

POLICY

Metro South Health Research Biorepositories

PL2017/53
Version No. 2.0

POLICY STATEMENT

Metro South Health research biorepositories aid clinicians and researchers in fostering research and accelerating the translation of research findings into clinical practice. Metro South Health has a statutory obligation to ensure all research biorepositories, which collect biospecimens from Metro South Health patients/participants, are managed in accordance with applicable legislation, regulation and ethical guidelines, as well as national and international standards.

The Metro South Health Research Biorepository Policy aims to ensure a collaborative, harmonised, clear and detailed publicly available governance framework, including policies, procedures, Standard Operating Procedures (SOPs) and supporting documents, is in place for the operation of all Metro South Health research biorepositories including but not limited to:

- establishment
- governance
- consent
- management
- procurement
- collection
- labelling
- registration
- processing/handling
- storage
- tracking
- retrieval
- dissemination/transfer
- use/access
- auditing/reporting/quality
- discontinuation/destruction of biospecimens, data and/or information.

OUTCOME

This policy applies to all Metro South Health employees and others (including visiting medical officers, visiting health professionals and researchers) who operate or access, or who propose to establish or access, a research biorepository that includes biospecimens collected, processed or stored within Metro South Health facilities.

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

1. Metro South Health has a role in providing a platform to support/facilitate a broad range of research, in an ethical and collaborative manner.
2. All research biorepositories established within Metro South Health must be established, governed managed and used in accordance with applicable legislation, regulation and ethical guidelines.
3. All Metro South Health research biorepositories must:
 - provide a resource for research that is valued by society and conducted within applicable legislation, regulations and ethical guidelines
 - ensure the collection, storage, transfer, access, use and disposal of biospecimens and data are scientifically, legally and ethically appropriate
 - secure the sustainability of the research biorepository, the protection of patient's/participants' privacy, the confidentiality of data and ongoing public trust and involvement.
4. Metro South Health research tissue banks, biobanks, tumour banks and general biospecimen collections (collective term 'research biorepositories') must be operated throughout their existence with integrity, transparency, accountability and respect for human rights and freedoms.
5. The establishment, governance, management, operation, access to, and use of research biorepositories in Metro South Health and its processes for research project activities (ie the Metro South Health Research Biorepository Governance Framework) must be reviewed by the Metro South Health Human Research Ethics Committee (HREC).
6. All Metro South Health research biorepositories must be approved by the Metro South Health HREC and may be monitored for compliance against the Metro South Health Research Biorepository Governance Framework.
7. Given the significant resource implications of establishing and maintaining a research biorepository, the scientific and financial feasibility of the research biorepository must be assessed, the scientific need demonstrated, and the financial resources secured prior to establishment. Principal Investigators and Custodians must be explicit and transparent about the nature and source of its financing/funding.
8. The research biorepository Custodian must strive to ensure data and materials are shared with others in the research community so that resources are not unnecessarily duplicated and knowledge, understanding and improved health outcomes are advanced efficiently.
9. The provision of governance oversight in order to establish principles, policies, procedures and SOPs is a requirement as a statutory body.
10. Research biorepositories must aim to streamline activities where possible by utilising the integrated electronic Medical Record (ieMR) to assist researchers in being informed and empowered to be partners in research.
11. Metro South Health aims to increase its ability to retain and attract high quality health and medical researchers by providing high quality research biorepository services.

12. To enable efficient collaboration at a Metro South Health, state, national and/or international level, Custodians must ensure that aggregate and general results of research conducted using its resources, regardless of outcome, are made publically available either in the form of publications or through other means. This includes identification of scientific and business uncertainties and risks associated with the establishment, operation and use of a research biorepository in Metro South Health.
13. Increase research translation, innovation and outcomes-driven research by; encouraging rapid and transparent access to biospecimens for research purposes, culminating in improved health outcomes and greater productivity, by facilitating collaboration, harmonisation, sustainability and partnership between Metro South Health, Translational Research Institute, university and education institutions, government, other research organisations, investment and philanthropic sectors and industry.
14. The research biorepository Custodian must ensure risks to individuals, their family and potentially identifiable populations or groups whose biospecimens and data are included in the research biorepository and used for research are minimised.
15. Establish a network to aid in facilitating and coordinating timely and transparent HREC applications to ensure safety, quality and ethical operation of Metro South Health research biorepositories.

