



## TEMPORARY EXCLUSION CRITERIA FORM

ID NUMBER:									
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FORM CODE: TEC  
VERSION: 2.0 07/07/2020

Event: \_\_\_\_\_

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

**Instructions:** This form should be completed during the phone call conducted to schedule the participant for any clinic visit in order to determine whether the visit should be scheduled or delayed. This form should also be reviewed and completed at the beginning of the participant's clinic visit after informed consent has been obtained to ensure that the visit can be conducted safely. Please note that this study screener will be used in conjunction with any institutional requirements for COVID-19 screening in the days before and immediately at the start of visits.

**Thank you for your participation in the SPIROMICS study. We have made some important findings in COPD and are pleased to say that NIH has funded another SPIROMICS examination. I am calling now to see if you would be interested in participating in this SPIROMICS exam and, if so, to find a convenient time for you to come back in to the clinic and see us. Please note that we are taking every precaution to make sure that this visit is safe for you, and that includes screening you for symptoms of possible COVID-19.**

**Before scheduling the exam, I would like to ask you some questions.**

**Instructions:** If any of the following occurred within the last 6 weeks the participant should be phoned and re-screened after six weeks has passed prior to scheduling the SPIROMICS visit.]

- 1) Do any of the following statements apply to you (within the last 6 weeks)? (click all that apply)
- You have had a pulmonary exacerbation or worsening of your COPD symptoms in the last 6 weeks.
  - You have had an upper respiratory infection (a cold) in the last 6 weeks.
  - You have had a heart attack within the last 6 weeks.
  - You have been told you have unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heart beat within the last 6 weeks.
  - You have had eye, chest, or abdominal surgery within the last 6 weeks.

**Instructions:** If any of the following occurred within the last month the participant should be phoned and re-screened after one month has passed prior to scheduling the SPIROMICS visit.]

- 2) Have you taken antibiotics or steroids for an acute problem within the last month?
- No<sub>0</sub>
  - Yes<sub>1</sub>

**(do not read)** Note: This does not apply to participants who are on chronic prednisone therapy of <10 mg per day or <20 mg every other day or participants who are currently on chronic, prophylactic, or suppressive antibiotic therapy.

**(do not read)** Note: Tuberculosis (TB) is a chronic infection that often affects the lungs and is rare in the US. Active TB is characterized by symptoms such as chronic coughing, coughing up blood, chest pain or pain when breathing or coughing, unintentional weight loss, loss of appetite, fatigue, fever, night sweats, and chills.

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3) Has a physician recently told you that you have active tuberculosis?

- No<sub>0</sub>  
 Yes<sub>1</sub> → **Please review with the SPIROMICS PI before proceeding.**

4) **(do not ask)** What is the sex of the participant?

- Male<sub>1</sub> → **Go to 5**  
 Female<sub>2</sub>

4a) Are you of child-bearing potential?

- No<sub>0</sub> → **Go to 5**  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

**[Instructions:** *If yes to 4a, a pregnancy test should be performed. The SPIROMICS visit, specifically the CT Scan, should only be continued if the participant's pregnancy test is negative.]*

4b) Is there any chance you are pregnant?

- No<sub>0</sub>  
 Yes<sub>1</sub>

4c) Have you given birth in the last 3 months?

- No<sub>0</sub>  
 Yes<sub>1</sub>

**[Instructions:** *If yes to 4c, the participant should be phoned and re-screened a minimum of three months after the birth to schedule the SPIROMICS visit.]*

**Instructions:** *Please indicate if you have experienced new or worsening of any of the following symptoms within the past two weeks.*

5) Fever

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

6) Cough

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

7) Shortness of breath

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

8) Sore throat

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

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9) Muscle aches

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

10) Diarrhea

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

11) Fatigue

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

12) Nasal congestion

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

13) Headache

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

14) Chills/rigors

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

15) New onset loss of smell

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

16) Altered sense of taste

- No<sub>0</sub>
- Yes<sub>1</sub>
- Don't know<sub>2</sub>

**(do not read)** Note: If the participant answered yes or don't know to one or more of the above symptoms within the past two weeks then the participant should be phoned and re-screened after one month has passed prior to scheduling any SPIROMICS visit.

**END OF FORM**