

Procedure

Metro North HHS - wide

Effective from: March 2019
Review due by: March 2022

Research: Complaints and breaches of the Code

Background

Metro North Hospital and Health Service (MNHHS) is committed to upholding the highest standards of research integrity by ensuring that all research conducted by, or in collaboration with, MNHHS complies with the relevant legislation, regulatory guidelines, codes of conduct, national best practice guidelines, Standard Operating Procedures and institutional policies.

The [Metro North Research Policy](#) provides a framework to promote the responsible and ethical design, conduct and communication of research, and is based on the principles of the *National Statement on Ethical Conduct in Human Research* (National Statement) and the *Australian Code for the Responsible Conduct of Research* (the Code) in the context of institutional policies, state and federal legislation and regulatory guidelines. It is the expectation that all those who conduct research within MNHHS will be aware of and comply with the Code, the National Statement, and the relevant laws, regulations, guidelines and codes of practice that apply to the conduct of research.

MNHHS has a responsibility to manage concerns about the conduct of research performed under the scope of this procedure, and is responsible for investigating concerns, complaints or allegations of breaches of the Code. MNHHS may impose serious penalties, including termination of employment, upon a finding of a sufficiently serious breach, or breaches, of the Code.

Purpose and Intent

This procedure outlines the process for the receipt, investigation, management and resolution of complaints with regard to research, and allegations of a potential breach of the Code.

Scope and Target Audience

This procedure applies to all MNHHS staff, whether permanent, temporary and casual, who participate in research activities. This procedure shall only apply to research performed:

- at a MNHHS facility; or,
- by MNHHS employees; or,
- in relation to MNHHS patients during an occasion of treatment.

This procedure does not cover research or clinical services performed outside of these parameters, and any such allegations should be directed to the relevant institutions responsible for that research activity.

Principles

The paramount principle is that MNHHS and researchers shall comply with the requirements of the Code, specifically the hallmark principles of responsible research conduct. This procedure applies to departures from the principles and responsibilities of the Code by those involved in the conduct, management and administration of research, which are referred to as a breach of the Code.

1. A breach of the Code

- A breach of the Code is defined as behaviour that fails to meet the principles or responsibilities of the Code, or fails to comply with relevant policies or legislation, and may refer to a single breach or multiple breaches. A serious breach of the Code is sufficiently serious to be categorised as being worse conduct than a mere breach of the Code. A serious breach of the Code may be constituted by repeated and persistent breaches of the Code.
- Breaches of the Code, investigations and corrective and disciplinary actions occur on a spectrum, from minor to major. The seriousness of a breach of the code is to be determined on a case-by-case basis and requires good judgement, careful deliberation, and appreciation of the context and accepted disciplinary norms.

2. Procedural fairness

- In all cases, and at all stages of the receipt, handling and management of complaints and investigation of an alleged breach of the Code, due regard must be given to the principles of procedural fairness to enable a proportional, fair, impartial, timely, transparent and confidential process, and all other legal requirements related to the making of such decisions.
- 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).
- Management of all complaints and allegations of breaches of the Code must be sensitive to and carefully consider the rights, needs and concerns of all involved including the complainant, the research participants, patients and the researchers.

Procedure

This procedure is to be read in conjunction with the National Health and Medical Research Council (NHMRC) *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* (the Guide).

1. Receiving Complaints

As complaints or allegations of a breach of the Code may arise from a variety of sources, including research participants, researchers, MNHHS staff members, or other external or third parties, they may be initially received by any staff member of MNHHS. To promote responsible research conduct and provide advice to those with complaints or concerns about potential breaches of the Code, Research Integrity Advisors (RIA) are the preferred first point of contact regarding a research complaint.

1.1. Research Integrity Advisor (RIA)

RIAs are people with research experience, analytical skills, empathy, good communication skills, knowledge of MNHHS' procedures and the Code, and familiarity with the accepted practices in research, particularly in the health service setting. A network of RIA's has been nominated across MNHHS and are listed in [Appendix 2 – Roles and Responsibilities](#). RIA's will:

- Inform the complainant about relevant institutional processes and available options, including how to make a complaint.
- Treat all allegations of a breach of the Code and discussions with the potential complainant confidentially and with due sensitivity subject to directing the matter as described in this procedure.
- Not advise on matters where they have a potential, perceived or actual conflict of interest.
- Not investigate or assess a complaint, and will not make contact with the person who is the subject of the complaint and must not be involved in any subsequent investigation.

