Metro North - wide

Policy

Effective from: February 2020
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Research 004365

Policy statement

Metro North Hospital and Health Service (Metro North) supports excellence in research to enable generation of new knowledge that will lead to improved capacity to deliver the best quality health care for our community. Metro North is committed to the highest standards of research integrity and expects all those who conduct research in the HHS to comply with the relevant legislative, regulatory and governing frameworks applicable to research.

This policy and the Research Procedures provide a framework to promote responsible and ethical design, conduct and communication of research. Each are based on the principles of the *National Statement on Ethical Conduct in Human Research* 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.

This policy provides overarching guidance for all research undertaken in Metro North and has been established to support Metro North's mission to deliver exceptional health outcomes through globally recognised discovery and translation of research.

Purpose and intent

The purpose of this policy is to ensure that all research conducted by, or in collaboration with, Metro North is of the highest ethical and scientific standard, and complies with the relevant legislation, regulatory guidelines, codes of conduct, national best practice guidelines, Standard Operating Procedures and institutional policies.

The intent of this Policy is to provide a framework to promote responsible and ethical research whilst also respecting the human rights of every patient and person to the greatest extent possible in accordance with the *Human Rights Act 2019* (Qld).

Scope and target audience

This policy 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 undertake, administrate, review and/or govern research involving Metro North

- all settings across the health continuum including community, primary, acute, rehabilitation and residential care health services within Metro North
- any person/external entity undertaking research at a Metro North facility and/or involving Metro North patients, staff and/or resources and infrastructure.

Principles

This policy provides a framework to promote excellence through research integrity and is based on the principles and values outlined in the *Australian Code for the Responsible Conduct of Research* (the Code) and the *National Statement on Ethical Conduct in Human Research (National Statement).*

The following hallmark principles of responsible research conduct outlined in the Code provide the framework for integrity in the design, conduct and communication of research:

- **Honesty** in the development, undertaking and reporting of research
- **Rigour** in the development, undertaking and reporting of research
- **Transparency** in declaring interests and reporting research methodology, data and findings
- **Fairness** in the treatment of others
- **Respect** for research participants, the wider community, animals and the environment
- **Recognition** of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular significance to them
- **Accountability** for the development, undertaking and reporting of research
- **Promotion** of responsible research practices

The National Statement outlines the values of *respect* for human beings, *research merit and integrity*, *justice* and *beneficence* to inform and guide the ethical design, review, conduct and communication of research. The National Statement must be used to inform research that is funded by, or takes place under the auspices of, any bodies that developed the National Statement, including the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC), and Universities Australia (formerly the Australian Vice-Chancellors' Committee).

It is expected that all who are responsible for research will adhere to the Code and the National Statement in the design, ethical conduct and review of research in Metro North. The Code and the National Statement do not incorporate all the laws, regulations and guidelines and other codes of practice that apply to the conduct of research.

It is the responsibility of all parties who propose to undertake, administrate, review and/or govern research involving Metro North to be aware of, understand, and comply with relevant legislation, codes of conduct, national best practice guidelines, Standard Operating Procedures, and institutional policies and procedures.

Institutional Responsibilities

Metro North has an obligation to encourage and support quality research and is accountable for how research is undertaken. In line with the *Metro North Research Strategy 2017-2022*, and to foster research integrity, Metro North will:

- Lead excellence in patient-centred care
- Engage our employees with a research-active culture to develop, attract and retain high calibre research expertise
- Establish integrated research information, management and communication systems
- Enhance sustainable research capacity through management of infrastructure and resources

- Support strategic collaborations and partnerships to drive globally recognised discovery and translation

Responsible research conduct is fostered and underpinned by the research culture of Metro North. Metro North has an obligation to encourage and support responsible research conduct and adheres to the specific institutional responsibilities outlined in the Code.

Researcher Responsibilities

Researchers will ensure the principles and values of responsible and ethical research conduct are manifest in all aspects of their research. Specifically, researchers will use best endeavours to adhere to the responsibilities of researchers, as outlined in the Code.

Approvals to conduct research

In order to conduct human research in Metro North, it is a requirement that all research first obtains:

- Human Research Ethics Committee (HREC) review, **and**
- Research Governance (Site Authorisation) approval

Human research shall not commence until both processes are formally completed.

