INSTRUCTIONS FOR INDUCED SPUTUM WORKSEET
FOR POST ALBUTEROL FEV_1 > 50% PREDICTED VALUE
ISW, VERSION A (QxQ)

I. GENERAL INSTRUCTIONS

The Induced Sputum Worksheet is filled out by the clinician performing the sputum induction at the baseline visit.

The sputum sample should be kept on ice throughout the induction procedure. A second specimen cup labeled "waste" should be used to capture any saliva-salt water expectorant.
The participant should be encouraged to use the "waste" cup, rather than to swallow any fluid build up.

Participants whose initial FEV1 is less than 35% predicted should not be included in the sputum induction portion of SPIROMICS.

The clinician conducting the sputum induction should confirm in DMS that a complete medical history and current health status assessments were completed during the Fasting block (first block) of the study visit.

Participants should have fasted for two hours prior to the induction.
Vital sign assessment (heart rate, respirations, temperature and blood pressure) should be repeated prior to sputum induction.

For participants without COPD, only those with asthma will be treated with a bronchodilator.

If at any timed point during the procedure the spirometry drops between 10-19% of post-bronchodilator baseline you may continue the test, but <u>never</u> increase the concentration of saline.

If at any point during the procedure, a participant's FEV1 decreases by 20% from baseline or if the subject becomes distressed and requests that the test be terminated the procedure must be stopped immediately.

Always be prepared to administer a dose of albuterol if necessary. If a second dose of albuterol is given perform spirometry after 10 minutes. The participant should not be discharged unless the FEV1 is within 10% of baseline, and lung sounds and vital signs have been assessed and are within normal range.

Once a test is terminated it may not be re-started under any circumstances.

A peak flow meter or other device capable of assessing FEV1 may be used in place of a spirometer if a spirometer is not available or to reduce participant fatigue.

If there is any question about the quality of the effort, allow the participant to rest for another minute or so and repeat.

The participant should be seated in a non-rolling chair and instructed to relax and to inhale through the mouth and exhale through the nose when breathing saline.

The sputum sample should be kept on ice throughout the induction procedure. A second specimen cup labeled "waste" should be used to capture any saliva-salt water expectorant.
The participant should be encouraged to use the "waste" cup, rather than to swallow any fluid build up.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form.

FORM DATE: Record date this is being completed. Select the date from the pop up calendar or type in the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

INITIALS: Record the staff code of the person entering the data on this form. 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

Item 1a. Record best *post albuterol* FEV1 value.

Item 1b. Calculate and record what a 10% fall in the best *post albuterol* FEV1 is. *This is the threshold value to determine whether or not to increase saline concentration.*

Item 2a. Record best *post albuterol* FEV1 value.

Item 2b. Calculate and record what a 20% fall in the best *post albuterol* FEV1 value is. *This is the threshold value to determine whether or not to continue the induction.*

Item 3. Albuterol prior to induction: Record Y (Yes) or N (No) if a dose of albuterol was administered prior to the sputum induction.

Item 3a. Was this a re-dosing: Record Y (Yes) if this was a re-dosing because over 165 minutes have passed since the initial bronchodilator dose for PFTs. Record N (No) if this was not a re-dosing of bronchodilator after PFTs.

Item 3b. Number of puffs of albuterol: Record the number of puffs of albuterol given.

Item 4. Trial 1: Record baseline FEV1 in Liters.

Item 5. Trial 2: Record baseline FEV1 in Liters.

Item 6. Trial 3: Record baseline FEV1 in Liters.

Item 7. Record the name of the qualified healthcare provider (MD, RN, RCP) or PI that reviewed the baseline spirometry.

Item 8. Check Yes if spirometry is in acceptable range to continue. Check No if it is not in acceptable range to continue (less than 35% predicted). If No skip out of form.

Item 9. Trial 1: Record 10 minute post albuterol FEV1 in Liters.

