

Human Ethics Procedure

Section 1 - Background and Purpose

(1) 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. Human research is governed in Australia by the [National Statement on Ethical Conduct in Human Research \(2007\) \(National Statement\)](#). The purpose of the National Statement is to promote ethically good research that accords participants with the respect and protection that is due to them, and is of benefit to the wider community.

(2) La Trobe University has set in place policies and procedures to ensure that human research conducted by La Trobe staff and students conforms to the National Statement, other related legislative requirements and current best practice. The Human Research Ethics Committee (HREC) is responsible for ensuring compliance with the National Statement by reviewing, approving and monitoring all human research conducted by La Trobe staff and students.

Section 2 - Scope

(3) Refer to the [Research Integrity Policy](#).

Section 3 - Policy Statement

(4) Refer to the [Research Integrity Policy](#).

Section 4 - Procedures

Part A - Regulatory Environment

(5) Research practice at the University, including human research, is the responsibility of the Deputy Vice-Chancellor (Research and Industry Engagement) (DVC(RIE)). The DVC(RIE) 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 Human Research Ethics Committee (HREC) and the College Human Ethics Sub-Committees (CHESCs). The HREC reports to the Research and Graduate Studies Committee (RGSC) which is chaired by the DVC(RIE).

Part B - Relevant Legislation and Guidelines

(6) Human research is governed by the National Statement. In Victoria, human research also needs to comply with the requirements of state regulators, including Privacy Victoria, the Department of Health and 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. La Trobe researchers and research trainees are also expected to adhere to responsible research practice as established by the [Australian Code for the Responsible Conduct of Research \(2018\)](#).

Part C - Role of the Human Research Ethics Committee

(7) La Trobe University has established the Human Research Ethics Committee (HREC) as a registered Human Research Ethics Committee (HREC). The HREC is responsible for the ethical review and monitoring of human research conducted by La Trobe staff and students, in accordance with the National Statement. The College Human Ethics Sub-Committees (CHESCs) are formally constituted sub-committees of the HREC.

(8) All human research involving more than negligible risk is reviewed and approved by the HREC (above low risk) or CHESCs (low risk) prior to the commencement of projects. There are two CHESCs dedicated to the review of low risk proposals:

- a. The SHE CHESC reviews proposals which are conducted by researchers from the College of Science, Health and Engineering.
- b. The ASSC CHESC reviews proposals which are conducted by researchers from the College of Arts, Social Sciences and Commerce.

(9) The CHESCs may also review low risk research conducted by staff from Central and Support Services.

(10) The role of the HREC and CHESCs is to ensure that;

- a. projects promote and facilitate ethically sound research that is of benefit to the community;
- b. researchers respect the rights and welfare of human participants in research; and
- c. any risks of unfair burden or harm from research procedures are minimised.

(11) National Statement training support, record keeping and secretariat support to the HREC and CHESCs is provided by Ethics and Integrity in the Research Office.

Part D - HREC Terms of Reference

(12) THE HREC terms of reference are publicly available in the Directory of Committees and on the Research Office website.

(13) The CHESC terms of reference is also available on request.

Part E - HREC Membership

(14) The La Trobe University HREC has a membership that allows it to fulfil its terms of reference and is compliant with the [National Statement](#). In order to meet the National Statement requirements, the HREC has a minimum membership of eight people, with at least one third of the members from outside the University and a gender balance. Members are appointed in the following categories:

- a. HREC Chair who has suitable experience, whose other responsibilities will not impair the UHEC's capacity to carry out its obligations under the National Statement;
- b. HREC 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;
- c. Lay Woman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- d. Lay Man who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- e. 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;

- f. Pastoral Carer who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
- g. Lawyer who is not engaged to advise the University;
- h. Content Specialists (at least two) with current research experience that is relevant to research proposals to be considered for review.

(15) No member can be appointed in more than one category.

(16) To assist the HREC in decision-making processes, the Committee may seek expert advice from outside the Committee. The Committee may also invite observers and/or presenters to meetings.

(17) As the minimum membership for a Human Research Ethics Committee is eight; therefore it is preferable that eight members attend meetings including a Chairperson, one Lay Man, one Lay Woman, one Health Professional, one Pastoral Carer, one Lawyer and two Content Specialists. If members cannot attend, they are asked to submit out of session comments to ensure all categories are represented.

(18) The HREC 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 HREC, the Chair should possess the following attributes:

- a. the ability to bring impartiality to the task;
- b. the skills to manage the business of the HREC;
- c. the ability to communicate, negotiate and to resolve conflict; and
- d. an understanding of the ethical issues involved in human research.

(19) The HREC Deputy Chair should be capable to represent the Chair as required. In the absence of the Chair the Deputy Chair will act in the position of Chair.

(20) Positions for HREC members who are not employed by the University will be advertised for expressions of interest. These will be reviewed by the HREC Chair and the HREC Executive Officer. Appointments are made on invitation by the University pending a successful interview with University representatives (which includes the HREC Chair) and subsequent approval by RGSC. Heads of School are expected to nominate content specialists to sit on the HREC. The Chair and Deputy Chair of the CHESCs are also appointed as content specialists on the HREC. As part of the appointment process, invited members are required to declare real and potential conflicts of interest and factors that may preclude them from the nominated Category.

(21) 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 HREC and sign a confidentiality agreement designed for La Trobe University HREC 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 for a second term.

