29731

COPDGene
COPD Genetic Epidemiology

Interviewer (initials) | COPDGene ID

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

Adverse Event Report

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

Fill in only one event circle per sheet.

Describe briefly the adverse event that occurred ***during or within 24 hours*** of the COPDGene study visit.

Standard Definitions

Adverse Event (AE) Any event that caused or increased the risk of harm to the research subject

Unanticipated AE Any adverse event not included in the informed consent

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Date of the adverse event Month / Day / Year

Event is ○ **Anticipated** ○ **Unanticipated**

Severity of Adverse Event

- ○ **Mild** Did not pose significant or permanent risk of harm
- ○ **Moderate** Caused discomfort, may have required treatment, but did not pose permanent risk of harm
- ○ **Serious *** Caused significant discomfort, required treatment, posed permanent risk of harm; hospitalization; life-threatening; fatal

Relationship of Adverse Event to participation in the COPDGene study

- ○ **Not Related** Event is clearly unrelated to participation
- ○ **Possible** Event may be related to participation
- ○ **Probable** Event is likely related to participation
- ○ **Definitely** Event is clearly related to participation

Anticipated Adverse Events

Blood Samples	○ Hematoma	○ Infection	○ Phlebitis	○ Syncope	○ Other
Six-Minute Walk Test	○ Chest pain	○ Fall	○ Shortness of breath	○ Other	
Spirometry	○ Chest pain	○ Shortness of breath	○ Syncope	○ Other	

* If the adverse event is ***serious***, then complete the ***Serious Adverse Event Report***.