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| **EXPEDITED SAFETY REPORT FORM** | | | |
| Reporting requirement  All sites to report to the Sponsor-Investigator all \*SAEs, SUSARs and USMs within 24 hours of site staff becoming aware of the event.  *\*Except those identified in the protocol as not needing immediate reporting* | | | |
| **HREC Reference #** |  | | |
| **Project title** |  | | |
| **SAFETY EVENT TYPE** | ☐ SAE | ☐ SUSAR | ☐ USM |

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| **Section A: Local Site Details** | |
| **Site Name:** |  |
| **Site Principal Investigator:** |  |
| **Date site staff became aware of the safety event:** |  |

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| **Section B: Participant Details** | |
| **Participant Enrolment OR Randomisation No.:** |  |
| **Participant Initials:** |  |
| **SEX:** (please tick) |  |
| **Date of Birth** (DD/MMM/YYYY)**:** |  |
| **Weight** (XXX.X Kg)**:** |  |

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| **Section C: Event Details** | |
| **SAE Term:**  *(verbatim, as it appears in the source document, e.g. participant’s medical notes)* |  |
| **Severity Grade:**  *(According to the grading scale provided in the study protocol)* |  |
| **Date of Onset** (DD/MMM/YYYY)**:** |  |
| **SAE Category:**  *(Tick all that apply)* | ☐ Results in Death  ☐ Is Life Threatening  ☐ Requires or prolongs inpatient hospitalisation  ☐ Results in persistent or significant disability or incapacity  ☐ Is a congenital anomaly or birth defect  ☐ Other significant medical event |
| **Contributing Factor(s):**  *(Tick all that apply)* | ☐ Study Intervention  ☐ Concomitant Intervention; *specify*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Concurrent/Concomitant Medication; *specify*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Concurrent Disorder; *specify*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Concurrent Clinical Trial\*; *specify Clinical Trial;* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Other; *specify*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Trial Stage:** | ☐ Screening  ☐ Treatment  ☐ Follow-up  ☐ Other, *specify*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Event description and management:**  *(Use additional pages if necessary, provide relevant redacted reports/supplementary information)* | |

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| **Section D: Intervention Details** | |
| **Intervention Name:** |  |
| **Intervention Administration Details:**  **(dose, frequency etc)** |  |
| **Safety Event Relationship to the Intervention:** | ☐ Unrelated  ☐ Unlikely to be related  ☐ Possibly related  ☐ Probably related  ☐ Definitely related |

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| **Section D: Action Taken** | |
| **Action Taken:** | ☐ None  ☐ Intervention reduced  ☐ Intervention delayed  ☐ Intervention delayed & reduced  ☐ Withdrawn from Intervention |
| **Was an Urgent Safety Measure (USM) instigated?**  *A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety.* | \* ☐ Yes ☐ No  \*Report to local RGO within 72 hours of becoming aware of event (if applicable) |
| **Treatment Given for SAE:**  *(if applicable)* |  |
| **SAE Outcome:** | ☐ Recovering/Resolving (outcome to be updated later)  ☐ Recovered/Resolved  ☐ Recovered/Resolved with sequelae; *specify sequelae: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Fatal; *specify cause of death \_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Unknown; *specify reason unknown*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Section E: Investigator Signature** | |
| **Investigator Name:** |  | |
| **Investigator Signature:** |  | |
| **Date:** |  | |

**Please email one signed copy to the Sponsor–Investigator <***insert name and email address***) and retain the signed original in the Site Investigator File**