

**MATER HEALTH SERVICES
HUMAN RESEARCH ETHICS COMMITTEE**

Terms of Reference

1 Accountability

- 1.1 In accordance with the National Statement on Ethical Conduct Human Research (2007), all research projects involving humans and relating to health will be considered by the Mater Health Services Human Research Ethics Committee (MHS HREC). This Committee is accountable to the Mater Health Services Board of Directors, via the Research Support Committee.
- 1.2 The MHS HREC is guided by the National Statement on Ethical Conduct in Human Research, The Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – annotated with TGA comments, Human Research Ethics Committees and the TGA, Guidelines approved under Section 95A of the Privacy Act 1988 (December 2001), Guidelines Under Section 95 of the Privacy Act 1988 March 2000, When does quality assurance in health care require independent ethical review? NHMRC 20th February 2003, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research NHMRC 5th June 2003, Code of Ethical Standards for Catholic Health and Aged Care Services in Australia Catholic Health Australia 2001.
- 1.3 The MHS HREC, before granting approval to a research study involving humans, must be satisfied that the protocol conforms to:
 - 1.3.1 The NHMRC National Statement;
 - 1.3.2 Where relevant, the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMH/ICH-135/95) adopted by the TGA;
 - 1.3.3 Any requirements of relevant Commonwealth or State/Territory laws;
 - 1.3.4 CHA Code of Ethical Standards;
 - 1.3.5 Where relevant, overseas regulatory requirements.
- 1.4 The MHS HREC is assisted by the Scientific Sub-Committee (SSC). This Sub-Committee provides advice on scientific, technical and clinical aspects of human research protocols and clinical trials, and on compliance with regulatory requirements.
- 1.5 Membership of both Committees is approved by the Research Support Committee of the Board.



2 Mechanisms of Reporting

Formal mechanisms of reporting include the following:

- 2.1 Minutes of all MHS HREC meetings are provided to the MHS Research Support Committee of the Board.
- 2.2 MHS HREC Annual Compliance Report is provided to the Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC-AHEC).
- 2.3 Submissions are provided to the Board (through the Research Support Committee) as requested by the Board or initiated by the MHS HREC.

3 Scope of Responsibilities

The Mater Health Services Human Research Ethics Committee is responsible for human research:

- 3.1 designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results; [National Statement Section 1.1 (d)]
- 3.2 justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities; National Statement 1.1 (a)]
- 3.3 considering the ethical implications of proposed research programs which involve human experimentation so as to ensure continued compliance with the National Statement on Ethical Conduct in Human Research, March 2007;
- 3.4 ensuring that proposed research protocols comply with the Catholic moral principles relating to the delivery of health care; [CHA, Code of Ethical Standards]
- 3.5 making available principles and guidelines relating to research and ethics, taking account of statutory and legislative requirements;
- 3.6 maintaining a register of proposed and approved research proposals;
- 3.7 monitoring the conduct of research projects which involve human experimentation until their completion, including at a minimum, annual reports of all research projects.

The MHS HREC shall:

- 3.8 Advise the Board on policy requirements relating to the National Statement, and any other relevant State, Territory and Commonwealth legislation relating to human experimentation.
- 3.9 Carry out ethical reviews and approve, request amendment of, or reject a research proposal on ethical grounds, monitor review and if necessary withdraw approval for any research project.
- 3.10 Consider whether expert advice is required for the proper consideration of a particular proposal, and where required, the Committee may recommend to MHS that an appropriate expert/s be commissioned to provide that advice.
- 3.11 Ensure that, where a project involves more than one institution, the project has met ethical approval from each participating institution.
- 3.12 Provide information and reports to the NHMRC on request.
- 3.13 Provide information and reports to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care, where appropriate.
- 3.14 Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas agency, the MHS HREC will endeavour to meet those requirements. Investigators should notify the MHS HREC of the requirements before the grant is accepted.

4 Indemnity

- 4.1 The Mater Misericordiae Health Services Brisbane Limited accepts legal responsibility for decisions made and advice given, and indemnifies all members.

