



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 embrace change and strive to know more, learn more and do better.
- *Courage* – We respectfully question for clarity and have the strength and confidence to Speak Up.

1. Committee Name

Darling Downs Health Human Research Ethics Committee (HREC)

2. Authorisation

- The committee functions under the authority of the Health Service Chief Executive
- The committee reports to the Executive Safety & Quality Committee
- The committee has authority to create relevant sub-committees or other subordinate bodies it deems necessary to assist the committee in discharging its responsibilities.
- The Chair is authorised to sign the Terms of Reference of such sub-committees and other subsidiary bodies when reviewed by this committee
- 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 project 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Officer and Coordinating Principal Investigator, when the HREC considers that ethical approval for research should be withdrawn.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.
- 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.

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4. Committee responsibilities concerning Standards and Plan Objectives

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

- Darling Downs Health Strategic Plan 2020-2024
- 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
- Research Ethics and Governance Health Service Directive QH-HSD-035:2022

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 (SOPs) accessed from the QH Office of Precision Medicine and Research (OPMR) 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 (SOPs) and shall be consulted with regard to any changes.
- All issues involving research governance will be dealt with in accordance with the QH Research Governance Standard Operating Procedures, accessed from the OPMR website.
- 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 SOPs.
- 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 humans 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.

6. Risk and Fraud 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.
- Adopt a zero tolerance for corrupt conduct, fraudulent activities or maladministration and promote awareness of staff roles and responsibilities in relation to fraud risk management.
- As per the *National Statement on Ethical Conduct in Human Research* Section 5.1.9

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7. Sub committees

Scientific Review Sub-Committee

8. Key Performance Indicators/Deliverables

Domain	Performance Indicator	Assessment/Reporting Timeframe	Audit Arrangements
Darling Downs Health Strategic Plan 2020-2024	Improving everyday - Promote health research undertaken in the health service.	Contribution to annual Research Activity Report	Report tabled at Darling Downs Health Executive Safety and Quality.
ISO National Standards	9.1 Monitoring, measurement, analysis and evaluation.	Accreditation response – ongoing	ISO accreditation compliance audit
National Statement on Ethical Conduct in Human Research 2007 (updated 2018) Australian Code for Responsible Conduct of Research (2018)	NHMRC HREC annual certification	NHMRC report annually	NHMRC compliance audit
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	Confirmed minutes to Darling Downs Health Executive Safety and Quality
Risk Management	All Risks are reviewed, recommendations considered and implemented in accordance with risk management framework.	Report on trended Risks	As required

9. Membership

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

Chair:

- A chairperson, with suitable experience, whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement.

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:

- 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;

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- 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.

Proxies:

- Proxies are not used for the HREC. At least two members are recruited for each category and this provides coverage and consistency in their knowledge and experience.

It is the responsibility of the Chair to induct new members using the Committee Manual.

10. Quorum arrangements

In line with the *National Statement on Ethical Conduct in Human Research* 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 below 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.

11. 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.

12. Frequency of meetings

- Meetings will be held monthly except for January when no meeting will be held.
- Wednesday
- 4:30pm
- Meeting dates will be available on Darling Downs Health QHEPS and OMPR website.

13. Agenda, Papers, Minutes, Actions and Summary

- The Agenda and any papers for the meeting are to be circulated electronically to the members one week before the meeting.
- Minutes will be confirmed at the next meeting of the committee.

14. 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.

15. 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.

16. Decision making

- Committee recommendations are made by general agreement and consensus.

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17. Evaluation

The Human Research Ethics Committee 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.

18. Secretariat

- The secretariat to the Committee is provided by:
 - Research Ethics and Governance Officer, (07) 4616 6696.

19. Changes to Terms of Reference

These Terms of Reference may be altered following committee consultation and endorsement by the Health Service 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 Hospital and Health Service committee was formally approved by Shirley-Anne Gardiner, A/Health Service Chief Executive on 17 / 08 / 2022.

Signature Shirley-Anne Gardiner

A/Chairperson Ms Michelle Cameron

Signature Ms Michelle Cameron