Metro North Research

Procedure

Effective from: December 2019
Review date: December 2020

Research: Monitoring PROC004412

Purpose and intent

Metro North Hospital and Health Service (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 Human Research Ethics Committee (HREC), governance and regulatory compliance.

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.

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.

Scope and target audience

This procedure applies to:

- all Metro North Hospital and Health Service (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)
- all settings across the health continuum including community, primary, acute, rehabilitation and residential care health services within Metro North
- all external stakeholders conducting research activities approved by a Metro North HREC or authorised to be conducted at a Metro North facility.

Procedure

Monitoring of research may be conducted by:

- the researcher(s)
- Metro North Research Monitoring Officer
- The Royal Brisbane and Women's Hospital (RBWH) and The Prince Charles Hospital (TPCH) HREC, or
- Metro North Research Governance Officers (RGOs).

Each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored.

Research monitoring ensures that Metro North satisfies its responsibilities under the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), the Australian Code for Responsible Conduct of Research (2018) and Good Clinical Practice (ICH-GCP E6 (R2))).

By monitoring, Metro North exercises appropriate quality control over a research project and verifies that research is being conducted according to the approved protocol and documentation, relevant contractual arrangements and regulatory approvals.

The frequency and type of monitoring will reflect the degree of risk to research participants and will encompass ongoing education of researchers in the responsible and ethical conduct of research.

Annual/final progress reports

Submission of a progress report on at least an annual basis is a mandatory requirement for ongoing ethical approval or site authorisation.

- For projects approved by a Metro North HREC, the annual report should be submitted to the approving HREC and relevant site RGO(s) on the template located on the Metro North Research website.
- For projects approved by an external HREC, the annual report submitted to the approving HREC can be submitted to each relevant RGO, provided it includes details of recruitment numbers and activity at the Metro North site.

At the conclusion of a study, a Final Report must be submitted to both the approving HREC and each relevant RGO.

Safety reporting

Relevant safety reports must be submitted to the approving HREC and relevant RGO(s), with the type and frequency prescribed by the approved HREC or relevant RGO.

On site monitoring of research

Selection of projects

Any project being conducted at a Metro North facility could be chosen for on-site monitoring, with the following scheduling priority:

- Studies where a complaint has been received in relation to the research project
- Studies for which a potential safety concern or any other concern about the conduct of the project has been identified
- Studies with non-compliant research approvals

- Interventional clinical trials sponsored by Metro North.
- Interventional clinical trials without external on-site monitoring as arranged by the Sponsor
- A proportion of randomly selected projects from each Metro North facility

Staff involved

The Research Monitor

The Research Monitor should be independent to the research team and should be qualified by training and experience to conduct Monitoring Visits, with their qualification documented (ICH GCP 5.18.2).

Coordinating Principal Investigator and/or Site Principal Investigator

The Coordinating Principal Investigator (CPI), if located at Metro North and/or the nominated Site Principal Investigator(s) (PI) must fully co-operate with the on-site monitoring process and ensure that they respond to all queries and implement all necessary changes in the required time frame.

Members of the Research Team

The Study Coordinator or Contact Person nominated by the PI for the project at each site should be available during the Monitoring Visit to provide any documentation or answer questions as required.

Notification of on-site monitoring visit

The CPI, if located at Metro North and/or the PI will be notified in writing at least two weeks in advance if his/her study has been identified for a monitoring visit. This notification will be by way of email, to the email address stored on file in the research database.

A self-audit tool template will also be attached to the request for the monitoring visit notification, with a request that this be completed and returned by email 3 working days before the scheduled visit. The monitoring visit will be scheduled at a mutually convenient time.

Monitoring Process

1. A meeting will be arranged with the study personnel to:

- introduce the purpose of the monitoring visit
- ask any preliminary questions about the project or associated documentation
- review the site delegation log (if applicable)
- answer any questions about the monitoring process

2. The clinical trial master file or investigator site file will be reviewed to ensure that all study specific/regulatory essential documents are retained and that all required documentation has been approved or acknowledged as required by the HREC and/or relevant RGO.
3. Source data verification will be conducted including:

- reviewing informed consent forms and recruitment/consent process
- reviewing hardcopy and/or electronic hospital medical records or other system records to verify eligibility and results recorded
- reviewing case report forms
- reviewing study treatments, according to the approved Protocol
- reviewing study follow up, according to the approved Protocol

- capturing safety events and ensuring appropriate reporting of these to the relevant bodies as required.
- ensuring appropriate access of confidential medical information
- ensuring appropriate access and storage of study samples and data

4. Source data verification will be conducted on an appropriate number of participants and according to the endpoints outlined in the approved Protocol.
5. If applicable, investigational product or device storage and accountability will be reviewed.
6. A meeting with the PI and or designated Contact Person will be undertaken to discuss monitoring visit findings including recommendations or gaps in compliance. These may include:

- Protocol compliance
- Regulatory requirements
- Staff and delegated responsibilities
- Documentation in use and approval of amendments
- Recruitment and informed consent process
- Staff Training
- Issues with Investigational Product/Device retention or accountability
- Safety Reporting
- Storage of samples and study data/files
- Access to confidential health information and data protection

7. **Monitoring Report**

The Research Monitor will prepare a Monitoring Visit Report and letter. The Monitoring Visit Letter and Report will outline the findings of the visit and may include a list of recommendations or actions to be completed. The letter and report will be issued within 2 weeks of the monitoring visit.

