



Terms of Reference: Central Human Research Ethics Committee

Statement of Purpose

The University of Melbourne (University) is committed to ensuring that human research is ethically reviewed and monitored in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

The University has established a framework for the review, approval and monitoring of human research in accordance with the requirements of the *National Statement* and the *Australian Code for the Responsible Conduct of Research (2018)*. The University's Central Human Research Ethics Committee ('the Committee' or 'CHREC') is convened by the Deputy Vice-Chancellor (Research) to support this commitment through the provision of advice and expertise on strategic matters pertaining to human research ethics, and to guide the prioritisation of investment in education and other capability-building initiatives.

In these terms of reference 'human research' means research involving people, their data or their biospecimens.

1. Functions

- 1.1. The functions of the CHREC are to have oversight of matters pertaining to human research ethics on behalf of the University. The CHREC will:
 - a. provide advice to the Office of Research Ethics and Integrity (OREI) and the Deputy Vice-Chancellor (Research), through the Research Ethics and Integrity Strategy Committee (REISC) on:
 - i. strategic matters relating to human research ethics at the University; and
 - ii. policies and guidelines for the ethical review of research involving humans, including data and their biospecimens, aligned to the institutional responsibilities under the National Statement;
 - b. consider emerging issues that may impact the University's obligations under the National Statement and other relevant regulations or codes of practice, whether arising from internal or external factors;
 - c. act as a consultative panel of experts for the University's Ethics Shared Service (ESS) initiatives, including providing advice on policies and procedures;
 - d. establish and determine the composition and scope of work of sub-committees and working groups, from time-to-time, as required; and
 - e. receive reports on the health of the University's Ethics Shared Service from OREI, including service performance metrics and analyses of incidents.

2. Membership

- 2.1. The CHREC has the following members:
 - a. Chair – a senior staff member of the University, appointed by the Deputy Vice-Chancellor (Research);
 - b. Chairs of each of the Greater Than Low Risk (GTLR) human research ethics committees;
 - c. At least two Chairs of the Low or Negligible Risk (LNR) human research ethics committees;
 - d. At least two Research Ethics Advisors (REAs), one STEMM and one HASS;
 - e. A postgraduate student appointed by the Chair following advice from GSA; and

- f. Director, Office of Research Ethics and Integrity (or Delegate).
- 2.2. The Chair may invite people for particular purposes and a specified period in order to effectively discharge the committee's functions.
- 2.3. The CHREC must appoint from among its members a Deputy Chair who will have the authority to act for the Chair in the Chair's absence.
- 2.4. Membership will normally be reviewed at least every three years, in line with the human research ethics committee terms of service.
- 2.5. Members will be provided with formal notification of membership.

3. Proceedings

- 3.1. The CHREC will meet once per quarter.
- 3.2. Meetings will be held face to face (in person or by videoconference) where possible.
- 3.5. Quorum is reached when 50% or greater of the current membership is in attendance.
- 3.6. Secretariat support to the CHREC will be provided by the Office of Research Ethics and Integrity.
- 3.7. All decisions of the Committee will be recorded in minutes.
- 3.8. The CHREC reports regularly to the Research Ethics and Integrity Strategy Committee (REISC).

References:

Australian Code for the Responsible Conduct of Research (2018)

National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

Terms of reference: Greater Than Low Risk committees

Statement of purpose

The University of Melbourne (the University) is committed to ensuring that human research is ethically reviewed and monitored in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

In these terms of reference 'research' has a broad definition and includes investigation undertaken to gain knowledge and understanding or to train researchers. 'Human research' means research involving people, their data or their biospecimens.

Greater Than Low Risk committees

Greater Than Low Risk (GTLR) committees are established by the University in accordance with paragraphs 5.1.24 to 5.1.37 of the National Statement.

1. Functions

1.1. The functions of the GTLR committees are to:

- 1.1.1. On behalf of the University, undertake review of applications deemed to involve more than low risk.
- 1.1.2. Consider the ethical implications of proposed research applications involving humans as participants in the research, and to decide with respect to those applications whether they satisfy the requirements of the National Statement and accepted ethical standards and codes.
- 1.1.3. Monitor research projects conducted by staff and students in accordance with University guidelines.
- 1.1.4. Receive reports of incidents and complaints about the conduct of research, and assist in resolution as required with participants, researchers or others on the conduct of projects.
- 1.1.5. Receive, handle and seek to resolve complaints about the conduct of that GTLR committee in reviewing research proposals, on advice from the Office of Research Ethics and Integrity.

