



Terms of Reference for Queensland Health Central Office Human Research Ethics Committee [EC0034]

Office of Health and Medical Research

Queensland Health

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**Queensland Health Central Office
Human Research Ethics Committee
EC0034**

Terms of Reference

INTRODUCTION

Preamble

The Queensland Health Central Office Human Research Ethics Committee [EC0034] is a committee established by Centre for Healthcare Improvement (CHI), 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)*.

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 Office of Health and Medical Research, and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn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
- The Queensland Health Central Office Human Research Ethics Committee will undertake ethical review in the following research fields:
 - *Epidemiology and population health research*
 - *Health services research*
 - *Data linkage research*
 - *Other research as deemed appropriate by the HREC Chair, in accordance with the expertise of the HREC members.*
- Epidemiological research will include research which studies diseases in populations. The main aims of the research are to:
 - Describe disease patterns in human populations.
 - Identify the causes of diseases (also known as aetiology).
 - Provide data essential for the management, evaluation and planning of services for the prevention, control and treatment of disease.

- Population health and data linkage research will include research undertaken to improve health and enhance the delivery of health care services by the use of linkable data from a range of health datasets which may be across jurisdictions and sectors.
- Health services research will include research which studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and ultimately our health and well-being.

Relationships and reporting

The Queensland Health Central Office Human Research Ethics Committee will:

- Report and be accountable to the Chief Executive Officer of the Centre for Healthcare Improvement by:
 - Tabling of all amendments to the Queensland Health Central Office HREC Terms of Reference at the Centre for Healthcare Improvement executive management meeting
 - Tabling of Queensland Health Central Office HREC monthly meeting minutes at the Centre for Healthcare Improvement executive management meeting
 - Tabling of Queensland Health Central Office HREC NHMRC annual report for institutions with a Human Research Ethics Committee at the Centre for Healthcare Improvement executive management meeting annually.
 - Tabling of Queensland Health Central Office HREC list of HREC members and their associated National Statement on Ethical Conduct in Human Research categories of research at the Centre for Healthcare Improvement executive management meeting annually.
- 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.
- Process the charging of 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.
- Make public the membership of the HREC on the QH Research Ethics and Governance Unit website.

1. HREC ESTABLISHMENT

1.1 HREC Composition

- 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 woman, 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.
- The minimum membership of an HREC is eight.
- As far as possible there will be equal numbers of men and women.
- At least one third of the members will be from outside the institution for which the HREC is reviewing research.
- 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.
- 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

- The CEO of the Centre for Healthcare Improvement (CHI) or delegate shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
- Membership appointments to the HREC will be considered for review every three years.
- Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the CEO of CHI or delegate
- The Chairperson and members may serve longer terms with the approval of the Chief Executive Officer of CHI or delegate.
- Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive Officer of CHI or delegate.
- 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.
- 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.
- The Chief Executive Officer of CHI or delegate 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.
- 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.
- 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.
- 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.
- A small gift of appreciation, not above the QH reportable threshold, may be made to HREC members each year in recognition of the very substantial time commitment and intellectual input they make to Queensland Health. Refer to FMPM Circular No. 4/2010 Giving & receiving of Gifts & benefits for advice:
http://qheps.health.qld.gov.au/finance/sfs/fmpm/documents/circulars/gifts_policy.pdf
- The Director, Research Ethics and Governance Unit, Office of Health & Medical Research or delegate will attend the HREC meetings, as required, as an observer. The role of the Director, Research Ethics and Governance Unit will be as a non voting, HREC Advisor regarding the regulation of and access to Queensland Health databases and collections.

1.3 Education for HREC members

- Newly appointed members shall be provided with adequate orientation, induction and mentoring.
- 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 Centre for Health Care Improvement.
- Members will attend continuing education and training in research ethics at least every two years.

1.4 HREC Sub-committees

- The HREC may appoint such sub-committees 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.
- The Chair of any such subcommittee will be appointed by the Chief Executive of Centre for Healthcare Improvement.
- Members of the subcommittee need not be members of the HREC.

1.5 HREC Liability coverage

- 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) in accordance with HR Policy I3.
- 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) in accordance with HR Policy I3.

