

Terms of Reference for Queensland Health Cairns & Hinterland Health Service District Human Research Ethics Committee

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Cairns & Hinterland Health Service District - **HUMAN RESEARCH ETHICS
COMMITTEE
EC00157**

Terms of Reference

INTRODUCTION

Preamble

The Cairns & Hinterland Health Service District *HREC EC00157* is a committee established by Cairns & Hinterland Health Service District Queensland Health (QH) that is constituted and functions in accordance with the NHMRC '*National Statement on Ethical Conduct in Human Research*' (2007) - the *National Statement (NS)*; and complies with the '*Australian Code for Responsible Conduct of Research* (2007) and *QH Research Management Policy and Framework (QHRMP; 2008)*.

Lead HREC

A lead HREC is a HREC which has been certified to undertake the single ethical review of research projects to be conducted at more than one site.

The Cairns & Hinterland Health Service District HREC has not been certified to undertake single ethical review.

HREC objectives

- Protect the mental and physical welfare, rights, dignity and safety of participants of research
- Facilitate ethical research through efficient and effective review processes
- Promote ethical standards of human research
- To ensure that all clinical and health research is conducted ethically and responsibly

HREC functions and responsibilities

- Provide independent, competent and timely review of research projects in respect of their ethical acceptability
- Monitor approved research studies for which the HREC has given approval and provide advice at any time to the relevant District Chief Executive Officer (DCEO), through the relevant Research Governance officer (RGO) and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn
- Obtain expert opinions (external or internal) as required to provide scientific/technical assessment on human research protocols and evaluation of research clinical trials/studies and compliance with regulatory requirements
- Register on the Australian Research Database (AU RED) all research applications submitted to the HREC, any monitoring and reporting requirements and any ongoing approval status of proposals including amendments

Relationships and reporting

The Cairns & Hinterland Health Service District HREC will:

- Report to the DCEO via the District Executive Committee where it was constituted.
- Submit a report annually to the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee to maintain accreditation and registration as a compliant human research ethics committee.
- Liaise with Queensland Health Service Districts, Universities, other research facilities and research personnel as appropriate.
- Charge fees to the sponsors of commercial research, as per the QH Research Management Policy, both for the processing (initial application and amendment submissions) and consideration of the protocols.

- Acknowledge that the District CEO of individual Health Service Districts will have the right to not approve the conduct of a research project within its District.
- The Cairns & Hinterland Health Service District HREC's jurisdiction will also include research occurring in the Cape York Health Service District and the Torres Strait & Northern Peninsula Area Health Service District.

1. HREC ESTABLISHMENT

1.1. HREC Composition

- 1.1.1. The HREC membership appointment will be constituted in accordance with the National Statement and will include the following:
- (a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
 - (b) at least two lay people, one man and one women, 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; **and**
 - (g) at least one Indigenous person.
- 1.1.2. The minimum membership of an HREC is eight.
- 1.1.3. As far as possible there should be equal numbers of men and women.
- 1.1.4. At least one third of the members should be from outside the institution for which the HREC is reviewing research.

1.2. HREC appointment of members

- 1.2.1. The Cairns & Hinterland Health Service District CEO shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
- 1.2.2. Membership appointments to the HREC will be considered for review every three years.
- 1.2.3. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- 1.2.4. Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- 1.2.5. Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive.
- 1.2.6. The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive.
- 1.2.7. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
- 1.2.8. Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.
- 1.2.9. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

- 1.2.10. The institutional CEO may terminate the appointment of any member of the HREC if the CEO 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;
 - the person has failed to carry out their duties as an HREC member.
- 1.2.11. Members will be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.
- 1.2.12. Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.
- 1.2.13. Members will be required 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.

1.3. Education for HREC members

- 1.3.1. Newly appointed members shall be provided with adequate orientation and mentoring.
- 1.3.2. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the Cairns & Hinterland Health Service District.
- 1.3.3. Members will attend continuing education and training in research ethics at least every two years.

