|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Action Taken with IP** | **Severity** | **Relationship to Study IP** | **Outcome of Event** | **Serious** |
| 1 - None2 - IP Interrupted3 - IP Discontinued4 - Treated with Concomitant Medication5 – Dose Modified | 1 - Mild2 - Moderate3 – Severe4. Life Threatening | 1 - Not Related2 - Probably NOT Related3 - Possibly Related4 - Probably Related5 - Related | 1 - Resolved, No Sequelae 2 - AE still present- no treatment 3 - AE still present- being treated 4 - Residual effects present-not treated 5 - Residual effects present- treated 6 - Death 7 - Unknown  | 1 - No 2 - YesIf Yes, Complete SAE form  |

|  |
| --- |
| **ADVERSE EVENT LOG** |

Study Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event** | **Date of Onset** | **Date of Site Knowledge** | **Action Taken** | **Severity** *(Investigator Assessed)* | **Relationship to IP** *(Investigator Assessed)* | **Outcome** | **Date of Outcome** | **Serious** | **Date IRB notified** | **✓ if Continuing at End of study** |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Investigator initials at time of assessment: |  |
| Date: |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Investigator initials at time of assessment: |  |
| Date: |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Investigator initials at time of assessment: |  |
| Date: |

|  |  |
| --- | --- |
| Investigator Signature at end of study | Date: |