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| **EXPEDITED SAFETY REPORT FORM** |
| Reporting requirementAll 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**