

# Terms of Reference

## Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160)

### Purpose

The purpose of the Gold Coast Hospital and Health Service Human Research Ethics Committee (GCHREC) is constituted and functions in accordance and compliance with the:

- National Statement on Ethical Conduct in Human Research 2023 ('National Statement')
- Australian Code for the Responsible Conduct of Research
- Queensland Health: Research Ethics and Governance Health Service Directive
- Department of Health Research Management Policy (QH-POL-013:2022) (or its replacement).
- National Safety and Quality Health Service Standards
- Human Rights Act 2019

The role of the GCHREC is to “approve, request amendment of, or reject a research proposal on ethical grounds” (National Statement on Ethical Conduct in Human Research 2023 5.2.7, p 94). The Chair, upon recommendation of the Committee, may grant ethical approval for research proposals. The GCHREC has been certified by the National Health and Medical Research Council (NHMRC) – EC00160, to conduct reviews of research conducted within jurisdictions participating in the National Mutual Acceptance (NMA) model and participates in the Queensland Health single ethical review process.

The GCHREC protects research participants to ensure that all clinical, research and management practices are conducted in accordance with the ethical principles as set out in the National Statement 2023. Key objectives of the Committee are to:

- Safeguard the mental and physical welfare, rights, dignity and safety of participants involved in human research;
- Facilitate and promote high quality ethical research through efficient and effective review processes; and
- Ensure that all clinical and health research conducted within or in collaboration with GCHHS is conducted responsibly and in the interests of the wider community.

These Terms of Reference establish the Committee's purpose, scope and functions, objectives, key performance indicators, guiding principles, membership, reporting and administrative arrangements.

### Scope and function

The GCHREC is appointed by the Gold Coast Hospital and Health Service and considers submitted research protocols involving humans across GCHHS and other jurisdictions participating in the NMA.

The GCHREC has a regulatory/advisory role and does not hold financial, procurement or any other form of delegation. As the GCHREC role is advisory in nature, it does not replace management's primary responsibilities and delegations.

The functions of the GCHREC set out below are a non-exhaustive description of how the GCHREC will give effect to its purpose:

- Provide balanced, independent, and timely review of research protocols eliciting expert opinion where necessary, involving human participants in respect to their ethical acceptability and scientific merit.
- Review and where appropriate recommend approval of research.
- Oversee approved research protocols during the research until completion to ensure they comply with approved ethical standards, legislation, codes of practice and policies.

- Obtain expert opinions (external or internal) as required to provide scientific/technical assessment and evaluation of health and medical research protocols enabling compliance with regulatory requirements
- The GCHREC shall consider non-research matters which require consideration by a formally constituted Human Research Ethics Committee, e.g. as specified by the Therapeutic Goods Administration.

## Authority and Decision Making

The GCHREC will oversee the monitoring of approved research until completion and the provision of final reports to ensure that the research has complied with approved ethical standards along with relevant legislation, regulations, codes of practice, policies and procedures.

Decisions by the GCHREC as to whether the research protocol meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the GCHREC.

The Committee may make recommendations related to health and medical research conduct within or in collaboration with GCHHS to the Executive Research Council for approval or noting. Issues unable to be resolved by the Committee will be escalated to the Executive Director Strategy, Transformation and Major Capital.

Formal mechanisms of standard reporting include the HREC Annual Compliance Report to the NHMRC, minutes for all GCHREC meetings signed off by the Chair, and reporting to relevant GCHHS committees as required.

## Membership

Consideration should be taken when selecting members of a Committee with regards to who are the subject matter experts, who is a member with voting power and who is a standing invitee. Members and guests will act in accordance with the Code of Conduct.

The ED STMC shall appoint members of the HREC, in consultation with the HREC and other senior HHS officials, as deemed appropriate.

The membership of the GCHREC is constituted according to the National Statement:

*5.1.30 The minimum membership of an HREC is eight and must include the following categories:*

- (a) a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- (b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- (c) a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
- (d) a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;
- (e) a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters; and
- (f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend

Additional members will be considered by the Chair, GCHREC and recommended to the GCHREC for membership of the Committee.

The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms subject to the approval of the ED STMC.

**Conflict of Interest**

- To meet the ethical obligations under the Public-Sector Ethics Act 1994, members must declare any conflicts of interest, whether actual, potential, apparent, or likely to arise, and manage those in consultation with the Chair. In relation to specific agenda items of Committee meetings, real, potential, or apparent conflicts of interest are to be advised at the beginning of each Committee meeting. A register of conflicts of interest will be maintained by the Secretariat.
- Committee members (and other attendees) must, at the start of the meeting, declare any conflicts of interest whether actual, potential, or perceived. The Chair of the Committee must require the conflicted person to leave the room while the remaining members determine whether the conflicted person is entitled to attend the meeting for the discussion.

**Confidentiality**

- Members of the Committee may receive information that is regarded as ‘commercial-in-confidence’, clinically confidential or has privacy implications. Members acknowledge their responsibility to maintain confidentiality of all information that is not in the public domain.

