

Metro North Health Human Research Ethics Committee B

Terms of Reference

1. Introduction

The Metro North Health (MNH) Human Research Ethics Committee (HREC) B (EC00168) is a committee established by Metro North Health, that is constituted and functions in accordance with the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research' (2007) (updated 2018)- the National Statement ; and complies with the 'Australian Code for Responsible Conduct of Research (2007); The World Medical Association "Declaration of Helsinki"; the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2); The Public Health Act 2005; The Guardianship Regime; The Human Rights Act 2019 (Qld); and other health policies.

2. Objectives

- 2.1. To identify the ethical implications and consequences of the proposed research and provide strategies that minimise risks and harms.
- 2.2. To ensure proposed research is designed with respect for all participants.
- 2.3. To ensure proposed research is justifiable by its potential benefit, which may include its contribution to knowledge and understanding, improved social welfare and individual wellbeing, and appropriate to the skill and expertise of the respective researchers.
- 2.4. To ensure that proposed research meets the requirements of the National Statement and is consistent with Queensland Health policies and relevant Commonwealth and State/Territory statutory and legislative requirements.

3. Functions and Responsibilities

- 3.1. Review and approve in line with its NHMRC certification via single ethical review for multi-centre research and in accordance with Queensland Health policies and procedures, and Memoranda of Understanding between Queensland Health and public sector health services in other States and Territories, Mater Health Services Brisbane and QIMR Berghofer Medical Research Institute.
- 3.2. Provide independent, competent and timely ethical review and oversight to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards of research.
- 3.3. Provide ongoing monitoring of approved research studies.
- 3.4. Provide advice, as required, to the MNH Chief Executive (CE) or Delegate when the HREC considers that ethics approval for a research study should be withdrawn.
- 3.5. Obtain expert opinions (external or internal) as required to provide legal, scientific and technical assessment of research protocols, evaluation of clinical trials and compliance with regulatory requirements.
- 3.6. Maintain a register on the state-wide database of, all research applications submitted to the HREC, monitoring and reporting requirements and ongoing approval status of proposals, including amendments.
- 3.7. Establish sub-committees and/or working groups, as required, in accordance with the National Statement to facilitate the ethical review of research projects.
- 3.8. Review and evaluate non-research submissions which require consideration by a formally constituted HREC for example, authorised prescriber applications as specified by the Therapeutics Goods Administration.

4. Relationships and Reporting

- 4.1. The MNH HRECs report to the MNH CE via the Metro North Executive Director Research, as Delegate.

- 4.2. A report is submitted annually to the NHMRC and the Australian Health Ethics Committee, to maintain HREC registration and accreditation.

5. Establishment

5.1. Composition

The HREC membership will be constituted in accordance with the National Statement and will include:

- a. a chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
- b. appropriate consumer engagement; that being 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 and/or Torres Strait Islander, a minister of religion.
- e. at least one lawyer, where possible one who is not engaged to advise the institution.
- 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.
- g. as far as possible there should be equal numbers of men and women.
- h. at least one third of the members should be from outside the institution for which the HREC is reviewing research.

5.2. Appointment of Chairperson and Deputy Chairperson(s)

- 5.2.1. The Chairperson and Deputy Chairperson of the HREC are appointed by the MNH Chief Executive or their Delegate
- 5.2.2. In the absence of the Chairperson, or by mutual agreement, the Deputy Chairperson will perform the duties of the Chairperson.
- 5.2.3. In the absence of both the Chairperson and Deputy Chairperson, an Acting Chairperson may be appointed by the MNH CE or their Delegate.

5.3. Appointment of Members

- 5.3.1. The MNH Chief Executive or their Delegate shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials.
- 5.3.2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- 5.3.3. Before appointment, potential members will be required to undergo a criminal history check and provide a copy of their Curriculum Vitae to confirm qualifications. Upon appointment, members acknowledge in writing their acceptance of the terms of reference of the HREC and any requirements for confidentiality and conflict of interest required by Queensland Health.
- 5.3.4. Members are appointed for a period of three years and may serve consecutive terms as approved by the MNH Chief Executive or their Delegate.
- 5.3.5. Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- 5.3.6. The Chairperson and Deputy Chairperson(s) may serve longer terms with the approval of the MNH Chief Executive or their Delegate.
- 5.3.7. Reappointment will be considered by the Chairperson of the HREC who will then make a recommendation to the MNH Chief Executive or their Delegate.

5.3.8. 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 will notify the member in writing of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.

5.3.9. 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.

5.3.10. The MNH Chief Executive or their Delegate may terminate the appointment of any member of the HREC if they are of the opinion that:

- a. it is necessary for the proper and effective functioning of the HREC
- b. the person is not a fit and proper person to serve on an HREC
- c. the person has failed to carry out their duties as an HREC member

5.3.11. 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 an HREC member.

5.3.12. Members are not offered remuneration; however, members will be reimbursed for legitimate expenses incurred in attending HREC meetings, or otherwise in carrying out the business of the HREC.

