

PROCEDURE

Research Management - Research Complaints and Misconduct

PR2017/124
Version No. 2.0

PURPOSE

To promote the responsible conduct of research, the Metro South Health Research Management Compliance Framework establishes key principles which promotes awareness and encourages responsible conduct by researchers. This procedure sets out the roles and responsibilities of the Metro South Hospital and Health Service ('Metro South Health') in handling 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 Metro South Health.

OUTCOME

Adherence to this procedure will ensure all research conducted within Metro South Health or in collaboration with external entities and institutions, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This procedure applies to:

- all Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants
- all personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this procedure may amount to research misconduct on the part of the responsible individual. This procedure must be read in conjunction with other Metro South Health Research Management procedures.

KEY PRINCIPLES

The following key principles guide Metro South Health in managing research complaints and research misconduct matters.

- Metro South Health employees involved in research must be aware of and abide by the [Australian Code for the Responsible Conduct of Research 2018](#) ('the Code'). The Code articulates the broad principles that characterise an honest, ethical and conscientious research culture. It establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.
- In support of the Code, a [Guide to Managing and Investigating Potential Breaches of the Code 2018](#) ('the Guide') assists Metro South Health in the management, investigation and resolution of complaints about potential breaches of the Code.

- Metro South Health mandates compliance with the Code and is committed to ensuring a system is in place to promote appropriate conduct; see also [Research Integrity Procedure \(2018/176\)](#), discourage all breaches and appropriately manage identified serious breaches of the Code (ie research misconduct) or unethical behaviour in its research activities. All allegations of research misconduct will be investigated, and, where necessary, managed in accordance with this procedure, whilst ensuring procedural fairness. Investigations must also result in findings of fact to determine whether a breach of the Code has occurred.
- All researchers must be appropriately trained in relevant research policies and procedures and Metro South Health's expectations for ethical and responsible behaviour.
- All concerns raised regarding failures to comply with regulations, potential research misconduct or allegations of research misconduct, must be made in good faith. Concerns will be investigated in an impartial, timely, fair and transparent manner while maintaining confidentiality.
- Consistent with relevant laws, rules, regulations, and practices Metro South Health is committed to the protection of the privacy and/or confidentiality of respondents, complainants and patients/participants identifiable from research records or evidence.
- Concerns and complaints assist Metro South Health and its Human Research Ethics Committee (HREC) to undertake continuous improvement of its research activities and processes, particularly in relation to the ethical conduct of research, research governance and research management.
- All persons involved in research, whether patients, research participants, employees, researchers or Principal Investigators, have a right to report or make complaints and/or raise concerns/allegations in relation to research-related matters directly or through a representative. Complaints and/or allegations may be made to Metro South Health about researchers, the conduct of research or about the conduct of a research-related committee or other review body and may be made by patients, research participants, researchers, staff or other interested persons or bodies.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Crime and Corruption Act 2001 (Qld)*
- *Criminal Code Act 1899 (Qld)*
- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology (QLD) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Industrial Relations Act 1999 (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 Ethics Act 1994 (Qld)*
- *Public Service Act 2008 (Qld)*
- *Right to Information Act 2009 (Qld)*
- *Statutory Bodies Financial Management Act 1982 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*

Regulations and standards

- Gene Technology Regulations 2001 (Cth)
- Hospital and Health Boards Regulation 2012 (Qld)

- Information Privacy Regulation 2009 (Qld)
- Public Health Regulation 2005 (Qld)
- Public Service Regulation 2008 (Qld)
- Right to Information Regulation 2009 (Qld)
- Statutory Bodies Financial Arrangements Regulation 2007 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)

Statements, papers and guidelines

- [Australian Privacy Principles](#)
- National Health and Medical Research Council (NHMRC):
 - [National Statement on Ethical Conduct in Human Research 2007 – Updated 2018](#)
 - [Australian Code for the Responsible Conduct of Research 2018](#)
 - [Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research 2018](#)
 - [Australian Code for the Care and Use of Animals for Scientific Purposes 2013](#)
 - [Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008](#)
- Queensland Government:
 - [Code of Conduct for the Queensland Public Service](#)
 - [Chief Information Office: Information access and use policy \(IS33\)](#)
- [Singapore Statement on Research Integrity](#)
- Therapeutic Goods Administration:
 - [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)
 - [The Australian Clinical Trial Handbook](#)
- [World Medical Association Declaration of Helsinki](#)

Metro South Health policies, procedures, manuals and frameworks

- [Research Integrity Procedure \(PR2018/176\)](#)
- [Research Data Integrity and Information \(PR2017/125\)](#)
- [Risk Management Policy \(PL2018/62\)](#)
- [Risk Management Procedure \(PR2018/97\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Finance Management Practice Manual \(FMPM\)](#)
- [Discipline Action Procedure \(WS.H.PR.1.0\)](#)
- [Management of Conflict of Interest Policy \(PL2014/38\)](#)
- [Management of Conflict of Interest - All Staff Procedure \(PR2016/66\)](#)
- [WHS Risk Management Procedure \(WS.M.PR.1.0\)](#)
- [Workplace Conduct - Ethics, Integrity and Accountability Procedure \(WS.E.PR.1.0\)](#)
- [Reporting Corrupt Conduct Procedure \(WS.E.PR.1.1\)](#)
- [Public Interest Disclosure \(PID\) Procedure \(WS.E.PR.1.2\)](#)
- [Employee Complaints Procedure \(WS.E.PR.1.3\)](#)
- [Suspension With or Without Salary Procedure \(WS.H.PR.1.1\)](#)
- [Engagement of External Legal Advice Procedure \(WS.H.PR.1.3\)](#)

RESPONSIBILITIES

Executive Management

- Ensure those involved in the management and investigation of potential breaches of the Code have the requisite skills and expertise and are appropriately resourced.
- Promote a culture that fosters and values responsible conduct of research, as outlined in the [Research Integrity Procedure \(PR2018/176\)](#) and implement systems for the management of concerns, complaints or allegations about potential breaches of the Code related to research for which Metro South Health is responsible.
- 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.

