



BRONCHOSCOPY INCLUSION/EXCLUSION CRITERIA FORM

ID NUMBER:

FORM CODE: BIE
VERSION: 2.0 03/06/12

Visit
Number

SEQ #

0a) Form Date / /

0b) Staff Code

Instructions: This form should be completed immediately after the participant signs the informed consent. This form, along with spirometry, determines eligibility for the Bronchoscopy substudy. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.

**I am now going to ask you a series of questions to determine if you are eligible for the study.
Please answer as completely and accurately as possible.**

1) (do not ask) Did participant meet all the requirements of the main Spiromics study? (Y/N)

2) (do not ask) Is this participant male or female?.....

Female F

Male M → **Go to Item 3**

2a) Are you of child-bearing potential?

Yes

No.....

Don't know.....

2b) Is there any chance you are is pregnant? (Y/N)

3) How old are you? years

4a) Do you use supplemental oxygen while at rest (sitting or lying down)? (Y/N)

4b) (do not read) Is the subjects PaO2 < 60 or SaO2 <88% (Y/N).....

ID NUMBER:									
------------	--	--	--	--	--	--	--	--	--

FORM CODE: BIE
VERSION: 2.0 03/06/12

Visit Number		
-----------------	--	--

SEQ #			
-------	--	--	--

4c) (do not read) Does the use of supplemental oxygen described in 4a or 4b make the participant ineligible? (Y/N).....

5a) Are you currently taking any medications that thins your blood, such as Warfarin or Clopidogrel? (Y/N).....

5b) If yes, please list _____

5c) (do not ask) Does the anticoagulation listed in 5b make the participant ineligible? (Y/N)

6a) Have you ever been diagnosed with cardiac disease? (Y/N)

6b) Please describe: _____

6c) (do not ask) Does the cardiac disease listed in 6b make the participant ineligible? (Y/N)

7a) Have you ever been diagnosed with any other heart or lung disease? (Y/N)

7b) Please describe: _____

7c) (do not ask) Does the heart or lung disease listed in 7b make the participant ineligible? (Y/N)

8) (do not ask) Is participant's post bronchodilator FEV1 greater than 30% predicted? (Y/N)

9a) (do not ask) 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? (Y/N).....

9b) Please describe: _____

ID NUMBER:									
------------	--	--	--	--	--	--	--	--	--

FORM CODE: BIE
VERSION: 2.0 03/06/12

Visit
Number

--	--

SEQ #

--	--	--

10a)(do not ask) Did the study physician order any additional lab tests prior to
bronchoscopy? (Y/N).....

10b) If yes, please describe: _____

10c) (do not ask) Were the results of the lab work abnormal? (Y/N)

10d) (do not ask) Do the results of blood work described in 10b and 10c
make the participant ineligible? (Y/N).....