

# Terms of Reference

## Gold Coast HHS Human Research Ethics Committee [EC00160]

**Ratified:** February 2018

**Review Date:** February 2019

### 1.0 Purpose

**1.1** The Gold Coast Hospital and Health Service Human Research Ethics Committee [EC00160] (HREC), is a committee established by the Gold Coast Hospital and Health Service (GCHHS) and is constituted and functions in accordance with the NHMRC '*National Statement on Ethical Conduct in Human Research*' (2007) – Updated May 2015; and complies with the '*Australian Code for Responsible Conduct of Research (2007)* and Department of Health Research Management Policy (QH-POL-013:2015).

The HREC is a nationally certified committee.

The objectives of the HREC are to:

- i) Ensure human research submitted for review is designed with respect for the participants and is not compromised by the aims of the research, by the way it is carried out, or by the results;
- ii) Advise the Gold Coast Hospital and Health Service on ethical issues relating to human research;
- iii) Evaluate and approve suitable human research proposals in line with NHMRC guidelines and Queensland Health policies; and
- iv) Monitor and review approved human research proposals.

The HREC acts in a consultative and advisory capacity with researchers to ensure that all research is conducted in an ethical and scientifically robust manner.

### 2.0 Scope and Functions

**2.1** The HREC will:

- Provide independent, competent and timely ethical review and oversight of human research to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards of human research.
- 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 (GCHHS CE), or Delegate, through the relevant Research Governance Officer/s (RGO) and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn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 (AURED) all research applications and associated documents submitted to the HREC, any monitoring and reporting requirements, and any ongoing approval status of proposals including amendments

### 3.0 Membership (Positions held only)

**3.1** 3.1.1 The HREC membership 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;

<b>3.0 Membership (Positions held only)</b>	
	<ul style="list-style-type: none"> <li>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;</li> <li>d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;</li> <li>e) at least one lawyer, where possible one who is not engaged to advise the institution; and</li> <li>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.</li> </ul> <p>3.1.2. The minimum membership of an HREC is eight.</p> <p>3.1.3 As far as possible, there should be equal numbers of men and women.</p> <p>3.1.4 At least one third of the members should be from outside the institution for which the HREC is reviewing research</p> <p>3.1.5 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.</p>
<b>3.6</b>	Other observers may be invited to a meeting of the HREC. The observers will be required to sign a confidentiality agreement.
<b>4.0 Chairperson (Position held only)</b>	
<b>4.1</b>	Chair of HREC
<b>5.0 Secretariat (Position held only)</b>	
<b>5.1</b>	Secretarial support will be provided by the HREC Coordinator and /or Research Ethics and Communications Officer of the Office for Research Governance and Development.
<b>5.2</b>	The HREC Coordinator has the delegation to sign correspondence on behalf of the Chair where the Chair and/or HREC have made a decision on the submission.
<b>5.3</b>	The HREC Coordinator has the delegation to make a decision and sign correspondence for submissions of an administrative nature, including administrative amendments.
<b>6.0 Appointment of HREC Members</b>	
<b>6.1</b>	The GCHHS CE shall appoint members of the HREC, in consultation with the HREC and other senior HHS officials, as deemed appropriate.
<b>6.2</b>	Membership appointments to the HREC will be considered for review every three years.
<b>6.3</b>	Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
<b>6.4</b>	Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
<b>6.5</b>	The Chair shall formally designate a member/s of the Committee as Deputy Chair/s. This person/people 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 the GCHHS CE appoints a replacement, or for a time not exceeding six consecutive meetings.
<b>6.6</b>	Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the GCHHS CE.

