



The Prince Charles Hospital Human Research Ethics Committee (EC00168) Terms of Reference

Metro North Hospital and Health Service

Contents.....	<u>Error! Bookmark not defined.</u>
Introduction	3
Preamble	3
Lead HREC.....	3
HREC objectives.....	3
HREC functions and responsibilities	3
Relationships and reporting	4
1 HREC establishment	4
1.1 HREC composition	4
1.2 HREC appointment of members.....	5
1.3 Education for HREC members	6
1.4 HREC sub-committees.....	7
1.5 HREC liability coverage.....	7
1.6 National certification for multi-centred ethical review	7
2 HREC procedures	8
2.1 Standard operating procedures	8
2.2 Submissions.....	8
2.3 Protocols.....	9
2.4 Meetings	9
2.5 Monitoring	<u>1142</u>
2.6 Handling complaints.....	12
3 HREC responsibilities to the institution	<u>1243</u>
3.1 Monthly meeting with the Executive Director Medical Services regarding ethical and governance processes who in turn provide feedback to the Executive Director TPCH.....	<u>1243</u>
3.2 Executive Director Medical Services attends the HREC meeting as a non-voting member and is, therefore, kept informed and updated of HREC processes and workings of the committee.	<u>1243</u>
4 Amendment to the terms of reference	<u>1243</u>
.....	13
4.1 The views of the members are discussed at the next scheduled meeting of the TPCHHREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.	13
4.2 The proposal is ratified if two thirds of the members agree to the amendment.	13
4.3 The Chairperson sends the amendment to the Executive Director for review and approval.....	13

Introduction

Preamble

The Prince Charles Hospital Human Research Ethics Committee (TPCH HREC - EC00168) is a committee established by Metro North Hospital and Health Services, 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); The World Medical Association "Declaration of Helsinki"; The CPMP/ICH Note for Guidance on Good Clinical Practice (CPMH/ICH-135/95); The Public Health Act 2005 (updated 2015); and other health policies.

Lead HREC

A lead HREC is a HREC which has been certified by NHMRC to undertake the single ethical review of research projects [SERP] to be conducted at more than one site.

The Prince Charles Hospital Human Research Ethics

Committee [TPCH HREC] has applied for certification and certified to undertake single ethical review in the following research fields:

- Clinical trials of drugs and devices Phase 0, I;II; III; IV
- Population health and/or public health
- Clinical Interventional research other than clinical trials
- Qualitative health research
- Mental Health
- Other – Alcohol and Drugs,
- Other - Sexual Health

HREC objectives

- Protect the mental and physical welfare, rights, dignity and safety of participants of research
- Facilitate ethical research through efficient and effective review processes
- Promote ethical standards of human research
- To ensure that all clinical and health research is conducted ethically and responsibly

HREC functions and responsibilities

- Provide independent, competent and timely review of research projects submitted by affiliated and non-affiliated researchers in line with its certification via single ethics review for multicentre research and in accordance with the Queensland Health Directive: Research Ethics and Governance in respect of their ethical acceptability

- Monitors approved research studies for which the HREC has given approval and provide advice as required to the Chief Executive, Metro North Hospital and Health Services (CE, MNHHS) via the Executive Director, TPCH, through the Research Governance officer (RGO) and coordinating principal investigator.
- Obtain expert opinions (external or internal) as required [National Statement 5.1.33] 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

Relationships and reporting

The TPCH HREC will:

- Report to the CE Metro North Hospital and Health Service [MNHHS] via the Executive Director
 - The Prince Charles Hospital where constituted.
- 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 the Health Innovation, Investment and Research Office [HiiRO]; Hospital and Health Service Boards [HHS], Universities, other research institutes; research facilities and research personnel as appropriate.
- Charge fees to the sponsors of commercial research, both for the processing (initial application and amendment) submissions and consideration of the protocols.
- Acknowledge that the CE of individual Hospital and Health Services will have the right to not approve the conduct of a research project.

1 HREC establishment

1.1 HREC composition

1.1.1 The TPCH HREC Chairperson and the Executive Officer Research, report to the TPCH Executive Director of Medical Services (EDMS) regarding the constitution and function of the Committee and the ethical acceptability of research applications submitted for consideration.

The membership of the TPCH HREC is constituted according to the National Statement [Section 5.1.30]

- 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 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, 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.

1.1.2 The minimum membership of an HREC is eight.

1.1.3 As far as possible there should be equal numbers of men and women.

1.1.4 At least one third of the members should be from outside the institution for which the HREC is reviewing research [National Statement 5.1.29 (b)]

1.2 HREC appointment of members

1.2.1 The Prince Charles Hospital, Metro North Hospital and Health Services [MNHHS] Executive Director shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.

1.2.2 Membership appointments to the HREC will be considered for review every three years [National Statement 5.1.34].

1.2.3 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.

