

# Terms of reference

## CQHHS Human Research Ethics Committee

<b>Date:</b>	<b>Developed</b> 17/02/15	<b>Reviewed</b> December 2018	<b>Next Review Date</b> By end 2019
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### Purpose

The Human Ethics Research Committee's functions, as determined under the National Statement on Ethical Conduct in Human Research, 2007 (as amended from time to time) are to:

1. examine written proposals relevant to the use of humans in research and approve only those investigations which conform to the Central Queensland Hospital and Health Service's requirements;
2. maintain a register of approved research proposals, received from affiliated and non-affiliated researchers on an annual basis, and provide written authorisation for the commencement of such projects and activities.
3. The HREC has not been NHMRC Certified to undertake the single ethical review of research projects to be conducted at more than one site.
4. The HREC primarily provides ethics review for research being conducted in Central Queensland Hospital and Health Service however can provide ethics review for external entities including but not limited to private sites, general practitioners and other government departments in Australia, within the Committee's scope of knowledge or expertise.

### Objectives

The Human Ethics Research Committee (HREC) is responsible for:

1. ensuring the Commonwealth and State legislation and the codes of practice adopted by the National Health and Medical Research Council (NHMRC and other relevant authorities are complied with);
2. monitoring the progress of approved research projects in order to determine that research protocols are preserved in the form in which they were approved;
3. ensuring that all persons involved in research involving human participants are informed of any policy and procedures in relation to the ethical conduct of such research;
4. monitoring approved projects by way of review of annual and final reports

This Committee operates in accordance with the CQHHS Clinical Governance Framework and incorporates the intent of NSQHS Standard One: Clinical Governance and Standard Two: Partnering with Consumers with acknowledgement of linkages between all National Standards in business decision making.

### Membership

As determined by the National Statement on Ethical Conduct in Human Research 2007 the membership of this Committee shall be:

- Appointed members:
- a. a chairperson

- b. at least two members who are 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 member with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g. a nurse or allied health professional);
- d. at least one member who performs a pastoral care role in a community such as 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.

Ex-officio members:

- a. The Executive Director Rockhampton Hospital (or their nominee) holds an ex-officio position on the Committee
- b. The Executive Director Medical Services (or their nominee) holds an ex-officio position on the Committee.

Each appointment shall normally be for a term of three years and in a voluntary capacity and no remuneration is payable. At the end of the term of office, expressions of interest will be called for the position, and incumbent members will be invited to re-apply, should they elect to do so. It is recognised that in some circumstances, the availability of suitably qualified potential members will require some members to serve for longer periods. Where more applications are received than places available, the Chair of the Committee will conduct interviews to determine appointees.

## HREC Procedures

As determined by the National Statement on Ethical Conduct in Human Research 2007:

- a. Attendance is to be recorded in the minutes.
- b. Where there is less than full attendance at a meeting, the Chair must be satisfied, before a decision is reached, that all members have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered. The contribution of information and opinion from a committee member under able attend a face to face meeting will be considered along with those opinions and feedback of other Committee members in final decision making.
- c. In general, decisions of the HREC will be reached by general agreement and consensus. The deliberations of the Committee will be held in confidence.
- d. The Committee will communicate with researchers, including by face-to-face, by telephone and in writing. Where appropriate face-to-face meetings will be used to resolve issues about research proposals that have not been resolved by written or telephone communication.
- e. The Committee will report to the Health Service Chief Executive through the Executive Sponsor of the HREC, the Executive Director, Rockhampton Hospital as and when required through the reporting structures of the HHS.
- f. The Committee will promptly notify researchers of decisions made by the Committee
- g. The Committee will maintain a record of all research proposals received and reviewed through AU RED which includes the information required by paragraph 5.2.24 of the National Statement.
- h. Monitoring of research given institutional approval and reporting and handling of adverse events will be conducted in accordance with the processes in Schedule A.
- i. The Committee will receive and handle complaints in accordance with the processes in Schedule B.
- j. The Committee may invite researcher/s, and researchers may request to be present for discussion of their proposed research. The Chairperson will determine the action to be taken. Any observers will be asked to sign a Confidentiality Agreement prior to entering the meeting.
- k. Process the charging of fees instigated by Queensland Health 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.

