# **Adverse Event Log**

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| Severity | **Study Intervention Relationship** | Action Taken Regarding Study Participation | **Outcome of AE** | Expected | Serious Adverse Event (SAE) |
| 1 = Mild  2 = Moderate  3 = Severe | 1= Not related  2 = Unlikely related  3 = Possibly related  4 = Probably related  5 = Definitely related | 1 = None  2 = Study intervention modification  3 = Study intervention discontinued  4 = Participant withdrawn from study | 1 = Resolved  2 = Recovered with sequelae  3 = Ongoing/Continuing treatment  4 = Condition worsening  5 = Unknown | 1 = Yes  2 = No | 1 = Yes  2 = No |

| ID # | Adverse Event Description | Date(s) | Severity | Relationship | Action Taken | Outcome | Expected | SAE | Investigator Name & Date |
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* Any unexpected or serious adverse events should be reported immediately, and no more than 5 working days after the study team learns of the event, to the CSU IRB.
* Any expected adverse events that are not considered serious (as defined in the attached Protocol) should be tracked on the adverse event log and provided at annual continuing review.