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|  | **Research and Graduate Studies Committee**  **University Human Ethics Committee**  **College Human Ethics Sub-Committees** |
| **Research Office** |  |

**Incident and Serious Adverse Event Report Form – HUMAN RESEARCH ETHICS**

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| **1. Approval Number** |  | |
| **2. Project Title** |  | |
| **3. Chief Investigator / Supervisor:**  (academic staff members only) | Name:  Email address: | |
| **4. Student** (if applicable) | Name:  Email address: | |
| **5. Project Duration:**  (subject to annual review) | Project commenced:         /     / | Project concludes:         /     / |

A **Serious Adverse Event (SAE**) is defined as any untoward medical occurrence in a clinical trial or other clinical research project that:

* results in death;
* is life-threatening;
* requires in-patient hospitalisation or prolongation of existing hospitalisation;
* results in a persistent or significant disability/incapacity;
* is a congenital anomaly/birth defect; or
* is a medically important event or reaction

An **Incident** is defined as any event that has serious or unanticipated adverse effects on research participants, as well as any unforeseen events that might affect the continued ethical acceptability of the project.

## 6. DESRIPTION OF SAE/INCIDENT: please include the location of the event and the date first noticed.

**7. RELATION TO THE PROJECT:** Please advise if the SAE or Incident was specifically related to, possibly related to or probably related to the study protocol.

**8. ACTION TAKEN –**

**9.** **IMPACT ON PARTICIPANTS**: If the continued ethical acceptability of the project or the safety of participants is impacted by this event, please advise whether the approved human ethics application will require a modification and attach the modification form. *Please note the University Human Ethics Committee may require the protocol to be modified as a result of the SAE/Incident.*

*The report must be submitted electronically by the Chief investigator from their La Trobe University staff email account.* *If the Chief Investigator is unable to submit the form, please ensure they are copied into the email to demonstrate they are aware of the submission.*

**Please submit your form to** [**humanethics@latrobe.edu.au**](mailto:humanethics@latrobe.edu.au)

Website: <http://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics>