## Subject Information:

Site Name:

Subject ID:

1. Sex: Male  Female
2. Age**:** (please provide)
3. Weight: (please provide)  lbs or  kgs
4. Height: (please provide)  inches or  cm

## Serious Adverse Event (SAE) Information:

1. Date of Onset: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Resolution Date: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)  Not resolved

1. Adverse Events:
2. Describe event or problem:
3. Outcomes attributed to event (check all that apply):

Death on

Life-threatening event

In-patient hospitalization/prolongation of present hospitilization

Persistent or significant disability/incapacity

Required intervention to prevent permanent impairment/damage

Congenital anomaly/birth defect

Other, specify:

1. Record treatment for event or attach appropriate documentation:

Table 1 Treatment for Event

| Record treatment for event |
| --- |
| Data to be filled in by site |

1. Record relevant tests or laboratory data, including dates or attach the appropriate documentation:

Table 2 Relevant Tests or Laboratory Data

| Record relevant tests or laboratory data |
| --- |
| Data to be filled in by site |

1. Record concomitant medications or attach the appropriate Case Report Form (CRF) page(s):

Table 3 Concomitant Medications

| Record concomitant medications |
| --- |
| Data to be filled in by site |

1. Record relevant history including pre-existing medical conditions or attach appropriate CRF page(s):

Table 4 Relevant History

| Record relevant History including pre-existing medical conditions |
| --- |
| Data to be filled in by site |

## Study Intervention Information:

1. Name of study intervention:
2. Describe administration of study intervention (e.g. dose, frequency and route used for a drug):
3. Was study intervention discontinued due to the event?

Yes  No  N/A

1. Was the seriousness of the event abated after discontinuation of the study intervention?

Yes  No  N/A

1. Did event reappear after reintroduction of the study intervention?

Yes  No  N/A

1. Was study blind broken?

Yes  No  N/A

## Principal Investigator’s Assessment

1. Principal Investigator’s Opinion of what caused the event:

Study intervention

Concomitant medication, Specify:

Concurrent disorder, Specify:

Withdrawal of study intervention, Specify:

1. Was this type of event anticipated in the protocol and consent form?

Yes  No

1. Comments:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Reporter Information

1. Principal Investigator’s name and address: (please specify)
2. Reporter name and telephone number: (please specify)
3. Type of report:

Initial report  Follow-up report  Final report

1. Date Report Completed:

**Sponsor’s Assessment**

1. Does this adverse event meet the definition to be a serious adverse event?[[1]](#footnote-1)

Yes  No

1. Does this adverse event meet the definition to be an unexpected event?[[2]](#footnote-2)

Yes  No

1. Based on the sponsor’s assessment, is there at least a reasonable possibility that the adverse event was caused by use of the investigational agent or device?

Yes  No

## General Instructions

### ADVERSE EVENTS

Adverse events (AEs) document any unfavorable or untoward medical occurrence that is observed with use of a drug or medical device in a participant or subject enrolled in a study without regard for cause or relationship. Adverse events should be recorded using a standard medical terminology, such as the Medical Dictionary for Regulatory Activities (MedDRA) or Common Terminology Criteria for Adverse Events (CTCAE).

### SERIOUS ADVERSE EVENT Definition

Serious Adverse Event (SAE) - Any untoward medical occurrence that:

* Results in death,
* Is life-threatening,
* Requires inpatient hospitalization or prolongation of existing hospitalization,
* Results in persistent or significant disability or incapacity, or
* Is a congenital anomaly or birth defect.

### SAE REPORTING

The Serious Adverse Event (SAE) Report is used to provide detailed information about each SAE that occurs during the study. It contains the information MedWatch, the FDA Safety Information and Adverse Event Reporting Program, requires for reporting SAEs.

The study protocol should outline who should receive SAE Reports and in what time frame. Depending on the study, SAE Reports may have to be sent to the study coordinating center, Data Safety Monitoring Board (DSMB), the Institutional Review Board (IRB), and the NHLBI.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). All of the data elements are supplemental and should be collected only if the research team considers them appropriate for their study.

### REPORTING OF SAFETY REPORTS FOR STUDIES UNDER AN IND or IDE

For studies conducted under an Investigational New Drug (IND) or Investigational Device Exemption (IDE), the U.S. Food and Drug Administration describes guidelines for Sponsors to report events related to use of an investigational agent or medical device.

The Sponsor must assess the adverse event and prepare an IND Safety Report when the event meets all of the definitions to be categorized as (1) suspected (at least a reasonable possibility for causality), (2) serious and (3) unexpected.

Safety reporting requirements can be found on the U.S. Food and Drug Administration websitel: [U.S. Food and Drug Administration Investigational New Drug Reporting Requirements](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm).

## Specific Instructions

See [Food and Drug Administration Serious Adverse Event Report Form Instructions](http://www.fda.gov/medwaTCH/getforms.htm) for instructions on how to fill out the SAE Report.

1. Serious: An adverse event is defined by the investigator or sponsor as “serious” because it is life-threatening, results in death, requires in-patient hospitalization, prolongs existing hospitalization, results in persistent or significant disability, or is a congenital anomaly/birth defect. [↑](#footnote-ref-1)
2. Unexpected: An adverse event is categorized by the sponsor as “unexpected” because the adverse event has not been previously described in the Investigator’s Brochure or has increased in frequency or severity compared to what is described by the Investigator’s Brochure. [↑](#footnote-ref-2)