**Protocol Violation Report – HUMAN RESEARCH ETHICS**

**WHEN TO USE THIS FORM**

1. When La Trobe is the lead HREC and/or the incident happened at one of the La Trobe Campuses **AND**
2. To report **Protocol Violations** – failure to comply with the study protocol as approved by the lead HREC. It is a serious non-compliance with the protocol that can result in the exclusion of a participant or their results in the study and in some cases a

* There are safety or ethical implications for the participant/s
* The scientific integrity of the study is affected
* The study methodology caused the protocol deviation/violation to occur (e.g., exclusion criteria is too strict)
* The conduct of the study causes the protocol deviation/violation to occur (e.g., inadequate staff training)

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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 PROTOCOL VIOLATION DETAILS | |
| Date of violation | <<INSERT Day Month Year>> |
| Site where the Protocol Violation took place | <<INSERT Site Institution>> |
| Who the Protocol Violation been reported to | Coordinating Investigator  Sponsor *(if applicable)*  Site Institution *(if applicable)* |

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| 3.0 DESCRIPTION OF PROTOCOL VIOLATION | |
| Description of the Protocol Violation | <<INSERT Description of the incident, including reason/s why the violation 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 violation 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 prevent the violation from occuring again>> |

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| 4.0 DECLARATION  The Protocol Violation Report can be completed by the Sponsor, Site Principal Investigator or the Coordinating Investigator |
| By submitting this Protocol Violation Report, 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 Protocol Violation report:   1. To find your ethics project click on “My Ethics Approvals” tile and select the Ethics Approval Number you wish to submit a Protocol Violation report 2. At the top of the screen the “down” arrow and click “Create UAE/Safety Report” 3. Upload completed Protocol Violation Report 4. At the top of the screen click on “Submit to Research Office” |