Policy

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<th>Human Research Ethics Review Policy</th>
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**Our Mission**
As Mater Research, together with our partners, we conduct, enable and translate exceptional clinically relevant health research.

**Our Vision**
Achieving better health for all through exceptional research.

**Our Values**
- Mercy
- Dignity
- Care
- Commitment
- Quality

**Affirmation**
This governance document is consistent with the Mater Values and supports the Mater Research Mission and Vision by establishing and mandating appropriate controls to support the delivery of health care services.
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**Document Controls**

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### 1.2 Document Review and Approval

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<td>Corporate Policy Governance Committee</td>
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### 1.3 References

**Internal Documents**

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### External Documents

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<td>1</td>
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| 2 | Privacy Act, 1988  
Guidelines approved under Section 95 of the Privacy Act, 1988  
Guidelines approved under Section 95A of the Privacy Act, 1988  
Guidelines approved under Section 95AA of the Privacy Act, 1988 (Cth)  
Australian Privacy Principles |
| 3 | Public Health Act, 2005 |
| 4 | National Statement on Ethical Conduct in Human Research, National Health & Medical Research Council (NHMRC), 2007 (Updated in March 2014) (herein referred to as the National Statement) |
| 5 | Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003 |
| 6 | Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments. Therapeutic Goods Administration, 2000 |
| 7 | Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001 |
| 8 | Australian Code for the Responsible Conduct of Research, 2007 |
| 10 | The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, World Medical Association, 2008 |
# 2 Introduction

## 2.1 Purpose

This policy is to assist researchers, Human Research Ethics Committee (HREC) members and other reviewers to identify their responsibilities in relation to the human research ethics review of research at Mater Health Services (MHS). While the processes of ethics review are important, individual researchers and the institutions within which they work hold primary responsibility for ensuring that their research has research integrity.

## 2.2 Scope and Context

This policy applies to all Mater Research (MR) and MHS employees (permanent, temporary and casual) and students, non-MHS research collaborators, MR honorary appointees, sponsors and agents (including Visiting Medical Officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake human research involving patients and staff of the MHS.

Compliance with this policy is mandatory.

## 2.3 Definitions

<table>
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<th>Term</th>
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| Amendment                           | A change to the Human Research Ethics Committee (HREC) approved application including the protocol or supporting documentation. If the amendment is administrative in nature an HREC amendment review fee may be waived for commercially sponsored research. Examples of administrative amendments include:  
- correction of typographical errors in any study documentation;  
- amended contact details for the sponsor or study staff; and  
- appointment of new support staff. |
| Good Clinical Practice (GCP)        | An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. May also be referred to as ICH GCP (International Conference on Harmonisation). [http://ichgcp.net/](http://ichgcp.net/) |
| Multi-Centre Research (MCR)         | Research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution. |
This includes patient satisfaction surveys, surveillance and monitoring and clinical audits. If there are research elements then it will be reviewed under the research review process. |
| Serious Adverse Event (SAE)         | The precise definition of a Serious Adverse Event (SAE) will be determined by the Sponsor and included in the protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. |
2.4 Legislative Compliance

This policy mandates compliance with laws, regulations, guidelines and codes of practice governing:

a) the conduct of research in Australia; and
b) privacy, including the Privacy Act (1988) (including the Australian Privacy Principles), Hospital & Health Boards Act (2011) and Public Health Act (2005).

Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

2.5 Industry Standards


Suspected Unexpected Serious Adverse Reactions (SUSARs) are considered a subset of SAEs.
3 Principles

The following set of principles describes the objectives and outcomes of the policy:

3.1 Principle 1: Conduct of Research

Any human research that is conducted at MHS or for which MHS is responsible must be:

- ethically and scientifically reviewed and monitored in accordance with the “National Statement on Ethical Conduct in Human Research” (2007) (the National Statement); and
- designed and conducted with both prior ethical approval and research governance authorisation and in accordance 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), “Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research” (2003) and (for clinical trials) “TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments”.

3.2 Principle 2: Code of Ethical Standards for Catholic Health and Aged Care Services in Australia

Research is never to be undertaken on an embryo or fetus, or on tissue from an embryo or fetus, that has been procured through deliberate abortion. It is not permissible to produce embryos for research purposes or use embryos discarded from in vitro fertilisation (IVF) programmes for research purposes. Genetic research must not involve any techniques that may lead to the asexual creation or reproduction of human embryos or other eventualities that are contrary to respect for human life or human dignity.

3.3 Principle 3: Catholic Hospitals’ Pregnancy Avoidance

As a Catholic health care service, MHS is committed to reflecting the Church’s teaching regarding respect for the personal dignity of human life in all stages. In reproductive health matters the responsibility of Catholic health care is to give counsel which is both accurate and a witness to the teachings of the Church. It is acceptable within the Catholic teaching to counsel a woman and/or her partner to avoid becoming pregnant when either the woman or her partner is undergoing treatment that might affect an embryo/fetus. It is also acceptable to include a comprehensive statement of the risks, and the period during which pregnancy must be avoided as a consequence of participation in a study.

