35854

Interviewer (initials) | COPDGene ID

Month / Day / Year | Center (eg, NJC)

Serious Adverse Event Report

This is AE # 1 for *this* subject on *this* date.

Submit this form to the DCC within 2 days of when you learn of a ***serious adverse*** event.
If this a ***serious adverse*** event, also ***notify the DCC by email***.

1. Describe briefly the adverse event (use *Narrative Comment* on p 3 for detailed description).

2. Identify the protocol-related procedure that most closely preceded the event in *time*.

- O Blood draw
- O CT scan
- O Six-minute walk test
- O Spirometry

Date of the procedure Month / Day / Year

3. Identify the protocol-related procedure most likely related to the event.

- O Blood draw
- O CT scan
- O Six-minute walk test
- O Spirometry
- O None

Date of the procedure Month / Day / Year

4. In your opinion, what caused the event? Mark one.

- O Study procedure
- O Underlying disease
- O Concurrent disorder or comorbid condition: _____
- O Other event: _____

5. What aspects of the adverse event make it serious? Mark all that apply.

- O Fatal
- O Life-threatening
- O ER visit or hospitalization needed
- O Disabling or incapacitating

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6. If an ER visit or hospitalization was required, provide

	Month	Day	Year
a. Admission	__ /	__ /	____
b. Discharge	__ /	__ /	____

Reporting Investigator Certification

Please complete the *Narrative Comment* on page 3.

I certify that I have reviewed and verified the information on pp 1– 3 of this form.

Name, address, and signature of the Reporting Investigator:

Name _____

Address

Signature _____

Principal Investigator will send a copy of this form to (mark all)

- ☐ DCC
- ☐ Local IRB
- ☐ Other _____

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Serious Adverse Event: Narrative Comment

Describe in detail the adverse event and how you determined its relationship to the protocol.