Policy

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Our Mission	Our Vision	Our Values
As Mater Research, together with our partners, we conduct, enable and translate exceptional clinically relevant health research.	Achieving better health for all through exceptional research.	Mercy Dignity Care Commitment Quality

Affirmation

This governance document is consistent with the Mater Research Values and supports the Mater Research Mission and Vision by establishing and mandating appropriate controls to support the delivery of research services.

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1 Document Controls

1.1 Document Revision History

Version	Date	Description
1	26-May-2015	Version 1 Publish on Mater Document Centre

1.2 Document Review and Approval

Person Name / Committee	**Position** (if applicable)	**Function** (Owner | Review | Approve)
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Corporate Policy Governance Committee		Approve

1.3 References

Internal Documents

Document Type	**Document ID**	**Document Title**
Supporting	PR-RSH-300316	Research Misconduct Procedure
	CA-MSN-000001	Mater Mission, Vision and Values
	POL-1.100-A	Mater Research Mission and Goals
Related	PY-RSH-300310	Responsible Conduct of Research Policy
	PY-RSH-1.005.01	Code of Conduct Policy
	PY-PAL-020044	Managing Performance and Conduct Policy

External Documents

1	The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, World

	Medical Association, 2013
2	Australian Code for the Responsible Conduct of Research, 2007
3	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*)
4	Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001
5	Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003
6	NHMRC Research Misconduct Guidance: What do I do if I suspect research misconduct is occurring? (https://www.nhmrc.gov.au/research/responsible-conduct-research/reporting-research-misconduct)
7	NHMRC Research Misconduct Guidance: Research Misconducted Detected During Peer Review (https://www.nhmrc.gov.au/research/responsible-conduct-research/reporting-research-misconduct)
8	4.20.05 Research Misconduct Policy, The University of Queensland
9	Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, International Committee of Medical Journal Editors, 2013

2 Introduction

2.1 Purpose

This policy details the Mater Health Services (MHS) and Mater Research (MR) requirements for reporting and dealing with research misconduct.

Allegations of research misconduct will be made from time to time and a prompt and effective response is required in each case. All affected parties must be treated fairly, the situation remedied, and appropriate steps taken to maintain public confidence in the research endeavour.

2.2 Scope and Context

This policy applies to all MHS and MR 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 research involving patients, staff and resources of MHS and MR.

However, the responsibility for decisions on employment or sanctions of non MHS/MR employees who are involved in research at Mater and found to have committed research misconduct remains with the employee's own employing institution.

This policy does not apply to any other instances of misconduct other than those relating to research. Mater Health Services has a policy in place to deal with all other instances of misconduct (including serious misconduct) and this should be followed in all other cases (see PY-PAL-020044 Managing Performance and Conduct Policy).

2.3 Definitions

Term	Definition
The Australian Code for the Responsible Conduct of Research (*The Code*)	The *Australian Code for the Responsible Conduct of Research (2007)*. This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of The Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
Human Research	Research conducted with or about people, or their data or tissue as described in the *National Statement*.
Human Research Ethics Committee (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data research involves humans. HRECs are established by organisations which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies.
Mater Health Services (MHS)	"MHS" means Mater Misericordiae Health Services Brisbane Ltd ACN 096708922 owner and operator of the Mater Hospitals South Brisbane, Redland and other sites notified to the HREC.
Mater Research (MR)	"MR" means Mater Medical Research Institute Ltd ACN 109834719 owner and operator of Mater Research and Mater Medical Research Institute.
Mater Researcher	Employee of MHS or its subsidiary companies who is conducting research.
Procedural Fairness	The person who is the subject of the inquiry must be granted a fair hearing under the principle of procedural fairness. The objective decision maker(s) or panel of

	people established to conduct an inquiry that may lead to disciplinary action are responsible for ensuring procedural fairness. To ensure procedural fairness: • the allegations of research misconduct must be stated clearly in writing • the person facing the allegations has a right to be heard • the decision maker(s) or members of the panel must be free from bias or preconception and must conduct themselves in a manner that demonstrates this • the decision maker(s) or panel should provide its findings, and the reasons for those findings, in writing • there should be an avenue for the findings to be appealed. Also known as 'natural justice'.
Research	Original investigation undertaken to gain knowledge, understanding and insight as described in *The Code*.

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

- National Safety and Quality Health Service Standards; ISBN: 978-1-921983-04-7; September 2012; Standard 15 Corporate Systems and Safety
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments. Therapeutic Goods Administration (2000)
- Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, International Committee of Medical Journal Editors (2013)

3 Principles

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

3.1 Principle 1: Research Misconduct Instance

All researchers are required to follow *the Code*; in instances where *the Code* is not followed a breach has occurred. A breach does not necessarily indicate research misconduct, although it may be hard to differentiate. A complaint or allegation regarding research conduct will constitute an instance of research misconduct if it involves all of the following:

- an alleged breach of *the Code*;
- intent and deliberation, recklessness or gross and persistent negligence; and
- serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment.

3.2 Principle 2: Handling of Research Misconduct Complaints

Complaints about research and research related activities conducted and/or approved at Mater, which do not raise the possibility of misconduct, are to be forwarded to the appropriate agency, such as the HREC and Research Governance Office, the Animal Ethics Committee and the Therapeutic Goods Administration.

Where complaints about researchers or research raise the possibility of research misconduct they should be dealt with according to this policy; instances identified as a breach of *the Code* without serious consequence of wilfulness must be discussed with a supervisor or Adviser in Research Integrity. Where complaints about researchers are not defined as research misconduct or a breach, the relevant policy must be followed.

4 Policy Requirements

The following are the specific requirements of this policy.

4.1 Determination of Research Misconduct

Research misconduct includes:

a) fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of Research Misconduct by others.
b) repeated or continuing breaches of *the Code,* which individually do not constitute misconduct may be determined as misconduct where these have been the subject of previous counselling or specific direction.

Research misconduct does not include honest differences in judgement in management of the research project, and may not include honest errors that are minor or unintentional. However, breaches of *the Code* will require specific action by supervisors and responsible officers of the institution.

4.2 Responsibilities of Researchers and Mater Staff

All researchers and Mater staff not involved in research have an obligation to report potential research misconduct, that comes to their attention or that they should be reasonably aware of by virtue of their position within either MHS or MR and to cooperate in the investigation of such matters.

In the circumstances described above, researchers have a responsibility to report to an Adviser in Research Integrity (see Section 4.3), who will then provide advice in relation to the potential research misconduct issue. If an individual is unsure if their complaint is regarding research misconduct, they may discuss the matter informally with an Advisor in Research Integrity. These confidential discussions do not constitute a formal allegation.

The first step would be to establish whether the complaint can be appropriately dealt with at the Department level, after the initial discussion with the Research Integrity Advisor. If the complaint cannot be resolved at the Department level, a formal complaint or allegation must be made in writing to the Designated Person appointed to this role by the institution (see Section 4.4). If the Adviser in Research Integrity believes that the complaint falls outside the definition of Research Misconduct, the complaint should be dealt with under the relevant policy.

4.3 Nominated Advisers in Research Integrity

The Nominated Advisers in Research Integrity (Adviser) are persons familiar with the literature and guidelines on research misconduct who are able to give confidential advice to staff about what constitutes research misconduct, the responsibilities of a potential Complainant and the procedures for dealing with allegations. An Adviser should not be involved in a case if he or she has a Conflict of Interest (see PY-RSH-300302 Responsible Conduct of Research Policy).

The role of the Adviser is not to advise in the legal sense but to explain the options open to the person considering making an allegation. These options include:

- referring the matter directly to the Respondent (the researcher accused of misconduct);
- not proceeding or withdrawing the allegation if discussion resolves the concerns;
- referring the allegation to a person in a supervisory capacity for resolution at the local or departmental level;

- making an allegation of research misconduct in writing to the Designated Person.

The Adviser's role does not extend to investigation or assessment of the allegation.

The Adviser must not make contact with the Respondent and he or she must not be involved in any subsequent inquiry.

At MHS and MR the Advisers are:

- Executive Director, Mission Leadership, MHS
- Manager, Risk & Compliance Services, MHS
- Deputy Director (External Partnerships), MR

The University of Queensland (UQ) also has Research Integrity Advisers that can be contacted in the case of a potential case of research misconduct relating to a researcher with an honorary UQ appointment.

4.4 Nominated Designated Person in Research

A Nominated Designated Person is a senior person within MHS and/or MR management structure, experienced in research and research management. The MR Chief Operating Officer is the Nominated Designated Person in Research.

The role of the Nominated Designated Person in Research is to:

- receive written allegations;
- conduct a preliminary investigation including securing all relevant evidence; and
- provide advice to the MR Chief Executive Officer (CEO) and/or MHS CEO.

The Designated Person must maintain full records of all matters that relate to allegations of research misconduct.

To conduct an independent review, the Designated Person may communicate with the appropriate Chair of the review body which approved the research.

4.5 Principles for Reporting Research Misconduct

4.5.1 Procedural Fairness

Procedural fairness means ensuring that a fair decision is reached by an objective decision maker and is required in relation to any disciplinary action taken against a staff member.

4.5.2 Rights of Respondent

Relevant parties must not be informed of allegations of research misconduct until sufficient detail has been gathered that there is an allegation of research misconduct.

The Respondent has a right to procedural fairness.

4.5.3 Rights of Complainant

No staff member of MHS or MR is able to take action against an individual who reports an incident, in good faith, even if the accusation is not sustained. Where the outcome of a preliminary assessment or formal investigation indicates that an allegation has not been made in good faith, the MHS CEO/MR CEO may pursue disciplinary action against the Complainant.