INSTRUCTIONS FOR EXACERBATION ASSESSMENT FORM (VISIT 1)
EAF, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Assessment Form (Visit 1) (EAF) is to be completed during the participant's Exacerbation Substudy Visit 1.

Please note that items 1 and 2 will be populated based on the Telephone Exacerbation Assessment (TEA) data collection form entry.

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.

Item 1. **Date of phone contact:** This field will be populated with the date from the Telephone Exacerbation Assessment (TEA) collection form entry.

Item 2. **Date symptoms started:** This field will be populated with the date from the Telephone Exacerbation Assessment (TEA) collection form entry.

Item 3. **Clinic presentation within seven days:** Select only one option among the two possible choices.
- Select No if the participant **was unable** to present to the clinical center within seven days of the onset of exacerbation event. [Go to END]
- Select Yes if the participant **was able** to present to the clinical center within seven days of the onset of exacerbation event.

Item 4. **Ongoing symptoms:** Select only one option among the two possible choices.
- Select No if the exacerbation event symptoms **are not** ongoing.
- Select Yes if the exacerbation event symptoms **are** ongoing. [Go to Q5]

Item 4a. **End date of symptoms:** If the answer to Q4 was No, record the date the participant's exacerbation event symptoms stopped by either selecting the date from the pop-up calendar in the DMS or entering the date using the mm/dd/yyyy format.

Item 4b. **Inclusion determination:** Select only one option among the two possible choices.

- Select No if it has been **less than 48 hours** since the symptoms stopped.
- Select Yes if it has been **more than 48 hours** since the symptoms stopped. [Go to END]

Note: If it has been more than 48 hours since the symptoms stopped, the participant does not meet the inclusion criteria for exacerbation visit 1. Thank them and ask them to call if and when they have another exacerbation event.

REVIEW OF SYMPTOMS

Item 5. For Items 5a through 5c, ask the participant the question, *"Since the start of your exacerbation symptoms, have you experienced an increase and/or change in the following **major** symptoms for at least two or more consecutive days?"*

Item 5a. **Shortness of breath**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase and/or change in shortness of breath for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase and/or change in shortness of breath for at least two or more consecutive days.

Item 5b. **Change in sputum color**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase and/or change in sputum color (yellow/green) for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase and/or change in sputum color (yellow/green) for at least two or more consecutive days.

Item 5c. **Sputum volume**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase and/or change in sputum volume for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase and/or change in sputum volume for at least two or more consecutive days.

Item 6. For Items 6a through 6e, ask the participant the question, *"Since the start of your symptoms, have you experienced an increase in the following **minor** symptoms for at least two or more consecutive days?"*

Item 6a. **Nasal discharge**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase in nasal discharge for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase in nasal discharge for at least two or more consecutive days.

Item 6b. **Wheeze**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase in wheezing for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase in wheezing for at least two or more consecutive days.

Item 6c. **Sore throat**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase in sore throat for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase in sore throat for at least two or more consecutive days.

Item 6d. **Cough**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase in cough for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase in cough for at least two or more consecutive days.

Item 6e. **Fever**: Select only one option among the two possible choices.

- Select No if the participant **has not** experienced an increase in fever for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase in fever for at least two or more consecutive days.

PHYSICAL ASSESSMENT

Item 7. **Conditions other than or in addition to AECOPD:** Select only one option among the two possible choices.

- Select No if **you do not suspect** any conditions other than or in addition to Acute Exacerbation COPD (AECOPD). [Go to Q8]
- Select Yes if **you do suspect** any conditions other than or in addition to Acute Exacerbation COPD (AECOPD).

If you answered Yes to Q7, specify the conditions that were ruled out:

Item 7a. **Pneumonia**: Select this box if pneumonia was ruled out.

Item 7b. **Acute Respiratory Failure**: Select this box if acute respiratory failure was ruled out.

Item 7c. **Other**: Select this box if you suspect and have ruled out any other conditions.

Item 7c1. Use the space provided to specify any other suspected conditions that have been ruled out.

PHYSICAL ASSESSMENT/ VITAL SIGNS

Item 8. **Body Weight:** Record the participant's body weight in kilograms.

Item 9. **Body Mass Index (BMI):** Record the participant's body mass index. *Note: the BMI value will automatically calculate in the DMS using height from Visit 5 ANT2 form.*

Item 10. **Temperature:** Record the participant's temperature in °C.

Item 11. **Respiratory rate:** Record the participant's respiratory rate.

Item 12. **Heart rate:** Record the participant's heart rate.

Item 13. **Systolic blood pressure:** Record the participant's systolic blood pressure.

Item 14. **Diastolic blood pressure:** Record the participant's diastolic blood pressure.

Item 15. **O2 saturation:** Record the participant's oxygen saturation value.

Item 15a. **Supplemental oxygen:** Select only one option among the two possible choices.

- Select No if the participant **does not** currently use supplemental oxygen. [Go to Q16]
- Select Yes it the participant **does** currently use supplemental oxygen.

Item 15a1. **Newly prescribed oxygen therapy:** Select only one option among the two possible choices.

- Select No if the oxygen therapy **is not** newly prescribed.
- Select Yes if the oxygen therapy **is** newly prescribed.

Item 15a2. **Increased oxygen therapy:** Select only one option among the two possible choices.

- Select No if it **is not** an increase to the participant's usual oxygen therapy.
- Select Yes if it **is** an increase to the participant's usual oxygen therapy.

Item 16. **Chest examination:** Select only one option among the two possible choices.

- Select No if a chest examination **was not** conducted. [Go to Q17]
- Select Yes if a chest examination **was** conducted.

