

TERMS OF REFERENCE - HUMAN RESEARCH ETHICS COMMITTEE

SECTION 1 – OVERVIEW

Establishment of Committee

- 1.1 The Committee is established as a Committee of the University Council to oversee adherence to the Ethics Standards for all Human Research conducted at the University.
- 1.2 The establishment of this Committee and functions delegated to it by the Council are authorised under section 17 of the *University of New England Act 1993* (NSW).
- 1.3 The Human Research Ethics Committee (HREC) is required to maintain independence from the University in its decision-making processes relating to the ethical aspects of Human Research. The HREC members are appointed in their personal capacity, based on their knowledge, qualities and experience, and not in the capacity of a representative of the University or a representative of any other organisation, department or group.

Objectives

- 1.4 The HREC recognises the value of Human Research to the University and society in general and acknowledges the importance of maintaining public confidence in the University's adherence to the highest ethical standards when undertaking Human Research.
- 1.5 The objectives of the HREC is to ensure the safeguarding of the mental, social and physical welfare, rights, dignity, and safety of:
 - a. participants and their data or tissue in Human Research;
 - b. researchers, staff and students at the University; and
 - c. society in general,for all Human Research activities undertaken under the auspices of University.
- 1.6 To meet these objectives, the HREC is established to ensure that all Human Research activities undertaken by researchers, students and affiliates under the auspices of University are conducted in accordance with:
 - a. the *National Statement on Ethical Conduct in Human Research (2025)*, or any subsequently reviewed version that is the currently accepted National Statement in force (the *National Statement*);
 - b. the Australian Code for the Responsible Conduct of Research (the Code);
 - c. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (where applicable); and
 - d. other relevant legislation, regulation, standards or codes.(together, the "Ethics Standards")
- 1.7 The HREC embraces and follows the values and principles of ethical conduct as specified in the National Statement, namely, research merit and integrity, justice, beneficence and respect.

SECTION 2 – COMMITTEE MEMBERSHIP

Membership

- 2.1 The minimum voting membership of HREC shall be eight, and include:
- a. The Chair, who must have suitable research and academic experience, including previous membership of an HREC, have good standing within the University and, if currently an academic, be classified as a Level D or Level E academic (Category A);
 - b. at least two people, who bring a broader community or consumer perspective and who have no paid affiliation with the University (Category B);
 - c. at least one person with knowledge of and current experience in the professional care or treatment of people (e.g. a nurse, counsellor or allied health professional) (Category C);
 - d. a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder, or community leader, a chaplain or a minister of religion or other religious leaders (Category D);
 - e. at least one qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the University on research-related matters or any other matters (Category E); and
 - f. at least two people with current research experience that is relevant to the research proposals being considered by the HREC meetings they attend. These two members may be selected, according to need, from an established pool of inducted members (Category F).
- 2.2 No individual may represent more than one of the categories listed in 2.1 at any individual meeting but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting.

Additional member

- 2.3 For research proposals that involve participants who are Aboriginal and/or Torres Strait Islander, there will be at least one additional voting member, except where the member at 2.1(d) is an Aboriginal and/or Torres Strait Islander representative. The additional voting member must be a representative of Aboriginal and Torres Strait Islander interests or a person who has experience conducting research relating to Aboriginal and Torres Strait Islander peoples (Category G).

Appointment of members

- 2.4 Prospective members of the HREC will be recruited via a transparent and open selection process.
- 2.5 Members are appointed by the Vice Chancellor and Chief Executive Officer, or the Deputy Vice-Chancellor, Research as the Vice-Chancellor and Chief Executive Officer's nominee, in consultation with the Chair, and drawing on input from HREC members and also stakeholders not on the current HREC .
- 2.6 As part of the selection process for HREC members, the Vice Chancellor and Chief Executive Officer (or their nominee) will consider the composition of the HREC to ensure that, as far as reasonably practicable:
- a. each HREC meeting will have diversity, including gender diversity;

- b. the HREC accords with the University's Gender Representation on Decision Making and Advisory Committee Policy;
 - c. at least one third of members participating in each HREC meeting are from outside of the University;
 - d. that members represent categories identified in 2.1 and 2.3; and
 - e. that there is a suitable coverage of skills and seniority and expertise, including in emergent fields.
- 2.7 Appointment as a member is conditional upon the proposed member:
- a. providing an undertaking to the University, affirming:
 - i. that all matters of which they become aware during the course of their work on the HREC will be kept confidential;
 - ii. that any conflicts of interest, actual or perceived, that may arise during their tenure on the HREC will be declared; and
 - iii. that they have not been subject to any criminal conviction or disciplinary action that would prejudice their standing as a HREC member.
 - b. undertaking induction training that is relevant to the responsibilities of the HREC prior to attending their first HREC meeting.
- 2.8 The Deputy Vice-Chancellor, Research may appoint additional members to all categories, except for the position of Chair, to ensure the HREC remains compliant with the National Statement and has the expertise to review, approve and monitor Human Research. Such appointments will accord with the appointment requirements detailed in sections 2.4 to 2.7.