Where a complaint or allegation of a potential breach of the Code is in relation to:

- The conduct or management of a research project within the scope of this procedure, in the first instance it should be directed to the approving Human Research Ethics Committee (HREC) Chair or Administrator. If the approving HREC was not The Prince Charles Hospital HREC (EC00168) or the Royal Brisbane and Women's Hospital HREC (EC00172), the complaint or allegation should be directed to the relevant Facility Research Governance Officer (RGO).
- Where the complaint or allegation of a potential breach of the Code relates to a MNHHS researcher, or HREC and Governance processes, in the first instance, complaints can be directed to either the relevant Facility Director of Research or Executive Administration.

Upon receipt of a complaint or an allegation of a breach of the Code, the RIA shall offer the person considering, making or having made the allegation, a meeting or conference to discuss the allegation and explain the available options:

1. Not proceeding with, or withdrawal of, the complaint if discussion resolves the concerns or the complaint is deemed to be clearly not related to a breach of the Code;
2. Referral of the matter directly to the person against whom the allegation is being made;
3. Referring the allegation to a line manager for resolution by the local Department Head. The RIA may only offer to direct the allegation to the relevant local Department Head for resolution if;
 - 3.1 The alleged Breach(es) are trivial and inadvertent;
 - 3.2 The consequences of the alleged breaches of the Code have been or can be remedied;
 - 3.3 The researcher about whom the allegations are made has acknowledged the alleged breach;
 - 3.4 There is no actual or alleged conflict in the Department Head investigating or resolving the alleged breach of the Code.
4. Making a written allegation of a breach of the Code in writing to the Designated Officer (DO).

In all circumstances, the decision and reasoning for those decisions must be documented, in line with the available options above. Until the matter is referred to a Designated Officer (DO), the RIA will be responsible for documenting these decisions.

1.2. Designated Officer

The Designated Officer (DO) will be responsible for the receipt, management and investigation of complaints. The DO's role is to provide advice as to whether allegations appear to be justified and whether a prima facie case exists. The DO has the responsibility to maintain full records of all matters related to any allegations of a breach of the Code.

The DO is a senior member of the institution's management structure who is experienced in research and research management. The DO could be the Facility Director of Research, but must not be the Facility Executive Director. So as to ensure an independent review, the DO is not the HREC Chair, although can communicate with the HREC Chair when conducting the investigation. It is important that all conflicts of interest are appropriately disclosed and managed.

The RIA may assist the person making a formal complaint to the relevant DO by offering guidance as to where and how to lodge the complaint, 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. A person making a formal complaint may waive the opportunity for discussion with a RIA and proceed directly to put the matter in writing to the DO.

2. Preliminary Assessment

Where a complaint is received and the DO determines the complaint represents a potential breach of the Code, the matter will proceed to a preliminary assessment. If the complaint is deemed to not represent

an apparent breach of the Code, or considered to be raised in bad faith, it may be dismissed or referred to an alternate process. This will be documented by the DO and communicated to the complainant.

The DO shall conduct a preliminary assessment using reasonable means which they deem appropriate in the circumstance and shall within a reasonable timeframe provide advice to the Facility Executive Director or their delegated officer. The DO may be supported by an Assessment Officer (AO) who can support conduct of the preliminary assessment of a complaint. The DO may, as they deem appropriate:

- Confer with or put written questions to the MNHHS Researcher involved, the person that has raised the complaint, and/or the Department Head;
- Confer with the HREC Chair;
- Request and receive advice from an RIA; MNHHS Human Resources or Legal Services where appropriate.

When undertaking a preliminary assessment of allegations, the DO takes the following steps according to the requirements of the Code and the MNHHS policy on misconduct:

- Consider whether any immediate action be taken, e.g. refer allegation not related to research to other institutional disciplinary processes.
- Ensure local workplace is fair to all parties until the allegations are resolved.
- Obtain all documentation and evidence for use if allegations require further investigation.

The DO must provide a report with a recommendation for the Responsible Executive Officer (REO) to pursue one of the following courses of action:

- Where there is no evidence of a potential breach of the Code, dismissal of the complaint and/or allegations;
- Where there is no evidence of a potential breach of the Code, but requires action under other institutional processes, refer to the Department Head with instructions for course of action; or
- Where there is evidence of a potential breach of the Code, it may be dealt with under provisions related to the Code or the Research Policy, with corrective actions implemented and the complaint resolved, or
- Where there is evidence of a potential breach of the Code, establish an internal investigation, or
- Where there is evidence of a potential breach of the Code, establish an external investigation.

