**Clinical Trial - Safety Report**

**Serious Adverse Event/Reaction/Effect or Significant Safety Issue**

**WHEN TO USE THIS FORM**

1. When the trial involves an intervention (for example, Investigational Medicinal Product (IMP) or Investigational Medical Device (IMD) or a psychological or physical or behavioural intervention) **AND**
2. When La Trobe University is the reviewing HREC and/or the event happened at one of the La Trobe University Campuses and/or La Trobe University is the sponsor of the trial **AND**
3. The event falls within either of the following categories:

* Safety Event which is ‘not related’ (i.e., Serious Adverse Event) or ‘related’ (i.e., Serious Adverse Reaction/Effect) to the intervention, and results in:
  + 1. death
    2. serious deterioration in the health of the participant, that either resulted in:
* a life-threatening illness or injury, or
* a permanent impairment of a body structure or a body function, or
* in-patient or prolonged hospitalisation, or
* medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure of a body function
  + 1. foetal distress, foetal death or a congenital abnormality or birth defect.
* Significant Safety Issue (SSI) that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

1. For more information refer to the last page of this form for Definitions and Actions required.

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| 1.0 TRIAL DETAILS | |
| HREC Reference Number | <<INSERT approval number>> |
| Reviewing HREC | <<INSERT name of reviewing HREC>> |
| Site/Local Reference Number  *(if different from reviewing HREC reference number)* | <<INSERT site approval number>> |
| Trial Title | <<INSERT trial title>> |
| Coordinating Principal Investigator or Site Principal Investigator | **Name:** <<INSERT PI name>>  **Email:** <<INSERT PI email>>  **Telephone:** <<INSERT PI telephone>> |
| Sponsor Details | **Name:** <<INSERT Sponsor name>>  **Email:** <<INSERT Sponsor email>> **Telephone:** <<INSERT Sponsor telephone>> |
| Date of this report | <<INSERT DAY MONTH YEAR>> |

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| 2.0 SAFETY EVENT DETAILS | | | | |
| Date of Safety Event | <<INSERT DAY MONTH YEAR>> | | | |
| Site where the Safety Event took place | <<INSERT name of the place/location where the event took place>> | | | |
| Report status | Initial ReportFollow-up report | | | |
| Type of Safety Event | **Serious Adverse Event** (is a safety event that is not related to the intervention)  *Relationship to intervention*  Definitely related  Probably related  Possibly related  Unknown | **Serious Adverse Reaction** (is a safety event that is related to Investigational Medicinal Product (IMP) or behavioural intervention)  *Relationship to intervention*  Definitely related  Probably related  Possibly related  Unknown  *Was the event expected?*  Yes (if yes, the event is a Serious Adverse Reaction)  No(if no, the event is a Suspected Unexpected Serious Adverse Reaction – SUSAR)  *Refer to* [*Safety Reporting Flowchart*](#_+Adverse_Event_Classification) | **Serious Adverse Device Effect** (is a safety event that is related to Investigational Medicinal Device (IMD)  *Relationship to*  *intervention*  Definitely related  Probably related  Possibly related  Unknown  *Was the event anticipated?*  Yes (if yes, the event is a Serious Adverse Device Effect)  No (if no, the event is an Unanticipated Serious Adverse Device Effect – USADE)  *Refer to* [*Safety Reporting Flowchart*](#_+Adverse_Event_Classification) | **Significant Safety Issue** (is a safety issue that adversely affect the safety of participants or ethical acceptability of the trial)  *Refer to [Safety Reporting Flowchart](#_+Adverse_Event_Classification)* |
| Cause of Safety Event | <<INSERT cause of the event or reason(s) why the event occurred>> | | | |
| Good Clinical Practice/Protocol Deviation | Did the Event occur due to a deviation of the Good Clinical Practice or trial protocol?  Yes (if yes, complete and submit a ‘Good Clinical Practice / Protocol Deviation report’ in addition to this report)  No | | | |
| Who the Safety Event has been reported to | Sponsor  Site or Coordinating Principal Investigator/Other Site Investigators *(if applicable)*  Insurance  Reviewing HREC *(using reviewing HREC Template)*  TGA (using [TGA templates](https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events)) *(if applicable)* | | | |

