

UNIVERSITY OF TECHNOLOGY SYDNEY
HEALTH AND MEDICAL RESEARCH ETHICS COMMITTEE
TERMS OF REFERENCE

The University of Technology Sydney (UTS) Health and Medical Research Ethics Committee (MREC) is a Vice-Chancellor’s advisory committee that reports to the Deputy Vice-Chancellor (Research).

1. Objectives

- 1.1. The UTS MREC exists to consider the ethical implications of proposed human research projects in accordance with the National Statement on Ethical Conduct in Human Research (2023) (National Statement) and to promote ethical principles in human research.
- 1.2. UTS recognises and supports the responsibilities set out in the Australian Code for the Responsible Conduct of Research.
- 1.3. UTS recognises and supports the following values and principles of the National Statement:
 - Research merit and integrity
 - Justice
 - Beneficence
 - Respect

2. Functions

- 2.1. Protect the mental and physical welfare, rights, dignity and safety of human research participants, their data and/or human tissue.
- 2.2. Promote compliance with the National Statement (2023), the Australian Code for the Responsible Conduct of Research (2018) (The Code), applicable State and Commonwealth requirements, and all applicable legislation.
- 2.3. Protect the reputation of UTS as a place of ethical research by providing independent, competent, timely review and monitoring of human research projects with respect to

their ethical acceptability for as long as the projects are active.

- 2.4. Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data and primary materials (e.g., biological samples) samples collected during the conduct of research involving humans in accordance with Research Data Management Procedure and research Policy.
- 2.5. Review proposals from UTS-affiliated researchers for human research projects with the intent to identify potential risk and/or harm to the UTS staff members and/or students undertaking the research so these can be minimised.

3. Scope of Responsibility

- 3.1. Receive, review and monitor proposals for all health and medical human research projects (i.e. those involving health care including mental health, clinical trials, health information, genomic research and human tissues).
- 3.2. Develop and provide input on UTS policies and guidelines for human research ethics.
- 3.3. Educate and guide UTS staff members and/or students on the ethical conduct of research and processes/requirements for ethical review and approval.
- 3.4. Provide advice to the University, through the Deputy Vice-Chancellor (Research), on strategies to promote awareness of the ethical conduct of human research and on ethical issues including the ethical aspects of complaints against researchers or research projects and teaching protocols.

4. Composition

- 4.1. The MREC will be comprised of a minimum of eight members and will include the following categories of membership (Section 5.1.30):
 - A Chairperson, with suitable experience, whose other responsibilities will not impair the MREC's capacity to carry out its obligations under this National Statement;
 - at least two lay people, who have no paid affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - 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;
 - at least one person who performs a pastoral care role in a community, for example,

- an Aboriginal elder, community leader, a chaplain or a minister of religion;
- at least one lawyer, where possible one who is not engaged to advise the institution; and
 - at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.
- 4.2. No individual may represent more than one category listed above at a meeting, but may represent an alternative category if required to ensure minimum membership categories are represented to allow the meeting to proceed.
- 4.3. UTS may designate a member to carry out the duties of the Chairperson when the Chair is not available (i.e., Deputy Chair). When this member is acting as the Chair, the membership category filled by this member should be filled by another MREC member.
- 4.4. In addition to the minimum composition at 4.1, the MREC will include other categories of membership to represent minimum membership, or to have experience or expertise relevant to the work of the Committee. These include:
- Individuals with current research experience that is relevant to research proposals to be considered, nominated by the executive Deans of the relevant faculties.
 - At least one Faculty Representative who is familiar with the research methods predominantly reviewed by the UTS MREC.
 - Individuals with specialised technical expertise, such as statisticians or data security, storage and safety specialists.
 - Individuals with expertise related to participant groups, including participant advocates.
 - Individuals with expertise related to research contexts, such as clinical or community care.
 - Ex Officio member – Deputy Vice-Chancellor (Research) represented by the Pro Vice-Chancellor (Research).

5. Membership

- 5.1. The Chairperson, Deputy Chairperson, and all members will be appointed by the Deputy Vice-Chancellor (Research), and will receive a letter of appointment including the date of appointment, length of appointment, and responsibilities as an MREC member (National Statement 5.2.21 to 5.2.24).

