

The University of Queensland (UQ) Human Research Ethics Committees
TERMS of REFERENCE
June 2016

1. OBJECTIVES

The objectives of the Human Research Ethics Committees (HREC) are to:

- 1.1 Protect the mental and physical welfare, rights, dignity and safety of participants of research and minimise the risk of harm arising from research studies involving humans;
- 1.2 Promote ethical principles in human research by education of the academic community;
- 1.3 Review research in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates [National Statement]; and
- 1.4 Facilitate ethical human research through efficient and effective review processes.

2. FUNCTIONS

The HREC functions on behalf of UQ to:

- 2.1 Provide independent oversight of human research projects;
- 2.2 Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active;
- 2.3 Ensure the compliance of human research projects with the principles of the National Statement, and all other relevant Acts and legislative requirements for that type of research, and grant, withhold, temporarily suspend, or withdraw ethical approval;
- 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 biological samples collected during the conduct of research involving humans in accordance with UQ policy; and
- 2.5 Provide advice to the Deputy Vice-Chancellor (Research) on strategies to promote awareness and understanding of the ethical conduct of human research within UQ and the broader community.

3. ACCOUNTABILITY

- 3.1 The HREC is directly accountable to the Deputy Vice-Chancellor (Research). The minutes of each HREC meeting are forwarded Deputy Vice-Chancellor (Research) following confirmation.
- 3.2 The HREC provides an annual report to the Deputy Vice-Chancellor (Research) at the end of each calendar year.
- 3.3 The HREC brings to the attention of the Deputy Vice-Chancellor (Research) issues of significant concern.
- 3.4 The HREC provides the following report on behalf of UQ:
 - Annual Report to the National Health and Medical Research Council (NHMRC), and any other reports as required.
- 3.5 Monitoring Measures: The HREC will undertake its reviews in a timely and efficient manner and have mechanisms to monitor and evaluate its performance.

4. SCOPE OF RESPONSIBILITY

The responsibilities of the HREC are to:

- 4.1 Review human research applications where the research takes place:
- At UQ, carried out using equipment, facilities or premises owned by the University and/or the research is undertaken by any person who is a student or full-time, part-time or conjoint staff member of the University, or a personal formally recognised by UQ.
 - At locations external to UQ, from researchers who have no affiliation with UQ, but who wish to conduct research involving or impacting upon humans. Such applications will be accepted on the UQ Application Form, the National Ethics Application Form (NEAF), or Human Research Ethics Application (HREA). Such applications will incur a fee for the initial review, and subsequent fees for each and every modification to the project. The fee must be paid at the time of submission and prior to consideration of the application thus ensuring payment, whether or not approval is given. The Risk Management Unit will be advised of such applications by the Ethics Secretariat as required by UQ for indemnity and insurance purposes.
- 4.2 Provide education and training of UQ researchers, as well as HREC Panel members.

HREC Executive Committees

- 4.3 The HREC has an Executive Committee comprising at least the HREC Chairperson or their delegate and a member of the research office.
- 4.4 The HREC Executive Committee will meet face-to-face or electronically, preferably on a weekly basis.
- 4.5 The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including the following:
- Amendments to current HREC approved research projects;
 - Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
 - Annual progress reports and final reports; and
 - Serious adverse events and suspected unexpected serious adverse reactions reports.
- 4.6 The Executive Committee may choose to seek advice from other HREC members, as appropriate, before reaching a decision.
- 4.7 The minutes and decisions of the HREC Executive Committee are noted at the next HREC meeting, and any matters of significance (e.g. serious adverse events) will be included on the agenda of the next HREC meeting.

HREC Low/Negligible Risk subcommittee

- 4.8 The HREC may, at its discretion, appoint one or more Low/Negligible Risk subcommittees to carry out a review of low/negligible risk human research ethics applications submitted by students and members of staff of UQ. Members of the subcommittee need not be members of the HREC, and are appointed by the subcommittee Chairperson, who is appointed by the Chairperson of the relevant HREC(s).

5. ORGANISATIONAL CONTEXT

The HREC reports to the Deputy Vice-Chancellor (Research).

