

HUMAN RESEARCH ETHICS COMMITTEE

Terms of Reference

1. Purpose

The Townsville Hospital and Health Service Human Research Ethics Committee (the Committee) is established by the Townsville Hospital and Health Service and constituted according to the National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)* (refer to section 5.1). These Terms of Reference establish the Committee's purpose, functions, membership, guiding principles, reporting and administrative arrangements.

The purpose of the Committee is to review and make decisions on the ethical acceptability of research proposals that involve humans (including human tissue and data relating to humans).

The Committee primarily provides ethics review for research being conducted in Townsville Hospital and Health Service and other Queensland hospital and health services. However, the Committee 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 and expertise.

The Committee is located at and funded by the Townsville Hospital and Health Service, however the Committee operates independently from the Hospital and Health Service. Ethics review must be conducted in a transparent manner, guided by accepted national standards, and independent from institutional influence.

The Committee contributes to the National Safety and Quality Health Standards (Clinical Governance Standard) for the Townsville Hospital and Health Service, which ensures patients and consumers receive safe and high-quality health care. The Committee provides a robust and efficient service on behalf of the Hospital and Health Service, enhancing the health service reputation for research leadership in tropical health and medicine.

The Committee has certification from the National Health and Medical Research Council (NHMRC) to undertake ethics review of multi-centre research. A full list of the certification categories can be found on the NHMRC's website for certified institutions - <https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research>.

The Committee is responsible for monitoring the progress of approved research studies until completion, to ensure continued conformity with approved standards.

The objectives of the Committee are:

- To protect the mental and physical welfare, rights, dignity and safety of participants of research.
- To facilitate ethical research through efficient and effective review processes.
- To promote ethical standards of human research.
- To ensure that all clinical and health research is conducted ethically and responsibly.

The primary functions of the Committee (set out at clause 2 below) are a description of how the Committee carries out the purpose of the Committee.

2. Functions

The functions of the Committee are:

- Provide independent, competent and timely review of research studies with respect to their ethical acceptability.
- Monitor approved research studies for which the Committee has given approval and provide advice at any time to the relevant Health Service Chief Executive (HSCE), through the relevant Research Governance Officer and coordinating principal investigator, when the Committee considers that ethics approval for research should be withdrawn.
- Obtain expert opinions (external or internal) as required to provide scientific/technical assessment on human research proposals and evaluation of human research studies and compliance with regulatory requirements.
- Register on the nominated state-wide database all research applications submitted to the Committee, any monitoring and reporting requirements and any ongoing approval status of proposals including amendments.
- Establish Sub-Committees and/or Working Groups as required under the *National Statement on Ethical Conduct in Human Research – 2007 (updated 2018)* Section 5.

Before giving a favourable opinion, the Committee ensures that it is confident about the following issues, as applicable:

Scientific design and conduct of the study:

- Recruitment of research participants
- Care and protection of research participants
- Protection of research participants' confidentiality
- Informed consent processes
- Local community considerations

These should follow the values and principles of ethical conduct as described in the *National Statement on Ethical Conduct in Human Research – 2007 (updated 2018)*:

- Research merit and integrity
- Justice
- Beneficence
- Respect

If the research involves Aboriginal and/or Torres Strait Islander peoples then the research should also follow the research values as described in the NHMRC *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018*:

- Spirit and Integrity
- Cultural Continuity
- Equity
- Reciprocity
- Respect
- Responsibility

3. Authority

The Committee has authority to make independent decisions on the ethical acceptability of research proposals under the guidance of the National Health and Medical Research Council (NHMRC). The *NHMRC Act 1992* established two key national councils, the NHMRC and the Australian Health Ethics Committee. These councils are responsible for providing guidelines for Human Research Ethics Committees and research conducted in Australia. The NHMRC oversees the operations of all certified Human Research Ethics Committees, which includes the Townsville Human Research Ethics Committee.

The Committee is responsible [only for] the ethics review of research. For research being conducted in or with public health organisations, research studies cannot commence at any site until governance authorisation is granted from the Hospital and Health Service. The Hospital and Health Service can choose not to authorise a study regardless of ethics approval, however ethics approval must be obtained before governance authorisation can be granted.

