**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.*

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| **Severity** | **Study Intervention Relationship** | **Action Taken (choose all that apply)** | **Outcome of AE** | **Expected** | **Serious Adverse Event (SAE)** |
| 1 = Mild2 = Moderate3 = Severe | 1 = Not related2 = Unlikely related3 = Possibly related4 = Probably related5 = Definitely related | 1 = None2 = Study intervention discontinued3 = Study intervention modified4 = Concomitant medication given5 = Subject withdrawn from study6 = Hospitalization7 = Other | 1 = Recovered2 = Recovered with sequelae3 = Ongoing treatment4 = Condition worsened5 = Death 6 = Unknown | 1 = Yes2 = 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 |

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| **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** |
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| **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** |
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