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**SA DEPARTMENT FOR HEALTH AND WELLBEING**

**HUMAN RESEARCH ETHICS COMMITTEE**

**NOTIFICATION OF A STUDY-RELATED ADVERSE EVENT**

*It is a condition of approval that the DHW HREC must be advised of any serious or unexpected adverse events that take place while a participant is taking part in a study. Where possible an adverse event should be submitted by the investigators via the forms function in the Research GEMS online system.* *However, if the person reporting an adverse event does not have access to GEMS then completing and submitting this form will notify the DHW HREC Executive Officer who will take further action.*

***Unexpected Adverse Event:*** *an unforeseen harmful, unpleasant or undesirable response, reaction or outcome experienced by a research participant or researcher. Such incidents may include unanticipated physical, psychological, emotional, cultural, financial or legal harm. It may also include where an unexpected event has occurred which may potentially harm participants, researchers, or the study organisation.*

***Serious Adverse Event:*** *any untoward medical or psychological occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.*

|  |  |
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| **Your Name** |  |
| **Your Contact details** | **Email:**       **Phone:**       |
| **Study Title**  |  |
| **HREC Reference Number***(if known)* |       |
| **Coordinating Principal Investigator** *(if known)* | **Name & Institution:**      **Email:**       |
|  |  |
| **Date of Event** |       |
| **Description of Event**  |       |
| **Likely Cause of Event** |       |
| **Event Outcome** |       |
| **Do you believe that that adverse event was directly related to the research?** |  |
| **Was this event described as a risk in the Participant Information Sheet?** |  |
| **Other Comments** |       |

***Once completed, please send this form to:***

*SA DEPARTMENT FOR HEALTH AND WELLBEING HUMAN RESEARCH ETHICS COMMITTEE*

*Health.HumanResearchEthicsCommittee@sa.gov.au*

#### OFFICE USE ONLY

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| --- |
| COORDINATING PRINCIPAL INVESTIGATOR |
| **Name**      | **Signature:**  | **Date:**       |

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| HREC EXECUTIVE OFFICER |
| **Date Received:**       | **HREC Notified:**  | **Db Updated:**  |
| **HREC Executive Officer Comments:** |

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| CHAIR, DHW HUMAN RESEARCH ETHICS COMMITTEE |
| **Name:** | **Signature:** | **Date:**       |
| **HREC Chair Comments:** |

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| SITE RESEARCH GOVERNANCE OFFICER(S)*Please note: In accordance with SA Health and National reporting guidelines, the Research Governance Officer(s) where the Adverse Event occurred must be provided with copies of the report.* ***These signatures can be obtained separate to the HREC.*** |

|  |  |  |  |  |
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| **Site Name** | **RGO Name** | **Signature** | **Date** | **RGO Comments** |
|  |  |  |       |  |