5.3.13. Members are expected to act, at all times, in a manner consistent with proper and respectful behaviour to all people involved in the HREC, in accordance with the Code of Conduct for the Queensland Public Service.

5.3.14. Members will be required to sign a statement undertaking:

- a. that all matters of which they become aware during the course of his/her work on the HREC will be kept confidential;
- b. that any conflicts of interest, which exist or may arise during their tenure on the HREC, will be declared, and
- c. that they have not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as an HREC member.

5.4. Administrative Support

5.4.1. Administrative support will be provided by staff of the Metro North Office of Research

5.4.2. Administrative support will be provided in accordance with the National Statement and the Queensland Health Standard Operating Procedures for HREC Administrators.

5.4.3. The Chairperson delegates the HREC Coordinator(s), Research Ethics and Governance Manager, Deputy Director Research, Assistant HREC Coordinator and Research Administrative Officer(s) and to sign correspondence on behalf of the Chairperson where the Chairperson and/or HREC have made a decision on the submission.

5.4.4. The Chairperson delegates the HREC Coordinator(s), Research Ethics and Governance Manager, Deputy Director Research, Assistant HREC Coordinator and Research Administrative Officer(s) to make a decision and sign correspondence for submission of an administrative nature, including minor amendments.

5.5. Additional Membership Scope

5.5.1. As a contingency measure to address potential circumstances where Queensland Health HRECs require assistance, or research proposals require urgent review (such as the COVID-19 Global Pandemic), the Committee collaborates with the Department of Health, Office of Research and Innovation and other Queensland Health HRECs to voluntarily provide review of applications on behalf of the Queensland Health HRECs.

6. Induction, mentoring and education

- 6.1. New members are provided induction material and mentoring via the Chairperson, the Metro North Office of Research or other members of the HREC.
- 6.2. Members are required to attend continuing education and training in research ethics at least every three years [National Statement Section 5.2.3(c)].
- 6.3. Throughout their tenure, members are given the opportunity to attend conferences and workshops, supported by the Institution, that are relevant to the roles and responsibilities of the HREC.

7. HREC Sub-Committees

- 7.1. The HREC may appoint 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.
- 7.2. The Chair of any such sub-committee will be approved by the HREC Chairperson.
- 7.3. Members of the sub-committee need not be members of the HREC.
- 7.4. The HREC may also access a pool of inducted members in each membership category. These members may attend meetings, as needed, to meet minimum HREC requirements, and may also be available to provide expertise for the research under review [National Statement Section 5.1.31].
- 7.5. All reports and/or decisions from the sub-committees must be tabled at the next full HREC meeting for consideration and ratification.

8. HREC liability coverage

- 8.1. Queensland 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).
- 8.2. Queensland 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)

9. Frequency of meetings

- 9.1. Meetings will be held monthly.
- 9.2. A timetable for meeting dates will be published on the MNH Research Ethics and Governance website and on the Queensland Health website.
- 9.3. Meetings will normally be held at a MNH Facility.
- 9.4. Should the HREC be unable to meet at this location, the meeting will be held at an alternate location or via video conference.

10. HREC Procedures

- 10.1. The HREC will perform its functions, including the monitoring of research and handling of complaints, in accordance with the Standard Operating Procedures (SOP) for Queensland Health HREC Administrators or other applicable MNH or Queensland Health Policies and Procedures.
- 10.2. All HREC members shall have access to and/or be provided with copies of the SOP.

11. Applications

- 11.1. The HREC requires new applications to be submitted via the online Queensland Health Human Research Ethics Application System, Ethical Review Manager (ERM) (or alternative system). In all cases, the application should include a Protocol, as well as other relevant documentation, such as Participant Information Sheets and Consent Forms, Data Collection Sheets, Investigator Brochures, Questionnaires, etc., as set out in the checklist for submission hosted on the MNH website.
- 11.2. In the first instance, the HREC Chairperson and/or HREC Coordinator(s) will determine if additional expert review is required.

- 11.3 The final decision on approval or rejection of an application will be within a period of sixty (60) days excluding time associated with waiting for responses from researchers.
- 11.4 The HREC Chairperson or HREC Coordinator(s) reserve the right to reject submissions that are not of a suitable standard for review, or which are outside the scope of the HREC certification.

12. Agenda Items

- 12.1 The HREC Agenda, accompanied by all relevant documentation will be distributed to all members, not less than seven (7) days prior to the HREC meeting.
- 12.2 Where possible, the HREC will consider every application it receives at its next availing meeting following receipt, provided that the application is valid and received by the relevant closing date.
- 12.3 When a submission, including amendments, is accepted by the HREC, the HREC Administration Officer(s) will process the HREC review and approval as per the HREC SOP.

