BRONCHOSCOPY SUBSTUDY
INCLUSION/EXCLUSION CRITERIA FORM

ID NUMBER: ☐ ☐ ☐ ☐ ☐ ☐ ☐

FORM CODE: **BIE**
VERSION: 3.0 10/11/2019

Event: _____

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

> **_Instructions:_** *This form should be completed immediately after the participant signs the Bronchoscopy substudy informed consent. This form, along with spirometry, determines eligibility for the Bronchoscopy substudy.*

1) Does the participant's age at the time of visit make the participant ineligible?.

☐ No$_0$
☐ Yes$_1$ → **Go to 9**

2) Do you use supplemental oxygen while at rest (sitting or lying down)?

☐ No$_0$ → **Go to 3**
☐ Yes$_1$

   2a) Is the participant's $PaO_2 < 60\%$ or $SaO_2 < 88\%$?

   ☐ No$_0$
   ☐ Yes$_1$

   2b) Does the use of supplemental oxygen described in 2a make the participant ineligible?

   ☐ No$_0$
   ☐ Yes$_1$ → **Go to 9**

3) Are you currently taking any medication that thins your blood, such as anti-platelet medications such as Clopidegrel or Ticagelor, or anticoagulants such as Warfarin, Apixaban, Rivaroxaban, Dabigatran, or other similar medications?

☐ No$_0$ → **Go to 4**
☐ Yes$_1$

   3a) If Yes, please list: _____

   3b) Does the anticoagulant listed in 3a make the participant ineligible?

   ☐ No$_0$
   ☐ Yes$_1$ → **Go to 9**

4) Have you ever been diagnosed with cardiac disease?

☐ No$_0$ → **Go to 5**
☐ Yes$_1$

4a) If yes, please describe: _____

4b) Does the cardiac disease listed in 4a make the participant ineligible?

☐ No$_0$

☐ Yes$_1$ → **Go to 9**

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

☐ No$_0$ → **Go to 6**

☐ Yes$_1$

5a) If yes, please describe: _____

5b) Does the heart or lung disease listed in 5a make the participant ineligible?

☐ No$_0$

☐ Yes$_1$ → **Go to 9**

6) Is participant's post-bronchodilator FEV1 greater than 30% predicted?

☐ No$_0$ → **Go to 9**

☐ Yes$_1$

7) In the opinion of the investigator, are there any other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy substudy?

☐ No$_0$ → **Go to 8**

☐ Yes$_1$ → **Go to 9; after description in 7a**

7a) If yes, please describe: _____

8) Did the study physician order any additional lab tests prior to bronchoscopy?

☐ No$_0$ → **Go to 9**

☐ Yes$_1$

8a) If yes, please describe: _____

8b) Were the results of the lab work abnormal?

☐ No$_0$

☐ Yes$_1$

8c) Do the results of blood work described in 8a and 8b make the participant ineligible?

☐ No$_0$

☐ Yes$_1$

9) Is the participant eligible for enrollment in the SPIROMICS Bronchoscopy Substudy?

☐ No$_0$

☐ Yes$_1$

END OF FORM