

Terms of Reference

Far North Queensland Human Research Ethics Committee (EC00157)

Purpose

The **Far North Queensland Human Research Ethics Committee (FNQ HREC)** is an ethics committee which was originally established in 1993.

The Committee is constituted and functions in accordance with the National Health and Medical Research Council's (NHMRC) 'National Statement on Ethical Conduct in Human Research' (2007), updated 2018, and complies with the 'Australian Code for Responsible Conduct of Research (2018)' and the current Queensland Health (QH) Research Management Policy.

Function

The HREC functions on behalf of the department/HHS are to:

- Provide independent oversight of human research projects.
- Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active.
- Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethics approval and;
- Provide advice to the department/HHS on strategies to promote awareness of the ethical conduct of human research.

As per the [QH Standard Operating Procedures \(SOP\) for HREC Administrators](#).



Membership

As per the National Statement on Ethical Conduct in Human Research' (2007), updated 2018 (National Statement):

5.1.29 The minimum membership of a HREC is eight. As far as possible:

- (a) there should be equal numbers of men and women; and
- (b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.

5.1.30 This minimum membership is:

- (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.

The FNQ HREC also includes at least one person of Aboriginal and/or Torres Strait Islander origin in the minimum membership.

- There should be at least one Medical Practitioner present at each meeting.
- If the Chairperson is unable to Chair a meeting, the Chairperson will liaise with the Deputy Chair and advise the HREC Administrator if the Deputy Chair is able to Chair the meeting, or if the meeting will be Chaired by another member of the HREC.

Recruitment of Members

Recruitment of new members should be conducted in line with the [QH HREC Administrators Standard Operating Procedures \(SOP\)](#) and the [National Statement](#).

- Expressions of Interest (EOI) to join the FNQ HREC are to be submitted in writing to the HREC Administrator and should include the applicant's CV.
- The Chairperson considers the applicant's EOI and decides whether the applicant meets the current requirements of the Committee. The EOI should be considered by the Committee either at a meeting or out of session.
- The Committee decides whether to extend an invitation to attend a HREC meeting to the applicant. If the applicant is suitable for the Committee an Offer of Membership will be made.

Appointment of Members

Appointment of members should be conducted in line with the [QH HREC Administrators SOP](#) and the [National Statement](#).

- The Chairperson shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
- Membership appointments to the HREC will be considered for periodic review every three years. Review of membership and endorsement by the Chief Executive (CE) of the Cairns and Hinterland, Hospital and Health Service (CHHHS) will occur annually.
- Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chairperson.
- The Chairperson and Deputy Chairperson may serve longer terms with the approval of the Chief Executive.
- Members are not offered remuneration.
- 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.

Induction, Education and Training for HREC members

Orientation and training for members is conducted in line with the [QH HREC Administrators SOP](#).

- Newly appointed members shall be provided with adequate orientation, induction and mentoring.
- Prior to attending their first official meeting, new members should be provided with Terms of Reference and an advance schedule of meetings.
- Members shall be given the opportunity to attend conferences and workshops (virtual or in person) relevant to the work and responsibilities of the HREC, at the expense and discretion of the CHHHS.
- Members will attend continuing education and training (virtual or in person) in research ethics at least every three years.

Independent Scientific Review of HREC Applications

Scientific reviews will be conducted as per the [QH HREC Administrators SOP](#).

HREC Liability Coverage

- 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).
- 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).

National certification for multi-centre ethical review

- The FNQ HREC is a Registered HREC with the NHMRC. The FNQ HREC can only conduct ethical reviews of human research submissions that fall within the geographical locations of both the Cairns and Hinterland and Torres and Cape Hospital and Health Services, by way of an existing Memorandum of Understanding. The FNQ HREC is not a certified HREC and cannot conduct multi-centre ethical review.
- The FNQ HREC can review research submissions for non-Queensland Health research projects within the geographical jurisdiction of the Committee. Outside of geography review of studies for non-Queensland Health research projects, is only permitted if;
 - there is only one site in which the study relates and the membership of the HREC has the expertise to adequately review the study,
 - the site involved in the study is willing to accept the ethical review of the Committee and there is a HREC only indemnity in place.

HREC Procedures

Standard operating procedures

- The HREC will perform its functions according to the current Department of Health (DoH) Research Management Policy, Health Service Directive (HSD) – Research Ethics and Governance and the Standard Operating Procedures (SOP) for HREC Administrators.
- All HREC members shall have access to the DoH Research Management Policy, HSD and QH HREC Administrators SOP.

Research Study Submissions

All Studies

- Excluding exceptional circumstances, the HREC will consider every application that it receives at its next available meeting, provided that the application is valid and received by the relevant closing date.

