Research complaints and misconduct

PURPOSE

This work instruction sets out the roles and responsibilities of Metro South Health (MSH) in handling of research related complaints/allegations and research misconduct. It also establishes consistent and enforceable processes to manage any complaints and/or allegations that may be received about research undertaken at, in association with, or by MSH.

OUTCOME

This work instruction aims to:

- Outline the MSH-wide research complaints and misconduct process which adheres to the Australian Code for the Responsible Conduct of Research ('the Code') and Guide to Managing and Investigating Potential Breaches of the Code 2018 ('the Guide').
- Identify specific MSH Roles and Responsibilities under the Guide (Appendix 1).

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: RECEIPT OF A COMPLAINT AND/OR ALLEGATION

- Dependent on the content of the complaint and/or allegation, the person who initially receives the complaint or allegation, may perform initial inquiries, and attempt to informally resolve the complaint if there does not appear to be a breach of the Code.
- Persons in MSH who may receive or become aware of a complaint or allegation relating to research may include:
    - the research project contact person listed on the Participant Information and Consent form (PICF).
    - Principal Investigator, researcher and/or research student supervisor.
    - MSH Research Integrity Office (RIO) (e.g., Metro South Research; Manager, Research Integrity, and Compliance, Metro South Human Research Ethics Committee (MSHREC) Coordinator, Metro South Research Governance Office (MSHRGO)).
    - MSH Research Integrity Advisor (RIA).

1.1 Research integrity assessment tool

- Attachment 1: Research Integrity Assessment Tool may be used to determine if a matter may constitute a breach of the Code. It includes a non-onerous process which indicates:
    - where to lodge a complaint;
    - how written and verbal complaints are managed and documented;
    - the limitations of submitting anonymous complaints and/or complaints lodged by a third party; and
    - what information should be provided, and in what form, to enable a preliminary assessment.
- The complainant is encouraged to:
    - provide all information they hold pertinent to the complaint;
    - refer to the PICF for the relevant research project and contact one of the persons identified in the PICF in respect to complaints management; and/or
    - make a complaint to an external body however noting that in most circumstances complaints should be directed to the person identified in the PICF and/or Metro South Research.
- The complainant is not required to identify parts of the Code or relevant processes that may have been breached. MSH representatives may assist the complainant to lodge a complaint (e.g., MSH RIA). Where a complainant chooses not to proceed with a complaint, MSH still has an obligation to assess the nature of the complaint and whether to proceed to a preliminary assessment.

1.2 Consideration of complaints or allegations

- The person with knowledge of, or in receipt of the allegation, may discuss the matter with a MSH RIA or Metro South Research representative in the first instance, to determine:
    - if the matter involves MSH employee/s or participant/s;
    - if the matter pertains to the conduct of research; and/or
    - if it is appropriate to escalate the matter for consideration by the Manager, Research Integrity and Compliance, Metro South Research.
- If it is determined that the matter does not represent a potential breach of the Code, then it may be dismissed or referred to other relevant MSH processes or bodies or to a partner institution.
    - For example: the matter involves researchers employed by a University and is referred to the University’s Research Integrity office.
- If escalated, the Manager, Research Integrity and Compliance, Metro South Research may consider the information provided and/or gather additional information to:
    - Determine if the matter does not represent a potential breach of the Code; in which case it may be dismissed or referred to other relevant MSH processes or bodies.

- Determine if the matter should proceed for further review (i.e., preliminary assessment and/or further assessment).
    - For more serious breaches, determine the severity of a breach, and ensure that the matter is escalated to an appropriate Designated Officer (DO).
    - Note: The type of breach may influence the determination of the appropriate DO for escalation, for example:
        - For potential minor breaches, matters may be escalated to the Executive Director or Director, Metro South Research.
        - For potential serious breaches, matters may be escalated to the Executive Director, Human Resources (HR) or delegate.
            - Delegates are responsible for reporting the matter via RiskMan if the complaint is received from a consumer. Please refer to MSH procedure PR2021-251 Consumer feedback (complaints and compliments) management for more information.
        - Suspected corrupt conduct matters must be referred to the Director, Ethical Standards Unit (ESU) and will be managed in accordance with PR2023-364 Reporting and managing corrupt conduct procedure.
    - Note: the person who resolves the matter must ensure a record of the resolution is retained within research project files to be reviewed as part of the monitoring process.

2. STEP 2: ASSESSMENT

2.1 Preliminary assessment

- If there appears to be a breach of the Code, the DO, may direct an appropriate Assessment Officer (AO) to undertake a preliminary assessment in accordance with the Guide. The AO may:
    - consult with the DO, RIA, others in MSH and external experts (where necessary);
    - liaise with the complainant, respondent and other relevant parties (as appropriate);
    - secure evidence of a potential breach of the Code and manage records; and/or
    - provide a preliminary assessment report to the DO.
- The preliminary assessment is critical and should be handled with due care and attention. It serves as a filter to allow identification of matters that require further investigation and those that can be appropriately handled through other MSH processes.
- Appropriate communication with the complainant and respondent must occur throughout the assessment or management of a complaint, the welfare of the complainant and respondent is a key concern for MSH and support must be offered where available/if suitable.
- Following receipt of advice from the AO, the DO will determine:

- If there is evidence of a potential breach of the Code; the matter is referred for further assessment.
- If no further action is required by the RIO, RIA or AO (i.e., no evidence of a breach of the Code).
- If the matter may be resolved quickly and informally; if the potential breach of the Code is considered minor in accordance with the Guide.

- The next steps are based on responses, evidence and complexity:
  - the respondent is informed of the outcome of the preliminary assessment (if appropriate);
  - the complaint/allegation is resolved locally and/or corrective actions are implemented;
  - the matter is referred to other MSH processes (i.e., PRIME, the MSH ESU for corrupt conduct matters etc);
  - the complaint/allegation is dismissed; and/or
  - the complaint/allegation is referred for research conduct investigation.

2.2 Further assessment

- Following the preliminary assessment, the DO will decide whether a complaint is referred to an appropriate delegate for consideration as to what action should be taken (which may include management action, or the commencement of a research conduct investigation or discipline process).
- If the complaint or allegation is referred for research conduct investigation the matter will be managed in accordance with MSH ESU and HR processes where relevant, and with the Guide.
- The DO will ensure relevant input from Metro South Research in the development of a research conduct investigation report and in preparing documentation to enable an appropriate REO to make a determination.
- The possible outcomes from the assessment or research conduct investigation stage are described in the Guide.

3. STEP 3: BREACHES OF THE CODE

3.1 Breach

Following assessment, a complaint or allegation:

- The REO, or appropriate delegate as outlined with in the MSH HR Delegations, will determine whether a breach has occurred and decides on the extent of the breach.
- The REO or delegate decides on the appropriate course of action, which may include:
  - corrective action/s
    - attendance for research-related education and training
    - correcting the public record
    - retracting a publication

        - transfer or termination of grant funds.
    - notification to relevant human research ethics committee/s and research office/s, to recommend review or revoke of ethical clearance, Site Specific Assessment (SSA) authorisation and/or research funding.
    - referral to HR for consideration of disciplinary action under employment agreements and/or other MSH processes; and/or
    - systemic issues addressed and further education provided (where required).
- The REO in consultation with the DO, will ensure relevant input from Metro South Research in determining an appropriate course of action and development of corrective actions which takes into consideration the Code and Guide.
- The DO, in consultation with Metro South Research may also be required to report relevant matters to the NHMRC, within two weeks of the outcomes of a preliminary assessment, in accordance with the below policies (if required):
    - NHMRC policy on misconduct related to NHMRC funding (2016)
    - NHMRC research integrity and misconduct policy (2019).

4. STEP 4: RESEARCH MISCONDUCT

4.1 Research misconduct

- Following assessment, a complaint or allegation that involves a serious breach (including repeated or persistent breaches) may be determined to be research misconduct, as defined and described in the Guide.
- The REO or delegate will make the determination of research misconduct, in consideration of all relevant information.
- The REO or delegate will decide on the course of action, which may include corrective actions, disciplinary actions, or referral to other institutional and external processes in accordance with relevant policies, procedures and legislation.

