

# SECTION 1 - OVERVIEW

## Human Research Ethics Committee

(1) The Human Research Ethics Committee (HREC) is an independent decision-making body that reports to the UNE Research Committee.

(2) It is established in accordance with the requirements of the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), hereafter referred to as the National Statement.

(3) These Terms of Reference of the HREC prescribe:

- a. the members of the HREC, and members' method and term of appointment;
- b. the functions and terms of reference of the HREC; and
- c. other matters in connection with the HREC and its operation.

(4) The University of New England HREC embraces and complies with the National Statement and its four ethical values:

- a. respect;
- b. research merit and integrity;
- c. justice; and
- d. beneficence.

(5) A guiding principle of HREC is that participants are people: the Committee has a duty to them and takes their perspectives into account when it considers research proposals.

(6) It is an equally important principle that HREC supports and advises researchers and students in developing and undertaking research of a high ethical standard, and considers their safety and wellbeing in reviewing research proposals.

## Objectives

(7) The HREC functions as an independent decision-making body. It advises, the Deputy Vice-Chancellor Research, supports the Academic Board and reports to the Research Committee on:

- a. protecting the mental and physical welfare, rights, dignity and safety of participants in human research, their data or human tissue;
- b. promoting and supporting ethical standards of human research;
- c. using efficient and effective review process, in accordance with the National Statement, to maintain ethical standards in human research;
- d. protecting UNE's standing as a place of ethical research by reviewing research undertaken by UNE staff and students, and affiliates in accordance with the requirements of the National Statement; and
- e. reviewing research applications to identify potential safety concerns for participants, UNE staff and students and affiliates in the conduct of research.

# SECTION 2 - HUMAN RESEARCH ETHICS COMMITTEE MEMBERSHIP

## Membership

(8) The minimum membership of UNE HREC shall be eight, and include (NS 5.1.30):

- a. Chair

- i. the Chair of the HREC is appointed by the Vice-Chancellor and Chief Executive Officer, in consultation with the Deputy Vice-Chancellor Research. The Chair will have suitable experience and standing within the University. Their other responsibilities will not impair the HREC's capacity to carry out its responsibilities under the National Statement
- b. at least two lay people, a woman and a man who are not affiliated with UNE and who are not currently engaged in medical, scientific, legal or academic work;
- c. at least one person with knowledge of the current experience in the professional care, counselling and treatment of people (e.g. a nurse or allied health professional);
- d. at least one person who performs a pastoral care role in a community (e.g. an Aboriginal Elder or a minister of religion);
- e. at least one lawyer, who, if possible, is not engaged to advise UNE;
- f. a representative of Aboriginal and Torres Strait Islander interests;
- g. at least two academic members with current research experience that is relevant to research proposals being considered at an HREC meeting. The Chair of HREC and the Deputy Vice-Chancellor Research will consult over the appointment of up to 12 academic members, with experience in the research areas of:
  - i. information technology.
  - ii. the sciences; and
  - iii. psychology;
  - iv. health;
  - v. engineering and the built environment;
  - vi. education;
  - vii. business and law;
  - viii. arts and social sciences;

## **Appointment procedure**

(9) Prospective members of UNE HREC may be recruited by direct approach, nomination or by invitation to express an interest. They are appointed by the Vice-Chancellor and Chief Executive Officer, or the Deputy Vice-Chancellor Research as the Vice-Chancellor and Chief Executive Officer nominee.

(10) Members are appointed for their knowledge, qualities and experience and not as representative of any organisation or opinion. Appointments will recognise candidates with a broad knowledge of, and commitment to, ethical decision-making.

(11) On appointment members will sign a statement undertaking:

- a. that all matters of which they become aware during the course of their work on UNE HREC will be kept confidential;
- b. that any conflicts of interest, actual or perceived, that may arise during their tenure on UNE HREC will be declared; and
- c. that they have not been subject to any criminal conviction or disciplinary action that would prejudice their standing as an UNE HREC member.

(12) Additional members may be appointed to all categories, except for the position of Chair, so that the HREC remains compliant with the National Statement and has the body of expertise to review research.

(13) HREC members are appointed for a two-year term and may be re-appointed for a maximum of five consecutive terms.

### **Termination of appointment**

(14) The Deputy Vice-Chancellor Research may terminate in writing the appointment of any HREC member if the Deputy Vice-Chancellor Research is of the opinion that:

- a. it is necessary for the proper and effective functioning of the University HREC;
- b. the person is no longer qualified or fit to serve on the University HREC; or
- c. the person has failed to carry out their duties as a University HREC member.

### **Invited members**

(15) The UNE HREC may invite a researcher or researchers, and they may request, to attend meetings for discussion of their proposed research (NS 5.2.20).

(16) The UNE HREC may seek advice from experts to help in considering a research proposal (NS 5.2.21) under these conditions:

- a. the experts shall be bound by the same confidentiality requirements as UNE HREC members; and
- b. any conflicts of interest they have should be disclosed and managed.

### **Observers**

(17) The Chair may invite members of the UNE community and the wider community, who are not researchers, to attend UNE HREC meetings as observers.

