**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 – Mild  2 – Moderate  3 – Severe  4 – Life Threatening / Disabling  5 – Death | Relationship to test article (e.g., drug, device), procedures, conduct, or some other aspect of the study.  1 – Unrelated  2 – Unlikely  3 – Possible  4 – Probable  5 – Definite | 1 – None  2 – Medication  3 – Procedure  4 – Study Intervention Changed  5 – Study Intervention Stopped  6 – Hospitalization  7 – Other | 1 – Resolved / Returned to Baseline  2 – Continuing  3 – 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. |