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

**Responsibility:** To be used by Principal Investigators and study team members who document reportable events

**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.

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Principal Investigator** |  |
| **Site Name/Number** |  |
| **IRB Number** |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reportable event number | Study  Subject 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 | IRB  Outcome & Acknowledgement Date | Date sponsor notified (if required) |
| 1. |  |  |  |  |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |  |  |  |  |
| 5. |  |  |  |  |  |  |  |  |  |  |

**Reportable Events Log Template**