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## Governance

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Identify the appropriate governances for the Committee through:

- National Statement on Ethical Conduct in Human Research 2007 (NHMRC)
- Public Health Act 2005, Chapter 6, Part 4
- Hospital and Health Boards Act 2011
- Research Ethics and Governance Health Service Directive 01/07/2013 (QH-HSD-035:2013)
- *Australian Code for the Responsible Conduct of Research*
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

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## Principles of Operation

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### Chair

The Chair shall be as appointed by the Executive Director Rockhampton Hospital and will be a nominee from the Human Research Ethics Committee members, elected by the committee.

The Chair must:

- ensure that the Committee operates in accordance with the principles and requirements of the *National Statement on Ethical Conduct in Human Research* hereafter the Statement; the relevant policies of the Central Queensland Hospital and Health Service and the Department of Health, and the agreed Committee procedures;
- ensure that proposals are considered by the Committee and the outcomes conveyed to researchers in a timely manner;
- advise the executive sponsor regarding the level of resourcing required by the Committee;
- represent the Committee in any negotiations with management;
- ensure Committee records are maintained and made available for review by the institution and authorised external reviewers.

The Chair shall have delegated authority to:

- approve requests for extension to project where there is no change to the approved project protocols;
- consult with any other members of the Committee and any other parties to seek advice and assistance in addressing matters arising from any report of adverse occurrence or unforeseen event;
- suspend approval for a research/teaching project and advise the Principal Researcher(s), supervisor (if applicable), the executive sponsor and any other formal parties to the project to this effect in writing.

Where the Chair of the committee knows in advance that he/she will not be able to attend a meeting, he/she will approach another member to deputise as Chair. Where the absence is unplanned, the members present will elect one of their number as chair of that meeting.

No member can be appointed/represent two categories of membership. The Chair should be satisfied before a decision is reached that the views of those absent who belong to the minimum membership have been received and considered.

### Secretary/Research Governance Officer

The Committee shall be serviced by secretariat.

The Secretary/Research Governance Officer is responsible for the preparation and distribution of agenda documentation, taking minutes of each meeting, processing all follow-up correspondence, including advising researchers of the outcome of their applications, and all record keeping for the Committee.

## Removal of a Member from Office

Where a member does not attend three consecutive meetings of the committee without adequate cause, that person's membership may be terminated by the Chair. A person who has had their membership terminated may apply to the Chair to have their membership reinstated.

## Conflict of Interest

Committee members are required to bring to the attention of the Chair any conflict of interest or potential conflict they may have with any item on the committee's agenda. The Chair will determine the measures to manage such conflicts of interests and may include exclusion from the meeting, exclusion from the deliberations and requesting advice in writing.

## Meetings

Committee meetings may be held face-to-face, by telephone, videoconference, or other electronic means.

Committee meetings shall be held monthly, with additional meetings, as required and directed by the Chair. Committee members are required to be fully prepared for and make every reasonable effort to attend each meeting.

## Agendas and Minutes

Agendas and associated documentation will be distributed to members by the secretariat at least ten working days prior to any scheduled meeting, to an address nominated by each member. Agendas, associated documents and meeting papers are regarded as confidential.

Except with the express permission of the Chair, late papers will not be accepted, nor will the tabling of papers.

Committee records are subject to the Public Records Act 2002 and therefore must be retained in accordance with the Records Management Policy. Responsibility for ensuring appropriate records management for the committee rests with the Secretary under the direction of the Chair of the committee. The committee shall keep minutes of each meeting. All committee documentation shall be retained in the Central Queensland Hospital and Health Service's corporate electronic records management system. The 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. Decision will be recorded in AURED.

Minutes are to be prepared for each committee meeting. The draft minutes and action sheet of each meeting are to be reviewed by the Chair. A copy of the minutes, once they have been reviewed by the Chair, will be included in the agenda papers for the next committee meeting.

## Reporting Relationships

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This Committee reports to the Central Queensland Hospital and Health Service's Patient Safety, Quality & Risk Committee

The Committee shall submit a written report on its activities at least annually.