The research must be approved by an appropriately certified HREC and authorised by the Chief Executive (CE) or relevant delegate by submitting a Site-Specific-Assessment (SSA) application to a Research Governance Officer (RGO) for site authorisation. HREC review and Research Governance (Site Authorisation) processes in Metro North will be transparent and accountable and be undertaken in accordance with legislative and other institutional policy or regulatory requirements.

It is the responsibility of the Principal Investigator (PI) to ensure all research obtains requisite approvals prior to commencing. Research that does not involve humans, or involves animals, must first obtain requisite approval from the relevant institutional ethical review board or committee. HREC's do not provide ethical review and approval for animal research or non-human research.

HREC review

HREC review and approval is required to ensure that all human research conducted in Metro North is ethically acceptable in line with the National Statement, and in accordance with other relevant legislative and regulatory standards and guidelines. No research shall commence until the HREC review process has been completed and letter of approval from the reviewing HREC is received.

Metro North has two HREC's registered and certified with the NHMRC for researchers to submit applications for ethical review:

- The Prince Charles Hospital HREC (EC00168)
- Royal Brisbane and Women's Hospital HREC (EC00172)

Each Metro North HREC operates under published and accessible Terms of Reference and Membership structures, and are constituted and act in accordance with the:

- National Statement on Ethical Conduct in Human Research (National Statement)
- Declaration of Helsinki
- Australian Code for the Responsible Conduct of Research (the Code)
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
- Research Ethics and Governance Health Service Directive (QH-HSD-035:2016)
- Standard Operating Procedures for Queensland Health HREC Administrators

Applications are to be completed on either the Human Research Ethics Application (HREA) accessed via the Ethical Review Manager (ERM) website: https://au.forms.ethicalreviewmanager.com/.

Metro North requires the minimisation of duplication of ethical and legal review for multi-centre research and is a participant of the National Mutual Acceptance scheme; the national mechanism to allow specific types of multi-centre research to be reviewed by an NHMRC Certified HREC, and for that review to be accepted across all public health institutions within participating jurisdictions.

Metro North requires that site feasibility and resource implications be considered as applications for ethical review are submitted to the HREC. Where possible, prior to completion of HREC review, PIs will discuss site-specific arrangements (such as local resource implications and budget) with the relevant Heads of Department/s whose operations and clinical service may be impacted by the proposed research, the relevant Business Manager(s) and the institutional RGO, to assist in the timely and efficient completion of site-specific applications for governance approval.

Research Governance (Site Authorisation)

Research governance refers to the local institutional due diligence processes by which the suitability of a research study to take place in the context of the institution is assessed. It encompasses the assessment of legal, financial, resource, regulatory and contractual issues. This process ensures that all research conducted under the auspices of Metro North is properly assessed, accounted for and governed.

Site authorisation must be obtained for all facilities where the research will be conducted. This comprises the submission of a site-specific assessment (SSA) application to a Metro North RGO, linked to the Ethical Review Manager (ERM) HREA ethics application. Metro North RGOs operate under the minimum standard for research governance review of research outlined in the Standard Operating Procedures for Queensland Health Research Governance Officers.

Site authorisation is contingent upon receipt of HREC approval. Human research shall not commence until the research governance process has been completed, and authorisation from the HHS Chief Executive (CE) or delegate has been obtained. An SSA approval letter granting research authorisation is required before a research study can commence at any site.

Research management

1. Monitoring of approved research

Metro North is responsible for ensuring that all its approved research is monitored. Monitoring of research refers to the process of verifying that the conduct of research conforms to the approved research proposal.

The process of monitoring promotes the safety of research participants and best research practice through the confirmation of adherence to appropriate processes, collection of quality research data, appropriate record keeping, access and storage of research records. It also ensures relevant HREC, governance and regulatory compliance.

The purpose of research monitoring is to verify that research projects approved by a Metro North HREC and/or conducted in Metro North facilities follows the approved research proposal in order to; protect the rights and well-being of research participants; verify the accuracy of research data and ensure regulatory compliance by the institution; and provide a level of assurance of the quality of the researchers processes. Furthermore, monitoring provides an opportunity to educate and develop researchers, enhance quality processes and also prepare them for external funding or regulatory body audit processes.

