SOURCE
SPIROMICS Study of Early COPD Progression

INDUCED SPUTUM WORKSHEET

ID NUMBER:									

FORM CODE: ISP
VERSION: 2.0 09/09/2022

Event: _____

0a) Date of Collection: ☐☐ / ☐☐ / ☐☐☐☐ 0b) Staff Code: ☐☐☐

0c) Procedure Start Time: ☐☐:☐☐ AM_1 / PM_2

Instructions: *This form should be completed during the participant's clinic visit if post albuterol FEV_1 < 50% but ≥ 35% predicted.*

0d) Was sputum induction performed on this participant?

☐ No_0

☐ Yes_1 → **Go to 1**

0e) Reason procedure was not performed:

☐ < 35% FEV_1 prior to sputum induction$_1$

☐ Participant could not perform acceptable spirometry$_2$

☐ PI felt not safe$_3$

☐ Participant refused$_4$

☐ Other$_5$

0e1) If other, please specify: _____

If sputum induction was not performed, go to 30 after completing 0e.

3a11a1) Was the participant redosed with albuterol immediately prior to sputum induction? (e.g., > 165 minutes elapsed since initial bronchodilator dose for PFTs)

☐ No_0 → **Go to 2**

☐ Yes_1

3b11b1a) How many puffs of albuterol was the participant given? ☐ puffs

Record FEV_1 for all participants. Participants that are redosed perform and record 10 minutes post albuterol.

		Pre-Sputum Induction Baseline FEV_1
4a12)	Trial #1	
5a23)	Trial #2	
6a34)	Trial #3	

745) Trial spirometry reviewed by: _____

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85 6) Spirometry ok to continue?

☐ No0 → **Go to 23**

☐ Yes1

1a/1b9/9a 7) 10% fall from ☐☐.☐☐ multiplied by 0.9 is ☐☐.☐☐. Use this value to determine if saline is to be increased to the next highest concentration for next inhalation period (use best FEV_1 from trials 1-3 for calculation).

2a/2b10/10a 8) 20% fall from ☐☐.☐☐ multiplied by 0.8 is ☐☐.☐☐. Use this value to discontinue procedure, give albuterol. Perform PFTs at 10 minutes (use best FEV_1 from trials 1-3 for calculation).

		FEV_1
12a12 9)	1 min at 0.9% NaCl If FEV_1 < 20% drop, continue	
13a13 10)	2 min at 0.9% NaCl If FEV_1 < 20% drop, continue	
14a14 11)	5 min at 0.9% NaCl If FEV_1 < 20% drop, continue	
15a15 12)	7 min at 0.9% NaCl If FEV_1 < 20% drop, continue	
16 13)	First 7 minutes complete, continue induction? If $FEV_1 \geq$ 20% drop, then stop induction procedure.	☐ No0 → **Go to 23** ☐ Yes1
17 13a)	If yes, % NaCl used: **NOTE:** If FEV_1 < 10% drop, then increase to 3% NaCl after sample is collected. If FEV_1 = 10-19% drop, then continue at 0.9% NaCl.	☐ 0.9% $NaCl_1$ ☐ 3% $NaCl_0$
18a18 14)	1 min If FEV_1 < 20% drop, continue	
19a19 15)	2 min If FEV_1 < 20% drop, continue	
20a20 16)	5 min If FEV_1 < 20% drop, continue	
21a21 17)	7 min If FEV_1 < 20% drop, continue	

2218)	Second 7 minutes complete, continue induction? If $FEV_1 \geq$ 20% drop, then stop induction procedure.	☐ No$_0$ → **Go to 23** ☐ Yes$_1$
18a)	If yes, % NaCl used: **NOTE:** If continuing, use same saline concentration if FEV_1 = 10-19% drop. If FEV_1 < 10% drop, use next highest saline concentration.	☐ 0.9% NaCl$_1$ ☐ 3% NaCl$_0$ ☐ 4% NaCl$_2$
23a2319)	1 min If FEV_1 < 20% drop, continue	
24a2420)	2 min If FEV_1 < 20% drop, continue	
25a2521)	5 min If FEV_1 < 20% drop, continue	
26a2622)	7 min *Induction complete.*	
22a)	Did the participant complete the third 7 minutes of the induction?	☐ No$_0$ ☐ Yes$_1$

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!

23) Procedure End Time: ☐☐:☐☐ AM$_1$ / PM$_2$

2824) Was the induction terminated early?

☐ No$_0$ → **Go to 26**
☐ Yes$_1$

2925) Reason terminated early:

☐ FEV_1 dropped $\geq$ 20%$_1$
☐ Participant requested to stop$_2$
☐ Other$_3$

29a25a) Specify Other: _____

3026) Did the participant require additional albuterol?

☐ No$_0$ → **Go to 30**
☐ Yes$_1$

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

FEV_1

31a31 27)	Trial #1	
36a32 28)	Trial #2	
33a33 29)	Trial #3	

30) Was a sputum sample collected from the participant?

- ☐ No, Neither Induced or Spontaneous 0
- ☐ Yes, Induced Sample 1 → **Go to 30b**
- ☐ Yes, Induced and Spontaneous Sample 2 → **Go to End**
- ☐ Yes, Spontaneous Sample 3

30a) Why was an induced sputum sample not collected?

- ☐ Participant unable to produce sample 1
- ☐ Participant refused to produce sample 2
- ☐ Participant requested to stop during collection 3
- ☐ Sample not acceptable 4
- ☐ Other 5

30a1) Specify Other: _____

→ **IF 'No, Neither Induced or Spontaneous' to item 30 above, Go to 30b after item 30a**

→ **IF 'Yes, Spontaneous Sample' to item 30 above, Go to End after item 30a**

30b) Why was a spontaneous sputum sample not collected?

- ☐ Participant unable to produce sample 1
- ☐ Participant refused to produce sample 2
- ☐ Participant requested to stop during collection 3
- ☐ Sample not acceptable 4
- ☐ Other 5

30b1) Specify Other: _____

END OF FORM