- 5.2. Members are required to abide by the [UTS Conflict of Interest Disclosure Policy](#) and sign a confidentiality agreement, ensuring:
 - That all matters of which they become aware during the course of their work on the MREC will be kept confidential; and
 - That any conflicts of interest, which exist or may arise during their tenure on the MREC, will be declared;
- 5.3. Members are appointed for an initial period of one year. Thereafter, members may be appointed for a further two-year term and may then be re-appointed for a consecutive three-year term. All appointments are renewable at the discretion of the MREC Executive and the Deputy Vice-Chancellor (Research).
- 5.4. Members are required to attend at least 75% of the meetings held during each year of their appointment alongside the provision of written comments on the majority of the ethics applications being reviewed.
- 5.5. Lay members and non-institutional members will be provided honoraria per meeting and reimbursed for their travel costs.
- 5.6. A formal induction session and support will be provided to all new members in accordance with the requirements of the National Statement by the MREC Executive.
- 5.7. During their MREC membership on the MREC, members will be provided with opportunities to attend training and professional development relevant to their work on the committee.
- 5.8. Where practical, MREC membership should have gender diversity and ensure that at least one third of those participating in the meeting are from outside the institution.

6. Meetings

- 6.1. A quorum is required at each meeting for the MREC to reach a final decision on any agenda item as specified in the National Statement (5.1.30) attending in person or via telephone or videoconference. Quorum for meetings is at least one member from each category as specified in Section 4.1.
- 6.2. The Chairperson, Deputy Chairperson and the Ethics Secretariat shall form an Executive. The Executive is responsible for conducting the business of the MREC between meetings.

7. Executive Review Committee (ERC)

- 7.1. A subcommittee called the Executive Review Committee (ERC) will meet monthly to

discuss committee business and any urgent matters.

- 7.2. The Membership of the ERC will be as follows: Chairperson of the HREC, Chairperson of the MREC, Deputy Chairperson of the MREC, Deputy Chairperson of the MREC, and the Manager, Research Ethics (or delegate).
- 7.3. The decisions of the ERC will be noted on the agenda of the next corresponding meeting of the HREC or MREC as appropriate.

8. Ratification of approval for external review body

- 8.1. UTS may use the review processes of another institution or external ethics review body; which is inclusive of an overseas review body.
- 8.2. The review of the external approval will be conducted by the MREC Executive and noted by the MREC. Ratification of an external review body will only be accepted where the review aligns with the NHMRC National Statement 2023.
- 8.3. All institutional decisions to accept external ethics approval (including by an overseas ethics review body) will take account of the evidence of approval and applicable standards provided by the researchers (see 5.5.7); and be made on a case-by-case basis.

9. Exemption from Ethical Review

- 9.1. Research that may be eligible for exemption from ethics review includes research that carries a lower risk to participants or the community (National Statement 2023 5.1.17) by means of a risk assessment algorithm in the online system (Research Master).
- 9.2. Applications submitted using the exempt from ethical review form in Research Master will be reviewed by the MREC Executive and noted on the agenda at the next meeting of the MREC.

10. Faculty review of low risk research applications

- 10.1. Low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort (National Statement 2023 Chapter 2.1).
- 10.2. The ethics review and approval process for low-risk research shall be undertaken in accordance with the UTS Low Risk Terms of Reference.
- 10.3. Research involving low risk will be assessed by the risk assessment algorithm in Research

Master.

10.4. Low risk applications will be noted on the agenda of the next meeting of the MREC.

11. Declaration of interest

- a. An MREC member must declare to the MREC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Further, fill out a [declaration of interest](#) form in accordance with the [UTS Conflict of Interest Disclosure Policy](#). Conflicts of interest includes:
 - i. Personal involvement or participation in the research;
 - ii. Financial or other interest or affiliation;
 - iii. Involvement in competing research.
- b. An MREC member with a conflict of interest who is present at the meeting may:
 - i. be asked to absent themselves for a meeting or from any deliberations or decision-making about the research; or
 - ii. have this information disclosed to researchers.
- c. Disclosures of interest, determinations of conflict of interest and steps taken to manage those conflicts should be recorded in the meeting minutes.

12. Confidentiality

- a. MREC meetings are held in a closed session. The agenda and minutes of meetings, applications, supporting documentation and correspondence are all treated confidentially.

