



## Research Services Division

### Research Ethics and Integrity Unit

# Introduction to La Trobe University Research Ethics and Integrity Policies and Procedures

## Table of Contents

1. Overview.....	1
2. Conduct of Research.....	3
3. Human Research Ethics.....	5
4. Animal Ethics.....	7
5. Recombinant DNA Research.....	9
6. Addendum.....	11
7. Literature.....	11

## 1. Overview

All research conducted by La Trobe University researchers and research trainees is bound by the legislative requirements and guidelines set by government authorities. These regulatory environments for research are based on community expectations and on the risks to the community and the environment and change frequently to adapt to changes in attitude and technological advances.

La Trobe University is committed to abiding by the relevant federal and state legislation and has established clear policies and procedures for staff and students on general research and on research and teaching involving humans, animals and genetically modified organisms. Research ethics and integrity play a vital role in providing the framework for the responsible conduct of research.

The research ethics and integrity policy and procedures at La Trobe University are structured into the following components:

- **Conduct of Research:** the integrity of research, responsible practices in research and dealing with departures from best research practices, including the misconduct of research.
- **Human Research Ethics:** research involving human participants, including the assessment of real or potential risks to the health or wellbeing of human participants.
- **Animal Ethics:** research involving the use of animals, including the humane treatment of animals and the responsibilities of researchers towards their welfare.
- **Recombinant DNA Research:** research involving genetically modified organisms, in particular the assessment of risks to human health and the environment and the informed management of potential risks.

The following chapters provide greater details on La Trobe University's ethics and integrity policies and procedures. It is imperative that researchers and research trainees become familiar with these as relevant to their field of study. The La Trobe University research ethics and integrity framework covers areas of compliance which are prerequisites for funding from, amongst others, the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC).

It should be noted that this document is a living document, with on-going modifications to reflect the changing environment of research regulations. Researchers and research trainees are encouraged to source the most recent version from the [Research Ethics and Integrity website](#).

## 2. Conduct of Research

The majority of research funding in Australia is provided by public institutions such as the NHMRC or ARC and financed by federal and state governments. Funding bodies are aware that it is important to build and maintain a positive perception of research activities by the public and to introduce accountability in order to justify the public funding of research. Most of all, it is essential that public trust is gained by setting in place measures aimed at protecting the integrity of research.

Research integrity at Australian universities is covered by the *Statement and Guidelines on Research Practice* (1997). In response, La Trobe University developed the *Guidelines for the Conduct of Research* in 1998, with revisions approved in 2003. This document is currently the primary source for La Trobe University researchers regarding the conduct of research. However, the new *Australian Code for the Responsible Conduct of Research* was released in August 2007 to replace the *Statement* and La Trobe University is in the process of updating current policies and procedures to accommodate the new *Code*.

The current *Guidelines for the Conduct of Research* is made up of two parts, including *Part I Code of Conduct for the Responsible Practice of Research*, and *Part II Allegations of Misconduct in Research*.

The first part describes best practice in research, referring to broad principles and general considerations for researchers and institutions. Researchers are expected to adhere to the highest ethical standards and ethical principles and seek approval from ethics committees as required. Both researchers and institutions are responsible to ensure the safety of those associated with research. The new *Code* is specific about the need for institutions to monitor integrity performance by researchers and to undertake staff training in this area.

In addition, there are extensive details on the mechanisms ensuring correct data maintenance and storage and the provision of privacy and confidentiality arising from research projects, including honours and postgraduate research. The areas of authorship and publications are covered and researchers are strongly encouraged to consult the policy prior to the commencement of research. The roles and responsibilities of research trainees and supervisors are outlined in the context of

good research practice. The obligations by researchers to avoid conflict of interest are described. The new *Code* requires an extensive revision of the current *Guidelines* and places increased emphasis on training and education as well as on the monitoring of integrity procedures by institutions. It also adds requirements for the processes of peer review and collaborative research across institutions to the areas covered by research integrity.

The second part of the *Guidelines* focuses on dealing with allegations of research misconduct as specified in the *Statement and Guidelines on Research Practice* (1997). Research misconduct is defined and examples are given as to what may constitute misconduct. It is specified that La Trobe University schools must have at least one advisor on integrity in research whose role it is to provide confidential advice to researchers and complainants. Further sections then outline procedures in the case of misconduct of research, including those by higher degree candidates.

The new *Code* recognises that cases of research misconduct are likely to rise in frequency due to the increasingly competitive research environment and that past cases have been handled inappropriately by failing to protect the complainants. It is expected that cases of research misconduct can be reduced by increasing education and monitoring, and that the impact of such cases for the institution can be lessened by having in place proper policies and procedures to deal with potential cases.

The La Trobe University [Research Integrity website](#) provides support and reference material and the current policies and procedures for the conduct of responsible research.

