1. Is the adverse event serious?[[1]](#footnote-1)

No (Leave rest of form blank)

Yes (Complete rest of the form)

1. If YES, serious adverse event onset date?

## Serious Adverse Event (SAE) Information

1. Site SAE awareness date:
2. Ongoing?  No  Yes
   1. If NO, resolution date:
3. Adverse Event:
4. Outcomes attributed to event
   1. Did the adverse event result in death?

No  Yes

* 1. Is the adverse event life threatening?

No  Yes

* 1. Did the adverse event result in initial or prolonged hospitalization for the participant?

No  Yes

* 1. Did the adverse event require intervention to prevent permanent impairment or damage?

No  Yes

* 1. Did the adverse event result in persistent or significant disability or incapacity?

No  Yes

* 1. Is the adverse event associated with a congenital anomaly or birth defect?

No  Yes

* 1. Is the adverse event a medically important event not covered by other "serious" criteria?

No  Yes

* + 1. If YES, 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?

No  Yes

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

No  Yes

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

No  Yes  N/A

1. Was study blind broken?

No  Yes

1. Did the adverse event cause the participant to be discontinued from the study?

No  Yes

## 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:

Other, specify:

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

No  Yes

## 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?[[2]](#footnote-2)

No  Yes

1. Does this adverse event meet the definition to be an unexpected event?[[3]](#footnote-3)

No  Yes

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

No  Yes

1. Comments:

Recorder Signature: Date:

## General Instructions

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

Please see the Data Dictionary for element classifications.

## 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 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,
* Is a congenital anomaly or birth defect, or
* Is an Important Medical Event (IME)

### [Glossary of Clinical Research Terms](https://clinicaltrials.gov/study-basics/glossary)

[Clinical Data Interchange Standards Consortium (CDISC) Terminologies](https://www.cdisc.org/kb/ecrf/adverse-events)

## SAE Reporting

The Serious Adverse Event Report is used to provide detailed information about each SAE that occurs during the study. It contains the information that 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 NINDS.

## 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 website: [U.S. Food and Drug Administration Investigational New Drug Reporting Requirements](https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm)

## Specific Instructions

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

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Is the adverse event serious? – Choose either No or Yes. This question should only be answered YES if the outcome of the AE results in at least one of the following: death; a life-threatening experience; inpatient hospitalization; prolongation of existing hospitalization; a persistent or significant disability or incapacity; a congenital anomaly/birth defect; or an Important Medical Event. If an AE is serious, this provides a trigger that additional information must be provided by the site investigator. The site investigator then completes the SAE form. Additionally, the site institution and/or IRB may also have an SAE form and procedures for reporting SAEs. If NO, do not complete the rest of the form.
* SAE onset date – Record the date/time according to the [ISO 8601](https://www.iso.org/home.html), the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Site SAE awareness date – Record the date and time the site became aware of the serious adverse event. Record the date/time according to the [ISO 8601](https://www.iso.org/home.html), the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Resolution date – Record the date/time according to the [ISO 8601](https://www.iso.org/home.html), the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Adverse event – Text may be prepopulated from Adverse Events CRF.
* Relevant tests or laboratory data – See General CDE Data Standards [Laboratory Tests and Tracking](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/General/F0025_Laboratory_Tests_and_Tracking.docx) CRF Module
* Concomitant medications – See General CDE Data Standards [Prior and Concomitant Medications](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/General/F0020_Prior_and_Concomitant_Medications.docx) CRF Module
* Relevant history – See General CDE Data Standards [Medical History](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/General/F0013_Medical_History.docx) CRF Module
* Date report completed – Record the date/time according to the [ISO 8601](https://www.iso.org/home.html), the International Standard for the representation of dates and times. The date should be recorded to the level of granularity known (e.g., year, year and month, complete date) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.

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, is a congenital anomaly/birth defect, or is an important medical event. [↑](#footnote-ref-1)
2. 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, is a congenital anomaly/birth defect, or is an important medical event. [↑](#footnote-ref-2)
3. 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-3)