Serious Breach Report Form (Sponsor)

This form should be completed when the trial sponsor is reporting a serious breach to the AHCL Human Research Ethics Committee (HREC) or when a sponsor is providing additional/follow-up information following a third party report of a confirmed serious breach.

The completed form can be submitted by email to research@sah.org.au.

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| **STUDY DETAILS**Please provide the following details: |
| **Date of this Report:** |       |
| **AHCL HREC Project ID:** |       |
| **Project Title:** |       |
| **Coordinating Principal Investigator:** |       |
| **Sponsor:** |       |
| **Sponsor Contact Name (Australia):** |       |
| **Please indicate whether this is:** | [ ]  Initial Report [ ]  Follow-up Report |
| **Details of the organisation/ individual committing the serious breach:** |       |

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| **DETAILS OF THE SERIOUS BREACH** |
| **Indicate the impact of the serious breach on any of the following:** |
| [ ]  Participant safety | [ ]  Participant rights | [ ]  Reliability and robustness of data |
| **Please provide:** |
| **1. An explanation of where, how and when the serious breach occurred and how it was identified:** |       |
| **2. Any other relevant information (e.g. project status)** |       |

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| **DETAILS OF ANY ACTION TAKEN TO DATE\***\*If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with projected timelines for completion and provide any further information in a follow-up report. |
| **1. Any investigations you/others are conducting:** |       |
| **2. The outcome of those investigations if completed (or details of when they will be available/reported):** |       |
| **3. How the serious breach will be reported in the final report/publication:** |       |
| **4. Any corrective and preventative action implemented to ensure the serious breach does not occur again:** |       |

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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:** |  |