# **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.

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| **1 PROJECT DETAIL** | | | |
| Project title: |  | | |
| Ethics approval number: |  | Approval expiry date: | Enter a date |

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| Principal Investigator name: |  |

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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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| **4 PROJECT STATUS** | | |
|  | Work is in progress, indicate current stage:  Project set up  Study open and recruiting participants  Data Analysis  Write up | Anticipated date of completion: Enter a date |
| **EXTENSION REQUIRED?** | **If your project is in the final year of approval and you require an extension, you must submit a modification request via PRIME prior to the expiry date.** | |
| **NOT YET COMMENCED** | Project not commenced in reporting period | Anticipated date of commencement: Enter a date |

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| **5 PARTICIPANTS** | |
| What is your target sample size?  How many participants have been recruited over the reporting period (approximately)?  Total number of participants recruited to date (approximately) |  |
| How many participants have withdrawn from the project to date?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** | |
| Please provide details of any deviations from the approved protocol (project description) during the reporting period. |  |
| Please provide details of any emergent ethical issues related with the study that occurred during the reporting period |  |

| **7 RESEARCH RECORDS AND MATERIALS** | |
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| Please confirm research records and materials are being securely stored in accordance with the approved data management plan |  | |

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| **8 MODIFICATIONS TO THE APPROVED PROTOCOL (project description)**  *The La Trobe Ethics Review Body granted ethics approval for your project on the basis of a protocol submitted. A condition of approval requires any proposed modifications to the protocol being approved prior to implementation.* | | | |
| Have there been any modifications to the protocol in the reporting period **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 modification and the reasons why approval has not been sought. |
| * Investigators |  |  |  |
| * Study design and research plan |  |  |  |
| * Participants/records/materials/ samples |  |  |  |
| * Recruitment procedures |  |  |  |
| * Information and consent documents |  |  |  |
| * Something else |  |  |  |

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| **9 REPORT OF ACTIVITY** | |
| Provide a brief summary, in plain language, of the overall progress of the research project over the reporting period. |  |

| **10 ADVERSE EVENTS** | |
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| Over the reporting period, have there been any adverse events, other unforeseen incidents or unexpected outcomes? (*e.g. side effects of interventions or procedures, participant distress, breaches of participant privacy)* | **YES**   **NO** |
| Number of adverse event reports submitted to the ethics review body during the reporting period (approximate) |  |
| Were all adverse events or incidents reported to the ethics review body? | **YES**   **NO** |
| If any events or incidents were **not** reported to the ethics review body, please submit an unexcepted adverse event form as soon as possible. | |

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| **11 COMPLAINTS** | |
| Over the reporting period, have there been any complaints made to you about the project? | **YES**   **NO** |
| Were complaints reported to the EIB team? | **YES**   **NO** |
| If no, please provide a brief summary of the complaint and action/s taken in response |  |

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

Thank you for providing this annual report for your project. 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.”