Term of membership

- 2.9 The HREC members, except for the Chair and Deputy Chair, are appointed for a two-year term and may be re-appointed for a maximum of three consecutive terms.
- 2.10 The Chair is appointed for a two-year term and may be appointed for a further term of two years, unless there are exceptional circumstances requiring the Chair to remain appointed for more than two terms.
- 2.11 The Deputy Chair is appointed for a period of two years, renewable for a second term only.

Termination of appointment

- 2.12 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 HREC;
 - b. the person is no longer qualified or fit to serve on the HREC;
 - c. the person has failed to carry out their duties as a HREC member; or
 - d. The person fails to attend 75% of the HREC meetings without a valid reason. For Category Pool members, this is failure to attend 75% of the HREC meetings they have been selected to attend.

Vacancies

- 2.13 In the event that a member cannot continue to fulfil the requirements of their role before their term of office expires, the Chair must work with the Vice Chancellor and Chief Executive Officer (or their nominee) to formally appoint a new member to the role, in accordance with sections 2.4 to 2.7. If required, the Chair may take steps to find a temporary replacement that meets the requirements of the National Statement until the vacancy is filled.

Chair

- 2.14 The Chair shall be responsible for:
- a. impartially guiding the operation of the HREC and its meetings;
 - b. completing HREC business, including Chairing the HREC Sub-Committee for the review and approval of Low Risk and Minimal Risk applications, Minor Variations to approved research projects and reviewing progress and final reports for approved Low Risk and Minimal Risk research projects;
 - c. managing conflicts of interest related to the HREC; and
 - d. representing the HREC in any engagement with the University, the NHMRC or other party, as specified in the HREC Standard Operating Procedures.
- 2.15 The Chair must be provided with the necessary support and authority by the university to carry out the role.
- 2.16 The Chair's other responsibilities unrelated to HREC must not impair the HREC's capacity to carry out its obligations under the Ethics Standards.

Deputy Chair

- 2.17 The HREC will appoint a Deputy Chair from amongst the HREC members, having regard to the process and selection criteria specified in the HREC Standard Operating Procedures. The appointment of a Deputy Chair by the HREC is subject to the approval of the Deputy Vice-Chancellor, Research.
- 2.18 The Deputy Chair will:
- a. chair meetings of the HREC in the absence of the Chair; and
 - b. assist the Chair in completing HREC business, including Chairing the HREC Sub-Committee for the review and approval of Low Risk and Minimal Risk applications, Minor Variations to approved research projects and reviewing progress and final reports for approved Low Risk and Minimal Risk research projects.
- 2.19 Depending on the business needs of the HREC and following consultation between the Deputy Vice-Chancellor, Research and the Chair, an additional Deputy Chair may be appointed by the HREC members in accordance with the process set out in 2.17. The additional Deputy Chair will only act as Deputy Chair where the Deputy Chair is not in attendance at a HREC meeting or HREC Sub-Committee meeting.

Invitees

- 2.20 At the request of a HREC member or at the Chair's discretion, the Chair may invite:
- a. a researcher or researchers for discussion of their proposed research;
 - b. a person that has submitted a complaint or an appeal to the HREC; or

- c. a person that is the subject of a complaint or an appeal submitted to the HREC.

The invitee is only permitted to be present for discussion of, but not deliberations about, their proposed research, complaint or appeal.

- 2.21 Requests made by researchers to attend a HREC meeting to discuss their proposed research is at the discretion of the Chair.
- 2.22 The HREC may seek advice from experts to help in considering a research proposal. Experts may be invited to attend a HREC meeting and are only permitted to be present for discussion of matters relating to the advice provided.
- 2.23 The Chair may invite people from the University and the wider community to attend HREC meetings as observers. Any invited observers must not be involved in deliberations or decision making and at the request of the Chair, may be asked to exit the meeting for any in-camera discussion.
- 2.24 Experts and observers shall be bound by the same confidentiality requirements as HREC members and any conflicts of interest declared and managed in accordance with University policies.