1.6 National certification for multi centred ethical review

- 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
- Certification standards will be as per the Australian national certification standards.
- The responsibility for meeting these certification standards rests with the Centre for Healthcare Improvement

2. HREC PROCEDURES

2.1 Standard operating procedures

- The HREC will perform its functions in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) - the *National Statement (NS)*, the *Australian Code for Responsible Conduct of Research (2007)* and *QH Research Management Policy and Framework (QHRMP; 2008)* and all subsequent updates.
- The HREC will perform its functions, including monitoring of research and handling of complaints, according to written standard operating procedures (SOP) accessed from the QH Research Ethics and Governance Unit (REGU) website. These procedures shall be reviewed at least every three years and amended and updated as necessary.
- 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.
- All issues involving research governance will be dealt with in accordance with the QH Research Governance Standard Operating Procedures, accessed from the REGU website.

2.2 Submissions

All Studies

- 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.
- When a submission, including amendments, is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.
- Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HEC) for ethical and legal approval.
- The District CEO or Delegate is the person to grant authorisation of research projects on humans to be conducted within or in association with QH Districts.

Single Site Studies

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

Multi-centre Research Studies

- From 1 July 2010 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 QH HREC SOP.
- For multi-centre research studies an HREC, that has been assessed and certified under the national certification scheme, will be the single HREC body to conduct the ethical-scientific

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review of the study. No other HREC will be involved in the ethical review of an application which is being or has been reviewed by a certified HREC under the single ethical review process.

2.3 Meetings

General

- Meetings will be held in accordance with QH HREC SOP
- 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.
- 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.
- In line with the National Statement Sections 5.2.28 - 5.2.31 there is no quorum for HREC meetings. 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 has received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- 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.
- 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.
- In general, decisions of the HREC will be reached by general agreement and consensus.
- Members of the committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chairperson will determine the action to be taken.

Dates and venue

- Meetings will be held monthly except for December or January when no meetings will be held.
- Meeting dates will be available on the Research Ethics and Governance Unit website.
- Meetings will normally be held at on Level 3 of the Queensland Health Building at 147 Charlotte St Brisbane City, on the third Monday of every month with the exclusion on January and December between 9.30 -11.30 am.

Secretarial Support

- Secretarial support will be provided by the Ethics Administrator of the Research Ethics and Governance Unit.

Decisions from HREC meetings

- The minutes of meetings will be recorded on AU RED.
- 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 Conflicts of Interest

- Members will be required to sign a statement undertaking that any conflicts of interest, which exist or may arise during his/her tenure on the HREC, will be declared.
- HREC members will be required to declare any conflict of interest prior to or at any time during a HREC meeting. The Chairperson will determine the action to be taken. (National Statement section 5.2.4; Chapter 5.4)
- All conflicts of interest will be managed as per Research Management Policy and Framework 2010 Implementation Standard 5: Conflicts of Interest in Research

2.5 Monitoring

- Monitoring of research given institutional authorisation will be as per QH HREC & RGO SOP Section: HREC monitoring of research given institutional authorisation (Appendix A).

2.6 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 is Dr Jane Jacobs, Director, Research Ethics and Governance Unit, Office of Health and Medical Research, QH.
- The 'Designated Person' applicable to this committee is Professor Robin Mortimer, Executive Director, Office of Health and Medical Research, QH.

2.7 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 Research Ethics and Governance Unit, Office of Health and Medical Research. .
- 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.
- 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.

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.

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.

All amendments of the Queensland Health Central Office HREC Terms of Reference will be tabled at a Centre for Healthcare Improvement executive management meeting

Appendix A: HREC MONITORING OF RESEARCH GIVEN INSTITUTIONAL AUTHORISATION

General Policy on monitoring of research

- Research should normally commence within 12 months of the date of ethical approval.
- Should the study not commence within 12 months, the Principal Investigator (single site studies) or Coordinating Principal Investigator (CPI) (multi-centre studies) is required to provide the HREC with a written explanation for the delay.
- Should the project not commence within 24 months, the matter will be discussed at a meeting of the HREC. At the discretion of the HREC, the approved ethical decision may be suspended and the Principal Investigator / CPI required to submit a new application once the problems relating to the delay of the study have been fully addressed.
- To allow monitoring to occur, the HREC Chairperson or delegate may decide to allow other persons access to HREC application files. This decision may be taken at a HREC meeting or between meetings. The decision and reason for the decision to allow access to HREC files is to be minuted at the next HREC meeting. This may include random inspections of research sites, data, or consent documentation and interviews with research participants or other forms of feedback from them.
- All reports will be tabled at an HREC meeting and reviewed by the committee.
- All reports should be on the standard template accessed from the REGU website.

