



**Research and Graduate Studies Committee
University Human Ethics Committee**

Human Research Ethics Guidelines

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1 Why human ethics regulation?

Research makes an important and valuable contribution to society. Society nevertheless demands that safeguards are established which ensure that the rights and welfare of individuals who participate in human research studies are respected and that all possible risks to them as research participants as well as risks to the researchers are avoided or minimised.

Human research can involve very minor to highly significant risks and these raise many ethical considerations about the quality, safety and acceptability of research practices. In Australia, *the National Statement on Ethical Conduct in Human Research* (2007) (National Statement) and the *Australian Code for the Responsible Conduct of Research* (2007) express a national commitment to ethically good research and provide reflection, guidance and clarification on the shared responsibilities of institutions and researchers to the conduct of human research studies, its review and governance.

2 Principles of good research involving human participants

The *National Statement* outlines four key values which shape the principles of good research involving human participants:

- Respect - recognition of an individual's intrinsic worth and right of autonomy and, for persons with diminished autonomy, their entitlement to inclusion and protection.
- Merit and integrity – an assessment of the potential benefits to social welfare and individual well-being against the justification and appropriateness of the aims and design of the research.
- Beneficence - an understanding of the potential for harm of any kind or discomfort caused by the research and weighing this against the benefits.
- Justice - a commitment to fairness and consideration of issues of inclusion and exclusion, access and exploitation and the distribution of the benefits of research fairly.

Informed consent - It flows on from these principles that persons taking part in research must do so on the basis of *informed consent*. They must be provided with all information relevant to making a choice whether or not to participate and their decision to take part must be voluntary and free of any coercion or inducement. Where it is considered appropriate to conduct research involving participants with a diminished capacity to give informed consent, then arrangements for informed consent of a parent or guardian must be made.

3 How human research ethics is organised in Australia

In Australia, the *National Statement on Ethical Conduct in Human Research* (2007) is published by the National Health and Medical Research Council (NHMRC). The National Statement contains some rules that are statute law such as those contained in the NHMRC Act 1992 or the various Privacy Acts 1, 2 and 3. Other guidelines contained within the National Statement reflect best practice principles and are accepted by the Australian Vice Chancellors' Committee (AVCC), the Australian Research Council (ARC), all Australian universities and other research organisations. The National Statement obliges an institution to establish a Human Research Ethics Committee (HREC) for the primary purpose of reviewing its research studies involving humans.

Australian universities are required to comply with the guidelines found in the National Statement and a variety of measures have been put in place in order to ensure this compliance. For example, the NHMRC and ARC will not fund institutions that have no HREC, or research projects that avoid ethics review when required. In addition, human research conducted without ethics approval (if required) may not be covered by the institution's indemnity insurance and a thesis may not be accepted for examination if the research lacks the necessary ethical approvals. Most peer reviewed journals also require proof of ethical review before accepting an article for publication. La Trobe University now requires evidence of ethical approval before publications resulting from human research can be archived in the University library and counted in the research quantum.

The authority of an institution's HREC, as defined in the *National Statement* relates specifically to research that the institution either conducts, auspices or sponsors. HREC decisions are independent of university administration and the system serves to protect the rights of legitimate research as well as the rights of human participants.

4 How human research ethical review is organised at La Trobe

La Trobe University has a central University Human Ethics Committee (UHEC) set up according to requirements outlined in the National Statement. Membership includes at least one person in the following categories: a chairperson with suitable experience, a health professional, a legal representative, a minister of religion, a minimum of two community representatives, male and female, and at least two persons with current research expertise.

In addition, there are two College Human Ethics Sub-Committees (CHESCs) that are formally sub-committees of the UHEC. CHESCs review applications that pose no greater risk than discomfort. CHESCs review applications from their own disciplinary areas unless these need to be submitted to the UHEC. CHESC membership includes representation from most of the departments from which ethics review cases are likely to arise.

5 What human research requires ethics approval?

As a general rule, **all** research projects involving human participants or using their personal information or human body samples require ethics approval.

