SOURCE
SPIROMICS Study of Early COPD Progression

INDUCED SPUTUM WORKSHEET

ID NUMBER:									

FORM CODE: ISW
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 $FEV_1 \geq 50\%$ predicted.*

0d) Was sputum induction performed on this participant?

☐ No_0

☐ Yes_1 → **Go to 1**

0e) Reason procedure was not performed:

☐ Participant could not perform acceptable spirometry$_1$

☐ PI felt not safe$_2$

☐ Participant refused$_3$

☐ Other$_4$

0e1) If other, please specify: _____

If sputum induction was not performed, go to 24 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 17**

☐ Yes1

1a/1b9/9a 7) 10% fall from ☐☐.☐☐ multiplied by 0.9 is ☐☐.☐☐. Continue at present concentration – do not increase saline concentration (use best FEV_1 from trials 1-3 for calculation).

2a/2b10/10a 8) 20% fall from ☐☐.☐☐ multiplied by 0.8 is ☐☐.☐☐. Discontinue tests, give albuterol. Perform PFTs at 10 minutes post administration (use best FEV_1 from trials 1-3 for calculation).

		FEV_1
12a12 9)	2 min at 3% NaCl If FEV_1 < 20% drop, continue	
13a13 10)	7 min at 3% NaCl If FEV_1 < 20% drop, continue	
14 11)	First 7 minutes complete, continue induction? If FEV_1 ≥ 20% drop, then stop induction procedure.	☐ No0 → **Go to 17** ☐ Yes1
15 11a)	If yes, % NaCl used: **NOTE:** If FEV_1 < 10% drop, then increase to 4% NaCl after sample is collected. If FEV_1 = 10-19% drop, then continue at 3% NaCl.	☐ 3% NaCl1 ☐ 4% NaCl0
16a16 12)	2 min If FEV_1 < 20% drop, continue	
17a17 13)	7 min If FEV_1 < 20% drop, continue	
18 14)	Second 7 minutes complete, continue induction? If FEV_1 ≥ 20% drop, then stop induction procedure.	☐ No0 → **Go to 17** ☐ Yes1
19 14a)	If yes, % NaCl used: **NOTE:** If you did not increase % NaCl in step 11a, then continue at 3%. If you did increase NaCl to 4% and FEV_1 < 10% drop, then increase to 5%.	☐ 3% NaCl1 ☐ 4% NaCl2 ☐ 5% NaCl3

	If FEV_1 = 10-19% drop, then continue at 4% NaCl.	
20a20 15)	2 min If FEV_1 < 20% drop, continue	
21a21 16)	7 min *Induction complete.*	
16a)	Did the participant complete the third 7 minutes of the induction?	☐ No0 ☐ Yes1

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!

17) Procedure End Time: ☐☐:☐☐ AM1 / PM2

23 18) Was the induction terminated early?

☐ No0 → **Go to 20**
☐ Yes1

24 19) Reason terminated early:

☐ FEV_1 dropped ≥ 20%1
☐ Participant requested to stop2
☐ Other3

24a 19a) Specify Other: _____

25 20) Did the participant require additional albuterol?

☐ No0 → **Go to 24**
☐ Yes1

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
26a26 21)	Trial #1	
27a27 22)	Trial #2	
28a28 23)	Trial #3	

24) Was a sputum sample collected from the participant?

☐ No, Neither Induced or Spontaneous0
☐ Yes, Induced Sample1 → **Go to 24b**
☐ Yes, Induced and Spontaneous Sample2 → **Go to End**
☐ Yes, Spontaneous Sample3

24a) 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

24a1) Specify Other: _____

→ **IF 'No, Neither Induced or Spontaneous' to item 24 above, Go to 24b after item 24a**

→ **IF 'Yes, Spontaneous Sample' to item 24 above, Go to End after item 24a**

24b) 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

24b1) Specify Other: _____

END OF FORM