Terms of Reference

Children's Health Queensland Human Research Ethics Committee

Purpose

The Children's Health Queensland Human Research Ethics Committee (HREC), [EC00175] located at the Centre for Children's Health Research, Queensland Children's Hospital, is constituted and functions in accordance with the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research 2023; and complies with the 'Australian Code for Responsible Conduct of Research (2018)' and QH Research Management Policy and Framework.

The HREC ensures best-practice bioethics in all domains of paediatric healthcare in Queensland since its establishment in 1968. The Committee is the oldest paediatric Ethics Committee in Australia.

The HREC acts in a consultative and advisory capacity with researchers to ensure that all clinical, research and management practices are conducted in an ethical and scientifically robust manner. Key objectives of the HREC are to:

- To identify the ethical implications and consequences of the proposed research and provide advice on strategies that minimise risks and harms
- To ensure proposed research is designed with respect for all participants
- To ensure proposed research is justifiable by its potential benefit, which may include its contribution to knowledge and understanding, improved social welfare and individual wellbeing, is appropriate to the skill and expertise of the respective researchers; and
- To ensure that proposed research meets the requirements of the National Statement and is consistent with Queensland Health policies and relevant Commonwealth and State/Territory statutory and legislative requirements.

Scope of Responsibilities and Functions (National Statement 5.1.29)

The CHQ HREC is appointed by and acts in an advisory capacity to the Children's Health Queensland Hospital and Health Service. The Committee considers all research protocols within Children's Health Queensland (CHQ).

The CHQ Executive or Delegate, upon recommendation of the Committee, may grant approval for research proposals conducted within its facilities. The Committee also reviews multi-centre research from other Hospital and Health Services, Jurisdictions and practices (including private health facilities). The Committee may review proposals from external organisations on a case-by-case basis if required. The Committee is certified by the NHMRC to conduct reviews of Australian Multi-centre Research and participates in the National Mutual Acceptance Scheme.

The CHQ HREC is certified to undertake single ethical review of research undertaken in any of the following research categories:

- Paediatric clinical trials Phase I, II, III & IV

- Paediatric clinical trials drugs and devices
- Paediatric clinical interventional research other than clinical trials
- Paediatric population health and/or public health
- Paediatric qualitative research
- Paediatric mental health
- Paediatric justice health
- Other health and medical research – Paediatric research with adult component.

The CHQ HREC:

- Review and approve in line with its NHMRC certification via single ethical review for multi-centre research and in accordance with Queensland Health policies and procedures, and Memoranda of Understanding between Queensland Health and public sector health services in other States and Territories, Mater Health Services Brisbane and QIMR Berghofer Medical Research Institute
- Provide independent, competent and timely ethical review and oversight to protect the mental and physical welfare, rights, dignity and safety of participants in research and promotes ethical standards of research
- Provide ongoing monitoring of approved research studies
- Provides advice, as required, to the Executive Director Medical Services when the HREC considers ethics approval for a research study should be withdrawn
- Obtain expert opinions (external or internal) as required to provide legal, scientific and technical assessment of research protocols, evaluation of clinical trials and compliance with regulatory requirements
- Maintain a register on the state-wide database of, all research applications submitted to the HREC, monitoring and reporting requirements and ongoing approval status of proposals, including amendments, and;
- Review and evaluate non-research submissions which require consideration by a formally constituted HREC for example, authorised prescriber applications as specified by the Therapeutics Goods Administration.

Relationships and Reporting

The HREC was established by Children's Health Queensland in keeping with the National Statement on Ethical Conduct in Human Research (2023 section 5.1.24 – 5.1.28). Its reporting and liaison role includes:

- Reporting to the CHQ Hospital and Health Service (HHS) Chief Executive via the Executive Director of Medical Services. Formal mechanisms of reporting include: (a) submission of all minutes for HREC meetings signed by the Chairperson; (b) submission of the HREC Annual Compliance Report to the National Health and Medical Research Council (NHMRC). This ensures the annual re-accreditation and registration of the Committee as a compliant human research ethics committee; c) an Annual Report to the CHQ Executive; and d) regular reporting of research metrics, safety data and HREC activity to CHQ Board Research Committee;

- Liaising with all Queensland Health Services, Universities, other research facilities and research personnel on all matters relating to bioethics;
- Reviewing and potentially recommending approval of all research undertaken within CHQ HHS; and collaborating, in the context of multicentre research, with other centres based in other Hospital and Health Services, jurisdictions and practices, and;
- Overseeing the monitoring of approved research, in conjunction with the Monitoring and Compliance Officer until completion; and the receipt and review of final reports to ensure that the research has complied with approved ethical standards, and compliance with all relevant legislation, codes of practice, policies and regulations

