



## **Terms of Reference:**

# **Children's Health Services Human Research Ethics Committee**

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# QLD CHILDREN'S HEALTH SERVICES (RCH) HUMAN RESEARCH ETHICS COMMITTEE (EC00175)

## Terms of Reference

### INTRODUCTION

#### Preamble

The QLD Children's Health Services (RCH) Human Research Ethics Committee [EC00175] is a committee established by Children's Health Services, Queensland Health (QH) that is constituted and functions in accordance with the NHMRC '*National Statement on Ethical Conduct in Human Research*' (2007) - *the National Statement (NS)*; and complies with the '*Australian Code for Responsible Conduct of Research* (2007) and *QH Research Management Policy and Framework (QHRMP; 2008)*.

#### 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 relevant Health Services Chief Executive Officer (DCEO), 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(RGO) and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn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 submitted to the HREC, any monitoring and reporting requirements and any ongoing approval status of proposals including amendments

#### Relationships and reporting

The QLD Children's Health Services (RCH) HREC will:

- Report to the DCEO via the Chief Operations Manager where it was constituted.
- Submit a report annually to the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee to maintain accreditation and registration as a compliant human research ethics committee.
- Liaise with Queensland Health Services, Universities, other research facilities and research personnel as appropriate.
- Charge fees to the sponsors of commercial research, as per the QH Research Management Policy, both for the processing (initial application and amendment submissions) and consideration of the protocols.
- Acknowledge that the Health Services CEO of individual Health Services will have the right to not approve the conduct of a research project within its Health Services.

## 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.

### 1.2. HREC appointment of members

- 1.2.1. The Children's Health Services 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. Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive.
- 1.2.6. The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive.
- 1.2.7. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
- 1.2.8. Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.
- 1.2.9. 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.
- 1.2.10. The institutional CEO may terminate the appointment of any member of the HREC if the 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.

- 1.2.11. 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.
- 1.2.12. 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.
- 1.2.13. 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.

### **1.3. Education for HREC members**

- 1.3.1. Newly appointed members shall be provided with adequate orientation 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 Children's Health Services.
- 1.3.3. Members will attend continuing education and training in research ethics at least every two 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 Children's Health Services.
- 1.4.3. Members of the subcommittee need not be members of the HREC.

### **1.5. HREC Liability coverage**

- 1.5.1. QH 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).
- 1.5.2. QH 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 Queensland Government Insurance Fund (QGIF).

## **2. HREC PROCEDURES**

### **2.1. Standard operating procedures**

- 2.1.1. The HREC will perform its functions 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 changes thereto.

### **2.2. Submissions**

#### *All Studies*

- 2.2.1. Excluding exceptional circumstances the HREC will consider every correctly completed 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 is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.

### *Single Site Studies*

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

### *Multicentred Research Studies*

- 2.2.4. The submission of all multi-centre research studies being submitted through the single ethical review process, for review by the lead HREC, will be through the QH Central Coordination Service (CCS) as per the HREC SOP.

## **2.3. Protocols**

- 2.3.1. The HREC will require submissions to be in a standard format using the Application Form available on the online forms website: <https://ethicsform.org/au/SignIn.aspx>.
- 2.3.2. The HREC will require the researcher to electronically upload all supporting documents onto the online forms Application website.
- 2.3.3. The HREC will also require the researcher to submit hard copies of the submission as per the HREC requirements, available on the Research Ethics and Governance Unit website.
- 2.3.4. The Chair along with the members of the HREC Committee and HREC administrator will determine if any expert advice is required for any protocol.

## **2.4. Meetings**

### *General*

- 2.4.1. Meetings will be held in accordance with QH HREC SOP
- 2.4.2. The HREC agenda, accompanied by all required documentation for review of research proposals will be distributed not later than 10 days prior to the HREC meeting.
- 2.4.3. 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.
- 2.4.4. In line with the National Statement Sections 5.2.28 - 5.2.31, 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 has received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- 2.4.5. The contribution of information and opinion from a committee member unable to attend a face to face meeting will be considered along with those opinions and feedback of other committee members in the final decision making.
- 2.4.6. 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.
- 2.4.7. In general, decisions of the HREC will be reached by general agreement and consensus.
- 2.4.8. Members of the committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chairperson will determine the action to be taken.

### *Dates and venue*

- 2.4.9. Meetings will be held approximately every 6 weeks.
- 2.4.10. Meeting dates will be available on the Research Ethics and Governance Unit website.
- 2.4.11. Meetings will normally be held in the Queensland Children's Medical Research Institute Seminar Room.

### *Secretarial Support*

2.4.12. Secretarial support will be provided by the Ethics Co-ordinator.

### *Decisions from HREC meetings*

2.4.13. The minutes of meetings will be recorded on AU RED.

2.4.14. Minutes will 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.

2.4.15. Draft minutes will be forwarded to the Chair as soon as practical after the meeting.

2.4.16. Action following decisions recorded in the draft minutes will be initiated no sooner than 48 hours after circulation of draft minutes. Members who object to the progress of any actions recorded should contact the secretariat within that time frame.

2.4.17. As much as possible, electronic communication will be used to communicate with members and researchers.

2.4.18. Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.

## **2.5. Monitoring**

2.5.1. The HREC requires the Principal Investigator (or Coordinating Principal Investigator for multicentred studies) to:

- Keep adequate research records and provide access when requested to the HREC.
- Provide progress reports at intervals specified by the HREC and at completion of any research but not less than annually.
- Notify and provide reports, in a timely fashion, to the HREC of significant adverse events, side effects or complications occurring including the course of action taken at any time during the research.
- Notify the HREC of any complaints received from participants, staff, observers or 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.

2.5.2. The HREC may:

- If required, request an interview with the researchers, research participants or 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

## **2.6. Complaints**

### *Complaints concerning the conduct of a project*

2.6.1. As per the *Australian Code for the Responsible Conduct of Research 2007* the institution has nominated a '*designated person*' for handling research complaints, including research misconduct.

2.6.2. The '*designated person*' in the first instance is the Co-ordinator for the QLD Children's Health Services Ethics Committee.

2.6.3. Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the '*designated person*' of the institution where the approving HREC sits, to the secretariat of the approving HREC who will enter the complaint details on AU RED and to the local site RGO

2.6.4. Processing of research complaints, including research misconduct and fraud, will be as per the QH HREC SOP.

*Complaints concerning the HREC's review process including the HREC's rejection of an application*

- 2.6.5. Any concern or complaint about the approving HREC's review process should be directed to the attention of the Chairperson of the approving HREC, detailing it in writing.
- 2.6.6. The secretariat of the approving HREC will enter the complaint details on AU RED
- 2.6.7. Processing of research complaints regarding the HREC review process will be as per the QH HREC SOP.

### **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.