Research excellence

PURPOSE

This procedure describes processes for research excellence and sets up a framework for the responsible conduct of research. The identified processes provide a foundation for high-quality research, credibility, and community trust in the research endeavour, undertaken in Metro South Health (MSH).

OUTCOME

The intended outcome of this procedure is to:

- Uphold and promote the Australian Code for the Responsible Conduct of Research 2018 ('the Code') and outline processes for the conduct of research in MSH or research conducted under the auspices of MSH facilities/services.
- Ensure appropriate action is taken so that research is conducted in an ethical and scientifically robust manner by upholding principles outlined within the PL2023-92 Research Policy.
- Uphold principles outlined within Attachment 1: Research Excellence Handbook.

SCOPE

This procedure applies to all MSH employees and collaborators who conduct human research within or in association with MSH, or through access to MSH participants, health records or data. Adherence to this procedure will ensure all research conducted within MSH or in collaboration with external entities/organisations is of the highest ethical and scientific standard and is compliant with relevant legislation, standards, and guidelines. Failure to comply with this procedure may constitute professional or research misconduct on the part of the responsible individual.

PROCEDURE

1. RESEARCH INTEGRITY

- MSH recognises the necessity of cultivating an environment where ethical conduct and adherence to rigorous scientific principles are upheld at every stage of the research process.
- Principal Investigators have a responsibility to ensure that they uphold the principles of responsible research conduct and support and guide their research teams in research integrity. This includes leading by example and promoting a culture of responsible research.
- For more information see MSH work instruction WI2023-287 Research integrity.

1.1 Legal and ethical framework

- MSH researchers have a responsibility to familiarise themselves with legal and ethical regulations governing research in Australia. Key documents include the National Statement on Ethical Conduct in Human Research 2023 ('National Statement'), the Code, and relevant state or territory legislation.
- MSH researchers must be provided with information about the current requirements and responsibilities for the responsible conduct of research and guidance in good research practice in MSH.
- Principal Investigators and supervisors have a responsibility to provide a 'Research Induction' to all project team members upon their commencement in research. This may include completion of Metro South Research eLearning modules (i.e., Research Induction), references to relevant legislative requirements or government guidelines and information regarding relevant MSH policies and procedures, including:
    - The Code, the Public Service Code of Conduct, research policies and procedures and privacy requirements.
    - Any workplace health and safety or environmental protection requirements for research practices, specific equipment or workspaces including laboratories (biosafety).
- MSH researchers are responsible for staying updated on the latest developments in research ethics and best practice by attending training workshops, seminars, and conferences to enhance understanding of research integrity.

1.2 Mandatory research training and certification

- All researchers must be appropriately trained in relevant research policies and procedures and MSH's expectations for ethical and responsible behaviour.
- All MSH researchers must complete and provide the following mandatory requirements as outlined in Table 1:

Table 1: Mandatory requirements

Mandatory requirement	Role	Renewal	Evidence
Curriculum Vitas (CVs)	Principal Investigators/Coordinating Principal Investigators	2 year renewal	CV document
Good Clinical Practice (GCP)	All research team members	3 year renewal	GCP Certificate
Research Integrity	All research team members	3 year renewal	Research Integrity Certificate

2. QUALITY

2.1 Supervision

- Principal Investigators have a responsibility to ensure that each new research student or employee is paired with a responsible and appropriately qualified supervisor. Individuals who supervise research students and staff must:
    - provide advice in all matters of good research practice, including avoiding or acknowledging biases, consistent with the Code;
    - take all reasonable measures to ensure, as far as possible, the validity of research data obtained by a research student/employee under their supervision; and
    - adhere to the standard for behaviour outlined in the Code of Conduct for the Queensland Public Service and according to the International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016) ('GCP').
- Supervisors must ensure that research trainees are appropriately acknowledged for their work.

2.2 Quality management systems

- Principal Investigators must implement appropriate quality management systems for the conduct of their research project and take all reasonable measures to be satisfied that the research methods and outcomes of researchers under their supervision are suitable and valid.
- For more information see MSH work instruction WI2023-288 Research quality management systems.

3. DATA AND PRIVACY

- Principal Investigators must also ensure the validity of research data obtained by all members of the research team, including any student/research trainee under their supervision.
- Principal Investigators and researchers are responsible for privacy by ensuring appropriate security for any confidential material in accordance with MSH policies and procedures which complies with the *Information Privacy Act 2009* (Qld) and *Privacy Act 1988* (Cth).
- For more information see MSH work instruction WI2023-289 Research data and privacy.

4. AUTHORSHIP, PUBLICATION, AND PEER-REVIEW

- Principal Investigators, line managers, supervisors, and research student supervisors must support researchers and research students/trainees to appropriately reference and cite the work of others and give credit, including authorship where appropriate, to those who have contributed to the research.
- For more information see MSH work instruction WI2023-290 Research authorship, peer review and publication.

5. RESEARCH COMPLAINTS AND MISCONDUCT

- A failure to meet the principles and responsibilities set out in the Code is a breach of the Code.

- A breach of the Code occurs on a spectrum from minor breaches to those that are more serious. A serious breach of the Code that is carried out with intent or recklessness or negligence is particularly egregious and may be referred to as research misconduct.
- MSH work instruction WI2023-291 Research complaints and misconduct outlines the preferred model that MSH utilises to investigate and manage potential breaches, determine any corrective actions to ensure the integrity of the research record and when a finding of research misconduct may be made.

6. RISK ASSESSMENT AND MANAGEMENT

- Assessing risk is a fundamental aspect of responsible and ethical research conduct and a crucial and mandatory component of research.
- Risk assessment and management supports the National Statement and National Clinical Trials Governance Framework (NCTGF) by ensuring that the risk and benefit of research be assessed and that any risks are effectively minimised, mitigated or managed.
- For more information see MSH work instruction WI2023-292 Assessing and managing risk in research.

7. CONSUMER PARTNERSHIPS IN RESEARCH

- From July 2023 partnering with consumers became a mandatory component of the Australian Health Service Safety and Quality Accreditation Scheme.
- For more information see MSH guideline GL2021-75 Research Management - Partnering with Consumers in Research.

8. FIRST NATIONS RESEARCH - ADVOCATING FOR ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

- If the research involves Australian Indigenous communities or knowledge, MSH researchers must respect and adhere to Aboriginal and Torres Strait Islander research conventions, seek appropriate permissions, and engage in meaningful consultation with Australian Indigenous stakeholders.
- For more information see MSH guideline GL2023-97 Aboriginal and Torres Strait Islander health research.

9. TRANSLATION AND IMPACT

- In the health research community, translation involves the development of theoretical and basic research into changes in clinical practice and presenting complex research findings into understandable language for a broader audience. Impact involves communicating these findings effectively to various stakeholders.
- Impact may involve changing clinical practice or health outcomes through the implementation of research findings.
- Translation involves effective communication and ensures that the knowledge does not stay within the academic community but reaches those who can harness/maximise knowledge generated/findings for practical purposes.

- For more information, see MSH guideline GL2023-98 Research translation and impact.

RESPONSIBILITIES

Position	Responsibility	Audit Criteria
Executive Director, Metro South Research	• Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical and scientific review of all MSH research. • Establish and maintain a comprehensive a research excellence culture within which research is conducted. • Address any systemic issues relating to matters of research integrity and implement corrective actions.	• Research Policy Framework is publicly available
Director, Research Development, Metro South Research	• Ensure MSH systems are in place for the management of concerns, complaints, or allegations about potential breaches of the Code.	• MSH Research Complaints and Misconduct process
MSH Research Integrity Advisors (RIA)	• Provide support and advice regarding ethical conduct of research in MSH including conflicts of interest.	• MSH RIA Network
Researchers	• MSH researchers/employees working within MSH have shared responsibilities for ensuring the integrity of research.	• Mandatory completion of Research Integrity and GCP Training

DEFINITIONS

Term	Definition
Quality	Quality standards in research refer to the criteria used to evaluate the quality and validity of research studies. These standards are important to ensure that research studies are conducted in a rigorous and transparent manner, and that the findings can be trusted and used to inform decision-making.
Research	Clinical research – A type of scientific research that is conducted with human participants to understand, diagnose, prevent, or treat medical conditions or diseases. It involves the study of human biology, physiology, pharmacology, and psychology, among other disciplines, to improve our understanding of health and disease. Clinical research can take many forms, including