5 Composition and Membership of the MHS HREC

The MHS HREC Chairperson and Deputy Chairperson:

- 5.1 Both the Chairperson and Deputy Chairperson of the MHS HREC are appointed by the Board.
- 5.2 In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson.
- 5.3 In the absence of both the Chairperson and Deputy Chairperson, the Chairperson may appoint an Acting Chairperson.

6 The MHS HREC Coordinator

- 6.1 The MHS HREC Coordinator is an employee of the MHS and provides administrative advice on the Corporation's process of ethics review of research projects.
- 6.2 The Coordinator reports to the Chairperson of the MHS HREC in matters related to the activities of the Committee and to the MHS Executive Director Clinical Support Services regarding administrative issues.

7 Membership of the MHS HREC

- 7.1 The Mater Health Services Research Ethics Committee is constituted in accordance with the National Statement on Ethical Conduct in Human Research (2007). As a minimal requirement, eight men and women represent the following categories (National Statement 5.1.30);
- 7.1.1 a chairperson;
 - 7.1.2 at least two lay people, one man and one woman, who have no affiliation with the MHS and do not currently engage in medical, scientific, legal or academic work;
 - 7.1.3 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;
 - 7.1.4 at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
 - 7.1.5 at least one lawyer, who is not engaged to advise MHS; and
 - 7.1.6 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.
- 7.2 In addition, a nominated member of the Scientific Subcommittee will attend each meeting, to report back on scientific review, and discuss as required.
- 7.3 Additional members are included to ensure optimal functioning, taking into account:
- 7.3.1 the spread of disciplinary expertise across the Committee;
 - 7.3.2 age and gender balance;
 - 7.3.3 the balance between institutional/non-institutional and medical/non-medical members
 - 7.3.4 not less than half of the committee should consist of non-medical members or members who are not employed by Mater Health Services.

8 Terms and Conditions of Appointment of Members

- 8.1 MHS HREC members are appointed by the Research Support Committee of the Board. All changes to the MHS HREC membership are communicated to the NHMRC-AHEC, and other official research regulatory bodies as required.
- 8.2 To become a member of the MHS HREC expressions of interest may be forwarded to the Research Ethics office. At the time a vacancy becomes available this position may be filled from the list of interested persons or by advertisement in newspapers such as The Australian, Courier Mail or Church Resources.

9 Period of Appointment

- 9.1 MHS HREC members are generally appointed for a 3 year term.
- 9.2 A retiring member may be re-appointed.
- 9.3 Appointment may be terminated by either party after two months notice is given in writing.
- 9.4 Members should inform the Chairperson if leave of absence is required. If unable to attend three or more consecutive meetings, members should consider their availability to remain on the Committee.

10 Conditions of Appointment

- 10.1 Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience not as representatives of any organisation, group or opinion.
- 10.2 Before appointment, members acknowledge in writing their acceptance of the terms of reference of the MHS HREC and any requirements for confidentiality required by MHS.
- 10.3 Members receive a formal notice of appointment and assurances that they will be covered by MHS insurance policies as they relate to professional indemnity whilst performing the business of MHS HREC.
- 10.4 Members undertake appropriate induction, which includes mentoring by a current HREC member.
- 10.5 Members are required to attend continuing education or training programmes in research ethics at least every three years. [National Statement 5.2.3 (c)]

11 Remuneration

- 11.1 All essential and necessary expenses incurred by members in carrying out their MHS HREC duties will be reimbursed by MHS, on production of original receipts.
- 11.2 Parking will be provided at South Brisbane for members who are not staff of MHS.

12 Written Proposals

- 12.1 The MHS HREC requires hard copy submissions in a standard format for human research ethics approvals.
- 12.2 With respect to human experimentation proposals, researchers must conform to the requirements of the National Statement and provide the information which will enable scientific and ethical evaluation of the protocols.
- 12.3 With respect to clinical trial protocols, researchers must also conform to the requirements of the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA comments and provide the information which will enable clinical evaluation of the protocols.

13 Working Procedures

13.1 Frequency of Meetings

- 13.1.1 Eleven meetings are held each year. Meetings are held monthly except January. This ensures timely consideration and review of applications. [National Statement 5.1.37 (g)]
- 13.1.2 The MHS SSC meets two weeks prior to the HREC. Additional Sub-Committee meetings may be scheduled if required.
- 13.1.3 A timetable for meetings for the year will be promulgated by November of the preceding year and published on the MHS Internet.
- 13.1.4 The Chairperson can reschedule a meeting, convene additional meetings to consider urgent matters, or cancel a meeting if there is insufficient business.

