

## POLICY

# Metro South Health Research Management

PL2017/55  
Version No. 1.0

### POLICY STATEMENT

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The Metro South Hospital and Health Service (Metro South Health) is a leader in the translation of health and medical research. Metro South Health must ensure all research conducted within Metro South Health, or in collaboration with external entities, is of the highest ethical and scientific standard and undertaken in a manner that provides optimal outcomes for Metro South Health and the community.

The Metro South Health Research Management Policy aims to ensure a consistent, clear and detailed publically available compliance framework, including policies, procedures and supporting documentation, is in place to inform and guide Metro South Health researchers in the pursuit of research excellence.

### OUTCOME

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This Policy applies to all Metro South Health employees and others (including visiting medical officers, visiting health professionals, students and researchers) who propose to undertake research utilising Metro South Health participants, data, employees and/or resources.

It is the responsibility of facilities, departments, clinicians and researchers to be aware of and apply the principles and processes outlined within subsequent Metro South Health Procedures in conjunction with other relevant guidelines, standards, general and specific legal obligations (statutory or otherwise) as in place from time to time.

Failure to comply with this Policy and related procedures may amount to research misconduct on the part of the responsible individual.

### PRINCIPLES

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1. Metro South Health is committed to securing the health of our community through research and innovation, to deliver effective services to educate future generations.
2. Metro South Health is committed to fostering research that enhances patient care, challenges clinical practice and promotes innovative health service delivery.
3. All research in Metro South Health must comply with all relevant legislation, regulations, codes and guidelines (as applicable) and other regulations in place. Research ethics and governance compliance includes the ethical and scientific review of research, contractual and financial management of research and research authorisation by the relevant authority.
4. Metro South Health is committed to ensuring research conducted is based on four (4) key values: Research with Integrity; Responsible Conduct of Research; Appropriate Ethical Review of Research; Good Stewardship of Research Resources (Attachment 1).

5. Researchers must uphold Metro South Health's four (4) key values when undertaking research utilising Metro South Health participants, data, employees and/or resources.
6. All research and quality assurance research projects undertaken in Metro South Health or involving Metro South Health employees, participants and/or resources must be submitted to the Centres for Health Research for review and approval. The Centres for Health Research will undertake a governance review, including Site Specific Assessment (SSA) and monitoring, of each research project which will include ensuring that all research projects involving human research have been reviewed and approved by an NHMRC accredited Human Research Ethics Committee (HREC). Additionally, the Centres for Health Research will ensure that any research projects involving Genetically Modified Organisms (GMO) have been reviewed and approved by an accredited Institutional Biosafety Committee (IBC) and that any research projects involving animals have been reviewed and approved by an accredited institutional Animal Ethics Committee (AEC).
7. All research being undertaken in Metro South Health involving humans, including their data or biospecimens, must be conducted in a manner consistent with nationally recognised human research ethics and governance guidelines and legislation, including but not limited to:
  - a. National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) ('National Statement');
  - b. NHMRC Australian Code for Responsible Conduct of Research; and
  - c. Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice as annotated by the TGA.
8. All research being undertaken in Metro South Health must undergo ethical review by a Human HREC registered with the NHMRC and comply with Metro South Health research governance processes.
9. Metro South Health has a role in providing a platform to support/facilitate a broad range of research, in an ethical and collaborative manner, which meets the needs of clinicians and researchers whilst ensuring that all research conducted within Metro South Health facilities, or involving Metro South Health personnel, is conducted in a safe, responsible and ethical manner with the appropriate use of resources.
10. Metro South Health is committed to undertaking world-class research whose goal is to improve health care outcomes for our patients and the wider community.
11. Metro South Health is committed to achieving consistent research ethics and governance procedures and processes that facilitate research which allows for valid and accurate research activity reporting.
12. Metro South Health must ensure fair and transparent research management procedures and processes are used to investigate reported research misconduct and complaints.
13. Conflicts of interest must be disclosed and managed for all research to ensure the integrity of the research process prior to ethical consideration and commencement of research in Metro South Health.

14. Where appropriate research should have a plan of translation for the local Metro South Health community.
15. All efforts must be made to minimise duplication of HREC review of research and legal review of research agreements for multi-centre research across Queensland.
16. Metro South Health aims to increase its ability to retain and attract high quality health and medical researchers.
17. The Metro South Health Research Management Compliance Framework ensures the availability of documents which help guide good research compliance, conduct and management in Metro South Health.
18. The Centres for Health Research is responsible for providing advice, training and education to enable Metro South Health to be in compliance with the Metro South Health Research Management Compliance Framework.
19. The Metro South Health Research Management Compliance Framework ensures compliance with legislation, laws, regulations, guidelines and codes of practice governing the conduct of research in Australia. Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

