Policy

Effective from: December 2024
Review date: June 2026

Research 004365

NSQHS STANDARDS 1. Clinical Governance

Policy statement

Metro North Hospital and Health Service (Metro North Health) strives to deliver exceptional health outcomes through globally recognised discovery and translation of research. Metro North Health is committed to the highest standards of research integrity and expects all those who conduct research to comply with this policy.

This policy sets the framework for responsible and ethical design, conduct and communication of research by incorporating the principles outlined in national guidelines, legislation, national and international regulatory guidelines, policy, guidelines and directives as they relate to research.

Purpose and intent

The purpose of this policy is to ensure all research conducted by, or in collaboration with, Metro North Health 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 as they relate to research. 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 Health 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 Health.
- all settings across the health continuum including community, primary, acute, rehabilitation and residential care health services within Metro North Health.
- any person/external entity undertaking research at a Metro North Health facility and/or involving Metro North Health patients, staff and/or resources and infrastructure.

Activities deemed not research are considered out of scope of this policy.

Principles

This policy sets the framework for responsible and ethical design, conduct and communication of research by incorporating the principles outlined in national and international regulatory guidelines, state and federal legislation, policy, procedure and directives related to research.

This policy provides a framework for research integrity in Metro North Health and is based on the National Health and Medical Research Council (NHMRC) principles and values outlined in the:

- *National Statement on Ethical Conduct in Human Research 2023* (National Statement)
- *The Australian Code for the Responsible Conduct of Research* (the Code)
- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018* (Ethical Conduct)
- *Keeping research on track II 2018* (Keeping research on track).

It is expected that all who are responsible for research will adhere to the principles and values outlined in these key documents for the design, review, conduct and communication of research in Metro North Health.

Research approvals

Within Metro North, all research must obtain the requisite approvals prior to commencing and comply with all post-approval reporting requirements to maintain research approvals:

- All research conducted with or about people, their data or tissues, must obtain **Human Research Ethics Committee (HREC) review** from an appropriately certified HREC;
- All research conducted at a Metro North facility and/or involving Metro North Health patients, staff and/or resources and infrastructure, must receive **Site-authorisation** by the Chief Executive (CE) or relevant delegate for each facility.
- All research must comply with the **post-approval reporting** requirements as outlined in the relevant HREC and/or site authorisation approval documentation.

HREC review and Site authorisation processes in Metro North Health will be transparent, accountable and undertaken in accordance with legislative, policy and regulatory requirements.

The Principal Investigator (PI) of a research project is responsible for ensuring all requisite approvals are in place before undertaking research and complying with all post-approval reporting requirements.

All researchers have a responsibility to become familiar with the guidelines, codes, regulatory, legislative and policy requirements prior to submitting applications.

Research that commences without the requisite ethics and governance authorisation or that is found to not comply with post-approval reporting requirements is considered a breach of the Code and may also constitute a breach of State or Commonwealth legislation, including associated regulations, standards and/or policy. Research conducted without the requisite authorisations will be suspended while a preliminary assessment is undertaken by the delegate at the facility where the breach is identified.

Human Research Ethics Committee (HREC) review HREC review ensures all human research conducted in Metro North Health is ethically acceptable in accordance with the National Statement, codes for working with Aboriginal and Torres Strait Islander peoples, and relevant legislative and regulatory standards and national guidelines.

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

Metro North Health 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.

No human research shall commence until the HREC review process has been completed and a HREC approval letter from the reviewing HREC is received.

HREC's do not provide ethical review and approval for research that does not involve humans, their data or their tissue. Research that involves animals, must obtain requisite approval from the relevant institutional ethical review board or committee. All research that is conducted at a Metro North facility and/or involves Metro North Health resources and infrastructure, must obtain site authorisation prior to commencing.

Site authorisation

Site authorisation provides approval by the Chief Executive or appropriate delegate to undertake research and is required at each site (HHS or institution) where research will be undertaken. Also referred to as research governance, site-authorisation incorporates institutional due diligence processes that assess legal, financial, resource, regulatory and contractual considerations of a research project and ensures all research conducted under the auspices of Metro North Health is properly assessed, accounted for, and governed.

Applications for site authorisation must be submitted on a Site-Specific-Assessment (SSA) application form linked to the HREA application in ERM: https://au.forms.ethicalreviewmanager.com

Applications will be submitted for review by a Research Governance Officer (RGO) prior to CE or delegate authorisation. Metro North Health RGOs operate under the minimum standards for research governance review outlined in the standard operating procedures for Queensland Health RGOs.