Regarding studies that may involve participants who are able to conceive, the MHS HREC places paramount importance on the welfare of the research participants, and the welfare of any potential or actual unborn children. This is particularly the case in studies of interventions, such as drugs, that have the potential for harmful effects to a developing fetus, and/or an unborn child. All women participating in studies involving drugs whose effect on the unborn child are unknown are required to have a pregnancy test prior to entering the study and to be informed they could potentially be excluded from the study. Annexure A sets out the position on appropriate words.

3.4 Principle 4: Human Biospecimens in Laboratory Based Research

The use of human biospecimens in research must be carried out in accordance with the MHS HREC requirements (PY-RSH-300301 Collection, Storage, Use and Disposal of Human Biospecimens in Research Policy).

a) With advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples should always be regarded as, in principle, re-identifiable (National Statement Section 3.2).

b) Activities involving databanks must be in accordance with the National Statement Section 3.2.
4 Policy Requirements

The following are the specific requirements of this policy.

4.1 Ethics Review

Ethics review can be undertaken at various levels, according to the degree of risk involved in the research (see Mater Health Services Research Ethics Committee (MHS HREC) (EC00332) Terms of Reference Section 3.2 Levels of Ethical Review, and the Mater Health Services Human Research Ethics and Governance website for further detail http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee).

4.2 Review Processes

All research applications, regardless of their risk category, must be submitted for review by a HREC constituted in accordance with the National Statement. Research must be submitted to the HREC for ethical review and receive ethical approval (unless ethical review has been exempted) and research governance authorisation prior to commencement. Ethical review by the MHS HREC (EC00332) will be conducted in accordance with the MHS HREC Terms of Reference (Section 3.3 Review of Research Proposals, and the Mater Health Services Human Research Ethics and Governance website http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee). Only applications submitted via the Australian Online Forms for Research website will be accepted.

4.3 Monitoring Approved Research

All projects approved by an HREC will be monitored by that Committee. The monitoring will be in accordance with the NHMRC Framework for Monitoring.

Researchers are responsible for notifying the MHS HREC that mechanisms for monitoring are in place, and for satisfying the MHS HREC that the mechanisms are appropriate to the research (National Statement Sections 5.5.1 to 5.5.5).

4.4 Suspension or Cessation of Research

Researchers shall inform the relevant institution/s, the review body/bodies that approved the research and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion, and why. For research at more than one site it must be clearly established, before the research begins, how this information will be communicated (National Statement Section 5.5.6).

Where an HREC finds reason to believe that continuance of a research project will compromise participants’ welfare, it will immediately seek to establish whether ethical approval for the project should be withdrawn. Where ethical approval for a research project is withdrawn:

- The researcher, the institution/s and, where possible, the participants must be informed of the decision to withdraw ethical approval;
- The site or host or HRECs institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of the participants; and
- The research may not be resumed unless either the researcher subsequently establishes that continuance will not compromise participants’ welfare, or the research is modified, ethically reviewed and approved.

If reports of adverse events or unexpected outcomes are received, HRECs may require researchers to amend research procedures to protect participants. If such an amendment cannot achieve this the research may be suspended or stopped (National Statement Sections 5.5.7 to 5.5.10).
4.5 Conflict of Interest

If a conflict of interest arises which could or does have/potentially could have a bearing on research, the MHS HREC should be informed about the conflict as described in the MHS HREC Terms of Reference (Section 2.6.1) and PY-RSH-300302 Responsible Conduct of Research Policy. The HREC will reach a decision on how the conflict of interest should be managed. The MHS HREC should see that measures are adopted to manage conflicts of interest involving researchers.

4.6 Handling Complaints

Complaints may be made by research participants, researchers, staff or others about the conduct of research or about the conduct of the HREC or the Research Governance Office in reviewing research proposals.

4.6.1 Complaints concerning the conduct of a project

- All complaints regarding the conduct of the research study should be forwarded to the HREC Chairperson via the HREC Coordinator. The Institutional Research Governance Officer should also be informed by the Coordinating or site Principal Investigator.
- Participant Information Sheets must include HREC contact details to allow such complaints to be made.
- When such complaints raise the possibility of a potential conflict of interest, the process for receiving and resolving complaints and allegations is described in the MHS HREC Standard Operating Procedures (SOPs). In situations where a conflict of interest is suspected the PY-RSH-300302 Responsible Conduct of Research Policy is applied.
  When such complaints raise the possibility of research misconduct the process for receiving and resolving complaints and allegations is described in the MHS HREC SOPs. In situations where research misconduct is suspected the PY-RSH-300310 Research Misconduct Policy is applied.

4.7 Privacy

Relevant privacy legislation, specifically Sections 95, 95A and 95AA of the Privacy Act must be adhered to. The MHS HREC annually reports to the NHMRC applications approved or not approved applying Sections 95, 95A and 95AA.
Annexure A

In line with Catholic values, it is not acceptable to counsel a woman or her partner to use a contraceptive if the express purpose is to make intercourse infertile. The following words should not be used: oral contraceptive pill, condoms, intrauterine device (IUD), contraceptive, contraception or birth control. Statements in the application (e.g. participant information sheet) to the effect that participants must practise methods of contraception should not be included. If the study is to be conducted at MHS the following is the strongly recommended wording for patient information and consent forms (PICFs) that have been approved by an HREC:

The effects of [Name of investigational product] on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least [number] months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of [number] months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.