SOURCE
SPIROMICS Study of Early COPD Progression

BRONCHOSCOPY SUB-STUDY
TEMPORARY EXCLUSION CRITERIA FORM

ID NUMBER:									

FORM CODE: TEC
VERSION: 1.0 10/25/2022

Event: _____

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

Instructions: *This form should be completed during the phone call conducted to schedule the participant for the SOURCE Bronchoscopy Sub-study 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 SOURCE Bronchoscopy Sub-study. The following questions we will ask are to take 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 visit, I would like to ask you some questions.

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

1) Do any of the following statements apply to you?

	No$_0$	Yes$_1$
1a) You have had a pulmonary exacerbation or worsening of COPD symptoms, either solely participant-identified or that has been clinically treated, in the last six weeks.	☐	☐
1b) You have had an upper respiratory infection (a cold) in the last six weeks.	☐	☐
1c) You have had a heart attack within the last six weeks.	☐	☐
1d) You have been told you have unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heartbeat within the last six weeks.	☐	☐
1e) You have had eye, chest, or abdominal surgery within the last six weeks.	☐	☐

*[**Instructions:** If any of the following occurred within the last 30 days, the participant should be phoned and re-screened after 30 days has passed prior to scheduling the visit.]*

2) Have you taken antibiotics or steroids for an acute problem within the last 30 days?
☐ No$_0$
☐ Yes$_1$

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.

3) Has a physician recently told you that you have active tuberculosis?
☐ No$_0$
☐ Yes$_1$ → **Please review with the SOURCE PI before proceeding.**

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.

*[**Instructions:** If the participant answers 'Yes' or 'Don't know' to one or more of the following within the past two weeks, the participant should be phoned and re-screened after 30 days have passed prior to scheduling the visit.]*

4) Have you experienced new or worsening of any of the following symptoms within the past two weeks?

		No$_0$	Yes$_1$	Don't know$_2$
4a)	Fever	☐	☐	☐
4b)	Cough	☐	☐	☐
4c)	Shortness of breath	☐	☐	☐
4d)	Sore throat	☐	☐	☐
4e)	Muscle aches	☐	☐	☐
4f)	Diarrhea	☐	☐	☐
4g)	Fatigue	☐	☐	☐
4h)	Nasal congestion	☐	☐	☐
4i)	Headache	☐	☐	☐
4j)	Chills/rigors	☐	☐	☐
4k)	New onset loss of smell	☐	☐	☐
4l)	Altered sense of taste	☐	☐	☐

END OF FORM