

Terms of Reference

Far North Queensland Human Research Ethics Committee (EC00157)

Purpose

The **Far North Queensland Human Research Ethics Committee** (NHMRC Registration Number EC00157), is an ethics committee which was originally established in 1993. The Committee is constituted and functions in accordance with the 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 Queensland Health Research Management Policy (QH-POL-013:2015).

Memberships

Chair	Dr Edward Strivens
Members	xxxx
Proxies	Nil.
Other Participants	Nil.
Quorum	<p>The HREC membership is constituted in accordance with the National Statement and will include the following:</p> <ol style="list-style-type: none"> a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement; 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; 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; at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion; at least one lawyer, where possible one who is not engaged to advise the institution; and 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; and at least one person of Aboriginal and/or Torres Strait Islander origin. <ul style="list-style-type: none"> • The minimum membership of a HREC is eight (8). • As far as possible there should be equal numbers of men and women. • At least one third of the members should be from outside the institution for which the HREC is reviewing research. • There should be at least one Medical Officer present at each meeting, keeping in mind 5.1.31 of the <i>National Statement on the Ethical Conduct of Human Research (2007) Updated 2018</i> (No member may be appointed in more than one of the categories listed in paragraph 5.1.30). • If the Chair notifies the administrator that they are unable to Chair a meeting, If the Chair is unable to Chair a meeting, the Chair will liaise with the Deputy Chair and



advise the HREC Coordinator if the Deputy Chair is able to Chair the meeting, or, if the meeting will be Chaired by another Queensland Health member of the HREC.

Appointment of members

- The Cairns and Hinterland Hospital and Health Service Deputy Executive Director of Medical Services, Cairns and Hinterland Hospital and Health Service (DEDMS CHHS) 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 (CHHS) will occur annually.
- Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- Appointments will be in alignment with the minimum core membership requirements as outlined in the *National Statement on the Ethical Conduct of Human Research 2007 (updated March 2018)*, with consideration of continuity, development of expertise within the HREC and the regular input of fresh ideas and approaches in addition to the mandated minimum core membership taken onboard.
- Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive.
- The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive.
- Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
- Membership will lapse if a member fails to attend three consecutive meetings of the Committee without notifying the Chairperson, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership.
- 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 institutional CE may terminate the appointment of any member of the HREC if the CE 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.
- 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.
- 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.
- A list of HREC member roles and gender is listed on the Health, Innovation, Investment and Research (HIIRO) Webpage. 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.

Education for HREC members

- Newly appointed members shall be provided with adequate orientation and mentoring.
- 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 Cairns and

Hinterland Hospital and Health Service as outlined in a Memorandum written and signed by the CE of the Institution

- Members will attend continuing education and training in research ethics at least every two years.

Independent Scientific Review of HREC Applications

- Scientific Reviewers need not be members of the HREC, however HREC members can conduct scientific reviews for the Committee.
- The HREC may appoint such Scientific Reviewers 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.

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).
- As a contingency measure to address the COVID-19 Global Pandemic, the FNQ HREC is collaborating with HIIRO and other QH HRECs throughout Queensland to provide for business continuity and minimize disruption. HREC members will be asked to **voluntarily** review applications on behalf of other QH HRECs from across the state of Queensland as required. Members should be aware of this temporary additional scope and provide assistance and cooperation to ensure that the impact of COVID-19 on vital research is minimized. **As such, membership to one QH HREC is membership to all QH HRECs**

National certification for multi-centre ethical review

- Where an institution elects to nominate for certification the following will occur:
 - Institution undertakes self-assessment
 - Institution nominates to be assessed for certification by submitting paper work to national certification body
 - Certifying body undertakes desk top audit of institutional paper work
 - Certifying body conducts an onsite visit and issues draft report
 - Certifying body issues final report and, if approved, certification conditions.
- The Far North Queensland HREC is a registered HREC with the National Health and Medical Research Council. The Far North Queensland HREC can 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 responsibility for meeting these certification standards rests with the Cairns and Hinterland Hospital and Health Service which constituted the HREC.
- The Far North Queensland 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 Department of Health (DoH) Research Management Policy (QH-POL-013:2015) and Health Service Directive – Research Ethics and Governance (QH-HSD-035:2019).
- All HREC members shall have access to and/or be provided with copies of the DoH Research Management Policy and HSD and shall be consulted with regard to changes thereto.
- Standard Operating Procedures for HREC Administrators (SOP) - current version.

