**DO NOT USE THIS FORM FOR LEGALLY REPORTABLE EVENTS**

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| Complete this form to advise the HREC of an adverse or reportable event which have occurred during your approved research project which involves people. Email the completed form to humanethics@unisa.edu.au within 72 hours of the event.If your approval is from an institution other than UniSA, but you have a *recognition* of that approval from UniSA, you need to advise the other institution as a matter of priority. |

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| **SECTION 1: PROJECT DETAILS** |
| Chief Investigator |  |
| Project Title |  |
| Project Number |  | Original Approval Date |  |

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| **SECTION 2: EVENT TYPE** |
| [ ]  Adverse Event during clinical trial[ ]  Psychological or Emotional distress requiring referral to a support service | [ ]  Privacy or breach of confidentiality issues[ ]  Other |

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| **SECTION 3: REPORT STATUS** |
| [ ]  Initial Report | Date |
| [ ]  Follow up report  | Date |
| [ ]  Final Report | Date |

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| **SECTION 4: DETAILS OF EVENT** |
| Date of Event |  | Participant ID |  |
| Description of Event |
| Immediate actions taken to mitigate harm and risk; identify who has taken actions |

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| **SECTION 5: ADVERSE EVENTS DURING CLINICAL TRIAL ONLY**  |
| LIKELY CAUSE OF EVENT |
| [ ]  Study Drug/Treatment | [ ]  Progressive Disease |
| [ ]  Standard Treatment | [ ]  Concurrent Medication |
| [ ]  Concurrent Disorder |  |
| [ ]  Other *(please specify)*: |
| OUTCOME |
| [ ]  Fatal | [ ]  Hospitalisation required / prolonged |
| [ ]  Life threatening | [ ]  Permanent or significant disability / incapacity |
| [ ]  Other *(please specify)*: |

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| **SECTION 6: RELATIONSHIP TO STUDY** |
| [ ]  Directly related | [ ]  Not related |
| [ ]  Possibly related |  |
| If directly or possibly related, then please provide an assessment of the relationship of the event to the study: |

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| **SECTION 7: ADDITIONAL INFORMATION *(please answer each of the following)*** |
| Was this event anticipated in the approved UniSA HREC project? | [ ]  Yes | [ ]  No |
| Was this event described in the Participant Information Sheet? | [ ]  Yes | [ ]  No |
| Does this report raise additional safety concerns for the participants of this research? | [ ]  Yes | [ ]  No |
| Will there be changes made to your project as a result of this event? | [ ]  Yes | [ ]  No |
| *If yes, please submit a* [*Project Variation Form*](https://i.unisa.edu.au/siteassets/staff/ris/docs/project-variation-form-191004.docx) |
| Has the participant been withdrawn from the research due to this event? | [ ]  Yes | [ ]  No |
| If no, has medical advice been sought to determine if the participant is medically fit to continue? |
| [ ]  Not Applicable | [ ]  Yes | [ ]  No |
| Further comments: |

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| **SECTION 8: DECLARATION** |
| [ ]  I declare the information in this form is true and accurate.[ ]  The project has been conducted in accordance with the approved UniSA HREC project. |
| *Chief Investigator Signature* | *Printed Name* | *Date* |
| *Supervisor’s Signature (students only)* | *Printed Name* | *Date* |