This requirement applies to all members of the University – staff and students - including visiting and honorary researchers, those engaged in collaborative research with external institutions, contract research projects and all post-graduate and honours research projects.

An external research project taking place on the University's premises and involving La Trobe students or staff should notify the UHEC in the interest of protecting the University's reputation, whether the researcher is connected to La Trobe University or not.

There are however qualifications in detail to the general rule:

- Chance events and conversations may contribute to research but these events do not require ethics review.
- The collection and use of material that is on public record or within the public domain does not require ethics review.
- Ethics review is also not required for collecting and using information which is requested from an officer of an organisation whose role is deemed to include providing such information as long as the information collected is non-personal. The information sought may involve expressions of opinion but only where it is clearly part of the officer's role to give an opinion on the matter in question.

All researchers are urged to consult the National Statement, for further exploration of these issues and principles outlined above. If you are in doubt whether a particular research project requires ethical review, you can contact the Senior Human Ethics Officer for the UHEC, or Human Ethics Officer for the relevant CHESC.

6 Applying for ethics review at La Trobe

Ethics review is conducted on the basis of asking about the proposed research design and procedures, the prospective human subjects, and the possible impact on them and others. You will find the application forms used by the UHEC and CHESCs, together with Instructions and Guidelines for completing the form on the human ethics webpage: <http://www.latrobe.edu.au/researchers/ethics/human-ethics>

Please remember that the application forms are designed to cover eventualities in a very wide range of research and that it requests information related to possibilities of risks, in addition to a description of procedures. Nevertheless, with the exception of where you are

directed to move on to another question, please answer each question, if only with 'not applicable'.

Every question is designed to elicit information which may be of relevance to one of the principles of the National Statement, such as respect for persons, beneficence and justice. As an example, a question may be designed to find out if there are any factors that might diminish a participants' capacity to consent on an informed and voluntary basis.

External investigators who have no affiliation with La Trobe University and who have ethics approval from their home institution can recruit La Trobe students without La Trobe University Human Ethics Committee approval, provided that students are approached in their capacity as individuals rather than as a La Trobe cohort. If recruitment of participants will occur in a specific department or school, approval needs to be sought from the appropriate Head. The La Trobe University Human Ethics Committee has no jurisdiction over this type of research and the home institution's HREC is legally responsible for the conduct of their research. External investigators must clearly state to individuals that they are from another institution, that the research has not been through the La Trobe University Human Ethics Committee, and that no such representation should be inferred by the external investigator.

6.1 Application forms

An electronic version of the above-low risk and low risk application form is available via the La Trobe internet web site. Application forms for ethical review of teaching practical's may also be obtained from the website. Applicants are urged to download the most recent version of the application forms from the human ethics webpage: <http://www.latrobe.edu.au/researchers/ethics/human-ethics>

Investigators conducting collaborative research projects with external institutions need not use the La Trobe University ethics application forms but may submit the ethics application form used at the external institution. However, the UHEC / CHESC may request further information if necessary. Please review the Externally Approved Project Guidelines for more information on how to submit an application for review that has HREC approval from another institution.

6.2 To which ethics committee do I forward my application?

The review process associated with individual research proposals involving humans is dependent on the risks to which research subjects may be exposed and is governed by the National Statement.

The review system developed by La Trobe University is aimed at providing the most appropriate and effective review process to meet the requirements of the National Statement.