In accordance with the *National Statement on Ethical Conduct in Human Research* the Committee shall:

- provide information from its records to the NHMRC on request; and
- annually report to the NHMRC information relevant to its procedures.

## Escalation Methodology

### To Committee:

Issues, recommendations or escalations are to be sent to the secretariat of the committee for discussion of inclusion in the Agenda with the Chair. Details are to be received in the format of the 'Escalation Request'.

### From Committee to Governing Committee:

Issues, recommendations or escalations are to be sent to the secretariat of the governing committee in the format of the 'Escalation Request'. Any issues, recommendations or escalations are to be minuted. The minute number is to be noted on the Escalation Request, and the original is to be signed by the Chair of the Committee.

## Evaluation / Communication

The committee will conduct two evaluations on an annual basis:

Evaluation	Month Due	Forward to
Committee Self Assessment Report		Governing Committee
TOR Evaluation		Governing Committee

## Distribution of Minutes

- The committee secretary will prepare minutes of meetings and have them approved by the Chair before circulating to members within 5 working days.
- Meeting minutes are confirmed at the next meeting.
- Saved in – S:\CQHHS Committees

## Performance Indicators

In accordance with the *National Statement on Ethical Conduct in Human Research* the Committee shall:

- provide information from its records to the NHMRC on request; and
- annually report to the NHMRC information relevant to its procedures.

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## Endorsement

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Next Review Date: By End 2019

## Document Control

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Version	Date	Prepared by	Comments
v0.1	17.02.15	Secretariat	First Draft
v1.0	26.03.15	Secretariat	Approved by HREC
v1.1	24.09.15	Secretariat	Incorporating Comments from NHMRC
v2.0	29.10.15	Secretariat	Approved by HREC
v2.1	01.02.16	Secretariat	Incorporating Comments from NHMRC
v3.0	21.12.2017	Secretariat	Annual Review - extension of purpose
v4.0	06.12.2018	Secretariat	Annual Review – addition to objectives

*\*Drafts should use format vX.1 (eg. start at v0.1). Final versions should use format vX.0 (eg. v1.0).*

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## Schedule A: HREC Monitoring of Research Given Institutional Approval

### General Policy on Monitoring of Research

- Research should normally commence within 12 months of the date of ethical approval.
- Should the study not commence within 12 months, the Principal Investigator (PI) (single site studies) or Coordinating Principal Investigator (CP) (multiple-centre studies) is required to provide the HREC with a written explanation for the delay.
- Should the project not commence within 24 months, the matter will be discussed at a meeting of the HREC. At the discretion of the HREC, the approved ethical decision may be suspended and the PI/CPI required to submit a new application once the problems relating to the delay of the study have been fully addressed.
- To allow monitoring to occur, the HREC Chairperson or delegate may decide to allow other persons access to HREC application files. This decision may be taken at a HREC meeting or between meetings. The decision and reason for the decision to allow access to HREC files is minuted at the next HREC meeting. This include random inspections of research sites, data or consent documentation and interviews with research participants or other forms of feedback to them.
- All reports will be tabled at an HREC meeting and reviewed by the Committee.

### Duration of an Approved Ethical Decision

- The approved ethical decision of the main HREC applied for the expected duration of the research as specified in the approval letter, except where action is taken to suspend or terminate this decision.
- Where the PI/CPI proposes to extend the duration of the study this must be submitted for review to the HREC.

### Progress Reports

- Progress reports on all research given an approved decision should be submitted to the HREC at least annually or more frequently if the level of risk is assessed by the HREC to so indicate. The first Annual Report should be submitted 12 months after the date on which ethical approval was given.
- Reports must be submitted by the Principal investigator (or CPI for multi-site studies) and signed.
- Where a progress report is not received by the due date, the HREC Administrator will send a reminder letter. If the report is still not received after a further period of one month, the matter will be considered at the next meeting of the HREC.

### Final Reports

- A Final Report on a research given authorisation should be given to the HREC at completion of the research and should include a copy of the final published results.