6. MEMBERSHIP

6.1 Composition

6.1.1. The composition of the HREC is in accordance with the National Statement. Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one third of the members are external to UQ. The membership comprises representatives from the following categories:

- A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
- At least two members who are lay people, one man and one woman, with no affiliation with the institution or organisation and not currently involved in medical, scientific, legal or academic work;
- At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- At least one member who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
- At least one member who is a lawyer, where possible one who is not engaged to advise the institution for which the HREC is reviewing research; and
- At least two members with knowledge of and current research experience that is relevant to the applications to be considered at the meetings they attend.

6.1.2. To ensure the HREC is equipped to address all of the relevant considerations arising from the categories of research, some or all of the above membership categories may be represented by more than one person.

6.1.3. No member is appointed in more than one of the membership categories.

6.1.4. The HREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is given.

Such person(s) are not entitled to vote on any matter.

6.2 Appointments

6.2.1. HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent selection process.

6.2.2. Prospective members may be invited to observe a meeting of the HREC.

6.2.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson and the Ethics Coordinator. The selection committee interviews prospective members; may consult with HREC members and makes a recommendation on new appointments to the Deputy Vice-Chancellor (Research).

6.2.4. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.

6.2.5 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of new viewpoints.

6.2.6. Membership of the HREC, including member name and category of membership, is made publicly available on UQ's web site.

6.2.7. All members including the Chairperson, Deputy Chairperson and Chairperson of any subcommittee are appointed by the Deputy Vice-Chancellor (Research) or delegate. The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.

6.2.8. Eligible members (such as lay members or non-affiliated members) of the HREC will be offered an honorarium for attending each committee meeting. The value of the honorarium will be determined by institutional policy.

6.2.9. Upon appointment, members are provided with an orientation package and asked to sign a statement 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 conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and
- that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.

6.2.10. Members are appointed for a period of up to 3 years and may serve a total of 6 years (two consecutive terms), unless otherwise approved by the Deputy Vice-Chancellor (Research). The Deputy Vice-Chancellor (Research), in consultation with the Chairperson, may implement a probationary period.

6.2.11. The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Deputy Vice-Chancellor (Research). Members are advised when their term is due to expire. Reappointment will be by application to the Chairperson of the HREC who then makes a recommendation to the Deputy Vice-Chancellor (Research).

6.2.12. The Deputy Vice-Chancellor (Research) will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.

6.2.13. All members sign a conflict of interest declaration, which will be maintained on the member's personnel file.

6.2.14. Membership lapses if a member fails to attend:

- Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and
- At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

6.2.15. The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

6.2.16. Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to provide written notice to the Chairperson so that steps can be taken to fill the vacancy.

6.2.17. The appointment of any member of the HREC may be terminated if the Deputy Vice-Chancellor (Research) is 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; or
- The person has failed to carry out their duties as an HREC member.

6.2.18. Members are expected to participate in relevant specialised working groups as required.

6.2.19. The Chairperson is expected to be available between meetings to participate in HREC Executive Committee meetings where required.

6.2.20. UQ provides indemnity for members of the HREC for liabilities that arise as a result of the member exercising their duties in good faith.

6.3 Orientation and training for HREC members

6.3.1. New HREC members are provided with appropriate induction and support by UQ.

6.3.2. Orientation involves some or all of the following:

- Introduction to other HREC members prior to the HREC meeting;
- Provision of an orientation package including induction manual;
- Informal meeting with the Chairperson and Senior RMO Management to explain their responsibilities as an HREC member, the HREC processes and procedures;
- 'Partnering' with another HREC member in the same category; and
- Priority given to participate in internal and external training sessions and workshops.

6.3.3. Each member is:

- provided with a copy of, and expected to become familiar with, the National Statement and consult other guidelines relevant to the review of specific research applications; and
- encouraged to attend continuing education or professional development activities in research ethics once in each period of appointment.

7. CONDUCT OF BUSINESS

7.1 Procedures

7.1.1. The HREC conducts its business in accordance with the Terms of Reference and Operations Manual and/or Standard Operating Procedures.

7.1.2. The HREC Terms of Reference and Operations Manual and/or Standard Operating Procedures are made publicly available on UQ's web site.

7.2 Meetings

7.2.1. The HREC meets on a regular basis at least every month – the exception being in Dec/Jan, when a decision will be made by the Chairs and Ethics Coordinators as to when the meetings for these months will be held. The HREC holds at least 11 scheduled meetings in each year for the purpose of reviewing new applications.

