ADVERSE EVENTS FORM

ID NUMBER:								

FORM CODE: **AES**
VERSION: **2.0** 10/25/2017

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?
   - ☐ Clinic Visit 5[11]
   - ☐ Exacerbation Visit 5[12]
   - ☐ Bronchoscopy Visit 5[13]

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 symptoms that prevents 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