



*The Prince Charles Hospital*



**METRO NORTH HEALTH SERVICE DISTRICT - HUMAN RESEARCH ETHICS  
COMMITTEE  
(TPCHMNHSD HREC - EC168)**

**Terms of Reference**

**Preamble**

The Prince Charles Hospital, Metro North Health Service District HREC (TPCHMNHSD HREC – EC168) is a committee established by Metro North Health Service District, Queensland Health (QH) that is constituted and functions in accordance with the NHMRC '*National Statement on Ethical Conduct in Human Research*' (2007) - *the National Statement (NS)*; and complies with the '*Australian Code for Responsible Conduct of Research* (2007) and *QH Research Management Policy (QHMRP; 2008)*.

**Purpose and Scope of Responsibilities**

The TPCHMNHSD HREC reviews and oversees Human Research with researchers to ensure that all clinical and health research are conducted ethically and responsibly at TPCH.

The TPCHMNHSD HREC may obtain expert opinions (external or internal) from time to time to provide scientific/technical assessment on human research protocols and evaluation of research clinical trials/studies and compliance with regulatory requirements.

The TPCHMNHSD HREC shall: (*National Statement section 5.1.26*)

- (a) Advise the District CEO (DCEO), Metro North HSD via the Executive Director, TPCH, through the Chair TPCHMNHSD HREC of the ethical acceptability of research protocols submitted for consideration.
- (b) Monitors approved research studies being conducted at this District and provide advice at any time to the DCEO when the TPCHMNHSD HREC considers that ethical approval for research should be withdrawn.
- (c) Maintain a local register for all research protocols submitted to TPCHMNHSD HREC, which would include monitoring and reporting requirements and any ongoing approval status of proposals.
- (d) Provide an annual report listing of approved protocols for QH through the Office of Research, Ethics and Governance (OREG)
- (e) Provide an Annual Report 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.
- (f) Consider participating as a Lead Committee in a proposed National system of scientific and ethics review of multi-centre research for cardiothoracic, mental health, geriatric and palliative care, drug and alcohol; and sexual health services.

- (g) Review research protocols from the Sunshine, Wide Bay and Fraser Coast Health Service Districts and other private research institutions.

## Relationships

The TPCHMNHSD HREC will:

1. Report to the District CEO (DCEO), Metro North HSD, via the Executive Director, TPCH through the Chair, TPCHMNHSD HREC
2. Liaise with other Queensland Health Service Districts, Universities and other research facilities and research personnel through the Executive Officer Research and Ethics (EOR) Office of Research, Ethics and Governance.
3. Have the right to charge fees to the sponsors of commercial research both for the processing (initial application and amendment submissions) and consideration of the protocols and for the monitoring of the research.
4. Review and approve research which may then facilitate expedited HREC approval at other participating Health Service District/s subject to individual HREC site specific requirements and expedited review procedures.
5. District Manager of individual Health Service Districts where TPCHNHSD HREC had ethically approved a research protocol, will have the right to not approve the conduct of a research project within its District in the absence of adequate resources.

## HREC Procedures

- (a) **Composition and Appointment:** *(National Statement sections 5.1.29 - 5.1.34)*

*The TPCHMNHSD HREC membership appointment be constituted in accordance to the National Statement and will include the following:*

*“(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 women, 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."*

- Members will attend continuing education and training in research ethics at least every three years (*National Statement 5.2.3 (c)*).
- Membership appointments to the TPCHMNHSD HREC will be considered for review every three years (*National Statement 5.1.34*).

**(b) Protocols**

- The TPCHMNHSD HREC will normally require submissions to be in a standard format using the National Ethics Application Form (NEAF) from February 2009.
- Submissions may be made in hard copy currently (electronic form will be considered in the future).
- The Chair along with the members of the HREC Committee and Executive Officer Research and Ethics will determine if any expert advice is required for any protocol.

**(c) Meetings:** (*National Statement sections 5.1.37 and 5.2.28*)

- Meetings will be held monthly, except for January when there will be no scheduled meeting.
- Notice of meetings will be given to members for the current year and at least two (2) weeks before any date change to a meeting.
- A hard copy of the Protocols for consideration, including the NEAF, patient information & consent form, investigators brochures, questionnaires or other relevant correspondence (where applicable) and the written advice for any meeting will be forwarded to all members at least one (1) and preferably two (2) weeks before the meeting.

