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

# Adverse Event Tracking Log

***Check box if there were no adverse events to be recorded* □**

| Date Reported | Adverse Event Description[[1]](#endnote-1)\*  *(see instructions on reverse)* | Start Date | End Date | Outcome1 | Severity / Grade[[2]](#endnote-2)2 | Serious[[3]](#endnote-3)▲ (Y or N) | AE Treatment3 | Action Taken4 | [[4]](#endnote-4)†Expected (Y or N) | †Relatedness5 | †Suggests greater risk of harm (Y or N) | Assessor[[5]](#endnote-5)‡ Initials  & Date | PI Initials & Date (if PI is assessor, mark as N/A) |
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| **Outcome1** | **Severity / Grade2** | **AE Treatment3** | **Action Taken4 with Study Intervention** | **Relatedness5 to Study Participation** |
| --- | --- | --- | --- | --- |
| 0 – Fatal | 1 – Mild | 0 – None | 0 – None | 0 – Definitely related |
| 1 – Not recovered/not resolved | 2 – Moderate | 1 – Medication(s) | 1 – Interrupted (temporarily) | 1 – Probably related |
| 2 – Recovered w/o sequelae | 3 – Severe | 2 – Non-medication Treatment | 2 – Discontinued (permanently) | 2 – Possibly related |
| 3 – Recovered w/ sequelae | 4 – Life Threatening |  | 3 – Dose reduced | 3 – Unlikely |
| 4 – Recovering/Resolving | 5 – Death (Fatal) |  | 4 – Dose increased | 4 – Unrelated |
| 5 - Unknown |  |  | 5 – Dose delayed |  |

***Additional instructions on reverse side***

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

**Adverse Event Tracking Log**

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| Date Reported | Adverse Event Description\*  *(see instructions on reverse)* | Start Date | End Date | Outcome1 | Severity / Grade2 | Serious▲ (Y or N) | AE Treatment3 | Action Taken4 | †Expected (Y or N) | †Relatedness5 | †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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## Instructions for Use:

1. \* Adverse Event (AE) 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 as the AE.

   [↑](#endnote-ref-1)
2. 2 Severity grading should be conducted in accordance with the protocol defined rating scale. When the protocol does not define a scale, the following grade descriptions may be used:

   1. Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
   2. Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADLs (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.)
   3. Severe or medically significant but not immediately life-threatening; hospitalization of prolongation of hospitalization indicated; disabling; limiting self-care ADLs (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden)
   4. Life Threatening; urgent intervention indicated
   5. Death (Fatal)

   [↑](#endnote-ref-2)
3. ▲ As defined by the FDA, a Serious Adverse Event (SAE) is an event for which the outcome is death; or an event that is life-threatening, requires hospitalization or a prolongation of hospitalization, results in disability or permanent damage or a congenital anomaly/birth defect, requires intervention to prevent permanent impairment or damage, or is considered an important medical event. Further descriptions of these terms can be accessed on the FDA website: <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event> [↑](#endnote-ref-3)
4. † For studies in which the IU IRB is the IRB of Record, events that are assessed as (1) unexpected, (2) related or possibly related to study participation, and (3) suggest that the research places subjects or others at a greater risk of harm than previously known, must be reported to the IU IRB within 5 business days of notification/discovery of the event [↑](#endnote-ref-4)
5. ‡ 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. [↑](#endnote-ref-5)