**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  Yes  Date of report: | No  Yes  Date 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  Yes  Date of report: | No  Yes  Date 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  Yes  Date of report: | No  Yes  Date 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  Yes  Date of report: | No  Yes  Date 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.*