INSTRUCTIONS FOR EXACERBATION PHONE VISIT FORM (BASELINE)
EPV, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Phone Visit Form (Baseline) (EPV) is to be completed primarily over the phone for the participant's Exacerbation Substudy Phone Visit at Baseline.

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. **Self-collected samples within seven days of event onset:** Select only one option among the two possible choices.
- Select No if the participant **was unable** to self-collect samples within seven days of the onset of exacerbation event. [Go to END]
- Select Yes if the participant **was able** to self-collect samples 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. **More than 48 hours since symptoms stopped:** 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 this exacerbation event. 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.

REVIEW OF VITAL SIGNS

Item 7. **Able to take temperature:** Select only one option among the two possible choices.
- Select No if the participant **is not** able to take their temperature. [Go to Q8]
- Select Yes it the participant **is** able to take their temperature.

Item 7a. **Temperature**: Record the participant's temperature in °F.

Item 8. **Able to measure O2 saturation level:** Select only one option among the two possible choices.
- Select No if the participant **is not** able to measure their O2 saturation level. [Go to Q9]
- Select Yes it the participant **is** able to measure their O2 saturation level.

Item 8a. **O2 saturation**: Record the participant's O2 saturation level.

Item 8b. **Supplemental oxygen:** Select only one option among the two possible choices.
- Select No if the participant **does not** currently use supplemental oxygen. [Go to Q9]
- Select Yes it the participant **does** currently use supplemental oxygen.

  Item 8a1. **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 8a2. **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.

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 9. **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 Q10]
- 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 9a. **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 9b. **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.

Item 10. **Tested for COVID-19:** Select only one option among the three possible choices.

- Select No if the participant **has not** been tested for COVID-19 as part of this illness. [Go to Q11]
- Select Yes if the participant **has** been tested for COVID-19 as part of this illness.
- Select Unsure if the participant is unsure if they have been tested for COVID-19 as part of this illness. [Go to Q11]

Item 10a. **COVID-19 test result**: Select only one option among the three possible choices.

- Select Negative if the result was negative.
- Select Positive if the result was positive.
- Select Unsure if the participant is unsure of the test result.

Item 11. **Contact with anyone with COVID-19:** Select only one option among the three possible choices.

- Select No if the participant **has not** been in contact with anyone with COVID-19 in the last two weeks.
- Select Yes if the participant **has** been in contact with anyone with COVID-19 in the last two weeks.
- Select Unsure if the participant is unsure if they have been in contact with anyone with COVID-19 in the last two weeks.

Item 12. **Vaccinated against COVID-19:** Select only one option among the three possible choices.

- Select No if the participant **has not** been vaccinated against COVID-19. [Go to Q13]
- Select Yes if the participant **has** been vaccinated against COVID-19.
- Select Unsure if the participant is unsure if they have been vaccinated against COVID-19. [Go to Q13]

Item 12a. **Date of vaccination:** Record the date the participant was vaccinated against COVID-19.

SAMPLE COLLECTION TRACKING

Item 13a. **Did participant collect sputum sample:** Select only one option among the two possible choices.

- Select No if the participant **did not** collect and freeze the self-collected spontaneous sputum sample with seven days of exacerbation event onset.
- Select Yes if the participant **did** collect and freeze the self-collected spontaneous sputum sample with seven days of exacerbation event onset.

Item 13b. **Did participant collect nasal swab sample:** Select only one option among the two possible choices.
- Select No if the participant **did not** collect the nasal swab sample with seven days of exacerbation event onset.
- Select Yes if the participant **did** collect the nasal swab sample with seven days of exacerbation event onset.

Item 13c. **Did participant collect dried blood spot sample:** Select only one option among the two possible choices.
- Select No if the participant **did not** collect the dried blood spot sample with seven days of exacerbation event onset.
- Select Yes if the participant **did** collect the dried blood spot sample with seven days of exacerbation event onset.

EXACERBATION EVENT TREATMENT

Item 14. **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 Q15]
- Select Yes if the participant's clinical treatment or medication(s) **have** changed.

If Yes to Q14, complete Q14a – Q14g:

Item 14a. **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 Q14b]
- Select Yes if the participant **was** treated with antibiotics or antibiotics **were** changed.

Item 14a1. Specify the antibiotics.

Item 14a2. Enter the number of days prescribed.

Item 14b. **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 Q14c]
- Select Yes if the participant **was** treated with oral glucocorticosteroids or glucocorticosteroids **were** changed.

Item 14b1. Enter the number of days prescribed.

Item 14c. **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 Q14d]
- Select Yes if the participant **was** treated with a new inhaled glucocorticosteroid or a new inhaled glucocorticosteroid **was** prescribed.

Item 14c1. Enter the number of days prescribed.

Item 14d. **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 Q14e]
- Select Yes if the participant **was** treated with an increased inhaled glucocorticosteroid or an increased inhaled glucocorticosteroid dosage **was** prescribed.

Item 14d1. Enter the number of days prescribed.

Item 14e. **Methylxanthines (new)**: Select only one option among the two possible choices.

- Select No if the participant **was not** treated with new Methylxanthines or new Methylxanthines **were not** prescribed. [Go to Q14f]
- Select Yes if the participant **was** treated with new Methylxanthines or new Methylxanthines **were** prescribed.

Item 14e1. Enter the number of days prescribed.

Item 14f. **$ß_2$-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 Q14g]
- 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 14f1. Enter the number of days prescribed.

Item 14g. **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 Q15]
- Select Yes if the participant **did receive** other significant clinical treatments or medications.

Items 14g1 – 14g4a. Specify the other significant clinical treatments and/or medications and enter the number of days prescribed.

NOTE: If you are unable to communicate with the reviewing physician right away, the Exacerbation Phone Visit may end at this point and item 15 completed and entered at a later time.

PHYSICIAN REVIEW

Item 15. **Conditions other than or in addition to AECOPD:** Select only one option among the two possible choices.

- Select No if the reviewing physician **does not suspect** any conditions other than or in addition to Acute Exacerbation COPD (AECOPD). [Go to END]
- Select Yes if the reviewing physician **does suspect** any conditions other than or in addition to Acute Exacerbation COPD (AECOPD).

If Yes to Q15, specify the conditions that were ruled out:

Item 15a. **Pneumonia**: Select this box if pneumonia was ruled out.

Item 15b. **Acute Respiratory Failure**: Select this box if acute respiratory failure was ruled out.

Item 15c. **Other**: Select this box if you suspect and have ruled out any other conditions.

Item 15c1. Use the space provided to specify any other suspected conditions that have been ruled out.

Save and close the form.