14 Preparation of Agenda

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

15 Distribution of Materials of Decision Making

- 15.1 The Coordinator distributes the agenda, research applications and relevant papers to all HREC members prior to the meeting, allowing sufficient time for reading.

16 Meetings and Methods of Decision Making

- 16.1 Ideally the quorum for a MHS HREC meeting is the minimum membership as defined 7.1. [National Statement 5.2.29]
 - 16.1.1 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered. To assist with this, members who are unable to attend a meeting are encouraged to contribute their opinions prior to the meeting via written or oral submissions to the Coordinator or Chairperson. [National Statement 5.2.30]
- 16.2 Conflict of interest: Any member who has an interest or a conflict of interest in a research protocol before the Committee, including personal involvement or participation in the research, financial or other interest or affiliation, involvement in competing research [National Statement 5.4.5], must declare the interest and its nature at the beginning of the meeting. When a research protocol involves a Committee member, that member, will be required to leave the meeting before a final decision is taken.
- 16.3 Investigators may be invited to a meeting to clarify and represent their protocols.

- 16.4 Investigators may request to be present at a meeting for discussions of their proposed research.
[National Statement 5.2.18]
- 16.5 In general, decisions by MHS HREC are reached by general agreement rather than by a majority vote. Where one or more Committee members have serious concern about a project, that concern must be addressed before approval is given. Where a vote is taken, approval requires a majority of the Committee and a majority of external members who are present. An abstention is taken to be a vote against the proposal.

17 Expedited Review of Research Proposals between HREC Meetings

- 17.1 In general, all proposals must be submitted to the HREC for approval. Where a deficiency is identified by the MHS HREC or additional information is required, the MHS HREC may authorise the Chairperson or another delegate to approve the proposal executively when the Chairperson or delegate is satisfied that the deficiency has been addressed or the additional information has been provided.
- 17.2 If there is an urgent need for approval of a proposal, a submission for expedited approval may be made through the Coordinator to the Chairperson or Deputy Chairperson ("the Executive").
- 17.3 If the Executive is satisfied that the circumstances justify urgent review, the Executive may:
- 17.3.1 Decide that an approval ("Executive approval") can be given.
 - 17.3.2 Refer the application to any other member or members of the MHS HREC or MHS SSC for comment to assist the Executive in deciding whether approval should be given.
 - 17.3.3 Require amendment of the proposal.
 - 17.3.4 Refuse to give executive approval.
- 17.4 An executive approval does not require further approval but all executive approval will be submitted to the next meeting of the MHS HREC for noting.

18 Preparation of Minutes and Recording of Decisions

- 18.1 To encourage free and open discussion and to emphasise the collegiate character of MHS HREC deliberations, particular views of individual members are not recorded in the minutes unless specifically requested.
- 18.2 The minutes are produced as soon as practicable following the relevant meeting and checked by the Chairperson as a true and correct record. Copies of the minutes are sent to MHS HREC members at least 7 days prior to the next meeting.
- 18.3 Committee members are encouraged to provide written feedback regarding points to be addressed in particular, in the information sheets for participants.
- 18.4 To assist with the preparation of minutes, the proceedings of HREC meetings may be recorded.

19 Prompt Notification of Decisions

- 19.1 The Coordinator is responsible for communicating the HREC decisions to researchers by email as soon as practicable following the Committee meeting at which their research proposals have been discussed.

20 Researcher Compliance with Decisions

- 20.1 Researchers are expected to comply with decisions by the MHS HREC and any other recommendations or conditions as required by collaborating HREC/s.

21 Relationship to non-affiliated researchers

- 21.1 Researchers nominated as Principal Investigators who are not employed by the Mater Health Services require a Mater sponsor for all on-site research. Together with the researcher, the sponsor will define legal responsibility for the research, and determine processes for approving, conducting and monitoring the research. The Mater sponsor makes initial contact with potential participants on behalf of the researcher.

