



# INCLUSION/EXCLUSION CRITERIA FORM

ID NUMBER:

FORM CODE: IEC  
VERSION: 3.0 8/2/11

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 study eligibility. 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.**

**The first set of questions I am going to ask you will help us determine if you meet the criteria for one of the four categories we discussed when completing the informed consent.**

1) How old are you? .....  years

2) Do you currently or have you ever smoked cigarettes (that is, at least 100 cigarettes in your life)? (Y/N) .....  **→No, skip to 3**

2a) For how many years have you or did you smoke? ..... .

2b) On average, how many packs of cigarettes do you or did you smoke each day? .

2c) (do not ask participant) Participant's number of smoking pack-years (number of years smoking X number of packs per day)..... .

3) Have you ever been diagnosed with COPD, emphysema, or chronic bronchitis? (Y/N)

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

Female ..... F

Male ..... M → **Go to Item 5**

4a) Are you of child-bearing potential?

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Yes .....

No.....

Don't know.....

4b) Is there any chance you are pregnant? (Y/N).....

4c) Do you have plans to become pregnant in the next 3 years? (Y/N).....

5a) How tall are you? .....  inches

5b) How much do you weigh in pounds? .....

5c) (do not ask participant) Participant's BMI ((weight in pounds \* 703)/(height in inches) <sup>2</sup>) .....

**The next few questions ask about several different conditions that effect the lung. If your answer to any of them is yes, please wait until I am done reading and tell me when I am finished. You do not need answer each question individually.**

- Have you been told that you currently have interstitial lung disease, pulmonary fibrosis, cystic fibrosis, or bronchiectasis?
- Have you ever had lung volume reduction surgery or lung resection, that is had a part of your lung removed?
- Do you have active, chronic lung infection, such as tuberculosis?
- Have you had a pulmonary embolism or a clot in your lung in the past 2 years?

6) Do any of these statements apply to you? (Y/N/Don't know) .....

**Next, I am going to ask you about other medical conditions. As before, if your answer to any of them is yes, please wait until I am all done and tell me that when I am finished. You do not need answer each question individually.**

- Have you ever been diagnosed with severe kyphoscoliosis (severe curvature of the spine) or neuromuscular weakness?

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- Have you been diagnosed with HIV/AIDS?
- Have you ever been diagnosed with lung cancer?
- Have you been diagnosed with a cancer that spread to multiple locations in the body?

7) Do any of the above statements apply to you? (Y/N/Don't know) .....

**I am now going to ask you about some medical procedures you may have had in the past. Again, if your answer to any of them is yes, please wait until I am all done and tell me that when I am finished. You do not need answer each question individually.**

- Have you had an organ transplant?
- Have you ever had endobronchial valve therapy?
- Have you ever had difficulties with pulmonary function tests, spirometry, or lung function testing?

8) Do any of the above statements apply to you? (Y/N/Don't know) .....

**Next, I am going to ask you about your medication and drug use as well as problems you may have had in the past with certain medications. If your answer to any of them is yes, please wait until I am all done and tell me that when I am finished. You do not need answer each question individually.**

- Do you have a hypersensitivity to or intolerance of albuterol sulfate, ipratropium bromide, Atrovent, Pro-Air, Ventolin or Proventil or any components of these inhalers?
- Are you currently taking prednisone or other corticosteroid at more than 10mg every day or 20 mg every other day?
- Have you used any illegal drugs, not including marijuana, in the past 30 days?
- Have you ever used Ritalin as an IV drug?
- Have you ever used heroin?
- Have you used illegal IV drugs at all within the past 10 years?
- Have you used illegal IV drugs more than 5 times ever?

9) Do any of the above statements apply to you? (Y/N).....

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10a) Are you currently taking any immunosuppressives such as Cellcept, Immuran, or Cytosan? (Y/N)

10b) If yes, please list \_\_\_\_\_

10c) (do not ask) Does the participant take any immunosuppressives that result in  
ineligibility? (Y/N) .....

