



EXACERBATION SUBSTUDY INDUCED SPUTUM WORKSHEET

For post albuterol FEV₁ > 1.5 L

ID NUMBER:

FORM CODE: EIW
VERSION: 1.0 02/12/2020

Event _____

- 0a) Form Date: / / 0b) Staff Code
- 0c) Date Collected: / /
- 0d) Procedure Start Time: : AM₁ / PM₂ (circle one)

Instructions: This form should be completed during the participant's Exacerbation substudy visits if post albuterol FEV₁ > 1.5 L. If FEV₁ > 0.8 L and < 1.5 L use the EIP form instead of this form.

0e) Was sputum induction performed on this participant?

- No₀
 Yes₁ → **Go to 1**

0f) Reason sputum induction was not performed:

- Participant could not perform acceptable spirometry₁
 PI felt not safe₂
 Participant refused₃
 Other₄

Of1) If other, please specify: _____

Note: If sputum induction was not performed, go to 21 after completing item 0f.

1) Best pre-sputum induction, pre-bronchodilator FEV₁ . L

2) Best pre-sputum induction, post-bronchodilator FEV₁ . L

3) **10% fall in post-bronchodilator FEV₁** .

Calculation: FEV₁ from item 2 above multiplied by 0.9

4) **20% fall in post-bronchodilator FEV₁** .

Calculation: FEV₁ from item 2 above multiplied by 0.8

5) **FEV₁ 95% of pre-bronchodilator** .

Calculation: FEV₁ from item 1 above multiplied by 0.95

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Instructions: Remind subject 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.

6)	5 min at 4% NaCl Sputum produced?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
7a)	Spirometry Does FEV ₁ drop <10%?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 9
7b)	Does FEV ₁ drop 10-19% or more than 200 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁
7c)	Does FEV ₁ drop ≥20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
8a)	Repeat spirometry effort twice more: Does FEV ₁ drop ≤ 19% or less than 200 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁
8b)	Does FEV ₁ drop ≥20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
9)	5 min at 4% NaCl Sputum produced?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
10a)	Spirometry Does FEV ₁ drop <10%?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 12
10b)	Does FEV ₁ drop 10-19% or more than 200 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁
10c)	Does FEV ₁ drop ≥20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
11a)	Repeat spirometry effort twice more: Does FEV ₁ drop ≤ 19% or less than 200 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁
11b)	Does FEV ₁ drop ≥20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁ → Go to 13
12)	5 min at 4% NaCl Sputum produced?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁
13)	Spirometry Is FEV ₁ <95% pre-bronchodilator value (from question 5)%?	<input type="checkbox"/> No ₀	<input type="checkbox"/> Yes ₁

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14) Procedure End Time: : AM₁ / PM₂ (circle one)

15) Was the induction terminated early?

- No₀ → **Go to 17**
- Yes₁

16) Reason terminated early:

- FEV₁ dropped $\geq 20\%$ ₁
- Participant requested to stop₂
- Other₃

16a) Specify Other: _____

17) Did the participant require additional albuterol?

- No₀ → **Go to 21**
- Yes₁

If participant's FEV₁ dropped $\geq 20\%$ from baseline and/or if a 2nd dose of albuterol was required, conduct a 3 trial spirometry test post the sputum induction and record values here:

FEV₁

18)	Trial #1	
19)	Trial #2	
20)	Trial #3	

21) Was a sputum sample collected from the participant?

- No, Neither Induced or Spontaneous₀
- Yes, Induced Sample₁
- Yes, Induced and Spontaneous Sample₂
- Yes, Spontaneous Sample₃

END OF FORM