



**Queensland
Government**

TERMS OF REFERENCE

**Children's Health Queensland
Human Research Ethics Committee
EC00175**

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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' (2007); and complies with the 'Australian Code for Responsible Conduct of Research (2007) and QH Research Management Policy and Framework (QHRMP; 2010).

The HREC is the successor to the Ethics Committee of the (former) Royal Children's Hospital, Brisbane. This direct succession has ensured 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 protect the physical and mental welfare, rights, dignity and safety of all participants in healthcare research
- To facilitate ethical research through efficient and effective review processes
- To promote the highest ethical standards of human research
- To ensure that all clinical and health research is conducted ethically and responsibly

1. Scope of Responsibilities and Functions (National Statement 5.1.27)

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.

The CHQ Executive or Delegate, upon recommendation of the Committee, may grant approval for research proposals conducted within its facilities. Furthermore, the Committee reviews multi-centre research from other Hospital and Health Services, Jurisdictions and practices (including private health facilities). The committee can 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 Queensland Health single ethical review process.

The Children's Health Queensland Human Research Ethics Committee is certified to undertake single ethical review of research undertaken in each 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:

- Provides balanced, independent and timely review of research projects with respect to their ethical acceptability and scientific merit.
- Oversees approved protocols during the course of the research until completion to ensure that they comply with approved ethical standards, legislation, codes of practice and policies.
- May obtain expert opinions (external or internal) as required to provide scientific/technical assessment and safety evaluation of research protocols along with compliance with regulatory requirements.
- Through its Research Ethics Secretariat registers all research protocols submitted to the CHQ HREC along with all monitoring and reporting requirements. It considers and potentially approves all protocol amendments submitted to the HREC during the course of the research.

2. Relationships and Reporting

The HREC was established by Children's Health Queensland in keeping with the National Statement (2007 section 5.1.26). 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; and (c) an Annual Report to the CHQ Executive.
- 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.
- Overseeing the monitoring of approved research 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.

3. HREC Composition and Appointment (National Statement 5.1.29 – 5.1.34)

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, 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.

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 and other senior Health Service officials, as deemed appropriate.

3.5 HREC Liability Coverage

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.

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.

4. *Confidentiality and Conflict of Interest (National Statement 5.4.5)*

- Members of the HREC are required to sign a statement undertaking that any conflicts of interest, which exist or may arise during his or 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 (National Statement section 5.2.4; Chapter 5.4). The Chairperson normally asks any individual, present at meetings, to be excused from the meeting, during any discussion in which a conflict of interest is identified.

5. *Induction, Mentoring and Training*

New members are provided with an HREC Members' Induction manual, attend initial meetings as an observer, and are provided individual mentoring via the Chair and from time to time other members of the HREC.

All members 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.

6. *Remuneration*

All HREC members (except the Chair) provide their services and expertise totally on a voluntary and unpaid basis. All essential and necessary expenses incurred by the members in carrying out their HREC duties are reimbursed.

7. *Committee Procedures*

(a) **Protocol Submissions**

- The HREC requires all submissions to be in a standard format using the National 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;
- Informed consent process;
- Care and protection of research participants;
- Protection of research participants' confidentiality; and
- Local community considerations.

All submissions must adhere to the values and principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research (2007):

- Research merit and integrity
- Justice
- Beneficence
- Respect

(b) **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 (2007) recognised 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. Children's Health Queensland will accept the reviews of other Queensland Health Certified HRECs.

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 that 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.

(c) Meetings (National Statement Sections 5.1.37 and 5.2.28)

- Meetings are held every 6 weeks.
- Meeting dates are available on the websites of the CHQ Centre Children's Health Research, and of the Queensland Health Research Ethics and Governance Unit.
- 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 be forwarded to all members 1-2 weeks prior to the meeting.

(d) 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. Teleconference linkage to individual members unable to be present in person will be acceptable, if required.
- The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is taken.
- 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 the 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.
- 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.

(e) Secretariat Support

The HREC is supported by an experienced Human Research Ethics Co-ordinator. 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.

(f) 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.
- Advice to researchers, regarding the ethical consideration and approval of protocols, includes details of reporting requirements and monitoring processes.

8. *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 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 SAEs and SUSARs), complications and protocol violations that occur 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 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.
- 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.
- If considered necessary, request the opinion of external experts.

9. *Complaints (National Statement Section 5.6)*

In keeping the National Statement and the “Australian Code for the Responsible Conduct of Research 2007”, the institution has nominated a ‘designated person’ for handling research complaints, including research misconduct.

- 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.
- 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.
- 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.

10. *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 by a member of the HREC.
- 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	12/8/10	Amanda Smith	Minor administrative updates.
3	6/3/12	Amanda Smith	Minor administrative updates.
4	8/10/12	Amanda Smith	Minor administrative updates.
5	24/7/13	Amanda Smith	Minor administrative updates.
6	20/1/16	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.

Previous versions are recorded and are available for audit.