (BAL) specimens (data from both BALs combined) were not collected. [Go to Q26]
- Select Yes if the Bronchial Alveolar Lavage (BAL) specimens (data from both BALs combined) were collected.

Item 25a. If yes, indicate which lobe(s).

Item 25b. If yes, indicate which segment(s).

Item 25c. If yes, record amount infused.

Item 25d. If yes, record amount returned.

Item 25e. If yes, record the collection time.

NOTE: If less than 15cc of fluid was returned from the combined volume of the 20cc wash and the 2x40cc lavage, then the 1x50cc lavage should **not** be performed.

Item 25f. **BAL poor fluid return:** Select only one option among the two possible choices.

- Select No if the BAL was not stopped because of poor fluid return.
- Select Yes if the BAL was stopped because of poor fluid return.

Item 26. **Cytological Brushings for RNA:** Select only one option among the two possible choices.

- Select No if the Cytological Brushings for RNA (x3 for RNA in ipsilateral lower lobe) were not collected. [Go to Q27]
- Select Yes if the Cytological Brushings for RNA (x3 for RNA in ipsilateral lower lobe) were collected.

Item 26a. If yes, indicate which lobe.

Item 26b. If yes, indicate which segment.

Item 26c. If yes, record the number of brushes collected.

Item 26d. If yes, record the collection time.

Item 27. **Cytological Brushings for DNA:** Select only one option among the two possible choices.
- Select No if the Cytological Brushings for DNA (x2 for DNA in ipsilateral lower lobe) were not collected. [Go to Q28]
- Select Yes if the Cytological Brushings for DNA (x2 for DNA in ipsilateral lower lobe) were collected.

Item 27a. If yes, indicate which lobe.

Item 27b. If yes, indicate which segment.

Item 27c. If yes, record the number of brushes collected.

Item 27d. If yes, record the collection time.

Item 28. **Microcytology Brushes for mucin:** Select only one option among the two possible choices.
- Select No if the Microcytology Brushes for mucin (x2 in ipsilateral upper lobe bronchi) were not collected. [Go to Q29]
- Select Yes if the Microcytology Brushes for mucin (x2 in ipsilateral upper lobe bronchi) were collected.

Item 28a. If yes, indicate which lobe.

Item 28b. If yes, indicate which segment.

Item 28c. If yes, record the number of brushes collected.

Item 28d. If yes, record the collection time.

Item 29. **Small Airway Epithelial Brushings (optional):** Select only one option among the two possible choices.
- Select No if the Small Airway Epithelial Brushings were not collected. [Go to Q30]
- Select Yes if the Small Airway Epithelial Brushings were collected.

Item 29a. If yes, indicate which lobe(s).

Item 29b. If yes, indicate which segment(s).

Item 29c. If yes, record the number of brushes collected.

Item 29d. If yes, record the collection time.

Item 30. **Lidocaine 1% used:** Record the amount of Lidocaine 1% used.

Item 31. **Lidocaine 2% used:** Record the amount of Lidocaine 2% used.

Item 32. **Lidocaine 4% used:** Record the amount of Lidocaine 4% used.

Item 33. **Deviations from planned protocol:** Select only one option among the two possible choices.
- Select No if there were no deviations from the planned bronchoscopy collection protocol. [Go to Q34]
- Select Yes if there were deviations from the planned bronchoscopy collection protocol.

Item 33a. If yes, elaborate with detailed comments.

Item 34. **Post-bronchoscopy pulmonary function testing:** Select only one option among the two possible choices.
- Select No if there was no post-bronchoscopy pulmonary testing done. [Go to Q40]
- Select Yes if there was post-bronchoscopy pulmonary testing done.

Item 35. **Pre-bronchodilator FEV_1:** Record the best post-bronchoscopy, pre-bronchodilator result.

