FOLLOW-UP EXACERBATION ASSESSMENT FORM, EFA, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Follow-up Exacerbation Assessment Form (EFA) is to be completed during the participant's Exacerbation Substudy Visit 2.

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

Please answer every question on this form.

NOTE: Item 1 will be populated based on the EAF data collection form entry.

Item 1. **Date of Acute Exacerbation Visit 1:** This date will be populated based on the EAF data collection form entry.

Item 2. **Hospitalized or seen in urgent care/emergency facility:** Select only one option among the two possible choices.

- Select No if, after the acute exacerbation visit (visit 1), the participant was not hospitalized or seen in an urgent care/emergency facility for the event.
- Select Yes if, after the acute exacerbation visit (visit 1), the participant was hospitalized or seen in an urgent care/emergency facility for the event.

Item 3. **Returned to baseline status:** Select only one option among the two possible choices.

- Select No if the participant has not returned to baseline status with respect to their respiratory symptoms. [Go to Q4]
- Select Yes if the participant has returned to baseline status with respect to their respiratory symptoms.

Item 3a. Record the number of weeks it took before participant returned to baseline status.

Item 3b. Record the number of days it took before participant returned to baseline status.

Item 4. **Long-term changes to medical care:** Select only one option among the two possible choices.

- Select No if there have not been long-term changes to the participant's medical care since the exacerbation event. [Go to Q5]
- Select Yes if there have been long-term changes to the participant's medical care since the exacerbation event.

Item 4a. Select only one option among the two possible choices.
- Select No if the participant has no new or increased oxygen therapy.
- Select Yes if the participant has new or increased oxygen therapy.

Item 4b. Select only one option among the two possible choices.
- Select No if there have not been changes to the participant's medications. [Go to Q5]
- Select Yes if there have been changes to the participant's medications.

Item 4b1. Specify the changes to the participant's medications.

Physical Assessment/Vital Signs

Item 5. **Body Weight:** Record the participant's body weight in kilograms.

Item 6. **Body Mass Index (BMI):** This value will automatically calculate in the DMS using height from the Visit 5 ANT2 form.

Item 7. **Temperature:** Record the participant's temperature.

Item 8. **Respiratory rate:** Record the participant's respiratory rate.

Item 9. **Heart rate:** Record the participant's heart rate.

Item 10. **Systolic blood pressure:** Record the participant's systolic blood pressure.

Item 11. **Diastolic blood pressure:** Record the participant's diastolic blood pressure.

Item 12. **O2 saturation:** Record the participant's O2 saturation.

Item 12a. Select only one option among the two possible choices.
- Select No if supplemental oxygen is not used. [Go to Q11]
- Select Yes if supplemental oxygen is used.

Item 12a1. Specify how much supplemental oxygen is used.

Principal Investigator Assessment

Item 8. **Principal Investigator's assessment:** Select only one option among the three possible choices.
- Select No if the Principal Investigator determines this event was not an Acute Exacerbation COPD (AECOPD).
- Select Yes if the Principal Investigator determines this event was an Acute Exacerbation COPD (AECOPD).

Save and close the form.