INSTRUCTIONS FOR TELEPHONE EXACERBATION ASSESSMENT FORM
TEA, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Telephone Exacerbation Assessment Form (TEA) is to be completed over the telephone by trained study personnel when an Exacerbation Substudy participant calls the clinic with a suspected exacerbation event that they would like to report.

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 Exacerbation Visit 1 or another Exacerbation 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 symptoms first started:** Record the start date of the participant's symptoms by either selecting the date from the pop-up calendar in the data management system (DMS) or entering the date using the mm/dd/yyyy format.

Item 2. **Ongoing symptoms:** Select only one option among the two possible choices.
- Select No if the symptoms **are not** ongoing.
- Select Yes if the symptoms **are** ongoing. [Go to Q3]

Item 2a. **End date of symptoms:** Record the date on which the participant's 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 2b. **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. Thank them and ask them to call if and when they have another exacerbation event and end the call.

REVIEW OF SYMPTOMS

For Items 3 through 5, ask the participant the question, *"Since the start of your symptoms, have you experienced an increase or change in the following **major** symptoms for at least two or more consecutive days?"*

Item 3. **Shortness of breath**: Select only one option among the two possible choices.
- Select No if the participant **has not** experienced an increase or change in shortness of breath for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase or change in shortness of breath for at least two or more consecutive days.

Item 4. **Change in sputum color**: Select only one option among the two possible choices.
- Select No if the participant **has not** experienced a change in sputum color (yellow/green) for at least two or more consecutive days.
- Select Yes it the participant **has** experienced a change in sputum color (yellow/green) for at least two or more consecutive days.

Item 5. **Sputum volume**: Select only one option among the two possible choices.
- Select No if the participant **has not** experienced an increase or change in sputum volume for at least two or more consecutive days.
- Select Yes it the participant **has** experienced an increase or change in sputum volume for at least two or more consecutive days.

For items 6 through 10, 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 6. **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 7. **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 8. **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 9. **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 10. **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.

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 11. **Probable exacerbation determination**: Select only one option among the two possible choices.
- Select No if this **is not** a probable exacerbation as defined and based on the reported symptoms above.
- Select Yes if this **is** a probable exacerbation as defined and based on the reported symptoms above.

Item 12. **Participant willing to self-collect specimens**: Select only one option among the two possible choices.
- Select No if the participant is unwilling and/or unable to self-collect specimens within seven days of event onset.
- Select Yes if the participant is willing and able to self-collect specimens withing seven days of event onset. [Go to Q12a]

Item 12a. **Date Exacerbation substudy kit sent to participant**: Enter the date that Exacerbation substudy kit was sent to the participant.

Save and close the form.