1.2. GTLR committees only review research for which the Project Supervisor is a staff member (or equivalent) of the University. Students can not be named as Project Supervisors.

2. Membership

2.1. Membership of a GTLR committee should comprise:

- 2.1.1. A Chair, with suitable experience, whose other responsibilities will not impair the GTLR committee's capacity to carry out its obligations under the National Statement;
- 2.1.2. At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- 2.1.3. At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or allied health professional;
- 2.1.4. At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder or minister of religion;
- 2.1.5. At least one lawyer, where possible one who is not engaged to advise the institution; and

- 2.1.6. At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- 2.2. From time to time a GTLR committee may co-opt a person with particular expertise for a specified period.

3. Methods of operation

- 3.1. Each GTLR committee is to meet at least monthly, either in person or through an online meeting platform.
- 3.2. An Executive comprising the Chair and two other members of a GTLR committee may be appointed to approve minor amendments or revisions to projects. The Executive may not approve projects without prior discussion by the full committee. Any decisions taken by the Executive must be ratified by the committee at its next meeting.
- 3.3. Minutes, including decisions regarding application approvals made at the meetings, must be recorded in the Infonetica Ethics Review Manager platform for audit and compliance purposes.
- 3.4. Applications involving more than low risk must be discussed at a meeting of the GTLR committee. Details of discussions at the meeting are to be recorded, and comments entered by members into the Infonetica Ethics Review Manager platform prior to meetings.
- 3.5. In considering research projects, members should deliberate on the values and principles of the National Statement, exercise their judgement, and appreciate the context of the research proposed. Decisions should be reached by general agreement; they need not be unanimous.
- 3.6. Members may not review and approve their own research. In such cases, the member should declare a conflict of interest and be excused from review of that application.
- 3.7. In discharging its responsibilities, a GTLR committee may seek the assistance of such experts as it chooses. It may invite researchers, and researchers may request, to be present for discussion of their proposed research project.
- 3.8. There are no fees for ethics review by a GTLR committee.
- 3.9. GTLR committee activity will be reported quarterly to the University's Deputy Vice-Chancellor (Research).

Terms of reference: Low and Negligible Risk committees

Statement of purpose

The University of Melbourne (the University) is committed to ensuring that human research is ethically reviewed and monitored in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

In these terms of reference 'research' has a broad definition and includes investigation undertaken to gain knowledge and understanding or to train researchers. 'Human research' means research involving people, their data or their biospecimens.

Low and Negligible Risk committees

Low and Negligible Risk (LNR) committees are established by the University in accordance with paragraphs 5.1.18 to 5.1.23 of the National Statement.

4. Functions

4.1. The functions of the LNR committees are to:

- 4.1.1. On behalf of the University, undertake review of applications deemed to involve no more than inconvenience (negligible risk) or discomfort (low risk) (National Statement 5.1.18–5.1.21).
- 4.1.2. Consider the ethical implications of proposed research applications involving humans as participants in the research, and to decide with respect to those projects whether they satisfy the requirements of the National Statement and accepted ethical standards and codes.
- 4.1.3. Monitor research projects conducted by staff and students in accordance with University guidelines.
- 4.1.4. Receive reports of incidents and complaints about the conduct of research, and assist in resolution as required with participants, researchers or others on the conduct of projects.
- 4.1.5. Receive, handle and seek to resolve complaints about the conduct of that LNR committee in reviewing research proposals, on advice from the Office of Research Ethics and Integrity.

4.2. LNR committees only review research for which the Project Supervisor is a staff member (or equivalent) of the University. Students can not be named as Project Supervisors.

5. Membership

5.1. Membership of a LNR committee should comprise:

- 5.1.1. At least eight members of academic staff of the University, including one Chair.
- 5.1.2. A maximum of one currently enrolled University post-graduate student per LNR committee.

5.2. Membership is drawn from cognate academic divisions, to be monitored and advised by the Office of Research Ethics and Integrity according to use of the Ethics Shared Service.

5.3. From time to time a LNR committee may co-opt a person with particular expertise for a specified period.

6. Methods of operation

6.1. Each LNR committee is to meet at least monthly, either in person or through an online meeting platform.

6.2. An Executive comprising the Chair and two other members of a LNR committee may be appointed to approve minor amendments or revisions to projects. The Executive may

not approve projects without prior discussion by the full committee. Any decisions taken by the Executive must be ratified by the committee at its next meeting.

