

**Name of Committee:** Human Research Ethics Committee [EC00182]

**Endorsement and Authorisation:**

The Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Service District Human Research Ethics Committee (TDDHSD HREC) is authorised by the District Chief Executive Officer.

**Statement of Strategic Intent:**

The HREC is established by the Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Service District to ensure compliance with ethical standards in research involving humans approved within the Health Service District.

The HREC is constituted according to and complies with the NHMRC “*National Statement on Ethical Conduct in Human Research*” 2007 (National Statement).

**Aim:**

The Human Research Ethics Committee will aim to ensure only research meeting the requirements of the National Statement on Ethical Conduct in Research 2007, and any subsequent updates, involving Humans and evolving community expectations is undertaken within Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Services.

The TDDHSD HREC may obtain expert opinion or establish sub-committees to provide scientific/technical assessment on research protocols and evaluation of research studies to ensure compliance with regulatory requirements.

**Objectives:**

The HREC shall:

- Consider research protocols involving participation of human volunteers, employees, clients, patients or deceased persons, or the use of data and other material derived from human participants
- Recommend approval, monitor as required by the institution and legislative requirements, review and, if necessary, recommend withdrawing or suspending approval of research projects.
- Advise the District Chief Executive Officer on policy related to the conduct and management of human research.
- Where projects involve more than one institution, take account of the approval provided by other duly NHMRC registered HRECs and from 1 July 2010 comply with the requirements of the QH single ethical review process as per the QH HREC SOP Version 3.
- Maintain a register of all research protocols submitted to the HREC.
- Ensure appropriate fees are charged, as per QH Research Management Policy and Framework, to the sponsors of research for the processing and consideration of the protocols and for the monitoring of the research.

- Provide reports to the District Chief Executive Officer, NHMRC and Queensland Health Research Ethics & Governance Unit as required and at least annually.
- Consider all research proposals and projects in a risk management framework, detection and handling of unethical or fraudulent submissions or practices in consultation with the Designated Officer and advise the District Chief Executive Officer of any concerns or potential adverse impacts on research participants, researchers and all other relevant organisations and parties.
- Review all recommendations or requirements of the NHMRC and/or REGU, OHMR with respect to the ethical conduct of research and the role of Human Research and Ethics Committees and where appropriate, institute change.
- Review all recommendations of the NHMRC and/or REGU, OHMR with respect to the ethical treatment of humans and advise other committees as appropriate.

## **Membership:**

### *(i) Composition (National Statement section 5.1.29 – 5.1.34)*

- The minimum membership of the TDDHSD HREC complies with the National Statement. Additional members may be recruited at the discretion of the HREC.
- Members are appointed for their expertise and diversity of the categories and not in a representative capacity.
  - A chairperson, not necessarily an employee of the DD-WM (TDD) HSD and with no apparent conflict of interest, capable of articulately providing independent advice.
  - Two members who are lay people, one man and one woman from the Toowoomba community who have no affiliation with the DD-WM(TDD)HSD, are not currently involved in medical, scientific, or legal work. These people should have the ability to represent the community (with current or recent community involvement) and to mirror community standards.
  - Two member with training and experience in the areas of clinical based research sufficient to be able to understand and comment on issues of scientific merit
  - One nurse
  - One doctor
  - One Minister of Religion (of any faith), or a person who performs a similar role in the community such as an Aboriginal elder.
  - One lawyer – where possible one who is not engaged to advise the DD-WM (TDD) HSD.
  - Where there are significant indigenous ramifications to the research the committee may co-opt indigenous members where the indigenous community is inadequately represented on the committee.
  - A member cannot be appointed under more than one category, thus there must be a minimum of nine members.
- Staff appointed to this committee are not there to represent other staff or a departmental perspective, but to advise on the welfare of research participants and on issues relating to the ethical and scientific merit of research.
- The composition of the committee should provide a spread of disciplinary expertise across the committee as well as an age and gender balance.
- At least one third of the members shall be from outside the institution.
- At any one time, at least half the members appointed in the minimum membership categories listed above will have two or more years experience on a HREC.