Conflict of interest

- 2.25 The HREC will manage any conflicts of interest in accordance with the University's Conflict of Interest Policy and the Ethics Standards.
- 2.26 Members are required to disclose any perceived, potential or actual conflicts of interest in research to be reviewed, including any:
 - a. Personal involvement or participation in the research; or
 - b. Financial or other interest or affiliation; or
 - c. Involvement in competing research.
- 2.27 The HREC's measures to manage conflicts of interest may include exclusion of a member from a meeting, or from some of the HREC's deliberations.
- 2.28 If the member withdraws from the meeting, the HREC Secretary will record the member's declaration of a conflict of interest and absence in the minutes.
- 2.29 The member's withdrawal from the relevant part of the meeting will not affect the quorum.

SECTION 3 - HUMAN RESEARCH ETHICS COMMITTEE FUNCTIONS

Functions

- 3.1 The HREC is responsible for the ethics review, approval and monitoring of Human Research conducted by researchers, students, and affiliates under the auspices of the University.
- 3.2 The functions of the HREC are classified in the following domains: reviewing, approval, advisory, monitoring, communication, governance and conduct functions.

3.3 The HREC must discharge their duties for each function in accordance with the Ethics Standards under which HREC operates and the relevant University policies and procedures pertaining to ethical conduct for Human Research, including:

- a) Code of Conduct for Research Rule;
- b) Collaborative Research Rule;
- c) Management and Storage of Research Data and Materials Policy and Procedures;
- d) Open Access to UNE Research Publications and Data Policy;
- e) Research UNE Deposit, Collection and Access Rule;
- f) Records Management Procedures; and
- g) Knowledge Assets and Intellectual Property Policy.

Reviewing functions

3.4 The HREC responsibilities for reviewing research proposals involving Human Research include:

- a. reviewing research proposals from University researchers to determine if the research proposal is acceptable and compliant with the Ethics Standards, primarily the National Statement.
- b. at the discretion of the Chair and on a fee for service basis, reviewing Non-Affiliated Research proposals to determine if the research proposals are acceptable and compliant with the Ethics Standards, primarily the National Statement;
- c. reviewing Reciprocal Research requests, including the review of the approval from the issuing HREC, to determine if the research proposals are acceptable and compliant with the Ethics Standards, primarily the National Statement;
- d. requesting further information and/or clarification for a research proposal listed in 3.4 a. to c. to assist HREC's review and consideration of compliance with the Ethics Standards;
- e. delegating the review of Low Risk and Minimal Risk research proposals to the HREC Sub-Committee; and
- f. reviewing variations to existing research projects, except for variations to Low Risk and Minimal Risk proposals which will be delegated to the HREC Sub-Committee or review of a Minor Variation which will be delegated to the Chair for decision, in the event the request for a Minor Variation falls outside of the meeting calendar of the HREC or HREC Sub-Committee.

Approval functions

3.5 The HREC responsibilities for approving research proposals involving Human Research include:

- a. granting approval for:
 - i. University research proposals;
 - ii. Reciprocal Research proposals; and

- iii. Non-Affiliated Research proposals,
where the review has determined the proposal to be acceptable and in accordance with the Ethics Standards, primarily the National Statement;
- b. granting conditional approval for research proposals listed under 3.5(a), subject to the researcher amending the research proposal to accommodate the recommendations of the HREC to ensure compliance with the Ethics Standards.
- c. rejecting University research proposals, Non-Affiliated Research proposal or Reciprocal Research proposals where the review has determined the proposal to not be compliant with the Ethics Standards;
- d. suspending or withdrawing the approval granted for research projects listed under 3.5(a) where the HREC:
 - i. has reason to believe that continuance of the approved research is, or has the potential to be, ethically unacceptable; or
 - ii. has reason to believe that the approved research is not being conducted in accordance with the Ethics Standards or conditions of approval; or
 - iii. has been notified that a complaint has been received regarding the conduct of the researcher or the research.

notice of any withdrawal or suspension (under clause 3.5d), and any approval to recommence a withdrawn or suspended project will be issued by the Deputy Vice-Chancellor, Research on the recommendation of the HREC.
- e. delegating the approval of Low Risk and Minimal Risk research proposals to the HREC Sub-Committee;
- f. delegating the issuing of exemptions to the HREC Chair, in accordance with the exemption protocol specified in the HREC SOP; and
- g. approving, conditionally approving or rejecting variations to existing research projects, except for:
 - i. variations to Low Risk and Minimal Risk proposals which will be delegated to the HREC Sub-Committee; or
 - ii. a Minor Variation which will be delegated to the Chair for decision in the event the request for a Minor Variation falls outside of the meeting calendar for the HREC or HREC Sub-Committee, and noted by the HREC at the following HREC meeting.