The report should be provided to the REO and outcomes reported to the HREC and RGO where appropriate and feedback given to the parties involved in the allegations. If the advice to the REO is to investigate the matter further, the DO will not play any further role in the matter, except to be called to give evidence or expert opinion.

2.1. Responsible Executive Officer (REO)

The REO is the senior executive of the institution who has final responsibility for receiving reports of the outcomes and processes of assessment and investigation of potential and actual breaches of the Code and deciding actions to be taken.

3. Final Decision and Outcome

Upon receiving the formal report from the DO, the REO shall make a decision as to whether to accept the recommendation of the DO. The REO shall notify all parties, including the person raising the allegation and the DO of their initial decision. All inquiries established on the initial decision of the REO, including an internal or external investigation, shall be constituted and operate in accordance with the Guide to Managing and Investigating Potential Breaches of [the Australian Code for the Responsible Conduct of Research](#), Section 7. Investigation stage.

The Executive Director, Research MNHHS is available to provide advice to the DO or REO (Facility Executive Director) in complex cases (e.g. multiple facilities involved, multiple institutions involved, if an independent person is required to investigate an allegation where the DO has a potential conflict of interest or, where a case is unable to be resolved locally).

Upon finalisation of all steps arising from the preliminary assessment and investigation where appropriate, the REO shall make a final decision to resolve the matter. The final decision must include the final findings of the process in their decision. The REO may also include:

- Directions to correct the public record;
- Recommending or taking such disciplinary actions against a MNHHS employee who is the subject of the complaint, in accordance with the HR policies of MNHHS, which are appropriate in the circumstances;
- Recommending or taking such disciplinary actions against an employee that has made a mischievous complaint, in accordance with the HR policies of MNHHS, which are appropriate in the circumstances;
- Making recommendations or instituting policies and procedures to resolve or rectify research processes at the MNHHS;
- For any unauthorised disclosure of patient data, referral of the matter to the Department of Health or such other authority responsible for enforcing section 142 of the *Hospital and Health Boards Act 2011* (Qld);
- Such other steps required or deemed appropriate to resolve the specific or systemic issues discovered during the process.

The REO shall furnish their final decision to all relevant parties, including the Researcher, the person raising the allegation and the DO.

4. Collaborative Research

The MNHHS Procedure [Research: Partnership and Collaboration \(PROC004419\)](#) outlines principles for effective research partnerships and collaboration. Where a dispute, disagreement or complaint arises regarding collaborative research, researchers of all organisations will adhere to all relevant scientific and ethical codes and guidelines. Where researchers have university affiliations, they are advised to also refer to their institutional policies for relevant guidelines and procedures. Researchers are advised to consult with the terms and conditions of pre-existing multi partner agreements that may be relevant to proposed collaborative research. The decision made by the lead institution of the Collaboration/Partnership should be upheld and not challenged within another.

5. Corrupt and/or criminal misconduct

A breach of the Code may not necessarily involve matters that are criminal in nature, employee misconduct as defined within the *Public Service Act 2008* (Qld), corrupt conduct as per the definition within the *Crime and Corruption Act 2001* (Qld) or serious breaches of the Code of Conduct for Queensland Public Service. All employees of MNHHS have an obligation to report any suspicion or allegations of corrupt conduct on the part of any MNHHS employee as outlined in the Procedure [Requirements for Reporting Corrupt Conduct \(PROC173\)](#). The [Code of Conduct for the Queensland Public Service 2011](#) (Code of Conduct) and the *Public Service Act 2008* (Qld) outline the obligation of all employees to report suspected wrongdoing, which includes corrupt conduct. The MNHHS Procedure [Public Interest Disclosure \(PROC035\)](#) outlines the legislative provisions and procedures in place under the *Public Interest Disclosure Act 2010* (Qld), to assist MNHHS employees and the public in understanding their obligations in reporting wrongdoing that concerns MNHHS employees.

6. Clinical incident and patient safety reporting

If at any time it becomes apparent that the complaint relates to an activity that is a patient safety risk, or has the potential to harm patients or MNHHS staff, immediate action must be taken to minimise this harm. This action is outside the scope of this procedure, and MNHHS employees are referred to the Procedure [Patient safety alerts, notifications/advisories and communiques, Management of \(PROC123\)](#). Minimum standard processes for identifying and managing patient safety issues/risks are included in the MNHHS Policy [Clinical Governance \(POL033\)](#) and [Risk Management \(POL002090\)](#).

