# **Human Ethics Final Report**

**Instructions:** As part of the requirements of the National Statement on Ethical Conduct in Human Research (Section 5.5.5), the Principal Investigator must complete a final report for projects approved by the La Trobe University Human Research Ethics Committee or Low-risk Ethics Advisory Panel.

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| **1 PROJECT DETAIL** |
| Project title:  |       |
| Ethics Approval Number: |       |

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| **2 APPROVAL DATES**  |
| Approval date: | Enter a date | Approval Expiry date:  | Enter a date |

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| **3 INVESTIGATORS AND OTHER APPROVALS** |
| *It is the responsibility of the Principal Investigator named below to ensure that all information submitted to the LTU ethics review body is a true and correct record of activity for the reporting period.* |
| Principal Investigator Name: |       | School: |       |
| **Provide details of co-investigators and others involved in the project**  |
| Name:  |       | University ID: |       | Institution: |       |
| Name:  |       | University ID: |       | Institution: |       |
| Name:  |       | University ID: |       | Institution: |       |
| Name:  |       | University ID: |       | Institution: |       |

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| **4 PROJECT STATUS** |
| **NEVER COMMENCED** | [ ]  Work never commenced and approval no longer required  |
| **ABANDONED** | [ ]  Work commenced and was abandoned and approval no longer required | Date work was abandoned: Enter a date |
| **COMPLETED** | [ ]  Work as approved was completed by the expiry date of the ethics approval period  | Date of completion: Enter a date |

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| **5 PARTICIPANTS**  |
| How many participants were involved in the project? If the number of participants differs from the approved protocol, please explain. |       |
| How many participants withdrew from the project? |       |
| If known, briefly list the reasons for participants withdrawing. |       |

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| **6 RESEARCH PROTOCOL**  |
| Was the project conducted in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2018, or as amended 2023)?* |       |
| Was the project been conducted in accordance with the approved project description/protocol and any condition of the ethics review body (including any subsequent modifications)? |       |

| 7 **RESEARCH RECORDS AND MATERIALS** |
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| How are research records and materials being securely stored? |       |
| Where are they stored? |       |
| Who has access to them? |       |
| How long will they be retained? |       |
| If project is abandoned, what has happened to the records and materials that were collected? |       |

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| 8 **MODIFICATIONS TO THE APPROVED PROTOCOL***The ethics approval for your project was granted on the basis of a protocol submitted. A condition of approval required any proposed modifications to the protocol being approved prior to implementation as well.* |
| Were there any modifications to the protocol over the course of the project which have not been submitted? Modifications include changes to: | **YES**  | **NO** | If you answered **YES** to any of these options, please provide details of the modifications and the reasons why approval has not been sought.  |
| * Investigators
 |[ ] [ ]        |
| * Study design and research plan
 |[ ] [ ]        |
| * Participants/records/materials/ samples
 |[ ] [ ]        |
| * Method of recruitment
 |[ ] [ ]        |
| * Information and consent documents
 |[ ] [ ]        |
| * Other
 |[ ] [ ]        |

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| **9 REPORT OF ACTIVITY** |
| Provide a concise summary in plain language of the outcomes of the research. Include details of any data collection undertaken, difficulties encountered, and results/interpretations of any analyses conducted.  |       |
| Provide details of any publications or presentations of outcomes of research undertaken.  |       |
| If you agreed to give feedback or findings to participants, provide details what has been provided or when this will occur.  |       |

| **10 ADVERSE EVENTS AND OTHER INCIDENTS AND COMPLAINTS** |
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| Over the course of the project have there been any adverse events, other unforeseen incidents or unexpected outcomes in your project? (*e.g. side effects of drugs or procedures, participant distress, breaches of participant privacy, failure to obtain other necessary approvals)* | **YES** [ ]   **NO** [ ]   |
| If **YES,** please provide a brief summary of the issues and outcomes.  |       |
| Were all events or incidents reported to the ethics review body? | **YES** [ ]   **NO** [ ]  **NA** [ ]  |
| If the event or incident was not reported to the ethics review body, attach a report detailing the event. |       |
| How many participants were involved? |       |
| Please describe any complaints received in relation to the project.  |       |
| What action/s has been taken in response to any complaint? |       |

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| **11 COMMENTS FOR THE ETHICS REVIEW BODY** |
| Is there anything else you want to report to the Ethics Review Body? |       |

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| **REPORT COMPLETED BY:** |       |
| **DATE REPORT COMPLETED:** | Enter a date. |

To submit the report:

1. Save the entire document (including any supplementary information you are attaching) as one PDF document.
2. Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/).
3. Click on “My Ethics Approvals” tile and select the appropriate Ethics Approval Number.
4. Click the “down” blue arrow dropdown menu and click “Create Final Report.”
5. Click the 'Post Approval Documents' tab and upload the Final Report Form.
6. At the top of the screen click on “Submit to Research Office.”