**Purpose:** This template provides a recommended structure for recording and tracking adverse events for a research study.

**Responsibility:** To be used by Principal Investigators and study team members who are delegated to record and track adverse events for a research study.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory** text are indicated by italics and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included. Example text is included to further aid in document development and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted**.**
* **Example text** is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted..

**Adverse Event (AE)/Serious Adverse Event (SAE) Log Template**

**Study/Protocol ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Site Name/Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*This log is cumulative and captures adverse events (including serious adverse events) of all participants throughout the study. Each subject should be asked about the presence/absence of AEs at every study visit.*

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| --- | --- | --- | --- | --- | --- |
| Severity (CTC version: \_\_\_) | **Study Intervention Relationship** | Action Taken Regarding Study Participation | **Outcome of AE** | Expected | Serious Adverse Event (SAE) |
| 1 = Mild  2 = Moderate  3 = Severe  4 = Life-threatening  5 = Death | 1= Not related  2 = Unlikely related  3 = Possibly related  4 = Probably related  5 = Definitely related | 1 = None  2 = Study intervention modification  3 = Study intervention discontinued  4 = Concomitant medication administered  5 = Subject withdrawn from study  6 = Hospitalization  7 = Other | 1 = Resolved  2 = Recovered with sequelae  3 = Ongoing/Continuing treatment  4 = Condition worsening  5 = Death  6 = Unknown | 1 = Yes  2 = No (AE is not listed as side effect in Investigator’s Brochure, package insert, or as a characteristic of the study condition) | 1 = Yes (complete SAE Form)  2 = No |

| Subject # | Adverse Event Description | Start Date | Stop Date | Severity (CTC version: \_) | Relationship | Action Taken | Outcome | Expected | SAE | Investigator Initials & Date |
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