The following committees conduct the review and approval of human ethics applications proposed by La Trobe University researchers:

- University Human Ethics Committee (UHEC)
- College Human Ethics Sub-Committee – Science, Health and Engineering (CHESC SHE)
- College Human Ethics Sub-Committee – Arts, Social Sciences and Commerce (CHESC ASSC)

The relevant CHESC should be the point of contact if the study involves:

- **Negligible risk:** no ethical review is required. However, prior to commencing a study, researchers are required to submit a brief summary of their planned research and make a case for why the study is of negligible risk and not low risk as defined by the National Statement. Researchers must also complete and submit a risk assessment checklist along with the project summary to their relevant CHESC. Researchers are also expected to maintain auditable records of their negligible risk studies. The CHESCs will be required to provide summaries and risk assessment checklists of all negligible risk projects to the UHEC, if requested.
- **Low risk:** the application should be submitted for review to the relevant CHESC if the risks to human participants are 'low risk' as defined by the National Statement. The CHESC should forward the application to the UHEC if the risks are perceived to be greater than estimated by the chief investigator of the research project.

The University Human Ethics Committee (UHEC) should be the point of contact if the study involves:

- **More than low risk:** the application should be reviewed by the UHEC if the risk involved is 'more than low risk' as defined by the National Statement.
- **Specific participant groups or research methodologies** as detailed in the National Statement.

Note that it is a requirement that all members of the UHEC and CHESCs must be familiar with the National Statement on Ethical Conduct in Human Research (NS, section 5.1.19a).

Also note that the removal of **negligible risk** projects from formal ethical review has been accepted by the University, as outlined in the UHEC Terms of Reference, which provides that the procedures fulfill the obligations outlined above and in sections 5.1.10 to 5.1.17 of the National Statement.

In the case of research centres or institutes not aligned with a College, all ethical review matters should be referred to the UHEC who may advise that an application is submitted to either the UHEC or a CHESC depending on the level of risk determined.

6.3 How do I assess the risks involved in my research proposal?

6.3.1 Negligible risk classification:

The proposed research carries only negligible risk if it meets the requirements outlined in sections 2.1.7, 5.1.6-8 and 5.1.22-23 of the National Statement.

Research involving negligible risk should either: (a) contain no foreseeable risk of harm or discomfort or (b) be designed so that any foreseeable risk is not more than inconvenience. Research which involves risk, even if unlikely, which may be more serious than inconvenience is not classified as being of negligible risk.

Negligible risk studies may include –

- Research utilising existing collections of research data or records that contain only anonymous or fully de-identified data. Researchers must identify where the data is being held.
- Data from feedback surveys and quality assurance studies which only ask questions about a system, program, service or organisation under assessment and do not make comment on the individual recipients, clients, students or users.

Quality assurance outcomes, if used for conference presentations or articles must not in any way reveal the identity of the surveyed participants. The applied data should be in the form of aggregated numbers and percentages and must not reflect on the participants in such a way that it gives rise to some disadvantage or other type of harm.

6.3.2 Low risk classification:

Research carries low risk only if it meets the requirements of the sections 2.1.6 and 5.1.7 as well as 5.1.18-21 of the National Statement.

Research involving low risk only allows for risks no more serious than discomfort to the research participants (National Statement, section 2.1.6). Research which involves risk, even if unlikely, which may be more serious than discomfort, is not classified as being of low risk. Examples of low-risk studies may include:

- Research involving the use of standard tests and questionnaires administered appropriately to normal adult populations, and where data are recorded in such a manner that the participants are not and cannot be identified
- Research or evaluative procedures involving observation of public behaviour on unidentified participants, where data are recorded in such a manner that participants are not and cannot be identified

- Research or evaluative procedures involving collection of existing publicly available data, documents, records or specimens
- Research carried out in an educational setting using groups of participants, rather than individual participants and where data are recorded in such a manner that participants are not and cannot be identified
- Diagnostic ultrasound and magnetic resonance imaging (MRI) aside from other factors which may warrant a higher risk classification and as long as the research protocol meets acceptable clinical standards
- Research that may cause discomfort, either physical, psychological or social beyond normal levels of inconvenience

6.3.3 Above-low risk classification:

The classification of above-low risk research applies to all research which may involve risk to participants of more than discomfort as outlined in sections 5.1.6 and 5.1.24 of the National Statement. This includes research which:

