**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** |  |