**ATTACHMENT 1: SUMMARY OF ADVERSE EVENTS TEMPLATE**

|  |  |
| --- | --- |
| **IRB Number**: | **Study Drug or Intervention**: |
| **PI:** | **Submission Date:** |

How to complete the form:

* Column 1: Describe the adverse event.
* Columns 2-7: Indicate the number of occurrences under the appropriate column heading. For internal serious events, indicate whether the PI believes the number is related to the study intervention by placing -R (related) or -U (unrelated) after the number.
* All internal deaths are to be reported in a separate category and relatedness must be indicated.
* Relatedness is not required for external events; however, it may be noted or comments may be added to describe the opinion of the PI.
* You do not have to report on internal, non-serious expected events or internal, non-serious unexpected events that are not related.
* For multi-center studies, the central DSMB should be able to provide you with the necessary information.
* Add any comments you think will be helpful to the IRB (attachments are acceptable). You can use this log as a submission with the annual continuation.

**[Delete this sentence and the examples (in red) provided in the table below prior to submitting to the IRB]:**

**Summary of Individual Adverse Events:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event**  **Description** | **Internal**  **Non-Serious -**  **Unexpected**  **(related only)** | **Internal**  **Serious -**  **Expected**  **(no death)** | **Internal**  **Serious -Unexpected**  **(no death)** | **Internal**  **Death -**  **Expected** | **Internal**  **Death -**  **Unexpected** | **External**  **Serious/Death -**  **Expected** | **External**  **Serious/Death -**  **Unexpected** | **Comments**  *Any additional information that may be helpful to the IRB when conducting a review (e.g., ”consent modified to disclose events” or ”unable to determine relatedness of event”).* |
| *Headache* | *3-R* |  |  |  |  |  |  | *ICF was revised to disclose potential occurrence of headaches.* |
| *Heart Attack* |  |  |  |  |  |  | *1* | *PI believes this may be related, but external DSMB disagrees.* |