<b>6.0</b>	<b>Appointment of HREC Members</b>
<b>6.7</b>	The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms subject to the approval of the GCHHS CE.
<b>6.8</b>	Reappointment is by application to the Chair of the HREC who will then make a recommendation to the GCHHS CE.
<b>6.9</b>	Membership will lapse if a member fails without reasonable excuse or without notifying the Chair and/or HREC Coordinator 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.
<b>6.10</b>	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.
<b>6.11</b>	<p>The GCHHS CE may terminate the appointment of any member of the HREC if the GCHHS CE is of the opinion that:</p> <ul style="list-style-type: none"> <li>• It is necessary for the proper and effective functioning of the HREC;</li> <li>• The person is not a fit and proper person to serve on an HREC;</li> <li>• The person has failed to carry out their duties as an HREC member.</li> </ul>
<b>6.12</b>	Members will be provided with a letter of appointment which will include the 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.
<b>6.13</b>	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.
<b>6.14</b>	<p>Members will be required to sign a statement undertaking:</p> <ul style="list-style-type: none"> <li>• That all matters of which he/she becomes aware during the course of his/her work in the HREC will be kept confidential;</li> <li>• That any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and</li> <li>• That he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.</li> </ul>
<b>6.15</b>	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 <a href="https://www.qld.gov.au/gov/gifts-and-benefits">https://www.qld.gov.au/gov/gifts-and-benefits</a> for advice.
<b>7.0</b>	<b>Education of HREC Members</b>
<b>7.1</b>	Newly appointed members shall be provided with orientation, induction and mentoring.
<b>7.2</b>	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 GCHHS, and at the discretion of the Committee.
<b>7.3</b>	Members will attend continuing education and training in research ethics at least every three years.
<b>8.0</b>	<b>HREC Sub-Committees</b>
<b>8.1</b>	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.
<b>8.2</b>	The Chair of any such sub-committee will be appointed by the GCHHS CE.
<b>8.3</b>	<p>Members of the sub-committee need not be members of the HREC.</p> <p>8.3.1 Health Innovation, Investment and Research Office (HIRO) co-ordinates a substantial pool of available</p>

<b>8.0</b>	<b>HREC Sub-Committees</b>
	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. 8.3.2 External expert review can be sought by contacting HIIRO.
<b>8.4</b>	All reports from sub-committees must be tabled at the next full Committee meeting for consideration.
<b>9.0</b>	<b>HREC Liability Coverage</b>
<b>9.1</b>	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 through Queensland Government Insurance Fund (QGIF).
<b>9.2</b>	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 through QGIF.
<b>10.0</b>	<b>Frequency of Meetings</b>
<b>10.1</b>	Meetings will be held on the last Wednesday of the month, except for December where an HREC meeting will not be held. Meetings commence at 5:00 pm.
<b>10.2</b>	Meeting dates will be available on the HIIRO website.
<b>10.3</b>	Meetings will normally be held at Gold Coast University Hospital, Level 2 Pathology and Education Building, 1 Hospital Boulevard, Southport, 4215.
<b>11.0</b>	<b>Standard Operating Procedures</b>
<b>11.1</b>	The HREC will perform its functions, including monitoring of research and handling of complaints, according to the Standard Operating Procedures for Queensland Health HREC Administrators (QH HREC SOP).
<b>11.2</b>	All HREC members shall have access to and/or be provided with copies of the SOP.
<b>12.0</b>	<b>Agenda Items</b>
<b>12.1</b>	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.
<b>12.2</b>	The HREC will consider every application it receives at its next available meeting following receipt, provided that the application is valid and received by the relevant closing date.
<b>12.3</b>	When a submission, including amendments, is accepted by the HREC, the HREC Coordinator and /or Research Ethics and Communications Officer will continue the process of HREC review and approval as per the HREC SOP.
<b>13.0</b>	<b>Quorum</b>
<b>13.1</b>	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 (6 categories) 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 any views submitted been recorded and considered.
<b>14.0</b>	<b>Meetings</b>
<b>14.1</b>	Meetings will be held in accordance with QH HREC SOP.
<b>14.2</b>	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 the members that constitute the minimum membership of the HREC.

<b>14.0</b>	<b>Meetings</b>
14.3	Members who are unable to attend a meeting will be encouraged to contribute and advise their opinions via submission to the HREC Secretariat prior to the meeting.
14.4	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 decision making.
14.5	In general, decisions of the HREC will be reached by general agreement and consensus.
14.6	Members of the HREC 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.
<b>15.0</b>	<b>Minutes</b>
15.1	A copy of the minutes of meetings will be provided to the HHS CE or his/her delegate for noting on a quarterly basis.
15.2	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.
15.3	The minutes of meetings will be uploaded to AU RED.
15.4	Decisions of the HREC concerning an application will be recorded and communicated, in writing, to the Principal Investigator and contact person. Decisions of the Committee shall be signed either by the Chair at the time of the meeting, or delegated to the Secretariat, as required.
15.5	Decisions of the Committee shall be signed by the Chair and the HREC Secretariat at the next meeting of the HREC following ratification by the members.
<b>16.0</b>	<b>Access to Information / Confidentiality</b>
16.1	Members of the Committee have the right to access information and documents relevant to issues being considered within the terms of reference. It is acknowledged that certain issues being examined may be of a confidential and/or sensitive nature, which will require members of the Committee, and the Secretariat, to exercise utmost tact and discretion and ensure any confidential information will remain confidential
<b>17.0</b>	<b>Out-of-Session Functions of the Committee</b>
17.1	Depending on the particular issues in question, it may be useful or necessary to disseminate information to members of the Committee outside of scheduled meetings.
<b>18.0</b>	<b>Consumer Engagement</b>
18.1	As per the National Statement (5.1.30(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 are appointed as members of the HREC.
<b>19.0</b>	<b>Complaints</b>
19.1	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.
19.2	Advisors in Research Integrity: The HREC shall recommend for the approval of the HHS CE a suitable number of Advisors in Research Integrity as described under Section 10 of the Australian Code for the Responsible Conduct of Research.
19.3	Designated Person: <ul style="list-style-type: none"> <li>The HREC shall cooperate fully with any investigation into research integrity constituted under section 10</li> </ul>

