Research integrity

PURPOSE

This work instruction identifies an effective process to ensure research integrity and credibility of research conducted within or in collaboration with Metro South Health (MSH).

OUTCOME

This work instruction aims 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 all research conducted within MSH or in collaboration with external entities, is of the highest ethical standards and best practices to maintain research integrity.
- Outline a MSH-wide process that can be adapted by MSH research teams to implement research integrity processes for their research projects.

This work instruction outlines processes described in MSH procedure PR2023-411 Research excellence and upholds principles outlined within the Research Excellence Handbook.

SCOPE

This work instruction 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.

WORK INSTRUCTION

1. STEP 1: RESEARCH INTEGRITY TRAINING

- In support of the MSH Research Strategy, three research integrity online modules are available and accessible to all MSH employees via MSHLearn:
    1. Research integrity – concepts (20-25 min completion time)
    2. Research integrity – probity and bias (20-25 min completion time)
    3. Research integrity – breaches of the Code (20-25 min completion time)
- The total time to complete all three modules is approximately 60 mins (one certificate generated).
- From 1 January 2024, all three MSH Research Integrity Training online modules are mandatory for all MSH employees undertaking research in MSH.
- As part of this mandate, all researchers seeking authorisation of research from 1 January 2024 must provide evidence of Research Integrity Training completion (i.e., a valid Research Integrity Training Certificate), as part of the Site Specific Authorisation (SSA) process. MSH work instruction WI2023-301 Site specific assessment of research outlines this process.

- A three-year renewal requirement will also be implemented.
- MSH employees must complete all three MSH Research Integrity Training online modules via MSHLearn to meet the mandatory requirement (even if they have completed other research integrity training via their affiliated university).
- The Principal Investigator/Coordinating Principal Investigator at the site has the responsibility for ensuring that all members of the research team undertake research integrity training prior to the commencement of the study.
- External researchers on a research project (i.e., non-MSH employees) may provide evidence of research integrity training from their University or Institute (as applicable).
- External access to MSH Research Integrity Training online modules can be facilitated.

2. STEP 2: ETHICAL APPROVAL AND INFORMED CONSENT

- If the research involves human subjects, or any other ethically sensitive areas, MSH researchers must seek ethical approval from the relevant Human Research Ethics Committee (HREC). MSH work instruction WI2023-299 Ethical and scientific review of research provides more information.
- When involving human participants, MSH researchers must obtain informed consent from all participants. Participants must be provided with clear and comprehensive information about the research, its objectives, potential risks, and their rights to withdraw. MSH guideline GL2023-100 Research Participant Information and Consent Form (PICF) provides more information.

3. STEP 3: DATA MANAGEMENT, STORAGE AND RECORDS

- At the commencement of a research project, MSH researchers must establish a secure and organised system for data management. As part of this, data must be stored in compliance with data protection laws and best practices, including data encryption and regular backups. MSH work instruction WI2023-289 Research data and privacy provides more information.
- It is also vital to maintain thorough and accurate records of research activities, including any deviations from the initial research plan. This documentation will support the integrity of the research.
- MSH researchers are also responsible for maintaining transparency in research by documenting every step of the work (i.e., keep detailed records of the methodology, data, and analysis, making it easier to verify and reproduce results).

4. STEP 4: AUTHORSHIP, PUBLICATION AND OPEN ACCESS

- MSH researchers must adhere to guidelines for authorship and publication ethics by clearly defining the roles and contributions of all authors, avoiding plagiarism, and disclosing any potential conflicts of interest when submitting research for publication.
- MSH researchers should consider making the research data and findings available for verification and replication. Open access and data sharing can enhance transparency and trust in the research work.
- MSH work instruction WI2023-290 Research authorship, peer review and publication provides more information.

5. STEP 5: RESEARCH FUNDING AND FINANCIAL CONTRACTS

- MSH researchers must be transparent about the sources of research funding and declare any financial conflicts of interest.
- It is also important to ensure that research is not influenced by the funding source, and report findings objectively.
- MSH procedures PR2023-412 Research support and management and PR2023-413 Research administration and compliance provide more information.

6. STEP 6: RESPONSIBLE CONDUCT OF RESEARCH AND COLLABORATION

- MSH research must follow the principles of responsible research conduct by avoiding fabrication, falsification, or manipulation of data, and always acknowledging the work of others through proper citation and referencing.
- Engaging in peer review processes and collaborative research efforts help ensure that research is subjected to scrutiny by experts and can lead to more robust results.
- MSH researchers should also routinely evaluate research processes and results by seeking feedback from peers, mentors, or colleagues to identify and rectify any potential issues.

7. STEP 7: ENVIRONMENTAL AND BIOSAFETY COMPLIANCE

- If the research involves environmental or biosafety considerations, MSH researchers must comply with relevant regulations and best practices to minimise potential harm.
- If conducting research in the Translational Research Institute (TRI), MSH researchers must adhere to TRI Work Health and Safety and biosafety policies and procedures.