Item 36. **Additional albuterol:** Select only one option among the two possible choices.
- Select No if additional albuterol was not administered post-bronchoscopy, pre-bronchodilator. [Go to Q37]
- Select Yes if additional albuterol was administered post-bronchoscopy, pre-bronchodilator.

Item 36a. If yes, record how many micrograms of additional albuterol were administered post-bronchoscopy, pre-bronchodilator.

Item 37. **Post-bronchodilator FEV_1:** Record the best post-bronchoscopy, post-bronchodilator result.

Item 38. **Additional albuterol:** Select only one option among the two possible choices.
- Select No if additional albuterol was not administered post-bronchoscopy, post bronchodilator. [Go to Q40]
- Select Yes if additional albuterol was administered post-bronchoscopy, post-bronchodilator.

Item 38a. If yes, record how many micrograms of additional albuterol were administered post-bronchoscopy, post-bronchodilator.

Item 39. **Post-bronchodilator FEV_1:** Record the best post-bronchoscopy, post-bronchodilator reading.

POST-BRONCHOSCOPY PROCEDURES STATUS

Item 40. **Adverse Events:** Select only one option among the two possible choices.
- Select No if the participant did not experience any adverse events during the bronchoscopy. [Go to Q41]
- Select Yes if the participant did experience any adverse events during the bronchoscopy.

Item 40a. If yes, list all relevant adverse events.

Item 41. **Overnight observation:** Select only one option among the two possible choices.
- Select No if the participant did not need to be admitted for overnight observation post bronchoscopy. [Go to Q44]
- Select Yes if the participant did need to be admitted for overnight observation post bronchoscopy.

Item 42. **Discharge:** Check all that applied upon participant's discharge

Item 42a. Check box if participant was alert/responsive upon discharge.

Item 42b. Check box if participant was oriented to time, person, place upon discharge.

Item 42c. Check box if participant's heart rate was less than 100/min upon discharge.

Item 42d. Check box if participant could ambulate without difficulty upon discharge.

Item 42e. Check box if participant could take sips of water without difficulty or cough upon discharge.

Item 42f. Check box if post-bronchoscopy pulmonary function testing was done and FEV1 was greater than 90% of the pre-BD baseline FEV1 upon discharge.

Item 42g. Check box if participant had no complaints of chest discomfort upon discharge.

Item 43. **Additional comments regarding discharge:** Record any additional comments you have regarding the participant upon discharge.

POST-DISCHARGE FOLLOW-UP

Item 44. **Participant contact night of bronchoscopy procedure:** Select only one option among the two possible choices.

- Select No if the participant was not contacted the night of the bronchoscopy procedure. [Go to Q45]
- Select Yes if the participant was contacted the night of the bronchoscopy procedure.

Item 44a1. If yes, record the staff code of the person who contacted the participant.

Item 44A2. If yes, record the date of contact.

Item 44B. Select only one option among the two possible choices.

- Select No if there were no problems reported by the participant on the night of the bronchoscopy procedure. [Go to Q45]
- Select Yes if there were problems reported by the participant on the night of the bronchoscopy procedure.

Item 44b1. If yes, describe the problems reported by the participant on the night of the bronchoscopy procedure.

Item 45. **Participant contact 24 hours after bronchoscopy procedure:** Select only one option among the two possible choices.

- Select No if the participant was not contacted 24 hours after the bronchoscopy procedure. [Go to END]
- Select Yes if the participant was contacted 24 hours after the bronchoscopy procedure.

Item 45a1. If yes, record the staff code of the person who contacted the participant.

Item 45A2. If yes, record the date of contact.

Item 45B. Select only one option among the two possible choices.

- Select No if there were no problems reported by the participant 24 hours after the bronchoscopy procedure. [Go to END]
- Select Yes if there were problems reported by the participant 24 hours after the bronchoscopy procedure.

Item 45b1. If yes, describe the problems reported by the participant 24 hours after the bronchoscopy procedure.

Save and close the form.