



**INSTRUCTIONS FOR EXACERBATION SUBSTUDY
INDUCED SPUTUM WORKSHEET FORM
For post albuterol FEV₁ > 0.8 L and < 1.5 L**

EIP, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Substudy Induced Sputum Worksheet Form is to be completed during the participant's Exacerbation substudy visits if post albuterol FEV₁ > 0.8 L and < 1.5 L. **If FEV₁ > 1.5 L use the EIW form instead of this form.**

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 sputum induction is not performed.
- Select Yes if sputum induction is performed. [Go to Q1]

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

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

Item 0f1. **Specify Other:** In the space provided, record reason sputum induction was not performed on participant.

Note: If sputum induction was not performed go to Q23 after completing item 0f.

- Item 1. **Best pre-sputum induction, pre-bronchodilator FEV₁**: This will be prefilled from SDF3c. (If completing this form on paper, record the best pre-sputum induction, pre-bronchodilator FEV₁ value from the pre-bronchodilator spirometry measurements from SDF3c)
- Item 2. **Best pre-sputum induction, post-bronchodilator FEV₁**: This will be prefilled from SDF5c. (If completing this form on paper, record the best pre-sputum induction, post-bronchodilator FEV₁ value from the post-bronchodilator spirometry measurements from SDF5c)
- Item 3. **10% fall in post-bronchodilator FEV₁**: This item will be prefilled with a calculation of FEV₁ from item 2 above multiplied by 0.9 Use this calculated value to determine if FEV₁ drops below 10%. (If completing this form on paper, this value will need to be calculated by multiplying the value from Item 2 by 0.9)
- Item 4. **20% fall in post-bronchodilator FEV₁**: This item will be prefilled with a calculation of FEV₁ from item 2 above multiplied by 0.8 Use this calculated value to determine if FEV₁ drops below 20%. (If completing this form on paper, this value will need to be calculated by multiplying the value from Item 2 by 0.8)
- Item 5. **FEV₁ 95% of pre-bronchodilator**: This item will be prefilled with a calculation of FEV₁ from item 1 above multiplied by 0.95 Use this calculated value to answer Q15. (If completing this form on paper, this value will need to be calculated by multiplying the value from Item 1 by 0.95)

Instructions: Remind participant to rinse mouth and cheeks thoroughly, gargle - spit into sink. Clear throat, scraping throat and roof of mouth - spit into sink. Blow nose – discard. Deep cough from chest and spit into sputum sample cup. DO NOT HAWK OR SCRAPE when producing sample. Passively bring it past the throat into the cup.

- Item 6. **2 min at 0.9% NaCl**: Select only one option among the two possible choices.
- Select No if sputum was not produced after 2 minutes at 0.9% NaCl.
 - Select Yes if sputum was produced after 2 minutes at 0.9% NaCl. [Go to Q15]

Spirometry if no sputum produced after 2 min at 0.9% NaCl

- Item 7. **FEV₁ drop < 20%**: Select only one option among the two possible choices.
- Select No if FEV₁ does not drop < 20% after 2 minutes at 0.9% NaCl. [Go to Q15]
 - Select Yes if FEV₁ does drop < 20% after 2 minutes at 0.9% NaCl.

- Item 8. **3 min at 0.9% NaCl**: Select only one option among the two possible choices.
- Select No if sputum was not produced after 3 minutes at 0.9% NaCl.
 - Select Yes if sputum was produced after 3 minutes at 0.9% NaCl. [Go to Q15]

Spirometry if no sputum produced after 3 min at 0.9% NaCl

- Item 9a. **FEV₁ drop <10%**: Select only one option among the two possible choices.
- Select No if FEV₁ does not drop < 10% after 3 minutes at 0.9% NaCl.
 - Select Yes if FEV₁ does drop < 10% after 3 minutes at 0.9% NaCl. [Go to Q11]
- Item 9b. **FEV₁ drop 10-19% or more than 200 mL**: Select only one option among the two possible choices.
- Select No if FEV₁ does not drop 10-19% or more than 200 mL (whichever is greater) after 3 minutes at 0.9% NaCl.
 - Select Yes if FEV₁ does drop 10-19% or more than 200 mL (whichever is greater) after 3 minutes at 0.9% NaCl.

