**Adverse Event Log** Subject #: Subject Initials:

**Study Title:** [ ]  No Adverse Events Reported for this Subject

**IRB Control #: PI: Sponsor:**

**Note: All AEs, which generally include ANY medical event, should be recorded on this log. Adverse events that meet the following criteria must be reported to the IRB immediately: Severity = 3, 4, 5, Relationship = 3, 4, 5, and Unexpected. See GA 120 for complete information.**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event** | **Start Date** | **Stop Date** | **Date PI/Study Team became Aware** | **Severity** | **Relationship**  | **Action Taken** | **Outcome** | **Unexpected**  | **Serious**  | **Submitted to IRB** |
|  |  |  |  |  |  |  |  | [ ] Yes[ ] No | [ ] Yes[ ] No | [ ] Yes[ ] No |
|  |  |  |  |  |  |  |  | [ ] Yes[ ] No | [ ] Yes[ ] No | [ ] Yes[ ] No |
|  |  |  |  |  |  |  |  | [ ] Yes[ ] No | [ ] Yes[ ] No | [ ] Yes[ ] No |
|  |  |  |  |  |  |  |  | [ ] Yes[ ] No | [ ] Yes[ ] No | [ ] Yes[ ] No |
|  |  |  |  |  |  |  |  | [ ] Yes[ ] No | [ ] Yes[ ] No | [ ] Yes[ ] No |

**Investigator Signature:** **Date:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Severity | Relationship | Action Taken | Outcome | Unexpected |
| 1 – Mild2 – Moderate 3 – Severe4 – Life Threatening / Disabling5 – Death | Relationship to test article (e.g., drug, device), procedures, conduct, or some other aspect of the study.1 – Unrelated2 – Unlikely3 – Possible4 – Probable5 – Definite  | 1 – None2 – Medication 3 – Procedure4 – Study Intervention Changed5 – Study Intervention Stopped6 – Hospitalization7 – Other | 1 – Resolved / Returned to Baseline 2 – Continuing3 – Death | Unexpected indicates that an event is not listed, or is listed with a different specificity or greater severity or frequency, in the investigator’s brochure, device brochure, product insert, protocol or consent form. |