DOCUMENT TYPE	**D**	
ACADEMIC	**1**	
RESEARCH AND RESEARCH TRAINING	**3**	
RESEARCH CONDUCT	**3**	
NUMBER	**003**	Policy Database Document Reference Number **133003D**

HUMAN ETHICS PROCEDURE

Parent Policy Title	Research Integrity Policy
Associated Documents	Research Misconduct Procedures
Preamble	Research conducted with or about people or their data or tissue has the potential to raise conflicts with ethical considerations. It can also 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 acceptance for their research within the wider community.
General	La Trobe University seeks to affirm the rights of the researcher to carry out legitimate investigations while safeguarding its reputation and minimising the potential for claims of negligence against the University and its researchers. This Procedure aims to ensure that human research conducted by La Trobe University researchers and students conforms to current legislative requirements and best practices.
Table of Contents	

Item	Section
Regulatory Environment	1.
Relevant Legislation and Guidelines	2.
Role of the University Human Ethics Committee	3.
UHEC Terms of Reference	4.
UHEC Membership	5.
PEER Terms of Reference	6.
PEER Membership	7.
Review and Monitoring	8.
Conflict of Interest	9.
Multi-centre Research	10.
Annual Reporting	11.
Additional Operating Guidelines	12.
Complaints, Adverse Events and Non-compliance	13.

1. Regulatory Environment	Research practice at the University, including human research, is the responsibility of the Deputy Vice-Chancellor (Research). The DVC(R) reports to the National Health and Medical Research Council (NHMRC), the Office for Human Research Protection (OHRP, U.S.) and the Health Services

	Commissioner (Victoria). The instrument to regulate and monitor all human research by La Trobe University researchers and students is the University Human Ethics Committee (UHEC) and its Panels of Expedited Review (PEERs). The UHEC is a sub-committee of the Research and Graduate Studies Committee (RGSC) which is chaired by the DVC(R).
2. Relevant Legislation and Guidelines	Human research is governed by the *National Statement on Ethical Conduct in Human Research* (2007), or *National Statement*. In Victoria, human research also needs to comply with the requirements of state regulators, including Privacy Victoria, the Department of Human Services and the Department of Justice. Researchers should consult with the legislation of other states and countries when planning to conduct research outside Victoria.
3. Role of the University Human Ethics Committee	All human research and teaching involving more than negligible risk is reviewed and approved by the UHEC (above low risk) or its PEERs (low risk) prior to the commencement of projects. The UHEC and its PEERs apply a set of principles, outlined in the *National Statement*, that govern the ethical conduct of people whose work involves low risk or above low risk research or teaching. These principles are based on the values of research merit and integrity, justice, beneficence and respect. The role of the UHEC and its PEERs is to ensure that • projects promote and facilitate ethically sound research that is of benefit to the community, • researchers and teachers respect the rights and welfare of human participants in research, and • any risks of unfair burden or harm from research procedures are minimised. There are two PEERs dedicated to the expedited review of low risk proposals: • PEER 1 reviews proposals which generally fall into the Fields of Research of the Faculties of Health Sciences and Science, Technology & Engineering. • PEER 2 reviews proposals which generally fall into the Fields of Research of the Faculties of Humanities & Social Sciences, Education and Law & Management. Policy/education support and secretariat to the UHEC and PEERs are provided by the Research Compliance Unit.
4. UHEC Terms of Reference	As determined by the Academic Board, the UHEC is an authorised body formed to: (i) ensure that the human research conducted by La Trobe University staff and research trainees expresses and enshrines the rights of those being researched and also the rights of the researchers (ii) decide, in reviewing research proposals, whether risks associated with projects are justified by potential benefits