Monitoring functions

- 3.6 The HREC responsibilities for monitoring the conduct of research involving Human Research includes:
 - a. monitoring the conduct of all research projects approved by the HREC and its Sub-Committee, including review and deliberation (if required) of periodic progress reports, closure reports, incident reports and complaints register;

- b. maintaining an accurate efficient and accessible database of all proposed and approved research projects ;
- c. visiting, auditing or contacting research sites, where appropriate, or undertaking documentation audits to monitor ethical aspects of approved research projects by appropriately trained individuals; and
- d. for Low Risk and Minimal Risk research proposals, delegating the activities under 3.6a and 3.6c. to the HREC Sub-Committee.

Advising functions

- 3.7 The HREC has the responsibility to provide advice, guidance and training on the Ethics Standards to:
- a. researchers, staff and students at the University that are involved in Human Research;
 - b. the Deputy Vice-Chancellor, Research on ethical issues, including the ethical aspects of any complaint against researchers, research projects or teaching protocols; and
 - c. the University Management and the Research Committee, as required.

Communication functions

- 3.8 The HREC notes that good ethics review of Human Research requires open communication between the HREC and researchers and good governance requires transparency through regular reporting on matters determined by the HREC. It will discharge this responsibility by:
- a. promoting awareness of the Ethics Standards among researchers and students, through mandatory training and guidance published online or in newsletters/communications from Research Services and the Graduate Research School;
 - b. making the HREC and the Human Research Ethics staff readily accessible to researchers;
 - c. communicating the outcomes of research proposal review or approval to researchers in a timely manner;
 - d. reviewing and approving of periodic reports prepared by the Chair and/or Human Research Ethics Officer for submission to the Deputy Vice-Chancellor, Research, University Committees and the National Health & Medical Research Council (NHMRC).
 - e. proactively engaging with UNE Schools and researchers to discuss their applications or answer questions around ethics applications.

Appeals and Complaints functions

- 3.9 Complaints and Appeals are managed in accordance with the *Standard Operating Procedures for Complaints and Appeals*. This process deals with:
- a. an appeal against HREC's decision to reject a research proposal;
 - b. an appeal against HREC's approval of a research proposal;
 - c. complaints relating to the ethical conduct of an approved research project or the conduct of a researcher, including potential breach of Ethics Standards;

- d. complaints/appeals concerning the conduct of the Committee and its members, including the Chair and the Secretary.

Governance functions

3.10 The HREC has the following responsibilities for matters of governance:

- a. Requesting that the University, through the Deputy Vice-Chancellor, Research, periodically review and amend policies, procedures and other documents which relate to HREC operations, including the HREC Standard Operating Procedure (SOP) and the Terms of Reference for the HREC and HREC Sub-Committee, to ensure they remain aligned with Ethics Standards and University policies.
- b. Annual self-review be conducted by the Chair in accordance with section 5.13 of these TOR and the HREC SOP.

Authority

3.11 The 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

4.1 The 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.

Delegation and Sub-Committees

- 4.2 The HREC may delegate authority to act on its behalf to the Chair, Deputy Chair, Sub-Committees, and the Human Research Ethics Officer for specific activities, as provided for in the HREC Terms of Reference and HREC SOP, provided it is consistent with the Ethics Standards. Any exercise of a delegation must be reported to the HREC at the following meeting and ratified by the HREC (if applicable).
- 4.3 The HREC may convene such Sub-Committees as necessary to fulfil HREC responsibilities, provided it is compliant with the Ethics Standards. The Chair, in consultation with the HREC, will determine and approve the Terms of Reference for any Sub-Committee.

SECTION 5 - CONDUCT OF HUMAN RESEARCH ETHICS COMMITTEE

Reporting

5.1 The Chair will report **to Deputy Vice-Chancellor, Research and** the University Research Committee on **the** business of the HREC, as specified in the HREC SOP, or as requested by Deputy Vice-Chancellor, Research and the University Research Committee from time to time.

Procedures

5.2 The HREC conducts its business in accordance with these Terms of Reference and the HREC SOP.

Meetings

- 5.3 The HREC must meet once a month from February to December (unless there are no applications for a particular month).

