

MATER HEALTH SERVICES

HUMAN RESEARCH ETHICS COMMITTEE–(EC00332)

TERMS OF REFERENCE

Purpose

The Mater Health Services (the 'Institution') Human Research Ethics Committee (HREC) is constituted and functions in accordance with the '*National Statement on Ethical Conduct in Human Research*' 2007 (the 'National Statement'), Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003, and complies with the '*Australian Code for the Responsible Conduct of Research*' 2007, Catholic Health Australia '*Code of Ethical Standards for Catholic Health and Aged Care Services in Australia*' 2001 and relevant privacy protocols including the *Health Services Act 1991*, the *Privacy Act 1988*, *Public Health Act 2005* and National Privacy Principles.

Guidance is also provided to the HREC by the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – annotated with TGA comments.

The HREC acts in a consultative and advisory capacity with researchers to ensure that all clinical, research and management practices are conducted in an ethical and scientifically robust manner.

1. *Scope, responsibilities and functions*

In accordance with the National Statement, all research projects involving humans will be considered by the HREC.

The HREC is responsible for:

- Ensuring that human research is 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 1.1 (d)*].
- Ensuring that human research is 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)*].
- Considering the ethical implications of proposed research programs which involve human experimentation so as to ensure continued compliance with the National Statement.

- Ensuring that proposed research protocols comply with the Catholic moral principles relating to the delivery of health care (“Code of Ethical Standards for Catholic Health and Aged Care Services in Australia Catholic Health Australia” 2001).
- Making available principles and guidelines relating to research and ethics, taking account of statutory and legislative requirements.
- Maintaining a register of proposed and approved research proposals.
- Overseeing the conduct of research projects which involve human experimentation until their completion, including, at a minimum, annual reports of all research projects. Specific monitoring of the conduct of research will be conducted via the Research Governance Office and in the case of multi-centre research, the co-ordinating principal investigator at the respective Institution.

The HREC shall:

- Advise the Institution on policy requirements relating to the National Statement, and any other relevant State, Territory and Commonwealth legislation relating to human experimentation.
- Carry out research ethics 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.
- Consider whether expert advice is required for the proper consideration of a particular proposal, and where required, the HREC may recommend that an appropriate expert/s be commissioned to provide that advice.
- Ensure that where a project involves more than one institution, the project, wherever possible, will aim to implement systems to promote the efficient ethical review of research projects. This includes mutual acceptance of ethical review for multi-centre research and streamlined ethical review for approval of multi-site clinical trials, in order to minimise any unnecessary duplication in the review of that research.
- Provide information and reports to the NHMRC as required and on request.
- Provide information and reports to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing, where appropriate.
- Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas funding body, the HREC will endeavour to meet those requirements. Investigators/Researchers should notify the HREC of the requirements before the grant is accepted.

The HREC may be assisted by the Scientific Advisory Committee (SAC). The SAC provides advice on scientific, technical and clinical aspects of human research protocols and clinical trials, and on compliance with regulatory requirements. The functions of the SAC include the review and where appropriate, the recommendation for forwarding to the HREC including:

- Review of new research projects from scientific and regulatory viewpoints.
- Review of project amendments, correspondence, external and internal serious adverse events, annual reports and final reports.
- Review of Low & Negligible risk applications and/or provide assistance to the HREC Chairperson for 'executive approval' review that requires specific expertise from members of this Advisory Committee.
- Provision of recommendations to the HREC.
- Consideration of other matters relating to the committee's operation that may be of relevance to the HREC.

The SAC shall reach a quorum (majority of members which includes at a minimum a clinician) at each meeting. The SAC meets monthly, except in January prior to the HREC meeting.

The composition and membership of the SAC is as follows:

- Appointment of members to the SAC occurs by nomination from the Chairs of the SAC and HREC to the Board for approval.
- The Chairperson of the SAC is a representative of category (f) membership set out in section 5.1.30 of the National Statement. Members nominated to category (f) have "current research experience that is relevant to research proposals to be considered at the meetings they attend".

The appointment of SAC members is usually for a period of 3 years, same as the HREC members (see section 3.1 below).

2. Relationships and reporting

The HREC is accountable to the MHS Board and the CEO of Mater Health Services via the Director/CEO of Mater Medical Research Institute (MMRI).

Formal mechanisms of reporting include the following:

- HREC Annual Compliance Report is provided to the Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC-AHEC);
- Minutes of all HREC meetings are signed off by the Chairperson and provided to the Institution and MMRI CEOs.
- Annual report to MHS CEO, the Director/CEO of the MMRI and MHS Board.

3. HREC composition and appointment

The HREC is constituted in accordance with the National Statement. As a minimal requirement, eight men and women represent the following categories (*National Statement* 5.1.30):

- A chairperson, with suitable experience, whose other responsibilities, will not impair the HREC's capacity to carry out its obligations under the *National Statement*.
- At least two lay people, one man and one woman, who have no affiliation with Mater Health Services and do not currently engage in medical, scientific, legal or academic work.
- 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.
- At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion.
- At least one lawyer, who is not engaged to advise Mater Health Services.
- 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.

In addition, a nominated member of the Scientific Advisory Committee will attend each meeting, to report back on scientific review, and discuss as required.

Additional members are included to ensure optimal functioning, taking into account:

- The spread of disciplinary expertise across the Committee.
- Age and gender balance.
- The balance between institutional/non-institutional and medical/non-medical members.
- Not less than half of the committee should consist of non-medical members or members who are not employed by Mater Health Services.

The Chairperson may appoint a Deputy Chairperson to perform the duties of the Chairperson. In the absence of both the Chairperson and Deputy Chairperson, the Chairperson may appoint an Acting Chairperson.

3.1 Membership of the HREC

Members are appointed by the Institution's Board. All changes to the HREC membership are communicated to the NHMRC-AHEC, and other official research regulatory bodies as required.

Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, not as representatives of any organisation, group or opinion.

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

Membership appointments to the HREC will be considered for review every three years (*National Statement 5.1.34*).

To become a member of the 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.

3.2 Confidentiality and 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.

Before appointment, members acknowledge in writing their acceptance of the terms of reference of the HREC and any requirements for confidentiality required by the Institution.

3.3 Induction, Mentoring and Training

Members undertake appropriate induction, which includes mentoring by a current HREC member.

Members are required to attend continuing education or training programmes in research ethics at least every three years. [*National Statement 5.2.3 (c)*]

3.4 Remuneration

All essential and necessary expenses incurred by members in carrying out their HREC duties will be reimbursed, on presentation of original receipts.

4. HREC Procedures

The HREC operates according to written human research policies. These policies are reviewed and updated as required.

4.1 Submission Process

The HREC requires hard copy submissions in a standard format for human research ethics approvals as per the HREC deadlines.

With respect to human experimentation proposals, researchers must conform to the requirements of the National Statement and provide the information necessary to enable scientific and ethical evaluation of the protocols.

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 necessary to enable clinical evaluation of the protocols.

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

- Deviations from the protocol.
- Withdrawal of approval by another HREC or institution.
- New information and/or unforeseen events that might affect continued ethical acceptability of the project.
- Allegation or suspicion of scientific fraud.

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

- Serious or unexpected adverse effects on participants.
- Any information that would indicate an increase risk to participants.

4.2 Frequency of Meetings

Meetings are held monthly except January. This ensures timely consideration and review of applications [*National Statement 5.1.37 (g)*].

A timetable for meetings for the year will be distributed by November of the preceding year and published on the Mater Health Services internet and Mater campus intranet.

The Chairperson can reschedule a meeting, convene additional meetings to consider urgent matters, or cancel a meeting if there is insufficient business.

4.3 Meeting Protocol

Decisions by an HREC about whether a research proposal meets the requirements of the National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership (*National Statement 5.2.29*).

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 submissions to the Coordinator or Chairperson (*National Statement 5.2.30*).

Researchers/ investigators may be invited to, or request to be present at, a meeting to clarify and represent their research projects.

In general, decisions by the 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.

4.4 Review of Research Proposals between HREC Meetings

In general, all proposals must be submitted to the HREC for approval. Where a deficiency is identified by the HREC or additional information is required, the 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.

Under exceptional circumstances (e.g. matter of public policy, urgent threat to public health and/or in the national interest), a submission for expedited approval may be made through the Coordinator to the Chairperson or Deputy Chairperson.

