# Adverse Event Form

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| **STUDY NAME** | |
| **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Pt\_ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **This form is cumulative and captures adverse events of a single participant throughout the study.** |

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| **Severity** | Study Intervention Relationship | **Action Taken Regarding Study Intervention** | Outcome of AE | **Expected** | **Serious Adverse Event (SAE)** |
| 1 = Mild  2 = Moderate  3 = Severe  4 = Life-Threatening | 0 = Not related  1 = Unlikely related  2 = Possibly related  3 = Probably related  4 = Definitely related | 0 = None  1 = Dose modification  2 = Medical Intervention  3 = Hospitalization  4 = Intervention discontinued  5 = Other | 1 = Resolved  2 = Recovered with minor sequelae  3 = Recovered with major sequelae  4 = Ongoing/Continuing treatment  5 = Condition worsening  6 = Death  7 = Unknown | 1 = Yes  2 = No | 1 = Yes  2 = No  (if yes, complete SAE form) |

**At end of study only: Check this box if participant had no adverse events Checkbox. None**

| **Adverse Event** | **Start Date** | **Stop Date** | **Severity** | **Relationship** | **Action Taken** | **Outcome of AE** | **Expected?** | **SAE?** |
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