Terms of Reference for

Queensland Health

Townsville Hospital and Health Service
Human Research Ethics Committee

EC00183
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INTRODUCTION

Preamble
The Townsville Human Research Ethics Committee EC00183 is a committee established by the Townsville Hospital, 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 (QH-POL-013:2010).

Certified Institution
• A certified institution is an institution which has achieved certification of its HREC processes, in order to undertake the single ethical review of research projects to be conducted at more than one site. The Townsville HREC has sought certification to undertake multi-centre ethical review in the following research fields:
  • Population Health
  • Clinical Interventions
  • Qualitative Research, and
  • Mental Health

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 Chief Executive (CE), 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(RGO) and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn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 Townsville HREC will:
• Report to the Chief Executive via the Clinical Innovation, Education and Research Committee.
• 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.
• Report any complaints to the Chief Executive.
• Liaise with Queensland Hospital and Health Services, 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 CE of individual Hospital and Health Services will have the right to veto the conduct of a research project within its District.
• Consider research proposals from neighbouring Hospital and Health Services that from time to time request that ethical reviews be conducted on their behalf. Presently, this includes North West Hospital and Health Service and Mackay Hospital and Health Service.
• Make public the membership categories of the HREC on the QH Health and Medical Research website.

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.
(g) At the discretion of the chair and in consultation with the Chief Executives of neighbouring Hospital and Health Services referred to in the last clause of ‘Relationships and reporting’ above (for whom, from time to time, Townsville HREC conducts ethical reviews), one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a doctor, nurse or allied health professional from the neighbouring Hospital and Health Service.

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.
1.1.5. At any one time, at least half the members appointed in the minimum membership categories listed under the National Statement (5.1.30) will have two or more years experience on a HREC.
1.1.6. Annually the HREC Chair will assess the categories and quantities of research received and align, as required, the expertise of the committee with the research studies received for review.

1.2. HREC appointment of members

1.2.1. The Townsville Hospital’s CE 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 CE may terminate the appointment of any member of the HREC if:

• 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, induction 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 Townsville District Health Service.

1.3.3. Members will attend continuing education and training in research ethics at least every two years.

1.4. HREC Sub-committees

1.4.1. The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, review of research involving Aboriginal or Torres Strait Islander groups or ethical review of minimal risk research, submitted to the HREC.

1.4.2. The Chair of any such subcommittee will be appointed by the Chief Executive of the Townsville Hospital and Health Service in consultation with the HREC Chair.

1.4.3. Members of subcommittees 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. Confidentiality

1.6.1. All documents and correspondence from and to the Committee will be kept confidential.

1.6.2. All Committee meetings and deliberations will be kept in confidence. Reporting of such deliberations will be outcomes only and statistical data only will be provided to the appropriate governing bodies.

1.6.3. Where possible all documents and correspondence from the HREC will be marked confidential.

2. HREC PROCEDURES

2.1. Standard operating procedures

2.1.1. The HREC will perform its functions, including monitoring of research and handling of complaints, 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. The HREC will consider every 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. Eligible low and negligible risk applications may be reviewed by a sub-committee out of session, provided that the application is valid and does not seek a waiver of consent.

2.2.3. When a submission is accepted by the HREC, the HREC Coordinator will continue the process of HREC review and approval as per the HREC SOP.

Single Site Studies

2.2.4. All submissions of all single site studies, for review by the HREC, will be made directly to the Townsville HREC.

Multi-centre Research Studies

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

2.3. Meetings

General

2.3.1. Meetings will be held in accordance with QH HREC SOP.

2.3.2. The HREC agenda, accompanied by all required documentation for review of research proposals will be distributed not later than 5 working days prior to the HREC meeting.

2.3.3. Decisions by the Committee 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.
2.3.4 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.

2.3.5 Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via submission to the HREC Coordinator prior to the meeting.

2.3.6 Members of the committee are required to declare any interests they have in relation to an application or any other matter for consideration at the meeting. Such a declaration may be made orally at the meeting, prior to the matter being considered or in writing to the Chair prior to the meeting. Declarations of interest will be managed in accordance with the QH HREC SOP.

2.3.7 The Director of Health and Medical Research or delegate will attend the HREC meetings, as required, as an observer. The role of the Director of Health and Medical Research will be as non-voting, HREC advisor regarding regulation of and access to Queensland Health databases and collections.

2.3.8 The HREC may invite researcher/s and expert reviewers, and researchers may request, to be present for discussion of the proposed research. This will be done in line with the National Statement guidelines and the Standard Operating Procedures.

2.3.9 Requests for observership at one or more HREC meetings will be considered by the Chairperson in the first instance. Observers are bound by the same confidentiality requirements as HREC members.

Dates and venue
2.3.7 Meetings will be held monthly except for January where HREC meetings will not be held.

2.3.8 Meeting dates will be available on the Health and Medical Research website.

2.3.9 Meetings will normally be held at the Medical Administration Meeting Room on the first Thursday of every month at 5.30 pm.

Secretarial Support
2.3.10 Secretarial support will be provided by the HREC Coordinator

Decisions from HREC meetings
2.3.11 The minutes of meetings will be recorded on AU RED.2.3.12. 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.

2.3.13 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent have had an opportunity to contribute and that sufficient input has been received to make a decision on a proposal.

2.3.14 In general, decisions of the HREC will be reached by general agreement and consensus.

2.3.15 Decisions of the Committee will be recorded and communicated in writing to the Principal Investigator or contact person for the proposal within 10 days of the meeting.

Record Keeping
2.3.16 A hard copy of the minutes and agendas of meetings will be retained and archived according to district procedure THSDSUP100511 v1.

2.3.17 An electronic copy of the minutes and agendas of meetings will be retained with the Townsville Hospital and Health Service Committee Registry.

2.3.18 Research applications and related correspondence will be retained and archived according to district procedure THSDSUP100511 v1.

2.4 Monitoring
- Monitoring of research given institutional authorisation will be as per QH HREC & RGO SOP Section: HREC monitoring of research given institutional authorisation.
2.5 Complaints

- Research complaints concerning the conduct of a project and/or a HREC’s review process, including the HREC’s rejection of an application should be managed as per the QH HREC SOP.
- The ‘Advisor in Research’ applicable to this committee will be provided by contacting the HREC Coordinator.
- The ‘Designated Person’ applicable to this committee will be provided by contacting the HREC Coordinator.

2.6 Access to External Expert Reviewers

- The HREC may seek the written advice of an external expert reviewer on any aspects of an application that are relevant to the formation of an ethical decision, and which lie beyond the expertise of the members or on which the Committee is unable to agree.

- The QH Panel of External Expert Reviewers can be accessed at any time by the HREC, by contacting the QH Health and Medical Research Preventive Health unit.

- Expert Reviewers are not voting members of the HREC, and should not be involved in the business of the Committee other than that related to the application on which their advice is sought.

- At any time a HREC member can make a request for external expert review to the HREC Coordinator or the HREC Chair, consensus will be obtained from the HREC by flying minute to facilitate efficient ethical review.

- If possible, a copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

- The expert reviewer may be invited to attend the meeting in person for discussion of the application concerned.

- Expert Reviewers are subject to the same confidentiality requirements as HREC members and are required to sign a confidentiality agreement prior to access to proposal documents or attending HREC meetings.

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 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.