



Human Research Ethics COMMITTEE Terms of Reference

Our Vision

- Caring for our Communities: Healthier Together

Our Values

- *Compassion* – We engage with others and demonstrate empathy, care, kindness, support and understanding.
- *Integrity* – We are open, honest, approachable, equitable and consistent in everything we do.
- *Dignity* – We treat others with respect, display reasonableness and take pride in what we do.
- *Innovation* – We strive to know more, learn more and do better.
- *Courage* – We respectfully question for clarity, have the strength to act and embrace change for the better.

1. Committee Name

Human Research Ethics Committee

2. Authorisation

- The Darling Downs Health Human Research Ethics Committee (HREC) reports to and is accountable to the Chief Executive of Darling Downs Health.
- The HREC is a certified institution and has achieved NHMRC certification in order to undertake single ethical review of research projects to be conducted at more than one site. It has been certified to undertake single ethical review in the following research categories:
 - Clinical trials Phase III
 - Clinical trials Phase IV
 - Clinical trials devices
 - Clinical intervention research other than clinical trials
 - Qualitative health research
 - Mental health research
 - Other health and medical research - rural and/or remote health research

3. Committee purpose

- The purpose of the Human Research Ethics Committee is to:
- 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 Chief Executive, through the Research Governance Officer and Coordinating Principal Investigator, when the HREC considers that ethical approval for research should be withdrawn.
- Obtain expert opinions (external and internal) as required to provide scientific/technical assessment on human research protocols and evaluation of research clinical trials/studies and compliance with regulatory requirements.
- Monitor on Ethical Review Manager (ERM), all research applications submitted to the HREC and any ongoing approval status of proposals including amendments.
- 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.

Human Research Ethics COMMITTEE

Terms of Reference

- Liaise with Queensland Health Hospital and Health Services, Universities, other research facilities and research personnel as appropriate.
- 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.
- Acknowledge that the Chief Executive of individual Hospital and Health Services will have the right to not approve the conduct of a research project within its Service.
- Make public the membership categories of the HREC on the QH Health Innovation, Investment and Research Office (HIRO) website.

4. Committee responsibilities concerning Standards and Plan Objectives

The Human Research Ethics Committee is to oversight the HHS's response to the following requirements of Standards and objectives of Strategic Plans:

- Darling Downs Health Strategic Plan 2016 - 2020
- ISO Standard 9.1
- National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)
- Australian Code for the Responsible Conduct of Research 2018
- Queensland Health Research Management Policy QH-POL-013:2015
- Queensland Health Research Management Standard QH-IMP-013-1:2015

5. Scope of the Committee

To contribute to the management and delivery of health services the Darling Downs Health Human Research Ethics Committee undertakes the following:

- The HREC will perform its functions in accordance with the *National Statement on Ethical Conduct in Human Research (2007, updated 2018) – the National Statement (NS)*, the *Australian Code for Responsible Conduct of Research (2018)* and *QH Research Management Policy QH-POL-013:2015* and *QH Research Management Standard QH-IMP-013-1:2015* and all subsequent updates.
- The HREC will perform its functions, including monitoring of research and handling of complaints, according to written standard operating procedures (SOP) accessed from the QH Health Innovation, Investment and Research Officer (HIRO) website. These procedures shall be reviewed at least every three years and amended and updated as necessary.
- All HREC members shall have access to and/or be provided with copies of the Standard Operating Procedures (SOP) and shall be consulted with regard to changes thereto.
- All issues involving research governance will be dealt with in accordance with the QH Research Governance Standard Operating Procedures, accessed from the HIRO website.

Submissions All Studies

- The HREC 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.
- When a submission, including amendments, is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.
- Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HREC) for ethical and legal approval.
- The HHS Chief Executive or Delegate is the person to grant authorisation of research projects on human to be conducted within or in association with Queensland Health Services.
- For multi-centre research studies, an HREC that has been assessed and certified under the national NHMRC certification scheme, will be the single HREC body to conduct the ethical-scientific review of the study. No other HREC will be involved in the ethical review of the application which is being or has been reviewed by a certified HREC under the single ethical review process.

