

Terms of Reference for Queensland Health Gold Coast Hospital and Health Service Human Research Ethics Committee EC00160

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Change Log			
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03 November 2011	I Pieper	2.5.4 Designated Person	
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GOLD COAST HOSPITAL AND HEALTH SERVICE - HUMAN RESEARCH ETHICS COMMITTEE EC00160

Terms of Reference

INTRODUCTION

Preamble

The Gold Coast Hospital and Health Service Human Research Ethics Committee, is a committee established by the **Gold Coast Hospital and Health Service (GCHHS)** of Queensland Health and is constituted and functions in accordance with the NHMRC '*National Statement on Ethical Conduct in Human Research*' (2007) - *the National Statement*; and complies with the '*Australian Code for Responsible Conduct of Research* (2007) and *QH Research Management Policy and Framework (QHRMP; 2008)*. The Committee is a nationally registered HREC; NHMRC code EC00160.

Purpose

The purpose of the Committee is to:

- Advise the Gold Coast Hospital and Health Service on ethical issues relating to human research;
- Evaluate and approve suitable human research proposals in line with NHMRC guidelines and Queensland Health policies; and
- Monitor and review approved human research proposals

Certified Institution

A certified institution is an institution which has achieved certification of its HREC processes, under the NHMRC HoMER certification scheme, in order to undertake the single ethical review of research projects to be conducted at more than one site.

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 Gold Coast Hospital and Health Service – Human Research Ethics Committee has been certified to undertake single ethical review in the following research fields:

- Clinical Trials, Phase I;
- Clinical Trials, Phase II;
- Clinical Trials, Phase III;
- Clinical Device Trials;
- Clinical Interventional Studies, other than Clinical Trials;
- Qualitative Health Research; and
- Mental Health Research

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 Gold Coast Hospital and Health Service Chief Executive Officer (-GCHHS CEO), or Delegate, 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 and associated documents submitted to the HREC, any monitoring and reporting requirements and any ongoing approval status of proposals including amendments
- The HREC will ensure that relevant training is provided for HREC members to enable the HREC to meet its obligations under its NHMRC accreditation and as a committee within Queensland Health.
- The HREC will be responsible for ensuring that adequate recruitment is undertaken to meet the minimum membership requirements under Section 5.1.30 of the National Statement.

Relationships and reporting

The Gold Coast Hospital and Health Service Human Research Ethics Committee HREC will:

- Report to the GCHHS CEO via Executive Officer Team meetings and formally through the minutes of the HREC meetings provided to the District Executive Team Meeting for noting.
- Submit a report annually to the 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.
- Acknowledge that the GCHHS CEO, or Delegate, of individual Health Service Districts will have the right to not approve the conduct of a research project within its Jurisdiction.
- Report annually to the NHMRC, as the certifying body under the National Certification Scheme, on the number of multi-centre research proposals reviewed by Research Ethics and Governance Unit (REGU). Report -annually on changes to the HREC composition and/or HREC administrative officers via the NHMRC annual report.

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.
- 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.

1.2. HREC appointment of members

- 1.2.1. The Gold Coast Hospital and Health Service 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. The Chair shall formally designate a member of the Committee as Deputy Chair. This person shall act as Chair in the event that the Chair is unavailable, or as requested. Should the Committee Chair resign, or be removed from the Committee, the Deputy Chair shall act in his or her stead until such time that he GCHHS CEO shall appoint a replacement, or for a time not exceeding three consecutive meetings.
- 1.2.6. Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the GCHHS Chief Executive Officer.

