Procedure

Effective from: December 2019
Review date: December 2020

Research: Conflict of interest PROC004414

Purpose and intent

The Metro North Hospital and Health Service (Metro North) is committed to the highest standards of research integrity and expects all those who conduct research to comply with the relevant legislative, regulatory and governing frameworks applicable to research.

The Metro North Research Policy (POL004365) and Research Procedures are 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), relevant state and federal legislations, institutional policies and regulatory guidelines, and provide a framework to promote the responsible and ethical design, conduct and communication of research.

Disclosure of interests and identification and management of conflicts of interest is necessary in order to maintain the integrity and reliability of research outcomes, mitigate the risks associated with complex relationships, especially those between Metro North and other private or public organisations, and to ensure public trust in those individuals and organisations involved in research. This procedure is provided to inform those involved in research of the procedure for disclosing interests and managing any conflicts that may arise, or may be perceived to arise, from those interests.

Scope and target audience

This procedure/protocol/guideline applies to:

- all Metro North clinical and non-clinical staff (permanent, temporary and casual) and all organisations and individuals acting as its agents (including Visiting Medical Officers and other partners, contractors, consultants and volunteers) who participates an activity associated with research, regardless of whether the research activity is conducted at or with Metro North
- individuals on scientific or grant review committees or panels convened by Metro North
- all members of a Metro North HREC
- all settings across the health continuum including community, primary, acute, rehabilitation and residential care health services within Metro North

Procedure

Section 186 of the *Public Service Act 2008* (Qld) provides that public service employees must disclose any interests that conflict or may conflict with the duties of their employment and cannot act further in the matter to which a conflict relates unless their Chief Executive allows them to.

Nothing in this procedure withdraws the requirement for Metro North staff to comply with these provisions, as set out in the Metro North Policy (POL003365) Managing conflict of interest and Procedure (PROC003366) Managing conflict of interest – MNHHS employees.

The National Health and Medical Research Council (NHMRC) Disclosure of interests and management of conflict of interest guideline sets out best practice principles for disclosure of interests, the responsibilities of institutions and researchers, resolution of disputes and breaches of the Code with respect to conflict of interest in research, and should be read in conjunction with this procedure.

Disclosure of interests

The Australian Code for the Responsible Conduct of Research (the Code) requires that researchers disclose all interests that are relevant, or could appear to be relevant, to proposed or ongoing research.

Where required, relevant interests may need to be disclosed to funding bodies, research participants, publishers and journal editors, collaborators and the public.

Where Metro North has interests that are relevant to individual research projects or research programs that may merit disclosure to researchers, funding bodies, research participants, publishers and journal editors, collaborators or the public, this should be disclosed.

The disclosure of interests, and update of and disclosures following a change in circumstances, must occur in a timely fashion and at least annually whilst the research remains active.

The types of interest that may require disclosure in research may include financial, personal, familial, professional and organisational.

- Guide those involved in research in making appropriate disclosures of relevant interests to research participants, other relevant parties and the public, and to funding bodies, where required

Conflict of interest

The Code outlines the principle of **transparency** in declaring interests and disclosing and managing conflicts of interest as a hallmark of responsible research conduct, specifically setting researcher responsibility (R24) *disclose and manage actual, potential or perceived conflicts of interest.*

The Code states that a conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are, or may be, unduly influenced by other interests. Having multiple interests does not necessarily constitute a conflict of interest.

The perception that a conflict of interest exists is a serious matter and can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research. A conflict of interest may be actual, perceived or potential and requires defining when being considered. A conflict of interest may include conflict of roles, private interests, personal relationships and personal benefits arising from the research.

Any conflicts of interest should be declared as part of any of the following activities:

- HREC and scientific review board or committees;
- HREC and site-specific assessment (SSA) applications;
- Submission or assessment of applications to funding bodies; and
- Any submission or review of publication, reporting or presentation of research results.

In all cases a full disclosure of the circumstances giving rise to a conflict of interest situation are required. A conflict of interest can potentially affect how someone designs research and/or reports their research outcomes or influence how research manuscripts, proposals and funding applications are reviewed. Conflicts of interest can bias guideline recommendations to disproportionately favour new, expensive and less effective treatments and products.

For researchers, potential conflicts of interest can arise from past relationships with clinical trial sponsors for whom they may have conducted earlier research, acted as an advisory board member or authored a paper that used the same sponsor's results. Links to funding bodies, industry partners and research development organisations can also lead to conflicts of interest.