Legislation and other authority

Hospital and Health Boards Act 2011 (Qld)

Information Privacy Act 2009 (Qld)

Public Service Act 2008 (Qld)

Crime and Corruption Act 2001 (Qld)

Criminal Code Act 1899 (Qld)

Public Interest Disclosure Act 2010 (Qld)

Queensland Institute of Medical Research Act 1945 (Qld)

[Australian Code for the Responsible Conduct of Research, 2018 \(the Code\)](#)

[Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research \(the Guide\)](#)

[National Statement on Ethical Conduct in Human Research \(2007\) – Updated 2018](#)

Related Documents

[Research Policy Metro North HHS \(POL004365\)](#)

[Research: Monitoring \(PROC004412\)](#)

[Research: Financial Management \(PROC004413\)](#)

[Research: Conflict of Interest \(PROC004414\)](#)

[Research: Intellectual Property \(PROC004415\)](#)

[Research: Authorship \(PROC004416\)](#)

[Research: Responsible Reporting \(PROC004417\)](#)

[Research: Honorary Appointments, Research Students and Visitors \(PROC004418\)](#)

[Research: Partnership and Collaboration \(PROC004419\)](#)

[Research: Gender Equity \(PROC004420\)](#)

[Metro North HHS Research Strategy 2017-2022](#)

[Requirements for Reporting Corrupt Conduct \(PROC173\)](#)

Health Service Directive 35 – Research Ethics and Governance

[Queensland Department of Health Code of Conduct](#)

[Public Interest Disclosure \(PROC035\)](#)