- 6.3. Minutes, including decisions regarding application approvals made at the meetings, must be recorded in the Infonetica Ethics Review Manager platform for audit and compliance purposes.
- 6.4. Applications involving low and negligible risk should be discussed at a meeting of the LNR committee. Details of discussions at the meeting are to be recorded, and comments entered by members into the Infonetica Ethics Review Manager platform prior to meetings.
- 6.5. In considering research projects, members should deliberate on the values and principles of the National Statement, exercise their judgement, and appreciate the context of the research proposed. Decisions should be reached by general agreement; they need not be unanimous.
- 6.6. Members may not review and approve their own research. In such cases, the member should declare a conflict of interest and be excused from reviewing that application.
- 6.7. Members of LNR committees should refer any research they identify as involving more than low risk to a University Greater Than Low Risk committee.
- 6.8. In discharging its responsibilities, a LNR committee may seek the assistance of such experts as it chooses. It may invite researchers, and researchers may request, to be present for discussion of their proposed research project.
- 6.9. There are no fees for ethics review by a LNR committee.
- 6.10. LNR committee activity will be reported quarterly to the University's Deputy Vice-Chancellor (Research).

Terms of Service: Human Research Ethics Committees

The University of Melbourne (University) is committed to ensuring that human research is ethically reviewed and monitored in accordance with the ***National Statement on Ethical Conduct in Human Research 2007 (updated 2018)***. In recognition of the valuable contribution that human research ethics committee members make in upholding the University's commitment, these Terms of Service seek to outline the obligations of committee members, and the University in conducting activities related to the ethical review and monitoring of human research.

Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, not as representatives of any organisation, group, or opinion. Upon appointment, members sign a Deed of Confidentiality and receive a formal letter of appointment, which includes assurance that the University provides indemnity for liabilities that arise as a result of the member exercising their duties in good faith.

1. Length of service

- 1.1 Human Ethics Committee members are requested to commit to a minimum term of one year of service. Subject to meeting the member obligations and code of conduct below, membership is extended for another two years of service. Members approaching the end of a three-year term are eligible for reappointment at the discretion of the University.

2. Member obligations

Upon accepting appointment to a committee, members agree to:

- 2.1 Maintain familiarity and serve in accordance with the relevant codes and guidelines, including but not limited to the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.
- 2.2 Maintain familiarity and serve in accordance with any relevant University policies, including but not limited to the Provision and Acceptable use of IT Policy (MPF1314), the Appropriate Workplace Behaviour Policy (MPF1328) and the Privacy Policy (MPF1104).
- 2.3 Review meeting papers and lodge application review comments in the Infonetica Ethics Review Manager platform prior to committee meetings. Meeting papers are circulated to members one week prior to each meeting.
- 2.4 Attend meetings approximately once monthly (or as scheduled) for their duration or, in the case of inability to attend, give advance notice of absence to the secretariat.
- 2.5 Provide advance notice to the secretariat as early as possible if planning to resign from the committee.
- 2.6 Attend information sessions and other training seminars provided by the University, as required.

3. University obligations

The University agrees to:

- 3.1 Provide members with access to the relevant University IT systems, including the Infonetica Ethics Review Manager platform, and timely access to meeting papers within this platform.
- 3.2 Provide appropriate resources and support to members to enable them to fulfill their roles.

- 3.3 Provide accurate and timely advice to members on all matters relating to human research ethics and committee governance and processes.
- 3.4 Facilitate education and training for members and conduct inductions for members prior to their first meeting.
- 3.5 Remunerate members who are external to the University with an honorarium payment per meeting attended.

4. Code of Conduct

During committee meetings and when otherwise performing their duties as committee members, members must:

- 4.1 Demonstrate respect and professional communication in all interactions.
- 4.2 Not directly or indirectly engage in, or incite or assist others to engage in, any of the following behaviours:
 - unlawful discrimination;
 - harassment;
 - sexual harassment;
 - sexual assault;
 - physical or verbal assault;
 - bullying;
 - stalking;
 - victimisation; or
 - vilification of an individual or group of individuals.

Each of the above are defined in the Glossary of the Appropriate Workplace Behaviour Policy (MPF1328).

- 4.3 Keep confidential any information relating to the committee's activities and operations. It is understood that members may need to seek information or advice from external sources in order to properly fulfill their roles. Such activity is appropriate and encouraged, provided that no intellectual property, commercial in confidence, ethics application material or identifying information is revealed to external parties in the process.
- 4.4 Disclose any actual, potential or perceived conflicts of interest at the beginning of each meeting, or when they become known.