<b>Chair</b>	<p>The Chair will be appointed by ED STMC in accordance with the National Statement Section 5.1.30:</p> <p>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 ED STMC appoints a replacement, or for a time not exceeding six consecutive meetings.</p>
<b>Secretariat</b>	<p>The Secretariat support function will be provided by the Office of Research Governance and Development.</p> <p>The role of the Secretariat includes:</p> <ul style="list-style-type: none"> <li>• the preparation of meeting papers and administrative support</li> <li>• prepare and maintain a corporate file of the Committee’s records</li> <li>• delegated responsibility to sign correspondence on behalf of the Chair where the Chair and/or GCHREC have made a decision on a submission, and</li> <li>• delegated responsibility to make a decision and sign correspondence for submissions of an administrative nature, including administrative amendments</li> </ul>
<b>Members</b>	<p>Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the ED STMC.</p> <p>Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. 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. In addition:</p> <ul style="list-style-type: none"> <li>• Members provide their services and expertise on a voluntary basis. Other than the HREC Chairperson, 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.</li> <li>• Newly appointed members shall be provided with orientation, induction and mentoring and attend continuing education and training in research ethics at least every three (3) years relevant to the work and responsibilities of the HREC, at the expense of the GCHHS, and at the discretion of the Committee.</li> </ul>

	<ul style="list-style-type: none"><li>• Reappointment is by offer, or application to the Chair of the HREC who will then make a recommendation to the ED STMC.</li><li>• 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.</li><li>• 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.</li></ul> <p>The ED STMC may terminate the appointment of any member of the HREC if the ED STMC 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 and the person has failed to carry out their duties as an HREC member.</p> <p>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.</p>
<b>Invited Guests</b>	<p>Other clinical and non-clinical staff invited guests may be required to attend, either to provide subject matter expertise or additional information to the GCHREC. All invited guests will be orientated to the confidentiality and privacy requirements incumbent upon committee functions by the Secretariat.</p> <p>Where agreed by the Chair, members may occasionally invite persons outside the membership of the committee to attend a meeting of the committee and participate in its deliberations. Typically, these persons will have specialist technical knowledge or insight into a particular discussion. Invited guests do not assume membership or participate formally in the consensus process of developing a recommendation from the meeting.</p> <p>Pool of expert reviewers:</p> <p>The Office of Research and Innovation co-ordinates a substantial pool of available experts in a wide variety of research areas. These experts can provide reports on specific studies upon request. These experts may be accessed at any time that the HREC requires additional scientific expertise. The GCHREC 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.</p>

## Risk Management

The Enterprise Risk Management Framework of the Gold Coast HHS includes the roles, responsibilities, and reporting requirements of various Committees within the Gold Coast HHS. The GCHREC is responsible for reviewing relevant compliance accountabilities identified in the GCHHS Compliance Register and escalating any compliance breaches or potential breaches to the relevant Executive/manager or governing committee.

The risk management role of the GCHREC when required, is to:

- Identify actual or emerging risks in the course of filling its functions.
- Analyse and evaluate the risk.
- Escalate to decision makers when required.

Queensland Health provides indemnity for members of the HREC and Expert reviewers 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).

## Work Plan and Reporting

The Committee Workplan shown at Appendix 1 has been developed in line with the responsibilities and key performance indicators outlined in the Terms of Reference. Each year, the Committee Workplan will form the basis of an Annual Committee Workplan to be developed throughout the year to include additional discussion items as and when required.

The GCHREC will:

- Report to the Executive Director of Strategy, Transformation, Major Capital and Digital.
- 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 Hospital and Health Services, Universities, other research facilities and research personnel, as appropriate.

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.

## Key Performance Indicators / Deliverables

The agreed KPIs for the Committee include:

- Service agreement KPIs, which the Committee is responsible for;
- ACHS accreditation indicators; and
- Other agreed KPIs

The GCHREC will consider the function and operating principles of the Committee as part of the broader review of the Committee structure no later than November for the forward year.

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.

Key Performance Indicators (KPI) for the committee are:

- As per the National Health and Medical Research Council requirements, the HREC will review applications within 60 days (excluding stop clock days).
- Make public the waivers of consent granted via the GCHHS Annual Research Report.
- Report number of HREC applications reviewed and average HREC review times as required and on a quarterly basis to the GCHHS Board.

## Governance

In performing its functions, the Committee must recognise and adhere to the principles set out in Section 13 of the Hospital and Health Boards Act 2011(Qld), Section 25 of the Public Service Act 2008 (Qld), and Section 61 of the Financial Accountability Act 2009 (Qld).

Members of, and attendees at the Committee, must conduct themselves in accordance with the Gold Coast Hospital and Health Service Values:

- Integrity,
- Community First,
- Excellence,
- Respect,
- Compassion, and
- Empower.

