

James Cook University Human Research Ethics Committee (HREC)

Terms of Reference

1. Purpose

The HREC objectives are to:

- 1.1. Protect the mental and physical welfare, rights, dignity and safety of participants engaging in research.
- 1.2. Facilitate ethical research through efficient and effective review processes.
- 1.3. Promote ethical standards of human research.
- 1.4. Review research in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007 (hereafter referred to as *National Statement*) and the University's policies on human research and ethics.

2. Scope

- 2.1. The HREC will consider projects involving human participants for staff (including adjuncts), students and approved agents of JCU.
- 2.2. The HREC will accept an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other HRECs are registered with the Australian Health Ethics Committee.
- 2.3. The HREC will not provide ethical approval for research carried out by external people or organisations, or any research that is not being conducted under JCU auspices.

3. Functions

The HREC functions to:

- 3.1. Provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability and according to the values and principles of the *National Statement*.
- 3.2. Accept the approvals of other HRECs.
- 3.3. Provide ethical oversight, monitoring and advice for research projects involving humans.
- 3.4. Prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
- 3.5. Monitor approved research studies for which the Committee has given approval and provide advice at any time to the relevant and coordinating Principal Investigator and their Dean of College (if applicable), when the Committee considers that ethics approval for research should be withdrawn.
- 3.6. Perform an educational role regarding the ethics of research and teaching involving human participants at the University, and arrange for the dissemination of information regarding university policy, the operation of the Committee, and human ethics.
- 3.7. Ensure that the scientific evaluation of any proposal involving human subjects, human tissue and /or personal records is to an acceptable standard.
- 3.8. Provide advice to the Manager, Animal Welfare and Research Ethics and the Provost, on potential breaches of the *National Statement*, the University's human research ethics arrangements and/or relevant external regulations, codes and guidelines.

4. Accountability

- 4.1. The HREC is accountable to the Provost of JCU and University Council and is resourced and administered through JCU Connect.
- 4.2. The HREC will provide an annual report to the Provost on its activities and compliance with the *National Statement*, and the Chair and Manager, Animal Welfare and Research Ethics will meet to discuss this report and any issues to do with the operation of the HREC.
- 4.3. The HREC will provide an annual report to the NHMRC.

5. Membership

- 5.1. The HREC will have a minimum membership constituted in accordance with the *National Statement* (5.1.29-33) and will have a minimum membership of eight.
- 5.2. As far as possible, this will include:
 - 5.2.1. A Chair with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*.
 - 5.2.2. At least two lay people, one man and one woman who have no affiliation with the University and are not currently engaged in medical, scientific, legal or academic work.
 - 5.2.3. 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.
 - 5.2.4. At least one person who performs a pastoral care role in a community, for example, an Aboriginal and/or Torres Strait Islander elder, or a minister of religion.
 - 5.2.5. At least one lawyer, where possible one who is not engaged to advise the institution.
 - 5.2.6. At least two people with current research experience.
- 5.3. No member may be appointed in more than one of the categories.

Whenever possible:

- 5.4. There should be an equal number of men and women.
- 5.5. At least one-third of members should be from outside the University.
- 5.6. One or more members should be experienced in reflecting on and analysing ethical decision-making.
- 5.7. Meetings will be arranged to enable at least one member of each category to attend.

6. Appointment and Retirement of Members

- 6.1. Members will be appointed to the HREC using open and transparent processes, as outlined in the HREC's Operating Procedures.
- 6.2. The members of the Committee shall be appointed for a term of 3 years, unless they resign from the Committee or otherwise cease to be members. Members may be re-appointed for a further term/s.
- 6.3. Reappointment is by application to the Chair of the HREC who will then make a recommendation to the Provost.
- 6.4. Members will be required to sign agreements undertaking:
 - that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential.

- that any or perceived conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared.
 - that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
- 6.5. JCU will provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.
 - 6.6. Members, other than the Chair, will not be paid for their work on the HREC, although they will be refunded any expenses incurred while carrying out their duties.
 - 6.7. Newly appointed members will be provided with orientation, induction and adequate mentoring. To maintain NHMRC certification, members will attend continuing education and training in research ethics at least once every three years.
 - 6.8. A member may resign from the HREC at any time upon giving notice in writing to the Chair.
 - 6.9. The Provost may terminate the appointment of any member of the HREC if they are of the opinion that:
 - it is necessary for the proper and effective functioning of the HREC.
 - the person is not a fit and proper person to serve on an HREC.
 - the person has failed to carry out their duties as an HREC member.