Metro North Health requires site authorisation of human research be considered as applications for ethical review are submitted to the HREC, known as parallel review. Site authorisation is contingent upon receipt of HREC approval.

Research shall not commence until an SSA approval letter granting site authorisation from the HHS CE or delegate is received at each site where the research will be undertaken.

Post approval reporting

Metro North Health is responsible for ensuring all research approved by a Metro North Health HREC and/or with site authorisation to be conducted in Metro North Health facilities is appropriately monitored.

Monitoring of approved research protects the safety, rights and well-being of research participants and verifies the accuracy and quality of research data and record keeping requirements, including access and storage of research data.

Research monitoring ensures Metro North Health satisfies its responsibilities under the *National Statement*, *the Code* and Good Clinical Practice (ICH-GCP E6 (R2)). Monitoring ensures regulatory compliance by the institution and preparation for external funding or regulatory body audit processes, and provides confirmation of adherence to, and quality assurance of, researchers' compliance with approved protocol and documentation, relevant contractual arrangements and regulatory approvals.

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 study site files, consent documentation, source documents and research data.

Researchers have an obligation to research participants, the approving HREC and RGO(s) to meet post-approval reporting and monitoring requirements. Metro North Health researchers must ensure relevant annual and safety reports are submitted to the approving HREC and RGO(s), at the type and frequency prescribed by the approving HREC and relevant RGO.

For research approved by a Metro North Health HREC, researchers are required to submit a progress report on at least an annual basis for ongoing ethical approval and/or site authorisation. The annual report is due by 30th of April and should be submitted to the approving HREC and Metro North Health RGO on the correct template.

For projects approved by an external HREC, annual reporting requirements will be prescribed by the external HREC. The external annual report may also be submitted to the approving Metro North Health RGO, provided it includes details of recruitment numbers and activity at the Metro North Health site.

Unless otherwise stipulated in the approval letter, the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)* applies to safety monitoring and reporting of clinical trials being conducted by or at Metro North Health that involve therapeutic goods.

At the conclusion of a study, a Final Report together with a copy of the final results and details of any publications must be submitted to both the approving HREC and the relevant RGO(s).

Research integrity

Research integrity broadly refers to the scientific integrity of research and the professional integrity of the individuals who are responsible for research. Research integrity enables the community to have confidence and trust in the methods and the findings of research and more broadly in the scientific endeavour. Research integrity requires all those who undertake, administer, review and/or govern research involved in Metro North Health be aware of, understand, comply, and act in accordance with this policy.

The *National Statement* outlines the values of *respect*, *research merit and integrity*, *justice* and *beneficence* that shall inform and guide the ethical design, review, conduct and communication of research. It provides guidelines for researchers and those conducting ethical review of research and is applicable in the broader context of overall research governance. It emphasises institutions' responsibilities for the quality, safety, and ethical acceptability of research they sponsor or permit to be carried out under their auspices.

The Code establishes a framework for responsible research conduct by providing a foundation for high-quality research, credibility, and community trust in the research endeavour. Metro North Health has an obligation to encourage and support responsible research conduct through adherence to the specific institutional responsibilities and researcher responsibilities outlined in the Code. The Code is also supported by guides on specific topics to encourage responsible research conduct.

The guidelines *Ethical Conduct* and *Keeping research on track* work together with the *National Statement* and *the Code* to provide relevant advice and more specific information about ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities. They should be read alongside the *Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research 2020*. Together, these guidelines provide a framework for how researchers and participants should be working together on research with Aboriginal and Torres Strait Islander Peoples and communities.

The *National Statement, the Code, Ethical conduct* and *Keeping research on track* do not address all the mandatory requirements for research approval, compliance, and integrity. It is the responsibility of all parties who undertake, administer, review and/or govern research involving Metro North Health to be aware of, understand, and comply with the relevant legislation, codes of conduct, national best practice guidelines, standard operating procedures, and institutional policies and procedures as they relate to research.

Conflict of interest

A conflict of interest exists where an independent observer might reasonably conclude the professional actions of a person are or may be unduly influenced by other interests. The identification and management of a conflict of interest in research is necessary to maintain the integrity and reliability of research conduct and outcomes, mitigate risks associated with complex relationships between researchers and public and private organisations, and ensure public trust in individuals and organisations involved in research.

All Metro North Health employees have a responsibility to disclose 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.