HREC Composition and Appointment (National Statement 5.1.30– 5.1.47)

Establishment

The HREC membership is constituted in accordance with the NHMRC National Statement and includes members in each of 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

Each member is appointed by the Executive Director of Medical Services following consideration of recommendations from the Chair of the HREC, acting on behalf of the HREC, as deemed appropriate

Appointment of Chairperson and Deputy Chairperson

The Chairperson and Deputy Chairperson of the HREC are appointed by the CHQ Executive Director Medical Services.

In the absence of the Chairperson, or by mutual agreement, the Deputy Chairperson will perform the duties of the Chairperson.

In the absence of both the Chairperson and Deputy Chairperson, an Acting Chairperson may be appointed by the CHQ Executive Director Medical Services.

Appointment of Members

The CHQ Executive Director Medical Services shall appoint members of the HREC, in consultation with the HREC.

Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.

Before appointment, potential members will be required to provide a copy of their Curriculum Vitae to confirm qualifications. Upon appointment, members acknowledge in writing their acceptance of the terms of reference of the HREC and any requirements for confidentiality and conflict of interest required by Queensland Health.

Members are appointed for a period of three years and may serve consecutive terms as approved by the CHQ Executive Director Medical Services.

Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

The Chairperson and Deputy Chairperson(s) may serve longer terms with the approval of the CHQ Executive Director Medical Services.

Reappointment will be considered by the Chairperson of the HREC.

Membership will lapse if a member fails, without reasonable excuse or without notifying the Chairperson, to attend (or provide comments) to three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson will notify the member in writing 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 CHQ executive Director Medical Services may terminate the appointment of any member of the HREC if they are of the opinion that: a) it is necessary for the proper and effective functioning of the HREC b) the person is not a fit and proper person to serve on an HREC c) the person has failed to carry out their duties as an HREC member.

Members will be provided with a letter of appointment including the date of appointment, length of tenure, and assurance that indemnity will be provided by Queensland Health in respect to the conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as an HREC member. Members will also sign an annual Conflict of Interest Declaration.

Members are not offered remuneration; however, members will be reimbursed for legitimate expenses incurred in attending HREC meetings, or otherwise in carrying out the business of the HREC.

Members are expected to act, at all times, in a manner consistent with proper and respectful behaviour to all people involved in the HREC, in accordance with the Code of Conduct for the Queensland Public Service.

Members will be required to sign a statement undertaking: a) that all matters of which they become aware during the course of their work on the HREC will be kept confidential; b) that any conflicts of interest, which exist or may arise during their tenure on the HREC, will be declared, and c) that they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as an HREC member.

Administrative Support

The HREC is supported by an experienced Human Research Ethics Coordinator. This role includes all aspects relating to service of the HREC; extensive liaison and advisory functions, on behalf of the HREC, communicating with researchers; and a significant ambassadorial and educational role on all matters relating to best-practice healthcare, specifically in the bioethics domain

Administrative support will be provided by staff of the Research Director of Children's Health Queensland

Administrative support will be provided in accordance with the National Statement and the Queensland Health Standard Operating Procedures for HREC Administrators.

The Chairperson delegates the HREC Coordinator, and the HREC Support Officer to sign correspondence on behalf of the Chairperson where the Chairperson and/or HREC have made a decision on the submission.

The Chairperson delegates the HREC Coordinator, and the HREC Support Officer to make a decision and sign correspondence for submission of an administrative nature, including minor amendments.

HREC Liability Coverage

Queensland Health provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising their duties as a member in good faith.

Queensland Health provides indemnity for external expert reviewers for any liabilities that arise as a result of the reviewer exercising their duties in good faith.

Induction, Mentoring and Training

The CHQ Human Research Ethics Office provides new members with induction material and mentoring via the Chairperson, CHQ HREC Office and other members of the HREC. New members attend initial meetings as an observer.

All members are required to attend continuing education courses and training in research ethics and regulation (at least every three years). Throughout their tenure, members are given the opportunity to attend conferences and workshops, supported by Children's Health Queensland, that are relevant to the roles and responsibilities of the HREC.

All members are strongly encouraged to complete GCP training every 3 years.

Committee Procedures

Frequency of meetings

Meetings will be held every 6 weeks.

