

**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 (2007) (National Statement).
- 1.2. 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, the Australian Code for the Responsible Conduct of Research (2007) (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 UTS policy and guidelines.

- 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. Provide education and training for 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

- a) a chairperson, with suitable experience, whose other responsibilities will not impair the MREC's capacity to carry out its obligations under this National Statement;
- b) 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;
- c) 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;
- d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- e) at least one lawyer, where possible one who is not engaged to advise the institution; and
- f) 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.

Other categories of membership:

- Six Faculty Representatives 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 Human Research Ethics Committee (HREC).
- Ex Officio member – Deputy-Vice-Chancellor (Research) represented by the Dean of the Graduate Research School.

## 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.
- 5.2. The Deputy Chairperson shall share membership with the Deputy Chairperson of the HREC, to ensure consistency across the two Committees.
- 5.3. Members are required to sign a declaration of interest and confidentiality statement undertaking:
  - That all matters of which he/she becomes aware during the course of his/her work on the MREC will be kept confidential; and
  - That any conflicts of interest, which exist or may arise during his/her tenure on the MREC, will be declared;
- 5.4. 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 3 year term. All appointments are renewable at the discretion of the MREC Executive and the Deputy Vice-Chancellor (Research).
- 5.5. Members are required to attend at least 80% 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.
- 5.6. Lay members and non-institutional members will be reimbursed for their travel costs.
- 5.7. A formal induction session and support will be provided to all new members in accordance with the requirements of the National Statement.
- 5.8. During their membership on the MREC, members will be provided with opportunities to attend training and professional development relevant to their work on the committee.

## **6. Meetings**

- 6.1. A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each category as specified in the National Statement (5.1.30) attending in person or via telephone or videoconference.
- 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.
- 6.3. The Deputy Chairperson shall undertake the duties of the Chairperson for at least one meeting per year.

## **7. Executive Review Committee (ERC)**

- 7.1. A subcommittee called the Executive Review Committee (ERC) will review amendment applications, ratifications of external ethics approval, transfer of research from another institution, applications for noting, program approval applications, evaluation of teaching and learning activities, 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 HREC, Deputy Chairperson of the MREC, and the Research Ethics Manager.
- 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. Review of negligible risk research applications**

- 8.1. Research will be identified as conferring negligible risk 'where there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience' (National Statement section 2.1.7) by means of a risk assessment algorithm in the online system (Research Master).
- 8.2. Negligible risk applications will be noted on the Agenda at the next meeting of the MREC.

## **9. Faculty review of low risk research applications**

- 9.1. Research involving low risk 'where the only foreseeable risk is one of discomfort' (National Statement section 2.1.6) will be assessed via the risk assessment algorithm in Research Master.

- 9.2. The ethics review and approval process for low risk research shall be undertaken at the Faculty/School level in accordance with the National Statement (section 5.1.18 to 5.1.21).
- 9.3. The MREC shall review low risk research applications for those Centres/Units that do not have Faculty-associated low risk approval processes.
- 9.4. Low risk applications will be noted on the Agenda at the next meeting of the MREC.

## **10. Declaration of interest**

- 10.1. 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. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on research outcomes.
- 10.2. An MREC member with a conflict of interest who is present at the meeting may be asked to withdraw from the meeting (by leaving the room) or may remain in the room at the MREC's discretion.
- 10.3. The MREC member with a conflict of interest will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter.
- 10.4. The minutes will record the declaration of interest and the decision of the MREC on the procedures to be followed.

## **11. Confidentiality**

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

## **12. Record keeping and reporting**

- 12.1. The Ethics Secretariat will maintain a record of all research proposals received and reviewed in accordance with the National Statement (section 5.2.24).
- 12.2. The Ethics Secretariat will prepare and maintain official records of the MREC's activities, including agendas and minutes of all MREC meetings.
- 12.3. Files will be kept securely and confidentially in accordance with the requirements of the State Records Act 1998 (NSW) and the UTS Records Management Vice-Chancellor's Directive.

- 12.4. Records shall be retained for a minimum of 15 years after action completed, then destroyed.
- 12.5. The MREC will provide annual reports to the Deputy Vice-Chancellor (Research) and the National Health and Medical Research Council (NHMRC) as required.
- 12.6. MREC Terms of Reference will be available on the UTS Research Ethics & Integrity website.

### **13. Appeals and complaints**

#### **13.1. Appeals regarding MREC rejection of an application**

- 13.1.1. 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 in a timely manner. The MREC will notify the appellant of the course of action and determination in a timely manner.
- 13.1.2. If the appellant is not satisfied with the outcome, they will have the discretion to refer the appeal to the Director, Research Office.

#### **13.2. Complaints about the MREC's review process**

- 13.2.1. 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.
- 13.2.2. The Chairperson 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.
- 13.2.3. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.

#### **13.3. Complaints about the conduct of an approved research project**

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

- 13.3.2. Concerns or complaints from internal and external stakeholders received by email, telephone or in a face-to-face conversation will be recorded by the Research Ethics Manager and kept in a designated file in TRIM.
- 13.3.3. The Research Ethics Manager will acknowledge receipt of the complaint and undertake a preliminary investigation regarding the issues raised by the complainant.
- 13.3.4. The MREC Chair will be notified about the complaint and the results of the preliminary investigation and if necessary will provide advice about the appropriate resolution of the concern or complaint.
- 13.3.5. Complaints relating to the ethical approval of a research project will be notified to the UTS MREC.
- 13.3.6. Where the preliminary investigation finds that the complaint may also represent a breach of the *Australian Code for the Responsible Conduct of Research*, the Research Ethics Manager will refer it to the Designated Officer who will take responsibility for handling the allegation in accordance with the UTS Research Ethics and Integrity Policy.
- 13.3.7. The Chair and the MREC shall endorse the resolution of complaints relating to the ethical approval of a research project.
- 13.3.8. The complaint, and its proposed or actual resolution, will be notified to the Director - Research Office, the HREC (at its next meeting), and the Faculty's Associate Dean (Research) or equivalent.
- 13.3.9. The Research Ethics Manager will inform the complainant and the respondent of the outcome.
- 13.3.10. In exceptional cases, the MREC Chair, Deputy Chair or Research Ethics Manager may place an immediate suspension on a project upon receipt of a complaint. The researcher will be notified immediately if this occurs.
- 13.3.11. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.