- The Executive Director of Toowoomba Hospital/Director of Medical Services is the Executive Sponsor for the Committee, and shall also be an ex officio member.
  - The HREC is assisted where necessary by the Queensland Health Panel of External Expert Reviewers.
- (ii) *Recruitment and Selection and Appointment (National Statement section 5.1.34 – 5.1.36)*
- Recruitment to the HREC may be by word of mouth, expressions of interest, internal or external advertising.
  - The selection process should include, at a minimum, a meeting with the Chairperson and preferably, an additional HREC member (either with the Chair or separately at the discretion of the Chair). During this meeting, the attributes and desired qualities as outlined in the National Statement should be taken into consideration.
  - Membership is by appointment by the District Chief Executive Officer and a formal letter of appointment will be issued.
  - Proxies shall be appointed in each of the membership categories. Where possible members will nominate their own proxy.
- (iii) *Periods of Appointment (National Statement section 5.1.34)*
- Membership is for a period of three years, with possible extension.
- (iv) *Minimum Attendance*
- As a condition of membership, committee members should endeavour not to miss three consecutive meetings. If a member submits comments on agenda items to the Coordinator prior to the meeting, this will be counted as attendance. (*National Statement section 5.2.30*)
- (v) *Indemnity (National Statement section 5.1.9)*
- 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) according to HR Policy I3.
  - 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) according to HR Policy I3.
- (vi) *Confidentiality (National Statement section 5.2.19)*
- HREC members will regard research documentation as confidential and will take care to prevent it being disclosed outside the HREC except for the purpose for which it was provided.
- (vii) *Education and Training (National Statement section 5.1.28(b))*
- New HREC members and proxies will be provided with the Induction Guide together with copies of the relevant documents listed in the Guide.
  - New members may attend their first meeting as an observer only.
  - Members will be encouraged to attend relevant education and training sessions. The HREC Chairperson and Coordinator will provide ongoing support as required.
  - Proxies may also be invited to attend a meeting as an observer.
  - Members will attend continuing education and training in research ethics at least every 3 years (*National Statement section 5.2.3(c)*)

(viii) *Remuneration*

- HREC members provide services on a voluntary basis. All essential and necessary expenses will be reimbursed by the Darling Downs – West Moreton (Toowoomba Darling Downs) Health Service District on production of original receipts. Education and training expenses will also be met by the District as in (vii) above.

(ix) *Conflicts 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 and Framework 2010 Implementation Standard 5: Conflicts of Interest in Research.

**Reporting Relationships:**

- The Human Research Ethics Committee reports to the Darling Downs - West Moreton Health Service District Safety and Quality Committee and the Darling Downs - West Moreton Health Service District Chief Executive Officer.
- The Committee is also required to provide information from its records to the REGU, OHMR and NHRMC on request and shall report annually the information specified in the National Statement on Ethical Conduct in Research involving Humans (2007) and any subsequent updates.
- The HREC will liaise with other Queensland Health Districts/Directorates, the Mater Health Services, QIMR, universities, private organisations and other personnel involved in research.
- The HREC will liaise with principal investigators on matters relating to the protocol or ethics of a project including, where required, inviting investigators to attend relevant HREC meetings.

**Meeting Protocols:**

(i) *Chair:*

- The chairperson of the Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Service District Human Research Ethics Committee will be selected as described in membership above.
- The chairperson will chair every meeting when present. On occasions when the chairperson is absent or excluded because of a conflict of interest, the meeting will appoint a chair.

(ii) *Secretariat:*

- A secretariat function will be provided by the Coordinator Human Research Ethics Committee and Research Scholarships.
- The Coordinator assists and supports the Committee in carrying out their functions and in providing advice to researchers on the requirements for consideration for ethical approval. The Coordinator provides continuity of policy interpretation and informing investigators of the Committees' decisions and requirements for reporting on progress of research.
- The Coordinator reports to the Chairperson of the HREC and liaises with the Research Ethics and Governance Unit, Office of Health & Medical Research, Queensland Health.

(iii) *Frequency/Length of Meeting:*

- The Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Service District Human Research Ethics Committee will meet monthly, except in January, for 2 – 3 hours. The first meeting of the year will be in February.
- A schedule of meeting dates will be made available to HREC members in November of the preceding year.
- The TDDHSD SRC (Scientific Review Committee) will meet electronically two week prior to the HREC. Additional sub-committee meetings may be scheduled if required.