22 Multi-centre studies

22.1 Mutual Acceptance/Recognition Agreement/s [to comply with National Statement 5.3]

- 22.2 The MHS and MHS HREC may make a formal mutual acceptance/recognition agreement with a collaborating institution and its HREC. Where such an agreement exists the ethics approval procedure will be set out in the agreement.

22.3 For a particular project, MHS HREC and HREC/s of collaborating institutions may agree to adopt specific procedures for handling certain matters associated with the project, including review of serious or unexpected adverse event reports, and protocol deviations.

23 Other multicentre projects:

23.1 Unless MHS and MHS HREC has a formal mutual acceptance/recognition agreement applicable to the project, MHS investigators are required to submit human research ethics applications in accordance with these terms of reference.

24 Principal investigators must notify the MHS HREC:

24.1 If collaborating HREC/s approve a project subject to any provisos or reservations.

24.2 If another HREC has refused to approve the project.

24.3 Where there is a disagreement between HRECs, MHS HREC will work collaboratively with principal investigators and collaborating HREC/s to resolve matters.

25 Advice to HRECs of Collaborating Research Institutes

25.1 MHS HREC may communicate directly with HRECs of collaborating institutions concerning any issue relating to approval or adverse events.

26 Reporting of Changes to Protocol

Researchers are required to report anything that might warrant review of ethical approval of the protocol, including:

26.1.1 Deviations from the protocol.

26.1.2 Withdrawal of approval by another HREC or institution.

26.1.3 New information and/or unforeseen events that might affect continued ethical acceptability of the project.

26.1.4 Allegation or suspicion of scientific fraud.

27 Reporting of Serious Adverse Events

All researchers are required to immediately report anything that might warrant review of ethical approval of the protocol, including:

27.1.1 Serious or unexpected adverse effects on participants.

27.1.2 Any information that would indicate an increase risk to participants.

28 Monitoring

28.1 The MHS HREC requires:

- 28.1.1 Adequate records to be maintained for all human experimentation protocols.
 - 28.1.2 Regular reports from principal investigators, at least annually.
 - 28.1.3 Immediate reports in the event of serious or unexpected adverse effects on participants.
 - 28.1.4 Proposed changes in the protocol to be submitted for approval before implementation.
 - 28.1.5 Immediate reports about any unforeseen events that might affect continued ethical acceptability of the project.
 - 28.1.6 Reports from researchers if the research project is discontinued before the expected date of completion, giving reasons.
 - 28.1.7 Reports from other staff or personnel in MHS, as necessary.
 - 28.1.8 Reports/reviews from external experts, if required.
 - 28.1.9 Notification of published results/research publications.
- 28.2 If considered necessary, the MHS HREC may take action to ensure that a project is undertaken in accordance with the terms of an approval including, but not limited to requiring a report from the Principal Investigator, interviewing the researcher/s or research participants, inspecting a laboratory and commissioning an external review of the project.

29 Complaints, Receiving and Handling

- 29.1.1 Subject to any agreement under clause 22.1, participants in projects approved by MHS HREC must be provided with contact details which allow them to address complaints or concerns about the research to the MHS HREC Chairperson or Coordinator.
- 29.1.2 Complaints on the process of ethics review, project conduct or decisions of the MHS HREC should be made in writing to the Chairperson of the MHS HREC via the Coordinator.
- 29.1.3 The Chairperson will acknowledge the receipt of the complaint to the complainant with seven days.
- 29.1.4 The Chairperson will consider the complaint and will determine a course of action.
- 29.1.5 The complaint and the proposed action will be reported to the next meeting of the MHS HREC.
- 29.1.6 In the event that the response to the complaint has not been finalised within 60 days, the complainant will be notified in writing of progress.
- 29.1.7 If the complainant does not accept the decision of the MHS HREC Chairperson, then further consideration may be obtained by addressing the complaint to the MHS Board.

30 Discontinuation of Research Projects

In cases of non-compliance and/or where circumstances warrant that a research project should be discontinued, the MHS HREC will recommend to the MSH CEO and Executive and the collaborating research institute/s that the research project be discontinued or suspended.

31 Fees and Charges

MHS levies fees for ethical review of commercially sponsored studies. A schedule of the fees is available on the MHS Intranet and Internet.

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