**Serious Adverse Event (SAE) Recording Log**

**Study Sponsor Number: Study Name:**

* Ensure all SAEs are also documented in the trial subject’s medical notes, Case Report Form and SAE Reporting Form
* This log is to be kept at site and sent to sponsor on request
* The PI (or delegated medically qualified person) must provide causality assessments and sign and date each page

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| **Subject** **Trial ID** | **SAE Term***List one event per line**Provide final diagnosis, if known* *(not symptoms or procedures)* | **Start Date***DD-MMM-YYYY* | **Outcome**1. Recovered
2. Recovering
3. Not Recovered
4. Recovered with Sequelae
5. Fatal
6. Unknown
 | **Serious Criteria**1. Death
2. Life-threatening
3. Required / Prolonged Hospitalisation
4. Persistent or Significant Disability / Incapacity
5. Congenital Anomaly / Birth Defect
6. Important Medical Event
 | **Causality Relationship to IMP** *(as per protocol)*1. Definitely
2. Probably
3. Possibly
4. Unlikely
5. Not Related
6. Unknown ***OR***
7. Related (Reasonable Possibility)
8. Not Related (No Reasonable

Possibility) | **Date site made aware of SAE***DD-MMM-YYYY* | **Date initial SAE Reporting Form sent to JRO***DD-MMM-YYYY**or N/A if exempt from reporting as per protocol* |
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| **Chief/Principal Investigator Name:**(or delegated medically qualified person) |       | **Signature:** |  | **Date:** |       | **Page** |       | **of** |       |