**(d) Meeting Protocol:** (*National Statement sections 5.1.30, 5.2.28 – 5.2.31*)

- The TPCHMNHSD HREC will review completed NEAF applications form from January 2009.
- 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 TPCHMNHSD HREC.
- Where there is less than full attendance of the minimum membership 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 Chairperson or Executive Officer Research and Ethics prior to the meeting.
- Meetings will normally be held at The Prince Charles Hospital District Administration Office Meeting Room, Rode Road, Chermside, Qld, 4032.

- The principal investigator or a representative for the investigator may be invited to attend the relevant meeting to discuss a proposal but before any decision is taken, would be required to leave the meeting.
- Committee members associated with a research protocol being considered by the committee will be excluded from the meeting in the final discussion and voting process of that particular proposal.
- Where there is a conflict of interest, members of the committee will be required to declare this prior to or at any time during a meeting. The Chairperson will determine the action to be taken for the review of the submission.
- In general, decisions of TPCHNHSD HREC will be reached by general agreement rather than simple voting majorities.
- The appointed Chairperson will chair every meeting unless on occasions when the Chairperson is absent or excluded because of a conflict of interest, the meeting will be chaired by the Deputy Chairperson.

**(e) Secretarial Support**

- Secretarial support will be provided by staff of the Office of Research, Ethics and Governance.
- The minutes of meetings will be kept by a staff of the Office of Research, Ethics and Governance.
- 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.
- Draft minutes will be forwarded to the Chair as soon as practical after the meeting.
- Action following decisions recorded in the draft minutes will be initiated no sooner than 48 hours after circulation of draft minutes. Members who object to the progress of any actions recorded should contact the secretariat within that time frame.
- As much as possible, electronic communication will be used to communicate with members and Researchers.
- Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.

**(f) Monitoring: (National Statement Chapter 3.3.19 & 5.5)**

The TPCHMNHSD HREC requires the Researcher to:

- Keep adequate research records and provide access when requested to the TPCHMNHSD HREC.
- Provide progress reports at intervals specified by the TPCHMNHSD HREC and at completion of any research but not less than annually.
- Notify and provide reports to the HREC of significant adverse events, side effects or complications occurring including the course of action taken at any time during the research.
- Notify the HREC of any complaints received from participants, staff, observers or the community.
- Provide prospective advice of any proposed amendment(s) to be made to the protocol and approval of these prior to implementation.
- Notify and provide reasons to the HREC if the research is to be discontinued before the expected date of completion of the project.

- Provide a copy of published articles/results, presentations or posters at conferences etc. to the HREC.

The TPCHMNHSD HREC may:

- If required, request an interview with the researchers, research participants or other forms of feedback from them.
- If required, request random inspections or access to research sites, research data and consent documentation records.
- If considered necessary, request the opinion of external experts.

**(g) Handling Complaints: *(National Statement Chapter 5.6)***

- In the first instance all complaints will go to the Executive Officer Research, Ethics and Governance who will forward these concerns to the Chairperson of the HREC who will address the complaints.
- A copy of the complaints will be received by the secretariat of the TPCHMNHSD HREC who will monitor the complaints.
- Any complaints received by the researcher must be forwarded to the Chairperson or Executive Officer Research, Ethics and Governance, TPCHMNHSD HREC and to the Chairperson of the local HREC.
- Participant Information Sheet and Consent forms must include contact details to allow such complaints to be made.
- Complaints on the process, conduct or decisions of the TPCHMNHSD HREC should be made in writing to the Chairperson or Executive Officer Research, Ethics and Governance.
- All complaints will be acknowledged within seven (7) days.
- The Chairperson of TPCHMNHSD HREC will determine action to be taken. This may necessitate a special meeting of TPCHMNHSD HREC, which may be called without the usual 14 day requirement for notice, to consider such a complaint.
- The complainant will be advised of the decision of the TPCHMNHSD HREC within 30 days.
- If the complainant does not accept the decision of the TPCHMNHSD HREC, the complaint may be forwarded to the District CEO, via the Executive Director, TPCH whose decision will be final.