The Committee is constituted and functions in accordance with the following legislation and guidelines:

- *National Health and Medical Research Council Act 1992*(Cth)
<http://www.comlaw.gov.au/Details/C2006C00354> [
- *Hospital and Health Boards Act 2011* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNA11.pdf>
- *World Medical Association Declaration of Helsinki 2013*
<http://www.wma.net/en/30publications/10policies/b3/>
- *National Health and Medical Research Council 'National Statement on Ethical Conduct in Human Research' 2007 (Updated 2018)* (National Statement)
<https://www.nhmrc.gov.au/guidelines-publications/e72>
- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholder 2018*
<https://www.nhmrc.gov.au/guidelines-publications/e52>
- *Australian Code for Responsible Conduct of Research 2018*
<https://www.nhmrc.gov.au/guidelines-publications/r39>
- *Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes*
<http://www.arpansa.gov.au/publications/codes/rps8.cfm>
- *Public Health Act 2005* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf>
- *Privacy Act 1988* (Qld) ss 95, 95(a)
<http://www.comlaw.gov.au/Details/C2015C00089>
- *Human Rights Act 2019* (Qld)
<https://www.legislation.qld.gov.au/view/pdf/asmade/act-2019-005>

4. Membership

The Chair of the Committee is Human Research Ethics Committee (HREC) Chairperson ('the Chair'), and is appointed for a three year term by a formal recruitment process, led by the Executive Director of Clinical Governance in consultation with the HSCE. If required, the Chair may nominate one or more members as Deputy Chair.

The Membership of the Committee is constituted in accordance with *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)* Chapter 5.1 as follows:

5.1.29 The minimum membership of an 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.

5.1.31 No member may be appointed in more than one of the categories listed in paragraph 5.1.30, but institutions are encouraged to establish a pool of inducted members in each category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review.

5.1.32 Wherever possible one or more of the members listed in 5.1.30 should be experienced in reflecting on and analysing ethical decision-making.

5.1.33 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

5.1.34 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.

5.1.35 Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.

5.1.36 Members should be provided with a formal notice of appointment.

Membership eligibility will be determined by the Chair, in consultation with the HSCE. Prospective members of the Committee may be recruited by direct approach, nomination or by advertisement.

Members are appointed for a period of three years. New members who are external to the Townsville Hospital and Health Service will be subject to a criminal history check prior to commencement. Appointments will allow for continuity, the development of expertise within the Committee and the regular input of fresh ideas and approaches. Reappointment of members is by application to the Chair who will make a recommendation to the HSCE.

In making appointments to the Committee, the Chair and the HSCE must seek to ensure that the membership of the Committee includes a balance of skills and knowledge in order to achieve the purpose of the Committee. Annually the Chair will assess the categories and quantities of research received and align, as required, the expertise of the Committee with the research proposals received for review.

A member may resign from the Committee at any time upon giving two weeks' notice in writing to the Chair.

Newly appointed members will be provided with orientation, induction and adequate mentoring. To maintain NHMRC certification, members will attend continuing education and training in research ethics at least every three years through application to the Townsville Hospital and Health Service.

Members are appointed as volunteers and are not offered remuneration, with the exception of the Chair. However, members will be reimbursed for legitimate expenses incurred in attending Committee meetings or in otherwise carrying out the business of the Committee (see Standard Operating Procedures).

Townsville Hospital and Health Service provides indemnity for members 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).

5. Additional Membership Scope

As a contingency measure to address potential circumstances where Queensland Health (QH) HRECs require assistance or studies require urgent review (such as the COVID-19 Global Pandemic), the Committee collaborates with the Health Innovation Investment Research Office and other Queensland Health (QH) HRECs to provide for business continuity and minimize disruption. Members may be asked to voluntarily review applications on behalf of other QH HRECs from across the state of Queensland. Members should be aware of this temporary additional scope and provide assistance and cooperation where they are able to minimise the impact on vital research.

In this scenario, Townsville Hospital and Health Service will continue to provide indemnity for members for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith, via the insurance fund QGIF.

6. Guiding Principles

The Committee must apply and act in accordance with the guidelines applicable to the type and/or categories of research which it is reviewing. These guidelines may include all or some of the documents listed in Section 3. Authority.