### Urgent Safety Measures

- The CPI or Site PI at a trial site may, take appropriate urgent safety measures in order to protect the participants of a clinical trial against any immediate hazard to their health and safety. The HREC must be notified immediately and in any event within 3 days that such measures have been taken. The notice should set out the reasons for the urgent safety measures and the plan for further action. QH policy is that these requirements should apply to all research with an approved decision from a HREC and authorisation by the District CEO or Delegate of the QH District.
- Notifications of urgent safety measures should be reviewed at a meeting of the HREC. The HREC should consider whether the measures taken are appropriate in relation to the apparent risk to participants, and what further action the sponsor or investigator(s) propose to take, for example the submission of amendments to the protocol. Where any concern arises about the safety or welfare of

participants or the conduct of the research, the HREC should address these with the Principal Investigator in writing.

#### **Early Termination of Study by the Principal Investigator**

- Where a research project is terminated or suspended by the PI/CPI prematurely, the HREC must be promptly informed and provided with a detailed written explanation of the circumstances, having regard to the ongoing safety and welfare of any research participants who may be receiving study treatment.

#### **Suspension or Withdrawal of HREC Approval**

- The HREC may suspend or withdraw its ethical approval if it is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with its ethical approval and that, as a result, the welfare and rights of participants are not or will not be protected.
- Where the HREC considers it appropriate that the adverse event/s and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the Coordinating Principal Investigator (or Site Principal Investigator for single site studies).
- An Investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC or district/site Research Governance Office/r and will be escalated through the management of the organisation via the Executive Sponsor, the Executive Director Rockhampton Hospital.

#### **HRECs and Adverse Event Reporting in Australian for Clinical Trials**

- The Principal Investigator / CPI must capture and report AEs, including SAEs, which occur at their site to the sponsor in accordance with the study protocol. The Principal Investigator / CPI must report all SAEs to the sponsor immediately (within 24 hours of finding out about the event) in accordance with the study protocol and GCP guidelines as adopted by the TGA. The requirements for adverse event reporting to HRECs by Investigators will be in accordance with the Australian Health Ethics Committee (AHEC) Position Statement
- The local PI must notify the reviewing HREC directly (within 24 hours of finding out about the event) of all SAEs occurring at the sites under the monitoring responsibility of the HREC
- The local PI must notify the local RGO (within 24 hours of finding out about the event) of all SAEs occurring at the site

#### **Fully Sponsored Pharmaceutical or similar trials**

- HRECs should be provided with a copy of the SAE notification as soon as possible and within a one month maximum time lapse;
- If the event is serious and unexpected and may affect other participants on the trial, the HREC and Institution must receive immediate notification (that is, within 24 hours of the investigator becoming aware of the event)

## Schedule B: Complaints

### General Policy on complaints

- 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.

### Handling Complaints regarding the research study including research misconduct and/or fraud

- The handling of complaints should be aligned with the requirements of the Australian Code for the Responsible Conduct of Research Section 10 and the National Statement on Ethical Conduct in Human Research Section 5.6
- A copy of the complaint may be received by the secretariat of the HREC, the researcher or any other body.
- Consent forms must include contact details of the institution to allow such complaints to be made.
- The complaint should be forwarded, in the first instance, to the appropriate HOD/Supervisor or HSCE within the institution to be dealt with at departmental level.
- The HOD/Supervisor or HSCE within the institution must notify the HREC, who will enter the complaint details on AU RED, & local RGO that a complaint has been received and what processes are being undertaken to resolve the complaint.
- If the matter is not resolved at departmental level it is then referred to the 'Designated Person' (as defined in Code of Conduct Section 10.2)
- An HREC is not usually involved in conducting inquiries into cases of research misconduct and fraud but may be called upon to give advice.

### Handling Complaints regarding HREC processes

- Complaints on the process, conduct or decisions of the HREC should be made in writing to the Chairperson or Secretary of the HREC.
- All complaints will be acknowledged within seven (7) days.
- The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This may necessitate a special meeting of the HREC, which may be called without the usual 14 day requirement for notice, to consider such a complaint.
- 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 forwarded for review to the HSCE or delegate.