**Appendix 7: Expedited Safety Report Form**

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| **EXPEDITED SAFETY REPORT FORM** | |
| Reporting requirement: All sites to report to Sponsor-Investigator all \*SAEs, SUSARs and USMs within 24 hours of **trial** 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 Local Site** | | | | |
| **Site:** | |  | | |
| **Local Site Principal Investigator:** | |  | | |
| **Participant Enrolment OR Randomisation No.:** | |  | | |
| **Date the safety event occurred:** | |  | | |
| **Date Local Site Principal Investigator became aware of the safety event:** | |  | | |
| **Participant’s date of birth, age and weight:** | |  | | |
| **Event description and management:** | | | | |
| **Event outcome (synopsis):** | | | | |
| **Trial phase**  *(amend to reflect protocol)* | ☐ Screening  ☐ Treatment  ☐ Follow Up | |  | |
| **Relationship to the trial drug** | | ☐ Unrelated  ☐ Possibly related  ☐ Probably related  ☐ Definitely related | | |
| **Expectedness (only complete for SAEs that are probably/possibly related):** | | ☐ Not applicable  ☐ Expected  ☐ \*Unexpected  \*Report SUSAR to local RGO 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 local RGO within 72 hours of becoming aware of event | | |
| Name and Signature (of local PI or delegate) | | | | Date |

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| **Section B: To be completed by the Sponsor-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 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 within 72 hours of becoming aware of event |
| **Is this event a SUSAR?** | \* ☐ 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 amending as a result of this safety event?**  (If Yes, submit an amended protocol to approving HREC) | ☐ Yes ☐ No |
| **Do the participant information statements require amending as a result of this safety event?**  (If Yes, submit a**n amendment** request to approving HREC and RGOs 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 |
| Name and Signature (Associate investigator)) | Date |

**Please email one signed copy to the Principal Investigator (Prof David Hunter-Smith; david.hunter-smith@monash.edu) and retain the signed original in the Site Investigator File**