SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

ADVERSE EVENTS

ID NUMBER:									

FORM CODE: **AES**
VERSION: **1.0 10/23/2024**

Event: _____

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

Instructions: *This form should be completed if a participant has an adverse event.*
An adverse event is defined as an unexpected or unintentional medical occurrence that happens to a participant ***during a research procedure****. Adverse events can include physical or psychological harm or putting the participant at risk. Serious adverse events (SAEs) include events that result in death, are life-threatening, require hospitalization, or cause a significant disability.*
If an unanticipated problem occurs that indicates a greater risk of harm to the participants, the Adverse Event form should be entered in addition to the Protocol Deviation/Violation report form.

1) With which study visit is this Adverse Event associated?

☐ In-person Clinic Visit (E1)1
☐ Other6

1a) If Other, please describe: _____

2) Adverse Event: _____

2a) Start Date: ☐☐ / ☐☐ / ☐☐☐☐

2b) Stop Date: ☐☐ / ☐☐ / ☐☐☐☐

2c) Severity:

☐ Mild1

Event results in mild or transient discomfort, not requiring intervention or treatment; does not limit or interfere with daily activities (e.g., insomnia, mild headache).

☐ Moderate2

Event is sufficiently discomforting so as to limit or interfere with daily activities; may require interventional treatment (e.g., fever requiring antipyretic medication).

☐ Severe3

Event results in significant symptom(s) that prevent(s) normal daily activities; may require hospitalization or invasive intervention (e.g., anemia resulting in blood transfusion).

2d) Outcome of Adverse Event:

- ☐ 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$_7$

2e) Was the Adverse Event expected?

- ☐ No$_0$
- ☐ Yes$_1$

2f) Was the Adverse Event serious?

- ☐ No$_0$
- ☐ Yes$_1$

2g) Please provide a detailed narrative description of the event:

_____

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END OF FORM