**La Trobe University Exemption from Ethical Review**

**Reference documents:** [**National Statement on Ethical Conduct in Human Research 2023**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

[**La Trobe Human Research Ethics Procedure**](https://policies.latrobe.edu.au/document/view.php?id=112)

**Introduction**

The [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)  (National Statement) (5.1.15-17) provides information on, and criteria for, the exemption eligibility for some types of human research from ethical review. The decision to grant an exemption from ethical review for a La Trobe University (La Trobe) research project falls to the Ethics, Integrity and Biosafety Team in collaboration with the La Trobe Human Research Ethics Committee (La Trobe HREC) or the La Trobe University Low-Risk Sub-Committee (LRSC).

The National Statement supplies guidance in Chapter 2.1 for determining risk and in Chapter 3.1, Element 4 on identifiability of information, data management, secondary use of information and sharing of data and information that must be considered by researchers in making a submission for exemption from ethical review and by the La Trobe HREC or LEAP in their decision-making.

**What is Exempt from Ethical Review?**

***National Statement 5.1.17***

Research that may be eligible for exemption from ethics review by the La Trobe HREC or the LEAP includes research that carries a lower risk to participants or the community **and** satisfies at least one of the following conditions:

* the research involves the use of information or data collections from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree:
  + not to attempt to re-identify those with whom the information or data is associated;
  + to take all reasonable steps to prevent
    - re-identification of the information or data for unauthorised purposes and
    - access to the information or data by those who are not authorised; and
  + that any sharing of any research data during or after the project will not create any added risks of re-identification of the information or data.
* the research is restricted to surveys and observation of public behaviour using information that was, or will be, collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research.
* the research is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only.
* the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

**What may not be Exempt from Ethical Review?**

Human research that is not eligible for exemption from ethical review includes research that:

* is low-risk or greater than low-risk (National Statement 2.1).
* will use shared or banked data or information that is stored in a form that can identify individuals is used in research that qualifies as lower risk research (National Statement 3.1.61).
* will require prospective collection of human biospecimens or the use of stored biospecimens that may be re-identifiable (National Statement 3.2.1 - 3.2.3).
* is to be conducted with categories of participants where specific ethical considerations have been identified and should be considered (National Statement 4.1 – 4.8).
* will involve the use of personal information without consent, to conduct such research, a waiver of the requirement for consent would need to be granted by the La Trobe HREC (National Statement 5.1.16).
* will involve the secondary use of Aboriginal and/or Torres Strait Islander Peoples’ data.

# Submission for Exemption from Ethical Review

Researchers should engage in a risk assessment for a project at the start. This will help in figuring out the right ethical review pathway, including what might be exempt. If you think your project might be exempt, the attached checklist may help you in supporting your risk assessment when considering a request for an ethical review exemption.

Researchers should assess their projects under the National Statement and this instruction. If it meets the criteria outlined above, complete the Request for Exemption form in PRIME. If your assessment shows that your project does not meet the exemption criteria, continue to the standard human research ethics application pathway in PRIME.

Researchers are encouraged to complete the checklist first as a part of their risk assessment and consult with a Human Research Ethics Advisor if there are any questions or concerns.

# Key things to remember:

Things to remember:

* During the lifecycle of your project, you should return to the risk assessment to determine if your project continues to meet the same review criteria. Amendments to a project may change its risk level and this could necessitate future review by an ethics committee even if it was granted an exemption at the outset.
* If you obtain data from a data custodian, you must upload evidence of permission to access data and any conditions associated with the permission.
* A data management plan should be included with your submission to meet La Trobe requirements.
* All La Trobe human research is subject to risk-based monitoring, inclusive of research that has been exempt from ethical review.

# Request for Ethical Review Exemption Assessment (complete all questions)

**Will your research activity research involve the following?**

|  |  |  |
| --- | --- | --- |
| Description | Yes | No |
| Interventions and/or therapies, including clinical and non-clinical trials and innovations |  |  |
| Human genetics |  |  |
| Human biospecimens (including tissue, blood, urine, sputum and any derivative of these, such as cell lines) |  |  |
| Human embryos/gametes, including the derivation of human embryonic stem cell lines |  |  |
| Active concealment or planned deception |  |  |
| Exposure of illegal activity |  |  |
| A waiver of consent for research where the research participants will characteristically not know that they, or their tissue or data, participate in the research |  |  |
| An opt-out approach for collection and/or use of personal health information or personal information in health or medical research |  |  |
| Women who are pregnant / the human foetus |  |  |
| People highly dependent on medical care who may be unable to give consent |  |  |
| People with a cognitive impairment, an intellectual disability, or a mental illness |  |  |
| Aboriginal and Torres Strait Islander Peoples or Communities |  |  |
| Considering the likelihood of harm in your research activity, does it exceed the National Statement profile of minimal risk:   * No risk of harm or discomfort * Potential for minor burden or Inconvenience |  |  |

**If you answered YES to any of the above, you need to submit a full ethics application in PRIME for allocation to the La Trobe HREC or the LEAP as your activity does *not* meet exemption criteria.**

**Existing Collections of non-identifiable data about human beings**

|  |  |  |  |
| --- | --- | --- | --- |
| Description | Yes | No | Action |
| Will your research activity involve use of secondary non-identifiable data (no identifiable or re-identifiable data) only? |  |  | **If No: Submit full application** |
| Is the data for my research activity from an existing, publicly available data source, either collected by you or by someone else? |  |  | **If Yes: Request Exemption**  **If No: Submit full application** |

# Project Submission

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| This form should be emailed to [humanethics@latrobe.edu.au](file:///\\ltu.edu.au\GroupDrives\CA%20-%20Research%20Office\Ethics%20Integrity%20&%20Biosafety\02.%20Human%20Ethics\03.%20Exemption\01.%20Exemption%20Forms\humanethics@latrobe.edu.au) in support of a Request for Ethical Review Exemption. Research projects exempt from ethical review remain subject to monitoring, data retention requirements, and other La Trobe compliance requirements.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 1. **Project title** | |  | | | | | | 1. **Principal Investigator (Primary Supervisor in case of student research)** | | | | | | | | **Name** | *Title, given name, and family name* | | | | | | | **School or Institute** |  | | | | **Staff Id #** |  | | **Telephone** |  | | **Email** |  | | |  |  |  |  |  | | --- | --- | --- | --- | | **Co-investigators, including students and non-La Trobe investigators** | | | | | **Researcher** | **Title, given name, and family name** | **Position, School or Institute** | **Email** | | **1** |  |  |  | | **2** |  |  |  | | **3** |  |  |  |  |  |  | | --- | --- | | 1. **Aim of this project (Plain language)** | *Describe the purpose of this research in plain language (max. 500 words)* | | 1. **Research design** | *Use this space to briefly explain the research design (max. 500 words)* | | **Data: Source and  Custodian** | *Please include the source of the data (e.g., web site, published report, etc.) including copies of any data custodian approval and conditions, Data Transfer Agreements or special conditions.* | | 1. **Exemption Justification** | *Justify your request for exemption based on the National Statement on Ethical Conduct in Human Research, Chapter 5.1.22, and upload a copy of your completed checklist.* | | 1. **Research Dates** | Start Date:  End Date: | | 1. **Additional Information** |  | | 1. **Declaration** | **By submitting this application:**   * I accept legal and ethical responsibility for the conduct of this project. * I confirm this project meets the ethical review exemption requirements of the National Statement and La Trobe University. * I confirm that I will comply with the La Trobe University Research Policy and supporting procedures. | |