



TEMPORARY EXCLUSION CRITERIA FORM

ID NUMBER:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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FORM CODE: TEC
VERSION: 1.0 08/29/2018

Event: _____

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

Instructions: This form should be completed during the phone call conducted to schedule the participant for clinic visit 5 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 5 after informed consent has been obtained to ensure that the visit can be conducted safely.

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.

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 clinic visit 5.]

- 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 clinic visit 5.]

- 2) Have you taken antibiotics or steroids for an acute problem within the last month?
- No₀
 - Yes₁

(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.

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

No₀
 Yes₁ → **Please review with the SPIROMICS PI before proceeding.**

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

- Male₁ → **Go to END**
 Female₂

4a) Are you of child-bearing potential?

- No₀ → **Go to END**
 Yes₁
 Don't know₂

[Instructions: *If yes to 4a, a pregnancy test should be performed. Clinic visit 5, specifically the CT Scan, should only be continued if the participant's pregnancy test is negative.]*

4b) Is there any chance you are pregnant?

- No₀
 Yes₁

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

- No₀
 Yes₁

[Instructions: *If yes to 4c, the participant should be phoned and re-screened a minimum of three months after the birth to schedule clinic visit 5.]*

END OF FORM