Conflict of interest involving researchers

It is a researcher's own responsibility to disclose any potential conflict of interest. Disclosure is required for submission or assessment of any ethics and SSA applications, funding applications, publications, presentations, press releases and media interviews, and review of applications for new positions and or promotions.

Individuals can foster disclosure by being open and transparent about any relationships that could be perceived as potential or actual conflict of interest. Metro North encourages disclosure by maintaining a register of conflicts of interest and having procedures in place to manage inadequate disclosure and concerns about lack of disclosure.

Applications for funding of research projects require full disclosure including potential personal, professional and institutional benefits that may be generated by the project.

Hospital Foundations and other funding bodies within Metro North (e.g. Private Practice Trust Funds) have published procedures for managing such conflicts disclosures for both grant funding applications and for scientific review processes and panel deliberations.

Conflict of interest Involving HREC Members

Each HREC in Metro North will have published procedures for managing conflict of interest discussions, including how the committee manages multi-institutional research applications with multiple partners and multiple investigators.

A formal record must be kept of how each conflict has been managed within the committee proceedings, or minutes, of the meeting at which the matter is discussed, including who was involved, what the conflict was and how it was managed, even if information is omitted due to specific confidential issues related to the discussion and decision-making.

Potential conflict of interest should be considered by independent, expert scientific reviewers that provide *ad hoc* advice to HREC committees.

In the setting of HREC and scientific review boards or committees, where a conflict of interest cannot be resolved, the party(ies) should withdraw from the decision-making process (e.g. where a study is to be approved by an HREC, if a conflict of interest is identified, the person(s) is absented from the decision making process).

Conflict of interest involving grant and funding review

Metro North requires the disclosure of interests by any Panel Reviewers and Committee Members for grants administered by the Metro North Office of Research.

Identifying and managing a conflict of interest

A researcher, or individual involved with a research activity, is required to maintain records of activities that may be relevant to the assessment of whether a conflict of interest exists (for example: consultancies;

membership of a board of directors, advisory group or committee; receipt of or delegation to receive funds, services or equipment from outside bodies to support research activities).

When an actual, perceived or potential conflict of interest is identified and relates to research activity performed by a Metro North employee (or any individual within the scope of the Metro North Policy Managing conflict of interest) it should be reported by completing and submitting a Conflict of Interest Disclosure Form (PROC:119 Managing conflict of interest - Appendix 4).

Compliance with external disclosure of interest policies

All Metro North staff are expected to comply with the disclosure of interest policies and procedures of external bodies that the researcher or staff member engages or is affiliated with, for example funders, conference sponsors or organisers and publishers. Relevant roles may include, but not be limited to: company director, not-for-profit board member, scientific advisor or editor.

Breaches of the Code

Metro North HHS has a responsibility to investigate, assess and manage any concerns related to conflict of interest that may constitute a potential breach of the Code. As an example, this might include:

- Failing to disclose a relevant interest in a timely manner
- Failing to abide by any decisions as to the management of a conflict of interest.

A potential breach of the Code will be managed in accordance with the Metro North Procedure Research: Complaints and breaches of the Code (PROC004421) and the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (the Investigation Guide).

Dispute resolution

The Metro North Procedure Research: Complaints and breaches of the Code (PROC004421) provides the mechanism for raising concerns and the fair and timely resolution of any disputes about identification or management of conflict of interest, including disputes involving multiple institutions.

Partnering with consumers

The active involvement of consumers and community members in health and medical research benefits the quality and direction of research. Consumer and community involvement is about research being carried out with or by consumers and community members rather than to, about or for them.

Patients and family members are to be encouraged and given the opportunity to ask questions, clarify information and actively participate in the development and communication of research. Staff are responsible for providing information in a way that is understandable and that meets their needs and are to check consumer's understanding of discussions.

Refer to the NHMRC Statement on Consumer and Community involvement in Health and Medical Research for further guidance on research with consumers.

Aboriginal and Torres Strait Islander considerations

The National Health and Medical Research Council (NHMRC) provide Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018 and Keeping research on track II 2018 as ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples. These documents should be read alongside the Guidelines for Ethical Research in Australian Indigenous Studies 2012.

The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS), The Lowitja Institute and the Queensland Aboriginal and Islander Health Council QAIHC provide further resources.