Term	Definition
	observational studies, randomised controlled trials, and retrospective analyses of patient data. In some cases, clinical research involves testing new drugs, medical devices, or other interventions in human subjects to evaluate their safety and efficacy. Clinical research is typically conducted in a controlled environment, such as a hospital, and is overseen by a team of researchers, including physicians, nurses, and other healthcare professionals. The goal of clinical research is to generate new knowledge that can improve patient outcomes, inform clinical practice, and advance the science of health care. Non-clinical research – The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research excellence	When conducting or sponsoring research and/or utilising MSH participants, data, employees and/or resources, MSH and researchers must strive to achieve research excellence by upholding principles underpinned by the following elements: research integrity, quality, data and privacy, finance and business management and impact and translation. See PL2023-92 Research Policy for more information regarding research excellence principles in MSH.
Research Policy Framework	A framework inclusive of policy, procedures, work instructions, guidelines and supporting documents, aligned to MSH research practices.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Crime and Corruption Act 2001* (Qld) • *Criminal Code Act 1899* (Qld) • *Defence Trade Controls Act 2012* (Cth) • *Gene Technology (Queensland) Act 2016* (Qld) • *Gene Technology Act 2000* (Cth) • *Hospital and Health Boards Act 2011* (Qld) • *Human Rights Act 2019* (Qld) • *Industrial Relations Act 2016* (Qld) • *Information Privacy Act 2009 (*Qld) • *National Health and Medical Research Council Act 1992* (Cth) • *Privacy Act 1988* (Cth) • *Public Health Act 2005* (Qld)

- *Public Interest Disclosure Act 2010* (Qld)
- *Public Sector Act 2022* (Qld)
- *Public Sector Ethics Act 1994* (Qld)
- *Statutory Bodies Financial Arrangements Act 1982* (Qld)
- *Therapeutic Goods Act 1989* (Cth)

Regulations

- Gene Technology Regulations 2001 (Cth)
- Hospital and Health Boards Regulation 2012 (Qld)
- Information Privacy Regulation 2009 (Qld)
- National Safety and Quality Health Service Standards 2017 (Cth)
- Public Service Regulation 2018 (Qld)
- Statutory Bodies Financial Arrangements Regulation 2019 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)

National Health and Medical Research Council (NHMRC)

- Australian Code for the Responsible Conduct of Human Research 2018 and supporting guides
    - Authorship
    - Collaborative research
    - Disclosure of interests and management of conflicts of interest
    - Management of data and information in research
    - Peer review
    - Publication and dissemination of research
    - Research Integrity Advisors
    - Supervision
- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018
- National Statement on Ethical Conduct in Human Research 2023

Therapeutic Goods Administration

- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016)

Department of Health

- General Retention and Disposal Schedule
- Health Sector (Clinical Records) Retention and Disposal Schedule
- Health Sector (Corporate Records) Retention and Disposal Schedule
- QH-HSD-035:2023 Health Service Directive: Research Ethics and Governance Directive

	• IS18:2018 Information security policy • Public Service Code of Conduct • QH-POL-013:2022 Research Management Policy • QH-IMP-013:1:2022 Research Management Standard

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	**Metro South Health** • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Contract Management Framework **Policies and procedures** • PL2018-62 Risk Management • PR2018-97 Risk Management • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • WI2023-287 Research integrity • WI2023-288 Research quality management systems • WI2023-289 Research data and privacy • WI2023-290 Research authorship, peer review and publication • WI2023-291 Research complaints and misconduct • WI2023-292 Assessing and managing risk in research **Guidelines** • GL2021-75 Research Management - Partnering with Consumers in Research • GL2023-97 Aboriginal and Torres Strait Islander health research • GL2023-98 Research translation and impact **Attachments** • Attachment 1: Research Excellence Handbook

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting, and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, give proper consideration to human rights.

When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

CONSEQUENCE CATEGORY

Consequence category	Reputation Stakeholder and Community
Level of consequence	Moderate
What will be monitored	Research integrity, quality, data and privacy, risk assessment and management
How (method or tool)	• Research Policy Framework – publicly available • MSH Research Complaints and Misconduct process • MSH Research Integrity Advisor Network • Mandatory completion of Research Integrity and GCP Training
Frequency	Annually
Responsible officer	Executive Director, Metro South Research
Reporting to	Metro South Health Research Council

PROCEDURE DETAILS

Procedure Name	Research excellence
Procedure Number	PR2023-411
Current Version	V1.0
Keywords	Research excellence, integrity, conflicts of interest, quality, good clinical practice, research mandatory training
Primary Policy Reference	PL2023-92 Research Policy
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Endorsing Committee / Authority	Metro South Health Research Council
Document Author	Manager, Research Development, Metro South Research
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REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	13/12/2023	Chief People, Engagement and Research Officer	New document