## Committee performance and changes to the Terms of Reference

The GCHREC will review its performance on annual basis through an annual self-assessment process (refer Appendix 2) and advise the ED STMC of the results of such assessment.

The Chair may provide Committee members with feedback on their contribution to the Committee's activities, and periodically arrange professional development for Committee members.

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 ED STMC/Chief Executive -

- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

## Meeting Operations

<p><b>Frequency of Meetings</b></p>	<p>Committee meetings will be held monthly, except for December when there will be no scheduled meeting. However, in months involving significantly higher submission numbers a second meeting may be held following an adequate period of notice to members (minimum two weeks).</p> <p>An annual calendar of meeting dates will be published and made available on the Gold Coast Health Research website.</p> <p>Cancellation and re-scheduling of meetings will be at the discretion of the Chair. Notice of meetings will be given to members for the current year and at least two (2) weeks prior to a meeting.</p>
<p><b>Retention of Records</b></p>	<p>Files must be kept securely and confidentially in accordance with the requirements of the Public Records Act 2002. Records must also be retained in accordance with Queensland Government's General Retention and Disposal Schedule for Administrative Records. In general, papers considered by the Committee are retained permanently.</p> <p>Meeting documentation, agendas, minutes, action items and supporting papers will be filed and stored by the Secretariat electronically.</p>
<p><b>Quorum Arrangements</b></p>	<p>In line with the National Statement Sections 5.2.3 - 5.2.5 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 have been recorded and considered. (National Statement 5.2.5)</p> <p>Members participating in a meeting by use of technology, such as teleconferencing, are taken to be present at the meeting.</p>

<b>Agenda</b>	<p>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.</p> <p>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.</p> <p>When a submission, including amendments, is accepted by the HREC, the HREC Coordinator and /or Research Ethics Officer will continue the process of HREC review and approval as per the HREC SOP. The agenda should be set allowing for appropriate consultation to include emerging issues and emphasis on the most significant risks and threats.</p> <p>Members wishing to place items on the agenda must notify the Secretariat at least ten (10) business days prior to the scheduled meeting. The agenda must be cleared by the Chair prior to distribution to members. Late agenda items will be tabled at the discretion of the Chair.</p>
<b>Papers, Submissions and Reports</b>	<p>Papers in respect to agenda items are to be supplied to the Secretariat no later than ten (10) business days prior to the scheduled meeting via email to <a href="mailto:GCHEthics@health.qld.gov.au">GCHEthics@health.qld.gov.au</a>, or if related to a specific research application, must be submitted via the ERM portal.</p> <p>Papers must be submitted on the correct cover paper template, available from the Secretariat. All papers must be submitted in Word format (as per Committee cover paper template), unless otherwise agreed. The numbers and names of electronic attachments must mirror the numbers and names used in the cover paper. Papers are quality reviewed by the Secretariat and cleared by the Chair before distribution to the Committee.</p> <p>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.</p>
<b>Minutes</b>	<p>Minutes of meetings will be prepared by the Secretariat within three business days of the meeting. Minutes (and action items) must be cleared by the Chair within five business days of the meeting, subject to confirmation by the Committee at the next meeting, prior to distribution to Members.</p> <p>Minutes will be distributed to all Members immediately, once cleared by the Chair. Minutes are included in the meeting papers and are taken as draft until they are ratified at the next meeting of the Committee. Meeting minutes must reflect compliance considerations and their part in any decision-making process.</p> <p>A copy of the minutes of meetings will be provided to the ED STMC or his/her delegate for noting on a quarterly basis. 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.</p> <p>The minutes of meetings will be uploaded to ERM, or its replacement.</p>


	<p>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.</p> <p>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.</p>
<b>Urgent out of sessions matters</b>	<p>Items can be managed out-of-session where the item is urgent and must be considered before the next scheduled meeting. Out-of-session matters must be ratified at the next meeting of the Committee.</p>

**Terms of Reference Approval**

These Terms of Reference have been endorsed by the GCHREC, approved by the ED STMC and noted by the Executive Research Council

**Name: Sandip Kumar**

**Position: Executive Director, Strategy, Transformation, Major Capital and Digital**

Signature:  ..... Date: .....24/04/24.....

**Document History**

Date	Nature of Amendment	Version
13 <sup>th</sup> October 2023	Transfer of TOR onto corporate template and update to all sections to align with National Statement 2023	v1.1



Deliverable	Description	Responsible	Category (R, N, F)*	Due date/s
<b>Review Work Plan and Committee Terms of Reference</b>	<b>Annual Review of the Committee Terms of Reference with attached work plan.</b>	<b>Secretariat</b>		
<b>Review of Committee Evaluation</b>	<b>Annual Review of the Committee Evaluation (Effectiveness and Efficiency)</b>	<b>HREC Coordinator</b>		
<b>National Standards Governance Committee</b>	<b>Quarterly Completion of National Standard Self – Assessment and Monitoring Tool</b>	<b>HREC Coordinator</b>		

\* Category: Recommendation to the ED STMC (R), Noting (N), Feedback

