**NIMH Subject Specific Adverse Event (AE) Log Template**

***Tool Summary*** *(Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template provides a recommended structure for recording and tracking subject specific AEs*

***Audience/User:*** *Site Monitors, Principal Investigators, and study team members who are delegated to record and track subject specific AEs for a research study*

***How to Use This Template***

*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.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be update.*

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

**NIMH Subject-Specific Adverse Event (AE) Log Template**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Severity | **Study Intervention Relationship** | Action Taken Regarding Study Participation | **Outcome of AE** | Expected | Serious Adverse Event (SAE) |
| 1 = Mild  2 = Moderate  3 = Severe | 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 |

At end of study only, check here if no AEs occurred: **Checkbox. No AEs**

| Adverse Event | Visit # | Start Date | Stop Date | Severity | Relationship | Action Taken | Outcome | Expected | SAE | Investigator Initials & Date |
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