INSTRUCTIONS FOR ADVERSE EVENTS FORM
AES, VERSION 2.0 QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Adverse Events Form (AES) is completed by the study physician (or by the study coordinator then confirmed by the study physician)

This form can be completed at Visit 5, bronchoscopy sub study visit, as well as any unexpected or exacerbation visits.

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.

The DMS allows multiple adverse events to be recorded on items 2a through g. Collect data for all adverse events reported.

To add multiple events, you will start a new instance of the form. To do this, click on the new instance icon located in the third column from the right (a white page with a green plus sign in the upper left-hand corner). This will bring up a dialog box that reads: “Select Number of Next Occurrence”. Make sure it says “Next” in the text box, and then click “Submit”. Once you have done this, it will bring up another AES form, and you can select the study visit the AE is associated with (e.g., if you have two AEs associated with the Exacerbation Visit, you would enter the first incident, and associate it with the Exacerbation Visit, complete that form, open a second instance of the AES, and select Exacerbation Visit again when entering the second AE.

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.

Please do not include symptoms related to COPD that are recorded on other data collection forms.

Severity of adverse events may have varied over the rating period. Record the **HIGHEST** severity rating determined.

For standardization of data collection, the clinician should ask the participant; *“Have you had any physical or health problems since your last visit? Have you cut down on the things you usually do because of not feeling physically able since your last visit?”* If there is no evidence of any adverse events, answer ‘N’ to item 1 and the form is complete.

If there is evidence of a problem the clinician should first record the problem (e.g., “sinus infection”).

Item 1: Enter the number which corresponds to the study visit this AES form is associated with (e.g., Clinic Visit 5=11, Exacerbation Visit 5=12, Bronchoscopy Visit 5=13

Item 2. Adverse Event: Specify the type of AE in the space provided.

Item 2a: Record the start date of the adverse event listed by either selecting the dates from the pop-up calendar in the data management system or entering the date using the mm/dd/yyyy format.

Item 2b: Record the stop date of the adverse event listed by either selecting the dates from the pop-up calendar in the data management system or entering the date using the mm/dd/yyyy format.

Following this the clinician should inquire further (e.g., *“How often does this happen?”, “Does this interfere with your daily activities?”*) in order to make a judgment about the *severity* of the problem. The clinician should then select “**Mild**”, “**Moderate**’ or “**Severe**” in the box provided, according to their judgment of severity. In rating severity, the clinician should keep in mind the general definitions of mild, moderate, and severe as well as the specific definition of severe given for each of the individual problems listed.

The general definitions for mild, moderate, and severe are as follows:

A mild adverse event is defined as: resulting in mild or transient discomfort, not requiring intervention or treatment; does not limit or interfere with daily activities.

A moderate adverse event is defined as: sufficiently discomforting so as to limit or interfere with daily activities; may require intervention or treatment.

A severe adverse event is defined as: results in significant symptoms that prevent normal daily activities; may require hospitalization or invasive intervention.

Item 2d: In the box provided select the outcome of the adverse event (i.e. Resolved, No Sequelae = 1, Still present- no treatment = 2, Still present-being treated = 3, Residual effects present – not treated = 4, Residual effects present – treated = 5, Death = 6, Unknown = 7.).

Item 2e: Enter Y (yes) or N (no) regarding if the AE was expected or not. Was the event due to the progression of their COPD? If yes, then Yes it’s expected. If not, then No it’s unexpected. Examples of unexpected might be that they tripped over an obstacle in the hallway and injured their knee while doing the 6-minute walk or experienced a fall walking to the CT scan. An expected adverse event in this population might be that the participant experienced syncope during spirometry testing.

Item 2f: Enter Y (yes) or N (no) if the AE was serious or not. Serious is defined as the following:

- Death
- Life-threatening AE (“life-threatening” means that the study subject was, in the opinion of the investigator or sponsor, at immediate risk of death from the reaction as it occurred and required immediate intervention)
- Inpatient hospitalization or prolongation of existing hospitalization (hospitalization is defined as >=24 hours inpatient)
- Results in persistent or significant disability or incapacity
- Important medical event that may not result in one of the above outcomes, but may jeopardize the health of the study participant or require medical or surgical intervention to prevent one of the outcomes listed in the above definition of serious event

Item 2g: Provide a narrative description of the AE event in the space provided.