### 3. Human Research Ethics

Research conducted with or about people or their data or tissue has the potential to raise conflicts with ethical considerations and to expose research participants to sometimes significant risks. Despite the often beneficial nature of human research for the public good, it is a challenge for institutions and researchers to maintain public confidence and to gain ethical acceptance for their research by the wider community. To help in this process, the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice Chancellors' Committee have jointly developed the *National Statement on Ethical Conduct in Human Research* which governs the way that research involving humans is conducted by researchers based in Australia.

According to the *Statement*, research involving humans is required to promote and facilitate ethically good research and foster research that is of benefit to the community. Researchers must ensure that the rights and welfare of human participants in research are fully respected and that any risks of unfair burden, exploitation, inconvenience, discomfort or harm from research procedures are minimised. It is the duty of the University to affirm the rights of the researcher to carry out legitimate investigation and to safeguard the University's reputation for research that it conducts and sponsors as well as to minimise the potential for claims of negligence to be made against the University and its researchers.

The *Statement* sets out standards for the ethical design, review and conduct of human research in Australia. Accordingly, La Trobe University has established policies and procedures that promote the ethical conduct of human research by its researchers and research trainees as outlined on the [Human Research Ethics website](#). Human ethics matters are assessed and monitored by the University Human Ethics Committee (UHEC) which reports to the Office of the Deputy Vice-Chancellor (Research). The UHEC is constituted according to NHMRC requirements. Its terms of reference can be accessed on the [UHEC web page](#). In addition, there are five Panels for Expedited Review (PEERs) [these are currently linked to faculties but are expected to be administered centrally in the near future], which assist the UHEC in training, education and review duties as outlined on the [PEER page](#).

All human research must conform to La Trobe University requirements as described on the [Guidelines and Policies web page](#). In Victoria, human research must also comply with additional state regulations, including Privacy Victoria, the Department of Human Services and the Department of Justice. Researchers must consult with the legislation of other states and countries when planning to conduct research outside Victoria. The requirement for researchers to have their research proposals approved and monitored depends on the level of risk that is associated with a particular project.

Projects which fall into the 'exempt' category do not require ethics approval but researchers must comply with the Code for the Responsible Conduct of Research. Projects which fall into the 'low risk' or 'above low risk' categories must be reviewed and approved by a PEER if they are low risk or the UHEC if they are above low risk. Application guidelines and a template of the common application form are available on the [Application Procedures and Reporting web page](#). This web page contains a risk assessment form that should be consulted in the early stages of planning a human research project.

Researchers applying for ethics approval must submit the most recent version of the application form. All applications are reviewed out of session and decisions are later ratified at the next relevant committee meeting. Applications and any additional support material should be lodged well in advance of the proposed start date, allowing approximately two weeks minimum for a first reply for a low risk application and six to eight weeks for an above low risk application. When the committee is satisfied that the project fully complies with the NHMRC guidelines and other applicable codes, the applicant will be advised accordingly and informed of the standard terms and conditions governing full approval of projects. Annual and final reporting are requirements as outlined on the [Application Procedures and Reporting web page](#).

Applicants should note that the chief investigator responsible for projects must be an academic staff member of the University who is responsible for the training of co-investigators. The Research Services Division provides regular workshops on human ethics procedures, and faculties offer seminars on discipline-specific issues. Significant efforts are under way to ease application procedures in 2008. This should result in simpler procedures for applications dealing with low risk and in faster turn-over times for applications.

## 4. Animal Ethics

The use of live non-human vertebrates and higher-order invertebrates (cephalopods including octopus, squid, cuttlefish and nautilus, and decapod crustaceans including lobster, crab, yabbie and crayfish) in research and teaching is governed by state and federal legislation. The primary aim of this legislation is to ensure that appropriate attention is given to animal welfare and the humane treatment of animals in research and teaching, and that public attitudes are reflected in the development of humane procedures.

La Trobe University has set in place policies and procedures to ensure that animal usage conforms to current legislative requirements and best practice. The University is registered with the NHMRC and the Victorian Bureau of Animal Welfare (BAW) as well as with the equivalent agencies of several other states depending on where research is conducted.

All La Trobe University staff and students who use live non-human vertebrate and higher-order invertebrate animals for experimental or teaching purposes are bound by the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004). This document and other relevant Australian State and Commonwealth legislation can be found on the La Trobe University [Animal Ethics website](#). In addition to the *Code*, states have their own acts and regulations. In Victoria, animal usage is governed by the *Prevention of Cruelty to Animals Act 1986*.

Animal usage by La Trobe University staff and students is regulated and monitored by the La Trobe University Animal Ethics Committee (AEC) through the Office of the Deputy Vice-Chancellor (Research). All proposed animal usage must be reviewed and approved by the AEC prior to its planned commencement. Most proposals must be reviewed and discussed in formal, in-person meetings where proponents ('experimenters') are interviewed about their proposal. The exception is approval for observational field work as defined by the AEC policy on observational studies displayed on the [AEC Guidelines and Policies web page](#).

Experimenters must be associated with registered license holders who, in the case of La Trobe University, are the heads of schools or research centres that use animals. The license holders answer to the Deputy Vice-Chancellor (Research) and to BAW.

