Research: Conflict of Interest

Contents

Background ............................................................................................................................................. 1
Purpose and Intent .................................................................................................................................. 2
Scope and Target Audience .................................................................................................................... 2
Principles ................................................................................................................................................. 2
Procedure / process ................................................................................................................................ 2
Conflict of Interest involving Researchers ............................................................................................ 2
Conflicts of Interest Involving HREC Members ..................................................................................... 3
Reporting a Conflict of Interest ............................................................................................................. 3
Legislation and other authority .............................................................................................................. 3
Related Documents ................................................................................................................................. 3
Relevant Standards .................................................................................................................................. 4
Appendix 1- Definition of terms ................................................................................................................ 4
Document History .................................................................................................................................... 6
AUTHORISATION ................................................................................................................................... 6

Background

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

Conflicting interests can damage research in a variety of ways. They can affect how someone designs research and/or reports their research outcomes or influence how research manuscripts, proposals and funding applications are reviewed.

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

Even if a researcher does not act against their professional duties, the existence of a conflict of interest can bring into question the credibility of research and the organisations conducting it. This is why managing conflicts of interest, whether real, perceived or potential, is increasingly important.
Purpose and Intent

To provide a process for the handling and documenting conflict of interest declarations by researchers, Human Research Ethics Committees (HRECs) and scientific and grant review committees within Metro North Hospital and Health Service (Metro North HHS).

This Procedure is to be read in conjunction with the existing Metro North HHS Policy for Managing Conflicts of Interest (POL: 040) and provides explicit guidance for conflicts in respect of research matters.

Scope and Target Audience

This Procedure applies to all Metro North HHS staff, whether permanent, temporary and casual who participate in research activities, scientific and grant review processes and committees and to all members of a HREC.

Principal Investigators (PIs) or the relevant delegate are expected to ensure that where research activities involve external partners, all conflicts of interest are appropriately declared and recorded.

Principles

Conflicts of interest are relatively common, but can only be managed if they are declared. Any conflicts of interest should be declared as part of any of the following activities:

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

Members of a HREC and scientific review boards or committees require published approaches for handling conflict of interest amongst committee membership.

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

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

Everything in this procedure is in addition to section 186 of the Public Service Act 2008 (Qld), which provides that public service employees must disclose any interests that conflict or may conflict with the duties of their employment and cannot act further in the matter to which a conflict relates unless their Chief Executive allows them to. Nothing in this procedure withdraws the requirement for Metro North HSS staff to comply with this provision.

Procedure / process

Conflict of Interest involving Researchers

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

Individuals can foster disclosure by being open and transparent about any relationships that could be perceived as potential or actual conflict of interest. Metro North HHS encourages disclosure by maintaining a register of conflicts of interest and having procedures in place to manage inadequate disclosure and concerns about lack of disclosure.
Applications for funding of research projects require full disclosure including potential personal, professional and institutional benefits that may be generated by the project.

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

**Conflicts of Interest Involving HREC Members**

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

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

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

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

**Reporting a Conflict of Interest**

When an actual, perceived or potential conflict of interest is identified, it should be reported by completing and submitting a Conflict of Interest Disclosure Form (PROC:119 Managing conflict of interest - Appendix 4). For further guidance on managing a conflict of interest, please refer to the Metro North HHS Policy Managing conflict of interest.

**Legislation and other authority**

- Public Interest Disclosures Act 2010 (Qld)
- Public Sector Ethics Act 1994 (Qld)
- Public Service Act 2008 (Qld)
- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for the Responsible Conduct of Research 2007

**Related Documents**

- Policy (POL040) Managing conflict of interest
- Procedure (PROC090) Managing conflict of interest – MNHHS employees
- Policy (POL: 001) Research Policy
- Procedure (PROC: 001) Research: Monitoring
- Procedure (PROC: 003) Research: Conflict of Interest
- Procedure (PROC: 004) Research: Intellectual Property
- Procedure (PROC: 005) Research: Authorship
- Procedure (PROC: 006) Research: Responsible Reporting
## Relevant Standards

ACHS EQuIP National Standards - Standard 15: Corporate Systems and Safety

### Appendix 1- Definition of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Authorship</td>
<td>Authorship refers to the attribution of contributors to academic publications. Authorship must be determined based on substantial scholarly contributions.</td>
</tr>
<tr>
<td>Code, the</td>
<td>The Australian Code for the Responsible Conduct of Research (2007). This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of the Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.</td>
</tr>
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| Conflict of Interest | A conflict of interest in the context of research exists where either:  
  - a person’s individual interests or responsibilities have the potential to influence carrying out of institutional roles or professional obligations in research.  
  - an institution’s interests or responsibilities have the potential to influence the carrying out of its research obligations.  
  
  A conflict may relate to financial interests or other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.  
  A conflict of interest may compromise the research process itself and/or the institutional processes governing research, and may lead researchers or institutions to base decisions about the research on factors outside the research requirements.  
  A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual’s integrity or an institution’s management practices. |
<p>| Ethics             | The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.                                                                                                                                                                                                                                                                                                                                                   |
| HREC Administrator | An employee of the institution who provides administrative support and advice on the institution’s processes for ethical review of research.                                                                                                                                                                                                                                                                                                                                                   |</p>
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<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Human Research Ethics Committee (HREC)</td>
<td>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.</td>
</tr>
<tr>
<td>Metro North HHS</td>
<td>Metro North Hospital and Health Service</td>
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<tr>
<td>National Statement, the</td>
<td>The National Statement on Ethical Conduct in Human Research (2007) Revised 2009. A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors’ Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions’ responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices. <a href="http://www.nhmrc.gov.au/guidelines/publications/e72">http://www.nhmrc.gov.au/guidelines/publications/e72</a></td>
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| 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.                                                                                                                                 |
| Research                                                              | The original investigation undertaken to gain knowledge, understanding and insight. 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.                                                                                                                                                            |
| Researcher                                                            | Person or persons who conducts research, including academics, research trainees, Honours and Higher Degree Research students and professional staff.                                                                                                                                                                                           |
# Document History

<table>
<thead>
<tr>
<th>Custodian</th>
<th>Executive Director, Research Metro North HHS</th>
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<tbody>
<tr>
<td>Risk rating</td>
<td>Low</td>
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<tr>
<td>Compliance evaluation and audit</td>
<td>Summary data of research breaches of the code investigations will be reported to the Chief Executive and Executive Director, Research Metro North HHS</td>
</tr>
<tr>
<td>Replaces Document/s</td>
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<tr>
<td>Document replaced</td>
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<td>Key stakeholders</td>
<td>Executive Director, Operations</td>
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<td></td>
<td>Executive Directors, Clinical Directorates</td>
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<td>HREC Chair &amp; Coordinator, RBWH &amp; TPCH</td>
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<td></td>
<td>Research Governance Officers</td>
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<td>Director, Research (Clinical Directorates)</td>
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<td></td>
<td>Executive Director (Metro North): Clinical Services, Medical Services, Nursing and Midwifery Services, Allied Health</td>
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<tr>
<td></td>
<td>Chief Finance Officer (Financial Control, Information Technology, Legal, Human Resources, Communications, Engagement)</td>
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## Marketing Strategy
Marketing through MNHHS Research website, newsletter and regular email to all line managers. Notification through Safety and Quality Units to key stakeholders.

## Key words
Research, conflict of interest, disclosure

### AUTHORISATION

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<td>Executive Director, Research Metro North HHS</td>
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The signed version is retained by the relevant Safety and Quality area, Metro North Hospital and Health Service.