Centres for Health Research

- Manage concerns or complaints and investigate potential breaches of the Code related to research for which they are responsible.
- Develop, disseminate, implement and review Metro South Health processes that promote adherence to the Code and regularly review the effectiveness the process.
- Demonstrate 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.
- Determine the appropriate composition of any investigation Panel, conduct investigations as appropriate and advise other entities and institutions of the outcome of a preliminary assessment or investigation (where appropriate).
- Address any systemic issues relating to matters of research integrity and implement corrective actions.

Principal Investigators, delegates, supervisors and research student supervisors

- Comply with Metro South Health 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.

Employees, researchers and students

- Ensure that their research conduct and research practice reflects the principles and responsibilities as set out in the Code as well as professional (ethical and legal) standards. Ensure compliance with legislative, national guidelines and Metro South Health policy and procedure requirements for participant contact, consent and confidentiality of participant information and conduct research that is consistent with professional privileges and training.

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 Metro South Health are outlined below. Metro South Health has delegated the roles and functions for the investigation and management of potential breaches of the Code to appropriate persons within the Health Service:

Responsible Executive Officer (REO)	• Executive Director, PAH-EQII Network
Research Integrity Office (RIO)	• Centres for Health Research, Metro South Health
Designated Officer (DO)	• Director, Research Development, Centres for Health Research
Research Integrity Advisor/s (RIA/s)	• Manager, Research Compliance, Centres for Health Research • Representatives from Metro South Health 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 Metro South Health 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 Metro South Health RIO is the unit with responsibilities that include the management of responses to potential and found breaches of the Code in Metro South Health. It is integral to the promotion of the responsible conduct of research under its auspices. Provision of, or access to, an 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 Officer (DO)

The Metro South Health 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)

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

The role of the RIA includes informing someone (ie member of the community or a participant), with concerns about research conduct, about relevant Metro South Health 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 Metro South Health processes
- making a complaint about a potential breach of the Code in writing to the DO.

In Metro South Health, RIAs are people with research experience, analytical skills, empathy, good communication skills, knowledge of Metro South Health's processes and the Code, and familiarity with accepted practices in research. The Metro South Health 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:

- RIA
- Metro South Health HREC Coordinator — ethical and scientific matters
- Research Governance Officer — Site Specific Assessment and contract matters
- Research Grants Administrator or funding body — funding or Metro South Health Research Support Scheme 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.

SUPPORTING DOCUMENTS

Attachment 1 - [Application](#)

Attachment 2 - [Flowchart - Management and investigation of a potential breach of the Code](#)

Attachment 3 - [Research Integrity Assessment Tool](#)

Attachment 4 - [Investigation Panel Checklist](#)

Attachment 5 - [Panel Terms of Reference Template](#)

Attachment 6 - [Reporting the Findings of the Investigation Checklist](#)

DEFINITIONS

See the [Metro South Health Research Management Glossary](#)

PROCEDURE - RESEARCH COMPLAINTS AND MISCONDUCT

STEP 1: Participant Information and Consent Form (PICF)

Researchers are responsible for including relevant contact details for the for the research project in the Participant Information and Consent Form (PICF). All PICFs for research projects being conducted in Metro South Health must include the following paragraph:

'If you have any complaints about any aspect of the research project, the way it is being conducted or any questions about being a research participant in general, you may contact the:

Metro South Health Human Research Ethics (HREC) Office

Metro South Health Research Governance Office

Metro South Health Research Integrity Officer

<https://metrosouth.health.qld.gov.au/research/contact-us>'

Participants may utilise the listed contact details on a PICF to submit a complaint either verbally (in person or by telephone), or in writing to the research project team and/or the reviewing HREC. Alternatively, complainants can lodge a concern, allegation or complaint with the Metro South Health:

- RIA/s or DO
- HREC Chair or Coordinator
- Staff Integrity and Investigations
- Workforce Services
- department/division contact
- relevant delegate.

Complainants are encouraged to review [Attachment 3 - Research Integrity Assessment Tool](#) before lodging a complaint

STEP 2: 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, for example the research project contact person listed on the PICF — Principal Investigator, researcher and/or research student supervisor, HREC Coordinator or RIA, may perform initial inquiries and attempt to informally resolve the complaint if there does not appear to be a breach of the Code.

If the complaint can be resolved quickly and informally the Principal Investigator must ensure a record of the resolution is retained within research project files as this will be reviewed as part of the on-site monitoring process. Please see [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information.

If there does appear to be a breach of the Code, the person in receipt of the complaint and/or allegation must consult and/or refer the matter to the DO who:

- determines if the matter involves Metro South Health employee/s or participant/s
- decides if the matter pertains to the conduct of research
- determines whether the complaint relates to a potential breach of the Code and, if it does, if the matter proceeds to preliminary assessment
- ensures appropriate communication with the complainant and respondent occurs throughout the initial enquiries or management of a complaint — the welfare of the complainant and respondent is a key concern for Metro South Health and support must be offered where available/if suitable.