A timetable for meeting dates will be published on the CHQ Research Ethics and Governance website and on the Queensland Health website.

Attendance can be in-person or via videoconference.

Members may nominate to attend alternate meetings by prior arrangement with CHQ HREC Chairperson.

A copy of the agenda, previous minutes, new protocols for consideration, (including the HREA, patient information and consent forms, questionnaires or other relevant correspondence, where applicable), along with any other papers relevant to the agenda of the meeting, will are forwarded to all members 1-2 weeks prior to the meeting.

HREC Procedures

The HREC will perform its functions, including the monitoring of research and handling of complaints, in accordance with the Standard Operating Procedures (SOP) for Queensland Health HREC Administrators or other applicable CHQ or Queensland Health Policies and Procedures.

All HREC members shall have access to and/or be provided with copies of the SOP.

Applications

- The HREC requires all submissions to be in a standard format using the National Human Research Ethics Application Form (HREA) form available on the Ethical Review Manager (ERM) Website.
- The HREC requires researchers to (i) electronically upload all supporting documents onto the ERM website and (ii) submit hard copies of the protocol and associated study documentation.
- The Chair in consultation with the Committee members, will determine if any additional expert advice in relation to scientific review is required.

Before giving approval for a submitted research project, or amendment, the HREC requires assurance that current best-practice bioethical themes apply to all aspects of:

- Scientific design and conduct of the study;
- Recruitment of research participants and appropriate consumer engagement has been considered;
- Informed consent process;
- Care and protection of research participants;
- Protection of research participants' confidentiality; and
- Local community considerations, particularly if the research may involve Aboriginal and/or Torres Straight Island population.

All submissions must adhere to the values and principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research (2023):

- Research merit and integrity
- Justice
- Beneficence
- Respect

Levels of Ethical Review

Low and Negligible Risk Research (National Statement Section 2 and Section 4.1.20-5.1.23)

Research that carries only negligible risk and involves the use of existing collections of data (or records that contain only non-identifiable data about human beings) may be exempted from full ethical review. The National Statement (2023) recognises that the levels of ethical review for low risk and negligible risk research may include, but need not be limited to:

a. Review or assessment at departmental level by the Head of Department;

b. Review or assessment by a departmental committee of peers (with or without external or independent members);

c. Delegated review with reporting to an HREC; or

d. Review by a subcommittee of an HREC.

In keeping with the National Statement, the CHQ HREC provides review of low risk research protocols via a Low Risk Review Panel. The Low Risk Review Panel will recommend approval of the low risk protocol, to be ratified by the HREC at the next meeting.

Research identified as higher than Low Risk

Any research identified as involving more than low risk must be referred to the HREC for full review, except in exceptional circumstances as stated below.

Multi-centre research studies reviewed and approved by another HREC

The HREC may approve a protocol without further ethical review, which another NHMRC-certified ethics committee has approved; and, in addition, the protocol conforms to the required standards of the HREC. The HREC reserves the right to ratify any previous decision; or to instigate its own review process; or to request amendments or clarification; or to reject the protocol.

Exceptional circumstances exempt from full ethical review

In exceptional circumstances, where as a matter of public policy, and in the national interest, it is essential than an application should be reviewed urgently (to allow health-related research to commence as quickly as possible), the CHQ HREC may grant approval under exceptional circumstances for a protocol where:

- Another Committee has approved the protocol and the protocol appears to conform to the requirements of the HREC; and
- Informed clinical opinion necessitates urgent approval of the protocol.

Meeting Protocol (National Statement Sections 5.2.1-5.2.4, 5.2.28-5.2.31)

- Decisions by the HREC 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 HREC;
- Where there is less than full attendance of the minimum membership at a meeting, the Chair must be satisfied, before a decision is reached, that those members unable to attend the meeting have received all papers and have had an opportunity to contribute their views and that the views of all members have been recorded and considered. Members who are unable to attend a meeting are asked to contribute and advise their opinion to the HREC Coordinator prior to the meeting;
- Meetings are held in the Boardroom on Level 6, Centre for Children's Health Research Building;

- The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting to discuss a proposal but will be required to leave the meeting before any decision is taken. For all Phase 1/2 projects, Project Investigator (or a representative) must attend the meeting to provide an overview of the project;
- Members of the Committee will be required to declare any conflict of interest (real or perceived) prior to, or at any time during a meeting, such as when the member is associated with a research protocol under review by the Committee. The Committee will determine any action to be taken including excluding the member from the meeting during deliberation of the particular protocol;
- In general, decisions of the HREC are reached by a consensus rather than by simple voting majorities, and;
- The appointed Chair chairs every meeting. If the Chair is absent (due to unavoidable circumstances), or is excluded because of a conflict of interest, the meeting is chaired by the Deputy Chair.

