

REVIEW, APPROVAL & MONITORING OF RESEARCH INVOLVING HUMANS POLICY N^o: MHS-CSS-ResEth-2.04

PRINCIPLE:

The Mater Health Services promotes high standards in research and the ethical conduct of research. Principally the National Statement on Ethical Conduct in Human Research <http://www.nhmrc.gov.au/publications/synopses/files/e72.pdf> outlines the requirements as recommended by the National Health and Medical Research Council of Australia.

To conduct research at the Mater you will be required to apply to the Human Research Ethics Committee for approval. The Committee meets monthly except in January. The Committee is made up of a Scientific Sub-Committee and the HREC.

POLICY:

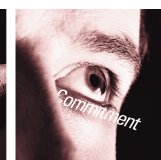
1. All research projects involving human participants and relating to health must be considered and approved by the Mater Health Services Human Research Ethics Committee prior to commencement. The Mater Research Ethics office is responsible for coordinating the process of submission, screening, review, amendment and approval of research proposals submitted for research ethical clearance.
2. For review of QA/Audit projects please refer to “What is Research?” <http://www.mater.org.au/getdoc/ff14f406-223a-47ee-8234-f20812acfe70/WhatIsResearch.aspx> and contact the Research Ethics Coordinator.

Scientific Sub-Committee

All studies submitted will be reviewed by the SSC. Studies will proceed to the HREC if they are considered to be scientifically sound. The SSC may request amendments or a re-submission before the study may proceed to the HREC.

Human Research Ethics Committee

Studies that have been reviewed by the SSC and recommended to be scientifically sound will be reviewed by the HREC. External researchers to the hospital will be required to liaise with a Mater sponsor.



WORK INSTRUCTIONS/PROCEDURE:

To find out further details please go to <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx> or contact the Research Ethics office.

Coordinator
Room 235 Level 2 Aubigny Place
Mater Health Services
Raymond Terrace
South Brisbane 4101

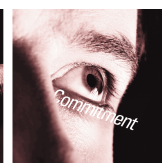
Ph: + 61 7 3163 1585
Fax: + 61 7 3163 1571

Email: research.ethics@mater.org.au

Ethics Review Process:

Requests for ethics approval of research should be submitted to the Mater Research Ethics office by the closing date each month except in December. These dates can be obtained from <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx> or by contacting the Research Ethics office on extension 07 3163 1585. The Human Research Ethics Committee is supported by the Scientific Sub-Committee. This process involves the following steps.

1. Initial screening by the Research Ethics Coordinator to ensure the documentation is complete and meets standard requirements.
2. Proposals are forwarded to the Scientific Sub-Committee two weeks prior to the meeting.
3. Communication with the principal investigator regarding amendments to the protocol based on scientific evaluation.
4. Referral of Scientific Sub-Committee recommendations and research proposal to members of the Human Research Ethics Committee for consideration.
5. Collation of any Committee members' ethical assessments prior to full committee review of the research proposal.



Duration of Approval

Principal investigators are notified initially by email regarding outcomes. Formally signed approval letters are forwarded as soon as possible after the meeting. Approval is granted for the duration of the project, or a maximum of three years, whichever is earlier. Exact dates of approval will be included in the approval letter.

Conditions of Approval

Any departure from the protocol detailed in the research proposal submitted to the Research Ethics committee must be reported immediately to the Committee.

When an investigator proposes amendments to an approved protocol that are considered to be minor (including extension of approval), a written request for approval must be submitted to the Chairperson, through the Coordinator. If the researcher is requesting extension of approval it is required that the current Information Sheet and Consent Form be submitted at the same time to ensure any updates are incorporated in the extension. Amendments will be assessed on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee. The Committee may also choose to view amendments electronically. Further information may be obtained from the Research Ethics office.

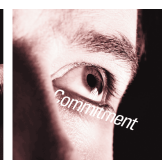
Where substantive changes to an approved protocol are proposed, the investigator is required to submit a full, new research proposal for consideration by the Committee.

Participants should be advised that the research has been approved by the Mater Health Services Human Research Ethics Committee and that they may contact the Research Secretariat on 3163 1585, should they have any complaints about the conduct of the research, or wish to raise any concerns.

Monitoring of Approved Protocols

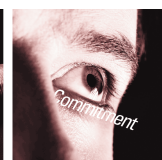
In accordance with the NHMRC National Statement on Ethical Conduct in Human Research, the Committee is responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. Principal Investigators are required to provide written reports of approved projects at least annually, or at intervals determined by the Committee. The Committee may also choose to conduct interim audits of research.

All research projects involving human participants and relating to health must be considered and approved by the Mater Health Services Human Research Ethics Committee prior to commencement.



See the Attached documents:

- Minimum Requirements for Research Ethics Proposals
<http://www.mater.org.au/getdoc/97c1c377-0e88-4d34-be2e-7916aa719c14/MinimumRequirementsForResearchEthicsProposals.aspx>
- 2007 Meeting dates <http://www.mater.org.au/getdoc/9f7bea42-967f-424c-8603-b193635b0159/Calendar2007.aspx>
- Application Form <https://www.neaf.gov.au/Default.aspx> or
<http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx>.
- Consent Guidelines <http://www.mater.org.au/getdoc/0f531b68-5229-4cd3-9fc0-d119e2a666a6/ConsentGuidelines.aspx>
- Staff Info Sheet <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx>
- Budget requirements <http://www.mater.org.au/getdoc/56b9c039-8c0f-4f93-aa3f-6376aec056e0/BudgetRequirements.aspx> or speak with your Management Accountant.
- HREC Composition [http://www.mater.org.au/getdoc/1669a051-b3d4-4399-a362-1aa62b9a5ac8/HRECComposition-\(1\).aspx](http://www.mater.org.au/getdoc/1669a051-b3d4-4399-a362-1aa62b9a5ac8/HRECComposition-(1).aspx)
- Risks in Research <http://www.mater.org.au/getdoc/b3f20cea-8a19-437f-bc26-af6bc3c812e4/RiskInResearch.aspx>
- What is Research <http://www.mater.org.au/getdoc/ff14f406-223a-47ee-8234-f20812acfe70/WhatIsResearch.aspx>
- Schedule of Fees <http://www.mater.org.au/getdoc/dbff9324-aeb5-4216-b1fb-7bd93a4e71cc/ScheduleOfFees.aspx>
- Adverse Event Guidelines, <http://www.mater.org.au/getdoc/a65bc0b1-c3aa-42b1-9f23-7e0fbbe72bbd/AdverseEventGuidelines.aspx>
- Initial Serious Adverse Event Report,
<http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx>
- Follow Up Adverse Event Report <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx>



- Progress Report <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx>

REFERENCES:

National Statement on Ethical Conduct in Human Research
<http://www.nhmrc.gov.au/publications/synopses/files/e72.pdf>

Guidelines approved under Section 95A of the Privacy Act 1988 (December 2001)
<http://www.nhmrc.gov.au/publications/synopses/files/e43.pdf>

Guidelines Under Section 95 of the Privacy Act 1988 March 2000
<http://www.nhmrc.gov.au/publications/synopses/files/e26.pdf>

When does quality assurance in health care require independent ethical review? NHMRC 20th February 2003
<http://www.nhmrc.gov.au/ethics/human/conduct/guidelines/files/e46.pdf>

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. NHMRC 5th June 2003
<http://www.nhmrc.gov.au/ethics/human/conduct/guidelines/files/e52.pdf>

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
Annotated with TGA comments July 2000
<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Code of Ethical Standards for Catholic Health and Aged Care Services in Australia
Catholic Health Australia 2001
<http://intranet.mater.org.au/cms/uploads/documents/codeofethics.pdf>