(22) Changes in the membership structure are approved by RGSC and noted in the minutes of the next UHEC meeting. Membership may be terminated by the Research Office or RGSC at any time by providing not less than 24 hours' notice in writing. In general, members may voluntarily resign during their appointment by providing five working days' notice in writing to the HREC Chair. Members that are staff of the University may need to seek approval from their Head of School or College Provost prior to submitting a notice of resignation.

Part F - CHESC Membership

(23) Each CHESC has a membership that allows it to fulfil its terms of reference, with separate persons appointed to

each of the following categories:

- a. CHESC Chair who has suitable experience, whose other responsibilities will not impair the CHESC's capacity to carry out its obligations under the National Statement;
- b. CHESC Deputy Chair who has suitable experience, whose other responsibilities will not impair the CHESC's capacity to carry out its obligations under the National Statement;
- c. Content Specialists with current research experience that is relevant to research proposals to be considered for review.

(24) The CHESC Chairs and Deputy Chairs are appointed by the College Provosts and approved by the RGSC. Terms of appointment are determined by the College Provosts.

(25) Content Specialists are nominated by the CHESC Chairs on the advice of Heads of School and approved by the HREC Chair. Membership terms are for three years with the opportunity for renewal.

Part G - Review and Monitoring

(26) Above low risk proposals are reviewed by representatives from the eight categories that constitute the HREC 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 HREC. Approval is issued subject to ratification by the HREC at a quorate meeting.

(27) Low risk proposals are reviewed by two CHESC content specialists and a CHESC Chair or Deputy Chair. CHESC approval is issued subject to ratification by the HREC at a quorate meeting.

(28) The HREC meets at least six times a year to discuss applications and changes to relevant guidelines and procedures. The CHESCs hold meetings twice a year to discuss applications and the review process.

(29) Agendas and minutes for HREC meetings are prepared by the HREC Executive Officer, who ensures the agenda and papers are sent out at least five days before the meeting to allow adequate time for review. All review decisions made by the HREC will be communicated to researchers in writing in a timely manner.

(30) 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 HREC or CHESC from which approval was obtained. The HREC Chair reviews Serious Adverse Events, Adverse Events and Incident reports in the first instance to ensure appropriate action occurs immediately. All reports are then discussed by the HREC at a quorate meeting.

(31) The HREC and CHESC 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.

(32) HREC and CHESC 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. Any decisions to suspend or withdraw ethics approval will be communicated to the research team in writing. The Head of School and Deputy Vice-Chancellor (Research and Industry Engagement) may also need to be informed, this will be determined on a case by case basis.

Part H - Conflict of Interest

(33) The HREC and CHESCs deal with situations in which a conflict of interest arises by:

- a. 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.
- b. Making it a requirement to declare conflicts of interest at the start of each HREC meeting and to document the declarations and resolutions in the minutes of the meeting.
- c. 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).
- d. Considering and responding to any concern raised by an investigator of other party that a member has an interest that may have influenced the objectivity of a committee decision. In this case, the complaint is dealt with by the HREC with the complainant informed, in writing, of the UHEC response. If the complainant is not satisfied with the HREC response, a grievance may be lodged with RGSC or the University Ombudsman.
- e. Including a question on Human Ethics application forms asking researchers to declare any conflicts of interest.

Part I - Externally Approved Projects

(34) 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 research approved by another HREC where La Trobe University researchers are involved.

(35) The review is conducted by the HREC/CHESC Chair or Deputy Chair in consultation with content experts if required and approvals sent for ratification to the HREC. 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.

Part J - Annual Reporting

(36) CHESCs report to the HREC annually through submission of annual reports to be completed by 1 March covering the previous calendar year. The HREC reports to RGSC, ensuring inclusion of the CHESC reports by 31 March. The annual reports include:

- a. numbers and types of projects assessed and approved or rejected;
- b. numbers of complaints received and how they were dealt with;
- c. activities reported to the HREC from the CHESCs;
- d. activities that have supported the educational needs of HREC members;
- e. procedural changes;
- f. administrative or other difficulties being experienced; and
- g. any matters that may affect the University's ability to maintain compliance with the National Statement and if necessary the provision of suitable recommendations.

(37) In addition, the HREC 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(RIE).

Part K - Additional Operating Guidelines

(38) Other human ethics operating guidelines such as guidelines for Participant Information Statements and Consent Forms are approved by the HREC and displayed in their most current form on the Human Ethics website.

Part L - Complaints and Non-compliance

(39) 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. Such concerns can be submitted in writing to the HREC Executive Officer.

(40) Complaints or grievances by La Trobe University personnel about decisions reached by the HREC or CHESCs can be submitted in writing to the DVC(RIE) or the University Ombudsman.

(41) Any unplanned impacts on human research participants or researchers outside the scope of a HREC or CHESC-approved project need to be reported promptly by the responsible personnel to the HREC Executive Officer.

(42) 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 Procedure](#).

Section 5 - Definitions

(43) For the purpose of this Procedure:

- a. Above low risk (research): research which may lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.
- b. Compliance: acting in accordance with the National Statement.
- c. Discomfort: a negative accompaniment or effect of research, less serious than harm.
- d. 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.
- e. Low risk (research): research in which the only foreseeable risk is one of discomfort.
- f. Negligible risk (research): research in which there is no foreseeable risk of harm or discomfort.

Status and Details

Status	Current
Effective Date	28th November 2016
Review Date	15th March 2019
Approval Authority	Academic Board
Approval Date	27th November 2016
Expiry Date	Not Applicable
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