



INSTRUCTIONS FOR TEMPORARY EXCLUSION CRITERIA FORM TEC, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Temporary Exclusion Criteria Form should be completed during the phone call conducted to schedule the participant for clinic visit 5 to determine that the participant should in fact be scheduled at that that time.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS staff code of the person who collected the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data, please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Item 1. **Occurred within last 6 weeks.** Select all the options among the five possible choices based on what the subject reports as occurring within the last six weeks.

- Select 'You have had a pulmonary exacerbation or worsening of your COPD symptoms in the last 6 weeks' if the subject reports having a pulmonary exacerbation or worsening of COPD symptoms in the last 6 weeks.
- Select 'You have had an upper respiratory infection (a cold) in the last 6 weeks' if the subject reports having an upper respiratory infection (a cold) in the last 6 weeks.
- Select 'You have had a heart attack within the last 6 weeks' if the subject reports having a heart attack within the last 6 weeks.
- Select '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' if the subject reports being told he/she has unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heart beat within the last 6 weeks.
- Select 'You have had eye, chest, or abdominal surgery within the last 6 weeks' if the subject reports having eye, chest, or abdominal surgery within the last 6 weeks.

Note: If any of the statements apply, the subject should be phoned and re-screened after six weeks has passed prior to scheduling clinic visit 5.

Item 2. **Antibiotics or steroids.** Select only one option among the two possible choices based on what the subject reports as occurring within the past month.

- Select No if the subject reports not taking antibiotics or steroids within the past month.
- Select Yes if the subject reports taking antibiotics or steroids within the past month.

Note: If yes, the subject should be phoned and re-screened after one month has passed prior to scheduling clinic Visit 5. 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.

Item 3. **Active tuberculosis.** Select only one option among the two possible choices.

- Select No if the subject reports not having active tuberculosis.
- Select Yes if the subject reports having active tuberculosis. [Review with PI required 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.

Item 4. **Participant sex.** Select only one option among the two possible choices.

- Select Male if the subject is male. [Go to end]
- Select Female if the subject is female.

Item 4a. **Child-bearing potential.** Select only one option among the two possible choices.

- Select No if the subject reports not having child-bearing potential. [Go to end]
- Select Yes if the subject reports having child-bearing potential.
- Select Don't Know if the subject is unsure.

Note: If yes, 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.

Item 4b. **Chance of pregnancy.** Select only one option among the two possible choices.

- Select No if the subject reports not having any chance of pregnancy.
- Select Yes if the subject reports having chance of pregnancy.

Item 4c. **Given birth in last 3 months.** Select only one option among the two possible choices.

- Select No if the subject reports not giving birth in the last three months.
- Select Yes if the subject reports giving birth in the last three months.

Note: If yes, the participant should be phoned and re-screened a minimum of three months after the birth to schedule clinic visit 5.

Save and close the form.