1.4. HREC Scientific Reviewer

- 1.4.1. The HREC may appoint such Scientific Reviewers as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC.
- 1.4.2. Scientific Reviewers need not be members of the HREC.

1.5. HREC Liability coverage

- 1.5.1. QH provides 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. Indemnity is provided through Queensland Government Insurance Fund (QGIF).
- 1.5.2. QH provides indemnity for external expert reviewers for any liabilities that arise as a result of the reviewer exercising his or her duties in good faith. Such indemnity is provided through Queensland Government Insurance Fund (QGIF).

1.6. National certification for multi centred ethical review

- 1.6.1. Where an institution elects to nominate for certification the following will occur:
 - Institution undertakes self assessment
 - Institution nominates to be assessed for certification by submitting paper work to national certification body
 - Certifying body undertakes desk top audit of institutional paper work
 - Certifying body conducts an onsite visit and issues draft report
 - Certifying body issues final report and, if approved, certification conditions
- 1.6.2. The Cairns & Hinterland Health Service District HREC has not been certified to conduct single ethical review.
- 1.6.3. Certification standards will be as per the Australian national certification standards.

- 1.6.4. The responsibility for meeting these certification standards rests with the Cairns & Hinterland Health Service District which constituted the HREC.

2. HREC PROCEDURES

2.1. Standard operating procedures

- 2.1.1. The HREC will perform its functions according to written standard operating procedures (SOP). These procedures shall be reviewed at least every three years and amended and updated as necessary.
- 2.1.2. All HREC members shall have access to and/or be provided with copies of the SOP and shall be consulted with regard to changes thereto.

2.2. Submissions

All Studies

- 2.2.1. Excluding exceptional circumstances the HREC will consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is valid and received by the relevant closing date.
- 2.2.2. When a submission is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.

Single Site Studies

- 2.2.3. All submissions of all single site studies, for review by the HREC, will be made directly to the reviewing HREC.

Multicentred Research Studies

- 2.2.4. The submission of all multi-centre research studies being submitted through the single ethical review process, for review by the lead HREC, will be through the QH Central Coordination Service (CCS) as per the HREC SOP.

2.3. Protocols

- 2.3.1. The HREC will require submissions to be in a standard format using the National Ethics Application Form (NEAF) available on the online forms website: <https://ethicsform.org/au/SignIn.aspx>.
- 2.3.2. The HREC will require the researcher to electronically upload all supporting documents onto the online forms NEAF website.
- 2.3.3. The HREC will also require the researcher to submit hard copies of the submission as per the HREC requirements, available on the Research Ethics and Governance Unit website.
- 2.3.4. The Chair along with the members of the HREC Committee and HREC administrator will determine if any expert advice is required for any protocol.

2.4. Meetings

- 2.4.1. Meetings will be held monthly except for January where HREC meetings will not be held.
- 2.4.2. Meeting dates will be available on the Research Ethics and Governance Unit website.
- 2.4.3. Notice of meetings will be given to members for the current year and at least two (2) weeks before any date change to a meeting.
- 2.4.4. A hard copy of the agenda, previous minutes, protocols for consideration, including the NEAF, patient information & consent form, investigators brochures, questionnaires or other relevant correspondence (where applicable) and the written advice for any meeting will be forwarded to all members at least one (1) week before the meeting.

Meeting Protocol

- 2.4.5. Decisions by the HREC about whether the research project meets the requirements of the National Statement will be informed by the exchange of opinions from each of the members that constitute the minimum membership of the HREC.
- 2.4.6. Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- 2.4.7. The contribution of information and opinion from a committee member unable to attend a face to face meeting will be considered along with those opinions and feedback of other committee members in the final decision making.
- 2.4.8. Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via submission to the HREC administrator prior to the meeting.
- 2.4.9. Committee members associated with a research protocol being considered by the committee will be excluded from the meeting in the final discussion and voting process of that particular proposal.
- 2.4.10. Where there is a conflict of interest, members of the committee will be required to declare this prior to or at any time during a meeting. The Chairperson will determine the action to be taken for the review of the submission.
- 2.4.11. In general, decisions of HREC will be reached by general agreement rather than simple voting majorities.
- 2.4.12. The appointed Chairperson will chair every meeting unless on occasions when the Chairperson is absent or excluded because of a conflict of interest, the meeting will be chaired by the Deputy Chairperson.
- 2.4.13. Meetings will normally be held at monthly intervals (excepting January) in the HRM Conference Room, Block A, Level 4 at Cairns Base Hospital.
- 2.4.14. The principal investigator or a representative for the investigator may be invited to attend the relevant meeting to discuss a proposal but before any decision is taken, would be required to leave the meeting.