4.2 Corrupt conduct

- Matters which constitute research misconduct may also constitute suspected corrupt conduct and will be managed in accordance with MSH procedure PR2023-364 Reporting and managing corrupt conduct.
- If it is determined that the complaint or allegation pertains to fraud or other corrupt conduct or criminal behaviour, that relates to NHMRC or Medical Research Future Fund (MRFF) funding, the NHMRC must be notified within one week of a determination.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Executive Management Team	• Promote a culture that fosters and values responsible conduct of research and implements systems for the management of concerns, complaints or allegations about potential breaches of the Code related to research for which MSH is responsible. • Ensure those involved in the management and investigation of potential breaches of the Code have the requisite skills and expertise and are appropriately resourced.	N/A
Executive Director, Metro South Research	• Ensure accountability mechanisms for implementing the Code, including responsibilities to funding agencies, considers additional considerations for; collaborative research and special circumstances, such as corrupt conduct and/or criminal behaviour or safety issues, that may arise at any stage of the management of investigation of a potential breach of the Code and trigger more immediate action.	N/A
Manager, Research Integrity and Compliance	• Ensure concerns, complaints and investigations of potential breaches of the Code related to research are appropriately managed by relevant MSH bodies (e.g., Human Resources and/or Ethical Standards Unit). • Develop, disseminate, implement and review MSH processes that promote adherence to the Code and regularly review the effectiveness the process. • Implement processes that enable complainants to lodge complaints formally in the knowledge that these will be addressed sensitively and with care, to avoid adverse consequences for the individual.	N/A

Director, Ethical Standards Unit (ESU)	• Review information to determine if the matter raises a reasonable suspicion of corrupt conduct under section 15 of the *Crime and Corruption Act 2001* (Qld). • If the matter raises a reasonable suspicion of corrupt conduct, attend to any legislative requirements regarding notification to the Crime and Corruption Commission, as required under the Directions issued to Metro South Health by the Crime and Corruption Commission. • Facilitate an appropriate delegate's consideration of a corrupt conduct matter to determine how it will be dealt with.	N/A
Human Resources	• Assist in the management of any HR matters which may not constitute corrupt conduct but are still considered a breach of the Code.	N/A
Principal Investigator (PI)/ Coordinating Principal Investigator (CPI) - responsible officer	• Comply with MSH policies and procedures including referral of the issues in accordance with this procedure when required. Failure to address issues properly may represent research misconduct and may be grounds for disciplinary action.	N/A
Employees, researchers, research student supervisors and students	• Ensure compliance with legislative, national guidelines and MSH policy and procedure requirements for participant contact, consent and confidentiality of participant information and conduct research that is consistent with professional privileges and training.	N/A

DEFINITIONS

Term	Definition
Allegation	Claim or assertion arising from a preliminary assessment that there are reasonable grounds to believe a breach of the Code has occurred. May refer to a single allegation or multiple allegations.

Breach	A failure to meet the principles and responsibilities of the Code. May refer to a single breach or multiple breaches.
Complainant	An individual who raises a concern about potential misconduct in research or who makes an allegation of research misconduct.
Confidentiality	Treatment of information so that it is not divulged in ways that are inconsistent with the understanding of the original disclosure. Particularly, the ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient/participant, unless the patient/participant gives consent permitting disclosure.
Conflict of Interest (COI)	A COI, including research and lobbyist activity, arises in any situation where personal, pecuniary (financial) or non-pecuniary interest has the potential to compromise or has the appearance of compromising professional judgement and influence decisions.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation** • *Crime and Corruption Act 2001* (Qld) • *Criminal Code Act 1899* (Qld) • *Defence Trade Controls Act 2012* (Cth) • *Gene Technology Act 2000* (Cth) • *Gene Technology (Queensland) Act 2016* (Qld) • *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)
- 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)

- National Statement on Ethical Conduct in Human Research (2023) ('National Statement')
- 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
    - Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018
    - Management of data and information in research
    - Peer review
    - Publication and dissemination of research
    - Research Integrity Advisors
    - Supervision

Therapeutic Goods Administration

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

Department of Health

- Public Service Code of Conduct
- QH-HSD-035:2023 Health Service Directive: Research Ethics and Governance Directive
- QH-POL-013:2022 Research Management Policy
- QH-IMP-013:1:2022 Research Management Standard
- General Retention and Disposal Schedule
- Health Sector (Clinical Records) Retention and Disposal Schedule
- Health Sector (Corporate Records) Retention and Disposal Schedule
- Information security policy [IS18:2018]

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	**Policies and procedures** • PL2014-38 Management of conflict of interest • PR2016-66 Management of conflict of interest - all staff • PR2021-251 Consumer feedback (complaints and compliments) management • PR2023-364 Reporting and managing corrupt conduct procedure • PR2023-411 Research excellence • 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 • WI2023-292 Assessing and managing risk in research **Guidelines** • GL2021-75 Partnering with consumers in research • GL2023-97 Aboriginal and Torres Strait Islander health research • GL2023-98 Research translation and impact **Attachments** • Attachment 1: Research Integrity Assessment Tool

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

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1.0	7/12/2023	14/12/2023	Executive Director, Metro South Research	• New document which supersedes PR2017-124 Research Complaints & Misconduct.
1.1	5/02/2025	20/02/2025	Executive Director Metro South Research	• Amendment to item 1.2 regarding delegates responsibility for reporting via Riskman • Addition of reference to PR2021-251 to item 1.2

APPENDICES

1. APPENDIX 1: SPECIFIC ROLES AND RESPONSIBILITIES UNDER THE GUIDE

The roles and responsibilities of those involved in the management and investigation of potential breaches of the Code, in accordance with the Guide, in MSH are outlined in Table 1 below. MSH has delegated the roles and functions for the investigation and management of potential breaches of the Code to appropriate persons within the Health Service:

Table 1: Roles and responsibilities in management and investigation of potential breaches	
Responsible Executive Officer (REO)	Chief Executive Officer, Metro South Health (or delegate) Chief People, Engagement and Research Officer (or delegate)
Research Integrity Office (RIO)	Metro South Research
Designated Office/r (DO)	MSH Executive Director, Human Resources (or delegate) Executive Director, Metro South Research Director, Research Development, Metro South Research Director, Ethical Standards Unit (for suspected corrupt conduct)
Research Integrity Advisor/s (RIA/s)	Manager, Research Integrity & Compliance, Metro South Research Representatives from MSH facilities and services, as determined from time-to-time.
Assessment Officer (AO)	Nominated by the DO or RIA
Review Officer (RO)	Nominated by the DO or RIA

Individuals involved in the investigation process must be appropriately indemnified.

Responsible Executive Officer (REO)

In MSH the REO has final responsibility for receiving reports of the; outcomes of processes of assessment or investigation of potential or found breaches of the Code. The REO also decides on the course of action to be taken.

Research Integrity Office (RIO)

The MSH RIO is the unit with responsibilities that include the management of responses to potential and found breaches of the Code in MSH. It is integral to the promotion of the responsible conduct of research under its auspices. Provision of, or access to, a MSH RIO function promotes the responsible conduct of research and its functions include:

- education and advice on responsible conduct of research to all staff, research students and RIAs
- supporting a network of RIAs – this may include other institutions RIAs (if required)
- developing and managing processes related to the responsible conduct of research

- receiving complaints/allegations about potential breaches of the Code
- supporting the conduct of preliminary assessments and investigations
- promoting a consistent and robust approach to managing and investigating potential breaches of the Code.

Designated Office/r (DO)

The MSH DO receives complaints and allegations about the conduct of research and/or potential breaches of the Code and oversees their management and investigation (where required).

Research Integrity Advisors (RIAs)

MSH RIAs promote the responsible conduct of research and provide advice to those with concerns about potential breaches of the Code. An RIA must have knowledge of the Code and relevant MSH processes.

The role of the RIA includes informing someone (ie member of the community or a participant), with concerns about research conduct, about relevant MSH processes and available options, including how to make a complaint. Outcomes of the discussion between the RIA and the complainant may include:

- not proceeding if the complaint is clearly not related to a breach of the Code
- proceeding under other MSH processes
- making a complaint about a potential breach of the Code in writing to the DO.

In MSH, RIAs are people with research experience, analytical skills, empathy, good communication skills, knowledge of MSH's processes and the Code, and familiarity with accepted practices in research. The MSH RIA may liaise with external institution's RIAs to discuss matters which may arise because of collaborative research.

An RIA is not to advise on matters where they have a potential, perceived or actual conflict of interest. The RIA's role does not extend to investigation or assessment of the complaint, including contacting the person who is the subject of that complaint or being involved in any subsequent investigation other than as witness or to provide testimony, unless appointed by the DO as an AO.

Assessment Officer (AO)

An AO is a person or persons appointed by the DO to conduct a preliminary assessment of a complaint about research, for example:

- HR consultant
- RIA
- MSHREC Coordinator — ethical and scientific matters
- Metro South Research Governance Officer (MSRGO) — Site Specific Assessment (SSA) and contract matters

- Research Grants Administrator, Research Support Coordinator or funding body — funding or MSH Research Support Scheme (RSS) matters.

Review Officer (RO)

A RO is a senior officer with responsibility for receiving requests for a procedural review of an investigation of a breach of the Code as appointed by the DO.