## LEGISLATION OR OTHER AUTHORITY

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### Legislation

- *Australian Radiation Protection and Nuclear Safety Act 1998 (Cth)*
- *Coroners Act 2003 (Qld)*
- *Defence Trade Controls Act 2012 (Cth)*
- *Financial Accountability Act 2009 (Qld)*
- *Financial Management and Accountability Act 1997 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Guardianship and Administration Act 2000 (Qld)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Powers of Attorney Act 1998 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*
- *Public Health Act 2005 (Qld)*
- *Research Involving Human Embryos Act 2002 (Cth)*
- *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*

### Regulations and Standards

- Financial and Performance Management Standard 2009 (Qld)
- Gene Technology Regulations 2001 (Cth)
- Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015 (Qld)

- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)
- Transplantation and Anatomy Regulation 2004 (Qld)

### Statements, Papers and Guidelines

- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA):
  - [Code of Practice: Exposure of Humans to Ionizing Radiation for Research Purposes 2005](#)
  - [National Standard for Limiting Occupational Exposure to Ionizing Radiation 1995](#)
  - [Recommendations for Limiting Exposure to Ionizing Radiation 1995](#)
- [International Society for Pharmacoepidemiology: Guidelines for Good Pharmacoepidemiology Practices \(GPP\) 2015](#)
- Medicines Australia:
  - [Clinical Trials Research Agreements](#)
  - [Indemnity and Compensation Guidelines](#)
- Medical Technology Association of Australia (MTAA):
  - [Compensation Guidelines](#)
  - [Indemnity Form for HREC review only](#)
  - [Standard Clinical Investigation Research Agreement](#)
  - [Standard Indemnity Form for a clinical investigation](#)
- National Health and Medical Research Council (NHMRC):
  - [Australian Code for the Care and Use of Animals for Scientific Purposes 8<sup>th</sup> Edition 2013](#)
  - [Australian Code for the Responsible Conduct of Research 2007](#)
  - [Certification Handbook: National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012](#)
  - [Framework for Monitoring: Guidance for the national approach to single ethics review for multi-centre research 2012](#)
  - [Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008](#)
  - [National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#)
  - [Research Governance Handbook: Guidance for the national approach to single ethical review 2011](#)
  - [Standardised Participant Information and Consent Forms](#)
  - [Statement on Consumer and Community Involvement in Health and Medical Research \(2016\)](#)
  - [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods](#)
  - [Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003](#)
- [Office of the Gene Technology Regulator: National Framework of Ethical Principles in Gene Technology 2012](#)
- Queensland Government:
  - [General Retention and Disposal Schedule for Administrative Records \(HREC and RGO administrative records\) QDAN249 v.7](#)
  - [Health Sector \(Clinical Records\) Retention and Disposal Schedule QDAN 683.1](#)
  - [Queensland Biotechnology Code of Ethics: Update of the Code of Ethical Practice for Biotechnology in Queensland \(2006\)](#)

- Queensland Health:
  - [Fee Schedule and Site Information for Commercially Sponsored Research 2010](#)
  - [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
  - [Junior Doctor Research Fellowship Funding Rules: Round Two 2016](#)
  - [Research Fellowship Funding Agreement Rules](#)
  - [Researcher User Guide \(RUG\) 2010](#)
  - [Standard Operating Procedures for Queensland Health HREC Administrators 2013](#)
  - [Standard Operating Procedures for Queensland Health Research Governance Officers 2013](#)
- [Singapore Statement on Research Integrity](#)
- Therapeutic Goods Administration (TGA):
  - [Access to Unapproved Therapeutic Goods - Clinical Trials in Australia 2004](#)
  - [Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting \(CPMP/ICH/377/95\) 2000](#)
  - [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)
  - [The Australian Clinical Trial Handbook 2006](#)

#### **Metro South Health Policies, Procedures, Manuals, Frameworks etc.**

- [Finance Management Practice Manual \(FMPPM\)](#)
- [Integrated Risk Management Framework](#)
- [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#)
- [Management of Conflict of Interest Policy \(PL 2014/0038\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Risk Assessment Guide \(V12 6-11-2013\)](#)
- [Risk Management Policy \(PL2013-06\)](#)

#### **Metro South Health Research Management Procedures**

- [Compliance Framework Procedure \(PR2017/112\)](#)
- [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#)
- [Specific Human and Animal Ethical and Scientific Review Requirements Procedure \(PR2017/114\)](#)
- [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#)
- [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#)
- [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#)
- [PowerTrials - Electronic Medical Record Research Support Module Procedure \(PR2017/118\)](#)
- [Research Grants Administration Procedure \(PR2017/119\)](#)
- [Metro South Health Research Support Scheme \(RSS\) Procedure \(PR2017/120\)](#)

## SUPPORTING DOCUMENTS

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Attachment 1 - [Metro South Health Research Management Values](#)

Attachment 2 - [Metro South Health Research Management Glossary](#)

## DEFINITIONS

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See the [Metro South Health Research Management Glossary](#)

## POLICY DETAILS

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**Policy Number**

PL2017/55

**Policy Name**

Metro South Health Research Management Policy

**Supersedes**

Nil

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20 July 2017

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**Date of Next Review**

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### Metro South Health Research Management Values

#### Value 1: Research with Integrity

Metro South Health's support of integrity in research and strong research culture is aligned with the Queensland Government's objectives for the community as outlined in the [My health, Queensland's future: Advancing health 2026](#) strategy for Queensland's health system, and is fundamental to the conduct of research within the Health Service.

