



## INSTRUCTIONS FOR INDUCED SPUTUM WORKSHEET FORM ISP, VERSION 3.0, 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 1. **Baseline #1 FEV<sub>1</sub>** Record the value of the FEV<sub>1</sub> at baseline the first time it is measured.

Item 2. **Baseline #2 FEV<sub>1</sub>** Record the value of the FEV<sub>1</sub> at baseline the second time it is measured.

Item 3. **Baseline #3 FEV<sub>1</sub>** Record the value of the FEV<sub>1</sub> at baseline the third time it is measured.

Item 4. **Baseline spirometry reviewer** Record the name of the study staff member who reviewed the baseline spirometry measures.

Item 5. **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]
- Select Yes if the spirometry measures reviewer deems that spirometry is acceptable to continue.

Item 6. **Trial #1 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at 10 min post albuterol the first time it is measured.

Item 7. **Trial #2 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at 10 min post albuterol the second time it is measured.

Item 8. **Trial #3 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at 10 min post albuterol the third time it is measured.

Item 9. **10% Fall** Use the use best post albuterol FEV<sub>1</sub> to record the value of FEV<sub>1</sub> the multiply that number by 0.9. Enter the calculated number into the box provided. Use this calculated value to determine if saline is to be increased to 3% after the first 7 min.

Item 10. **20% Fall** Use the use best post albuterol FEV<sub>1</sub> to record the value of FEV<sub>1</sub> the multiply that number by 0.8. Enter the calculated number into the box provided. Use this calculated value indicates a 20% drop in FEV<sub>1</sub>, discontinue tests, give albuterol. Perform PFTs at 10 minutes.

Item 11. **Albuterol prior to sputum induction** Select only one option among the two possible choices.

- Select No if the participant was not given albuterol prior to sputum induction. [Go to Q12]
- Select Yes if the participant was given albuterol prior to sputum induction.

Item 11a. **Albuterol redosing** Select only one option among the two possible choices.

- Select No if the albuterol given to the participant prior to sputum induction was not a redosing (e.g., >165 minutes after initial bronchodilator dose for PFTs).
- Select Yes if the albuterol given to the participant prior to sputum induction was a redosing (e.g., >165 minutes after initial bronchodilator dose for PFTs).

Item 11b. **Number of albuterol puffs** Record the number of albuterol puffs given to the participant in the box provided.

### First measure:

Item 12. **1 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 1 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 13. **2 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 14. **5 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 5 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 15. **7 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 0.9% NaCl.

Item 16. **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, induction did not continue. [Go to Q27]
- Select Yes if after the first 7 minutes are complete, induction did continue.

Item 17. **% NaCl used** Select only one option among the two possible choices.

- Select 0.9% NaCl if 0.9% NaCl was used during the first 7 minutes of induction.
- Select 3% NaCl if 3% NaCl was used during the first 7 minutes of induction.

**Note:** If FEV<sub>1</sub> <10% drop, then increase to 3% NaCl after sample is collected.  
If FEV<sub>1</sub> =11-19% drop, then continue at 0.9% NaCl.  
If FEV<sub>1</sub> >20% drop, then stop induction procedure.

### Second measure:

Item 18. **1 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 1 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 19. **2 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 20. **5 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 5 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 21. **7 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 0.9% NaCl.

Item 22. **Second 7 minutes complete, continue induction** Select only one option among the two possible choices.

- Select No if after the first 7 minutes are complete, induction did not continue. [Go to Q27]
- Select Yes if after the first 7 minutes are complete, induction did continue.

**Note:** If continuing, use same saline concentration.

**Third measure:**

Item 23. **1 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 1 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 24. **2 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 25. **5 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 5 min at 0.9% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 26. **7 min at 0.9% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 0.9% NaCl.

Item 26a. **Procedure End Time** Record the time the procedure ended in hours:minutes in 24-hour clock time.

Item 27. **Participant able to produce sputum** Select only one option among the two possible choices.

- Select No if the participant was unable to produce sputum.
- Select Yes if the participant was able to produce sputum.

Item 28. **Induction ended early** Select only one option among the two possible choices.

- Select No if the induction was not ended early. [Go to Q30]
- Select Yes if the induction was ended early.

Item 29. **Reason terminated early** Select only one option among the three possible choices.

- Select FEV<sub>1</sub> dropped >20% if the induction was ended early because the participant's FEV<sub>1</sub> dropped >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 29a. **Specify other** Record the other reason the induction was ended early in the space provided.

**Note:** If participant's FEV<sub>1</sub> dropped >20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

Item 30. **Trial #1 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at post-induction spirometry the first time it is measured.

Item 31. **Trial #2 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at post-induction spirometry the second time it is measured.

Item 32. **Trial #3 FEV<sub>1</sub>** Record the value of FEV<sub>1</sub> at post-induction spirometry the third time it is measured.

Save and close the form.