The Committee must also recognise and adhere to the principles set out in the following legislation or documents, in carrying out the Committee's functions:

- *National Health and Medical Research Council Act 1992*(Cth)
<http://www.comlaw.gov.au/Details/C2006C00354>
- *Hospital and Health Boards Act 2011* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNA11.pdf>
- *Hospital and Health Boards Regulation 2012* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNR12.pdf>
- *Public Service Act 2008* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PublicServA08.pdf>
- *Financial Accountability Act 2009* (Qld)
<https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/F/FinAccountA09.pdf>
- *CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) adopted by the Therapeutic Goods Administration 2000*
<https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>
- other relevant requirements of Commonwealth and State/Territory laws including the Health Service's Research Management Policy and corresponding procedures.

7. Risk Management

A proactive approach to risk management will underpin the business of the Committee which will:

- Identify risks and mitigating strategies associated with all decisions made;
- Implement processes to enable the Committee to identify, monitor and manage critical risks with respect to the Functions of the Committee defined at clause 2;
- Function in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*; and
- Provide education and induction to members to manage compliance with all appropriate guidelines and legislation.

8. Reporting

The Committee must report annually on its activities to the Townsville Hospital and Health Service Board via the HSCE.

The Committee must report annually to the NHMRC to maintain certification and registration as a compliant Human Research Ethics Committee. Evidence of ongoing NHMRC certification must be reported to the HSCE.

The Committee will report any complaints to the relevant site Research Governance Officer/s if it is related to research activities and/or conduct.

The Committee must provide a 6-monthly activity report to the Townsville Hospital and Health Service Research Development Committee.

9. Administrative Arrangements

Standard Operating Procedures

The Committee will perform its functions, including monitoring of research and handling of complaints, according to written local and or State standard operating procedures (SOP).

All members shall have access to the SOP and shall be consulted with regard to changes thereto. Current Queensland Health SOP can be found at this website:

http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Submissions

The Committee will consider every application which it receives, at its next available meeting following receipt, provided that the application is valid and received by the relevant closing date. Eligible low and negligible risk applications (as defined by the *National Statement on Ethical Conduct in Human Research - 2007 (updated 2018)*, Section 2.1) may be reviewed by two members and the Chair out of session, provided that the application is valid. When a submission is accepted by the Committee, the HREC Coordinator will facilitate the process of HREC review and approval as per the SOP in conjunction with Townsville Hospital and Health Service procedures.

Meetings

The Committee is expected to hold ordinary meetings monthly except for January.

Cancellation and re-scheduling of meetings will be at the discretion of the Chair of the Committee.

Decisions by the Committee about whether the research study 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 Committee. In general, decisions of the Committee will be reached by general agreement.

Out of session Activities

The HSCE has delegated the following decisions to the Chair, and Deputy Chair if the Chair position is vacant or is on leave:

The power to review and:

- acknowledge standard research reporting including:
 - Annual reports
 - Final reports and results
 - Safety Reports
 - Protocol violations
- approve amendments to active research studies previously approved by the Committee;
- endorse applications as non-research for the purposes of publication, including quality assurance activities submitted for review;

- approve multi-centre research studies which have been reviewed and approved by another NHMRC certified HREC but fall outside the scope of the National Approach to single ethics review of multi-centred research studies;
- escalate research related matters as necessary to the relevant institution, Hospital and Health Service or other body; and
- endorse applications to the Therapeutic Goods Administration under the Authorised Prescriber Scheme.

The Chair has delegated the following decisions to the Coordinator:

- the power to review and approve minor and administrative amendments to active research studies previously approved by the Committee.

The Chair or Delegate must exercise his/her judgement and experience to escalate any research correspondence that requires further advice or review to the relevant person within an institution, Townsville Hospital and Health Service, or other.

All decisions made by the Chair or Delegate pursuant to this delegation must be reported and noted by the Committee through a standing agenda item for Out of Session Activities.

Meeting Plan, Agenda and Work Plan

A forward meeting plan, including meeting dates and standing agenda items will be set by the Chair of the Committee each year.

Attendance at Meetings and Quorum

Meetings can be held in person, by phone or by video-conference or other means approved by the Chair of the Committee.

A quorum for a meeting of the Committee is one-half of the number of the voting members (including the Chair of the Committee) or if one-half is not a whole number, the next highest whole number. As per the *National Statement on Ethical Conduct in Human Research – 2007 (updated 2018) Section 5.2.28*, as far as possible, each Committee meeting should be arranged to enable at least one member in each category to attend.

Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via submission to the HREC Coordinator prior to the meeting. The contribution of information and opinion from a committee member unable to attend a meeting will be considered along with those opinions and feedback of other committee members in the final decision making

Where there is less than full attendance of the membership categories at a meeting, the Chair should be satisfied, before a decision is reached, that absent members have had an opportunity to contribute and that sufficient input has been received to make a decision on a proposal.

The Chair of the Committee may from time to time request a Townsville Hospital and Health Service executive, employee, expert reviewer, researcher or external party to attend a meeting of the Committee. For the avoidance of doubt, this person (or people):

- does not assume membership and is not entitled to participate in any decision-making processes of the Committee;
- is only entitled to attend for that part of the meeting as authorised by the Chair of the Committee; and
- is bound by the same confidentiality requirements as Committee members.

Secretariat

The HREC Coordinator ('the Secretariat') is to provide secretariat support to the Committee, including the preparation of meeting papers and administrative support.

Files must be kept securely and confidentially in accordance with the requirements of the *Public Records Act 2002*. Records must be retained in accordance with Queensland Government's General Retention and Disposal Schedule for Administrative Records:

<http://www.archives.qld.gov.au/downloads/GeneralDisposalSchedule.pdf>.

In general, papers (including electronic records) considered by the Committee are retained permanently.

Committee Meeting Papers

The Secretariat will endeavour to distribute meeting papers to the Committee members at least five (5) working days before the scheduled Committee meeting date.

The Chair of the Committee may allow the distribution of additional meeting papers closer to the meeting or to be tabled at the meeting.

Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for changes to the proposal, linking those reasons to the National Statement.

Decisions of the Committee will be recorded and communicated in writing to the principal investigator (the applicant) and contact person for the submission within ten (10) days of the meeting.

Monitoring

Monitoring of research given institutional authorisation will be as per the *National Statement on Ethical Conduct in Human Research – 2007 (updated 2018)*.

At a minimum studies are reviewed annually, through provision of a progress report by the coordinating/principal investigator. Studies may also be reviewed more frequently depending on the risk associated with the study, which may be determined by the Committee at the time of approval.

As part of the ethics review of a research study the Committee will assess if the monitoring mechanisms put in place by the researchers are appropriate for the research (as described in the Monitoring section of the protocol). The HREC can request additional mechanisms to be implemented if necessary.

Where conditions require the need to suspend or withdraw ethical approval the HREC will follow the *National Statement on Ethical Conduct in Human Research – 2007 (updated 2018)* Section 5.5.7 – 5.5.10.

Complaints

Research complaints concerning the conduct of a study and/or the Committee's review process, including the Committee's rejection of an application should be managed as per the Townsville Hospital and Health Service Research Complaints and Research Misconduct Management Procedure and the *Australian Code for the Responsible Conduct of Research 2018*.

The 'Research Integrity Advisor' and the 'Designated Person' applicable to this Committee can be provided by contacting the Chair or the HREC Coordinator.

Access to External Expert Reviewers

The Committee may seek the written advice of an external expert reviewer on any aspects of an application that are relevant to the formation of an ethical decision, and which lie beyond the expertise of the members or on which the Committee is unable to agree.

The Queensland Health Panel of External Expert Reviewers can be accessed at any time by the Committee, by contacting the QH Health Innovation, Investment and Research Office.

Expert Reviewers are volunteers, non-remunerated and not voting members of the Committee, and should not be involved in the business of the Committee other than that related to the application on which their advice is sought.

At any time, a Committee member can make a request for external expert review to the HREC Coordinator or the Chair; the HREC Coordinator will liaise with the Committee for general agreement to facilitate efficient ethical review.

If possible, a copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

The expert reviewer may be invited to attend the meeting in person (or by phone) for discussion of the application concerned.

Expert Reviewers are subject to the same confidentiality requirements as HREC members and are required to sign a confidentiality agreement and declaration of conflict of interest prior to access to proposal documents or attending Committee meetings.

10. Conflicts of Interest

To meet the ethical obligations under the National Statement and the *Public Sector Ethics Act 1994* (Qld), Committee members must declare any conflicts of interest whether actual, potential, apparent, or likely to arise, and manage those in consultation with the Chair.