1.2.4 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

1.2.5 Before appointment, members acknowledge in writing their acceptance of the terms of reference of the TPCH HREC and any requirements for confidentiality and conflict of interest required by Queensland Health.

1.2.6 Members are appointed for a period of three years and may serve consecutive terms as approved by the Executive Director, The Prince Charles Hospital.

1.2.7 The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Executive Director.

1.2.8 Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Executive Director.

1.2.9 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.

- 1.2.10 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.**
- 1.2.11 The institutional Executive Director may terminate the appointment of any member of the HREC if the Executive Director 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.
- 1.2.12 Members will be provided with a letter of appointment including the date of appointment, length of tenure, assurance that indemnity will be provided by Queensland Health in respect to the conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.**
- 1.2.13 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.**
- 1.2.14 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.

1.3 Education for HREC members

- 1.3.1 Newly appointed members shall be provided with adequate orientation and mentoring.**
- 1.3.2 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of The Prince Charles Hospital Metro North Hospital and Health Services [MNHHS].**
- 1.3.3 Members will attend continuing education and training in research ethics at least every three years [National Statement 5.2.3 (c)].**

1.4 HREC sub-committees

- 1.4.1** The HREC may appoint such sub-committees as it sees fit or as required from time to time to carry out a scientific or technical review of a research proposal, or ethical review of low or minimal risk research, submitted to the HREC.
- 1.4.2** The Chair of any such subcommittee will be appointed by the Executive Director of The Prince Charles Hospital Metro North Hospital and Health Services [MNHHS].
- 1.4.3** Members of the subcommittee need not be members of the HREC.

1.5 HREC liability coverage

- 1.5.1** 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).
- 1.5.2** 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).

1.6 National certification for multi-centred ethical review

- 1.6.1** Where an institution elects to nominate for certification the following will occur:
- Institution undertakes self-assessment
 - Institution nominates to be assessed for certification by submitting paper work to national certification body
 - Certifying body undertakes desk top audit of institutional paper work
 - Certifying body conducts an onsite visit and issues draft report
 - Certifying body issues final report and, if approved, certification conditions
- 1.6.2** The TPCH HREC applied for certification to conduct single ethical review, was assessed on 19 May 2010 and received full certification as Lead HREC from 1 Jan 2011 – 31 Dec 2016 in the fields of:
- Clinical trials Phase I, II, III & IV relating to; Adult Cardiac Medicine and Surgery [including all Drugs and Devices], Adult Thoracic Medicine and Surgery [including Drugs and Devices], Heart and Lung transplantation, Orthopaedics; Internal Medicine and General Surgery; and Emergency Medicine [Adult and Paediatrics]
 - Population health research
 - Clinical interventional research other than clinical trials - Cardiac Rehabilitation Programs, Nursing Interventions, Allied Health Practices, Medical, Nursing and Allied Health Education Programs
 - Qualitative health research
 - Mental health

- Sexual health research
- Alcohol and drugs studies research

1.6.3 Certification standards will be as per the Australian national certification standards.

1.6.4 The responsibility for meeting these certification standards rests with The Prince Charles Hospital Metro North Hospital and Health Service [MNHHS] which constituted the HREC.

2 HREC procedures

2.1 Standard operating procedures

2.1.1 The HREC will perform its functions according to written standard operating procedures (SOP). These procedures shall be reviewed at least every three years and amended and updated as necessary.

2.1.2 All HREC members shall have access to and/or be provided with copies of the SOP and shall be consulted with regard to changes thereto.

2.2 Submissions

All Studies

2.2.1 Excluding exceptional circumstances the HREC will consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is valid and received by the relevant closing date.

2.2.2 When a submission is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.

Single Site Studies

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

Multicentre Research Studies

2.2.4 The submission of all multi-centre research studies being submitted through the single ethical review process [SERP], for review by the lead HREC, will be submitted directly to the lead HREC.

2.3 Protocols

- 2.3.1 The HREC will require submissions to be in a standard format using the National Ethics Application Form (NEAF) available on the online forms website:
<https://www.ethicsform.org/au/SignIn.aspx>
- 2.3.2 The HREC will require the researcher to electronically upload all supporting documents onto the online forms NEAF website.
- 2.3.3 The HREC will also require the researcher to submit both hard and electronic copies of the submission as per the HREC requirements, available on the Metro North Research website.
- 2.3.4 The Chair along with the members of the HREC Committee and HREC administrator will determine if any expert advice is required for any protocol.

2.4 Meetings

- 2.4.1 Eleven meetings will be held on a monthly basis except for December.
- 2.4.2 Meeting dates will be published on the Metro North Research website.
- 2.4.3 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.
- 2.4.4 A hard and/or electronic copy of the agenda, previous minutes, protocols for consideration, including the NEAF, patient information & consent form questionnaires or other relevant documents (where applicable); and the written information for any meeting will be forwarded to all members approximately ten [10] days before each meeting.