Duration of an approved ethical decision

- The approved ethical decision of the main HREC applies for the expected duration of the research as specified in the approval letter, except where action is taken to suspend or terminate the decision.
- Where the Principal Investigator / CPI proposes to extend the duration of the study, for example to allow more time for recruitment of participants, this must be submitted for review to the HREC.

Progress reports

- Progress reports on all research given an approved decision should be submitted to the HREC at least annually, or more frequently if the level of risk is assessed by the HREC to so indicate. The first Annual Report should be submitted 12 months after the date on which ethical approval was given.
- Reports must be submitted by the Principal Investigator (or CPI for multi-centre studies) and signed.
- Annual reports should be accompanied by the reporting letter from the Data Safety Monitoring Board, if applicable.
- Where a progress report is not received by the due date, the HREC Administrator will send a reminder letter. If the report is still not received after a further period of one month, the matter will be considered at the next meeting of the HREC.

Final Reports

- A final report on all research given District authorisation should be submitted to the HREC at completion of the research and should include a copy of the final published results.

Urgent Safety Measures

- The Coordinating Principal Investigator, or a Site Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect the participants of a clinical trial against any immediate hazard to their health or safety. The HREC must be notified immediately and in any event within 3 days that such measures have been taken. The notice should set out the reasons for the urgent safety measures and the plan for further

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action. QH policy is that these requirements should apply to all research with an approved decision from a HREC and authorisation by the District CEO or Delegate of the QH District.

- Notifications of urgent safety measures should be reviewed at a meeting of the HREC. The HREC should consider whether the measures taken are appropriate in relation to the apparent risk to participants, and what further action the sponsor or investigator(s) propose to take, for example the submission of amendments to the protocol. Where any concern arises about the safety or welfare of participants or the conduct of the research, the HREC should address these with the Principal Investigator in writing.

Early Termination of Study by the Principal Investigator

- Where a research project is terminated or suspended by the Principal Investigator / CPI prematurely, the HREC must be promptly informed and provided with a detailed written explanation of the circumstances, having regard to the ongoing safety and welfare of any research participants who may be receiving study treatment.

Suspension or Withdrawal of HREC Approval

- The HREC may suspend or withdraw its ethical approval if it is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with its ethical approval and that, as a result, the welfare and rights of participants are not or will not be protected.
- Where the HREC considers it appropriate that the adverse event/s and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the Coordinating Principal Investigator (or Site Principal Investigator for single site studies).
- An Investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC or district/site Research Governance Office/r.

HRECs and Adverse Event Reporting in Australian for Clinical Trials

- The Principal Investigator / CPI must capture and report AEs, including SAEs, which occur at their site to the sponsor in accordance with the study protocol. The Principal Investigator / CPI must report all SAEs to the sponsor immediately (within 24 hours of finding out about the event) in accordance with the study protocol and GCP guidelines as adopted by the TGA. The requirements for adverse event reporting to HRECs by Investigators will be in accordance with the Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements.
http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

Fully Sponsored Pharmaceutical or similar trials

- HRECs should be provided with a copy of the SAE notification as soon as possible and within a one month maximum time lapse;
- If the event is serious and unexpected and may affect other participants on the trial, the HREC and Institution must receive immediate notification (that is, within 24 hours of the investigator becoming aware of the event)

Non Sponsored Trials

- Non sponsored trials with only a local DSM Committee are required to immediately provide notification to the HREC within 24 hours of the investigator becoming aware of the event. If it is considered that the SAE is related to the study, immediate notification to the HREC and Institution administration is required.

Tracking of Medical Devices

- Tracking of medical devices is as per the TGA requirements and Australian Medical Devices Guidelines: Medical Device TGA SAE Forms and guidelines:
http://www.tga.gov.au/docs/pdf/forms/iris_mdir03b.pdf and
http://www.tga.gov.au/docs/pdf/forms/iris_udir03c.pdf
<http://www.tga.gov.au/docs/pdf/devguid11.pdf>
- Device identifiers are to be placed into patients medical notes and manufacturers are required to maintain a tracking system