DDHHS Human Research Ethics Committee
Terms of Reference

Our Vision
• To deliver excellence in rural and regional healthcare.

Our Purpose
• Delivering quality healthcare in partnership with our communities.

Our Values
• Caring – We deliver care, we care for each other and we care about the service we provide.
• Doing the right thing – We respect the people we serve and try our best. We treat each other respectfully and we respect the law and standards.
• Openness to learning and change – We continually review practice and the services we provide.
• Being safe, effective and efficient – We will measure and own our performance and use this information to inform ways to improve our services. We will manage public resources effectively, efficiently and economically.
• Being open and transparent – We work for the public and we will keep our patients, clients, staff, stakeholders and community informed.

1. Committee Name
Darling Downs Hospital and Health Service Human Research Ethics Committee (EC00182).

2. Authorisation
The Darling Downs Hospital and Health Service Human Research Ethics Committee (DDHHS HREC) reports to and is accountable to the Chief Executive of the Darling Downs Hospital and Health Service.

The DDHHS HREC is a certified institution and has achieved NHMRC certification in order to undertake the 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 studies other than clinical trials
• Qualitative health research
• Mental health research
• Rural and/or remote health research
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3. Committee purpose

Committee Vision: Deliver quality and timely reviews of health ethics applications by ensuring integrity in research by partnering with researchers and the community for a better more informed future.

Relationships and Reporting:

- Provide independent, competent and timely review of research projects in respect of their ethical acceptability
- Monitor approved research studies for which the DDHHS HREC has given approval and provide advice at any time to the relevant Chief Executive (CE), through the research governance officer, and coordinating principal investigator, when the DDHHS HREC considers that ethical approval for research should be withdrawn
- Obtain expert opinions (external or 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 Australian Research Database (AU RED) all research applications submitted to the HREC, any monitoring and reporting requirements 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.
- 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 Research Ethics and Governance Unit website.

4. Committee responsibilities concerning Standards and Plan Objectives

The DDHHS HREC Committee is to oversight the DDHHS response to the following requirements of Standards and objectives of Strategic Plans:

- DDHHS Strategic Plan 2013 – 2017
- EQUIP Standard 15.4
- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for Responsible Conduct of Research 2007
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5. Scope of the Committee

To contribute to the management and delivery of health services the DDHHS HREC Committee undertakes the following:

- The DDHHS HREC will perform its functions, including monitoring of research and handling of complaints, according to written standard operating procedures (SOP) accessed from the Qld Health Research Ethics and Governance Unit (REGU) 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 Procedure (SOP) and shall be consulted with regard to changes thereto.
- All issues involving research governance will be dealt with in accordance with the Qld Health Research Governance Standard Operating Procedures, accessed from the REGU website.

Submissions All Studies

- The DDHHS 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-HEC) 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 Qld Health Services.

Single Site Studies

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

Multi-centre Research Studies

- All multi-centre research studies being submitted through the single ethical review process, for review by a HREC, will be through the Qld Health Central Coordination Service (CCS) as per the Qld Health HREC SOP.
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- 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 an application which is being or has been reviewed by a certified HREC under the single ethical review process.

6. Risk management

- The DDHHS 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.

Qld Health 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) in accordance with QH-Pol-152:2012. Qld Health 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) in accordance with QH-Pol-152:2012.

7. Sub committees

- The DDHHS 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 DDHHS HREC.
- The DDHHS HREC takes advice from the DDHHS Scientific Review Subcommittee. This subcommittee provides advice on scientific and technical aspects of research protocols involving human participants or subjects and gives feedback to the DDHHS HREC for investigators to enable them to address any issues of concern.
- The Chair of any such subcommittee will be appointed by the Chief Executive of the Darling Downs Hospital and Health Service.
- Members of the subcommittee need not be members of the DDHHS HREC.
### 8. Key Performance Indicators/Deliverables