	(iii) approve, request amendment of, or reject above low risk research proposals on ethical grounds (iv) monitor the PEERs and their review and monitoring of human research (v) provide induction and continuing education for La Trobe University researchers and research trainees conducting human research and training for new UHEC and PEER members (vi) decide whether research proposals submitted to the UHEC and PEERs for review meet the requirements of the *National Statement* (vii) investigate potential conflicts of interest and complaints regarding the ethical conduct of human research by members of the University (viii) maintain appropriate records of all research proposals received and approved (ix) report to the Academic Board through RGSC via the approved minutes and the annual report (x) report via the DVC(R) to regulatory authorities, including the NHMRC, the Health Services Commissioner (Victoria) and other authorities as required.
5. UHEC Membership	The La Trobe University UHEC has a membership that allows it to fulfil its terms of reference, with at least one third of the members from outside the University and including separate persons appointed to each of the following categories: **UHEC Chair** who has suitable experience, whose other responsibilities will not impair the UHEC's capacity to carry out its obligations under the *National Statement*; **UHEC Deputy Chair** who has suitable experience, whose other responsibilities will not impair the UHEC's capacity to carry out its obligations under the *National Statement*; **Lay Woman** who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work; **Lay Man** who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work; **Health Professional** with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional; **Pastoral Carer** who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion; **Lawyer** who is not engaged to advise the University; **Content Specialists** (at least two) with current research experience that is relevant to research proposals to be considered for review. To assist the UHEC in decision-making processes, the Committee may have to seek expert advice from outside the Committee. The UHEC Chair should either hold a senior position in the University or, if an external appointee, be given a commitment by the University to provide

	the necessary support and authority to carry out the role. To perform a key role in the successful operation of the UHEC, the Chair should possess the following attributes: (i) the ability to bring impartiality to the task; (ii) the skills to manage the business of the UHEC; (iii) the ability to communicate, negotiate and to resolve conflict; and (iv) understanding of the ethical issues involved in human research. The UHEC Deputy Chair should be capable and enabled to represent the Chair as required. In the absence of the Chair the Deputy Chair will act in the position of Chair. Appointments to the UHEC are made on invitation by the University pending a successful interview with University representatives nominated by RGSC and subsequent approval by RGSC. As part of the interview process, invited members are requested to declare real and potential conflicts of interest and factors that may preclude them from the nominated Category. Appointees are sent a letter of appointment outlining that the appointment is offered on the condition that members accept the terms of reference of the UHEC and that they sign the enclosed confidentiality agreement for La Trobe University UHEC members. Appointments take effect upon acceptance, in writing, of the letter of appointment and its conditions. Membership terms are three years with the opportunity for renewal. Changes in the membership are approved by RGSC and noted in the minutes of the next UHEC meeting. Memberships may be terminated by RGSC at any time by providing not less than 24 hours notice in writing. In general, members may voluntarily retire during their appointment by providing not less than 24 hours notice in writing to the DVC(R). Members that are staff of the University may need to seek approval from their Head of School or Dean prior to submitting a notice of retirement.
6. PEER Terms of Reference	As determined by Academic Board, the PEERs are authorised bodies to: (i) ensure that the low risk human research conducted by La Trobe University staff and research trainees expresses and enshrines the rights of those being researched and also the rights of the researchers (ii) decide, in reviewing low research proposals, whether risks associated with projects are justified by potential benefits (iii) approve, request amendment of, or reject low risk research proposals on ethical grounds (iv) decide whether low risk research proposals submitted to the PEERs for review meet the requirements of the *National Statement* (v) provide advice if research can be exempt from ethical review, including whether the research meets the requirements of the National Statement and is ethically acceptable (vi) refer to the UHEC any research that is identified as above low risk (vii) forward allegations of potential conflicts of interest and complaints regarding the ethical conduct of human research by members of the