Members will exercise honesty, objectivity, independence and probity in the discharge of their duties and responsibilities at all times, and not engage knowingly in acts or activities that have the potential to discredit the Townsville Hospital and Health Service.

Members will refrain from entering into any activity that may prejudice their ability to carry out their duties and responsibilities objectively and will, at all times, act in a proper and prudent manner in the use of information acquired in the course of their duties.

Declarations of conflicts of interest must be one of the first standing agenda items on the Committee's agenda.

Committee Members must, at the relevant agenda item declare any conflicts of interest whether actual, potential, or perceived ('the Conflicted Member'). The Chair of the Committee must require the Conflicted Member to leave the room whilst the remaining members determine whether the Conflicted Member is entitled to attend the meeting for the purpose of the discussion and not vote, or whether the Conflicted Member should leave the room for the purposes of the discussion (Schedule 1 section 9(4) of the Act).

11. Confidentiality

All Committee meetings and deliberations will be kept in confidence. Reporting of such deliberations will be outcomes only and statistical data only will be provided to the appropriate governing bodies, except as mandated by law.

The Members of the Committee acknowledge that:

- Members will receive information (verbal and written) that is commercially sensitive, private and confidential and which may be protected by doctrines such as legal professional privilege;
- A Member's duty to maintain confidentiality and to exercise discretion are paramount and the duty survives the termination or expiry of membership of the Committee;
- Members must maintain and secure access to the Committee meeting papers (whether printed, electronic or in some other form/instrument); by keeping same in a safe and secure location; password protected (if electronic); separate from any other business or responsibilities of the Member; and in a manner where the meeting papers/information is protected.
- Members are required to sign a deed of confidentiality before commencing their tenure.

12. Expulsion of Members

A Member may, by written notice, be expelled from the Committee by the HSCE on recommendation of the Committee Chair.

Membership will lapse if a member fails to attend three consecutive meetings of the Committee, without reasonable excuse or without notifying the Chair and unless exceptional circumstances exist. The Chair will notify the member in writing of such lapse of membership.

13. Evaluation

At the end of each meeting a member of the Committee will undertake a verbal assessment of the meeting.

At the end of each calendar year the Committee will undertake a self-assessment of performance as directed by the Chair of the Committee.

14. Review of the Terms of Reference

The Terms of Reference are submitted to the HSCE for approval. Once approved, the new or revised Terms of Reference are submitted to NHMRC for noting as part of the Committee's certification.

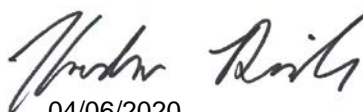
These Terms of Reference may be altered following Committee consultation and endorsement by the HSCE.

The Committee must review these Terms of Reference every two (2) years or earlier if considered necessary by the Chair and/or the HSCE.

15. Terms of Reference Approval

Endorsed by Committee Chair: Dr Hudson Birden

Signature:



Date: 04/06/2020

Approved by Townsville HSCE: Mr Kieran Keyes

Signature:

Date:

Document History

Version	Date	Nature of Amendment
3.0	22 May 2015	Amalgamation of previous Committee terms of reference V2.1 April 2014 and new Townsville Hospital and Health Service ToR template V2.2 Jan 2015
3.1	17 June 2015	Minor amendments discussed with HSCE, HREC Coordinator and Chair
3.1	02 July 2015	Endorsed by Human Research Ethics Committee
3.2	17 February 2016	Minor amendments incorporated as required by HSCE
3.2	03 March 2016	Endorsed by Human Research Ethics Committee
3.2	11 March 2016	Approved by HSCE
4.0	20 March 2017	Update to monitoring arrangements as per update from NHRMC in November 2016, and update to delegations by HREC Coordinator
4.1	20 April 2017	Minor amendments as per discussions between SHGA, Research Governance Officer, Chair HREC and HREC Coordinator
4.2	19 May 2017	Correction from Therapeutic Goods Association to Therapeutic Goods Administration (HSCE request)
4.2	04 July 2017	Endorsed by Human Research Ethics Committee
4.2	11 July 2017	Approved by HSCE
5.0	14 May 2020	Update to include COVID-19 contingency measure and other minor administrative changes
5.1	04 June 2020	Endorsed by Human Research Ethics Committee
5.1	16 June 2020	Endorsed by Research Development Committee