Meeting Protocol

- 2.4.5 Decisions by the TPCH HREC 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 HREC.**
- 2.4.6 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 have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.**
- 2.4.7 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.**
- 2.4.8 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.**
- 2.4.9 Committee members associated with a research protocol being considered by the committee will declare any conflict of interest [COI] which will be formally recorded in the minutes; and be excluded from the meeting in the final discussion and voting process of that particular proposal.**
- 2.4.10 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.**
- 2.4.11 In general, decisions of TPCH HREC will be reached by general agreement rather than simple voting majorities.**
- 2.4.12 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.**
- 2.4.13 Meetings will normally be held at The Prince Charles Hospital, Rode Road, Chermside, Qld 4032.**
- 2.4.14 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.**

Secretarial Support

- 2.4.15 Secretarial support will be provided by officers of Research, Ethics and Governance Unit [REaGU], TPCHMNHHS.**

Decisions from HREC meetings

- 2.4.16** The minutes of meetings will be recorded on AU RED.
- 2.4.17** 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.
- 2.4.18** Draft minutes will be forwarded to the Chair as soon as practical after the meeting.
- 2.4.19** As much as possible, electronic communication will be used to communicate with members and researchers.
- 2.4.20** Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.

2.5 Monitoring

The TPCH HREC requires the Principal Investigator (or Coordinating Principal Investigator for multicentre studies) to:

- 2.5.1.1** Keep adequate and accurate research records and provide access to when requested by the TPCH HREC.
- 2.5.1.2** Provide progress reports at intervals specified by the TPCH HREC and at completion of any research but not less than annually.
- 2.5.1.3** Notify and provide reports, serious adverse events and adverse events that materially impact on the ethical acceptability of the project in a timely fashion to the TPCH HREC..
- 2.5.1.4** Notify the TPCH HREC of any complaints received from participants, staff, observers or the community.
- 2.5.1.5** Provide prospective advice of any proposed amendment(s) to be made to the protocol and approval of these prior to implementation.
- 2.5.1.6** Notify and provide reasons to the TPCH HREC if the research is to be discontinued before the expected date of completion of the project.
- 2.5.1.7** Provide a copy of published articles/results, presentations or posters at conferences etc. to the TPCH HREC.

The TPCH HREC may:

- 2.5.2** If required, request an interview with the researchers, research participants or other forms of feedback from them.
- 2.5.3** Monitor/audit or access research sites, research data and consent documentation records and report findings to the Committee.

2.6 Handling complaints

Complaints concerning the conduct of a project

- 2.6.1 **As per the Australian Code for the Responsible Conduct of Research 2007 the institution has nominated a 'designated person' for handling research complaints, including research misconduct.**
- 2.6.2 **The 'designated person' for the TPCH HREC is Anne Carle, Executive Officer, REaGU**
- 2.6.3 **Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the 'designated person' of the institution where the approving HREC sits, to the secretariat of the approving HREC who will enter the complaint details on AU RED and to the local site RGO**
- 2.6.4 **Processing of research complaints, including research misconduct and fraud, will be as per the QH HREC SOP.**

Complaints concerning the TPCH HREC's review process including the HREC's rejection of an application

- 2.6.5 **Any concern or complaint about the TPCH HREC's review process should be directed to the attention of the Chairperson of the approving HREC, detailing it in writing.**
- 2.6.6 **The REaGU administration officer of the TPCH HREC will enter the complaint details on AU RED**
- 2.6.7 **Processing of research complaints regarding the TPCH HREC review process will be as per the MNHHS HREC SOP.**

3 HREC responsibilities to the institution

- 3.1 **Monthly meeting with the Executive Director Medical Services regarding ethical and governance processes who in turn provide feedback to the Executive Director TPCH**
- 3.2 **Executive Director Medical Services attends the HREC meeting as a non-voting member and is, therefore, kept informed and updated of HREC processes and workings of the committee.**

4 Amendment to the terms of reference

These Terms of Reference may be amended by following the procedure below:

Proposals made by a TPCH HREC member:

- 4.1 The views of the members are discussed at the next scheduled meeting of the TPCH HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.**
- 4.2 The proposal is ratified if two thirds of the members agree to the amendment.**
- 4.3 The Chairperson sends the amendment to the Executive Director for review and approval.**

Proposals made by the Executive Director will be sent to the TPCH HREC and to any relevant person to seek their views.

Approved by:

Signature: Date:

Mr Anthony Williams
Executor Director - The Prince Charles Hospital Metro North Hospital and Health Service

For further information, please use the contact details below:

The Prince Charles Hospital

Research, Ethics and Governance Unit

Building 14

The Prince Charles Hospital

Rode Road, Chermside, Qld 4032

Email: ResearchTPCH@health.qld.gov.au

Phone: 07 3139 4500

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28/09/2015	1.0	Executive Officer, Research Ethics and Governance Unit Anne.Carle@health.qld.gov.au 07 3139 4500