### **Casual vacancies**

(18) In the event that a membership lapses before a term of office expires, the Chair may take steps to fill a casual vacancy.

### **Chair**

(19) The Chair will be appointed for a two-year term of office and is renewable for a further two years only.

### **Deputy Chair/s**

(20) The HREC will elect from among its members up to two Deputy Chair/s for a period of two years, renewable for a second term, who will:

- a. chair meetings of the HREC in the absence of the Chair; and
- b. assist the Chair in completing HREC business, including in reviewing and approving low/negligible risk applications for expedited ethical review.

### **Gender representation objectives**

(21) UNE HREC follows the requirement of the National Statement (Section 5 Processes of Research Governance and Ethical review 5.1.29a) that, as far as possible, there should be equal numbers of men and women on a HREC.

### **Balance**

(22) As far as possible there should be:

- a. appropriate representation of the diversity of UNE's cultural environment; and
- b. at least one third of members who are from outside the University.

## **Indemnity**

(23) UNE indemnifies members for actions in the course of their conduct as HREC members.

## **Remuneration**

(24) The Chair and the Deputy Chair/s of HREC will receive a honorarium as a condition of their appointment. There is no other remuneration for HREC members. Those members who are not University staff may, however, be remunerated for travel, parking and other costs associated with attending to the business of HREC. The HREC service of members who are University staff may be recognised in their workload allocation.

## **Conflict of interest**

(25) In accordance with the UNE Conflict of Interest Policy, Conflict of Interest Procedures and the National Statement (Section 5.4 Conflicts of Interest) UNE will adopt measures to manage conflict of interest.

(26) Members are required to disclose any perceived or actual conflict of interest in research to be reviewed, including any:

- a. personal involvement or participation in the research;
- b. financial or other interest or affiliation; or
- c. involvement in competing research.

(27) UNE HREC's measures to manage conflicts of interest may include exclusion from a meeting, or from some of UNE HREC's deliberations.

(28) If the member withdraws from the meeting, the UNE HREC Secretary will record the member's declaration of interest and absence in the minutes.

(29) The member's withdrawal from the relevant part of the meeting will not affect the quorum.

## **Training**

(30) UNE HREC members must have an understanding of the national regulatory and legislative requirements and the relevant UNE policies dealing with ethical research conduct.

(31) Newly-appointed members will receive induction training that is relevant to the responsibilities of the HREC, in accordance with the National Statement (Chapter 5 Responsibilities of HRECs, Other Ethical Review Bodies, and Researchers 5.2.3).

(32) UNE HREC members will be required to attend continuing education or training programs on research ethics at least every two years.

(33) At the discretion of the Chair, training and development in research ethics and associated procedures will also be available to UNE Representatives and Higher Degree by Research students.

# **SECTION 3 - HUMAN RESEARCH ETHICS COMMITTEE FUNCTIONS**

## **Functions**

(34) The functions of UNE HREC are classified in the following domains: reviewing, approval, advisory, monitoring and communication functions.

## Reviewing functions

- (35) The HREC is responsible for reviewing applications for ethics approval which includes:
- a. reviewing the ethical aspects of research proposals involving human research from UNE staff and students, and from non-affiliated researchers, to determine whether they are acceptable and consistent with national regulatory and legislative requirements, particularly:
    - i. the National Statement;
    - ii. the Australian Code for the Responsible Conduct of Research; and
    - iii. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research.
  - b. establishing procedures to promote good ethical review, as outlined in the National Statement (CI's 5.1.28 and 5.1.37).
  - c. ensuring the compliance of research proposals with UNE policies on human research and attendant procedures, including:
    - i. Code of Conduct for Research Rule;
    - ii. Collaborative Research Rule;
    - iii. Management and Storage of Research Data and Materials Policy and Procedures;
    - iv. Open Access to UNE Research Publications and Data Policy;
    - v. Research UNE Deposit, Collection and Access Rule;
    - vi. Records Management Rule and Procedures; and
    - vii. Knowledge Assets and Intellectual Property Policy.
  - d. at the discretion of the Chair and on a fee for service basis, accepts and reviews research proposals from external organisations or researchers with no direct link to UNE.

## Approval functions

- (36) HREC responsibilities for approving applications includes:
- a. granting approvals for research projects, where review has determined them to be ethically acceptable and in accordance with relevant standards and guidelines, including:
    - i. UNE researchers' requirements that proposed research involving human beings to provide sufficient detail/information for UNE HREC to make a judgment on the ethical aspects of the research;
  - b. withholding, withdrawing, suspending, restricting or terminating ethical approval for research proposals where, through review, UNE HREC has determined them to be ethically unacceptable and not in accordance with relevant standards and guidelines;
  - c. reviewing requests from UNE staff and external researchers to recognise ethical approval granted by another registered HREC for research to be conducted on UNE premises;
  - d. recording and acknowledging approvals involving UNE staff, which have been issued by another registered HREC for research which is to be carried out elsewhere; and
  - e. granting approvals for research proposals from external organisations with no direct links to UNE.