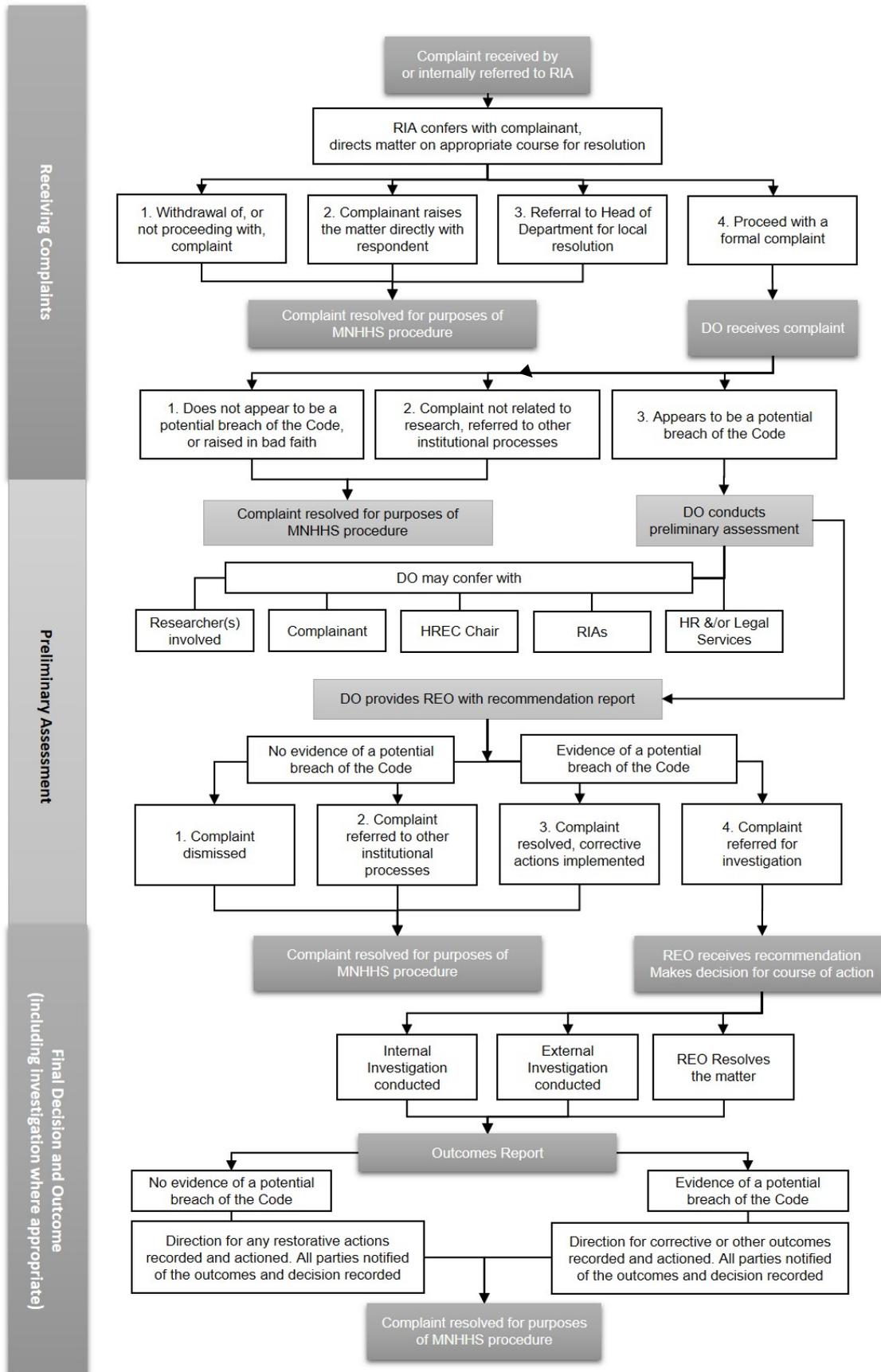
Relevant Standards

Australian Commission on Safety and Quality in Health Care - National Safety and Quality Health Care Standards Second Edition



Standard 1 – Clinical Governance

Appendix 1 – Research complaints and breaches of the Code process



Appendix 2 – Roles and Responsibilities

Role	Role Description	Recommended Individual
Responsible Executive Officer (REO)	The senior officer in an institution who has final responsibility for receiving reports of the outcomes of processes of assessment or investigation of potential and actual breaches of the code and deciding on the course of action to be taken.	<p><i>For Facility/Directorate matters:</i> e.g. Facility Executive Director</p> <p><i>For MNHHS-wide matters:</i> Chief Executive (CE) MNHHS OR Delegate appointed authority by the CE: Executive Director, Operations MNHHS</p>
Designated Officer (DO)	A senior professional or academic institutional officer(s) appointed to receive complaints about the conduct of research or allegations of a potential breach of the Code and to oversee their management and investigation where required.	<p><i>For Facility/Directorate matters:</i> Facility Director of Research OR Nominated delegate where no position exists or position is vacant</p> <p><i>For MNHHS-wide matters:</i> Executive Director, Research MNHHS</p>
Research Integrity Advisor (RIA)	A person or persons with knowledge of the Code and relevant institutional processes nominated by MNHHS to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Code.	<p><i>For MNHHS-wide matters:</i> Assistant Director, MNHHS Research OR Research Monitoring Officer, MNHHS</p>
	Royal Brisbane and Women's Hospital	Chair, RBWH HREC Research Governance Officer, RBWH
	The Prince Charles Hospital	Research Governance Officer, TPCH Chair, TPCH HREC Executive Officer, Research Ethics and Governance Unit TPCH
	Redcliffe Hospital	Research Governance Officer, Redcliffe
	Caboolture, Kilcoy and Woodford	Research Governance Officer, Caboolture
	Community Services Directorate	Research Governance Officer, Community Services OR Director Research Advocacy, Oral Health
	Metro North Mental Health (MNMH)	Principal Research Fellow, MNMH or Senior Research Fellow, MNMH
Assessment Officer (AO)	A person who conducts a preliminary assessment of a complaint or a concern about research.	To be appointed on a case-by-case basis by the Designated Officer.

Appendix 3 – Definition of terms

Term	Definition
Allegation	A claim or assertion that is put to a respondent following a finding of a preliminary assessment that there are reasonable grounds to believe a breach of the Code has occurred.
Breach of the Code	Behaviour that fails to meet the principles or responsibilities of the Code, or fails to comply with relevant policies or legislation. May refer to a single breach or multiple breaches. For the purposes of the Metro North Hospital and Health Service, all unauthorised uses and disclosures of information about a patient shall be deemed a breach of the Code.
Code, the	The Australian Code for the Responsible Conduct of Research (2007) This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of the Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
Complainant	A person or persons who has made a complaint about the conduct of research.
Confidential Information	Has the meaning set out in section 139 of the <i>Hospital and Health Boards Act 2011</i> (Qld)
Conflict of Interest	<p>A conflict of interest in the context of research exists where either:</p> <ul style="list-style-type: none"> • a person's individual interests or responsibilities have the potential to influence carrying out of institutional roles or professional obligations in research. • an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations. <p>A conflict may relate to financial interests or other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.</p> <p>A conflict of interest may compromise the research process itself and/or the institutional processes governing research, and may lead researchers or institutions to base decisions about the research on factors outside the research requirements.</p> <p>A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual's integrity or an institution's management practices.</p>
Coordinating Principal Investigator (CPI)	<p>The Investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site PIs and Reviewing HREC.</p> <p>The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible.</p> <p>For single site studies the terms Coordinating Principal Investigator,</p>