	University to the UHEC to investigate (viii) maintain appropriate records of all research proposals received and approved (ix) report to UHEC via the approved minutes and the annual report.
7. PEER Membership	Each PEER has a membership that allows it to fulfil its terms of reference, with separate persons appointed to each of the following categories: **PEER Chair** who has suitable experience, whose other responsibilities will not impair the PEER's capacity to carry out its obligations under the *National Statement*; **PEER Deputy Chair** who has suitable experience, whose other responsibilities will not impair the PEER's capacity to carry out its obligations under the *National Statement*; **Content Specialists** with current research experience that is relevant to research proposals to be considered for review. The PEER Chair and Deputy Chairs are nominated by the DVC(R) on the advice of the UHEC Chair and Deans of Faculties and approved by the RGSC. Terms of appointment are for three years, with the opportunity for renewal. The PEER Chair and Deputy Chair rotate in their role annually to ensure fair representation of each faculty. Content Specialists are nominated by the PEER Chairs on the advice of Heads of School and approved by the UHEC Chair. Membership terms are for three years with the opportunity for renewal. One third of Content Specialists will be elected as Mentors to produce advice for applicants on the development of human ethics proposals and provided with a lower reviewing duty.
8. Review and Monitoring	Above low risk proposals are reviewed by representatives from the eight categories that constitute the UHEC unless the Chair directs otherwise and assigns members from less than the eight categories but which, in the Chair's view, provides adequate review. Proposals are available for comment to all members of the UHEC. Approval is issued subject to ratification by the UHEC at a quorate meeting (quorum consists of at least one member per category present). Low risk proposals are reviewed by two PEER content specialists and a PEER Chair or Deputy Chair and made available for comment to all PEER members. PEER approval is issued subject to ratification by the UHEC at a quorate meeting. The PEERs themselves hold quorate meetings at least quarterly to discuss applications and the review process (PEER quorum consists of the Chair or Deputy Chair and at least one third of the Content Specialists present). To assist in the review process the UHEC and PEERs may seek specialist advice from outside the Committee membership provided that confidentiality of the ethics proposal is maintained. Researchers monitor their research for compliance with the approved proposal and subsequent, approved modifications to the original proposal

	and promptly report adverse events or unexpected outcomes to the UHEC or PEER from which approval was obtained. The UHEC and PEER monitor research through the review of annual and final reports and have the authority to audit research with the focus of compliance with approved protocols and prevention of adverse events. UHEC and PEER Chairs are authorised to suspend projects where monitoring activities suggest non-compliance with approved protocols or adverse impacts for human participants. Follow-up and remedial actions are taken in consultation with the UHEC and in consideration of the requirements of the La Trobe Research Misconduct Procedures.
9. Conflict of Interest	The UHEC and its PEERs deal with situations in which a conflict of interest arises, including any situation where a member of the UHEC/PEER has an interest that may be seen to influence the objectivity of a decision by: (i) Requiring members to disclose the nature of their interest and conflict as soon as practicable after they become aware of anything that may be reasonably considered to be a conflict of interest. (ii) Making it a requirement to declare conflicts of interest at the start of each UHEC/PEER meeting and to document the declarations and resolutions in the minutes of the quorate meeting. (iii) Requiring a member whose objectivity may be influenced by an interest (including consideration of a proposal submitted by that member) to leave the meeting at an appropriate time (certainly during the decision-making process). (iv) Considering and responding to any concern raised by an investigator of other party that an UHEC/PEER member has an interest that may have influenced the objectivity of an UHEC/PEER decision. In this case, the complaint is dealt with the UHEC and the UHEC Chair person advises the complainant, in writing, of the UHEC response. If the complainant is not satisfied with the UHEC response, a grievance may be lodged with RGSC or the University Ombudsman. (v) Including questions on Human Ethics application forms asking researchers to declare any conflicts of interest and to include the considerations of conflict of interest in the ethical review. (vi) Providing advice on matters of conflict of interest, without breaching confidentiality.
10. Multi-centre Research	The *National Statement* asks that duplication of ethics review be avoided. Accordingly, La Trobe University accepts human ethics approvals from other human ethics committees registered with the NHMRC and processes multi-centre research proposals under expedited review procedures where La Trobe University researchers are involved but the Chief Investigator is from another institution. The expedited review is conducted by the UHEC Chair or Deputy Chair in consultation with content experts if required and approvals sent for ratification to the UHEC. La Trobe University reserves the right to place conditions on involvement or refuse involvement should approved proposals not conform to the requirements of the *National Statement*, other relevant

