

INSTRUCTIONS FOR PULMONARY FUNCTION ELIGIBILITY FORM PFE, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Pulmonary Function Eligibility Form is completed during the participant's Clinic Visit 5.

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 or abstracted. 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 or abstracted 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. **Smoked within the last hour.** Select only one option among the two possible choices.
 - Select No if the subject reports not having smoked within the last hour.
 - Select Yes if the subject reports having smoked within the last hour.

If Yes, wait a minimum of 30 minutes prior to conducting PFEs.

- Item 2. **COPD Medication within the last 24 hours.** Select only one option among the two possible choices.
 - Select No if the subject reports not having taken any medication for your COPD within the last 24 hours.
 - Select Yes if the subject reports having taken any medication for your COPD within the last 24 hours. [Go to Q7]
- Item 3. Oral bronchodilator. Select only one option among the two possible choices.
 - Select No if the subject reports not having taken a pill (Metaproterenol, Terbutaline, Theophylline, Theo 24, Theochron, Uniphyl).
 - Select Yes if the subject reports having taken a pill (Metaproterenol, Terbutaline, Theophylline, Theo 24, Theochron, Uniphyl). [Go to Q4]
- Item 3a. **Time take oral bronchodilator**. Record the time that the subject reported taking a pill (Metaproterenol, Terbutaline, Theophylline, Theo 24, Theochron, Uniphyl) in hours:minutes.
- Item 4. Once-a-day bronchodilator. Select only one option among the two possible choices.
 - Select No if the subject reports not having taken a once-a-day inhaled bronchodilator.
 - Select Yes if the subject reports having taken a once-a-day inhaled bronchodilator. [Go to Q5]
- Item 4a. **Time taken once-a-day bronchodilator.** Record the time that the subject reported taking a once-a-day inhaled bronchodilator in hours:minutes.

- Item 5. **Twice-a-day inhaled bronchodilator.** Select only one option among the two possible choices.
 - Select No if the subject reports not having taken a twice-a-day inhaled bronchodilator.
 - Select Yes if the subject reports having taken a twice-a-day inhaled bronchodilator. [Go to Q6]
- Item 5a. **Time taken oral bronchodilator.** Record the time that the subject reported taking a twice-a-day inhaled bronchodilator in hours:minutes.
- Item 6. Short acting (rescue) bronchodilator. Select only one option among the two possible choices.
 - Select No if the subject reports not having taken a short acting (rescue) bronchodilator including by nebulizer (Acuneb, Atrovent, Combivent, Duoneb, ProAir, Proventil, Ventolin, Xopenex).
 - Select Yes if the subject reports having taken a short acting (rescue) bronchodilator including by nebulizer (Acuneb, Atrovent, Combivent, Duoneb, ProAir, Proventil, Ventolin, Xopenex). [Go to Q7]
- Item 6a. **Time taken short acting (rescue) bronchodilator.** Record the time that the subject reported taking a short acting (rescue) bronchodilator including by nebulizer (Acuneb, Atrovent, Combivent, Duoneb, ProAir, Proventil, Ventolin, Xopenex) in hours:minutes.

Note: If <300 minutes since last ipratropium dose or <165 minutes since last short-acting beta agonist dose, see partial dosing instructions in PFE MOP.

- Item 7. **Caffeine-containing beverages.** Select only one option among the two possible choices.
 - Select No if the subject reports not having taken any caffeine-containing beverages (coffee, tea, cola, energy drinks) in the past 6 hours.
 - Select Yes if the subject reports having any caffeine-containing beverages (coffee, tea, cola, energy drinks) in the past 6 hours.

Save and close the form.