ADVERSE EVENTS FORM

SPIROMICS

ID NUMBER: ⬚⬚⬚⬚⬚⬚⬚⬚

FORM CODE: **AES**
VERSION: **1.0** 6/10/14

Visit Number ⬚⬚   SEQ # ⬚⬚⬚

0a) Form Date............ ⬚⬚/⬚⬚/⬚⬚⬚⬚

0b) Initials .... ⬚⬚⬚

> *Instructions:* *This form should be completed if a participant has an adverse event. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes*

1) Which study visit is this adverse event associated with? .... ⬚

Baseline.....................	1
Year 1........................	2
Year 2........................	3
Year 3........................	4
Exacerbation Visit......	5
Exacerbation Visit 2...	6
Exacerbation Visit 3...	7
Bronchoscopy Visit 1.	8
Bronchoscopy Visit 2.	9
Repeatability Visit......	10

2) Adverse Event: _____

   a) Start Date: ⬚⬚/⬚⬚/⬚⬚⬚⬚

   b) Stop Date: ⬚⬚/⬚⬚/⬚⬚⬚⬚

   c) 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).

d) 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

e) Was Adverse Event expected? (Y/N) .... ☐

f) Was Adverse Event Serious? (Y/N) .... ☐

g) Please provide a narrative description of the event:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____