Monitoring of research may take various forms, including reports from researchers; review of safety reports; reports from independent agencies including Data and Safety Monitoring Boards and on-site monitoring of research which involves the review of study site files, consent documentation, source documents and research data.

All Metro North staff (permanent, temporary and casual) and external stakeholders conducting research projects approved by a Metro North HREC or authorised to be conducted at a Metro North facility are expected to refer to and comply with the Metro North procedure Research: Monitoring (PROC004412).

2. Financial management

The principles for the management of research funds in Metro North are aligned with the Code, including the principle of **accountability** for the development, undertaking and reporting of research:

- comply with relevant legislation, policies and guidelines
- ensure good stewardship of public resources used to conduct research
- consider the consequences and outcomes of research prior to its communication.

The Code outlines the expectation that researchers will uphold the principles of responsible research conduct in all aspects of research. To this end, researchers will *comply with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible research conduct*. Compliance with the Code is a prerequisite for receipt of NHMRC and Australian Research Council (ARC) funding. The Principal Investigator (PI) and all researchers are responsible for:

- ensuring transparent and accountable management of research funds
- the management of costs associated with their research and for reporting financial outcomes.

Under the *Financial Accountability Act 2009* (Qld), Metro North must be accountable for all funds being managed internally. Metro North employees must ensure they behave ethically when engaging in the use of public monies for the purposes of research. The *Public Sector Ethics Act 1994* establishes the following fundamental ethical obligations:

- integrity and impartiality
- promoting the public good
- commitment to the system of government
- accountability and transparency.

At all times, there exists an overriding principle regarding the use of public monies, that all decisions and actions must be publicly defensible. Expenditure must be undertaken ethically, honestly and fairly.

Those responsible for the financial management and accountability of research funds are expected to refer to and comply with the Metro North procedure Research: Financial Management (PROC004413).

3. Conflict of interest

A conflict of interest arises where an individual could be motivated to act against their professional obligations or responsibilities by interests apart from those obligations and responsibilities. It is 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.

Conflicting interests can damage research in a variety of ways. They can 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 are relatively common but can only be managed if they are declared. Any conflicts of interest should be declared as part of any of the following activities:

- Human Research Ethics Committee (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.

A conflict of interest may be actual, perceived or potential and requires defining when being considered. In all cases a full disclosure of the circumstances giving rise to a conflict of interest situation are required.

A conflict of interest may include: conflict of roles, private interests, personal relationships and personal benefits arising from the research.

All Metro North staff, whether permanent, temporary and casual, who participate in research activities, scientific and grant review processes and committees, and all members of a HREC are expected to refer to and comply with the Metro North procedure Research: Conflict of Interest (PROC004414).

4. Intellectual property

Intellectual Property is an important asset in the provision of health services in the twenty-first century and is an integral component of Metro North' research strategy, teaching functions, and to its broader operations to support research innovation activities.

Metro North is committed to appropriate and responsible creation, management and commercialisation of Intellectual Property in order to maximise positive health outcomes by promotion of knowledge transfer to commercialise its research outputs where appropriate, to facilitate and encourage access of others to such innovation.

Where possible and appropriate, Metro North aspires to the principles of:

- Recognising the creative efforts of employees, students and visitors.
- Using Intellectual Property for the maximum benefit of the public health sector.
- Minimising legal and commercial risks in relation to Intellectual Property.
- Ensuring collaborations and the handling of research and development commercialisation matters with employees in relation to Intellectual Property are fair, reasonable and ethical.
- Taking account of the wishes of inventors, authors and contributors of Intellectual Property of the Metro North.

These five principles shall guide the overarching approach to Intellectual Property by the Metro North.

All staff, students and visitors engaged in the creation, management or commercialisation of Intellectual Property associated with Metro North research are expected to refer to and comply with the Metro North procedure Research: Intellectual Property (PROC004415).

5. Authorship

Metro North adheres to the Code in relation to its research activities and its obligation to support publication and dissemination of research outcomes to the research and wider community. Under the Code, researchers have a responsibility to appropriately acknowledge the role of others in research and to responsibly communicate research results and outcomes. As a result, authorship of a scientific communication is a role that comes with responsibilities to ensure the accurate reporting of findings.