	legislation or potentially expose the University to undue risk. Where the Chief Investigator is a La Trobe University staff member, primary approval is obtained from the La Trobe University UHEC using the La Trobe University human ethics application form or the National Ethics Application Form. Other institutions are expected to follow the recommendations of the *National Statement* and to likewise accept approvals by the La Trobe University UHEC.
11. Annual Reporting	PEERs report to the UHEC at least quarterly in the form of minutes taken at quorate meetings and annual reports to be completed by 31 March covering the previous calendar year. The UHEC reports to RGSC in the same manner. The annual reports include: (i) numbers and types of projects assessed and approved or rejected; (ii) numbers of complaints received and how they were dealt with; (iii) activities reported to the UHEC from its PEERs; (iv) activities that have supported the educational needs of UHEC members; (v) procedural changes; (vi) administrative or other difficulties being experienced; and (vii) any matters that may affect the University's ability to maintain compliance with the *National Statement* and if necessary the provision of suitable recommendations. In addition, the UHEC report to regulatory authorities, including NHMRC, the Health Services Commissioner (Victoria) and other authorities as required. Such reports are authorised and signed by the DVC(R).
12. Additional Operating Guidelines	Other UHEC/PEER operating guidelines such as rulings on record keeping by investigators, risk assessment, teaching projects, activities and practical exercises involving human participants, and guidelines for staff and student surveys and participant information are approved by the UHEC and displayed in their most current form on the UHEC web site.
13. Complaints, Adverse Events and Non-compliance	The University has established a complaints and grievances mechanism for La Trobe University personnel, students and persons external to the University to allow the voicing of concerns regarding human research and teaching. Such concerns can be submitted in writing to the UHEC Secretariat. Complaints or grievances by La Trobe University personnel about decisions reached by the UHEC or PEERs can be submitted in writing to the DVC(R) or the University Ombudsman. Any unplanned impacts on human research participants or researchers outside the scope of a UHEC or PEER-approved project need to be reported promptly by the responsible personnel to the UHEC Secretariat. Allegations of breach or research misconduct, including evidence of human research conducted without ethics approval, must be dealt with according to the La Trobe University Research Misconduct Procedures.

DOCUMENT TYPE	**D**	
ACADEMIC	**1**	
RESEARCH AND RESEARCH TRAINING	**3**	
RESEARCH CONDUCT	**3**	
NUMBER	**003**	Policy Database Document Reference Number **133003D**

Status	Endorsed by Academic Board, 14 September 2011, Minute 451.3.3; RGSC 26 August 2011. Prior approvals: Academic Board, 12 August 2009, Minute 433.3.2; RGSC 31 July 2009, Minute 120.5.1.5 The implementation of the latest version of this procedure supersedes all previous versions of this procedure.
Approval Body	Academic Board
Initiating Body	Research and Graduate Studies Committee
Definitions	**Above low risk (research):** research which may lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage. **Compliance:** acting in accordance with the *National Statement*. **Discomfort:** a negative accompaniment or effect of research, less serious than harm. **Ethics:** a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when human beings are involved in research. **Low risk (research):** research in which the only foreseeable risk is one of discomfort. **Negligible risk (research):** research in which there is no foreseeable risk of harm or discomfort.
Date Effective	14 September 2011
Next Review Date	September 2014
Keywords	Human research; human ethics; human ethics committee; ethical review;
Owner/Sponsor	Director, Research Services
Author	Manager, Research Compliance
Contact person or area	researchintegrity@latrobe.edu.au