# **Adverse Event Log**

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| Severity | **Study Intervention Relationship** | Action TakenRegarding Study Participation | **Outcome of AE** | Expected | Serious AdverseEvent (SAE) |
| 1 = Mild2 = Moderate3 = Severe | 1= Not related2 = Unlikely related3 = Possibly related4 = Probably related5 = Definitely related | 1 = None2 = Study intervention modification3 = Study intervention discontinued4 = Participant withdrawn from study  | 1 = Resolved2 = Recovered with sequelae3 = Ongoing/Continuing treatment4 = Condition worsening5 = Unknown | 1 = Yes2 = No | 1 = Yes 2 = No |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.