If the DO determines that the complaint does not represent a potential breach of the Code, then it may be dismissed or referred to other relevant Metro South Health processes.

If the DO determines 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.

STEP 3: Preliminary assessment

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 Metro South Health processes. As part of the preliminary assessment, the DO may assign a suitably qualified AO who may:

- conduct a preliminary assessment (overseen by the DO if required)
- consult with the DO, RIA, others in Metro South Health 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
- provide a report to DO.

If there is no evidence of a potential breach of the Code and/or if the matter is referred, no further action is required by the RIO, DO, RIA or AO. If the matter pertains to the conduct of research the complaint/allegation must be recorded on the Centres for Health Research Compliance Register.

STEP 5: Outcome

Following and/or during the preliminary assessment, the DO will decide whether a complaint is referred for an investigation, resolved without need for investigation, referred to other Metro South Health processes (including local resolution), or dismissed.

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 Metro South Health processes (ie PRIME, corrupt conduct etc)
- the complaint/allegation is dismissed
- the complaint/allegation is referred for investigation by a Panel.

If it is determined that the matter requires further investigation, approval to convene a Panel must be sought from the Metro South Health Chief Executive Officer or relevant delegate.

The DO must also 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).

STEP 4: Investigation and establishing an appropriate Panel

If the complaint or allegation is referred for investigation the DO must:

- prepare statement of allegation
- establish Terms of Reference

- nominate Panel members (including a Chair)
- notify the respondent and/or other involved parties.

The nature of the investigation may vary depending on complexity of the complaint/allegation. The DO will notify all who are required to attend or participate in the investigation, in particular the respondent (if required), and will:

- provide Panel with all relevant documentation
- ensure the Panel works within Metro South Health's processes and the Guide
- schedule meetings and/or hearings, and record interviews if necessary
- provide relevant written information to the respondent and relevant others
- assist the Panel when required.

The Panel will complete an investigation into a potential breach of the Code, produce a report on the findings of facts and make recommendations (is appropriate) to the REO and/or delegate in writing. The REO determines whether a breach of the Code has occurred, decide on the extent of a breach and a course of action, which may include corrective actions and/or referral to other Metro South Health processes.

STEP 5: Inform the respondent

Following consideration by the REO, the respondent will be informed and notified in writing of the outcome of the Panel and will be provided with appeal options (if required). The respondent will also be notified if the matter will be referred to other Metro South Health processes.

Note: Whilst a matter may not constitute a breach of the Code it may still require assessment and review through other Metro South Health processes (ie PRIME, disciplinary, corrupt conduct, AHPRA etc).

STEP 6: Outcome

Once a determination and recommendation of actions has been made the following may occur:

- notification to the Metro South Health HREC Coordinator, Research Governance Officer or Research Grants Administrator/funding body to review or revoke; ethical clearance, research governance authorisation and/or research funding
- corrective action/s made (for example correcting the public record or retracting a publication)
- referral to Workforce Services for consideration of disciplinary action under employment agreements and/or other Metro South Health processes
- systemic issues addressed and further education provided (where required).

PROCEDURE DETAILS

Procedure Number

PR2017/124

Procedure Name

Metro South Health Research Management -
Research Complaints and Misconduct
Procedure

Policy Reference

PL2017/55

Metro South Health Research Management
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ATTACHMENT 1 - APPLICATION

1.0 Breaches of the Code

Metro South Health is committed to adhering to all principles and practices outlined in the Code. The [Research Integrity Procedure \(2018/176\)](#) outlines the expectations and process for the conduct of research in Metro South Health or research conducted under the auspices of Metro South Health facilities/services. Complaints and/or allegations about breaches of the Code will be addressed under the provisions of the Code and this procedure.

The Guide outlines the preferred model for institutions to use 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. The Australian Research Integrity Committee will use the Guide as a benchmark for reviewing how an institution funded by National Health and Medical Research Council (NHMRC) or Australian Research Council (ARC) has managed a potential breach of the Code.

Metro South Health has; implemented accountability mechanisms and processes to uphold principles outlined within the Code and the Guide and established a model for managing and investigating potential breaches of the Code which:

- considers Metro South Health workplace policies, procedures and agreements, other external institutional processes and the law
- ensures that the processes used to manage and investigate potential breaches of the Code are procedurally fair and do not hinder the timely implementation of all corrective actions
- considers NHMRC and ARC expectations regarding institutions in receipt of public research funds
- operates separately from and prior to other Metro South Health processes (when appropriate), as breaches of the Code are likely to be distinct from other forms of misconduct/corrupt conduct in the workplace, such as sexual harassment, bullying and discrimination
- considers workplace, disciplinary and student agreements which may prevail
- ensures that disciplinary issues, which are outside the scope of this procedure, are managed by Workforce Services
- ensures that clinical incidents, which are outside the scope of this procedure, are managed in accordance with clinical ethics and incident reporting requirements.