(iv) *Submissions*

- Closing dates for submission of applications will be advertised on the intranet/internet. Applications received after the deadline will be placed on the next HREC agenda. Early submission to the Coordinator allows correction of obvious omissions prior to consideration by HREC members.
- The HREC require protocol submission to be in accordance with Queensland Health policy and in the standard format. Electronic submission is required, with a single original hard copy containing relevant signatures + 17 collated copies to be provided.
- From 1 July 2010, the submission of multi-centre research projects will be through the QH Central Coordinating Service as per QH HREC SOP Version 3

(v) *Quorum: (National Statement section 5.2.28 – 5.2.30)*

- No quorum exists for this meeting. Where there is less than full attendance at a meeting, the Chairperson must be satisfied, before a decision is reached that the minimum membership (as defined in the National Statement) have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered. In the event that one of the members is absent, a suitable proxy may be present in their place. Committee members should notify the Chairperson or Secretariat, in advance, of their proxy nomination.
- Members unable to attend are encouraged to provide written comments to the Coordinator prior to the meeting. These comments will be made available to other committee members. (See (iv) *Minimum Attendance* on page 3)

(vi) *Decision making: (National Statement section 5.2.28 – 5.2.31)*

- Decisions, in general, shall be reached by consensus. Where this is not possible despite efforts to achieve unanimity, six members of the committee are required to support a decision for it to be accepted.
- Serious concerns of one or more members will be addressed before ethical approval is given.
- Researchers may be invited to speak to their protocols at HREC meetings but will not be present for discussion or decision-making.
- The Committee may, in accordance with the National Statement, take account of prior review of a research proposal by another duly constituted HREC. From 1 July 2010 the HREC will comply with the direction of the QH Director General regarding the model of single ethical review as described in QH HREC SOP Version 3.

(vii) *Documentation: (National Statement section 5.2.23 – 5.2.27)*

- The advertised deadlines allow time for compulsory review by the SRC to enable applicants to modify their applications prior to the HREC meetings.

- The SRC may request amendments or a re-submission before the application may proceed to the HREC.
- The Agenda will be distributed not later than 10 working days prior to the meeting and will include copies of any submitted research proposals. As far as possible distribution will be electronic.
- The Minutes will be prepared in line with the DD-WM(TDD)HSD format for meetings – e.g. actions, responsible person, due date, outcome, etc. The Minutes should reflect not only decisions made but the ethical issues canvassed in reaching a decision.
- To emphasise the consensual nature of HREC deliberations, particular views of individual members are not recorded unless specifically requested. Should a member disagree with a decision of the committee and request this to be noted in the minutes this should be done.
- Decisions and requests to investigators for further information should reference the National Statement as recommended by the National Statement
- The minutes must record where a member with a possible conflict of interest in a proposal left the meeting temporarily.
- The Minutes should be produced, within fourteen days following the meeting, and should be checked by the Chairperson and ratified by the HREC as a true record at the next meeting. Minutes will be distributed to all members of the committee with the agenda of the next meeting.
- The final recommendation of the HREC will be communicated to Coordinating Principal Investigator or delegate within 10 working days of the meeting. It will be the Coordinating Principal Investigator or delegate's responsibility to communicate with the local site Principal Investigators, where applicable, and relevant Research Governance Officer(s) to obtain District(s) authorisation to commence the research.

(viii) *Low and negligible Risk (LNR) Research (National Statement section 5.1.18 – 5.1.21)*

- A formal process for review of low and negligible risk protocols will be encouraged in line with the Queensland Health Research Management Policy and the National Statement. In general, all new proposals which involve other than minimal risk to participants must be submitted to the whole committee.
- The process for review of low and negligible risk protocols is:
  - The committee secretariat will upload the application details onto AU RED
  - Protocol is assessed by the HREC Chair and one other HREC member
  - The committee secretariat notifies Principal Investigator of the outcome.

(ix) *Amendments*

- The Chairperson may provide interim approval of amendments in the interest of participant safety or well-being.
- Interim approval given by the Chairperson will be subject to ratification by the full committee at its next meeting.
- In general, amendments will be processed as per the QH HREC SOP Version 3.