## Monitoring functions

- (37) HREC responsibilities for monitoring research conduct includes:

- a. monitoring the conduct of approved research projects by requiring researchers to submit annual and completion reports;
- b. reviewing, approving or withholding approval on variations to existing ethical approval; and
- c. maintaining an accurate efficient and accessible database of all proposed and approved research projects (NS 5.2.25-5.2.29).

### **Advising functions**

(38) HREC is responsible for providing advice to assist with:

- a. supporting researchers and students involved in human research; and
- b. advising the Deputy Vice-Chancellor Research on ethical issues, including the ethical aspects of any complaint against researchers, research projects or teaching protocols.

### **Communication functions**

(39) The HREC notes that good ethical review requires open communication between review bodies and researchers (National Statement Chapter 5.2 Responsibilities of HRECs, Other Review Bodies, and Researchers 5.2.14). It will discharge this responsibility by:

- a. promoting awareness of the National Statement among researchers and students;
- b. making UNE HREC and its staff readily accessible to researchers; and
- c. communicating the outcomes of review to researchers in a timely manner.

### **Authority**

(40) UNE HREC is authorised to seek data and information from the University through the Deputy Vice-Chancellor Research to meet its duties and functions.

## **SECTION 4 - DELEGATIONS**

### **Delegation from Council**

(41) UNE HREC has delegated authority from the Council under Sec 17 of the University of New England Act 1993 (NSW) to perform on its behalf the reviewing, approval, advisory, monitoring and communication functions set out in the Terms of Reference above, and all matters ancillary to those functions.

(42) UNE HREC may delegate authority to act on its behalf to the Chair, Deputy Chair, sub-Committees and the Human Research Ethics Officer. Any person or body delegated will report to HREC.

### **Sub-Committees**

(43) The Chair of HREC may convene such sub-committees as may be necessary to fulfil HREC responsibilities. The Chair, in consultation with HREC, will determine the Terms of Reference for any sub-committee.

## **SECTION 5 - CONDUCT OF HUMAN RESEARCH ETHICS COMMITTEE**

### **Reporting to the Deputy Vice-Chancellor Research and to the Research Committee**

(44) The Chair of the HREC reports to the Deputy Vice-Chancellor Research through the Director Research Services.

## **Procedures**

(45) UNE HREC conducts its business in accordance with these Terms of Reference and the Standard Operating Procedures.

## **Meetings**

(46) UNE HREC meets at least eight times a year to review high-risk applications and as required in order to review lower and negligible risk applications, and to perform its other functions.

## **Business papers**

(47) Unless the Chair directs otherwise, HREC business papers are distributed to committee members and official attendees at least seven days prior to the meeting, or such shorter period as is practicable in the circumstances.

## **Confidentiality**

(48) Because of the confidential nature of the business of the HREC, there should be no public disclosure of business papers, minutes, or other information associated with the work of the Committee. This is consistent with CI 5.1.37 of the National Statement, which directs HREC and other ethical review bodies to exercise appropriate confidentiality of the content of applications and the deliberations of review bodies.

## **Quorum**

(49) At any meeting of the HREC that considers high-risk applications, one half of the voting membership plus one constitutes a quorum.

(50) Where there is less than full attendance at an UNE HREC meeting, the Chair must be satisfied that, before a decision is reached, members have received all papers, have had an opportunity to contribute their views and have their views considered and recorded.

## **Use of technology**

(51) For its business papers, meetings and otherwise to conduct its business, the HREC and its members may use technology including telephone, video-conferencing, telepresence, email and internet as arranged by the Chair and/or Committee Secretary.

## **Resolutions**

(52) The Human Research Ethics Committee may pass a resolution by 'flying minute' provided that the resolution has been approved by a simple majority of the Committee members at the time the resolution is made.

## **Confirmation of minutes**

(53) Draft minutes will normally be circulated to members for comment promptly after each meeting. Next, the minutes (with any necessary changes) will be circulated for adoption by the HREC. The minutes will be finalised and adopted when they have been approved by a majority of the members that were present at the relevant meeting. Alternatively, the minutes may be included in the business papers for the next Committee meeting and considered and adopted by the Committee at that meeting.

## **Self-review**

(54) Once annually the HREC shall devote part of one meeting to the review of its policies, practices and procedures over the preceding twelve months.

## **Secretary to the HREC**

(55) Human Research Ethics Officer will provide secretarial and administrative support to the HREC.

## **SECTION 6 - INTERPRETATION**

(56) This document should be interpreted using the following principles:

- a. Where Human Research Ethics Committee membership is defined by reference to an office held (eg. 'Chair of Academic Board'), that office-bearer is a member ex officio and has all of the same rights and responsibilities (including voting) as other Committee members whilst holding the office specified.
- b. This document does not override or otherwise affect:
  - i. the Authority Retained by Council Rule; or
  - ii. the Vice-Chancellor Functions Rule;
  - iii. however, it operates as a delegation of certain authorities that have been retained by Council.

(57) The existing terms of reference and any other documents governing the Human Research Ethics Committee at the Effective Date Terms of Reference are approved, are replaced and have no further operation.