Significant Safety Issue Report Form

This report is to be completed for all clinical trials (therapeutic goods and non-therapeutic goods) approved by AHCL HREC and submitted to the AHCL HREC by email to [research@sah.org.au](mailto:research@sah.org.au).

Significant Safety Issues[[1]](#footnote-1) (SSIs) that have been implemented as an Urgent Safety Measure (USM) should be reported within 72 hours of the sponsor becoming aware of the issue. All other SSIs should be reported within 15 calendar days of the sponsor becoming aware of the issue.

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| **STUDY DETAILS** | |
| **AHCL HREC Project ID:** |  |
| **Project Title:** |  |
| **Protocol No. (if applicable):** |  |
| **Sponsor (if applicable):** |  |
| **Principal Investigator:** |  |
| **Date of this Report:** |  |

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| **DETAILS OF THE SIGNIFICANT SAFETY ISSUE (SSI)** | |
| **Date the SSI occurred:** |  |
| **Please provide all relevant details of the SSI:** |  |

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| **ACTIONS RESULTING FROM THE SSI**  Select all that apply | | |
| **Implementation of an Urgent Safety Measure** | | |
| Please specify the urgent safety measure taken and why it was necessary: |  | |
| **Notification of an amendment** | | |
| Is the *Amendment Application Form* provided with this report? | | Yes  No |
| If No, describe the nature of any planned amendment (e.g. revised Protocol or PICF) and the expected timeframe for submission of the *Amendment Application Form* to the AHCL HREC: |  | |
| **Temporary halt of the trial for safety reasons** | | |
| Please describe the scope of the halt e.g. suspension of recruitment, cessation/ interruption of trial treatment/ intervention: |  | |
| Please provide details of the number of participants still receiving treatment in Australia at the time of the temporary halt, and their proposed management: |  | |
| Please provide details of the number of participants still receiving treatment at **Sydney Adventist Hospital** at the time of the temporary halt, and their proposed management: |  | |
| **Early termination of the trial for safety reasons** | | |
| Please provide details of the number of participants still receiving treatment in Australia at the time of early termination, and their proposed management: |  | |
| Please provide details of the number of participants still receiving treatment at **Sydney Adventist Hospital** at the time of the temporary halt, and their proposed management: |  | |
| Please also comment on the consequences of early termination for the evaluation of the study results and provide the anticipated date when the Final Report will be provided to the AHCL HREC, if not provided with this report: |  | |

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| **DECLARATION** | |
| I declare that the information provided in this report is true and accurate.  Reported by (please select one and provide your contact details and signature below): | |
| Sponsor | |
| Sponsor’s delegate: person or organisation authorised by the sponsor | |
| **Organisation:** |  |
| **Contact Name:** |  |
| **Telephone:** |  |
| **Email:** |  |
| **Signature:** |  |
| **Date:** |  |

1. The NHMRC define a Significant Safety Issue (SSI) and Urgent Safety Measure (USM) as follows:

   SSI: A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

   USM: A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety.

   Note: This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions. [↑](#footnote-ref-1)