SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

Incident, Deviation, and Violation Tracking, PDF
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

Complete this form for each protocol deviation/violation or any promptly reportable information. If the information pertains to more than one participant, please use 000000 as the ID in CDART. Any incident that meets the criteria of the prompt reporting requirements of the WCG HRP-071 Policy must be reported to the IRB within 5 calendar days. In these specific cases, complete and attach a copy of the Promptly Reportable Information Form to this form in CDART. File the physical copy of this form and the PRI form (as applicable) in the participants' records and the regulatory binder. Please refer to the QxQ and MOP for additional guidance.

Definitions:

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)
Any problem or incident which in the opinion of the local investigator was unanticipated, serious, and at least possibly related to the research procedures.

Protocol Deviation
An accidental or unintentional change to a research protocol that DOES NOT significantly affect the participant's rights, safety, or welfare, or the integrity of the data. A protocol deviation can be minor, such as changing minor wording on a survey, or major, such as not following inclusion or exclusion criteria.

Protocol Violation
An intentional change to a research protocol that DOES significantly affect the participant's rights, safety, or welfare, or the integrity of the data. A protocol violation can lead to a patient being excluded from the study, or their results being excluded.

Please answer every question on this form. *NOTE: All response options in the paper form may not appear in CDART (e.g., 'Don't know', 'Declines to answer', etc.). Beside each item input is a small double bracket icon which looks like this: ». Clicking this icon displays a field dialogue box in which the "Field Status" selection menu allows you to choose from the following options: 'Refused', 'No response', 'Doesn't know', 'Not applicable', 'Maximum value', 'Minimum value', and 'Missing'.* **See MOP 6 – Section 3.2 for additional instructions on how to select a Field Status option.**

II. INSTRUCTIONS FOR INDIVIDUAL ITEMS

Header Information: Consists of key fields which uniquely identify each subject and recorded occurrence of a form. For the "ID NUMBER", record the 2 or 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at the clinic visit (E1), a follow-up phone call, or "other."

Item 0a. Record the date the data was collected or abstracted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 0b. Record the SPIROMICS III 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 III data, please contact the GIC in order to receive your own individual staff code.

Item 0c. This item will be automatically assigned by CDART.

Item 1. Enter the date the site learned of the incident in MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 2. Enter the start date of the incident in MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 3. Enter the stop date of the incident in MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 4. Select only one option among the three possible choices according to the definitions provided in the instructions.

Item 5. Select only one option among the two possible choices. If '**Yes**' is selected, then complete the Adverse Events (AES) form.

Item 6. Select only one option among the two possible choices. If '**Yes**' is selected, then complete the Reason for Study Withdrawal (RSW) form.

Item 7. Incident Type:

Item 7a-i. Select all incident types that apply.

Item 7f1a-c. If 7f is selected, select all types of breach that apply.

Item 7i1. If 7i is selected, specify other incident type.

Item 8. Reason for Incident:

Item 8a-i. Select all reasons for incident that apply.

Item 8i1. If 8i is selected, specify other reason for incident.

Item 9-12. Select only one option among the three possible choices.

Item 13. Provide a detailed description of the incident.

Item 14. Describe any **actions already taken** to address the incident. If no actions have been taken, mark the field status as "Not Applicable" (see instructions in section I above).

Item 15. Describe any **planned actions** to prevent recurrence of the incident. If there are no planned actions, mark the field status as "Not Applicable" (see instructions in section I above).

Select **Save and Close** at the bottom of the page/screen.