1.1 Definition of breach

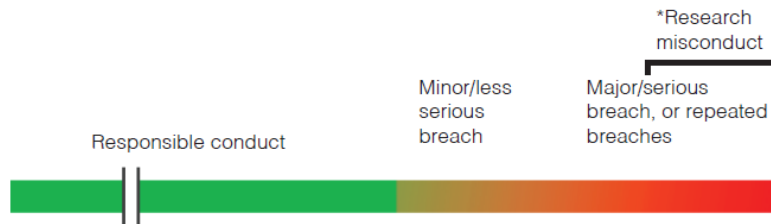
A breach is defined as a failure to meet the principles and responsibilities of the Code, and may refer to a single breach or multiple breaches. Examples of breaches of the Code include, but are not limited to:

- not meeting required research standards
- fabrication, falsification, misrepresentation
- plagiarism
- research data management
- supervision
- authorship
- conflicts of interest
- peer review.

Please see the [Guide \(Section 2.1\)](#) for more information regarding the above examples.

1.2 Breaches occur on a spectrum

Breaches of the Code occur on a spectrum, from minor (less serious) to major (more serious).



Major breaches would typically require investigation while some minor breaches may be addressed at the preliminary assessment stage. There are also some matters that relate to research administration that can easily be rectified at the local level and resolved prior to the need to consider a preliminary assessment. Unintentional administrative errors, clerical errors or oversights are some examples of this. Repeated or persistent breaches will likely constitute a serious breach.

1.3 Determining the seriousness of a breach

Once a breach has been found, the seriousness of a breach should be determined. This will require deliberation and an exercise of judgement. In considering the seriousness of a breach of the Code, the factors to be considered (without excluding other factors) are:

- the extent of the departure from accepted practice
- the extent to which research participants, the wider community, animals and the environment are, or may have been, affected by the breach
- the extent to which it affects the trustworthiness of research
- the level of experience of the researcher
- whether there are repeated breaches by the researcher
- whether other Metro South Health institutional failures have contributed to the breach
- any other mitigating or aggravating circumstances.

1.4 Research misconduct

Research misconduct is a serious breach of the Code which is also intentional or reckless or negligent. Metro South Health acknowledges that the egregious nature of some serious (major) breaches may constitute 'research misconduct' which, in-turn, must be considered in the context of other Metro South Health processes (ie disciplinary).

Regardless of whether a Code investigation is completed separately to, or integrated with, a clinical incident or disciplinary process, Metro South Health must ensure that these do not conflict, or hinder the timely implementation of all corrective actions. The use of the term 'research misconduct', or any processes triggered by its use, must not prohibit any corrective actions, such as amendments to the public record or assurance of participant safety.

Consideration of the type of behaviour may be used to infer whether the breach is intentional or reckless or negligent. Fabrication and falsification are types of breaches that are commonly recognised as being undertaken intentionally or recklessly and are examples of research misconduct.

Research misconduct does not include honest differences in judgement. Unintentional errors do not usually constitute research misconduct unless they result from behaviour that is reckless or negligent. Repeated or persistent breaches will likely constitute a serious breach, which will trigger consideration of research misconduct. It also includes avoidable failure to follow research protocols as approved by a HREC, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment and the wilful concealment or facilitation of research misconduct by others.

1.5 Principles of procedural fairness

The principles of procedural fairness (also referred to as natural justice) apply to managing and investigating potential breaches of the Code. These principles encapsulate the hearing rule (an opportunity to be heard), the rule against bias (decision-makers do not have a personal interest in the outcome) and the evidence rule (decisions are based on evidence). Metro South Health's process for managing and investigating potential breaches of the Code must be:

- Proportional — Investigations and subsequent actions must be proportional to the extent of the potential breach of the Code.
- Fair — Investigations must afford procedural fairness to respondents and, where appropriate, complainants and others who may be adversely affected by any investigation.
- Impartial — Investigators and decision-makers must be impartial and declare any interests that do, may, or may be perceived to jeopardise their impartiality. These interests are to be appropriately managed.
- Timely — Investigations into potential breaches must be conducted in a timely manner to avoid undue delays and to mitigate the impact on those involved.
- Transparent — Information about Metro South Health processes are readily available and/or provided to respondents, complainants, all employees and students engaged in research. Metro South Health must also ensure accurate records are maintained for all parts of the process, with records held centrally and in accordance with the relevant legislation.
- Confidential — Information will be treated as confidential and not disclosed unless required.

1.6 Other Metro South Health processes

Throughout this procedure 'other Metro South Health processes' is mentioned and refers to processes including but not limited to: PRIME/clinical incidents, AHPRA notification, disciplinary and/or corrupt conduct.

If it is determined that the matter; does not involve a Metro South Health employee or participant; is unrelated to the conduct of research and/or is not a potential breach of the Code (with supporting evidence), it may be referred to:

- [Metro South Health RiskMan](#)
- hospital Patient Safety and Quality Unit
- Metro South Health Workforce Services
- Metro South Health Staff Integrity and Investigations
- hospital Patient Liaison Officer (PLO)
- delegate/line manager
- University or external institution's RIO.

2.0 Consideration and management of complaints and allegations

A complaint or allegation about a potential breach of the Code occurs when a concern is raised or identified that one or more researchers have conducted research that is not in accordance with the principles and responsibilities of the Code.

Well-defined processes for receiving and managing concerns, allegations and complaints (hereafter only referred to as complaints) and communicating with the complainant are essential. These processes are readily accessible on Metro South Health's Research [website](#) and the key considerations for these processes are described below.

Complaints may be dismissed at any stage for a variety of reasons, including if the complaint appears to have been made in bad faith or is vexatious. Alternatively, a complaint may trigger other processes or require immediate action if corrupt or criminal behaviour is potentially involved (refer to [Section 6.1](#)) or if it relates to an activity that could harm humans, animals or the environment (refer to [Section 6.2](#)).