LEGISLATION OR OTHER AUTHORITY

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 Stock Exchange (ASX) Corporate Governance Council: [Corporate Governance Principles and Best Practice Recommendations](#)
- Canadian Tissue Repository Network: [Policies and Standard Operating Procedures](#)
- Government of Western Australia: [Guidelines for Human biobanks, genetic research databases and associated data](#)
- International Society for Biological and Environmental Repositories (ISBER): [Best Practices: Recommendations for Repositories Fourth Edition](#)
- National Cancer Institute: [Best Practices for Biospecimen Resources](#)
- National Health and Medical Research Council (NHMRC):
 - [National Statement on Ethical Conduct in Human Research 2007](#)
 - [Australian Code for the Responsible Conduct of Research 2018](#)
 - [Biobanks Information Paper 2010](#)
 - [Australian code for the care and use of animals for scientific purposes 8th edition \(2013\)](#)
 - [Best practice methodology in the use of animals for scientific purposes \(2017\)](#)
- Medical Research Council: [Use of Human Samples in Medical Research](#)
- National Pathology Accreditation Advisory Council: [Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials \(Fourth Edition\) 2013](#)
- Organisation for Economic Co-operation and Development (OECD)
 - [Guidelines on Human Biobanks and Genetic Research Databases](#)
 - [G20/OECD Principles of Corporate Governance](#)
- The Royal College of Pathologists of Australasia: [Biobanking Guideline 2014](#)
- World Health Organisation (WHO): [Common Minimum Technical Standards and Protocols for Biological Resource Centres Dedicated to Cancer Research](#)

Metro South Health policies, procedures, manuals and frameworks

- [Metro South Health Research Management Policy \(PL2017/55\)](#)
- [Risk Management Policy \(PL2013-06\)](#)
- [Integrated Risk Management Framework](#)
- [Risk Assessment Tool](#)
- [Management of Conflict of Interest Policy \(PL2014/0038\)](#)
- [Management of Conflict of Interest – All Staff Procedure \(PR2016-66\)](#)
- [Finance Management Practice Manual \(FMPM\)](#)

Metro South Health research biorepositories procedures

- [Governance, Oversight and Management Procedure \(PR2017/98\)](#)
- [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#)
- [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#)
- [Operational Arrangements Procedure \(PR2017/101\)](#)
- [Acquisition, Attainment and Recruitment Procedure \(PR2017/102\)](#)
- [Facility, Equipment, Storage and Security Procedure \(PR2017/103\)](#)
- [Collection, Processing, Handling and Retrieval Procedure \(PR2017/104\)](#)
- [Disposal, Lab/Fridge Merge and Closure Procedure \(PR2017/105\)](#)
- [Access and Applications for Samples Procedure \(PR2017/106\)](#)
- [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#)
- [Emergency Preparedness and Work Health and Safety Procedure \(PR2017/108\)](#)
- [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#)
- [Quality Management System \(Assurance and Control\) Procedure \(PR2017/110\)](#)
- [Standard Operating Procedures \(SOPs\) Procedure \(PR2017/11\)](#)

SUPPORTING DOCUMENTS

Attachment 1 - [Metro South Health Research Biorepositories Glossary](#)

DEFINITIONS

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

POLICY DETAILS

Policy Number

PL2017/53

Policy Name

Metro South Health Research Biorepositories Policy

Supersedes

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26 June 2018

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29 June 2018

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26 June 2021 (within the next 3 years)