SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

INCIDENT, DEVIATION, AND VIOLATION TRACKING

ID NUMBER:									

FORM CODE: PDF
VERSION: 1.0 11/05/2024

Event: _____

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

Instructions: Complete this form for each protocol deviation/violation and file the physical copy with in participants' record. Please refer to the QxQ for additional guidance. If the protocol deviation/violation does not pertain to a specific participant, please use 000000 as the PID in CDART and file the physical copy in the regulatory binder.

Definitions:

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

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

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

3) Incident Stop Date: ☐☐ / ☐☐ / ☐☐☐☐

4) Incident categorized as: *(Select all that apply by definitions provided in Instructions above)*

- ☐ UPIRTSO$_1$
- ☐ Protocol Deviation$_2$
- ☐ Protocol Violation$_3$

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

- ☐ No$_0$
- ☐ Yes$_1$ → **Complete Adverse Event Form (AEF)**

6) Did this incident result in participant withdrawal?

☐ No$_0$

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

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

7a) Inappropriate enrollment ☐

7b) Informed assent/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 ☐

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

7f1) Inappropriate sharing or disclosure of a participant's personal identifiers and/or PHI ☐

7f2) Privacy incident ☐

7f3) 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)?

☐ Yes$_1$

☐ No$_0$

☐ Unsure$_2$

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

☐ Yes$_1$

☐ No$_0$

☐ Unsure$_2$

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

☐ Yes$_1$

☐ No$_0$

☐ Unsure$_2$

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

☐ Yes$_1$

☐ No$_0$

☐ Unsure$_2$

13) Detailed Incident Description:

_____

_____

_____

_____

_____

_____

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

15) Describe any preventive actions taken to prevent recurrence (or Mark this field status as “Not Applicable”):