Metro North expects that where appropriate, all who are involved in research will aspire to the following principles regarding research authorship:

- Fairness – appropriate credit, including authorship, will be given to those who have contributed to research; the work of others will be appropriately referenced and cited.
- Contribution – to be named as an author, an individual must have made a substantial scholarly contribution to the work and be able to take responsibility for at least that part of the work to which they contributed.

- Active Inclusion – all persons designated as authors must qualify for authorship, and all who qualify must be offered authorship. A person who qualifies as an author must not be included or excluded as an author without their written permission.
- Agreed Understanding – collaborating researchers should agree on authorship of a publication as early as reasonably possible in the research project, and this should be reviewed periodically throughout the project.

It is expected that all Metro North staff, whether permanent, temporary or casual, who participate in research activities will determine the authorship of research publications and resolution of disputes in accordance with the Metro North procedure Research: Authorship (PROC004416).

6. Responsible reporting

In accordance with the Code, researchers within Metro North undertake to responsibly communicate and disseminate the outcomes of all research undertaken within its facilities to contribute to the collective knowledge base and to extract maximum benefit from the research activity for the health service and the academic community.

The overarching purpose of research is to generate new knowledge that leads to benefits for effective and efficient delivery of quality patient care. Those who undertake research within the have a responsibility to undertake informed, well designed and executed research that addresses knowledge gaps and generates outcomes that have potential to be translated into health care advances. There is an obligation to publish research outcomes and disseminate results of research to a wide range of relevant audiences including academic peers, the health sector and the community.

The procedure for responsible and complete reporting of all research undertaken by Metro North researchers are outlined in the Metro North procedure Research: Responsible Reporting (PROC004417)

7. Honorary appointments, research students and visitors

Metro North regularly receives requests to accept individuals who are not employed by the into Metro North facilities for the purpose of contributing to research activities. Such requests may include:

- Individuals engaged on an honorary basis from other hospitals, academic institutions or organisations or otherwise personally; or
- Research students enrolled in universities; or
- Individuals invited as a visitor or observer.

In the interests of patient safety, facilities have an obligation to ensure that all persons engaged within Metro North for research activities comply with relevant Metro North policies, work place health and safety and patient confidentiality requirements.

Accordingly, it is a requirement that individuals who are not employed by Metro North, but are engaged in an honorary appointment, as a research student or as a visitor be subject to certain terms and conditions during any engagement within Metro North facilities for the purposes of research.

All Metro North staff, whether permanent, temporary or casual, that engage, supervise and interact with honorary research appointees, research students and visitors are expected to adhere to the procedure Research: Honorary Appointments, Students and Visitors (PROC004418). This procedure also applies to those honorary research appointees, research students and visitors.

8. Partnership and collaboration

Metro North supports local, national and international collaborative research and partnerships with health services, academic institutions and commercial organisations.

It is a key priority of the Metro North Research Strategy, to establish strategic partnerships and research collaborations with organisations including Hospital and not-for-profit Foundations, Universities, Research Institutes, Government and industry.

Metro North values the benefits to clinical service that research collaboration and partnership affords, including the potential to enrich and educate staff, access and use of additional skill sets, the creation of new knowledge and increased capacity to provide excellent, evidenced-based quality health care services.

The following principles are to be applied for effective partnerships and collaboration:

- Balanced Contributions: Research collaborations and partnerships built on mutually beneficial contributions from Metro North researchers and other organisations.
- Extending Capability: Partnerships between organisations facilitates access to a wider skill base and enhances capacity to co-create new knowledge, for the benefit of patients.
- Shared Objectives: Relationships based on a desire to meet the strategic objectives and shared interests of two or more organisations form the basis of productive partnerships.
- Clarity: Effective research collaborations and partnerships consider from the commencement of discussions the level and type of engagement which is expected of researchers, students, visitors, commercial partners and academic institutions.
- Agreement: Research collaborations and partnerships may involve a specific research collaboration agreement that outlines the expectations of both parties regarding responsibilities, confidentiality, collaborative research activities and any transfer of data or materials between institutions.