HREC Decisions

- The minutes of all HREC meetings are recorded on the ERM Database;
- Minutes 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 where applicable;
- Draft minutes are forwarded to the Chair as soon as practical after the meeting;
- Action following decisions recorded in the draft minutes are initiated no sooner than 48 hours after circulation of draft minutes, and;
- Advice to researchers, regarding the ethical consideration and approval of protocols, includes details of reporting requirements and monitoring processes.

Monitoring (National Statement Sections 5.5 and 3.3

Both the Institution and the HREC act in accordance with the National Statement in relation to monitoring approved research. Such requires the Principal Researcher (including Co-ordinating Principal Investigator for multicentre research) to:

- Keep adequate records (hard copy and/or electronic) and provide access to those records when requested to the HREC;
- Provide annual progress reports at intervals specified by the HREC and at completion of any research;
- Notify and provide reports, in a timely fashion, to the HREC of significant events (including Serious Adverse Events [SAE] and/or Suspected Unexpected Serious Adverse Reactions [SUSAR]), complications and protocol violations occuring at any time during the conduct of research, detailing the course of action taken. Where relevant, Principal Investigators will notify the outcome of monitoring visits by trial sponsors. In relation to sponsored clinical trials and investigator-initiated trials involving drug or device interventions the notification of adverse events should be in keeping with the NHMRC Monitoring Framework;
- Notify the HREC of any complaints received from research participants; and from staff, observers or members of the community;
- Provide prospective advice of any proposed amendment(s) to be made to the protocol and seek approval of these prior to implementation;

- Notify and provide reasons to the HREC if the research is to be discontinued before the expected date of completion of the project, and;
- Provide a copy of published articles/results, presentations or posters at conferences etc. to the HREC.

The HREC may:

- If required, request an interview with the researchers, research participants or seek other forms of feedback from them;
- If required, request random inspections or access to research sites, research data and consent documentation records, and;
- If considered necessary, request the opinion of external experts.

Complaints (National Statement Section 5.6)

In keeping the National Statement and the "Australian Code for the Responsible Conduct of Research 2018", the institution has nominated a 'designated person' for handling research complaints, including research misconduct.

Research Participants

- The 'designated person' in the first instance is the Co-ordinator for the Children's Health Queensland Ethics Committee;
- Information Sheets must include contact details of the HREC Co-ordinator to ensure such complaints can be communicated;

Researchers

- Complaints on the process, conduct or decisions of the HREC should be made in writing to the Chair of the HREC via the Co-ordinator. The Chair of the HREC will determine action to be taken. This may necessitate a special meeting of the HREC;
- All complaints will be acknowledged with seven days. The complainant will be advised of the decision of the HREC within 30 days. If the complainant does not accept the decision of the HREC, the complaint may be communicated to the Executive Director of Medical Services for further consideration, and;
- Any concerns, complaints or allegations about the conduct of a research protocol will be recorded in a register and also to the local site Research Governance Officer. Processing of research complaints regarding the HREC review process is in accordance with the Queensland Government Department of Health HREC Administrators SOP and will also be recorded in a register.

Amendment to the Terms of Reference

These Terms of Reference may be amended by following the procedure below:

- The proposal must be in writing and circulated to all HREC members for their consideration to allow for the views of members to be discussed at the next scheduled meeting of the HREC for ratification;
- Proposed amendments may be made be a member of the HREC, and;
- The Chairperson shall send the amendment to the Executive Director of Medical Services.

Document History

Version	Date	Changed by	Nature of amendment
1	27/1/10	Amanda Smith	Creation of document.
2, 3, 4, 5, 6	12/8/10	Amanda Smith	Minor administrative updates.
7	13/3/17	Amanda Smith	Review of approved document.
8	27/11/18	Amanda Smith	Update to Institution, Database and Ethics submission names.
9	12/8/20	Amanda Smith	Remove QLD LNR reference, minor administrative updates.
10	21/7/21	Amanda Smith	Updated branding and minor administrative updates.
11	26/9/22	Amanda Smith	Minor administrative updates.
12	5/9/24	Amanda Smith/Rebecca Doyle	Significant updates to incorporate updated National Statement

Previous versions are recorded and available for audit.