Copies of the Monitoring Visit Report and letter will be sent to:

- The PI
- The Site Contact, Study Coordinator or other members of the study team, as agreed with the PI
- The relevant Head of Department, as appropriate
- The relevant RGO. The RGO may forward on the monitoring report to an approving HREC, as deemed appropriate
- The approving HREC, if significant issues that may impact the ongoing ethical acceptability of the study are identified

8. **Follow-up actions**

It is the PI's responsibility to ensure any necessary changes are implemented. Required actions and changes must be implemented within an agreed and timely manner. The Research Monitor and the RGO will liaise and assist the PI as needed. If issues are not resolved; the matter will be referred to the Director of Research of the relevant facility (or delegate) and if necessary, the approving HREC.

Researcher initiated monitoring of research

CPI's or clinical research coordinators who undertake approved research within Metro North may voluntarily choose to undertake their own self-audit process of their research at any time. The self-audit tool template will be made available on the Metro North Research website.

Partnering with consumers

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

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

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

Aboriginal and Torres Strait Islander considerations

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

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

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

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

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

Legislation and other authority

Anti-Discrimination Act 1991 (Qld)

Australian Institute of Health and Welfare Act 1987 (Cth)

Australian Research Council Act 2001 (Cth)

Circuit Layouts Act 1989 (Cth)

Copyright Act 1968 (Cth)

Designs Act 2003 (Cth)

Financial Accountability Act 2009 (Qld)

Financial and Performance Management Standard 2009 (Qld)

Guardianship and Administration Act 2000 (Qld)

Health Services Act 1991 (Cth)

Hospital and Health Boards Act 2011 (Qld)

Human Rights Act 2019 (Qld)

Industrial Relations Act 1999 (Qld)

Information Privacy Act 2009 (Qld)

Mental Health Act 2016 (Qld)

National Health and Medical Research Council Act 1992 (Cth)

Patents Act 1990 (Cth)

Public Governance, Performance and Accountability Act 2013 (Cth)

Public Health Act 2005 (Qld)

Public Interest Disclosures Act 2010 (Qld)

Public Records Act 2002 (Qld)

Public Sector Ethics Act 1994 (Qld)

Public Service Act 2008 (Qld)

Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)

Therapeutic Goods Act 1989 (Cth)

Therapeutic Goods Regulations 1990 (Cth)

Trade Marks Act 1995 (Cth)

Transplantation and Anatomy Act 1979 (Qld)

Work Health and Safety Act 2011 (Qld)

Workplace Health and Safety Act 1995 (QLD)

Related documents

Metro North Research Policy (POL004365)

Research: Monitoring (PROC004412)

Research: Financial management (PROC004413)

Research: Conflict of interest (PROC004414)

Research: Intellectual Property (PROC004415)

Research: Authorship (PROC004416)

Research: Responsible reporting (PROC004417)

Research: Honorary Appointments, Research Students and Visitors (PROC004418)

Research: Partnership and collaboration (PROC004419)

Research: Gender equity (PROC004420)

Research: Complaints and breaches of the Code (PROC004421)

Appendix 1- Definition of terms

Term	Definition
Annual Report/Progress Report	A report submitted by the Coordinating Principal Investigator (CPI) to relevant governing bodies documenting the annual progress and research project protocol compliance.
Author	An individual who has made a significant intellectual or scholarly contribution to research and its output and who has agreed to be listed as an author.
Authorship	Authorship refers to the attribution of contributors to academic publications. Authorship must be determined based on substantial scholarly contributions.
Breach	A failure to meet the principles and responsibilities of the Code. May refer to a single breach or multiple breaches.
Code, the	The *Australian Code for the Responsible Conduct of Research, 2018* (the Code) establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour. https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
Confidential Information	Confidential Information means any information that— (a) is about a person who is receiving or has received a public sector health service; and (b) could identify the person. *Hospital and Health Boards Act 2011* (Qld)
Confidentiality Agreement	An agreement made between Metro North and another entity for the purpose of secretly disclosing information between those parties. For clarity, this definition does not include an employment agreement with an employee of Metro North.
Coordinating Principal Investigator (CPI)	The Investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site PIs and Reviewing HREC. The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible. For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous.
Department Head	The person who supervises or directs the organisational unit in which the Researcher is engaged.
Electronic clinical record	A clinical record with data structured and represented in a manner suited to computer calculation and presentation.

	NOTE: The intended meaning of electronic clinical record is emerging. When this term is used today it implies the ability to compute the content of the record. Electronic health records are often described as records able to represent a lifetime record of health and care. Electronic health records may include records created in electronic format (born-digital records), database entries and other entities as well as digitized health records. (AS 2828.2 Health Records).
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.
Facility Executive Director	The executive officer of the Facility. At any time, the Chief Executive may step into the role described for the Facility Executive Director.
Final Report	A report submitted by the Coordinating Principal Investigator (CPI) to relevant governing bodies at the completion of a research project documenting the final project outcomes.
Good Clinical Practice (GCP)	An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants. May also be referred to as the International Conference on Harmonisation Good Clinical Practice (ICH GCP). For further information go to: http://ichgcp.net/
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.
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.
Patient	An individual who receives, or has received, care treatment or other services through a Metro North facility.
Preliminary Assessment	Used to describe the gathering and evaluating of evidence to establish whether a potential breach of the Code warrants further investigation.
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).
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.
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.
Supervisor	An individual responsible for the supervision of a research students, honorary appointee or other individual undertaking research.

Document history

Author	Executive Director, Research Metro North
Custodian	Executive Director, Research Metro North
Compliance evaluation and audit	Annual monitoring compliance reporting to the Chief Executive
Replaces Document/s	PROC004412 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, Research Governance, Human Research Ethics Committee (HREC) Monitoring, TGA, Research Monitor, Annual Report

Custodian Signature Date

Executive Director, Research, Metro North Hospital and Health Service

AUTHORISATION

Authorising Officer Signature Date

Executive Director, Research, Metro North Hospital and Health Service

The original signed version is kept in file at the Metro North Office of Research, Level 13 Block 7 RBWH, Metro North.