All Metro North employees are expected to adhere to the procedure Research: Partnership and Collaboration (PROC004419) for all aspects of collaborative research.

9. Gender equity

Metro North strives to enhance its research capability and consolidate the organisation's position as a world-class provider of healthcare by attracting and retaining highly competent clinicians and research leaders. Metro North aims for its clinical care and research to be enriched and informed by a diversity of perspectives afforded by the inclusion and success of women engaged in research at all levels of experience. In the context of existing policies to support diversity and inclusion in its workforce, and through active leadership, Metro North commits to improve gender equity through application of the following principles:

- Diversity and inclusion: Metro North research excellence benefits from supporting the talents of all researchers irrespective of gender and other diversity factors.
- Active leadership: Gender equity in research requires active leadership from all levels of the organisation and from men and women in senior roles.
- Excellence: Research excellence is achieved through the support for the highest quality researchers, irrespective of gender.
- Equity: Equal opportunities and capacity for participation in research enables success for all researchers.
- Flexibility: Flexible conditions of award as part of an organisational culture that supports career-life balance decisions for researchers.
- Mentorship and peer support: Mentorship of women in research, particularly early and mid-career researchers, is advantageous to success and career advancement.

The Metro North procedure Research: Gender Equity (PROC004420) provides a framework to support gender equity in research, and compliance with this procedure is mandatory.

10. Complaints and breaches of the Code

It is expected that all who are responsible for research in Metro North will adhere to this policy and the associated Metro North Research Procedures to ensure their research is of the highest ethical and scientific standard, and complies with the relevant legislation, regulatory guidelines, codes of conduct, national best practice guidelines, Standard Operating Procedures and institutional policies.

Metro North has a responsibility to manage concerns about the conduct of research performed under the scope of this policy, and is responsible for investigating concerns, complaints or allegations of breaches of the Code. Management of all complaints must be sensitive to and carefully consider the rights, needs and concerns of all involved including the complainant, research participants, patients and researchers. In all cases, and at all times, complaints should be handled with careful attention to the principles of procedural fairness and determined on the balance of probabilities:

- Proportional: Investigations into allegations and subsequent actions need to be proportional to the extent of the complaint.
- Fair: Investigations should afford procedural fairness at all stages in the process to respondents and, where appropriate, complainants and others who may potentially be adversely affected by any investigation.
- Impartial: Investigators and decision makers are to be impartial in any conflicts of interest that do, may, or may be perceived to jeopardise their impartiality should be disclosed and managed.
- Timely: Investigations into allegations should be conducted in a timely manner to avoid undue delays and the possible damaging effects on those involved that can result from drawn-out and unresolved investigations and decision-making.
- Transparent: Institutional processes should be readily available and/or provided to respondents, complainants, all employees and students engaged in research.
- Institutions need to ensure accurate records are maintained for all parts of the process, with records held centrally and in accordance with the relevant legislation.
- Confidential: Information should not be shared unless required.

All Metro North staff and external stakeholders who intend to discuss or raise a complaint regarding Metro North research are expected to, in the first instance, refer to the Metro North procedure Research: Complaints and Breaches of the Code (PROC004421) for further guidance.

11. Biobanking

The purpose of Biobanking is to generate and store are large collections of human biological materials (biospecimens) linked to relevant personal and health information, specifically for use in ethically approved health and medical research (NHMRC Biobanks Information Paper, 2010). Biobanks provide a valuable research resource to advance our understanding of complex human disease and to generate new knowledge that underpins future advances and implementation of personalized and precision medicine. Establishing quality biobanking systems is integral to our capacity to contribute to local and national biobank networks (National Research Infrastructure Roadmap 2016). It is expected that biobanks within Metro North will adhere to the following principles.

- Sustainable biobanks provide valuable biospecimen resources for current and future research to generate new knowledge and advance capacity to diagnose and treat complex human disease.
- Implementation and adherence to quality processes and management systems are fundamental to maintaining effective biobanking.
- Shared access to collected biospecimens by qualified and capable researchers for ethical research purposes maximises the value of biobanks for the benefit of the health service, researchers and patient community.

- Careful curation of biospecimens and associated data maximises the utility of biobanks and enhances research efficiency and productivity to maximise return on investment in biobanking.