Metro South Health researchers have a responsibility to ensure all their research activities are conducted with:

- Honesty - conveying information truthfully;
- Accuracy - avoiding research errors and reporting research findings precisely; and
- Objectivity - avoidance of inappropriate bias and presentation of research findings completely and impartially.

Metro South Health sponsors, Principal Investigators, researchers, students, research project teams and all Metro South Health employees have a responsibility to report any breach of research integrity and/or research misconduct in accordance with Metro South Health Policies and Procedures.

#### Value 2: Responsible Conduct of Research

Metro South Health is committed to providing an environment that supports and promotes the highest standards of research. To that end, Metro South Health has adopted the National Health and Medical Research Council (NHMRC) Australian Code for Responsible Conduct of Research ('the Code') as the foundation document for the guidance of researchers in relation to their responsibilities.

Metro South Health researchers have an obligation to ensure their conduct and activities are at all times in accordance with the Code which details the responsibilities of researchers in relation to:

- Maintaining high standards of responsible research including intellectual honesty and integrity, and scholarly and scientific rigour;
- Reporting research responsibly and ensuring that research findings are disseminated responsibly;
- Respecting human research participants, animals and the environment (written approval from appropriate Human Research Ethics Committees (HRECs), safety and other regulatory bodies must be obtained when required);
- Reporting research misconduct in a timely manner and in accordance with Metro South Health Policies and Procedures;
- Acknowledging of the role of others in research appropriately and responsibility communicating research results;
- Considering Aboriginal and Torres Strait Islander individuals, communities or groups whom are involved in, or affected by, research; and
- Encouraging consumer and community participation in research.



### **Value 3: Appropriate Ethical Review of Research**

Metro South Health promotes the consideration of ethical implications of research and the appropriate review of research in accordance with national frameworks. Metro South Health ensures all ethical implications (including scientific considerations) of all research are considered and appropriate action is taken to ensure the research is conducted in an ethical and scientifically robust manner.

Metro South Health researchers have an obligation to ensure the following:

- All research involving human participants (incorporating research that involves information about human participants - including but not limited to medical records) is:
  - Conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007) ('National Statement'); and
  - Reviewed and approved by a public health service based HREC that is certified by the NHMRC.
- All research involving Genetically Modified Organisms (GMO) is:
  - Conducted in accordance with the National Framework of Ethical Principles in Gene Technology 2012; and
  - Reviewed and approved by an accredited Institutional Biosafety Committee (IBC)
- All research involving animals is:
  - Conducted in accordance with the NHMRC Australian Code for the Care and Use of Animals for Scientific Purposes; and
  - Reviewed and approved by an appropriate institutional Animal Ethics Committee (AEC).

### **Value 4: Good Stewardship of Research Resources**

Stewardship is an ethic that embodies the responsible planning and management of resources. Metro South Health is committed to effective planning in relation to research and to the efficient and appropriate use of financial and non-financial resources used in the conduct of research. Metro South Health is also committed to utilising current information and technology to ensure good stewardship of research resources. Metro South Health researchers and personnel involved in the management of research have an obligation to ensure:

- The resources required to conduct research are appropriately identified and the availability of resources is confirmed prior to the commencement of research;
- Research grant funds provided through the Metro South Health Research Support Scheme are dispersed in accordance with relevant Procedures;
- All relevant approvals and agreements are in place prior to the commencement of research;
- Resources provided for research are used for their intended purpose and in accordance with relevant legislation, approvals and agreements; and
- The divestment of any resources that remain following the completion of the research is in accordance with relevant legislation, approvals, agreements and in the public interest.

The budget for all research projects undertaken by employees of Metro South Health or involving Metro South Health resources must be reviewed and approved by the relevant Business Manager. Final agreed budgets, prepared on the Metro South Health template for research projects and signed by both the Principal Investigator and the Business Manager, must be included with Site Specific Assessment (SSA) research project applications to the Metro South Health Research Governance Office/r.

Metro South Health must be involved in the research grants administration process if it is proposed for Metro South Health to be identified as the grant administering institution. Principal Investigators, researchers and research student supervisors who do not intend to list Metro South Health as the administering institution, are not required to follow provisions outlined within the Metro South Health Research Management Compliance Framework.