**NIMH Reportable Events Log Template**

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

***Purpose:*** *This template provides a recommended structure for documenting reportable events.*

***Audience/User:*** *Principal Investigators and study team members who document reportable events*

***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 updated.*

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| Protocol Title |  |
| Principal Investigator |  |
| Institution |  |
| IRB Number |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reportable event number | StudySubject ID | Event | Date of Event | Unanticipated? Y/N | Related to research? Y/N | Action(s) Taken | Date team learned of event | Date Reported to IRB | IRBOutcome & Acknowledgement Date | Date sponsor notified (if required) |
| 1. |  |  |  |  |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |  |  |  |  |
| 5. |  |  |  |  |  |  |  |  |  |  |

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