**Investigator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Protocol/IRB Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*This log captures adverse events (including serious adverse events) for the subject indicated above. Subject should be asked about the presence/absence of AEs/SAEs at every study visit.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Severity** | **Study Intervention Relationship** | **Action Taken  (choose all that apply)** | **Outcome of AE** | **Expected** | **Serious Adverse Event (SAE)** |
| 1 = Mild  2 = Moderate  3 = Severe | 1 = Not related  2 = Unlikely related  3 = Possibly related  4 = Probably related  5 = Definitely related | 1 = None  2 = Study intervention discontinued  3 = Study intervention modified  4 = Concomitant medication given  5 = Subject withdrawn from study  6 = Hospitalization  7 = Other | 1 = Recovered  2 = Recovered with sequelae  3 = Ongoing treatment  4 = Condition worsened  5 = Death  6 = Unknown | 1 = Yes  2 = No  (AE is not listed as a side effect in IB, package insert, or as a characteristic of the indication) | 1 = Yes  (complete SAE form)  2 = No |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event Description  (per protocol or CTCAE)** | **Start Date** | **PI/Sub-I Initials/Date** | **Stop Date** | **PI/Sub-I Initials/Date** | **Severity** | **Relationship** | **Action Taken** | **Outcome** | **Expected** | **SAE** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event Description  (per protocol or CTCAE)** | **Start Date** | **PI/Sub-I Initials/Date** | **Stop Date** | **PI/Sub-I Initials/Date** | **Severity** | **Relationship** | **Action Taken** | **Outcome** | **Expected** | **SAE** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |