

Policy Applies to:

All those seeking to undertake research within the Mercy environment (this includes Mercy hospital, Manaaki)

- Credentialed Specialists who wish to conduct research using Mercy patients or patient data, or staff as participants
- Staff employed at Mercy ;
- Employees/students of other organisations who wish to conduct research using patients or staff as participants

Related Standards:

- **New Zealand Public Health and Disability Act 2000** (New Zealand Health and Disability Ethics Committees)
- **EQuIP Standard:**
2.5 The organisation encourages and adequately governs the conduct of health and medical research to improve the safety and quality of health care.

2.5.1 The organisation's research programme develops a body of knowledge, protects staff, consumers/patients and has processes to appropriately manage the organisational risks associated with research.
- **Health Research Council** requirements in relation to research they have funded where Mercy Hospital is a nominated site
- Ministry of Health document "**Operational Standards for Ethics Committees**" March 2002 (updated April 2006)
- **Health & Disability Code of Patient Rights 1996**

Rationale:

Mercy recognises the importance of research as a scientific basis for clinical practice, to improve patient outcomes. It supports research within the parameters of this policy and where it is consistent with the organisation's philosophy and strategic goals. All research activities must meet ethical and legal standards as well as any organisational requirements. The delivery of care to patients takes precedence over other activities including research.

Research activities covered by this policy include:

- Credentialed Specialists as researchers and / or participants;
- Staff of Mercy as researchers and / or participants;
- Patients of Mercy;
- Use of Mercy facilities or equipment;
- Access to patient and Mercy records;
- Any other research activity carried out in Mercy for which ethical approval is required as set out in the Ministry of Health document "Operational Standards for Ethics Committees" March 2002 (updated April 2006)
<http://www.parliament.nz/resource/0000162273>

Definitions:

Clinical Audit; is a way of finding out whether you are doing what you should be doing by asking if you are following guidelines and applying best practice. e.g. for the purposes of this policy, not part of a hospital wide global audit activity.

Research; evaluates practice or compares alternative practices, with the purpose of contributing to a body of knowledge by asking what you should be doing

A low risk research project; is one in which the nature of the harm to an individual is minimal and no more than is encountered in daily life, can include clinical audit & quality improvement activities. e.g. would apply to completion of dissertations

Quality Improvement Activities; aim to improve health & disability support services by assessing the adequacy of existing practice against a standard e.g. for the purposes of this policy does not involve patients

Co-ordinating Investigator; The CI has the overall responsibility for the conduct of the research/study

Ethics Committee Coordinator; Role that supports the operational aspects of low risk research

Objectives:

- To ensure that patient wellbeing and patients' rights are protected
- To ensure ethical and legal standards of research are maintained
- To ensure the research is culturally safe and encompasses the principles of the Treaty of Waitangi
- To ensure that all research undertaken within the organisation has a nominated contact person within Mercy Hospital.
- To ensure that Mercy Hospital staff has access to research that improves patient outcomes
- To ensure research at Mercy Hospital is appropriate to our Catholic Tradition and Mercy Ethos.

Implementation:

- Most research involving patients must be submitted to/and approved by the New Zealand Health and Disability Ethics Committee (Multi Regional or Southern Regional)¹ or a relevant approved Tertiary Ethics Committee and have Ethics Committee approval to ensure that appropriate mechanisms are in place for identifying patients and gaining informed consent Research involving staff as

¹ http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-ethicalreview-role?Open&m_id=3.1

participants which is deemed 'low risk' must be registered using the attached form (appendix 1)

- All proposals are reviewed to ensure the research has:
 - an appropriate CI,
 - will be conducted in a safe and thorough manner, with due care given to participant wellbeing and rights and
 - that it is appropriate to Catholic Tradition and Mercy Ethos of the Hospital.
- The Ethics Committee reviews research proposals in a timely manner and provides feedback as to acceptance or otherwise to the researcher. While ethics review may not be required for audit and quality improvement activities, ethics review should be considered:
 - where there is any doubt that the audit could be defined as research;
 - when the method of evaluation is beyond usual practice or adds risk for the patient;
 - when it is anticipated or intended that this activity will lead to any publication which has a requirement for ethics approval.
- This review may be undertaken by the Ethics Committee Coordinator and / or Chairperson if the research is deemed 'Low Risk Research' and by the Mercy Hospital Ethics Committee if it is identified as being beyond the scope of Low Risk Research.
- The Chief Executive Officer may defer or suspend a project at any time in the interests of safety of patients or staff, or where financial or reputation risk to the sponsoring institution becomes apparent.
- Systems are in place to ensure clinical staff can access research to develop and maintain best practice e.g. Lippincott Database, AORN, ACORN and HealthLearn are available to clinical and non-clinical staff.

Evaluation:

Researchers will provide a 12 month update of their work (annually) if the research is not completed within a 12 month period. This will be disseminated to the Ethics committee for review.

An executive summary will be presented annually to the Board identifying:

- All research proposals accepted by the Ethics Committee in the preceding 12 months
- Current research being undertaken at Mercy Hospital

Executive summary of Research being undertaken/completed will also be reviewed annually at Quality & Risk Committee

Associated Documents

External (including but not exclusive):

- Operational Standard for Ethics Committees” Ministry of Health, March 2002 (Updated April 2006). <http://www.parliament.nz/resource/0000162273>
- Code of Ethical Standards for Catholic Health and Aged Care Services in Australia”, Catholic Health Australia 2001.
- Code of Health and Disability Services Consumers’ Rights 1996
- Health and Disability Commissioner Act 1994
- Health Information Privacy Code 1994
- Health Practitioners Competence Assurance Act 2003
- Human Rights Act 1993
- Human Tissue Act 2008
- New Zealand Bill of Rights Act 1990
- Privacy Act 1993
- Convention on Rights of The Child 1993
- Health Act 1956
- Official Information Act 1982Health Research Council guidelines
- The Medicines Act 1981 and
- The Medicines (database of medical devices) Regulations 2003
- The Misuse of Drugs Act 1975
- The Human Assisted Reproductive Technology Act 2004
- Medsafe NZ <http://medsafe.govt.nz/regulatory/clinicaltrials.asp>

Internal

- Ethics Directives of Mercy Hospital.
- Cultural Policy
- Privacy Policy
- Consent Policy

Acknowledgements

Professor Philip Hill, McAuley Chair, Centre for International Health, University of Otago.

Process:

Research requiring Ethics approval must have a Co-ordinating investigator (CI) who is responsible for;

- Obtaining appropriate ethics approval from;
 - New Zealand Health and Disability Ethics Committee (Multi Regional or Southern Regional) or a relevant approved Tertiary Ethics Committee
 - Mercy Hospital Ethics Committee

The CI will provide in their application to the Mercy Ethics committee;

- A copy of the Southern Regional or Multi-Regional Ethics Approval letter.
- Plus all paperwork submitted to the relevant ethics group in support of their research proposal.

Following receipt of a research request, projects that have Mercy named as a site and have New Zealand Health and Disability Ethics Committee approval are reviewed by the Mercy Ethics Committee to evaluate in relationship to our Catholic Tradition and Mercy Ethos.

The CI will be notified of acceptance or otherwise within 4 weeks of receipt of the request. If the research is accepted the CI will provide to the Mercy Ethics Committee on an annual basis progress reports at the completion of the project or if longer than 12 months at 12 monthly intervals.

Low risk research/clinical audit/ quality improvement activity deemed to not require ethics approval is registered using the attached form; Appendix 1. Approval of these activities will be managed by the Ethics Coordinator and members of the Senior Nursing team.