# **Human Ethics Annual 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 an annual report for projects approved by the La Trobe University Human Research Ethics Committee or Low-risk Ethics Advisory Panel. Annual reports must be submitted each year on the anniversary of the approval date for the approval period.

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| **1 PROJECT DETAIL** |
| Project title:  |       |
| Ethics Approval Number: |       | Approval Expiry date: | Enter a date |

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| **2 REPORTING PERIOD**  |
| This report is for the reporting period from: | Enter a date | to: | 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. Please add rows as needed to ensure all investigators are included.*  |
| 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** |
| **IN PROGRESS**  | [ ]  Work is in progress, indicate current stage:[ ]  Project establishment/Planning [ ]  Recruitment[ ]  Data Collection [ ]  Data Analysis[ ]  Write up [ ]  Other | Anticipated date of completion: Enter a date |
| **EXTENSION REQUIRED**  | [ ]  The project is continuing and an extension of ethics approval is required. [ ]  The project is for a student’s higher degree and data collection is completed. Anticipated date of completion: Enter a datePlease submit a modification request to extend the approval. |
| **NOT YET COMMENCED** | [ ]  Project not commenced in reporting period  | Anticipated date of commencement: Enter a date |

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| **5 PARTICIPANTS**  |
| How many participants are/have been involved in the project? If the number of participants differs from the approved protocol, please explain. |       |
| How many participants have withdrawn from the project to date? |       |
| If known, briefly list the reasons for participants withdrawing. |       |

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| **6 RESEARCH PROTOCOL**  |
| Has the project been conducted in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2018, or as amended 2023)?* |       |
| Has the project been conducted in accordance with the approved project description/protocol and any condition of the ethics review body (including any subsequent modifications)? |       |
| Have any ethical implications arisen during the research? Provide any details, including whether or not they were foreseen and how they were resolved. |  |
| For overseas research, did you identify any legal, ethical, governmental or other local requirements that you need to meet? Provide details. |  |

| **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? |       |

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| **8 VARIATIONS TO THE APPROVED PROTOCOL***The LTU Ethics Review Body granted ethics approval for your project on the basis of a protocol submitted. A condition of approval requires any proposed variations to the protocol being approved prior to implementation.* |
| Have there been any variations to the protocol in the reporting period which have not been submitted? Variations include changes to: | **YES**  | **NO** | If you answered **YES** to any of these options, please provide details of the variations 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 current status, progress and outcomes of the research for the reporting period. Include details of any data collection undertaken, difficulties encountered, and results/interpretations of any analyses conducted during the reporting period.  |       |
| Provide details of any publications or presentations of outcomes of research undertaken during the reporting period.  |       |
| If you agreed to give feedback or findings to participants, provide details what has been provided during the reporting period or when this will occur.  |       |
| What mechanisms have you used to monitor the conduct and progress of the research project? |       |
| Report on compliance with conditions of human research ethics approval. |       |
| If the project is ongoing, briefly outline the actions planned for the next year?  |       |

| **10 ADVERSE EVENTS AND OTHER INCIDENTS AND COMPLAINTS** |
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| In the reporting period, 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 HREC** |
| 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 Annual Report.”
5. Click the 'Post Approval Documents' tab and upload the Annual Report Form.
6. At the top of the screen click on “Submit to Research Office.”