## 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)