- Uses intrusive techniques, including some personality assessment tests
- Examines potentially sensitive or contentious topics or themes, such as studies of body image or personal health habits
- Involves minors as participants where there is individual or one-to-one interaction between investigators and participants
- Uses therapeutic techniques
- Involves secondary use of identifiable specimens or data collected for another study or purpose
- Seeks disclosure of information that may be prejudicial to participants, for example, which has the potential to be incriminating
- Involves any physical intervention or removal of body fluids or tissues, such as blood or urine samples, biopsies
- Involves a clinical trial of any drug, therapeutic product or biomaterial
- Involves qualifying the conditions of consent , such as circumstances where the purpose of the study is not fully disclosed to participants

- Uses a highly vulnerable participant population, for example - intellectually disabled individuals, people who have undergone trauma, psychologically disturbed individuals
- Involves the collection, use or disclosure of identified personal, health or sensitive information without the consent of the individuals in question

Examples of categories of above-low risk research to be reviewed by the UHEC include:

- Risk of physical, mental, or social harm
- Deception that includes concealment; or where the application of deception will likely affect participants adversely or pose additional risks to participants
- Possible breaches of legislation - usually relating to access to sensitive personal information
- Secondary use of existing human specimens
- Research involving Indigenous Australian and / or Torres Strait Islander participants or subject matter

6.4 Chair review

Expedited review by the CHESC/UHEC Chair without circulation to other members of the committee may be adopted in the following cases:

- Requests for modifications to projects already approved by the CHESC or UHEC, such as extensions of approval duration or minor changes to the procedures or other details of the study.
- Externally approved studies which are already approved by a fully constituted human research ethics committee (HREC) of an external agency in which a La Trobe staff member holds a joint appointment; or have been required to gain external approvals due to the study being located at a clinic or centre of another agency from which the study will be recruiting participants, provided that no La Trobe University students are involved as participants.
- Externally approved studies undertaken by La Trobe students which are of low risk can request expedited review by the relevant CHESC Chair except when the study

intends to recruit La Trobe students as participants. In these cases the externally approved study must come to the UHEC Chair for consideration.

6.5 Confidentiality

The University has a register of human ethics applications. The register is not a confidential document. Details maintained in the register include the name of the investigators, affiliated schools and departments, title of project, and a brief summary of the project aims.

Electronic copies of research proposals and all relevant correspondence are held in Research Office files. While applications are generally treated as confidential and are not disclosed to persons outside of the ethics committees, there are circumstances where applications are made available, for example, when an application is subject to a court subpoena or a request for information under the *Freedom of Information Act*.

If an application is part of a funded research project, there may be contractual obligations upon the part of the University and the investigators to maintain confidentiality. Any information of a commercial or patentable nature should be marked with 'Commercial-in-Confidence' when submitted.

6.6 General advice to applicants

To avoid delays in the process of approving your application, please ensure that:

- The application form is completed in full
- Lay language is used throughout
- There is a full description of what will be required of participants
- There is a clear description of how informed consent will be gained
- There is detailed information on how and where research data will be maintained and stored
- The form is signed by all investigators
- All relevant support documents are included with your application submission.

The application form is designed for use by all disciplines and some questions may not be applicable to your research project. Please use the "not applicable" boxes where appropriate.

6.7 Form lodgement and approval process

Applications should be lodged at **least 30 working days** prior to the date at which data collection is to begin. Data collection must not commence without written approval from the UHEC or relevant CHESC. Please also note that applications are normally considered by the UHEC / CHESCs within 10 to 12 days of receipt and are considered in order of receipt.

Instructions on how to lodge a form is outlined on the application cover page and on the

human ethics webpage.

6.8 Appeals procedures

If an application for ethics approval has been rejected by a CHESC, the investigator may lodge an appeal against this decision to the UHEC for consideration. If an application has not been approved by the UHEC, the applicant may request that the Committee review its decision. The Committee may co-opt expert advice in this situation. If the outcome is still considered unsatisfactory, the Office of the University Ombudsman can be approached to review the procedures by which the human ethics committee came to its decision.