It is important to document all decisions and reasons for those decisions. These decisions include, but are not limited to, whether to proceed to a preliminary assessment, whether to investigate a complaint or whether to cease investigating a complaint. Records and documentation must be retained in accordance with Metro South Health processes.

2.1 Initial receipt of complaints

Complaints may arise from a range of sources, including from Metro South Health. Metro South Health processes for submitting, receiving and documenting a complaint about a potential breach of the Code is outlined [here](#). The [Research Integrity Assessment Tool](#) (Attachment 3) 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
- 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 the one of the persons identified in the PICF in respect to complaints management or the Metro South Health RIO
- 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 the Metro South Health RIO.

The complainant is not required to identify parts of the Code or relevant processes that may have been breached.

Metro South Health representatives may assist the complainant to lodge a complaint. Where a complainant chooses not to proceed with a complaint, Metro South Health still has an obligation to assess the nature of the complaint and whether to proceed to a preliminary assessment.

2.2 Managing complaints about potential breaches of the Code

After the complaint is received, the DO determines whether the complaint relates to a potential breach of the Code and, if it does, the matter proceeds to preliminary assessment. While anonymous complaints may make subsequent processes more challenging, they may nonetheless identify potential breaches of the Code and therefore should still be considered, based on the information provided. To avoid compromising the preliminary assessment, anyone involved in managing a complaint should not share information unless required.

2.3 Protections available to the complainant

Depending on the nature of the complaint, relevant legislation may protect the complainant, for example, 'whistle-blower' or 'public interest disclosure' legislation. Ultimately, in its handling of any assessment or investigation, Metro South Health is responsible for ensuring the complainant is protected from adverse consequences for having made the complaint.

Metro South Health also has a responsibility to appropriately manage matters where a power imbalance exists, such as complaints brought by students and/or staff in more junior positions. Reprisal and threatening behaviour is not tolerated. Metro South Health processes reflect this and parties must be advised that any reprisals will trigger other Metro South Health processes (ie disciplinary).

2.4 Engagement with complainants

It is important to engage effectively with complainants as this can reveal additional information relevant to the matter and provides complainants with confidence that their complaint is being/has been considered appropriately. Consideration should be given to the extent to which a complainant may be affected by an outcome of a Code investigation and whether a complainant has direct interests at stake. This will help determine the appropriate level of involvement of, and communication with, a complainant throughout the preliminary assessment and investigation.

Complainants who may be directly affected by the outcome of a Code investigation (for example, someone who is involved in a dispute with the respondent) should be provided with as much detail as possible to provide assurance that their complaint is being/has been considered appropriately.

In contrast, for complainants who have only a general concern in the matter, it may be sufficient to provide minimal details to convey the outcome. These complainants will generally not have direct interests at stake and will not be directly affected by the outcome (for example, someone conducting peer review on a paper).

3.0 Preliminary Assessment

The purpose of the preliminary assessment is to gather and evaluate facts and information, and assess whether the complaint, if proven, would constitute a breach of the Code. A structured approach and careful collection and recording of facts and information are essential to conducting a robust preliminary assessment able to withstand subsequent scrutiny.

3.1 Conducting a preliminary assessment

The time taken for the preliminary assessment will vary significantly depending on the complexity of the complaint. The DO assigns the complaint to a suitable AO who is responsible for the conduct of the preliminary assessment, ensures timeliness and consults with the DO, as required.

The AO should ensure records of the preliminary assessment are prepared and retained, and that appropriate processes are followed. Expertise may be required from other sources, such as researchers from the same or aligned disciplines, especially where the complaint relates to specific disciplinary practice (for example, authorship). During the preliminary assessment the AO identifies, collects, inventories and secures facts and information. To avoid compromising the preliminary assessment, information should not be shared unless required. The correct collecting and securing of facts and information at the preliminary assessment stage is important as it can have implications for the management and resolution of the complaint, particularly if the matter progresses to an investigation. The AO also considers whether an expert needs to be engaged to provide specific and/or independent advice about the collection and storage of facts and information.

It might be necessary to discuss the matter with the respondent during a preliminary assessment to clarify the facts and/or information. In this case, the AO notifies the respondent and provides:

- sufficient detail for the respondent to understand the nature of the complaint
- an opportunity to respond in writing within a nominated timeframe — this may include an invitation to meet, with the option to bring a support person.

A record of meetings should be prepared and the respondent provided with a copy. The AO should consider:

- consultation with other Metro South Health process key contacts (ie Workforce Services, Staff Integrity and Investigations, Hospital Patient Liaison Officer and/or delegate/line manager)
- the involvement of those in supervisory roles in the potential breach
- the need to involve other institutions in the matter.

3.2 Outcomes from the preliminary assessment

On completion of the preliminary assessment, the AO provides written advice to the DO in a timely manner which includes:

- a summary of the process that was undertaken
- an inventory of the facts and information that was gathered and analysed
- an evaluation of facts and information
- how the potential breach relates to the principles and responsibilities of the Code and/or other Metro South Health processes
- recommendations for further action.

The preliminary assessment advice will be considered by the DO who determines, based on the facts and information presented, whether the matter should be:

- dismissed
- resolved locally with or without corrective actions
- referred for investigation
- referred to other Metro South Health processes.