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| 3.0 DESCRIPTION OF SAFETY EVENT | |
| Description of Safety Event | <<INSERT describe and explain the event, including who was involved; reason/s why the event occurred>> |
| Impact | Could the Event adversely affect safety of participants, or materially impact the continued ethical acceptability or conduct of the trial?  Definitely  Possibly  No |
| Impact on participant safety or participant rights | *<<INSERT a description of how participant safety and rights were impacted>>* |
| Impact on conduct of the trial (e.g., reliability and robustness of data) | <<INSERT a description of how the event impacts on the ethical acceptability of the trial>> |
| Impact on trial documentation | <<INSERT an explanation if the event requires a change to the trial protocol and/or any of the approved trial documents>>>> |
| *If modifications to the approved trial documentation need to be made, submit a modification request to the reviewing HREC. For immediate threats, modifications can be implemented prior to receiving written reviewing HREC approval.* | |
| Action(s) taken | **Urgent safety measure (USM)** (a measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety)  *Report without undue delay and no later than 72 hours of the measure being taken.*  <<INSERT reasons for the USM, measures taken to eliminate the safety hazards, further actions planned>>  **Modification(s) to the approved trial documentation**  *Report without undue delay and no later than 15 calendar days of the sponsor becoming aware of the issue.*  <<INSERT details of the modification(s)>>  **Temporary halt**  *Report without undue delay and no later than 15 calendar days of the sponsor’s decision to halt the trial.*  <<INSERT reasons for the halt, scop of the halt (e.g. suspension of recruitment or cessation/interruption of trial treatment), measures takes, further actions planned>>  **Early termination**  *Report without undue delay and no later than 15 calendar days of the sponsor’s decision to terminate the trial.*  <<INSERT reasons for the early termination, measures takes, further actions planned>>  **No action**  <<INSERT explanation for taking no action>>  **Other**  <<INSERT details and reasons for the other actions taken>> |

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| 4.0 DECLARATION  The Safety Event report can be completed by the Sponsor, Site Principal Investigator or Coordinating Principal Investigator |
| By submitting this Safety Event report, I the Sponsor/Site Principal Investigator/Coordinating Principal Investigator declare that:   * The information contained in this report is true and accurate; * This trial is being conducted in keeping with the conditions of reviewing HREC approval; * The trial is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016). |

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| 5.0 HOW TO SUBMIT THIS REPORT |
| Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/) to lodge 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 for 2. At the top of the screen click the “down” blue arrow dropdown menu and click “Create UAE/Safety Report” 3. Click the 'Post Approval Documents' tab and upload the completed report 4. In the progress bar at the top of the page, select "Review by Research Office" and then click "Mark as Current Status" to the right |

# Definitions and Actions required

# 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 adverse reaction related to the IMP that is both serious and unexpected and results in:   * death * is life threatening   *Report immediately but no later than 7 calendar days after becoming aware of the event (follow-up report within 8 calendar days)*   * requires hospitalisation or prolongation of existing hospitalisation * results in persistent or significant disability or incapacity * is a congenital anomaly or birth defect   *Report immediately but no later than 15 calendar days after becoming aware of the event* | * TGA * Sponsor *(if applicable)* * Site / Coordinating Principal Investigator *(if applicable)* * Other Site Investigators *(if applicable)* * Reviewing HREC *(if applicable)* * Site Institution *(if applicable)* * Insurance |

# Adverse Event Classification for Investigational Medical Devices (IMDs)

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| **Serious** | **Expected** | **Related** | **Event type** | **Reporting requirements** |
| Serious | Unexpected | Related | **Unanticipated Serious Adverse Device Effect (USADE)** – An adverse effect related to the IMD that is both serious and unanticipated (i.e., effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report), and results in:   * death * is life threatening   *Report immediately but no later than 7 calendar days after becoming aware of the event (follow-up report within 8 calendar days)*   * requires hospitalisation or prolongation of existing hospitalisation * results in persistent or significant disability or incapacity * is a congenital anomaly or birth defect   *Report immediately but no later than 15 calendar days after becoming aware of the event* | * TGA * Sponsor *(if applicable)* * Site / Coordinating Principal Investigator *(if applicable)* * Other Site Investigators *(if applicable)* * Reviewing HREC *(if applicable)* * Site Institution *(if applicable)* * Insurance |

# Significant Safety Issue (SSI)

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| **Event type** | **Reporting requirements** |
| **Significant Safety Issue (SSI) –** A safety issue that could adversely affect:   * the safety of participants * materially impact on the continued ethical acceptability or conduct of the trial   SSI requires below action(s):   * urgent safety measure\* * amendment to the approved trial protocol and/or documentation * temporary halt * early termination   *Significant safety issues that meet the definition of an urgent safety measure should be notified within 72 hours (note. strongly recommended that the sponsor contact the TGA within 24 hours of the measure being taken), and all other actions should be notified within 15 calendar days of the sponsor instigating or being made aware of the issue*  \*Urgent Safety Measures (USMs) are one type of significant safety issue where sponsors or trial investigators act immediately to protect participants from an immediate hazard to their health and safety. | * TGA * Sponsor *(if applicable)* * Site / Coordinating Principal Investigator *(if applicable)* * Other Site Investigators * Reviewing HREC * Site Institution *(if applicable)* * Insurance |