Principal Investigator: \_\_

IRB Number: \_\_ OnCore Protocol Number: \_\_ Subject ID# Page of

Short Protocol Title: \_

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SAE Number** | **SAE Description** | **Adverse Event\****(Select from Safety Profiler)* | **SAE Classification** | **Event****Start Date** | **Event End Date** | **Date Site Became Aware of Event (Reported Date)** |  **Grade** |  **Unexpected** **(Y or N)** |  **Attribution** | **Outcome** |
|  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |  |  |

\*look up corresponding AE at: <https://safetyprofiler-ctep.nci.nih.gov/>

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| --- | --- | --- | --- |
| **SAE Classification** | **Grade** | **Attribution** | **Outcome** |
| 1 - Fatal (resulted in death) | 1 - Mild | 0 – Definite | 0 – Fatal  |
| 2 - A life-threatening occurrence | 2 - Moderate | 1 – Probable | 1 – Not recovered/not resolved |
| 3 - Requires inpatient hospitalization or prolongation of existing hospitalization | 3 - Severe | 2 – Possible | 2 – Recovered w/sequelae |
| 4 - Results in persistent or significant disability/incapacity | 4 - Life Threatening | 3 – Unlikely | 3 – Recovered w/o sequelae |
| 5 - Results in congenital anomaly/birth defect | 5 – Death (Fatal) | 4 – Unrelated | 4 – Recovering/Resolving |
| 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. |  |  |  |

Instructions for entry into ICTR OnCore: <https://kb.wisc.edu/ictr/page.php?id=21220>