The Metro North Procedure Research: Biobanking provides a framework for the principles of biobank management.

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 (if required)

Term	Definition
Allegation	A claim or assertion arising from a preliminary assessment that there are reasonable grounds to believe a breach of the Code has occurred. May refer to a single allegation or multiple allegations.
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.
Clinical record	A collection of data and information gathered or generated to record the clinical care and health status of an individual or group. Also referred to as a Patient Chart, Patient Record, Medical Record, Healthcare Record, Current Encounter Chart (CEC).
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
Collaboration	A working relationship between researchers who together engage in research. A collaboration may occur between researchers internal or external to the one organisation and may be guided by formal agreements for a specific project.
Collaboration Agreement	An agreement made between Metro North and another entity for the purpose of performing research. For clarity, this definition does not include an employment agreement with an employee of Metro North.
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)
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]

[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.

	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.
Contributor	A person, body or institution who has enabled the research to be completed either through provision of facilities, funding, data collection and management, supervision, mentorship, statistical support, technical writing who has not made other contribution that would constitute authorship as defined in this document.
Ethical Review Manager (ERM)	The Ethical Review Manager (ERM) website is an online system that enables users to complete their research ethics applications for research electronically. The website hosts a licensed copy of the NHMRC's Human Research Ethics Application Form (HREA) for electronic submission to review committees within Queensland Health, Victoria and Mater Brisbane, as well as the Qld Health and Victorian Site-Specific Assessment (SSA) Form, Qld's Public Health Act Application (PHA) and the Victorian Specific Module (VSM). https://au.forms.ethicalreviewmanager.com
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.
Gender Equity	Women and men enjoying the same status; the same opportunities are available for both women and men to realise their full human rights and potential.
Honorary Appointment	An individual who requires access to a Metro North facility, service or patients, is engaged on a non-remunerated basis by Metro North for the purposes of research activities and is not a Metro North employee. Honorary appointees may be employed (remunerated) or engaged by a university, research institute, another hospital and health service, private or non-government organisation for the purposes of research. Honorary appointees may be engaged in roles including, but not limited to, research assistants, associates, fellows, clinical/research coordinators and similar positions.
HREC Administrator	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. The terms HREC Coordinator and HREC Administrator are interchangeable.
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
Monitoring	The process of verifying that the conduct of research conforms to the approved research proposal through the confirmation of adherence to appropriate processes, collection of quality research data, appropriate record keeping, access and storage of research records. It also ensures relevant HREC, governance and regulatory compliance.
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.
Partnership	A research partnership involves engagement between two or more organisations who share a common purpose and whose researchers and decision-makers work collaboratively together to create better health services and health outcomes through generating or sharing research knowledge. Partnerships may involve organisations from different sectors; health service, academia, industry or non-government organisations.
Patient	An individual who receives, or has received, care treatment or other services through a Metro North facility.
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).
Procedural fairness	That a fair and proper procedure is used when making a decision.
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 Monitor	Position independent to the research team, appropriately qualified by training and experience to conduct Monitoring Visits, with their qualification documented (ICH GCP 5.18.2).
Research Monitoring	The process of verifying that the conduct of research conforms to the approved research proposal through the confirmation of adherence to appropriate processes, collection of quality research data, appropriate record keeping, access and storage of research records. It also ensures relevant HREC, governance and regulatory compliance.
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.
Visitor	An individual not employed by Metro North who is invited to attend a clinical facility within Metro North for the purposes of research.

Document History

Author	Executive Director, Research Metro North
Custodian	Executive Director, Research Metro North
Compliance evaluation and audit	HREC & RGO annual reporting. Annual compliance reporting from related procedures will be collated and reported by the Executive Director, Research Metro North to the Chief Executive.
Replaces Document/s	POL004365 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, Human Research Ethics Committee (HREC), Research Governance, Monitoring, Financial management, Conflict of Interest, Intellectual Property, Authorship, Honorary Appointment, Research student, Visitor, Partnership Collaboration, Gender Equity, Data management, Biobank, Complaints, Breach, Ethics, Governance.

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AUTHORISATION

Signature Date

Chief Executive, Metro North Hospital and Health Service

The original signed version is kept in file at Clinical Governance Safety Quality and Risk, Metro North.