Where an evaluation of facts and information collected as part of a preliminary assessment does not support a referral of an allegation of a breach of the Code for investigation, the following actions should be considered:

- if the complaint has no basis in fact (for example, due to a misunderstanding or because the complaint is frivolous or vexatious), then efforts, if required, must be made to restore the reputation of any affected parties
- if a complaint is considered to have been made in bad faith or is vexatious, efforts to address this with the complainant should be taken under appropriate Metro South Health processes
- addressing any systemic issues that have been identified.

An admission by the respondent of a breach of the Code is not an end-point as it may still be necessary to investigate to identify appropriate corrective actions, any other parties that may be complicit or any other necessary steps. Where a respondent leaves Metro South Health following a complaint, Metro South Health has a continuing obligation to address the complaint. Metro South Health will provide the outcomes, if appropriate, to the respondent and complainant after the preliminary assessment in a timely manner.

4.0 Investigation stage

The purpose of the investigation is to make findings of fact to allow the REO to assess whether a breach of the Code has occurred, the extent of the breach and the recommended actions. This is done by examining the facts and information from the preliminary assessment, and gathering and examining further relevant evidence if required.

4.1 Preparing for the investigation

After the DO determines an investigation is required, the following steps should be taken:

- a clear statement of allegations is prepared
- the terms of reference for the investigation (Attachment 5 - [Panel Terms of Reference Template](#)) is developed
- nominate the Investigation Panel ('Panel') and Chair when the Panel is more than one person
- seek legal advice on matters of process where appropriate.

4.2 Composition of the Panel

A range of factors should be considered when determining the size and composition of the Panel including the potential consequences for those involved, the seniority of those involved and the need to maintain public confidence in research. These factors will affect the level of independence that is required of members from both Metro South Health, and the respondent and complainant. There will be occasions where some or all members should be external to Metro South Health. In selecting members for the Panel, the DO must also consider:

- the expertise and skills required:
 - selection of a person appropriately qualified as Chair
 - appropriate level of experience and expertise in the relevant discipline(s)

- the need for a person with prior experience of similar investigation panels or relevant experience
- knowledge and understanding of the responsible conduct of research
- appropriate number of members
- the need for members to be free from conflicts of interest or bias
- gender/diversity of members.

Once potential panel members have been selected, the DO will advise the respondent of the Panel's composition and provide an opportunity for the respondent to raise concerns. The RIO may assist the DO in deciding on the composition of the Panel and its final establishment.

4.3 Panel preparation

Once the Panel is established, it should be provided with all relevant information and documentation (Attachment 4 - [Investigation Panel Checklist](#)). It is expected that all Panel members are appointed in writing and external members are appropriately indemnified. Members of the Panel are expected to:

- work within Metro South Health's processes
- follow the procedure established for the Panel
- work within the terms of reference for the Panel
- respect any undertakings of confidentiality
- adhere to the principles of procedural fairness
- complete the investigation in a timely manner
- prepare a written report.

Appropriate resources are to be provided to the Panel including secretariat support (for example, RIO employees). The secretariat maintains the record of evidence.

4.4 Conduct of the investigation

The [principles of procedural fairness](#) must always be applied when undertaking the investigation. Investigations are to be thorough, robust and free from bias.

During the investigation, Panel members must ensure that relevant interests are disclosed and managed. If an interest cannot be managed (ie where a perceived or actual conflict of interest might be viewed as influencing the impartiality of the Panel, relevant Panel members must be recused).

All those required to attend the Panel should be given adequate notification.

Where the Panel is of the view that a party may be unable to represent themselves adequately due to the complexity of the matter, the Panel may need to take extra steps to ensure a fair investigation. This may include allowing extra time for parties to consider matters or encouraging a greater reliance on written evidence.

Where the process includes a support person, their role is to provide personal support, within reasonable limits, to the respondent and/or complainant. Their role is not to advocate, represent or speak on the other person's behalf. However, there may be times when a respondent and/or complainant requires a higher level of involvement from the support person and the Panel should consider this on a case-by-case basis.

The principles of procedural fairness do **not** include a right to legal representation, and the Panel should consider carefully whether to permit legal or specialist representation on request and on a case-by-case basis.

If the Panel allows a party or parties to have legal representation, the Panel should consider whether it also needs to be assisted with a similar level of representation. Legal representation may extend the timeframe of the investigation, increase the costs and overly formalise the investigation. Regardless of whether parties are legally represented, the investigation is not a court of law and cannot make legally binding findings.

As part of the investigation, the respondent should be provided with an opportunity to respond to the allegation and relevant evidence, and to provide additional evidence upon which the Panel may rely. If the respondent chooses not to respond or appear before the Panel where requested, the investigation continues in their absence. The complainant may also be given the opportunity to see relevant evidence used in the investigation (eg if they are directly affected by the investigation).

4.5 Initial Panel meeting

During its initial meeting, the Panel should:

- disclose and manage relevant interests
- be provided with all available information that will inform the investigation, which includes:
 - the initial complaint
 - all relevant information assembled by the AO
 - records of the conduct of the preliminary assessment
 - the report of the preliminary assessment
 - records of any communications on the matter involving the DO, the AO, the complainant and/or the respondent
- develop an investigation plan (described in Attachment 4 - [Investigation Panel Checklist](#)).

