SOURCE
SPIROMICS Study of Early COPD Progression

ADVERSE EVENTS FORM

ID NUMBER:									

FORM CODE: AES
VERSION: 1.0 02/24/2021

Event: _____

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

Instructions: *This form should be completed if a participant has an adverse event.*

1) Which study visit is this Adverse Event associated with?
- ☐ Baseline Visit$_1$
- ☐ 18-month Follow-up Visit$_2$
- ☐ 3-year Follow-up Visit$_3$
- ☐ Bronchoscopy Sub-study Visit 1$_4$
- ☐ Bronchoscopy Sub-study Visit 2$_5$
- ☐ Other$_6$

1a) If Other, please describe: _____

2) Adverse Event: _____

2a) Start Date: ☐☐ / ☐☐ / ☐☐☐☐

2b) Stop Date: ☐☐ / ☐☐ / ☐☐☐☐

2c) Severity:
- ☐ Mild$_1$
  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).
- ☐ Moderate$_2$
  Event is sufficiently discomforting so as to limit or interfere with daily activities; may require interventional treatment (e.g., fever requiring antipyretic medication).
- ☐ Severe$_3$
  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 narrative description of the event:

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END OF FORM