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| **MQ safety guidelines** **SAFETY REPORT FORM** |
| Reporting requirement: All sites to report to Macquarie University Clinical Trials Safety Officer via email ResearchSafetyReporting@mq.edu.au, cc. clinical.research@mqhealth.org.au all \*SAEs, USADEs, 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** |  |

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| **Section A: To be completed by the Macquarie University Site only** |
| **Site:** |  |
| **Principal Investigator:** |  |
| **Participant Enrolment OR Randomisation No.:** |  |
| **Date of onset (AE)/ date of the safety measure (USM) occurred:**  | Click to enter a date. |
| **Date Principal Investigator became aware of the safety event:** | Click to enter a date. |
| **Participant’s date of birth, age, and weight:** | Click to enter a date. |
| **Event description and management (*including reason for ‘serious’ criteria for SAE, and date the event became serious. Also include any action taken on the study drug (e.g., discontinued or interrupted*):** |
| **Event outcome (synopsis):** |
| **Study Phase***Amend to reflect protocol* | [ ]  Screening[ ]  Treatment[ ]  Follow-up  |
| **Relationship to the Investigational Product** | [ ]  Unrelated[ ]  Unlikely to be related[ ]  Possibly related [ ]  Probably related [ ]  Definitely related  |
| **Expectedness (only complete for SAEs/SADEs that are probably/possibly related):** | [ ]  Not applicable [ ]  Expected [ ]  **\***Unexpected **\***Report SUSAR/USADE to Macquarie University Clinical Trials Safety Officer within 72 hours of becoming aware of event |
| **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 Macquarie University Clinical Trials Safety Officer within 72 hours of becoming aware of event |
| **Name and Signature** (*PI or medically qualified delegate*) | **Date:**Click to enter a date. |

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| **Section B: To be completed by the Principal Investigator only** |
| **Is this event a Significant Safety Issue (SSI)?***A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial. Often SSIs do not fall within the definition of a Suspected Unexpected Serious Adverse Reaction (SUSAR), thus are not reported as SUSARs but require other action such as the reporting of an urgent safety measure (USM), an amendment, a temporary halt or early termination of a trial.* | **\*** [ ]  Yes [ ]  No**\***Report to TGA, HREC and all site PIs (if applicable) within 15 days of becoming aware of event |
| **Is this event an Urgent Safety Measure (USM)?***A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety.* | **\*** [ ]  Yes [ ]  No**\***Report to TGA, HREC and all site PIs (If applicable) within 72 hours of becoming aware of event |
| **Is this event a SUSAR/USADE?** | **\*** [ ]  Yes [ ]  No**\***Report to TGA within 7 days of becoming aware of the event if fatal/life threatening, otherwise report within 15 calendar days |
| **Does the protocol require an amendment as a result of this safety event?**(**If Yes**, submit an amendment request with the amended protocol to approving HREC) | [ ]  Yes [ ]  No |
| **Does the participant information sheet and consent form (PICF’s) require amending as a result of this safety event?**(If Yes, submit amendment request to approving HREC with the amended forms)  | [ ]  Yes [ ]  No |
| **Is a temporary halt or early termination of the trial required as a result of this safety event?**(**If Yes**, ensure actions are taken within 15 days of decision to halt) | [ ]  Yes [ ]  No |
| **Principal Investigator Name and Signature (*adobe e-sign preferred*):**  | **Date:**Click to enter a date. |

**Please email one signed copy to** **Macquarie University Clinical Trials Safety Officer at** **ResearchSafetyReporting@mq.edu.au****, cc.** **clinical.research@mqhealth.org.au** **and retain the signed original in the Site Investigator File.**

**Acknowledgement:** This template has been modified with permission by the authors from Clinical Research Development Office, Murdoch Children’s research Institute, Melbourne.