13. Meeting Protocol

- 13.1 As far as possible, each HREC meeting should be arranged to enable at least one member from each category to attend [National Statement 5.2.30]. Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, that the views of those absent who belong to the minimum membership have been received and considered [National Statement Section 5.2.32].
- 13.2 Decisions by the 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.
- 13.3 All members will be provided meeting papers and an opportunity to provide reviews. Where members are unable to attend the meeting but reviews have been forwarded, these reviews will be considered along with those opinions and feedback of other committee members in the final decision making.
- 13.4 Committee members associated with a research protocol being considered by the committee will declare any conflict of interest (COI) prior to or at any time during a meeting. This COI will be formally recorded in the minutes and the conflicted member will be excluded from the meeting during the discussion and voting process of that particular proposal.
- 13.5 The Principal Investigator, or a representative of the investigator, may be invited to attend a HREC meeting to discuss an application, but would be required to leave the meeting before a decision is made on the outcome.
- 13.6 Decisions of the MNH HREC will be reached by general agreement. where a majority of members support the proposal. Specifically, the decision need not be unanimous with objections to be noted in the minutes. Where consensus cannot be reached, decisions will be made by majority vote. In the event of a tie, the Chair has the casting vote.
- 13.7 The Chairperson may reschedule a HREC meeting or convene additional meetings of the full HREC or of sub-Committees, comprising of HREC members, to consider urgent matters or to facilitate approval of submitted studies.
- 13.8 Questions or issues raised by members should be linked to the relevant section of the National Statement.
- 13.9 Depending upon the particular issues in question, it may be useful or necessary to disseminate information to members of the committee outside of the scheduled meetings.
- 13.10 All decisions made out-of-session will be tabled at the next full Committee meeting for consideration and ratification.

14. Minutes

- 14.1 The minutes of meetings will be recorded and filed in accordance with the requirements of the *Public Records Act 2002 - Qld*.
- 14.2 Minutes will record major issues discussed, concerns expressed, decisions reached and reasons for rejection or requirement for change to the protocol, linking those reasons to the National Statement.

- 14.3 As much as possible, electronic communication will be used to communicate with members and researchers.
- 14.4 Draft minutes will be forwarded to the Chairperson as soon as practical after the meeting for review and confirmation.
- 14.5 Researchers will be advised the outcome of a study considered at the HREC meeting after Chairperson review of the Minutes.
- 14.6 The Minutes will be signed by the Chairperson at the next meeting of the HREC, following ratification by HREC members.

15. Monitoring

- 15.1 The HREC requires the Principal Investigator of a research study (or Coordinating Principal Investigator for multicentre studies) to:
 - 15.1.1 keep adequate and accurate research records and provide access to the records when requested by the HREC
 - 15.1.2 provide progress reports at intervals specified by the HREC and at the completion of any research, but not less than annually
 - 15.1.3 notify and provide reports, serious adverse events and adverse events that materially impact on the ethical acceptability of a project, in a timely fashion to the HREC
 - 15.1.4 notify the HREC of any complaints received from participants, staff, observers or the community
 - 15.1.5 provide prospective advice of any proposed amendment(s) to be made to the protocol and receive approval of these prior to implementation
 - 15.1.6 notify and provide reasons to the HREC if the research is to be discontinued before the expected date of completion of the project.
- 15.2 The HREC may:
 - 15.2.1 if required, request an interview with the researchers, research participants or request other forms of feedback from them
 - 15.2.2 monitor/audit or access research sites, research data and consent documentation records and report findings to the Committee.

16. Complaints

- 16.1 Research complaints concerning the conduct of a project and/or a HREC's review process, including the HREC's reflection of an application, should be managed as per the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research 2018.
- 16.2 In the first instance, complaints will be receipted and triaged by the receipting officer, noting this may be via the research office, clinical setting or the patient liaison service, and managed in accordance with the MNH Consumer Feedback (compliments, complaints & suggestions) Policy and Procedure.
- 16.3 Complaints concerning the HREC's review process should be made in writing and will be receipted by the HREC Administration and forwarded to the Chairperson for consideration.
- 16.4 In the event that the Chairperson cannot resolve the complaint, an independent sub-committee will be convened to consider the matter in accordance with any applicable Queensland Health or MNH SOPs Policies or Procedures.

17. Amendments to the Terms of Reference

- 17.1 These Terms of Reference may be amended:
 - 17.1.1 following Committee consultation and endorsement by the MNH CE or Delegate for approval. The Committee will review these Terms of Reference every two (2) years, or earlier, if consideration is necessary by the Chairperson and/or MNH CE or Delegate.

17.1.2 Once approved, the new or revised Terms of Reference are submitted to the NHMRC for noting as part of the Committee's certification.

Endorsement

Next review date: 20 /04 / 2025

The terms of reference are endorsed by:

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Dr Lynn Woodward
Chairperson, Metro North Health B
Metro North Hospital and Health Service

The terms of reference are approved:

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Professor Daniel Chamber,
Executive Director, Metro North Office of Research
Metro North Hospital and Health Service