Secretarial Support

- 2.4.15. Secretarial support will be provided by the Ethics Administrator.

Decisions from HREC meetings

- 2.4.16. The minutes of meetings will be recorded on AU RED.
- 2.4.17. Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol, linking those reasons to the National Statement.
- 2.4.18. Draft minutes will be forwarded to the Chair as soon as practical after the meeting.
- 2.4.19. Action following decisions recorded in the draft minutes will be initiated no sooner than 48 hours after circulation of draft minutes. Members who object to the progress of any actions recorded should contact the secretariat within that time frame.
- 2.4.20. As much as possible, electronic communication will be used to communicate with members and researchers.
- 2.4.21. Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.

2.5. Monitoring

- 2.5.1. The HREC requires the Principal Investigator (or Coordinating Principal Investigator for multicentred studies) to:
 - Keep adequate research records and provide access when requested to the HREC.
 - Provide progress reports at intervals specified by the HREC and at completion of any research but not less than annually.
 - Notify and provide reports, in a timely fashion, to the HREC of significant adverse events, side effects or complications occurring including the course of action taken at any time during the research.

- Notify the HREC of any complaints received from participants, staff, observers or the community.
 - Provide prospective advice of any proposed amendment(s) to be made to the protocol and approval of these prior to implementation.
 - Notify and provide reasons to the HREC if the research is to be discontinued before the expected date of completion of the project.
 - Provide a copy of published articles/results, presentations or posters at conferences etc. to the HREC.
- 2.5.2. The HREC may:
- If required, request an interview with the researchers, research participants or other forms of feedback from them.
 - If required, request random inspections or access to research sites, research data and consent documentation records.
 - If considered necessary, request the opinion of external experts.

2.6. Handling Complaints

Complaints concerning the conduct of a project

- 2.6.1. As per the *Australian Code for the Responsible Conduct of Research 2007* the institution has nominated a 'designated person' for handling research complaints, including research misconduct.
- 2.6.2. The 'designated person' for the Cairns & Hinterland Health Service District is The District Executive Director of Nursing.
- 2.6.3. Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the 'designated person' of the institution where the approving HREC sits, to the secretariat of the approving HREC who will enter the complaint details on AU RED and to the local site RGO
- 2.6.4. Processing of research complaints, including research misconduct and fraud, will be as per the QH HREC SOP.

Complaints concerning the HREC's review process including the HREC's rejection of an application

- 2.6.5. Any concern or complaint about the approving HREC's review process should be directed to the attention of the Chairperson of the approving HREC, detailing it in writing.
- 2.6.6. The secretariat of the approving HREC will enter the complaint details on AU RED
- 2.6.7. Processing of research complaints regarding the HREC review process will be as per the QH HREC SOP.

3. AMENDMENT TO THE TERMS OF REFERENCE

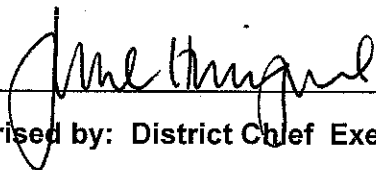
These Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.
- For those proposals made by the Chief Executive:
- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

Prior Review July 2009

Effective at: January 2011



Authorised by: District Chief Executive Officer

Julie Hartley-Jones
District Chief Executive Officer
Cairns & Hinterland Health Service District



Date