**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**](mailto: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| Has the participant been withdrawn from the research due to this event?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 |