Human Research Ethics COMMITTEE

Terms of Reference

6. Risk management

- The HREC is to adopt a pro-active approach to risk management.
- The Committee will:
 - Identify risks and mitigating strategies with all decisions and recommendations made.
 - Implement processes to enable the Committee to identify, monitor and arrange management of risks as they relate to the scope of the Committee.

As per the *National Statement on Ethical Conduct in Human Research* Section 5.1.9, QH provides HREC members with indemnity under Queensland Government Insurance Fund insurance policy.

7. Reporting

- The Committee must report quarterly on its activities to the Darling Downs Health Board via the HSCE and the Executive Quality and Safety Committee.
- The Committee must report annually to the National Health and Medical Research Council to maintain certification and registration as a compliant human research ethics committee.
- The Committee will report any complaints to the relevant site Research Governance Officer/s or designated complaints person if it related to research activities and/or conduct.

8. Sub committees

- 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.
- The HREC takes advice from the Scientific Review Sub-Committee. This sub-committee provides advice on scientific and technical aspects of research protocols involving human participants or subjects and gives feedback to the HREC for investigators to enable them to address any issues of concern.
- The Chair of any such sub-committee will be appointed by the Chief Executive of Darling Downs Health.
- Members of the sub-committee need not be members of the HREC.

9. Key Performance Indicators/Deliverables

Domain	Performance Indicator	Assessment/Reporting Timeframe	Audit Arrangements
Darling Downs Health Strategic Plan	L1. Embed the application of evidence-based practice and research into the organisation. P3. Ensure quality and consistency in our processes through compliance with appropriate standards and with legislative and regulatory requirements.	NHMRC and AHEC report annually	Table HREC list of members and their associated NHMRC categories of research, provide confirmed minutes, table the NHMRC and AHEC report at the Executive S&Q Committee meeting.
ISO National Standards	9.1 Monitoring, measurement, analysis and evaluation.	Accreditation response – On-going and annually	ISO accreditation compliance audit.
National Statement on Ethical Conduct in Human Research 2007 (updated 2018) Australian Code for Responsible	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	NHMRC and AHEC report annually	NHMRC compliance audit.

Human Research Ethics COMMITTEE

Terms of Reference

Conduct of Research (2018)	human research ethics committee.		
QH Research Management Policy QH-POL-013:2015 QH Research Management Standard QH-IMP-013-1:2015	Provide independent, competent and timely review of research projects in respect of their ethical acceptability.	Provide copies of confirmed monthly minutes and the NHMRC annual compliance report. On-going.	Forward minutes of meetings to the Executive Safety and Quality Committee. Compliance to the NHMRC audit.
Risk Management	All Risks are reviewed, recommendations considered and implemented in accordance with risk management framework.	Report on trended Risks	As required.

10. Membership

Membership eligibility is determined by the Chief Executive, Darling Downs Health.

- The HREC membership appointment will be consulted in accordance with the National Statement and will include the following:
 - a chairperson, with suitable experience, whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
 - 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;
 - 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 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.
- The minimum membership of an HREC is eight.
- As far as possible there will be equal numbers of men and women.
- At least one third of the members will be from outside the institution for which the HREC is reviewing research.
- At any one time, at least half the members appointed in the minimum membership categories listed under the National Statement (5.1.30) will have two or more years' experience on a HREC.
- Annually the HREC Chair will assess the categories and quantities of research received and align, as required, the expertise of the committee with the research studies received for review.

Chair:

- The Chief Executive of Darling Downs Health or delegate shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
If the Chair is absent from the meeting, or vacates the Chair during the meeting, the Chair must arrange an alternate Chair from amongst the members of the Committee. Failing this, the members should elect a Chair from amongst their number.

Members:

- Membership appointments to the HREC will be considered for review every three years.
- Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive of Darling Downs Health or delegate.

