

Human Research Ethics Guidelines

La Trobe University

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1 Why ethics regulation?

Today academic research is no longer seen as a gift from on high to the public – if it ever was. There is increasing distrust of genetic and pharmaceutical research as well as social survey research, and an increasing demand from the public to be consulted.

In part this reflects our increasingly technologised and depersonalised world, but in part it reflects a changed mood among the research community: scepticism towards the cheerful imperialism of much earlier science; a horror at the misuse of science; and an acknowledgment that research cannot cut itself off from society. Investigators are more conscious that if they are – literally – to *use* other humans as experimental subjects or as informants they must earn the trust of those other humans and show that they themselves are bound by clear standards.

This is the background to the emergence of ethical codes governing research into humans in most developed countries since the Second World War. The initial concern related to medical experiments but it was soon realised that behavioural and social research were sometimes just as capable of causing harm and therefore be subjected to ethical standards.

2 Principles of good research involving humans

Based on the 1978 Belmont report, the standards of good research involving humans are regarded to proceed from three ethical principles:

- i.* Respect for persons: individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- ii.* Beneficence: the obligation to minimise harm, of all kinds and not just physical harm, and to see that such harm as is caused is outweighed by benefits.
- iii.* Justice: the obligation to distribute the burdens and benefits of research fairly.

Informed consent: It flows from these principles, and especially from the first, 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 the choice whether or not to participate; 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 special arrangements, for instance, informed consent of a parent or guardian, must be made.

3 How research ethics review is organised

In Australia, the present state of this thinking is reflected in the National Statement on Ethical Conduct in Human Research (2007) issued 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^{1,2,3}. Other rules are considered best practice and accepted as binding by all Australian universities, the Australian Vice Chancellors' Committee (AVCC), the Australian Research Council (ARC), the leading Academies and other research organisations. Acceptance of the National Statement obliges an institution to set up a Human Research Ethics Committee (HREC) for the purpose of reviewing all research involving humans.

All research conducted in Australian universities must conform to the guidelines in the National Statement, and a variety of compliance measures have been put in place across the country. For example, the NHMRC and ARC will not fund institutions that have no HREC, nor research projects that avoid ethics review when required. Research conducted without ethics review may not be covered by the institution's indemnity insurance. Many universities withhold research funds and the

¹ Information Privacy Act 2000 (Vic)

² Health Records Act 2001 (Vic)

³ Privacy Act 1988 (Cth)

acceptance of theses for examination if the research lacks the necessary ethics approval; many journals require proof of ethics review before accepting an article for publication. La Trobe requires evidence of ethical approval before publications resulting from research with humans can be counted in the research quantum.

It is worth noting that, despite these provisions, the research ethics review is a system of self-regulation, run by researchers for researchers. HREC decisions are independent of university administrations; and the system serves to protect the rights of legitimate research as well as the rights of human participants. Many investigators who began as critics of the system have been won over upon closer examination, especially when they see a set of clear principles applying coherently across a range of disciplines.

4 How research ethics review is organised at La Trobe University

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 of the following categories: medical practitioner, lawyer, minister of religion, and a number of community representatives, both lay and professional.

In addition, there are five Faculty Human Ethics Committees (FHECs) that are formally sub-committees of the UHEC. FHECs review cases in their own disciplinary areas unless these need to be submitted to the UHEC. FHEC membership usually includes a representative of every discipline from which ethics review cases are likely to arise.

The contact details for the UHEC and the FHECs are detailed below:

Committee	Contact person	Phone number	E-mail
UHEC	Barbara Doherty	(03) 9479-1443	humanethics@latrobe.edu.au
Education FHEC	Joan Freeman	(03) 5444-2483	educationethics@latrobe.edu.au
Health Sciences FHEC	Natalie Humphries	(03) 9479-3573	n.humphries@latrobe.edu.au
Humanities and Social Sciences FHEC	Lorraine Chai	(03) 9479-3505	l.chai@latrobe.edu.au
Law and Management FHEC	Chiara Condotta	(03) 9479-1603	FLM_ERGS@latrobe.edu.au
Science, Technology and Engineering FHEC	Kaye Collins	(03) 9479-3698	k.collins@latrobe.edu.au

5 What research must be reviewed?

As a general rule, **all** research projects and teaching practicals involving human participants as subjects, or having an impact upon humans, require ethics approval.

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

All research taking place on the University's premises must have ethics approval in the interests of protecting the University's reputation, whether the researcher is connected to the University or not. University staff are advised to ensure that external researchers are formally classed as visiting investigators and that the research has ethics approval from the appropriate La Trobe University committee.

However there are qualifications in detail to the general rule:

- i.* Long-term experience and chance events and conversations may often influence research, but it would be absurd to require ethics review for them.
- ii.* The collection and use of material that is on the public record does not require ethics review.
- iii.* Ethics review is also not required for collecting and using material which is requested from an officer of an organisation where responding to such a request can reasonably be held to fall within the position description or role of the officer concerned. 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.

You are urged to consult the National Statement, especially pp. 2-14, for further exploration of these issues and examples of the different principles in the above. If you are in doubt whether a particular research project requires ethics review you should contact the Secretary of the UHEC, or a member of your FHEC.

6 Applying for ethics review

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 form used by the UHEC and FHECs, together with Instructions and Guidelines for completing the form, at www.latrobe.edu.au/rgso/ethics/.

