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| **Action Taken with IP** | **Severity** | **Relationship to Study IP** | **Outcome of Event** | **Serious** |
| 1 - None  2 - IP Interrupted  3 - IP Discontinued  4 - Treated with Concomitant Medication  5 – Dose Modified | 1 - Mild  2 - Moderate  3 – Severe  4. Life Threatening | 1 - Not Related  2 - Probably NOT Related  3 - Possibly Related  4 - Probably Related  5 - 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 - Yes  If Yes, Complete SAE form |

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| **ADVERSE EVENT LOG** |

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

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| **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** |
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|  | | | Investigator initials at time of assessment: | | | | | |  | | | |
| Date: | | | | | |
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|  | | | Investigator initials at time of assessment: | | | | | |  | | | |
| Date: | | | | | |
|  |  |  | |  |  |  |  |  | |  |  |  |
|  | | | Investigator initials at time of assessment: | | | | | |  | | | |
| Date: | | | | | |

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| Investigator Signature at end of study | Date: |