INSTRUCTIONS FOR INDUCED SPUTUM WORKSHEET FORM
ISW, VERSION 5.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Induced Sputum Worksheet Form is completed during the participant's Clinic Visit 5.

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. Form Date: Record the date form was completed. 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.

0c. 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.

0d. Procedure Start Time: Record the time the procedure began in hours:minutes in 24-hour clock time.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Item 0e. **Sputum induction performed** Select only one option among the two possible choices

- Select No if participant is unable to perform sputum induction
- Select Yes if participant is able to perform sputum induction [Go to 1]

Item 0f. **Reason sputum induction not performed** Select only one option among the possible choices

- Select first option if during the day participant was not able to perform acceptable spirometry
- Select second option if the site Principal Investigator felt sputum induction not safe for participant
- Select third option if participant refused sputum induction
- Select fourth option if there are other reason sputum induction was not performed on participant

Item 0f1. **Specify Other** Record reason sputum induction was not performed on participant in the space provided. For example, participant had to leave, participant prefers to complete on an alternate day, etc.

All options above with the exception of the fourth option, the participant may return within the 42-day window for the induction.

If sputum induction was not performed go to 26 after completing 0f.

Item 1. **Re-dosed with Albuterol immediately prior to sputum induction if >165 minutes elapsed since initial bronchodilator dose for PFTs** Select only one option among the two possible choices.

- Select No if the participant was not given albuterol prior to sputum induction. [Go to Q2]
- Select Yes if the participant was given albuterol prior to sputum induction.

Item 1b. **Number of albuterol puffs** Record the number of albuterol puffs given to the participant in the box provided.

Item 2. **Trial #1 FEV_1** Record the value of the FEV_1 during pre-sputum induction the first time it is measured.

Item 3. **Trial #2 FEV_1** Record the value of the FEV_1 during pre-sputum induction the second time it is measured.

Item 4. **Trial #3 FEV_1** Record the value of the FEV_1 during pre-sputum induction the third time it is measured.

Item 5. **Spirometry reviewer** Record the name of the study staff healthcare provider (MD, RN RCP) or PI who reviewed the baseline spirometry measures.

Item 6. **Spirometry ok to continue** Select only one option among the two possible choices.

- Select No if the spirometry measures reviewer deems that spirometry is not acceptable to continue. [Go to End 19]
- Select Yes if the spirometry measures reviewer deems that spirometry is acceptable to continue.

Item 7. **10% fall** enter the best FEV_1 value from Trial #1-3 for calculations. CDART will calculate the value entered for best FEV_1 multiplying that number by 0.9. Calculated value will prefill in the box provided once the form is saved then click on the double arrows  . Use this calculated value to determine if saline is to be increased to 3% after the first 7 min.

Item 8. **20% fall** enter the best FEV_1 value from Trial #1-3 for calculations. CDART will calculate the best FEV_1 multiplying that number by 0.8. Calculated value will prefill in the box provided. Once the form is saved then click on the double arrows  . Use this calculated value to discontinue procedure, give albuterol. Perform PFTs at 10 minutes.

First seven minutes measure:

Item 9. **2 min at 3% NaCl** Record the value of FEV_1 at 2 min at 3% NaCl. If FEV_1 <20% drop, continue.

Item 10. **7 min at 3% NaCl** Record the value of FEV_1 at 7 min at 3% NaCl. If FEV_1 <20% drop, continue.

Item 11. **First 7 minutes complete, continue induction** Select only one option among the two possible choices.

- Select No if after the first 7 minutes are complete, if FEV_1 $\geq$20% drop STOP induction. [Go to Q19]
- Select Yes if after the first 7 minutes are complete FEV_1 <10% or 10-19% drop, continue induction.

Item 12. **% NaCl used** Select only one option among the two possible choices.

- Select 3% NaCl continue using 3% NaCl if FEV_1=11-19% drop during the first 7 minutes of induction.
- Select 4% NaCl if FEV_1 <10% drop during the first 7 minutes of induction.

Second seven minutes measure:

Item 13.**2 min at 3% or 4% NaCl** Record the value of FEV_1 at 2 min. If FEV_1 <20% drop, continue.

Item 14.**7 min at 3% or 4% NaCl** Record the value of FEV_1 at 7 min. If FEV_1 <20% drop, continue.

Item 15. **Second 7 minutes complete, continue induction** Select only one option among the two possible choices.

- Select No if after the second 7 minutes are complete FEV_1 $\geq$20% drop, STOP induction. [Go to Q19]
- Select Yes if after the second 7 minutes are complete FEV_1 <10% drop or FEV_1 =10-19% drop, continue induction.

Item 16. **% NaCl used** Select only one option among the three possible choices.

- Select 3% NaCl if induction continue and 3% NaCl was used during the second 7 minutes. Continue this concentration if concentration was not increased in step 12.
- Select 4% NaCl if induction continue and 3% NaCl was used during the second 7 minutes of induction increase to 4% NaCl if FEV1 = 10-19% drop.
- Select 5% NaCl if induction continue and 4% NaCl was used during the second 7 minutes of induction increase to 5% NaCl if FEV1 <10% drop.

Third seven-minute measure:

Item 17.**2 min at 3%, 4% or 5% NaCl** Record the value of FEV_1 at 2 min if FEV_1 <20% drop, continue.

Item 18.**7 min at 3%, 4% or 5% NaCl** Record the final value of FEV_1 at 7 min, induction complete.

Item 18a. Third 7 minutes complete, Select only one option among the two possible choices.

- Select No if induction was not complete in the third 7 minutes.
- Select Yes if induction was complete after the third 7 minutes.

Item 19. **Procedure End Time** Record the time the procedure ended in hours:minutes in 24-hour clock time.

Item 20. **Induction ended early** Select only one option among the two possible choices.

- Select No if the induction was not ended early. [Go to Q22]
- Select Yes if the induction was ended early.

Item 21. **Reason terminated early** Select only one option among the three possible choices.

- Select FEV_1 dropped $\geq$20% if the induction was ended early because the participant's FEV_1 dropped $\geq$20%.
- Select Participant requested to stop if the induction was ended early because the participant requested to stop.
- Select Other if the induction was ended early because another reason.

Item 21a. **Specify other** Record the other reason the induction was ended early in the space provided.

Item 22. **Participant required additional albuterol** Select only one option among the two possible choices.

- Select No if the participant was not given a second dose of albuterol during the sputum induction process. [Go to 26]
- Select Yes if the participant was given a second dose of albuterol during the sputum induction process.

Note: If participant's FEV_1 dropped $\geq$20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

Item 23. **Trial #1 FEV_1** Record the value of FEV_1 at post-induction spirometry the first time it is measured.

Item 24. **Trial #2 FEV_1** Record the value of FEV_1 at post-induction spirometry the second time it is measured.

Item 25. **Trial #3 FEV_1** Record the value of FEV_1 at post-induction spirometry the third time it is measured.

Item 26. **Participant able to produce sputum** Select only one option among the two possible choices.

- Select No if the participant was unable to produce neither an induced sample nor a spontaneous sample.
- Select Yes if the participant was able to produce an induced (ONLY) sample during induction process.
- Select Yes if the participant produced both an induced sample and a spontaneous sample during induction process.
- Select Yes if the participant produced a spontaneous sample prior to induction.

When selecting Yes for Item 26 pay close attention to the type of sample that was collected when selecting from the drop down menu on this field in CDART

Save and close the form.