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| **PROTOCOL TITLE:** |
| **PROTOCOL NO.:** | **PRINCIPAL INVESTIGATOR:** | **SITE NAME:** |

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| **Subject ID No.** | **SAE Description** | **Adverse Event** | **SAE Classification**1 | **Event****Start Date** | **Event End Date** | **Date Site Became Aware of Event (Reported Date)** |  **Outcome**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. |  |  |

 **\* 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

† Per GCP, 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 Human Research Ethics Committee within 24 hours of notification/discovery of the event.