The form is detailed and many applicants find it daunting. Please remember that it is designed to cover eventualities in a very wide range of research, and that it has to ask about possibilities and risks, not just about what you expect to happen. Parts of the form may not be relevant to your research. Nevertheless, with the exception of where you are directed to move on to another question, please answer each question, if only with 'N/A'.

Every question is designed to elicit information which may be of relevance to one of the principles (respect for persons, beneficence and justice). For instance, Questions 8(c) ('Will any participants be ill or frail?') and 8(f) ('Compensation for participants') are designed to find out about factors that might diminish 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. The La Trobe University Human Ethics Committee has no jurisdiction over this type of research and the home institution/Human Ethics Committee is legally responsible for the conduct of the research. External investigator 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 no such representation should be inferred by the external investigator.

6.1 Application forms

An electronic version of the UHEC and FHEC application form is available via the World Wide Web at the UHEC web site. Application forms for the ethics approval of *Teaching Practicals* may be obtained from the relevant FHEC. Applicants are urged to download the most recent version of the application forms.

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 / FHEC may request further information if necessary. The UHEC and FHECs will, for example, accept applications for ethics approval completed on the DHS Core Application Form and Checklist. Investigators must be aware, however, that the

DHS Core Application Form does not request all of the information that is required by the UHEC / FHEC and that it is the responsibility of the investigator to ensure that the application includes all information required. To this end, instructions are provided in the document UHEC Guidelines for DHS Applicants.

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 on Ethical Conduct in Human Research 2007*.

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 deal with the review and approval of Human Ethics applications proposed by La Trobe University researchers:

- University Human Ethics Committee (UHEC)
- Faculty of Education Human Ethics Committee
- Faculty of Health Sciences Human Ethics Committee
- Faculty of Humanities and Social Sciences Human Ethics Committee
- Faculty of Law and Management Human Ethics Committee
- Faculty of Science, Technology and Engineering Human Ethics Committee

The relevant Faculty Human Ethics Committee (FHEC) should be the point of contact if the study involves:

- **Negligible risk:** no review is required. However, researchers are required to submit a brief summary of human research that involves only 'negligible risk' as defined by the National Statement to their FHEC prior to the commencement of studies, and FHECs are requested to provide summaries of all 'negligible risk' projects to the UHEC on a regular basis.
- **Low risk:** the application should be submitted for review to the relevant FHEC if the risks to human subjects are 'low risk' as defined by the National Statement. The FHEC 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.

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

Also note that the removal of **Negligible Risk** projects from formal human ethics review has been decided by the University and the UHEC as outlined in the UHEC Terms of Reference, provided that the procedures fulfill the obligations outlined above and in Sections 5.1.10 to 5.1.17 of the NHMRC National Statement on Ethical Conduct in Human Research (2007).

In the case of research centres or institutes not aligned with faculties, all matters should be referred to the UHEC.

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 such that any foreseeable risk should be no more than inconvenience. Research which involves risk, even if unlikely, which may be more serious than inconvenience, is not classified 'negligible risk'.

Negligible-risk studies that may be exempt from review include research utilizing existing collections of data or records that contain only non-identifiable data about human beings.

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 '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), 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 'More than low risk' classification:

The classification of 'more than 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 areas, such as studies of body image or sexuality;
- involves minors as participants where there is individual or one-to-one interaction between investigators and participants;
- uses therapeutic techniques;
- involves secondary use of 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 , *ie* 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 'more than low risk' research to be reviewed by the UHEC include:

- risk of physical, mental, or social harm;
- deception;
- possible breaches of legislation (usually relating to access to sensitive personal information);
- secondary use of existing human specimens;
- research involving Indigenous Australian (Aboriginal and / or Torres Strait Islander) participants or subject matter;
- research conducted overseas (National Statement Chapter 4.8).

If an investigator is in doubt, the application may be submitted to a FHEC for risk assessment.

If your research unit is not affiliated with any of the La Trobe University faculties (as is the case of some research centres) the application should be submitted to the UHEC.

6.4 Expedited review by the UHEC

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

- i.* projects approved by the ethics committee of an external agency where a University staff member holds a joint appointment, or which is funding a La Trobe University staff member's research or from which the researcher seeks to recruit participants, provided no La Trobe University students are involved.

- ii. requests for minor alterations to projects already approved by the UHEC, such as extensions of approval duration or minor changes to scope of the research.

6.5 Confidentiality

The University has a Register of Human Ethics Applications. The Register is not a confidential document. Details included in the register include the name of the investigators, affiliated schools / departments, title of project, and a brief summary of the project's aims.

Copies of applications are kept on file either at the Research and Graduate Studies Office, the relevant Faculty Office or in Central Records. While applications are generally treated as confidential and are not disclosed outside of the Ethics Committee, there are circumstances where applications are made available to persons outside of the Committee. For example, an application may be 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 'Commercial-in-Confidence' when submitted.

6.6 General advice to applicants

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

- it is typed;
- lay language is used throughout;
- all questions are answered;
- the form is signed by all investigators;
- there is a full description of what is required of participants; and
- all relevant attachments (as per the checklist in item 21 of the application form) are included with your application.

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 full approval from the Human Ethics Committee. Please also note that normally applications are considered by the UHEC / FHECs within 10 to 12 days of receipt and that projects considered "minimal risk" do not have to wait for the next UHEC / FHEC meeting. Applications are considered in order of receipt.

Form lodgment is outlined on the application cover sheet. FHEC web sites contain specific information for submission to the FHECs.

6.8 Appeals procedures

If an application for ethics approval has been rejected by a FHEC, 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 ethics committee came to its decision.