If the Chairperson is satisfied that the circumstances justify urgent review, the Chairperson may:

- Decide that an approval ('Executive approval') can be given.
- Refer the application to any other member or members of the HREC or SAC for comment to assist in deciding whether approval should be given.
- Require amendment of the proposal.
- Refuse to give executive approval.

An executive approval does not require further approval but all executive approval will be submitted to the next meeting of the HREC for noting.

In addition, the HREC has established a low risk and negligible risk review process for research projects eligible for low risk review. These applications will be reviewed by two members of the HREC or its Advisory Committee, and the Chairperson will aim to make a decision on the project in a timely fashion.

4.5 Secretariat Support

Secretariat support will be provided by staff of MMRI.

4.6 Preparation of Minutes and Recording of Decisions

To encourage free and open discussion and to emphasise the collegiate character of HREC deliberations, particular views of individual members are not recorded in the minutes unless specifically requested.

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 HREC members prior to the next meeting.

To assist with the preparation of minutes, the proceedings of HREC meetings may be recorded.

4.7 Communication of Decisions

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.

4.8 Researcher Compliance with Decisions

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

4.9 Relationship to Non-Affiliated Researchers

Researchers nominated as principal investigators who are not employed by 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 may make initial contact with potential participants on behalf of the researcher.

4.10 Multi-Centre Studies/Research Projects

The Institution and 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.

For a particular project, the Mater HREC and HREC/s of the collaborating institution/s 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.

Unless there is a formal mutual acceptance/recognition agreement applicable to the project, Mater investigators/ researchers are required to submit human research ethics applications in accordance with these terms of reference.

Principal investigators/researchers must notify the HREC if:

- the collaborating HREC/s approve a project subject to any provisos or reservations
- another HREC has refused to approve the project.

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

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

5. Monitoring

The HREC requires:

- Adequate records to be maintained for all human experimentation protocols/ research projects.

- Regular reports from principal investigators/ researchers, at least annually.
- Immediate reports in the event of serious or unexpected adverse effects on participants.
- Proposed changes in the protocol/ research project to be submitted for approval before implementation.
- Immediate reports about any unforeseen events that might affect continued ethical acceptability of the project.
- Reports from researchers if the research project is discontinued before the expected date of completion, giving reasons.
- Reports from other staff or personnel at Mater, as necessary.
- Reports/reviews from external experts, if required.
- Notification of published results/research publications.

If considered necessary, the 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/ researcher, interviewing the researcher/s or research participants, inspecting a laboratory and commissioning an external review of the project.

6. Discontinuation of Research Projects

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

7. Complaints – Receiving and Handling

Subject to any agreement, participants in projects approved by HREC must be provided with contact details which allow them to address complaints or concerns about the research to the Research Ethics Office. Complaints should be made in writing to the Chairperson of the HREC.

In the first instance all complaints on the process of ethics review, project conduct or decisions of the HREC will be forwarded to the Chairperson of the HREC.

The Chairperson will acknowledge the receipt of the complaint to the complainant within seven days.

The Chairperson will consider the complaint and will determine a course of action. The complaint and the proposed action will be reported to the next meeting of the HREC. This may necessitate a special meeting of the HREC, which may be called without the usual 14 day requirement for notice.

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.

If the complainant does not accept the decision of the HREC Chairperson, the complaint may be communicated by the Chairperson to the Institution CEO for further consideration.

Any concerns, complaints or allegations about the conduct of a research protocol/ project will be recorded.

8. Fees and Charges

Fees for ethical review of commercially sponsored studies are available on the Mater intranet and the internet.

Bibliography

- “Access to Unapproved Therapeutic Goods – Clinical Trials in Australia” Therapeutic Goods Administration, 2001
- “Guidelines approved under Section 95A of the Privacy Act”, 1988. National Health & Medical Research Council, 2001
- “Guidelines Under Section 95 of the Privacy Act”, 1988, National Health & Medical Research Council, 2000
- “Human Research Ethics Committees and the Therapeutic Goods Legislation”, Therapeutic Goods Administration, 2001
- “National Statement on Ethical Conduct in Human Research”, National Health & Medical Research Council, 2007”
- “Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95) – Annotated with TGA comments”. Therapeutic Goods Administration, 2000
- “Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments”. Therapeutic Goods Administration, 2000
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- “Conflict of Interest Policy”. Mater Health Services, 2006
- “The Values and Ethics: Guidance for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research”. National Health & Medical Research Council, 2003