<table>
<thead>
<tr>
<th>Domain</th>
<th>Performance Indicator</th>
<th>Assessment/Reporting Timeframe</th>
<th>Audit Arrangements</th>
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</thead>
<tbody>
<tr>
<td>DDHHS Strategic Plan 2013 – 2017</td>
<td>IP4. Review and improve our care. Monitoring of research given institutional authorisation will be as per QH HREC &amp; RGO SOP Version 3 Section: HREC monitoring of research given institutional authorisation. WF4. Engage clinicians to improve the service. Liaise with Queensland Health Hospital and Health Services, Universities, other research facilities and research personnel as appropriate.</td>
<td>NHMRC &amp; AHEC report Annually</td>
<td>Table DDHHS HREC list of members and their associated NHMRC categories of research, provide confirmed minutes, table the NHMRC &amp; Aust Health Ethics Committee report at the Executive S&amp;Q Committee meeting.</td>
</tr>
<tr>
<td>EQUIP National Guidelines</td>
<td>15.4 Research Governance Provide a report to the accreditation survey and respond to the recommendations of this body.</td>
<td>Accreditation response - On-going and annually</td>
<td>EQUIP accreditation compliance audit.</td>
</tr>
<tr>
<td>National Statement on Ethical Conduct in Human Research 2007 Australian Code for Responsible Conduct of Research 2007</td>
<td>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.</td>
<td>NHMRC &amp; AHEC report Annually</td>
<td>NHMRC compliance audit.</td>
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## 9. Membership

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

- The DDHHS HREC membership appointment will be constituted in accordance with the National Statement and will include the following:
  - (a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC capacity to carry out its obligations under the 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 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 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.
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Chair:
- The Chief Executive of the Darling Downs Hospital and Health Service or delegate shall appoint members of the DDHHS HREC, in consultation with the DDHHS 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 Hospital and Health Service or delegate.
- The Chairperson and members may serve longer terms with the approval of the Chief Executive of Darling Downs Hospital and Health Service or delegate.
- Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive of Darling Downs Hospital and Health Service 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 of Darling Downs Hospital and Health Service or delegate may terminate the appointment of any member of the HREC if the CEO 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.
- 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 Qld Health reportable threshold, may be made to HREC members each year in recognition of the very substantial time commitment and intellectual input they make to Queensland Health. Refer to Public Service Commission Directive 22/09 Gifts and Benefits for advice.

- The Director, Research Ethics and Governance Unit, Office of Health & Medical Research or delegate will attend the HREC meetings, as required, as an observer. The role of the Director, Research Ethics and Governance Unit will be as a non voting, HREC Advisor regarding the regulation of and access to Queensland Health databases and collections.
- It is the responsibility of the Chair to induct new members using the Committee Induction Manual.

10. 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 views 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 advise 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.
- Meeting dates will be available on the Research Ethics and Governance Unit 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 the email system) 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 applications, requests and reports. This medium will not be used if there are full NEAF applications for review.
13. Agenda, Papers, Minutes, Actions and Summary

- Secretarial support will be provided by the Coordinator, DDHHS HREC.
- Meetings will be held in accordance with Qld Health HREC Standard Operating Procedures
- The HREC agenda, accompanied by all required documentation for review of research proposals will be distributed not later than 5 working days prior to the HREC meeting.
- The minutes of meetings will be recorded on AU RED.
- 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.

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

- Members will be required to sign a statement undertaking that any conflicts of interest, which exist or may arise during his/her tenure on the HREC, will be declared.
- HREC members will be required to declare any conflict of interest prior to or at any time during a HREC meeting. The Chairperson will determine the action to be taken. (National Statement section 5.2.4; Chapter 5.4)
- All conflicts of interest will be managed as per Research Management Policy 2010 and Implementation Standard QH-IMP-013-4:2010 Conflicts of Interest in Research.

16. Decision making

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

17. Evaluation

The DDHHS HREC will be evaluated in terms of its performance against the approved Terms of Reference and key performance indicators through an annual self-assessment.

The committee will evaluate the conduct of the meeting using the attached Evaluation Form in March, June, September and December each year. These will be collated by the Secretariat.

18. Secretariat

The secretariat to the Committee is provided by:

   Human Research Ethics Coordinator, phone 4616 6696.

19. 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 Hospital and Health Service committee was formally approved by Dr Peter Gillies, Chief Executive, on / / .

Signature: .................................................................

Chairperson: Angela O’Shea (Acting)

Signature: .................................................................

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