There is currently no certified Aboriginal and Torres Strait Islander Human Research Ethics Committee (HREC) in Queensland. You may wish to contact one of these HREC's for more information:

- Australian Institute of Aboriginal and Torres Strait Islander Studies Research Ethics Committee
- Aboriginal Health & Medical Research Council Ethics Committee (NSW)
- Aboriginal Medical Service Western Sydney Ethics Committee (NSW)
- Human Research Ethics Committee for the Northern Territory Department of Health and Menzies School of Health Research
- Aboriginal Health Research Ethics Committee (SA)
- Western Australian Aboriginal Health Ethics Committee

Refer to the *Metro North Better Together Plan* or the *Queensland Health Aboriginal and Torres Strait Islander Cultural Capability Framework 2010-2033*

Legislation and other authority

Anti-Discrimination Act 1991 (Qld)

Australian Institute of Health and Welfare Act 1987 (Cth)

Australian Research Council Act 2001 (Cth)

Circuit Layouts Act 1989 (Cth)

Copyright Act 1968 (Cth)

Designs Act 2003 (Cth)

Financial Accountability Act 2009 (Qld)

Financial and Performance Management Standard 2009 (Qld)

Guardianship and Administration Act 2000 (Qld)

Health Services Act 1991 (Cth)

Hospital and Health Boards Act 2011 (Qld)

Human Rights Act 2019 (Qld)

Industrial Relations Act 1999 (Qld)

Information Privacy Act 2009 (Qld)

Mental Health Act 2016 (Qld)

National Health and Medical Research Council Act 1992 (Cth)

Patents Act 1990 (Cth)

Public Governance, Performance and Accountability Act 2013 (Cth)

Public Health Act 2005 (Qld)

Public Interest Disclosures Act 2010 (Qld)

Public Records Act 2002 (Qld)

Public Sector Ethics Act 1994 (Qld)

Public Service Act 2008 (Qld)

Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)

Therapeutic Goods Act 1989 (Cth)

Therapeutic Goods Regulations 1990 (Cth)

Trade Marks Act 1995 (Cth)

Transplantation and Anatomy Act 1979 (Qld)

Work Health and Safety Act 2011 (Qld)

Workplace Health and Safety Act 1995 (QLD)

Related documents

Metro North Research Policy (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)

Research: Complaints and breaches of the Code (PROC004421)

Appendix 1- Definition of terms

Term	Definition
Annual Report/Progress Report	A report submitted by the Coordinating Principal Investigator (CPI) to relevant governing bodies documenting the annual progress and research project protocol compliance.
Author	An individual who has made a significant intellectual or scholarly contribution to research and its output and who has agreed to be listed as an author.
Authorship	Authorship refers to the attribution of contributors to academic publications. Authorship must be determined based on substantial scholarly contributions.
Breach	A failure to meet the principles and responsibilities of the Code. May refer to a single breach or multiple breaches.
Code, the	The *Australian Code for the Responsible Conduct of Research, 2018* (the Code) establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.

	https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
Confidential Information	Confidential Information means any information that— (a) is about a person who is receiving or has received a public sector health service; and (b) could identify the person. *Hospital and Health Boards Act 2011* (Qld)
Confidentiality Agreement	An agreement made between Metro North and another entity for the purpose of secretly disclosing information between those parties. For clarity, this definition does not include an employment agreement with an employee of Metro North.
Conflict of Interest	A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests.[1] Where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or where an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.
Coordinating Principal Investigator (CPI)	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. 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. For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous.
Department Head	The person who supervises or directs the organisational 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.
Final Report	A report submitted by the Coordinating Principal Investigator (CPI) to relevant governing bodies at the completion of a research project documenting the final project outcomes.

[1] Australian Code for the Responsible Conduct of Research 2018. National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra.