All those asked to give evidence are to be provided with relevant, and if necessary de-identified, information including:

- the schedule of meetings and/or hearings they are asked to attend
- the relevant parts of the terms of reference for the investigation, if appropriate
- advice as to how the Panel intends to conduct interviews
- whether they may be accompanied by a support person
- advice about whether the interviews will be recorded
- whether an opportunity will be provided to comment on matters raised in the interview
- disclosing interests
- the confidentiality requirements
- the Panel's procedures.

The Panel is to determine whether, having regard to evidence and on the balance of probabilities, the respondent has breached the Code. To do this, the Panel:

- assesses the evidence (including its veracity) and considers if more may be required
- may request expert advice to assist the investigation
- arrives at findings of fact about the allegation
- identifies whether the principles and responsibilities of the Code have been breached
- considers the seriousness of any breach
- provides a report into its findings of fact consistent with its terms of reference
- makes recommendations as appropriate.

If the Panel finds during the investigation that the scope and/or the terms of reference are too limiting, it should refer the matter to the DO. The DO may decide to amend the scope of the investigation and the terms of reference. Should this occur, the respondent and relevant others are to be advised, and the respondent given the opportunity to respond to any new material arising from the increased scope.

5.0 Outcomes from the investigation

On completion of the investigation, the Panel prepares a draft written report of the investigation. Given that the report will be relied on by the REO to make a decision about whether a breach of the Code has occurred, it is essential that the report is detailed, accurate and cogent, and fully addresses the terms of reference. It is expected that the institution provides secretariat support (for example, RIO) to assist in the preparation of the draft report.

The draft report should contain findings of fact and any recommendations (Attachment 6 - [Reporting the Findings of the Investigation Checklist](#)). The draft report, or a summary of all relevant information on which the DO's decision will be based, should be provided to the respondent with a reasonable timeframe to comment. The timeframe given should reflect the complexity of the matter. The draft report, or a summary of the information, may also need to be provided to the complainant if they will be affected by the outcome.

Following consideration of any further information, the report is finalised. The DO will consider the findings of fact, evidence presented and any recommendations made by the Panel. The DO will also consider the extent of the breach, the appropriate corrective actions and if referral to disciplinary procedures is required. The DO will provide the final report to the REO with recommendations. Where systemic issues are identified as a contributing factor, these need to be referred to Metro South Health to be addressed.

5.1 Finding of no breach of the Code

If the REO decides that there has been no breach, the following will need to be considered:

- if the allegation has no basis in fact then efforts must be taken to restore the reputations of those alleged to have engaged in improper conduct
- if an allegation is considered to have been frivolous or vexatious, action to address this with the complainant should be taken under appropriate Metro South Health processes
- the mechanism for communication with, and support for, the respondent and complainant.

5.2 Finding of a breach of the Code

Where the REO accepts that a breach of the Code has been found, the REO decides Metro South Health's response, considering the extent of the breach and whether other institutions should be advised. In the case of joint, adjunct and/or honorary appointments of the respondent, Metro South Health will follow its own processes relating to these appointments and should consider seeking legal or other expert advice in relation to the management of these appointments with other institutions. All efforts should be taken to correct the public record of the research, including publications if a breach of the Code has affected the accuracy or trustworthiness of research findings and their dissemination.

5.3 Dissenting views

The Panel is encouraged to come to a consensus. If there are dissenting view(s), there should be opportunity for the Panel member to provide this view for inclusion in the draft and final report. As the dissenting view forms part of the draft report, it must be provided to the respondent and in some circumstances the complainant, if they will be affected by the outcome.

5.4 Communicating the findings

When the REO has considered the Panel's report, any decisions or actions are to be [communicated](#) to the respondent and the complainant. Subsequent actions may include informing relevant parties (such as funding bodies, other relevant authorities or other institutions) of the outcome. The REO should consider whether a public statement is appropriate to communicate the outcome of an investigation. In cases where the respondent resigns, the institution still has an obligation to address the findings of the investigation. The matter may also need to be referred to the new employing institution. In this case, institutions should consider seeking legal advice to ensure that any information disclosure can be made and is done appropriately and lawfully.

5.5 Mechanisms for review of a Code investigation

Only requests for a review of a Code investigation, on the grounds of procedural fairness, should be considered. The aim of a review is to affirm or not the outcome of the investigation. Information regarding Metro South Health review processes will be provided following an investigation and will include:

- where requests for review should be directed and timeframes for lodgement
- how a decision to proceed with a review will be made (ie who will make that decision and on what basis, such as an RO)
- ways a review may be conducted (ie refer back to Panel or to a more senior officer than the DO)
- how the outcomes of the review will be communicated.

When communicating the outcome of the investigation, Metro South Health must inform the respondent, and possibly the complainant if they are directly affected by the outcome, of their right to request a review and how to lodge a request for review, including timeframes and the information required for a request to be considered. The Australian Research Integrity Committee (ARIC) can provide an external review of any investigative processes into potential breaches of the Code used by institutions that receive any funding from the NHMRC or the ARC. Institutions should inform the respondent and possibly the complainant of their right to request a review by ARIC.

Additional review or complaints options will vary across jurisdictions (such as via ombudsman, court or other authorities) and are outside the scope of this Guide.

6.0 Additional considerations

6.1 Corrupt conduct and/or criminal behaviour

Some matters may involve potentially corrupt conduct and/or potential criminal behaviour. These matters require referral to an appropriate agency, for example, a crime commission and/or the police. They may also trigger other Metro South Health responsibilities and processes.

