**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 that occurred during your approved research project. Email the completed form to** **humanethics@latrobe.edu.au** **within 72 hours of the event.****Do not use this form if your project is a clinical trial, please use the relevant safety report form for clinical trials instead.** |

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

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| **SECTION 2: EVENT TYPE** |
| [ ]  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 |  |
| Location of Event |  |  |  |
| Description of Event |
| Immediate actions taken to mitigate harm and risk; identify who has taken actions |

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| **SECTION 6: RELATIONSHIP TO PROJECT** |
| [ ]  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 LTU HREC project? | [ ]  Yes | [ ]  No |
| Was this event described in the Participant Information Sheet? | [ ]  Yes | [ ]  No |
| Does this report raise additional safety concerns or rights for the participants of this research? | [ ]  Yes | [ ]  No |
| Will there be changes made to your project as a result of that impact? | [ ]  Yes | [ ]  No |
| *If yes, please submit a request for modification.* |
| Has the participant been withdrawn from the research due to this event? | [ ]  Yes | [ ]  No |
| If no, has medical or other 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 LTU HREC project. |
| *Principal Investigator Signature* | *Printed Name* | *Date* |
| *Supervisor’s Signature (students only)* | *Printed Name* | *Date* |

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| **REVIEW OUTCOME: HREC RECOMMENDATIONS** |
| [ ]  Action  |
| [ ]  No action  |