**Significant Safety Issue (SSI) Report (IMPs) – HUMAN RESEARCH ETHICS**

**WHEN TO USE THIS FORM**

1. When your study involves an Investigational Medicinal Product (IMP) **AND**
2. When La Trobe is the lead HREC and/or the incident happened at one of the La Trobe Campuses **AND**
3. To report Safety Events which are related, or possibly related to the IMP, and result in
4. death
5. is life threatening
6. requires hospitalisation or prolongation of existing hospitalisation
7. results in persistent or significant disability or incapacity
8. is a congenital anomaly or birth defect
9. Urgent safety amendments
10. Temporary halt/termination of the study
11. A safety event that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial

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| 1.0 PROJECT DETAILS | |
| Lead HREC Reference Number | <<INSERT approval number>> |
| Lead HREC | <<INSERT Name of Lead HREC>> |
| Site Reference Number  *(if different from lead HREC reference number)* | <<INSERT Site Approval Number>> |
| Project Title | <<INSERT Project Title>> |
| Coordinating Investigator | **Name:** <<INSERT CI Name>>  **Email:** <<INSERT CI Email>> |
| Site Principal Investigator | **Name:** <<INSERT Site PI Name>>  **Email:** <<INSERT Site PI Email>> |
| Sponsor Details | **Name:** <<INSERT Sponsor Name>>  **Email:** <<INSERT Sponsor Email>> |

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| 2.0 SIGNIFICANT SAFETY ISSUES (SSI) DETAILS | |
| Participant ID | <<INSERT Participant ID>> |
| Date of incident | <<INSERT DAY MONTH YEAR>> |
| Site where the incident took place | <<INSERT the Name of the Place where the incident took place>> |
| Report status | Initial ReportFollow-up report |
| SSI Type+  [Adverse Event Type Classification](#_+Adverse_Event_Classification) | **Report immediately or no later than within 7 calendar days after becoming aware of the event**  SUSAR (fatal or life-threatening)  **Report immediately or no later than within 15 calendar days after becoming aware of the event**  SUSAR (hospitalisation, disability, congenital anomaly or birth defect)  Amendment to Study Documentation (submit study amendment/modification form to lead HREC)  Temporary Halt/Early Termination |
| Relationship to the Study | Definitely related  Probably related  Unknown |
| Who the SSI has been reported to | Sponsor  Coordinating Investigator/Other Site Investigators *(if applicable)*  Site Institution’s Delegated Officer  Insurance *(if VMIA is providing insurance, report directly to them)*  Lead HREC *(using lead HREC Template)*  TGA (using [TGA template](https://www.tga.gov.au/changes-submission-adr-reports-unapproved-medicines-and-biologicals)) *(if applicable)* |

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| 3.0 DESCRIPTION OF SAFETY EVENT | |
| Description of the event | <<INSERT Description of the incident, including reason/s why the incident occurred>> |
| Impact on participant safety | <<INSERT a description of how participant safety was impacted>> |
| Impact on conduct of the research project | <<INSERT a description of how the incident impacts on the integrity of the study data>> |
| Impact on study documentation | <<INSERT An Explanation if the incidence requires a change to the study protocol, IB, PI, PICFs etc....i.e., any of the approved study documents>>>> |
| *If amendments to the approved study documentation need to be made, submit an amendment request to the lead HREC.*  *For immediate threats, amendments can be implemented prior to receiving written lead HREC approval.* | |
| Actions taken | <<INSERT An explanation for the corrective steps taken to eliminate the safety hazards>> |

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| 4.0 DECLARATION  The SSI form can be completed by the Sponsor, Site Principal Investigator or the Coordinating Investigator |
| By submitting this SSI form, I the Sponsor/Site Principal Investigator/Coordinating Investigator declare that:   * The information contained in this report is true and accurate; * That this project is being conducted in keeping with the conditions of lead HREC approval (and submit to any amendments approved); * That I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the information detailed in this report; * That the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007, or as amended) and Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016, or as amended). |

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| 5.0 HOW TO SUBMIT THIS FORM |
| Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/) to lodge a Safety report:   1. To find your ethics project click on “My Ethics Approvals” tile and select the Ethics Approval Number you wish to submit a Safety Report/Incident, 2. At the top of the screen the “down” arrow and click “Create UAE/Safety Report” 3. Upload completed Safety/Incident Report 4. At the top of the screen click on “Submit to Research Office” |

# +Adverse Event Classification for Investigational Medicinal Products (IMPs)

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| **Serious** | **Expected** | **Related** | **Event type** | **Reporting requirements** |
| Serious | Unexpected | Related | **Suspected Unexpected Serious Adverse Reaction (SUSAR)** – an **unexpected** event **related** to the intervention that results in:  *Reportable immediately but no later than 7 calendar days after becoming aware of the event (follow-up report within 8 calendar days)*   1. death 2. is life threatening   *Reportable immediately but no later than15 calendar days after becoming aware of the event*   1. requires hospitalisation or prolongation of existing hospitalisation 2. results in persistent or significant disability or incapacity 3. is a congenital anomaly or birth defect | * Sponsor * Coordinating Investigator * Other Site Principal Investigators * Site Institution * Insurance * Lead HREC * TGA |
| Serious | Unexpected | Related | **Amendment to Study Documentation –** Urgent amendment to study documentation required to address urgent safety issue to participants.  *Reportable immediately but no later than15 calendar days after becoming aware of the event*   * For immediate threats amendments can be implemented prior to receiving written approval from the lead HREC. | * Sponsor * Coordinating Investigator * Other Site Principal Investigators * Site Institution * Insurance * Lead HREC * TGA |
| Serious | Unexpected | Related | **Temporary Halt/Early Termination of Study –** Urgent halt or termination of study due to safety issues to participants.  *Reportable immediately but no later than15 calendar days after becoming aware of halting or terminating the study* | * Sponsor * Coordinating Investigator * Other Site Principal Investigators * Site Institution * Insurance * Lead HREC * TGA |