Suspected Breach Report Form (Institution/Individual)

This form should be completed when a third party (e.g. institution/individual) wishes to report a suspected breach of Good Clinical Practice or the Protocol directly to the AHCL Human Research Ethics Committee (HREC) without reporting through the sponsor.

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

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| **STUDY DETAILS**Please provide the following details (if known) |
| **Date of this Report:** |       |
| **AHCL HREC Project ID:** |       |
| **Project Title:** |       |
| **Principal Investigator:** |       |

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| **REPORTER DETAILS** |
| **Name:** |       |
| **Organisation:** |       |
| **Contact details:** | **Email:**       | **Phone:**       |
| **Role in/connection to the project:** |       |

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| **DETAILS OF THE SUSPECTED BREACH**Please provide: |
| **1. Details of the organisation/ individual committing the suspected breach:** |       |
| **2. An explanation of where, how and when the suspected breach was identified:** |       |
| **3. Any other relevant information:** |       |

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| **DECLARATION** |
| I declare that the information provided in this report is true and accurate.Reported by (please complete below): |
| **Organisation:** |  |
| **Contact Name:** |  |
| **Telephone:** |  |
| **Email:** |  |
| **Signature:** |  |
| **Date:** |  |