**These next questions address a few other issues that may effect your eligibility. If your answer to any of them is yes, please wait until I am all done and tell me that when I am finished. You do not need answer each question individually.**

- Do you plan to leave the area in the next 3 years?
- Do you currently reside in any kind of long-term care facility?
- Are you related by blood to a parent or sibling also participating in this study (that is, they are a biological relative)?

11) Do any of the above statements apply to you? (Y/N) .....

*Temporary Exclusion Criteria* (if yes to any of the following participant will need to be re-screened at a later date):

**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. If your answer to any of them is yes, please wait until I am all done and tell me that when I am finished. You do not need answer each question individually.**

- (COPD Patients only) Have you had a pulmonary exacerbation or worsening of your COPD symptoms, in the past 6 weeks?
- Have you had an upper respiratory infection in the past 6 weeks?
- Have you had a heart attack within the past 6 weeks?
- In the last six weeks, have you been told you have unstable heart disease, heart failure, or uncontrolled irregular heart beat?
- Have you had eye, chest, or abdominal surgery within the past 6 weeks?

12) Do any of the above statements apply to you? (Y/N) .....

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**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 has passed.**

- Have you used additional steroids beyond what you usually take or have you increased the dose of the steroids you usually take in the past 30 days?

13) Do any of the above statements apply to you? (Y/N).....

13a) Have you taken antibiotics in the last 30 days? (Y/N) .....

13b) Are you taking the antibiotics as part of a long-term or suppressive treatment?

(Y/N).....

13c) Have you been taking these long-term antibiotics continuously for at least

six weeks? (Y/N) .....

13d) (do not ask) Does the antibiotic therapy described in 13a-c make the

participant ineligible? (Y/N) .....

**(For female participants only) If you have given birth in the last three months, we will need to re-screen you once three months has passed.**

14) Have you given birth in the last 3 months? (Y/N) .....

*If the participant answers yes to questions 15-20, consult physician regarding eligibility*

**I have just a few more questions about other diseases that might effect your eligibility. Please answer to the best of your ability.**

15a) Have you ever been diagnosed with any other heart or lung disease? (Y/N).....

15b) Please describe: \_\_\_\_\_

15c) (do not ask) Does the heart or lung disease listed in 15b make the

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participant ineligible? (Y/N) .....

16a) Have you ever had any other kind of lung surgery? (Y/N) .....

16b) Please describe: \_\_\_\_\_

16c) (do not ask) Does the lung surgery listed in 16b make the

participant ineligible? (Y/N) .....

17a) Do you have any other significant illness? (Y/N) .....

17b) Please describe: \_\_\_\_\_

17c) (do not ask) Does the illness listed in 17b make the

participant ineligible? (Y/N) .....

18a) Do you have any metal implants in your chest, including cardiac stents, defibrillator, or pacemaker?  
(Y/N) .....

18b) Please describe: \_\_\_\_\_

18c) (do not ask) Does the metal implant listed in 18b make the

participant ineligible? (Y/N) .....

19a) Have you ever or are you currently undergoing chemotherapy or radiation treatments?  
(Y/N) .....

19b) Please describe: \_\_\_\_\_

19c) (do not ask) Does the chemotherapy or radiation treatment listed in 19b make the

participant ineligible? (Y/N) .....

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20a) Are you currently enrolled in any other clinical trial or research study? (Y/N) .....

20b) Please describe: \_\_\_\_\_

20c) Are you part of the control group in this study? .....

Yes ..... Y

No ..... N

Unknown ..... U

Does not apply ..... D

20d) (do not ask) Does the study described in 20b

make the participant ineligible? (Y/N) .....

21) Are you currently or were you ever enrolled in the COPD Gene Study? (Y/N) .....

22) Have you ever been diagnosed with asthma? (Y/N) .....