**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](mailto: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 |

|  |  |  |  |
| --- | --- | --- | --- |
| **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* |