

## PROCEDURE

# Metro South Health Research Biorepositories – Governance, Oversight and Management

PR2017/98  
Version No. 2.0

### PURPOSE

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Metro South Health is committed to the highest standards and practices in the operation of tissue banks, biobanks, tumour banks and biospecimen collections ('research biorepositories') for research purposes. This procedure describes processes for governance, oversight and management of research biorepositories in Metro South Health to ensure that the interests of the patient/participant and all other stakeholders are protected.

### OUTCOME

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Whilst research biorepositories must be operated in accordance with the Metro South Health Research Biorepository Governance Framework, principles may be adapted so that they are appropriate to the mission and goals of each research biorepository.

This procedure applies to:

- all Metro South Health employees who have established or propose to establish a research biorepository and/or collect biospecimens for storage purposes from patients/participants
- all persons external to Metro South Health who propose to collect biospecimens from Metro South Health patients/participants and/or access biospecimens collected from Metro South Health patients/participants
- researchers who propose to access biospecimens stored within a Metro South Health research biorepository
- all personnel involved in all aspects of research biorepositories and biospecimen collections in Metro South Health.

Failure to comply with this procedure may amount to research misconduct on the part of the responsible individual. This procedure must be read in conjunction with other Metro South Health Research Management and Research Biorepository procedures.

### KEY PRINCIPLES

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The following key principles guide Metro South Health research biorepositories in establishing appropriate governance, oversight and management mechanisms. The way in which individual Metro South Health research biorepositories put these principles into operation may be scaled in relation to the research biorepository's size of operations.

- All Metro South Health research biorepositories must be governed by the principles of transparency and accountability.

- A robust Metro South Health corporate governance structure must be implemented which encourages the creation of value (through entrepreneurship, innovation, development and exploration) and provides accountability and control systems which mitigate risks involved.
- Metro South Health research biorepositories and their personnel must be aware that appropriate governance, oversight and management principles can reassure research biorepository patients/participants that Metro South Health has processes in place to protect their interests in the use of their biospecimens and personal data.
- Metro South Health research biorepositories must comply with all provisions and documents contained within the Metro South Health Research Biorepository Governance Framework as applicable to their collection.
- The Metro South Health Research Biorepository Governance Framework is intended to be applicable to all research biorepositories).
- The Custodian must clearly formulate its governance structure and the responsibilities of its management and must make such information publicly available. The governance structure must be designed to ensure that the rights and well-being of the patients/participants prevail over the research interests of the operators and users of the research biorepository.
- It is the responsibility of all research biorepository personnel, researchers and partners to ensure that activities related to the research biorepository are carried out in accordance with prevailing norms and ethical principles.
- Metro South Health must ensure relevant information pertaining to the Metro South Health Research Biorepository Governance Framework, including governance, oversight and management, is made publicly available and easily accessible.
- The research biorepository must have in place oversight mechanisms to ensure that the governance, management, operation, access to, use of and discontinuation of the collection complies with legal requirements and ethical principles.

## LEGISLATION OR OTHER AUTHORITY

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### Legislation

- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*

### Regulations

- 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](#)
- Gene Technology Ethics and Community Consultative Committee: [National Framework of Ethical Principles in Gene Technology 2012](#)

- 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](#)
- Medical Research Council: [Use of Human Samples in Medical Research](#)
- 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 \(2017\)](#)
- 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)
  - [Best Practice Guidelines for Biological Resource Centres](#)
  - [Guidelines on Human Biobanks and Genetic Research Databases](#)
  - [G20/OECD Principles of Corporate Governance](#)
- [Queensland Biotechnology Code of Ethics](#)
- 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 \(PL2014/38\)](#)
- [Management of Conflict of Interest – All Staff Procedure \(PR2016/66\)](#)
- [Finance Management Practice Manual \(FMPM\)](#)

## **RESPONSIBILITIES**

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### **Executive Management**

Ensure collaborative, harmonised, clear and detailed publicly available policies, procedures and Standard Operating Procedures (SOPs) (where appropriate) are in place for the operation of all Metro South Health research biorepositories. Encourage sustainability through enhanced performance and promote timely and balanced disclosure of all material matters concerning research biorepositories in Metro South Health.

## **Centres for Health Research**

Update Metro South Health Research Biorepository Governance Framework documents in accordance with Metro South Health Research Biorepository Strategic Oversight Committee requirements. Provision of secretariat/administrative support to maintain and uphold principles outlined in the Metro South Health Research Biorepository Governance Framework.

