**Subject Initials Subject ID# Page \_\_\_\_ of \_\_\_\_**

**Serious Adverse Event Tracking Log *Check box if there were no serious adverse events to be recorded* 🞏**

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| **SAE Description** | **Adverse Event[[1]](#footnote-1)\***  *(Select from Safety Profiler, if applicable)* | **SAE Classification**1 | **Event**  **Start Date** | **Event End Date** | **Date Site Became Aware of Event (Reported Date)** | **Outcome**2 | **[[2]](#footnote-2)†Expected** (Y or N) | †**Relatedness**3 | †Suggests greater risk of harm (Y or N) | **Assessor Initials & Date** | **PI Initials & Date**  (if PI is assessor,  mark as N/A) |
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*Additional instructions on reverse side*

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| --- | --- | --- |
| **SAE Classification1** | **Outcome**2 | **Relatedness**3 |
| 1 - Fatal (resulted in death) | 0 – Fatal | 0 – Definite |
| 2 - A life-threatening occurrence | 1 – Not recovered/not resolved | 1 – Probable |
| 3 - Requires inpatient hospitalization or prolongation of existing hospitalization | 2 – Recovered w/sequelae | 2 – Possible |
| 4 - Results in persistent or significant disability/incapacity | 3 – Recovered w/o sequelae | 3 – Unlikely |
| 5 - Results in congenital anomaly/birth defect | 4 – Recovering/Resolving | 4 – Unrelated |
| 6 - A significant medical incident that, based upon appropriate medical judgment, may jeopardize the subject and require medical or surgical intervention to prevent one of the outcomes listed above. |  |  |

‡Per IU Policy, if the PI has delegated assessment of AEs, the assessor should be a qualified individual (with appropriate medical training and familiarity with the known safety profile of the study intervention. As the PI is ultimately responsible for overseeing all delegated tasks, the PI should periodically confirm his/her review and agreement with the assessments.

1. \* **Serious Adverse Event Description:**

   Record only one diagnosis, sign or symptom per line *(e.g., nausea and* *vomiting should not be recorded in the* *same entry, but as 2 separate entries)*.   
   • Using accepted medical terminology, enter the diagnosis (if known); otherwise enter a sign or symptom.   
   • Death should not be recorded as an event but should be recorded as the outcome of the event. The condition that resulted in the death should be recorded [↑](#footnote-ref-1)
2. † Per IU Policy, events that are assessed as (1) unexpected, (2) related or possibly related, and (3) suggest that the research places subjects or others at a greater risk of harm than previously known, must be reported to the IRB within 5 business days of notification/discovery of the event. [↑](#footnote-ref-2)