If you answered Yes to Q16, which conditions were present during the chest examination:

Item 16a. **Wheezes**: Select only one option among the two possible choices.

- Select No if wheezes **were not** present during the chest examination.
- Select Yes if wheezes **were** present during the chest examination.

Item 16b. **Crackles/rales**: Select only one option among the two possible choices.

- Select No if crackles/rales **were not** present during the chest examination.
- Select Yes if crackles/rales **were** present during the chest examination.

Item 16c. **Rhonchi sounds**: Select only one option among the two possible choices.

- Select No if rhonchi sounds **were not** present during the chest examination.
- Select Yes if rhonchi sounds **were** present during the chest examination.

Item 16d. **Diminished breathing sounds**: Select only one option among the two possible choices.

- Select No if diminished breathing sounds **were not** present during the chest examination.
- Select Yes if diminished breathing sounds **were** present during the chest examination.

Item 16e. **Increased respiratory rate and/or labored breathing**: Select only one option among the two possible choices.

- Select No if increased respiratory rate and or labored breathing **were not** present during the chest examination.
- Select Yes if increased respiratory rate and or labored breathing **were** present during the chest examination.

EXACERBATION EVENT DETERMINATION

Note: A probable exacerbation event is defined as an increase in two or more major symptoms **or** an increase in one major symptom and two minor symptoms.

Item 17. **Probable exacerbation event:** Select only one option among the two possible choices.

- Select No if this **is not** a probable exacerbation event based on the above definition. [Go to Q18]
- Select Yes if this **is** a probable exacerbation event based on the above definition.

Note: This field will be populated using the major and minor responses from Q5a-5c and Q6-6e.

Item 17a. **Event duration to date:** Choose the option that best describes the event duration to date.

- Select "Less than 1 day" if the event duration has been less than one day.
- Select "1-2 days" if the event duration has been 1 to 2 days.
- Select "3-5 days" if the event duration has been 3 to 5 days.
- Select "1 week" if the event duration has been 1 week.
- Select "More than 1 week" if the event duration has been more than 1 week.

Note: If the event duration is >5 days (e.g. six days) select "1 week."

Item 17b. **Suspected cause (etiology):** Choose the option that best describes the suspected cause of the exacerbation event.

- Select "Infection" if infection is the suspected cause of the exacerbation event.
- Select "Weather" if weather is the suspected cause of the exacerbation event.
- Select "3-5 days" if the event duration has been 3 to 5 days.
- Select "Treatment non-compliance" if treatment non-compliance is the suspected cause of the exacerbation event.
- Select "Unknown" if the suspected cause of the exacerbation event is unknown.

EXACERBATION EVENT TREATMENT

Item 18. **Changes in clinical treatment or medication(s):** Select only one option among the two possible choices.

- Select No if the participant's clinical treatment or medication(s) **have not** changed. [Go to Q19]
- Select Yes if the participant's clinical treatment or medication(s) **have** changed.

If you answered Yes to Q18, complete Q18a – Q18g:

Item 18a. **Antibiotics**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with antibiotics or antibiotics **were not** changed. (Go to Q18b)
- Select Yes if the participant **was** treated with antibiotics or antibiotics **were** changed.

Item 18a1. Specify the antibiotics.

Item 18a2. Enter the number of days prescribed.

Item 18b. **Oral glucocorticosteroids**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with oral glucocorticosteroids or glucocorticosteroids **were not** prescribed. (Go to Q18c)

- Select Yes if the participant **was** treated with oral glucocorticosteroids or glucocorticosteroids **were** changed.

Item 18b1. Enter the number of days prescribed.

Item 18c. **New inhaled glucocorticosteroid**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with a new inhaled glucocorticosteroid or a new inhaled glucocorticosteroid **was not** prescribed. (Go to Q18d)
- Select Yes if the participant **was** treated with a new inhaled glucocorticosteroid or a new inhaled glucocorticosteroid **was** prescribed.

Item 18c1. Enter the number of days prescribed.

Item 18d. **Increased inhaled glucocorticosteroid dosage**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with an increased inhaled glucocorticosteroid dosage or an increased inhaled glucocorticosteroid dosage **was not** prescribed. (Go to Q18e)
- Select Yes if the participant **was** treated with an increased inhaled glucocorticosteroid or an increased inhaled glucocorticosteroid dosage **was** prescribed.

Item 18d1. Enter the number of days prescribed.

Item 18e. **Methylxathines (new)**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with new Methylxathines or new Methylxathines **were not** prescribed. (Go to Q18f)
- Select Yes if the participant **was** treated with new Methylxathines or new Methylxathines **were** prescribed.

Item 18e1. Enter the number of days prescribed.

Item 18f. **ß$_2$-agonists (short-acting) (new or increased)**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with new or increased short-acting ß$_2$-agonists or new or increased short-acting ß$_2$-agonists **were not** prescribed. (Go to Q18g)
- Select Yes if the participant **was** treated with new or increased short-acting ß$_2$-agonists or new or increased short-acting ß$_2$-agonists **were** prescribed.

Item 18f1. Enter the number of days prescribed.

Item 18g. **Other significant clinical treatments or medications**: Select only one option among the two possible choices.

- Select No if the participant **did not receive** any other significant clinical treatments or medications. (Go to Q19)
- Select Yes if the participant **did receive** other significant clinical treatments or medications.

Item 18g1 – 18g4a. Specify the other significant clinical treatments and/or medications and enter the number of days prescribed.

Item 18g. **Criteria for sputum induction**: Select only one option among the two possible choices.

- Select No if you **do not support** the participant proceeding to sputum induction.
- Select Yes if you **do support** the participant proceeding to sputum induction.

Save and close the form.