<b>19.0</b>	<p><b>Complaints</b></p> <p>of the QH HREC SOP. The Committee shall support the duties of the Designated Person nominated to support the HHS CE in the investigation of any research complaint.</p> <ul style="list-style-type: none"> <li>The Designated Person for this Hospital and Health Service is the Director, Office for Research Governance and Development.</li> </ul>
<b>20.0</b>	<p><b>Reporting Relationships</b></p> <p>The Gold Coast Hospital and Health Service HREC will:</p> <ul style="list-style-type: none"> <li>Report to the GCHHS CE via the Executive Director of Clinical Governance, Education and Research.</li> <li>Report monthly to GCHHS Divisions and Executive Management Team and to the Board on a quarterly basis.</li> <li>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.</li> <li>Liaise with Queensland Hospital and Health Services, Universities, other research facilities and research personnel, as appropriate.</li> <li>Acknowledge that the GCHHS CE, or Delegate, of individual Hospital and Health Services will have the right to not approve the conduct of a research project within its Jurisdiction.</li> <li>Report annually to the NHMRC, as the certifying body under the National Certification Scheme, on the number of multi-centre research proposals reviewed by the HREC via the NHMRC annual report–. Report as required to the NHMRC, changes to the HREC composition and/or HREC administrative officers.</li> </ul>
<b>21.0</b>	<p><b>Periodic Performance Review</b></p> <p><b>21.1</b> The HREC will consider the function and operating principles of the Committee as part of the broader review of the Committee structure no later than September for the forward year.</p> <p>It will consider the outcomes and conduct of the Committee in the previous year and consider changes to the Terms of Reference for the year to come.</p> <p><b>21.2</b> Key Performance Indicators (KPI) for the committee are:</p> <ul style="list-style-type: none"> <li>As per the National Health and Medical Research Council requirements, the HREC will review applications within 60 days (excluding stop clock days).</li> <li>Make public the waivers of consent granted via the GCHHS Annual Research Report.</li> <li>Report number of HREC applications reviewed and average HREC review times as required and on a quarterly basis to the GCHHS Board.</li> </ul>
<b>22.0</b>	<p><b>Amendment to the Terms of Reference</b></p> <p>These Terms of Reference may be amended by following the procedure below:</p> <p>For those proposals made by a HREC member:</p> <ul style="list-style-type: none"> <li>The proposal must be in writing and circulated to all HREC members for their consideration.</li> <li>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.</li> <li>The proposal shall be ratified if two thirds of the members agree to the amendment.</li> <li>The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.</li> </ul> <p>For those proposals made by the Chief Executive:</p> <p>The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.</p>

<b>23.0 Change Log</b>			
<b>Date</b>	<b>Recommender</b>	<b>Change</b>	<b>Accepted</b>
24 November 2010	I Pieper	HoMER	24 November 2010
11 March 2011	M. Moriarty	Intro; 1.42; 1.51; 1.52; 2.3.10; 2.3.15; 2.5.3; 3	
03 November 2011	I Pieper	Administrative	
03 November 2011	I Pieper	2.2.6 MoU	
03 November 2011	I Pieper	2.5.4 Designated Person	
4 November 2011	T Chase	Administrative	
23 December 2011	I Pieper	Administrative for NHMRC reporting	
27 June 2012	I Pieper	Changes related to change of Institution	
27 June 2012	I Pieper	Include provision for Deputy Chair	25 July 2012
10 October 2012	I Pieper	Change of Logo	
18 December 2012	I Pieper	Designated Person change	23 January 2013
25 February 2014	V Constable / T Douglass	Administrative	
21 February 2017	V Druett / C Hoye	ToR template update, administrative changes, change of designated person, update in line with current legislation and processes.	
15 February 2017	C Hoye	Administrative and inclusion of delegation for the HREC Coordinator to make decisions on and sign correspondence for administrative submissions to the HREC.	28 February 2018