Item 10. Trial 2: Record 10 minute post albuterol FEV1 in Liters.

Item 11. Trial 3: Record 10 minute post albuterol FEV1 in Liters.

First 7-Minute Inhalation Period:

Start induction with 15ml of 3% saline. Start timer for 7 minutes. At the end of 2 minutes, stop the timer and nebulizer. Perform spirometry or peak flow to assess FEV1. It is acceptable to only obtain one effort at this point, if it is technically acceptable, and if it falls into the required range.

Item12. 2 minutes at 3% NaCl: Record FEV1 in Liters.

If the fall in FEV1 is less than 20%, restart the timer and nebulizer and continue 3% saline until 7 minutes have elapsed.

Item13. 7 minutes at 3% NaCl: Record FEV1 in Liters.

Have participant perform cleansing and cough procedure to obtain sputum sample per MOP 5.

Repeat spirometry.

If FEV1 has not fallen 10% or more, dispose of remaining saline and put 15ml (or total amount of saline when mixed) of 4% saline into the cup.

If FEV1 has fallen between 10-19% continue at 3% NaCl.

Item 14. Continue Induction: Check Yes if induction is continuing and go to Item 15. Check No if induction is stopping here and go to Item 22.

Item15. % of NaCl used: Check the appropriate box for the concentration of saline used for the second 7-minute induction (3% or 4% NaCl).

Start timer for 7 minutes. At the end of 2 minutes, stop the timer and nebulizer. Perform spirometry or peak flow to assess FEV1.

Second 7-Minute Inhalation Period

Item16. 2 minutes at 3 or 4% NaCl: Record FEV1 in Liters.

If the fall in FEV1 is less than 20%, restart the timer and nebulizer and continue saline until 7 minutes have elapsed.

Have participant repeat cleansing and cough procedure to obtain sputum sample per MOP 5.

Repeat spirometry.

Item17. 7 minutes at 3 or 4% NaCl: Record FEV1 in Liters.

If second 7 minute inhalation was with 4% NaCl and FEV1 has not fallen 10% or more, dispose of remaining saline and put 15ml of 5% saline into the cup.

If FEV1 has fallen between 10-19% continue at same saline concentration as second 7-minute inhalation period.

Item 18. Continue induction: Check Yes if induction is continuing and go to Item 19. Check No if induction is stopping here and go to Item 22.

Third 7-Minute Inhalation Period

Item 19. % of NaCl used: Check the appropriate box for the concentration of saline used for the third 7-minute induction (3%, 4% or 5% NaCl).

Start timer for 2 minutes. At the end of 2 minutes, stop the timer and nebulizer. Perform spirometry or peak flow to assess FEV1.

Item 20. 2 minutes at 3, 4 or 5% NaCl: Record FEV1 in Liters.

If the fall in FEV1 is less than 20%, restart the timer and nebulizer and continue saline until 7 minutes have elapsed.

Have participant repeat cleansing and cough procedure to obtain sputum sample per MOP 5.

Perform final spirometry.

Item 21. 7 minutes at 3, 4 or 5% NaCl: Record FEV1 in Liters

Item 22. Sputum production: Record Y (Yes) or N (No) if the participant was able to produce sputum.

Item 23. Early termination: Record Y (Yes) or N (No) if the induction was terminated early. If response is no, skip out of the form. If yes, answer Items 24-29.

Item 24. Reason for early termination: Record 1 if FEV1 drop = 20% or greater, 2 if participant requested to stop, 3 if other. If other specify in notelog.

Item 25. Additional albuterol: Record Y (Yes) or N (No) if additional albuterol was administered after the FEV1 drop of 20% or greater. If no, skip out of form.

Item 26. Trial 1: Record FEV1 in Liters

Item 27. Trial 2: Record FEV1 in Liters

Item 28. Trial 3: Record FEV1 in Liters

Item 29. Note reason and time point obtained: