

## External Researchers 006903



1. Clinical Governance



5. Comprehensive Care



6. Communicating for safety

### Policy statement

Metro North Hospital and Health Service (Metro North) regularly undertakes collaborative research with individuals who are not employed by Metro North or Queensland Health, or who are not otherwise appropriately engaged as an external health professional, student or a conjoint research appointment. These individuals are collectively referred to as external researchers. It is the position of Metro North that where external researchers request access to Metro North facilities, all external researchers and Metro North staff shall comply with this Policy.

### Purpose and intent

This policy outlines the mandatory requirements for external researchers who request access to Metro North facilities for the purposes of research. The purpose of this policy is to outline the minimum expectations of external researchers and the mandatory requirements for Metro North staff who engage external researchers. It is expected that all Metro North staff and external researchers will be aware of and abide by this Policy.

### 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).
- 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 or their data, Metro North staff and/or resources and infrastructure.

# Principles

## External researcher

External researcher refers to individuals:

- not employed by Metro North or Queensland Health who request access to a Metro North facility for the purposes of research; or,
- enrolled with a recognised research, teaching or academic institution who request access to a Metro North facility for the purposes of research, including students:
  - enrolled in a research higher degree, e.g., a research honours degree, research masters or doctoral program (PhD);
  - enrolled in a higher degree/postgraduate degree with a significant or substantial research component, research project or dissertation;
  - undertaking a research placement/project or gaining research experience not covered under the Queensland Health Student Placement Deed.

External researcher does **not** refer to an employee of Metro North undertaking research activities as an employee. As per Section 139A of the *Hospital and Health Boards Act 2011* (Qld) all public service employees are considered designated persons.

## Students

External researcher does **not** refer to students being educated or trained at a public sector health service facility as part of the requirements for:

- registration, enrolment or other authorisation (however described) to practice as a health professional; or,
- completion of a course of study qualifying a person for registration, enrolment or authorisation to practice as a health professional.

This also includes a person providing education or training at a public sector health service facility to a clinical placement student.

Students undertaking clinical placement or supervised practice at a Metro North facility, including research conducted as a component of that clinical placement, must be listed in the Queensland Health Student Placement Deed schedule. More information about the Student Placement Deed can be found on the [Queensland Health Clinical Placements](#) website.

## External health professionals

External researcher does **not** refer to external health professionals. As per the *Hospital and Health Boards Act 2011* (Qld) (HHB) *health professional* means:

- a) *A person registered under the Health Practitioner Regulation National Law; or*
- b) *A person, other than a person referred to in paragraph (a) who provides a health service, including, for example, audiologist, dietitian or social worker.*

Individuals who are engaged in delivering a public sector health service as per Section 139A of the *Hospital and Health Boards Act 2011* (Qld) and who are not public service employees are considered external health professionals. It is the responsibility of the individual to ensure the requirement for credentialing and defined scope of clinical practice is determined by the relevant profession specific delegate, as per [The Health Service Directive Credentialing and defining the scope of clinical practice \(QH-HSD-034: 2014\)](#).

Where an individual is engaged as an external health professional in delivering a public sector health service, the relevant profession specific delegate (i.e., Chief Medical Officer, Chief Allied Health Officer, Chief Nursing and Midwifery Officer or relevant facility professional delegate) must determine the requirement for credentialing and defined scope of clinical practice.

Where a professional delegate determines the individual is engaged as an external health professional, the responsibility for professional and operational governance of the external health professional sits with the relevant professional delegate.

Where a professional delegate determines the individual is **not** engaged as an external health professional, they are considered an external researcher and are expected to comply with this policy.

## Conjoint Appointments

External researcher does **not** refer to Conjoint Appointments with a contractual arrangement between Metro North and a collaborating organisation regarding the appointment of the researcher to interrelated roles across both institutions.

There are, in principle, three models by which Conjoint Appointments may be arranged. Where the Conjoint Appointee is employed in a position established by:

1. The collaborating organisation, Metro North will commonly make a financial contribution to a portion of the researcher's salary and/or costs; or,
2. Metro North, the collaborating organisation will commonly make a financial contribution to a portion of the researcher's salary and/or costs; or,
3. Both organisations, the individual will be appointed to two separate positions within each organisation, and will be considered an employee of both Metro North and the collaborating organisation.

Where the Conjoint Appointee is not employed by Metro North (Conjoint Appointment model 1, as above) the individual is not considered an employee as per the *Hospital and Health Boards Act Qld (2011)* Section 139A Meaning of a designated person Subsection (1) (b) a health service employee.

The agreement terms and conditions for Conjoint Appointments are expected to cover the mandatory requirements outlined in this policy. As such, where the agreement terms and conditions for individual Conjoint Appointment arrangements meet the minimum requirements of this policy the Conjoint Appointee is not required to complete the External Researcher Access form.

## Collaborating organisation

Where an external researcher undertakes research activities under the direction of their employer and as a part of their employment; or, as a research student under the direction of the University/Institution at which they are enrolled, the employer or University/Institution will be considered the collaborating organisation.

The collaborating organisation is responsible for ensuring the external researcher complies with all aspects of this Policy in its entirety.

Nothing contained within this policy creates a relationship of employer and employee, principal and agent, joint venture or partnership between Metro North and no party will hold itself out as an agent for another.

## Mandatory requirements

### Interaction with Metro North patients

Nothing contained within this policy constitutes authorisation or approval to contact and/or influence the care of Metro North patients.

Where the external researcher is a health professional and patient contact is expected, it is the responsibility of the external researcher to ensure the requirement for credentialing and defined scope of clinical practice is determined by the relevant profession specific delegate, as per [The Health Service Directive Credentialing and defining the scope of clinical practice \(QH-HSD-034: 2014\)](#).

When considering pre-screening, recruitment, survey or observation of patients:

- All engagement with patients for research purposes, including study recruitment, must have appropriate ethical approval from a certified Human Research Ethics Committee (HREC) and site-authorisation; and,
- A Metro North employee, preferably the treating clinician or care team, is to initially approach patients to seek their permission to be contacted regarding consent to participate in research.

## Insurance and indemnity

The Queensland Government Insurance Fund (QGIF) does not extend Property, General Liability, Professional Indemnity, Medical Indemnity, Personal Accident and Illness insurances and indemnities to other parties. As such, external researchers are not insured or indemnified by QGIF when accessing a Metro North facility for the purposes of undertaking research activities.

Where an external researcher undertakes research activities at a Metro North facility under the direction of a collaborating organisation, the collaborating organisation shall maintain insurances (Public Liability Insurance and Personal Accident and Illness Insurance) in relation to the conduct of the external researcher in such amounts as a prudent person would maintain given the substance and nature of the external researcher's visit.

The external researcher will be required to demonstrate evidence of the requisite Public Liability Insurance and Personal Accident and Illness Insurance where they undertake research activities under any of the below conditions:

- outside of any third-party employment arrangement (e.g., self-employment);
- outside of working hours, during periods of leave or otherwise not engaged by a collaborating organisation;
- where the employer's indemnity and insurance arrangements will not cover the activities or are not considered sufficient or appropriate for the research activities;
- where the research student's University/Institution at which they are enrolled will not cover the indemnity and insurance arrangements or are not considered sufficient or appropriate for a placement/research project.

## Specified Vaccine Preventable Disease (VPD) requirements

Compliance with following Queensland Health VPD documents is a mandatory requirement:

- [Health Service Directive: Vaccine Preventable Disease Screening for Contractors, Students and Volunteers QH-HSD-047:2016](#)
- [Health Service Directive Protocol: Protocol for Vaccine Preventable Disease Screening for Contractors, Students and Volunteers QH-HSD-047-1:2016](#)
- [Guideline: Vaccination of healthcare workers](#)
- [Human Resources Policy Recruitment and Selection B1 \(QH-POL-212\)](#)
- any document that replaces or supersedes the above.

A determination is to be made prior to an external researcher accessing a Metro North facility as to the requirement for Specified VPD evidence using the VPD Risk Roles checklist. Refer to the [Queensland Health – Mandatory vaccinations](#) website for further information.

Where it is determined the external researcher is in a VPD risk role and VPD evidence is required, the collaborating organisation:

- Warrants that the external researcher meets the VPD screening requirements as set out in the relevant VPD Documents.
- Must keep an up-to-date record all VPD Applicable Personnel's vaccination history or evidence of non-susceptibility to a Specified VPD.
- Agrees that Metro North may at any time require the collaborating organisation to produce documentary evidence of vaccination or proof of non-susceptibility to a Specified VPD of the VPD Applicable Personnel to Metro North's satisfaction and the collaborating organisation will immediately comply with the request.
- Acknowledges that failure to comply with this requirement is considered a breach of this Policy.

Where it is determined that Specified VPD evidence is required and there is no collaborating organisation, the external researcher must refer to the [Queensland Health – Providing evidence](#) website.

## Criminal History Checks

In line with [Human Resources Policy Employment Screening B40 \(QH-POL-122\)](#) attachment one - the requirements for criminal history checking must be determined and undertaken before an external researcher may access a Metro North facility. Refer to the [Queensland Health Criminal history checking](#) website for further information, including instructions on how to submit a request where required.

## Research Authorisations

Nothing contained within this Policy constitutes authorisation to commence or conduct research. All research conducted with or about people, or their data or tissue, in Metro North must first obtain the following approvals prior to commencing:

- Human Research Ethics Committee (HREC) review from an appropriately certified HREC, and
- Site-authorisation by the Chief Executive (CE) or relevant delegate by submitting a Site-Specific-Assessment (SSA) application for approval to a Research Governance Officer (RGO).

It is the responsibility of the Principal Investigator (PI) of a research project to ensure that all requisite approvals are in place and include, or are amended to include, the external researcher as required prior to commencing or undertaking any research.

## Queensland Health Information Systems, Privacy and Confidential Information

### Information System Access

The access and use of Queensland Health ICT services and information systems is governed by confidentiality and privacy legislation including:

- *Hospital and Health Boards Act 2011* (Qld) (HHBA) prohibits the disclosure of information that may identify a patient/client other than for those exceptions outlined in Part 7 of the HHBA.
- *Information Privacy Act 2009* (Qld), National Privacy Principles apply to the collection, security, use (access) and disclosure of personal information in circumstances not covered by the HHBA.
- *Public Health Act 2005* (Qld) provides an authorisation pathway to access confidential health information for the specific purposes of approved research activities.
- *Guardianship and Administration Act 2000* (Qld)
- *Coroners Act 2003* (Qld)

The following Queensland Health policies and standards provide the framework for lawful and appropriate authorisation for access and use of Queensland Health systems:

- [Digital Policy Use of ICT services & devices \(QH-POL-484:2021\)](#)
- [Digital Standard Use of ICT services & devices \(QH-IMP-484:2021\)](#)
- [Digital Standard Information access, use and disclosure \(QH-IMP-484-2:2021\)](#)
- [Digital Standard Use of Email standard](#)
- [Digital Standard Access control standard \(QH-IMP-484-4: 2021\)](#)
- [Guideline: User Access Management \(QH-GDL-469:2021\)](#)

As per the Guideline: User Access Management Section 3.3 Authorised users, Section 3.3.1 Access to health information by external researchers:

**There is no legal authority for researchers external to Queensland Health to directly access a Queensland Health information system, whether or not by secure means, for research purposes if the information system holds information with the capacity to identify an individual patient. Access to a Queensland Health information system that contains confidential information is restricted to designated persons for purposes permitted under the HHB Act only.**

Access to a Queensland Health information system that does not have the capacity to identify an individual patient may only be authorised for research purposes:

- Where there is a lawful and appropriate mechanism for an external researcher to access the Queensland Health information system; and,
- As a request submitted through the Online Provisioning System (OPS) by a staff member with appropriate delegations to authorise user access.

Where access to any Queensland Health information system is provisioned, the external researcher and the collaborating organisation acknowledge:

- They must only access or use the information system for the purposes approved by the delegate.
- They must comply with directions given by Metro North about access to the information system, and with all relevant Queensland Health and State information standards and policies.
- Any unauthorised access to or use of Queensland Health information systems or content may result in civil or criminal proceedings against any persons involved.
- The content of the information system is confidential to Queensland Health. The content must not be disclosed nor used for any purpose other than as necessary to the approved purpose.
- Queensland Health makes no representation or warranty about the availability or continuity of access to the information system, or about the completeness or correctness of any content.
- Queensland Health may monitor or audit the access to and use of the information system, and may suspend access at any time, with or without giving reasons. Queensland Health has no liability to the collaborating organisation in suspending the access.
- Queensland Health has no liability (whether in contract, tort including negligence, or otherwise) to the collaborating organisation or any other person in respect of the information system or its content, or their availability.
- The collaborating organisation indemnify Queensland Health against liability to any other person in relation to the use of the information system or its content.

## Privacy

Metro North is required by the Relevant Privacy Laws to maintain the confidentiality of Personal Information as defined in the *Information Privacy Act 2009* (Qld) and acknowledges that a breach of Metro North patient privacy may result in significant damages to the individual concerned and to Metro North.

To the extent such content contains personal information the external researcher must comply with the obligations in the *Information Privacy Act 2009* (Qld) as if they were Queensland Health. In particular, they must comply with all Relevant Privacy Laws in dealing with any Personal Information obtained by the collaborating organisation during the course of the research activities, including in respect of Personal Information provided by or on behalf Metro North as follows:

- a. Ensuring that any Personal Information collected or provided to the collaborating organisation is protected against loss and against unauthorised access, use, modification, disclosure or other misuse.
- b. Not using Personal Information other than for the purpose of the research activities and in accordance with the written consent of the person to whom the Personal Information relates, unless required or authorised under any law
- c. Not disclosing Personal Information without the prior written consent of Metro North and in accordance with the written consent of the person to whom the Personal Information relates, unless required or authorised under any law.
- d. Not transferring any Personal Information outside Australia, unless in accordance with the Relevant Privacy Laws.
- e. In the event of a privacy complaint, fully cooperating with Metro North to enable Metro North to respond to the complaint.
- f. Immediately notifying Metro North if the collaborating organisation becomes aware that a disclosure of Personal Information is or may be required or authorised by law.
- g. Complying with such other privacy and security measures as Metro North may reasonably advise the collaborating organisation from time to time.
- h. Upon request by Metro North, promptly returning any Personal Information to Metro North where Metro North reasonably considers such demand is required to comply with its legal or ethical obligations.
- i. Promptly notifying Metro North upon becoming aware of any action in relation to Personal Information which is a breach of the Relevant Privacy Laws.

## Confidential information

Confidential information held by the Department and Hospital and Health Services, including patient records, plays an important role in clinical research and generating an evidence base to improve healthcare services and health outcomes for individuals.

Nothing contained within this policy constitutes authorisation or approval to access or disclose confidential information, as defined in the *Hospital and Health Boards Act 2011* (Qld): Confidential information means information acquired by a person in the persons capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified.

Nothing contained within this policy constitutes conferral of an external researcher with status as a *designated person* as defined in Section 139A of the *Hospital and Health Boards Act Qld* (2011). A designated person must not disclose confidential information, either directly or indirectly, to another person unless that disclosure is permitted under the *Hospital and Health Boards Act 2011* (Qld). Subdivision 2 (Section 143-161) provides the permitted disclosures of confidential information.

A *designated person* may access confidential information for the care or treatment of a person. The use of confidential information (healthcare records) for research is a secondary purpose, for which a lawful

authorisation, for example informed patient consent and/or an authorised application under the PHA, is required. A legal authority must be identified to permit disclosure of confidential information held by the Department or an HHS, for research purposes. It is the responsibility of all parties to ensure requisite approvals are obtained before any confidential information can be disclosed, for example patient consent and/or a *Public Health Act 2005* (Qld) (PHA) approval.

## External Researcher Access Form

Where an external researcher requires access to a Metro North facility, they shall complete the External Researcher Access form. The completed form is to be signed by the collaborating organisation as evidence of authorisation and compliance with the terms of this policy.

The completed form is to be presented as evidence of authority when requesting a Metro North Identification badge and, where required, a proximity card.

## Identification badge

As per the [Metro North Procedure Security and Access Card](#) it is a mandatory requirement that all external researchers have a current Identification badge (ID badge) with an expiry date of not greater than one year (12 months) for each Metro North facility they access.

A Metro North staff member with appropriate delegation may authorise the ID Badge request form upon receipt of a completed External Researcher Access form, including nomination of a Metro North cost centre.

All requests must be signed by the Head of Department. Where the request relates to multiple departments the form is to be signed by an individual with delegation across multiple departments.

## Proximity card

A proximity card allowing building and facility access for external researchers:

- must only be requested where it is relevant to authorised research activities; and,
- must not authorise access to clinical or high-risk areas unless the relevant profession specific delegate has determined the requirement for credentialing and defined scope of clinical practice, or where the individual is not a health professional, the Head of Department has provided requisite approval; and,
- must not be authorised for access periods greater than one year (12 months).

A Metro North staff member with appropriate delegation may authorise a proximity card request form upon receipt of a completed External Researchers form, including nomination of a Metro North cost centre.

All requests must be signed by the Head of Department. Where the request relates to multiple department the form is to be signed by an individual with delegation across multiple departments.

## Orientation and mandatory training

It is a condition of access to a Metro North facility that the external researcher will undertake any relevant site induction or orientation as directed by Metro North from time to time. The collaborating organisation and the external researcher must:

- Comply with all rules, directions and procedures issued by Metro North, including those relating to security or workplace health and safety, which are in effect at the site or facility.
- Avoid unnecessary interference with the passage of people and vehicles.
- Not create nuisance or unreasonable noise and disturbance.

All external researchers must receive an orientation program upon commencement. At a minimum, the orientation program will include First Response Evacuation Instructions and General Evacuation



Instructions (GEI) (required by Fire & Rescue Service Regulation) and any workplace health and safety requirements relevant to the research activities in all work areas the external researcher is authorised to attend. Refer to the Queensland Health [Human Resources Policy Mandatory Training G6 \(QH-POL-183\)](#) for further guidance on determining mandatory training requirements.

## Roles and Accountabilities

### External researcher

All external researchers are to abide by:

- The [Australian Code for the Responsible Conduct of Research \(the Code\)](#); and,
- The [National Statement on Ethical Conduct in Human Research \(National Statement\)](#), and,
- Any applicable requirements of Australian law including the *Hospital and Health Boards Act 2011* (Qld), the *Public Health Act 2005 (Qld)*, the *Information Privacy Act 2009* (Qld) and the other relevant legislation, ethics obligations and guidelines which may be applicable from time to time (including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records); and,
- The [Metro North Research Policy](#), the Queensland Health [Policy Research Management](#) and [Standard Research Management](#) and any other applicable policy, guideline or reasonable request or direction issued by Metro North and/or notified to the collaborating organisation which relates to the information and/or assistance provided by Metro North.
- The same legislative requirements and ethical standards as paid employees, including the areas of workplace health and safety, Code of Conduct, standards of ethical behaviour including declarations of conflict of interest, patients/clients right to privacy and confidentiality, equal employment, anti-discrimination and human rights.

All external researchers are required to:

- Provide a signed copy of the External Researcher Access form as evidence of authorisation by the collaborating organisation to request an ID badge and, where required, a proximity card;
- Attend local orientation/induction programs prior to commencement to ensure compliance with any workplace health and safety obligations and mandatory training requirements;
- Always wear an ID badge when at a Metro North facility or service;
- Surrender their identification badge, proximity card (where provided), and any other items belonging to Queensland Health when an external researcher is no longer involved with Metro North; and,
- Appropriately declare and manage any conflicts of interest in line with the [Guideline Disclosure of Interests and Management of Conflict of Interests](#). In situations where issues or potential risks, conflict or conflict of interest arise and are not able to be resolved, Metro North may consider various options including ending the external researcher arrangement.

### Metro North staff

A Metro North employee must act as a contact person who will ensure the external researcher:

- adheres to the Australian Code for the Responsible Conduct of Research (the Code); and,
- is aware of, and abides by relevant policies and procedures of Metro North and any collaborating organisations, including expectations for ethical and responsible behaviour; and
- undertakes relevant orientation, mandatory training, and ongoing supervision requirements, as determined by the scope of engagement; and

A Metro North contact person will submit requisite forms, including ID Badge and Proximity card request forms and evidence of completed External Researcher Access form to the relevant Facility Executive Director or delegate for approval.

All Metro North staff who engage or work collaboratively with external researchers have an obligation to be aware of and abide by this policy.

All Metro North staff must comply with their human rights obligations under section 58 of the *Human Rights Act 2019* (Qld) by:

- (a) giving proper consideration to whether any actions or decisions may affect a person's human rights; and
- (b) acting or making decisions in a way that is compatible with human rights.

## 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 Sector Ethics Act 1994* (Qld)

*Public Service Act 2008* (Qld)

*Work Health and Safety Act 2011* (Qld)

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

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

[National Health and Medical Research Council \(NHMRC\) Guideline: Disclosure of interests and management of conflict of interests](#)

[Health Service Directive Credentialing and defining the scope of clinical practice \(QH-HSD-034: 2014\)](#)

[Health Service Directive: Vaccine Preventable Disease Screening for Contractors, Students and Volunteers QH-HSD-047:2016](#)

[Guideline: Vaccination of healthcare workers](#)

[Human Resources Policy Recruitment and Selection B1 \(QH-POL-212\)](#)

[Human Resources Policy Employment Screening B40 \(QH-POL-122\)](#)

[Human Resources Policy Mandatory Training G6 \(QH-POL-183\)](#)

[Digital Policy Use of ICT services & devices \(QH-POL-484:2021\)](#)

[Digital Standard Use of ICT services & devices \(QH-IMP-484:2021\)](#)

[Digital Standard Information access, use and disclosure \(QH-IMP-484-2:2021\)](#)

[Digital Standard Use of Email standard \(QH-IMP-484-3:2021\)](#)

[Digital Standard Access control standard \(QH-IMP-484-4: 2021\)](#)

[Guideline: User Access Management \(QH-GDL-469:2021\)](#)

[Policy Research Management \(QH-POL-013:2015\)](#)

[Standard Research Management \(QH-IMP-013:2015\)](#)

## References

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.

## Related Documents

[Queensland Health Clinical Placements](#)

[Queensland Health – providing evidence of mandatory vaccinations](#)

[Queensland Health – mandatory vaccinations](#)

[Queensland Health – criminal history checks](#)

Metro North External Researchers: Guideline for External Researchers

Metro North External Researchers: Guideline for Metro North Staff

## Appendix 1- Definition of terms

Term	Definition
Code, the	<p>The <i>Australian Code for the Responsible Conduct of Research, 2018</i> (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.</p> <p><a href="https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018">https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018</a></p>
Collaborating Organisation	<p>The organisation where an external researcher is employed and undertaking research activities at the direction of their employer as a part of their employment or,</p> <p>The university or institutions where a research student is enrolled to undertake research activities at the direction of the university or institution.</p>
Confidential Information	<p>Confidential Information means any information that—</p> <p>(a) is about a person who is receiving or has received a public sector health service; and (b) could identify the person.</p> <p><i>Hospital and Health Boards Act 2011</i> (Qld)</p>
Conflict of Interest	<p>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.<sup>1</sup></p> <p>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.</p>
Ethics	<p>The concepts of right and wrong, justice and injustice, virtue, and vice, good and bad, and activities to which these concepts apply.</p>

Term	Definition
External researcher	<p>External researcher refers to individuals:</p> <ul style="list-style-type: none"> <li>• not employed by Metro North or Queensland Health who request access to a Metro North facility for the purposes of research; or,</li> <li>• enrolled with a recognised research, teaching or academic institution who request access to a Metro North facility for the purposes of research, including students: <ul style="list-style-type: none"> <li>○ enrolled in a research higher degree, e.g., a research honours degree, research masters or doctoral program (PhD);</li> <li>○ enrolled in a higher degree/postgraduate degree with a significant or substantial research component, research project or dissertation;</li> <li>○ undertaking a research placement/project or gaining research experience not covered under the Queensland Health Student Placement Deed.</li> </ul> </li> </ul>
Facility	The site at which the research is performed or the researcher is engaged.
Human Research Ethics Committee (HREC)	<p>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.</p> <p>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.</p>
Metro North	Metro North Hospital and Health Service
National Statement, the	<p>The <i>National Statement on Ethical Conduct in Human Research (2007)</i> (Updated 2018) consists of a series of guidelines made in accordance with the <i>National Health and Medical Research Council Act 1992</i>.</p> <p><a href="https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018">https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018</a></p>
NHMRC	National Health and Medical Research Council
Patient	An individual who receives, or has received, care treatment or other services through a Metro North facility.
Personal Information	Information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Term	Definition
Principal Investigator (PI)	<p>The nominated delegate with primary responsibility and accountability for a research project.</p> <p>For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities.</p> <p>For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably.</p> <p>See also Coordinating Principal Investigator (CPI).</p>
Record	<p>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:</p> <ul style="list-style-type: none"> <li>• anything on which there is writing</li> <li>• anything on which there are marks, figures, symbols or perforations having a meaning for persons, including persons qualified to interpret them</li> <li>• anything from which sounds, images or writings can be reproduced with or without the aid of anything else, or</li> <li>• a map, plan drawing or photograph.</li> </ul>
Relevant Privacy Laws	<p>The Information Privacy Act 2009 (Qld), the Public Health Act 2005 (Qld), the Hospital and Health Boards Act 2011 (Qld) and any other legislation (including delegated and subordinate legislation such as regulations), code or guideline which applies in the relevant jurisdiction and which relates to the protection of Personal Information.</p>
Research	<p>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.</p>
Research Governance Officer (RGO)	<p>The Office(r) or coordinated function within an institution / HHS whose responsibilities are:</p> <ul style="list-style-type: none"> <li>• assessing the site-specific aspects of ethically approved research applications</li> <li>• making recommendations to the HHS CE or delegate as to whether a research study should be granted authorisation at that site; and</li> <li>• monitoring authorised research at the site to ensure it meets appropriate standards.</li> </ul>

Term	Definition
Research Student	<p>An individual enrolled in a course of study with a recognised research or teaching institution and may include:</p> <ul style="list-style-type: none"> <li>• Students enrolled in honours, research masters or doctoral program, or any substantial postgraduate research project or dissertation with a University.</li> <li>• Volunteer medical, nursing or allied health students gaining research experience.</li> </ul>
Researcher	A person(s) who conducts, or assists with the conduct of, research.
Site Authorisation	<p>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.</p> <p>Also referred to as Research Governance.</p>
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

<b>Author</b>	Research Strategy Officer, Metro North Research
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<b>Risk</b>	<b>Risk Rating</b> – Low (3)
<b>Compliance evaluation and audit</b>	Metro North External Researcher Access Form - register
<b>Replaces Document/s</b>	N/A New Policy
<b>Changes to practice from previous version</b>	N/A New Policy
<b>Education and training to support implementation</b>	Metro North External Researchers: Guideline for Metro North Staff Metro North External Researchers: Guideline for External Researchers
<b>Consultation</b>	<p><b>Key stakeholders</b></p> <p>Facility Directors of Research</p> <p>Facility Executive Directors</p> <p><b>Broad Consultation</b> facilitated through the following:</p> <p>Metro North Aboriginal and Torres Strait Islander Leadership Team</p> <p>Digital Metro North</p> <p>Metro North Medical Services</p> <p>Metro North Nursing and Midwifery Services</p> <p>Metro North Allied Health</p> <p>Metro North Communication</p> <p>Metro North Finance</p> <p>Metro North People and Culture</p> <p>Metro North Workplace Health and Safety</p> <p>Metro North Legal Services</p> <p>Metro North Risk and Compliance Officer</p> <p>Metro North Clinical Streams</p> <p>Metro North Engage</p> <p>Health Excellence Innovation Unit</p> <p>Clinical Directorate Safety and Quality Units</p> <p>Clinical Skills Development Centre</p>



<b>Marketing Strategy</b>	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.
<b>Key words</b>	External researcher; research; access; 006903

**Custodian Signature**

Date

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**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.