(x) *Monitoring and compliance (National Statement Chapter 5.5)*

- The HREC requires
  - The Coordinating Principal Investigator to keep adequate records and provide access to the HREC when requested.
  - Notification of significant events, side effects or complications occurring at any time during the research including the course of action taken.

- Notification of any complaints received from participants, staff, observers or the community
  - Notification and explanation of any proposed changes to the protocol and HREC approval prior to implementation of the changes.
  - Notification and explanation if the research is to be discontinued before the expected date of completion.
  - Interview with the researchers and/or participants if requested.
  - Opinion of external experts if considered necessary
  - A detailed report annually and at the completion of any research
  - Notification and a copy of published results, presentations at conferences, etc.
  - Notification of suspicion of scientific fraud.
- Where circumstances warrant temporary suspension or discontinuation of a research project, the HREC will communicate the HREC decision to the Coordinating Principal Investigator. For multi-centre studies, it will be the Coordinating Principal Investigator's responsibility to communicate the decision to the local site Principal Investigators and the local Site Principal Investigators' responsibility to notify the relevant RGOs .
  - Monitoring of research given institutional authorisation will be as per QH HREC SOP Version 3 & RGO SOP Version 3.

*(xi) Complaints concerning the conduct of a project*

- The existence of an independent complaint process must be made known to researchers and research participants.
- As per the Australian Code for the Responsible Conduct of Research (The Code) the institution has nominated 'advisers in research integrity' to advise possible complainants about research conduct issues and explain the options open to persons considering, making, or having made an allegation. The nominated 'adviser in research integrity' is Ms Angela O'Shea.
- As per The Code the institution has nominated a 'designated person' for handling research complaints, including research misconduct. The nominated 'designated person' is Dr Peter Gillies.
- Provision is required for participants or subjects in projects endorsed approved by the HREC to address complaints or concerns to the 'designated person' via the HREC Coordinator.
- Participant Information Sheets must include contact details for the HREC Coordinator for concerns and complaints regarding the research.
- Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the authorising HREC institution's designated person for handling research complaints, including research misconduct via the HREC Coordinator.
- Any complaints received must be entered on AU RED and also forwarded to the local site RGO where the complaint applies.
- Initially, complaints should be forwarded by the designated person to the relevant department to be dealt with at departmental level.
- The departmental decision will be reported back to the 'designated person' and the HREC secretariat.
- The 'designated person' will review the departmental decision and make a recommendation to the HREC on the appropriate course of action.
- If the complainant is not satisfied with the outcome of the 'designated person's' investigation, then he/she can refer the complaint to the institution's District Chief Executive Officer (DCEO) or his/her nominee for appeal.

- For allegations not resolved at departmental level and appeals, the institution's DCEO or his/her nominee will establish an investigating committee; nominating three independent individuals, who do not have any conflict of interest in the case and have appropriate expertise to evaluate the research issues, to review the case.
- The decision of the investigating committee will be final.
- All complaints will be acknowledged within seven (7) days.
- The complainant will be advised of the decision within 30 days.

(xii) *Complaints concerning the HREC's review process including the HREC's rejection of an application*

- Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing.
- The HREC Chairperson will notify the DCEO of any complaints received by him/her, as soon as possible. The DCEO will inform the Chairperson of any complaints received by him/her as soon as possible.
- The HREC Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC and the investigator on the appropriate course of action.
- If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the DCEO, or his/her nominee, or request the Chairperson to do so.
- The Chairperson will provide to the Chief Executive all relevant information about the complaint/concern.
- The Chief Executive will determine whether there is to be a further investigation of the complaint.
- If it is decided there is to be a further investigation, then the DCEO will convene an investigating committee to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.
- The decision of the investigating committee will be final.

### **Changes to the Terms of Reference:**

- These Terms of Reference may be altered by the District Chief Executive Officer following committee consultation or following published recommendations of the NHMRC.
- The Terms of Reference will be reviewed annually.

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This TDDHSD Committee was formally approved by: Pam Lane, District Chief Executive Officer

Authorised by: [signed by Peter Bristow](#)

Date: [on 19 May 2010](#)

Chair: Dr Peter Bristow

Review date: May 2011