**Adverse Event Log**

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| **Study Title:** | **Investigator Name:** |

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|  |  |  |  |  |  |  | **Intensity** | | | **Causality\*\*** | | | | | **Relationship to Study** | **IRB Reporting** | |
| **Participant #** | **Participant**  **Study Start** | **Participant**  **Study End** | **Adverse Event** | **\* Indicates SAE** | **AE Start** | **AE End** | **Mild** | **Mod.** | **Severe** | **1** | **2** | **3** | **4** | **5** | **Anticipated**  **or**  **Unanticipated** | **Prompt**  **or**  **Non-prompt** | **Serial #** |
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*\* Serious Adverse Event: An adverse event that was life-threatening, required hospitalization (initial or prolonged), caused disability or permanent damage, required intervention to prevent permanent impairment/damage, caused a congenital anomaly or birth defect, any death, or other serious adverse event.*

*\*\*Causality Key: 1 Definitely not, 2 Probably not, 3 Possibly, 4 Probably, 5 Definitely*

**“I have reviewed the above noted serious adverse events. These events do not warrant changes to the protocol or consent process. The risk/benefit ratio has not changed.”**

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***Investigator Signature Date***