13. Record keeping and reporting

- a. The Ethics Secretariat will maintain a record of all research proposals received and reviewed in accordance with the National Statement 5.2.19
- b. The Ethics Secretariat will prepare and maintain official records of the MREC's activities, including agendas and minutes of all MREC meetings.
- c. Files will be kept securely and confidentially in accordance with the requirements of the State Records Act 1998 (NSW) and the UTS Records Management Policy.
- d. Records shall be retained for a minimum of 15 years after action completed, then

destroyed.

- e. The MREC will provide annual reports to the Deputy Vice-Chancellor (Research), the NHMRC, and Research Committee as required.

14. Appeals and complaints

a. Appeals regarding MREC rejection of an application

14.1.1. Where the MREC has rejected an application, the investigator will be able to:

- Submit a new application to the MREC taking due account of the MREC's concerns. This will be processed and reviewed in the same way as any other new application; or
- Lodge an appeal with the MREC Chairperson specifying the grounds of the appeal in writing. The Chairperson will investigate the appeal and its validity, and recommend to the MREC an appropriate course of action at the following meeting of the MREC.

14.1.2. The MREC will notify the appellant of the course of action and determination in a timely manner.

14.1.3. If the appellant is not satisfied with the outcome, they will have the discretion to refer the appeal to the Director, Research Office.

b. Complaints about the MREC's review process

14.2.1. A complaint about the MREC's review process will be directed to the attention of the Chairperson of the MREC, detailing the grounds of the complaint. If first submitted to the MREC Secretariat, the complaint will be referred to the Chairperson.

14.2.2. The Chairperson (with support from the MREC Secretariat) will investigate the complaint and its validity and recommend to the MREC an appropriate course of action. The MREC will notify the complainant of the course of action and determination in a timely manner.

14.2.3. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.

c. Complaints about the conduct of an approved research project

14.3.1. Any concern or complaint about the ethical conduct of a research project will be directed to the Manager, Research Ethics.

14.3.2. Concerns or complaints from internal and external stakeholders received by email,

telephone or in a face-to-face conversation will be recorded by the Manager, Research Ethics and kept in a designated file in Content Manager.

- 14.3.3. The Manager, Research Ethics will acknowledge receipt of the complaint and undertake a preliminary assessment.
- 14.3.4. The MREC Chair will be notified about the complaint and the results of the preliminary assessment regarding the issues raised by the complainant, and if necessary will provide advice about an appropriate resolution. Where a resolution is established from the consultation with appropriate stakeholders the complainant will be notified by the Manager, Research Ethics. The correspondence will be recorded into Content Manager.
- 14.3.5. The outcome of assessment of the complaint will be reported back to the MREC Chair, complainant and/ or other appropriate funding bodies if required.
- 14.3.6. The Chair and the MREC shall endorse the resolution of complaints relating to the ethical approval of a research project.
- 14.3.7. The complaint, and its resolution, will be notified to the Director, Research Office, the MREC, and the Faculty's Associate Dean (Research), and the Head of School.
- 14.3.8. The Manager, Research Ethics will inform the complainant and the respondent of the outcome.
- 14.3.9. In exceptional cases, where we would have reason to believe that continuance of a research project will compromise participants' welfare or if the conditions of ethics approval for the project is not being adhered to the MREC Chair, Deputy Chair or Manager, Research Ethics may place an immediate suspension on a project upon receipt of a complaint. The researcher will be notified immediately if this occurs.
- 14.3.10. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.
- 14.3.11. Where the preliminary assessment finds the complaint may also represent a potential breach of The Code, the complaint will be assessed in accordance with the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* (The Guide) as detailed in the UTS Research Policy.

15. Monitoring

- a. The MREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety, and welfare of participants. This includes review of annual progress reports and final reports

16. Conduct of Business

- a. The MREC conducts its business in accordance with these Terms of Reference and Standard Operating Procedures.

17. Disagreements between the MREC and the institution

- a. In the event that any disagreements arise between the MREC and the University of Technology Sydney, the matter shall be referred to an independent mediator.

18. Closure of an institution and/or review body

- a. The MREC remains responsible for monitoring all approved research until this responsibility is successfully transferred to another institution and/or review body.