Metro South Health must have processes that encourage early identification of these matters. Where an external agency chooses to investigate, Metro South Health must seek advice on whether internal processing of the complaint as a potential breach of the Code can continue and, if so, with what authority and parameters, if any.

Following completion of an external investigation, Metro South Health may need to consider if there are outstanding matters, relevant to the Code, to be addressed internally, and may decide to initiate further internal processing.

It is important to note that this Procedure only pertains to the conduct of research. Any other matters of misconduct must be referred to an appropriate area such as Metro South Health Workforce Services, Staff Integrity and Investigations, hospital Patient Liaison Officer (PLO) and/or delegate. The matter may also be referred to a University or external institution's Human Resource area.

Whilst the Code introduces additional processes that are to be applied when allegations involve the conduct of research, all Metro South Health employees (including Principal Investigators, researchers and research student supervisors) have an obligation to disclose corrupt conduct, including fraud, misconduct and maladministration as prescribed in the *Public Sector Ethics Act 1994 (Qld)* and the Code of Conduct for the Queensland Public Service ("Code of Conduct").

The processes in the Code are not for the investigation of other forms of misconduct, although sometimes the conduct of research and research misconduct may be associated with other forms of misconduct and/or corrupt conduct. Therefore, it is vital that all complaints which may result in an allegation of misconduct and/or corrupt conduct are handled by appropriate Metro South Health personnel and in conjunction with the following Workforce Services Procedures if/when required:

- [Workplace Conduct - Ethics, Integrity and Accountability Procedure \(WS.E.PR.1.0\)](#)
- [Reporting Corrupt Conduct Procedure \(WS.E.PR.1.1\)](#)
- [Public Interest Disclosure \(PID\) Procedure \(WS.E.PR.1.2\)](#)
- [Employee Complaints Procedure \(WS.E.PR.1.3\)](#)

The Research Integrity Advisor and Designated Officer will be able to advise if the matter it is to be referred for resolution. Where the research participant is a Metro South Health patient, the relevant hospital Patient Liaison Officer (PLO) will be notified of the complaint by the Research Integrity Advisor and/or Designated Person.

6.2 Safety issues

If at any time it becomes apparent that the complaint relates to an activity that could harm humans, animals or the environment, immediate action must be taken to minimise the risk of harm. This action is at the discretion of Metro South Health and is independent of the Code investigation. These matters may require referral or notification to an appropriate agency (eg regulatory agencies, WorkSafe, AHPRA). They may also trigger other Metro South Health responsibilities and processes.

6.3 Public Interest Disclosure (PID)

Nothing in this procedure prevents a person from making allegations under the [Public Interest Disclosure Act 2010](#) (Qld). The Director, Staff Integrity and Investigation is the responsible officer for receiving and acting on public interest disclosures in Metro South Health. Please see [Public Interest Disclosure \(PID\) Procedure \(WS.E.PR.1.2\)](#) for more information.

6.4 Misconduct unsatisfactory performance unrelated to research

If at any stage in the application of this procedures it is considered that misconduct or unsatisfactory performance may have occurred which is not related to research activities, the relevant allegations may be referred to an appropriate officer for management in accordance with relevant Metro South Health processes.

6.5 Participation in research misconduct processes

Metro South Health may issue reasonable and lawful directions to staff members in relation to their participation in any preliminary investigation, or research misconduct inquiry.

6.6 Restoration of Reputation

If allegations of research misconduct or breaches of the Code are shown to be unsubstantiated, Metro South Health will take reasonable steps to reinstate the reputation of the respondent where this may have been damaged.

6.7 External Obligations

When allegations are made, Metro South Health may have an obligation to make statutory reports to other external organisations about matters that arise.

6.8 Frivolous and Vexatious Complaints

Individuals are expected to make complaints in good faith and complaints must not be vexatious, frivolous, misconceived or completely without substance. This procedure is not to be used as a forum for revenge, retribution or mischief. Examples of frivolous, vexatious and bad faith complaints include (but are not limited to):

- fabricating a complaint to get another person into trouble
- making trivial or petty complaints
- making repeated, unsubstantiated complaints
- seeking to re-agitate issues that have already been addressed or determined.

At any stage where such behaviour is suspected, this matter maybe referred to Workforce Services who may make an assessment that the complaint is vexatious, frivolous, misconceived without substance or that an alternative Metro South Health process is applicable to the subject matter of the complaint and, therefore, the matter will not be progressed through these procedures. Persons making frivolous or vexatious complaints may be subject to disciplinary action.

6.9 Record Keeping

Records of allegations and related documents must be retained and stored appropriately, including recommendations and actions taken. The RIA is responsible for ensuring that records are stored within the Centres for Health Research.

6.10 Collaborative research

Research is increasingly an inter-disciplinary, multi-institutional and a multi-national endeavour. This involves all aspects of research, including the initial collaboration, peer review, data management and dissemination of research output. Consideration should be given to how potential breaches of the Code will be investigated at the outset for collaborative research projects that reach across multiple institutions and jurisdictions.

Institutions should consider how preliminary assessments and investigations into potential breaches of the Code are to be conducted for multi-institutional collaborations on a case-by-case basis, taking into consideration issues such as the lead institution, where the complaint was lodged, contractual arrangements or where the events occurred. Institutions should cooperate if there is a potential breach of the Code to ensure that only one investigation is conducted. There should be clear communication between all parties throughout the investigation. Special consideration needs to be given to international collaborations since research practices and guidelines about the conduct of investigations differ between countries.