Animal usage is monitored by BAW and the AEC. All animal holding facilities must be registered with the BAW under the appropriate site license. It is a requirement of the *Prevention of Cruelty to Animals Act 1986* that La Trobe University is audited by BAW every three years regarding animal usage and welfare. In addition, the AEC inspects all registered animal holding facilities at least annually. La Trobe University also has an [Animal Welfare Officer](#) who conducts frequent inspections and advises researchers on animal welfare issues.

The AEC meets monthly except in January. Submission deadlines and meeting times are advertised on the [Animal Ethics Committee web page](#). Application procedures are outlined on the [Application Procedures web page](#). Experimenters must have received a formal approval letter via email prior to the commencement of animal usage. During the project duration, experimenters must report annually about progress as detailed on the [Reporting web page](#). Any changes to approved projects must be approved *a priori* by the AEC.

Researchers are encouraged to acknowledge their understanding of a key section of the *Code*, *i.e.*, the embracement of the three Rs, and to develop active mechanisms to adopt the inclusion of the principle in their research. This includes considering the replacement of animals with alternative methods, the reduction in the number of animals used, and the refinement of techniques to improve animal welfare.

The AEC web site provides supporting documents and references for experimenters as well as training material for honours and post-graduate students. New students and staff are encouraged to attend animal ethics workshops presented regularly by the Research Services Division. It is the responsibility of the chief investigator to arrange or provide adequate training in procedures for new or inexperienced personnel.

## 5. Recombinant DNA Research

New technologies bring about fresh and untested challenges regarding their benefits and the potential hazards they may introduce. The manipulation of genetic material, in particular work with recombinant DNA, attracts intense scrutiny by the wider community. There is great expectation by the public that risks associated with this type of research are identified and managed accordingly to protect the health and safety of people and the environment.

Recombinant DNA refers to DNA formed by combining segments of DNA from different organisms. Work with recombinant DNA is commonly referred to as 'gene technology' and involves the genetic modification of organisms by incorporation or deletion of one or more genes to introduce or alter a specific characteristic or characteristics. Recent advances in recombinant DNA research have seen the emergence of new techniques that enable the introduction of very precise changes to genetic material, allowing the transfer of properties of a single gene from one organism to another to form Genetically Modified Organisms (GMOs).

The Office of the Gene Technology Regulator (OGTR) was established by the federal government in conjunction with the *Gene Technology Act 2000* to protect individual health and safety and the environment against any potential risks posed by gene technology. The role of the OGTR is to provide regulatory support to institutions and organisation undertaking work with recombinant DNA and to ensure compliance with the *Act* and its amendments. In the *Act*, dealings with GMOs are categorised according to their risk potential and the necessary mandatory precautions for each type of dealing are identified.

Under the *Act*, La Trobe University is required to have an institutional biosafety committee. Accordingly, La Trobe University constituted the La Trobe University Genetic Manipulation Supervisory Committee (GMSC). The GMSC reports to the Office of the Deputy Vice-Chancellor (Research) and the OGTR on all gene technology research conducted at La Trobe University. The GMSC oversees all dealings within the university that involve recombinant DNA and / or GMOs as outlined on the [Recombinant DNA Research website](#).

The GMSC provides an informative resource for investigators and other interested parties working with or intending to work with recombinant DNA and / or GMOs. The [Guidelines and Policies web page](#) contains links to documents essential to maintaining safe research environments, including certification rules and checklists for laboratories. Up-to-date links to legislation regarding recombinant DNA research and GMOs can be found on the [Legislation and Codes web page](#).

Application procedures, reporting requirements and procedures to amend approved projects are outlined on the [Application Procedures and Reporting web page](#). Researchers should consider the level of risk they are dealing with in the early stages of project development and use the application procedures appropriate for the identified risk category. The 'How to apply for a GMO dealing' guidelines provide a detailed description of processes and links to relevant documents. All annual progress reports are now due on 12 February covering the previous calendar year.

Researchers are encouraged to participate in training sessions provided by the Research Services Division. All new researchers and research trainees must successfully complete an on-line training course prior to the commencement of research activities.

## 6. Addendum

Researchers should note that University regulations now require a statement of authorship in theses to declare that all research procedures reported in the thesis were approved by the relevant ethics committee and that the appropriate ethics approval was obtained prior to the commencement of the research. Many journals now also ask for a letter of approval from an ethics committee as a precondition for publication.

## 7. Literature

[Australian Code for the Responsible Conduct of Research 2007](#)

[National Statement on Ethical Conduct in Human Research 2007](#)

[Guidelines for the Generation, Breeding, Care and Use of Genetically Modified and Cloned Animals for Scientific Purposes 2006](#)

[Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 2004](#)

[La Trobe University Guidelines for the Conduct of Research 2003](#)

[Gene Technology Act 2000 \(compilation incorporating amendments up to Act No. 99 of 2007\)](#)