7.2.2. Meeting dates and application-closing dates are made publicly available on UQ's web site.

7.2.3. 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 (National Statement NS.5.2.28) attending in person or via telephone or videoconference.

7.2.4. A meeting of the HREC can proceed where there is less than a full attendance of the minimum membership at a meeting but only if the Chairperson is satisfied "that the views of those absent who belong to the minimum membership have been received and considered", for instance through prior submission of written comments (National Statement NS 5.2.30).

7.3 Declaration of interest

7.3.1. An HREC member declares to the HREC 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 the research outcomes.

7.3.2. The minutes record declaration of interest and the decision of the HREC on the procedures to be followed.

7.4 Confidentiality

7.4.1. HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

7.5 Decision making

7.5.1. The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by unanimous agreement.

7.5.2. Where a unanimous decision is not reached, the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.

7.5.3. Any significant minority view (i.e. 2 or more members) is noted in the minutes.

7.6 Records

7.6.1. The Ethics Secretariat will prepare and retain written records of all meetings of the HREC, including agendas and minutes of all meetings of the HREC and the HREC Executive.

7.6.2. The Ethics Secretariat will prepare and maintain an official file for each application received including a copy of the application, and any other relevant correspondence between the applicant and the HREC.

7.6.3 The HREC will also maintain a database of all the applications received and reviewed in accordance with the National Statement (NS 5.2.24).

7.6.4. Files are kept securely and confidentially in accordance with the requirements of UQ policy and the State Records Act.

7.6.5 Records will be held for sufficient time to allow for future reference. The minimum period for retention will be in accordance with the Australian Code for the Responsible Conduct of Research and the State Records Act, whichever is longer.

7.7 Monitoring research projects

7.7.1. The HREC 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, safety reports and reports of protocol violations.

7.7.2. The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

- Discussion of relevant aspects of the project with investigators, at any time;
 - Random inspection of research sites, data, or consent documentation;
 - Interview with research participants or other forms of feedback from them;
- and

- Request and review reports from independent agencies such as a Data and Safety Monitoring Board.

7.7.3. The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

8. APPEALS AND COMPLAINTS

8.1 Appeals regarding HREC rejection

8.1.1. Where the HREC has rejected an application, the investigator has the discretion to:

- Submit a new application to the same HREC, taking due account of the HREC's concerns; or
- Lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing.

The HREC Chairperson will respond directly to the appellant regarding the outcome of the review.

8.2 Appeals regarding HREC approval

8.2.1. Where the HREC has given a favourable decision on an application and

- An ethical or scientific issue is subsequently identified by any party; or
- It has become apparent that the decision was based on inconsistent application of policy and guidelines

a written appeal is lodged with the Chairperson in the first instance.

8.3 Appeals to the Deputy Vice-Chancellor (Research)

8.3.1. If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 8.1 and/or 8.2 and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Deputy Vice-Chancellor (Research) or request that the Chairperson do so through the Ethics Secretariat in the first instance. The Deputy Vice-Chancellor (Research) may refer the matter to another UQ HREC, external HREC, or seek other expert advice as appropriate.

8.4 Complaints about the conduct of HREC members

8.4.1. Complaints about the conduct of an HREC member are managed by the Deputy Vice-Chancellor (Research) who informs the Chairperson of the complaint.

8.5 Complaints about the conduct of an approved research project.

8.5.1. Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with UQ's complaint handling procedures.

9. FEES

9.1 A fee will not be charged for applications submitted for assessment by the HREC from researchers who are full time, part time, or conjoint appointees of UQ.

9.2 A fee may be charged for applications submitted for assessment by the HREC from researchers who have no formal affiliation with the University. These researchers will also be required to sign a contract with UQ detailing the terms and conditions under which the HREC will review the application and monitor the project.

10. REVIEW / AMENDMENTS OF THE TERMS OF REFERENCE

10.1 These Terms of Reference will be reviewed every three years and may be amended in consultation with the HREC.

11. TERMINATION OF HREC RESPONSIBILITY

11.1 Where the HREC is to be merged, closed or has ceased to function, UQ notifies the NHMRC and determines the appropriate course of action, such as the status of its registration with the NHMRC and the monitoring of previously approved research.