7. The Chair and Deputy Chair of the HREC

- 7.1. The Chair will hold a senior position in the University and would be expected to serve at least three years.
- 7.2. Prospective Chairs will preferably be nominated from existing members or by nomination from JCU Connect, and their appointment approved by the Provost.
- 7.3. A Deputy Chair will be nominated from and voted upon by existing committee members.
- 7.4. The Provost may terminate the tenure of the Chair if they are of the opinion that:
 - it is necessary for the proper and effective functioning of the HREC.
 - the person is not a fit and proper person to serve on an HREC.
 - the person has failed to carry out their duties as an HREC member.

8. Ethics Advisors

- 8.1. Human Ethics Advisors (HEA) will be appointed as delegates of the HREC to provide advice for researchers and review ethics applications for recommendation to the HREC. An HEA may also refer ethics matters to the HREC, where appropriate.
- 8.2. HEAs are appointed by the HREC Chair based on nominations received from the Dean of College in relevant discipline areas.
- 8.3. HEA are considered probationary until they have completed the approved Induction Training or have been exempted on the basis of prior experience and/or qualifications by the HREC Chair.
- 8.4. The roles of the HEA is outlined in the HREC's Operating Procedures.

9. The Executive

- 9.1. The HREC will establish an Executive whose role, will be to undertake review of human research that carries no more than low risk.
- 9.2. The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, annual reports, renewal requests, minor amendments and responses to review.

- 9.3. The minutes and decisions of all matters considered by the Executive will be tabled for ratification at the next HREC meeting.
- 9.4. The Executive will consist of the:
 - Chair.
 - One other member of the HREC.

10. Officers of the HREC

- 10.1. The Human Ethics Officer will provide administrative support to the HREC.
- 10.2. The Manager, Animal Welfare and Research Ethics will oversee the HREC's secretariat, ensure that adequate resources are provided to the HREC and its members for them to carry out their duties and for the HREC to operate in compliance with the *National Statement*.

11. Conduct of Business

Procedures

- 11.1. The HREC shall establish, implement, and document its working procedures concerning:
 - Frequency of meetings.
 - Attendance at meetings (including non-members and researchers).
 - Conduct and structure of meetings and deliberations
 - Preparation of agendas and minutes.
 - Timely distribution of applications prior to meetings.
 - Presentation of applications for ethical review.
 - Timely consideration and review of applications.
 - Identification, declaration and management of any conflicts of interest.
 - Prompt notification of decisions to researchers.
 - Record keeping.
 - Reporting and handling of adverse occurrences.
 - Receipt and handling of complaints.
 - Advising external institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project.
- 11.2. The HREC Operating Procedures will be reviewed at least once every three years, or more often as required.
- 11.3. The HREC's Terms of Reference and Operating Procedures will be made public on the HREC page of the JCU website.

Meetings

- 11.4. The HREC will meet a minimum of eleven times every year, with meetings being held monthly except for January.
- 11.5. As far as possible, at least one member of each category of membership should attend a meeting in order to form a quorum. Where a meeting is inquorate, decisions can be made where the Chair is satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.
- 11.6. The Committee may invite individuals with expert knowledge to provide information and advice to the Committee either in person or via electronic means.
- 11.7. The Committee may require the attendance of a researcher or student to attend a specific meeting of the Committee at which their application is to be discussed.

- 11.8. The Chair may approve a nominated alternate for any member at any particular meeting. An approved alternate shall have the same rights and responsibilities at that meeting as any other member.
- 11.9. The HREC will review all research that carries more than low risk as defined in the *National Statement*.
- 11.10. The Executive will review all research that carried low or negligible risk as defined in the *National Statement*.
- 11.11. Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether at a face-to-face meeting, by electronic means (e.g. secure phone or internet link) or where one of those members is absent, by the receipt and consideration of that member's views. Decisions need not involve unanimity.
- 11.12. At a meeting of the Committee, the Chair shall have a vote and, in the case of an equality of votes, a second or casting vote.

12. Monitoring of Research

- 12.1. The HREC will monitor research by reviewing annual and final project reports, adverse event reports and the HREC may conduct inspections of research sites at any time.
- 12.2. Annual and final project reports will be reviewed by the HREC.
- 12.3. Adverse event reports will be reviewed by the Executive.

13. Review of and Amendments to the Terms of Reference

- 13.1. These Terms of Reference will be reviewed annually as a part of the annual report process, and if amended, be approved by the HREC before final approval by the Provost.
- 13.2. The Terms of Reference may be amended following a request from a HREC member, the Chair, the Manager, Animal Welfare and Research Ethics or following review of a complaint concerning the HREC's processes.
- 13.3. Requests for amendment will be discussed at the next HREC meeting and if accepted, the amendment will be implemented and then a recommendation made to the Provost to have the updated document approved.