Research Study Submissions

All Studies

- 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.
- 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

- 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 HREC SOP with the exception of multicentre research studies which are Aboriginal and Torres Strait Islander targeted studies, in this circumstance, the study is reviewed by the HREC in closest proximity to the research site.

Protocols

- The HREC will require submissions to be in a standard format using the Human Research Ethics Application Form (HREA) available on the Ethics Review Manager (ERM) website: <https://au.forms.ethicalreviewmanager.com/>
- The HREC will require the researcher to electronically upload all supporting documents onto the ERM website.
- 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 (once available).
- The Chair along with the members of the HREC Committee and HREC administrator will determine if any expert advice is required for any protocol.

HREC Meetings

To occur approximately every 5 weeks each year, with annual meeting dates approved by members of the HREC in advance. The Chair may change an agreed meeting date in liaison with the members of the HREC.

Confidentiality

Meeting Protocols

1. Induction & Development

The following information is to be provided by the Secretariat and committee Chair to all Members prior to their first committee meeting:

- Terms of Reference which includes meeting protocols
- Contact details of committee Members
- Advance schedule of meetings

2. Role of Secretariat (Minute Taker)

Arrange meetings, seek approval from the Chair and Members of the Committee of proposed meeting dates annually in advance then book suitable venues and advise Members once all meeting details have been finalised. Liaise with Members as required. Prepare agenda and supporting papers, review and finalise with committee Chair and distribute to Members at least one (1) week prior to each meeting. Set up meeting i.e. room, equipment and teleconferencing facilities. Take minutes of meeting, liaising with the committee Chair and members as requested during the meeting. Prepare minutes and finalise with committee Chair before distributing within one (1) week of the held meeting. Maintain a record of all committee minutes, recommendations, action items, correspondence and other documentation in regard to committee resolutions/recommendations. Notify relevant stakeholders of committee decisions which require their attention/action after approval by the committee Chair. Follow up on actions items to ensure they are met with timelines. Maintain records of attendance. Escalate approved meeting minutes via Referral Note to Executive Committees as required as part of Committee registration requirements outlined by the National Health and Medical Research Council.

3. Role of Committee Chair

Ensure terms of reference and meeting protocols are met.

Confirm and approve content of agendas and minutes prior to distribution to committee Members. Liaise with the Secretariat during meetings and clarify/reiterate actions and decisions to be minuted before the next agenda item is addressed when deemed appropriate to do so. Manage meetings so they are conducted in a professional, orderly and timely manner. The Chair shall also call for members to declare any real or potential conflicts of interest at the start of each committee meeting or discussion of individual items presented amongst the Agenda papers.

4. Special Meetings and Out-of-Session Papers

Special meetings may be called at the discretion of the committee Chair. 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 committee Chair to ensure that all Members are appropriately briefed to enable informed deliberations to be made.

5. Agenda, Papers, Submissions and Reports

Members wishing to place items on the agenda must notify the Secretariat at least ten (14) days prior to the scheduled meeting. A referral note must be submitted including detailed descriptions on the subject, background and recommendation along with supporting documentation/reports to the Secretariat. Urgent/late items should be submitted to the Secretariat in the first instance however will be included at the discretion of the committee Chair.

6. Records

Meeting documentation, agendas, minutes, action items and supporting papers will be filed and stored by the Secretariat both electronically in the ERM System and also in hard copy in the designated HREC filing cabinets.

7. 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 Nursing and Midwifery (EDNM CHHS).

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

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

Any concern or complaint about the approving HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing.

The secretariat of the HREC will enter the complaint details on the ERM system

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

Should the complainant not be satisfied with the response of the Chairperson, the complaint could be escalated to the Executive Director of Medical Services, Cairns and Hinterland Hospital and Health Service.

Should the Executive Director of Medical Services, Cairns and Hinterland Hospital and Health Service deem it necessary, the complaint may be escalated to the Chief Executive for noting or any further action.

Endorsed By:



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

7/05/2020

Approved By:



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

19/5/2020

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