8. STEP 8: IDENTIFY AND MANAGE POTENTIAL, PERCEIVED OR ACTUAL CONFLICT OF INTERESTS

- Conflicts of interest in research must be declared and managed in the public interest.
- Persons involved in research, who have an interest that conflicts or may conflict with their duties, must disclose the interest, and comply with the directions of the relevant manager/delegate to ensure appropriate management of the conflict of interest.
- MSH policy PL2014-38 Management of Conflict of Interest Policy and MSH procedure PR2016-66 Management of Conflict of Interest - All Staff provides more information regarding conflicts of interest.
- Attachment 1: Research Conflicts of Interest Disclosure Form may be used to identify and manage potential, perceived or actual conflict of interests in research.

9. STEP 9: RESEARCH INTEGRITY ADVISOR NETWORK

- The MSH Research Integrity Advisor Network includes MSH employees with research experience, analytical skills, empathy, good communication skills, knowledge of MSH’s processes and the Code, and familiarity with accepted practices in research.
- MSH work instruction WI2023-291 Research complaints and misconduct provides further information.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Executive Management Team	• Responsible for implementation of the research policies and procedures and for fostering good research practices. • Leadership for embedding a culture of responsible research conduct.	N/A
Metro South Research	• Provision of information resources and services pertaining to research to MSH and oversight of research development in MSH. • Ensuring the administrative processes for ethical approval and SSA authorisation of all human research are in place and promotes research integrity.	N/A
Principal Investigator (PI)/ Coordinating Principal Investigator (CPI) - responsible officer	• Ensure research integrity is considered when developing research protocols and processes are in compliance with the Research Policy Framework.	N/A
Employees, researchers, research student supervisors and students	• Share responsibility and accountability for MSH's research being conducted according to appropriate regulatory, ethical and scientific standards.	N/A

DEFINITIONS

Term	Definition
Conflict of interest	A conflict of interest in research occurs when a researcher or a related party has financial, personal, or other interests that could potentially compromise the objectivity, integrity, or impartiality of the research, leading to potential bias in the research process or its outcomes. It's important to identify, disclose, and manage such conflicts to maintain research credibility and transparency.
Data management	A framework designed to efficiently organise, store, retrieve, and manipulate data. It encompasses various tools, processes, and technologies that facilitate the collection, storage, processing, and protection of data to meet an organisation's information needs while ensuring data accuracy, security, and accessibility.

Deviation	A deviation in research refers to a divergence or departure from the planned or expected course of a research project, including any unintended changes in methods, procedures, or data collection that can potentially impact the validity and reliability of the research findings. These deviations may require documentation and, in some cases, reporting to ensure research integrity and transparency.
Mandatory training	Mandatory training is a structured and required educational program or set of courses that individuals or employees must complete to ensure compliance with legal, regulatory, or organisational requirements. These training programs cover specific topics, skills, or knowledge areas that are essential for safety, compliance, or the effective functioning of an organisation.
Research integrity	Research integrity refers to the adherence to ethical principles, honesty, and transparency in the conduct of research. It involves maintaining high standards of intellectual honesty, accuracy, and ethical behaviour throughout the research process, from the design and data collection to analysis, publication, and dissemination of findings. Research integrity ensures the credibility and trustworthiness of research outcomes while upholding ethical values and responsible conduct in the pursuit of knowledge.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)**
	• *Hospital and Health Boards Act 2011* (Qld)
	• *National Health and Medical Research Council Act 1992* (Cth)
	• *Public Health Act 2005* (Qld)
	• *Public Sector Act 2022* (Qld)
	• *Public Sector Ethics Act 1994* (Qld)
	• *Therapeutic Goods Act 1989* (Cth)
	Regulations
	• Hospital and Health Boards Regulation 2012 (Qld)
	• Public Health Regulation 2018 (Qld)
	• Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
	• Therapeutic Goods Regulations 1990 (Cth)
	Other authority
	• 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 **Metro South Health** • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Human Resources (HR) Delegations Matrix and Schedule • Metro South Financial Delegation Schedule and Framework
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	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • 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 Conflicts of Interest Disclosure Form

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, to 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.

WORK INSTRUCTION DETAILS

Work Instruction Name	Research integrity
Work Instruction Number	WI2023-287
Current Version	V1.0
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Primary MSH or Directorate Procedure Reference	PR2023-411 Research excellence
Executive Sponsor	Executive Director, Metro South Research
Document Author	Manager, Research Development, Metro South Research
Next Review Date	December 2026

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	13/12/2023	Executive Director, Metro South Research	• Supersedes PR2018-176 Research Integrity Procedure • Highlights mandatory training requirements