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](mailto: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:** |  |