Single Site Studies

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

Multicentre Research Studies

- The submission of all multi-centre research studies being submitted through the single ethical review process, for review by the lead HREC, as per the QH HREC Administrators SOP with the exception of multicentre research studies which are Aboriginal and Torres Strait Islander focused studies, in this circumstance, the study is reviewed by the HREC in closest proximity to the research site.

HREC Meetings

- Meetings are to occur approximately every 5 weeks each year and may be held in-person or virtually.
- Annual meeting dates are to be approved by the Committee in advance. The Chairperson may change an agreed meeting date in liaison with the members of the HREC.
- Members who are unable to attend a meeting will be encouraged to contribute and advise their opinions via email to the HREC Administrator prior to the meeting.
- All members must declare any real or potential conflict of interest and manage those in consultation with the Chairperson and Secretariat, including absenting themselves throughout the meeting. The Secretariat should ensure recording of such absences is noted in the meeting minutes.

Meeting Protocols

1. Role of Secretariat

The role of Secretariat is provided by the HREC Administrator. The responsibilities of the Secretariate include but are not limited to the preparation of agenda documentation and distribution of the completed agenda papers ten (10) days prior to the meeting, taking and preparing minutes for each meeting, processing all follow-up correspondence, liaising with researchers, and all record keeping for the Committee.

As outlined in the QH HREC Administrators SOP.

2. Role of HREC Chairperson

As outlined in the QH HREC Administrators SOP, the HREC Chairperson is responsible for the conduct of HREC business and for ensuring that the HREC reaches decisions on all matters. Where the HREC Chairperson is unavailable for a HREC meeting, it will be chaired by the Deputy HREC Chair.

3. Special Meetings and Out-of-Session Papers

Special meetings may be called at the discretion of the Chairperson. Urgent issues may arise which require Members to consider papers out-of-session. In these instances, the Member putting forward the urgent matter will be required to liaise with the Secretariat and Chairperson to ensure that all Members are appropriately briefed to enable informed deliberations to be made.

4. Agenda, Papers, Submissions and Reports

Members wishing to place items on the agenda must notify the Secretariat at least fourteen (14) days prior to the scheduled meeting. A detailed description of the subject, background information, recommendation and supporting documentation/reports should be submitted to the Secretariat. Urgent/late items are to be submitted to the Secretariat in the first instance however will be included at the discretion of the Chairperson.

5. Records and Reporting

As outlined in the QH HREC Administrators SOP.

6. Complaints

Complaints concerning the conduct of a project

As per the *Australian Code for the Responsible Conduct of Research 2018* and *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018*, the institution has nominated persons for handling research complaints, including research misconduct. The

'designated person' for the Cairns and Hinterland Hospital and Health Service is the Executive Director of Medical Services (EDMS).

Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to Chairperson of the HREC who will investigate the complaint. If the matter once investigated, identifies a breach, the 'designated person' of the institution where the approving HREC sits, will meet with the Chairperson of the HREC along with the secretariat of the approving HREC.

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

Complaints concerning the HREC's review process:

Processing of research complaints regarding the HREC review process will be handled as per the QH HREC Administrators SOP.

Any concern or complaint about the approving HREC's review process should be directed to the attention of the HREC Chairperson in writing. The secretariat of the HREC will enter the complaint details on the ERM system.

Should the complainant not be satisfied with the response of the Chairperson, the complaint could be escalated to the Executive Director of Medical Services, CHHHS.

Should the Executive Director of Medical Services, CHHHS deem it necessary, the complaint may be escalated to the Chief Executive for noting or any further action.

Endorsed By:



Prof Edward Strivens
A/Chair – Far North Queensland Human
Research Ethics Committee
Cairns and Hinterland Hospital and Health Service

15/09/2022

Approved By:



Dr Donald Mackie
Executive Director of Medical Services
Cairns and Hinterland Hospital and Health Service

2, 11, 2022

Version	Date	Prepared by	Comments
1.0.	1993	Ethics Administrator	First release of approved document
2.0	2009	Ethics Administrator	First review and update of approved document
3.0	2011	Ethics Administrator	Second review and update of approved document
4.0	2014	Ethics Administrator	Third review and update of approved document
5.0	2016	Ethics Administrator	Fourth review and update of approved document
6.0	2017	Ethics Administrator	Fifth review and update of approved document
7.0	2019	Ethics Administrator	Sixth review and update of approved document
8.0	2020	Ethics Administrator	Seventh review and update of approved document
9.0	2022	Senior Business Coordinator	Eighth review and update of the approved document