- Item 9c. **FEV₁ drop \geq 20% or 400 mL:** Select only one option among the two possible choices.
- Select No if FEV₁ does not drop \geq 20% or 400 mL (whichever is greater) after 3 minutes at 0.9% NaCl.
 - Select Yes if FEV₁ does drop \geq 20% or 400 mL (whichever is greater) after 3 minutes at 0.9% NaCl. [Go to Q15]

Repeat Spirometry effort twice more

- Item 10a. **FEV₁ drop \leq 19% or less than 200 mL:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop \leq 19% or less than 200 mL (whichever is greater)
- Select Yes if FEV₁ does drop \leq 19% or less than 200 mL (whichever is greater)

- Item 10b. **FEV₁ drop \geq 20% or more than 400 mL:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop \geq 20% or 400 mL (whichever is greater).
- Select Yes if FEV₁ does drop \geq 20% or 400 mL (whichever is greater). [Go to Q15]

- Item 11. **5 min at 3% NaCl:** Select only one option among the two possible choices.

- Select No if sputum was not produced after 5 minutes at 3% NaCl.
- Select Yes if sputum was produced after 5 minutes at 3% NaCl. [Go to Q15]

Spirometry if no sputum produced after 5 min at 3% NaCl

- Item 12a. **FEV₁ drop $<$ 10%:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop $<$ 10% after 5 minutes at 3% NaCl.
- Select Yes if FEV₁ does drop $<$ 10% after 5 minutes at 3% NaCl. [Go to Q14]

- Item 12b. **FEV₁ drop 10-19% or more than 200 mL:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop 10-19% or more than 200 mL (whichever is greater) after 5 minutes at 3% NaCl.
- Select Yes if FEV₁ does drop 10-19% or more than 200 mL (whichever is greater) after 5 minutes at 3% NaCl.

- Item 12c. **FEV₁ drop \geq 20% or 400 mL:** Select only one option among the two possible choices

- Select No if FEV₁ does not drop \geq 20% or 400 mL (whichever is greater) after 5 minutes at 3% NaCl.
- Select Yes if FEV₁ does drop \geq 20% or 400 mL (whichever is greater) after 5 minutes at 3% NaCl. [Go to Q15]

Repeat Spirometry effort twice more

- Item 13a. **FEV₁ drop \leq 19% or less than 200 mL:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop \leq 19% or less than 200 mL (whichever is greater).
- Select Yes if FEV₁ does drop \leq 19% or less than 200 mL (whichever is greater).

- Item 13b. **FEV₁ drop \geq 20% or 400 mL:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop \geq 20% or 400 mL (whichever is greater).
- Select Yes if FEV₁ does drop \geq 20% or 400 mL (whichever is greater). [Go to Q15]

Item 14. **5 min at 4% NaCl:** Select only one option among the two possible choices.

- Select No if sputum was not produced after 5 minutes at 4% NaCl.
- Select Yes if sputum was produced after 5 minutes at 4% NaCl.

Final Spirometry

Item 15. **FEV₁ <95% pre-bronchodilator value (from step 5) %:** Select only one option among the two possible choices.

- Select No if FEV₁ does not drop <95% pre-bronchodilator value (from step 5) %
- Select Yes if FEV₁ does drop <95% pre-bronchodilator value (from step 5) %

Item 16. **Procedure End Time:** Record the procedure end time in hours: minutes in 24-hour clock time.

Item 17. **Induction early termination:** Select only one option among the two possible choices.

- Select No if the induction was not terminated early. [Go to Q19]
- Select Yes if the induction was terminated early.

Item 18. **Reason induction terminated early:** Select only one option among the three possible choices.

- Select first option if the reason was FEV₁ dropped $\geq 20\%$.
- Select second option if the reason was participant requested to stop.
- Select third option if the reason was not listed.

Item 18a. **Specify Other:** In the space provided, record reason induction was terminated early.

Item 19. **Additional albuterol:** Select only one option among the two possible choices.

- Select No if the participant did not require additional albuterol. [Go to Q23]
- Select Yes if the participant did require additional albuterol.

NOTE: If participant's FEV₁ dropped $\geq 20\%$ from baseline and/or if a 2nd dose of albuterol was required, a 3 trial spirometry test is to be conducted post the sputum induction and the values recorded in Q20 – Q22.

Item 20. **Trial #1:** Record the first post induction FEV₁

Item 21. **Trial #2:** Record the second post induction FEV₁

Item 22. **Trial #3:** Record the third post induction FEV₁

Item 23. **Sputum sample collection:** Select only one option among the four possible choices.

- Select first option if neither an induced nor spontaneous sample was collected from the participant.
- Select second option if only an induced sample was collected from the participant.
- Select third option if both induced and spontaneous samples were collected from the participant.
- Select fourth option if only a spontaneous sample was collected from the participant.

Save and close the form.