SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

INCIDENT, DEVIATION, AND VIOLATION TRACKING

ID NUMBER:									

FORM CODE: **PDF**
VERSION: **1.0 02/27/2025**

Event: _____

0a) Date of Collection: ☐☐ / ☐☐ / ☐☐☐☐ 0b) Staff Code: ☐☐☐

0c) Incident ID: ☐☐☐☐ (auto-assigned by CDART)

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.

1) Date site learned of the incident: ☐☐ / ☐☐ / ☐☐☐☐

2) Incident Start Date: ☐☐ / ☐☐ / ☐☐☐☐

3) Incident Stop Date: ☐☐ / ☐☐ / ☐☐☐☐

4) Incident categorized as: *(Select one per the definitions provided in the instructions above)*

- ☐ UPIRSO[1]
- ☐ Protocol Deviation[2]
- ☐ Protocol Violation[3]

5) Did this incident result in an adverse event (AE)?

☐ No$_0$

☐ Yes$_1$ → **Complete Adverse Events (AES) form**

6) Did this incident result in participant withdrawal?

☐ No$_0$

☐ Yes$_1$ → **Complete Reason for Study Withdrawal (RSW) form**

7) Incident Type: *(Select all that apply)*

7a) ☐ Inappropriate enrollment

7b) ☐ Informed consent process

7c) ☐ Test/procedure not done per protocol

7d) ☐ Test/procedure completed out of window

7e) ☐ Adverse event not reported per requirements

7f) ☐ Breach of confidentiality

7f1) If the incident was a breach of confidentiality, what type of breach?

7f1a) ☐ Inappropriate sharing or disclosure of a participant's personal identifiers and/or PHI

7f1b) ☐ Privacy incident

7f1c) ☐ Security incident

7g) ☐ Use of non-sIRB approved material

7h) ☐ Study implementation error

7i) ☐ Other

7i1) If other, please specify: _____

8) Reason for Incident: *(Select all that apply)*

8a) ☐ Study staff error

8b) ☐ Equipment error/failure

8c) ☐ Participant emergency/unexpected illness

8d) ☐ Participant non-compliance

8e) ☐ Participant refusal

8f) ☐ Scheduling issue

8g) ☐ Natural disaster/weather related

8h) ☐ Principal Investigator decision/judgement

8i) ☐ Other

8i1) If other, please specify: _____

9) Has this incident been identified as noncompliance previously for either this study or other studies that the PI has oversight of (e.g., deviation log, monitor or auditor report, CTQA findings, external IRB)?

- ☐ No$_0$
- ☐ Yes$_1$
- ☐ Unsure$_2$

10) Was this incident unexpected in nature, severity, and/or frequency?

- ☐ No$_0$
- ☐ Yes$_1$
- ☐ Unsure$_2$

11) Was this incident related to or potentially due to this research?

- ☐ No$_0$
- ☐ Yes$_1$
- ☐ Unsure$_2$

12) Does this incident suggest greater risk of physical, psychological, economic, legal, or social harm than previously recognized?

- ☐ No$_0$
- ☐ Yes$_1$
- ☐ Unsure$_2$

13) Detailed Incident Description:

14) Describe any **actions already taken** to address this incident (or mark this field status as “Not Applicable”):

15) Describe any **planned actions** to prevent recurrence (or mark this field status as “Not Applicable”):