- 1.2.7. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms without the approval of the Chief Executive Officer.
- 1.2.8. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the GCHHS Chief Executive Officer.
- 1.2.9. Membership will lapse if a member fails without reasonable excuse or without notifying the Chair to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chair will notify the member, in writing, of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.
- 1.2.10. A member may resign from the HREC at any time upon giving notice in writing to the Chair. Steps shall be taken to fill the vacancy of the former member.
- 1.2.11. The GCHHS CEO may terminate the appointment of any member of the HREC if the GCHHS 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.
- 1.2.12. 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.
- 1.2.13. 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.
- 1.2.14. 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.
- 1.2.15. A small gift of appreciation, not above the Queensland Government 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/financenetwork/financial_policy/docs/Gifts/gifts_policy.pdf

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 Gold Coast Hospital and Health Service, at the discretion of the Committee.
- 1.3.3. Members will attend continuing education and training in research ethics at least every three 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, 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 Gold Coast Hospital and Health Service.
- 1.4.3. Members of the subcommittee need not be members of the HREC.
 - 1.4.3.1. REGU co-ordinates a substantial pool of available experts in a wide variety of research areas. These experts will provide reports on specific studies upon request. This pool of talent may be accessed at any time that the HREC requires additional scientific expertise. The HREC will make use of this resource at any time where an application is to be considered and the committee deems it desirable that specific additional expertise be sought.
 - 1.4.3.2. External expert review can be sought by contacting REGU.
- 1.4.4. All reports from sub-committee must be tabled at the next full Committee meeting for consideration.

1.5. HREC Liability coverage

- 1.5.1. Queensland Health 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 under Indemnity for Queensland Health Medical Practitioners and Queensland Health Employees (IRM I3).
- 1.5.2. Queensland Health 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 under IRM I3.
- 1.5.3. Queensland Health extends this indemnity to reviewers providing expert opinion drawn from the pool of expert reviewers managed by REGU

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 any changes.

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. 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.
- 2.2.3. 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.

Single Site Studies

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

Multi-centre Research Studies

- 2.2.5. 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 Queensland Health Central Coordinating Service (CCS) as per the QH HREC SOP.
- 2.2.6. From 24 October 2011, submissions from Victorian sites to conduct sponsored clinical trials may be considered by the Committee, if appropriate. These studies will be allocated via the Central Coordinating Service, as per QH 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 to all members not later than seven 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. In line with the National Statement Sections 5.2.28 - 5.2.31 there is no quorum for HREC meetings, however, as far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend. 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.

- 2.3.5. The contribution of information and opinion from a committee member unable to personally attend a meeting will be considered along with those opinions and feedback of other Committee members in the final decision making.
- 2.3.6. 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.
- 2.3.7. In general, decisions of the HREC will be reached by general agreement and consensus.
- 2.3.8. Members of the committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chair will determine the action to be taken.

Dates and venue

- 2.3.9. Meetings will be held on the 4th Wednesday of the month, except for December where HREC meetings will not be held. Meetings will commence at 5 pm.
- 2.3.10. Meeting dates will be available on the Queensland Health REGU website.
- 2.3.11. Meetings will normally be held at Gold Coast University Hospital, 1 Hospital Boulevard, Southport, 4215.

Secretarial Support

- 2.3.12. Secretarial support will be provided by the HREC Co-ordinator of the Gold Coast Research Ethics and Governance Unit.

Decisions from HREC meetings

- 2.3.13. A copy of the minutes of meetings will be provided to the District CEO for noting.
- 2.3.14. The minutes of meetings will be recorded on AU RED.
- 2.3.15. Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol, application, or associated documents, linking those reasons to the National Statement.
- 2.3.16. Decisions of the Committee concerning an application will be recorded and communicated, in writing, to the Principal Investigator.
- 2.3.17. Decisions of the Committee shall be signed either by the Chair at the time of the meeting, or delegated to the Secretariat, as required.

2.4. Monitoring

- 2.4.1. Monitoring of research given institutional authorisation will be as per QH HREC & RGO SOP.

2.5. Complaints

- 2.5.1. 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.

Advisors in Research Integrity

- 2.5.2. The Committee shall recommend for the approval of the District CEO a suitable number of **Advisors in Research Integrity** as described under Section 10 of the Australian Code for the Responsible Conduct of Research.

Designated Person

- 2.5.3. The committee shall cooperate fully with any investigation into research integrity constituted under section 10 of the Queensland Health HREC SOP. Particularly the committee shall support the duties of the **Designated Person** nominated to support the District CEO in the investigation of any research complaint.
- 2.5.4. The **Designated Person** for this Hospital and Health Service is Marlene Moriarty, Manager of Legal Service.

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.