Human Research Ethics Application (HREA)	The HREA is the Nationally accepted online application form provided by the NHMRC that enables all Australian research involving human participants to be efficiently and effectively reviewed. https://hrea.gov.au/
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.
Intellectual Property	All rights in Australia or any other jurisdiction resulting from intellectual activity in the medical, industrial, scientific, artistic and literary fields, including any rights in, or rights to registration of: Works under the *Copyright Act 1968* (Cth) Designs under the *Designs Act 2005* (Cth) Inventions under the *Patent Act 1990* (Cth) Trade Marks under the *Trade Marks Act 1995* (Cth) Circuit layouts or integrated circuits under the *Circuit Layouts Act 1989* (Cth) Confidential information at common law and equity.
Investigation	Used to describe the action of investigating an allegation of a breach of the Code by the Panel, following the preliminary assessment. The purpose of the investigation is to determine whether a breach of the Code has occurred, and if so, the extent of that breach, and to make recommendations about further actions.
Metro North	Metro North Hospital and Health Service
National Statement, the	The *National Statement on Ethical Conduct in Human Research (2007)* (Updated 2018) consists of a series of guidelines made in accordance with the *National Health and Medical Research Council Act 1992*. The National Statement is intended for use by: • any researcher conducting research with human participants; • any member of an ethical review body reviewing that research; • those involved in research governance; and • potential research participants. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
NHMRC	National Health and Medical Research Council

Participant	A person who is a subject of research or whose data is collected, used or disclosed in the course of research.
Patient	An individual who receives, or has received, care treatment or other services through a Metro North facility.
Peer Review	The impartial and independent assessment of research by others working in the same or a related field.
Principal Investigator (PI)	The nominated delegate with primary responsibility and accountability for a research project. 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).
Publication	Dissemination of findings, whether in hardcopy, electronic or other tangible form, including: refereed and non-refereed books or journals; web-pages; eLearning resource packages; conference presentations, papers, proceedings, posters and abstracts; films; professional and institutional repositories; and patents, registered designs and intellectual property. A publication may be unsolicited or invited and may entail a primary research report or a review of previously published literature. A publication can also take the form of publication in an online platform or published proceedings of an organisation meeting or conference. Information submitted for publication must be an accurate representation of the research.
Record	Recorded information created or received by an entity in the transaction of business or the conduct of affairs that provides evidence of the business or affairs and includes: • anything on which there is writing • anything on which there are marks, figures, symbols or perforations having a meaning for persons, including persons qualified to interpret them • anything from which sounds, images or writings can be reproduced with or without the aid of anything else, or • a map, plan drawing or photograph.
Research	The original investigation undertaken to gain knowledge, understanding and insight. The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

Research 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: • 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 Output	A research output communicates or makes available the findings of research that may be in hardcopy, electronic or other form. Examples of research outputs include journal articles, book chapters, books, conference papers, reports, datasets, patents and patent applications, performances, videos and exhibitions.
Research Student	An individual enrolled in a course of study with a recognised research or teaching institution and may include: • Students enrolled in honours, research masters or doctoral program, or any substantial postgraduate research project or dissertation with a University. • Volunteer medical, nursing or allied health students gaining research experience.
Researcher	A person(s) who conducts, or assists with the conduct of, research.
Site Authorisation	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 Research Governance.
Site-Specific Assessment (SSA) Form	The SSA Form is a tool to assist RGOs in the research governance process to document the level of support and suitability of a research study to be conducted at a site, irrespective of whether that study is multi-centre or single site.

Document history

Author	Executive Director, Research Metro North
Custodian	Executive Director, Research Metro North
Compliance evaluation and audit	Summary data of research breaches of the code investigations will be reported to the Chief Executive and Executive Director, Research Metro North.
Replaces Document/s	PROC004414 V1.0
Consultation	**Key stakeholders** HREC Chair and Administrator Research Governance Officers (RGO) RBWH Executive Director of Research Director of Research and Education, Redcliffe **Broad Consultation** Metro North Aboriginal and Torres Strait Islander Unit Metro North Information Technology Metro North Nursing and Midwifery Metro North Allied Health Metro North Medical Services Metro North Finance Metro North Workplace Health and Safety Metro North Legal Unit Metro North Risk and Compliance Officer Metro North Emergency Medicine and Access Coordination Stream Clinical Operations Strategy Implementation Unit Clinical Directorate Safety and Quality Units Clinical Skills Development Centre
Marketing Strategy	A Policy, Procedure and Protocol Staff Update will be published online each month to update staff of all new and updated policies, procedures and protocols. This update will be emailed to all Safety and Quality Units in each clinical directorate and a broadcast email sent to all Metro North staff with a link to the published update.
Key words	Research, conflict of interest, disclosure, management

Custodian Signature Date

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AUTHORISATION

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The original signed version is kept in file at the Metro North Office of Research, Metro North.