Term	Definition
	Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous.
Department Head	The person who supervises or directs the organisation unit in which the Researcher is engaged.
Ethics	The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.
Facility	The site at which the Research is performed or the Researcher is engaged.
Facility Executive Director	The executive officer of the Facility. At any time, the Chief Executive may step into the role described for the Facility Executive Director.
HREC Administrator/Coordinator	An employee of the institution who provides administrative support and advice on the institution's processes for ethical review of research studies. The HREC Administrator reports to the Chair of the HREC in matters related to the activities of the Committee.
Human Research Ethics Committee (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data. HRECs are established by organisations, which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies. A Certified HREC has had its processes assessed and certified under the National Health and Medical Research Council (NHMRC) National Certification Scheme. NHMRC certification lasts for three years.
MNHHS	Metro North Hospital and Health Service
National Statement, the	The National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 . A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.
Patient	A person who is a subject of research or whose data is collected, used or disclosed in the course of research.
Principal Investigator (PI)	The nominated delegate with primary responsibility and accountability for a research project. <ul style="list-style-type: none"> For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities. For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably. See also Coordinating Principal Investigator (CPI)
Research	The original investigation undertaken to gain knowledge, understanding and insight. The creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings.

Term	Definition
	This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research Collaboration Agreement (RCA)	An agreement made between MNHHS and another entity for the purpose of determining those party's roles in Collaboration on Research. For clarity, this definition does not include an employment agreement with an employee of MNHHS
Research Ethics	Ethics as it applies to research with particular consideration of research risks and benefits as well as protection of the rights and safety of the community and research participants.
Research Governance	The process by which an RGO assesses the suitability of study to take place within their institution / HHS and recommends authorisation to the HHS CE. Once authorised, the study may commence at that institution / HHS. Also referred to as Site Authorisation.
Research Governance Officer (RGO)	The Office(r) or coordinated function within an institution / HHS whose responsibilities are: <ul style="list-style-type: none"> • assessing the site-specific aspects of ethically approved research applications; • making recommendations to the HHS CE or delegate as to whether a research study should be granted authorisation at that site; and • monitoring authorised research at the site to ensure it meets appropriate standards.
Research Misconduct	A term used in relation to Serious Breaches of the Code which is also intentional, reckless or negligent.
Researcher	A person or persons who conduct(s) research, including academics, research trainees, honours and higher degree research students and professional staff. A person or persons engaged in the performance of Research at the Facility and whom is the subject of an allegation of Breach of the Code.
Serious Breach of the Code	A term used in relation to a Breach of the Code which is sufficiently serious to be categorised as being worse conduct than a mere Breach of the Code. A Serious Breach of the Code may be constituted by repeated and persistent Breaches of the Code.

Document History

Custodian	Executive Director, Research MNHHS
Risk rating	Low
Compliance evaluation and audit	Summary data of investigations into potential breaches of the Code will be reported to the Executive Director, MNHHS and to the Executive Director, Research MNHHS.
Replaces Document/s	PROC004421 V1 Research: Complaints and Breaches of the Code
Document replaced	11/2017
Key stakeholders	Executive Director, Operations Executive Directors, Clinical Directorates HREC Chair & Coordinator, RBWH & TPCH Research Governance Officers Director, Research (Clinical Directorates) Executive Director (Metro North): Clinical Services, Medical Services, Nursing and Midwifery Services, Allied Health Chief Finance and Corporate Officer (Financial Control, Information Technology, Legal, Human Resources, Communications, Engagement) Director, Integrity Office
Marketing Strategy	Marketing through MNHHS Research website, newsletter and regular email to all line managers. Notification through Safety and Quality Units to key stakeholders.
Key words	Complaint, research, conduct, breach, the Code, misconduct

AUTHORISATION

Signature

Date

Executive Director, Research, Metro North Hospital and Health Service

A signed version is retained by the relevant Safety and Quality area, Metro North Hospital and Health Service.