**Study Title: IRB #:
Principal Investigator: Participant ID\*: Initial Consent Date\*:**

**Intervention Start Date\*: Intervention End Date\*: Off Study Date\*:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse event** | **Start and stop dates** | **Serious** | **Grade\*\*** | **Relationship to study** | **Anticipated** | **Action taken with the drug/device/intervention** | **Other actions taken**  | **Was the AE reported to the sponsor?**  | **Was the AE reported to the IRB? \*\*\*** | **PI initials and date** |
|  | Start:Stop: | [ ] Yes[ ]  No  | [ ]  Mild [ ] Moderate [ ]  Severe [ ] Life Threatening [ ] Death  | □Not related□Possibly related □Probably related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other |  | [ ]  No [ ] YesDate of report: | [ ]  No [ ] YesDate of report: |  |
|  | Start:Stop:  | [ ] Yes[ ]  No  | [ ]  Mild [ ] Moderate [ ]  Severe [ ] Life Threatening [ ] Death | □Not related□Possibly related □Probably related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other |  | [ ]  No [ ] YesDate of report: | [ ]  No [ ] YesDate of report: |  |
|  | Start:Stop: | [ ] Yes[ ]  No  | [ ]  Mild [ ] Moderate [ ]  Severe [ ] Life Threatening [ ] Death | □Not related□Possibly related □Probably related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other |  | [ ]  No [ ] YesDate of report: | [ ]  No [ ] YesDate of report: |  |
|  | Start:Stop: | [ ] Yes[ ]  No  | [ ]  Mild [ ] Moderate [ ]  Severe [ ] Life Threatening [ ] Death | □Not related□Possibly related □Probably related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other |  | [ ]  No [ ] YesDate of report: | [ ]  No [ ] YesDate of report: |  |

 *\* If you expect multiple AEs for the study, create a log for each participant. If you don’t expect many AEs on the study, delete the participant-specific header and add a column for participant initials and ID. If you will maintain one log for the entire study, maintain the log with the regulatory documentation.
\*\*Revise this column to meet the grading requirements of the protocol (e.g., “1-5” vs “mild-severe”).*

*\*\*\*To further document your assessment of this event and determine if it meets the Emory IRB’s reporting requirements, please complete the Emory IRB’s Reportable New Information Assessment Form.*