



## INSTRUCTIONS FOR INDUCED SPUTUM WORKSHEET FORM ISW, 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. Continue at present concentration – do not increase saline concentration.

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. Discontinue tests, give albuterol. Perform PFTs at 10 minutes post administration.

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. **2 min at 3% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 3% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 13. **7 min at 3% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 3% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 14. **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 Q22]
- Select Yes if after the first 7 minutes are complete, induction did continue.

Item 15. **% NaCl used** Select only one option among the two possible choices.

- Select 3% NaCl if 3% NaCl was used during the first 7 minutes of induction.
- Select 4% NaCl if 4% NaCl was used during the first 7 minutes of induction.

**Note:** If FEV<sub>1</sub> <10% drop, then increase to 4% NaCl after sample is collected.

If FEV<sub>1</sub> =11-19% drop, then continue at 3% NaCl.

If FEV<sub>1</sub> >20% drop, then stop induction procedure.

**Second measure:**

Item 16. **2 min at 4% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 4% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 17. **7 min at 4% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 4% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 18. **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 Q22]
- Select Yes if after the first 7 minutes are complete, induction did continue.

Item 19. **% NaCl used** Select only one option among the two possible choices.

- Select 3% NaCl if 3% NaCl was used during the first 7 minutes of induction.
- Select 4% NaCl if 4% NaCl was used during the first 7 minutes of induction.
- Select 5% NaCl if 5% NaCl was used during the first 7 minutes of induction.

**Note:** If you did not increase % NaCl in step 15, then continue at 3% unless FEV<sub>1</sub> >20% drop.

If you did increase NaCl to 4% and FEV<sub>1</sub> <10% drop, then increase to 5%.

If FEV<sub>1</sub> =11-19% drop, then continue at 4% NaCl.

If FEV<sub>1</sub> >20% drop, then stop induction procedure.

**Third measure:**

Item 20. **2 min at 4% NaCl** Record the value of FEV<sub>1</sub> at 2 min at 4% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 21. **7 min at 4% NaCl** Record the value of FEV<sub>1</sub> at 7 min at 4% NaCl. If FEV<sub>1</sub> <20% drop, continue.

Item 21a. **Procedure End Time** Record the time the procedure ended in hours:minutes in 24-hour clock time.

Item 22. **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 23. **Induction ended early** Select only one option among the two possible choices.

- Select No if the induction was not ended early. [Go to Q25]
- Select Yes if the induction was ended early.

Item 24. **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 24a. **Specify other** Record the other reason the induction was ended early in the space provided.

Item 25. **Participant required additional albuterol** Select only one option among the two possible choices.

- Select No if the participant did not require additional albuterol. [Go to End]
- Select Yes if the participant did require additional albuterol.

**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 26. **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 27. **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 28. **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.