All Metro North Health employees have an obligation to abide by the Metro North Health Policy 003365 Conflicts of Interest. The Procedure 003366 Conflicts of Interest, Declaring and Reporting provides the operational process for declaring and managing a conflict of interest, including the consequences for not disclosing, managing, or resolving a conflict of interest.

Authorship

Researchers have a responsibility to disseminate and communicate research findings responsibly, accurately and broadly in ways that contribute to public knowledge and understanding and permit scientific scrutiny of the findings. These findings may be communicated or made available through hardcopy, electronic or other formats as research outputs, including journal articles, book chapters, books, conference papers, reports, datasets, patents and patent applications, or other documents related to research such as research proposals, grant applications, reports, tenders, patents, and patent applications etc.

Authorship of research outputs, in particular research journal articles, confers credit and has important academic, social and financial implications. An author is an individual who has made a significant intellectual or scholarly contribution to research and its output, and who agrees to be listed as an author. A significant scholarly or intellectual contribution must include at least one, and should ideally include a combination of two or more of the following contributions:

- substantial contribution to the conception and design of the project or output
- acquisition, analysis or interpretation of research data, where significant intellectual judgement, planning, design or input was required
- contribution of knowledge, where justified, including Indigenous and consumer knowledge
- drafting significant parts of the research output or critically revising it for important intellectual content so as to contribute to its interpretation.

Authorship must not be attributed without a significant intellectual or scholarly contribution to the research output and, as a general rule those who have made a significant intellectual or scholarly contribution should be named as authors. Researchers are required to demonstrate fairness in the treatment of others and give credit, including authorship where appropriate, to those who have contributed to research.

Metro North Health expects that attribution of authorship will be an honest reflection of contribution to research, assigned fairly, and consistent with established disciplinary practice such as the International Committee of Medical Journal Editors (ICMJE) guidelines, and be communicated clearly and transparently between contributors of the research. All authors have an obligation to provide final approval of the version to be published and agree to be accountable for all aspects of the work. This includes ensuring questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Researchers must also recognise the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular significance to them and credit the contribution of Indigenous peoples and their knowledge. Metro North Health expects researchers to understand and apply the principles set out in the *Ethical conduct in human research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* in order to ensure research is safe, respectful, responsible, high quality and of benefit to Aboriginal and Torres Strait Islander people and communities. Recognising and acknowledging the individual and collective contribution of Aboriginal and Torres Strait Islander participants and groups is a core research integrity authorship principle.

Where there are concerns regarding authorship, Metro North Health staff are to refer to Metro North Health Human Resources Raising a workplace complaint or grievance: Employee Guide. The NHMRC guideline, *Authorship. A guide supporting the Australian Code for the Responsible Conduct of Research* supports

implementation of, and adherence to the Code, and provides further information regarding the responsibilities of researchers.

Financial management

The principle of accountability for the development, undertaking and reporting of research to ensure good stewardship of public resources used to conduct research is a hallmark principle of *the Code*.

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 NHMRC, the Australian Research Council (ARC), and Universities Australia. Compliance with the Code is a prerequisite for receipt of NHMRC and ARC funding.

Metro North Health is accountable for all funds managed internally, as per the *Financial Accountability Act 2009* (Qld). Metro North Health employees must ensure they behave ethically, honestly, and fairly when engaging in the use of public monies for the purposes of research. All decisions and actions regarding the use of public monies for research must be publicly defensible.

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

All employees who form a reasonable suspicion of fraudulent and corrupt conduct shall immediately report it to the most appropriate line manager, another Senior Executive or to the Integrity Unit in accordance with the Requirements for reporting suspected corrupt conduct as per the Metro North Health Requirements for Reporting Corrupt Conduct Policy 004227.

Intellectual property

Metro North Health is committed to appropriate and responsible creation, management and commercialisation of Intellectual Property (IP) in order to maximise positive health outcomes for our patients and the community. Metro North Health aspires to the use of IP for the maximum benefit of the public health sector and minimising the legal and commercial risks in relation to IP.

In accordance with general law principles, unless otherwise agreed, Metro North Health owns all IP created by employees in pursuance of the terms of their employment or using materials and resources of Metro North Health.

Aboriginal and Torres Strait Islander cultural and intellectual property is recognised in the *AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies 2012*. The rights of Indigenous peoples to their intangible heritage must be recognised, and research should be conducted in accordance with the principle of Indigenous peoples' rights to maintain, control, protect and develop their intangible heritage, including their cultural heritage, traditional knowledge, traditional cultural expressions and IP.

Rights in the traditional knowledge and traditional cultural expressions of Indigenous peoples must be respected, protected and maintained. Indigenous traditional knowledge and traditional cultural expressions are part of the heritage that exists in the cultural practices, resources and knowledge systems of Indigenous peoples, and that are passed on by them in expressing their cultural identity. To respect, protect and maintain these rights, researchers must have a good understanding of the nature of Indigenous traditional knowledge systems, traditional cultural expressions and IP.

This means anything that is written, spoken or created by Aboriginal and Torres Strait Islander Peoples, whether it is a story, a painting, a sculpture, an object, a dance, a song, or music (cultural practices) and any knowledge of their land, culture or kinship that is used to express their cultural identity, should be considered the cultural and IP of the contributor (and, potentially, their community) and should be respected as such. It is acknowledged that Aboriginal and Torres Strait Islander Peoples' IP continues to expand via

inclusion of contemporary creative and original works that have originated from Aboriginal and Torres Strait Islander cultural heritage.

Breaches of the Code

It is the responsibility of all those involved in research to ensure research conducted under the scope of this policy is of the highest ethical and scientific standard. Compliance with the relevant legislation, regulatory guidelines, codes of conduct, national best practice guidelines, Standard Operating Procedures and institutional policies and procedures, both as they relate to research and the broader health service context, are essential to this endeavour and the foundation of research integrity.

Metro North Health has a responsibility to manage concerns and investigate complaints or allegations regarding the conduct of research performed under the scope of this policy. This includes a potential breach of the *Australian Code for the Responsible Conduct of Research* (the Code). As research forms an intrinsic part of Metro North Health activities, service delivery, models of care and clinical practice, a complaint or allegation of a breach of the Code may also constitute a breach of the legislative and policy frameworks governing Metro North Health, including the Queensland Government's Public Service Code of Conduct.

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* sets out a model for managing and investigating potential breaches of the Code. It recognises that institutions need to consider the legal framework within which they are operating, as established workplace policy and processes may prevail over the NHMRC Guide.

The Metro North Health People & Culture resources for resolving workplace concerns: *Raising a workplace complaint or grievance: Employee Guide*; *Receiving a workplace complaint or grievance: Employee Guide*; and *Resolving Workplace Concerns: Manager Guide*, provide the framework for raising, receiving, and resolving workplace complaints, concerns or grievances in Metro North Health. These resources have been identified as meeting the appropriate benchmark set by the NHMRC Guide.

A Metro North Health Research delegate, for example a Facility Director of Research, is to be consulted, and given the opportunity provide research expertise, into the institutional processes regarding matters that involve research. This oversight and continual input is necessary to ensure there is an appropriate assessment as to whether a breach of the Code has occurred with respect to the principle of 'proportionality' set out in the Guide, and to ensure that conduct that is assessed as potentially breaching the Code is notified, or referred for further action to the relevant external institutions such as the ARC or the NHMRC.

Consumer engagement in research

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.

Ideally consumers should be involved from the research conception phase, when identifying and developing the research priorities and questions, throughout the conduct and implementation of research, to the dissemination and reporting of research findings, with the consumer role negotiated and clearly defined for each project. Metro North Health researchers can refer to the following documents for specific guidance:

- NHMRC Statement on Consumer and Community involvement in Health and Medical Research
- Metro North Health - Co-design Framework
- Consumer engagement in research
- Metro North Health - Collaborating in Health Strategy 2022-2024

Metro North Health staff can refer to the Consumer Engagement Policy and Reimbursement and Payment procedure for guidance on remuneration for the time and expertise of consumers where appropriate.

Financial considerations for consumer engagement activities should be considered early and built into research budgets and funding applications.

Aboriginal and Torres Strait Islander considerations

Metro North Health is committed to ensuring research and innovation will be the driver of improved health outcomes for Aboriginal and Torres Strait Islander people. The considerations for the ethical design and conduct of research with Aboriginal and Torres Strait Islander peoples are embedded throughout this policy.

The 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.

Legislation and other authority

Hospital and Health Boards Act 2011 (Qld)

Human Rights Act 2019 (Qld)

Industrial Relations Act 2016 (Qld)

Information Privacy Act 2009 (Qld)

National Health and Medical Research Council Act 1992 (Cth)

Public Health Act 2005 (Qld)

Public Records Act 2002 (Qld)

Public Sector Ethics Act 1994 (Qld)

Public Service Act 2008 (Qld)

Work Health and Safety Act 2011 (Qld)

Copyright Act 1968 (Cth)

Designs Act 2003 (Cth)

Patents Act 1990 (Cth)

Trade Marks Act 1995 (Cth)

Circuit Layouts Act 1989 (Cth)

National Statement on Ethical Conduct in Human Research (2023)

The Australian Code for the Responsible Conduct of Research (2018)

Ethical Conduct in research with Aboriginal and Torres Strait Island people and communities: Guidelines for researchers and stakeholders (2018) and Keeping research on track II 2018

Statement on consumer and community involvement in health and medical research (2016)

National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (2021)

International Council for Harmonisation Guidelines for Good Clinical Practice (ICH-GCP)

ISO 14155:2020 Clinical investigations of medical devices for human subjects – Good Clinical Practice.

Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)

NHMRC Guidelines: Data Safety Monitoring Board (2018)

NHMRC Risk-based Management and Monitoring of clinical trials involving therapeutic goods (2018)

NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)

NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research January 2012

NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review December 2011

Related documents

Queensland Health Digital Policy Use of ICT services & devices

Queensland Health Digital Standard Use of ICT services & devices

Queensland Health Digital Standard Information access, use and disclosure

Queensland Health Digital Standard Use of Email standard

Metro North Health Human Resources Resolving Workplace Concerns: Managers Guide

Metro North Health Human Resources Resolving a workplace complaint or grievance: Employee Guide

Metro North Health Human Resources Raising a workplace complaint or grievance: Employee Guide

Metro North Health Policy - Conflicts of Interest 003365

Metro North Health Procedure - Declaring and Managing Conflicts of Interest 003366

Metro North Health Procedure - Research: Financial Management 004413

Appendix 1 – Definition of terms

Term	Definition
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.
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.
Consumer	A consumer is a person who has used, or may potentially use, health services, or is a carer for a patient using health services. A consumer representative is a person who provides a consumer perspective, contributes consumer experiences, advocates for the interests of current and potential health service users, and take part in decision-making processes. Healthcare professionals or clinicians, such as Visiting Medical Officers, are not considered consumers in the context of the NSQHS Standards. Source: Australian Commission on Safety and Quality in Health Care
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

[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.

Term	Definition
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.
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 2003* (Cth) Inventions under the *Patents 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 Health	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

Term	Definition
	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 2023* 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.
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 Health 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).
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

Term	Definition
	• 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 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.
Researcher	A person(s) who conducts, or assists with the conduct of, research.

Term	Definition
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	Research Strategy Officer, Metro North Research
Custodian	Executive Director Research, Metro North Health
Risk	**Likelihood –** Rare **Consequence –** Minor **Risk Rating –** Low (4)
Compliance evaluation and audit	HREC Approval SSA Approval HREC Annual Report
Replaces Document/s	Policy 004365 Research V2.0 01/2023
Changes to practice from previous version	Minor review and update of hyperlinks. Reference to all stages of research approval (ethics, governance and post-approval reporting approvals).
Education and training to support implementation	The Metro North Research Office will publish help guides and Frequently Asked Questions (FAQs) on the Metro North Research website.
Consultation	**Key stakeholders** Research Governance Officers (RGO) Metro North Human Research Ethics Committee (HREC) Facility Directors of Research **Broad Consultation** facilitated through the following**:** Metro North Aboriginal and Torres Strait Islander Leadership Team Metro North Clinical Governance, Safety, Quality and Risk Digital Metro North Metro North Medical Services Metro North Nursing and Midwifery Services Metro North Allied Health Metro North Communication Metro North Finance Metro North People and Culture Metro North Workplace Health and Safety Metro North Legal Services Metro North Risk and Compliance Officer Metro North Clinical Streams Metro North Engage Health Excellence Innovation Unit

	Clinical Directorate Safety and Quality Units Clinical Skills Development Centre
Marketing Strategy	A Metro North 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, Ethics, Research Governance, Site Authorisation, Financial Management, Conflict of interest, Intellectual Property, Breaches of the Code, Authorship, Monitoring, Human Research Ethics Committee, HREC, Researcher, Principal Investigator, Clinical Trial; 004365

Custodian Signature Date

Executive Director Research, Metro North Hospital and Health Service

Authorising Officer Signature Date

Executive Director, Clinical Services, Metro North Hospital and Health Service

AUTHORISATION

Signature Date

Chief Executive, Metro North Hospital and Health Service

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