SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

TEMPORARY INCLUSION/EXCLUSION CRITERIA

ID NUMBER:									

FORM CODE: **IEC**
VERSION: **1.0 03/03/2025**

Event: _____

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

Instructions: *This form should be completed immediately after the participant signs the informed consent before proceeding with the study visit to determine if the participant is eligible for the study visit at this point in time or if the participant should be re-screened for completion of the study visit at a later date.*

I am going to ask you a few questions to ensure you are eligible for the study visit at this point in time. Please answer as completely and accurately as possible.

Note: Items 1 through 7 were removed.

8) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
8a) You have been diagnosed with severe kyphoscoliosis (severe curvature of the spine) or neuromuscular weakness.	☐	☐
8b) You have been diagnosed with HIV/AIDS.	☐	☐
8c) You have been diagnosed with lung cancer.	☐	☐
8d) You have been diagnosed with a cancer that spread to multiple locations in the body.	☐	☐

I am now going to ask you about some medical procedures you may have had.

9) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
9a) You have had an organ transplant.	☐	☐
9b) You have had endobronchial valve therapy.	☐	☐
9c) You have had difficulties with pulmonary function tests, spirometry, or lung function testing.	☐	☐

Next, I am going to ask you about your medication and drug use as well as problems you may have had with certain medications.

10) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
10a) You have a hypersensitivity to or intolerance of albuterol sulfate, ipratropium bromide, Atrovent, Pro-Air, Ventolin, or Proventil or any components of these inhalers.	☐	☐

10b) You are currently taking prednisone or other corticosteroid at more than 10 mg every day or 20 mg every other day. ☐ ☐

10c) You have used any illegal drugs, not including marijuana, in the past 30 days. ☐ ☐

10d) You have used Ritalin as an IV drug. ☐ ☐

10e) You have used heroin. ☐ ☐

10f) You have used illegal IV drugs at all within the past 10 years. ☐ ☐

10g) You have used illegal IV drugs more than five times ever. ☐ ☐

11) Are you currently taking any immunosuppressives such as CellCept, Imuran, or Cytoxan?

☐ No$_0$ → **Go to 13**

☐ Yes$_1$

11a) If Yes, please list: _____

Note: Item 12 was removed.

I would now like to ask you about conditions that may have occurred in the last six weeks. If one of these applies to you, we will need to re-screen you after six weeks have passed.

13) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
13a) You have had an upper respiratory infection in the past six weeks.	☐	☐
13b) You have had a heart attack within the past six weeks.	☐	☐
13c) You have had unstable heart disease, heart failure, or uncontrolled irregular heartbeat in the past six weeks.	☐	☐
13d) You have had eye, chest, or abdominal surgery within the past six weeks.	☐	☐

Now I would like to ask you about conditions that may have occurred in the last 30 days. If one of these applies to you, we will need to re-screen you after 30 days have passed.

14) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
14a) You have had an acute exacerbation of COPD, either solely participant-identified or that has been clinically treated, in the past 30 days.	☐	☐
14b) You have used additional steroids beyond what you usually take, or you have increased the dose of the steroids you usually take in the past 30 days.	☐	☐

15) Have you taken antibiotics in the last 30 days?

☐ No$_0$ → **Go to 16**
☐ Yes$_1$

15a) Are you taking the antibiotics as part of a long-term or suppressive treatment?

☐ No$_0$
☐ Yes$_1$

15b) Have you been taking these long-term antibiotics continuously for at least six weeks?

☐ No$_0$
☐ Yes$_1$

Instructions: *Item 16 is for female participants only. If the participant is male,* → ***Go to 17****.*

If you have given birth in the last three months, we will need to re-screen you once three months have passed.

16) Have you given birth in the last three months?

☐ No$_0$
☐ Yes$_1$

Instructions: *If the participant answers Yes to any one of the questions 17-22, please consult the study physician regarding impact on eligibility for the study visit at this point in time, which is at their discretion/decision, or whether the participant should be re-screened at a later point in time.*

I have just a few more questions about other diseases that might affect your eligibility for the study visit at this point in time. Please answer to the best of your ability.

17) Have you ever been diagnosed with any other heart or lung disease?

☐ No$_0$ → **Go to 18**
☐ Yes$_1$

17a) Please describe: _____

18) Have you ever had any other kind of lung surgery?

☐ No$_0$ → **Go to 19**
☐ Yes$_1$

18a) Please describe: _____

19) Do you have any other significant illness?

☐ No$_0$ → **Go to 20**
☐ Yes$_1$

19a) Please describe: _____

20) Do you have any metal implants in your chest, including cardiac stents, defibrillator, or pacemaker?

☐ No$_0$ → **Go to 21**
☐ Yes$_1$

20a) Please describe: _____

21) Have you ever or are you currently undergoing chemotherapy or radiation treatments?

☐ No$_0$ → **Go to 22**
☐ Yes$_1$

22) Are you currently enrolled in any other clinical trial or research study?

☐ No$_0$ → **Go to END**
☐ Yes$_1$

22a) Please describe: _____

END OF FORM