Human Research Ethics COMMITTEE

Terms of Reference

- The Chairperson and members may serve longer terms with the approval of the Chief Executive or delegate.
- Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive or delegate.
- 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.
- 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 Chief Executive or delegate may terminate the appointment of any member of the HREC if the Chief Executive 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.
- As a contingency measure to address the COVID-19 Global Pandemic, Darling Downs Health is collaborating with HIIRO and other QH HRECs throughout Queensland to provide for business continuity and minimise disruption. HREC members will be asked to voluntarily review application 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 to ensure that the impact of COVID-19 on vital research is minimised.
- 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.
- 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.
- A small gift of appreciation, not above the QH reportable threshold, may be made to the HREC members each year in recognition of the very substantial time commitment and intellectual input they make to QH. Refer to Public Service Commission Directive 22/09 Gifts and Benefits for advice.
- The Director, Health Innovation, Investment and Research Office or delegate will attend the HREC meetings, as required, as an observer. The role of the Director, HIIRO will be as a non voting, HREC Advisor regarding the regulation of and access to QH database and collections.
- It is the responsibility of the Chair to induct new members using the Committee Induction Manual.

11. Quorum arrangements

- In line with the National Statement Sections 5.2.28-5.2.31 there is no quorum for HREC meetings. Where there is less than full attendance of the minimum membership (8 members) at a meeting, the Chairperson must be satisfied, before a decision is reached, that the view 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.
- 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.
- Members who are unable to attend a meeting will be encouraged to contribute and advice their opinion via submission to the HREC Administrator prior to the meeting.

Human Research Ethics COMMITTEE

Terms of Reference

12. Other attendees

Non-members of the Committee who are attending should be discussed at least 24 hours before the meeting with the Chair. They should join the meeting for relevant sections of the Agenda only and do not take part in the decision making but can participate in the discussion as appropriate and decided by the Chair.

13. Frequency of meetings

- Meetings will be held monthly except for January when no meeting will be held.
- Meeting dates will be available on Darling Downs Health QHEPS and HIIRO website.
- Meetings will normally be held on the second Thursday of every month commencing at 4:30pm with the exclusion of January.
- Virtual meetings (held via email) will replace face-to-face meetings when the Chair determines that the business of the committee can be conducted via this medium without jeopardising the ability of all members to contribute comments to application, request and reports. This medium will not be used if there are full HREA applications for review.

14. Agenda, Papers, Minutes, Actions and Summary

- Meetings will be held in accordance with the QH HREC Standard Operating Procedures.
- The Agenda and any papers for the meeting are to be circulated electronically to the members one week before the meeting.
- 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.

15. Urgent out of session matters

- Any urgent matters can be managed as an out of session paper. However, the proponent of such a matter must ensure that it is minuted at the next meeting of the Committee.

16. Conflict of interest

All members must declare any real or potential conflict of interest, and manage those in consultation with the Chair, including absenting themselves through the meeting, relevant sections and ensuring the recording of such absences.

17. Decision making

- Decision 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 minimum membership of the HREC.
- In general, decisions of the HREC will be reached by general agreement and consensus.

18. Evaluation

The HREC will be evaluated in terms of its performance against the approved Terms of Reference and key performance indicators through an annual self-assessment using the [Evaluation Form](#). These will be collated by the Secretariat.

19. Secretariat

- The secretariat to the Committee is provided by:
 - Ethics and Research Governance Coordinator, phone 4616 6696.

Human Research Ethics COMMITTEE

Terms of Reference

20. Changes to Terms of Reference

These Terms of Reference may be altered following committee consultation and endorsement by the Chief Executive, on the recommendation of the Committee.

These Terms of Reference will be reviewed in June of each year in conjunction with the annual committee performance evaluation.

This Darling Downs Health committee was formally approved by Dr Peter Gillies, Chief Executive, on / /

Signature

Chairperson Ms Angela O'Shea

Signature