Agenda and Business papers

- 5.4 The HREC agenda and business papers must be made available to Committee members at least seven business days prior to the meeting. Any additional agenda items or documents may be tabled at short notice, with prior approval of the Chair.

Confidentiality

- 5.5 Members are not permitted to disclose business papers, minutes, or other information associated with the work of the HREC to persons outside of the Committee, unless with express permission from the HREC.

Quorum

- 5.6 At any meeting of the HREC, the attendance of at least one half of the minimum membership categories (i.e. 8) will constitute a quorum, subject to the requirements of 5.8 being met.

- 5.7 Where there is less than full attendance of minimum membership categories at a HREC meeting, the Chair must be satisfied that the views and recommendation of the members who are not present have been received and considered by all members of the HREC participating in the meeting before a decision is reached and recorded in the minutes.

Use of technology

- 5.8 For its business papers, meetings and to otherwise conduct its business, the HREC and its members may use technology including telephone, videoconferencing, telepresence, email, and internet as arranged by the Chair and/or HREC Secretary. The HREC will employ any new technology solutions that are of relevance to the functions of the HREC, provided such technology is compliant with University policies.

Resolutions

- 5.9 The HREC should attempt to reach decisions by consensus. Where a consensus cannot be reached, the HREC may pass a resolution at a meeting by a simple majority of the attending members, having regard to the written opinions submitted by members not in attendance. In the event the resolution does not receive a majority of votes, the result is deemed not passed. However, the proposal may be re-submitted to the HREC.
- 5.10 At the discretion of the Chair, a resolution may be passed by a 'flying minute' provided that the resolution has been approved by a simple majority of the Committee members at the time the resolution is made. In the event there is a tie, the resolution is deemed not passed. However, the resolution can be resubmitted at another HREC meeting.

Confirmation of minutes

- 5.11 The minutes will be circulated to members after the HREC meeting for review and endorsement. The minutes will be included in the business papers for the next Committee meeting and adopted, with amendments (if any) by the Committee at that meeting.

Self-review

- 5.12 Once annually the HREC shall devote part of one meeting to the review of its policies, practices, and procedures over the preceding twelve months. Any comments or recommendations arising from this review will be forwarded to the Deputy Vice-Chancellor, Research for approval and, where necessary, action.

Secretary to the HREC

- 5.13 The Human Research Ethics Officer will provide secretarial and administrative support to the HREC and its Sub-Committees, as provided for in the HREC SOP. The Secretary/Human Research Ethics Officer shall be a non-voting member of the HREC and its sub-committees.

SECTION 6 - INTERPRETATION

6.1 This document should be interpreted using the following principles:

- a. Where the HREC membership is defined by reference to an office held (e.g. Chair), 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. Upon approval, these Terms of Reference will supersede any existing Terms of Reference or other documents governing the HREC.
- c. To the extent of any inconsistency between the Terms of Reference and the HREC SOP, the Terms of Reference shall prevail. To the extent of any inconsistency between the Ethics Standards and the Terms of Reference or HREC SOP, the Ethics Standards shall prevail.

6.2 Definitions:

Ethics Standards means

- i. the National Statement;
- ii. the Australian Code for the Responsible Conduct of Research (the Code);
- iii. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research; and
- iv. other relevant legislation, regulation, standards or codes.

Human Research means research that is conducted with or about people, or their data or tissue, including the following:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

Low Risk means research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden.

Minimal Risk means research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience.

Minor Variation means a variation to an approved research project, limited to:

- i. extension of time for completion of the research project;
- ii. addition of a researcher to the research project;
- iii. addition of participants; and/or

- iv. procedural change or methodological change that, in the opinion of the Chair, is not material in nature. For example, amendment to the wording in a research question to address ambiguity provided that it does not change the context of the approved research proposal.

National Statement means the National Statement on Ethical Conduct in Human Research (2023) made in accordance with the *National Health and Medical Research Council Act 1992*

NHMRC means the National Health & Medical Research Council, established under the *National Health and Medical Research Council Act 1992* by the Commonwealth Department of Health.

Non-Affiliated Research means a research proposal from a Non-Affiliated Researcher

Non-Affiliated Researcher means a researcher or organisation that has no affiliation to the University.

Periodically means that UNE policies in regard to the HREC functions will be reviewed every two years.

Reciprocal Research means a research proposal, involving University researchers and Non-Affiliated Researchers, that has obtained approval from a HREC other than the University's HREC.

The Code means Australian Code for the Responsible Conduct of Research.