## **Research Biorepository Strategic Oversight Committee**

Provide oversight of the Metro South Health Research Biorepository Governance Framework by keeping abreast of international, national and state-wide legislation, regulations and guidelines. Promote Metro South Health strategic requirements and ethical and responsible decision-making which respects the rights of Metro South Health patients/participants. Provide guidance and assistance to Research Biorepository Management and Scientific Review Committees (where applicable) and Custodians of Metro South Health collections.

## **Custodian/Principal Investigator — responsible officer**

Ensure a research biorepository internal governance structure is in place for the management and oversight of the collection in compliance with the Metro South Health Research Biorepository Governance Framework.

## **Researchers**

Adhere to all relevant policies, procedures and SOPs when accessing biospecimens from Metro South Health research biorepositories.

## **SUPPORTING DOCUMENTS**

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Attachment 1 - [Application](#)

Attachment 2 - [Metro South Health Research Biorepository Governance Framework](#)

Attachment 3 - [Metro South Health Research Biorepository Compliance Matrix](#)

## **DEFINITIONS**

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

## **PROCEDURE – GOVERNANCE, OVERSIGHT AND MANAGEMENT**

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### **STEP 1: Governance**

All Metro South Health research biorepositories must comply with legislative and best practice principles outlined within the Metro South Health Research Biorepository Governance Framework ([Attachment 2](#)).

Custodians must refer to the Metro South Health Research Biorepository Compliance Matrix ([Attachment 3](#)) for further information on corporate governance compliance requirements. The Custodian must comply with the Metro South Health Research Biorepository Governance Framework and develop applicable documents and governance arrangements within a research biorepository internal governance structure. Applicable documents and governance arrangements include but are not limited to; Research Biorepository Management Committee, Scientific-Review Committee, Research Protocol and Standard Operating Procedures (SOPs).

## **STEP 2: Oversight — technical**

The Metro South Health Research Biorepository Strategic Oversight Committee is responsible for ensuring compliance with the Metro South Health Research Biorepository Governance Framework.

Metro South Health research biorepositories must implement oversight arrangements in compliance with the Metro South Health Research Biorepository Governance Framework. Arrangements may include the establishment of a Research Biorepository Management Committee and a Research Biorepository Scientific Committee. Research project specific collections must clearly articulate oversight arrangements as part of the Research Protocol if not establishing Management and Scientific Committees.

The Custodian of the research biorepository must submit reports to relevant bodies (eg Metro South Health Finance Committee) on compliance with applicable laws, regulations, ethics guidelines and international instruments as required. Please see [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#) for more information.

## **STEP 3: Management — regulatory**

The research biorepository's Human Research Ethics Committee Application (HREA), Research Protocol, Participant Information and Consent Form (PICF) and other applicable documents (eg personnel Curriculum Vitae) must be approved, prior to its establishment, by the Metro South Health Human Research Ethics Committee (HREC). The specific roles and responsibilities of those involved in the research biorepository's activities must be clearly identified within each Research Protocol. Please see Metro South Health Research Management - [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information regarding the Metro South Health HREC and [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) for more information regarding Research Protocols.

The research biorepository must obtain approval for modifications and amendments that significantly alter the Research Protocol or PICF from the Metro South Health HREC and Metro South Health Research Governance Offices.

Please see Metro South Health Research Management - [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

Where Research Protocols are significantly modified and where broad and enduring consent hasn't been received, in some circumstances, the research biorepository Custodian must ensure that a new consent is obtained from the patient/participant. Where obtaining new consent is not possible (eg incapacitation or death), the Custodian may seek a waiver of consent from the Metro South Health HREC. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

The Metro South Health Research On-site Monitoring Office may coordinate/routine monitoring, for research being conducted in or in collaboration with Metro South Health. The monitoring process ensures that the research project is being or has been conducted in the manner proposed to, and approved by the Metro South Health HREC and in accordance with institutional requirements (ie Metro South Health Research Biorepository Governance Framework). Please see Metro South Health Research Management - [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information.

**STEP 4: Management — financial/cost**

Financial/cost management must be coordinated and managed by the Custodian and/or director of the research biorepository in accordance with the Metro South Health [Finance Management Practice Manual \(FMPM\)](#). Please see [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.

**STEP 5: Management — operational**

Operational management must be overseen by the Custodian and/or director of the research biorepository. Please see [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.

**STEP 6: Conflicts of Interest**

All conflicts of interest must be declared in compliance with Metro South Health Management of Conflict of Interest [Policy](#) and [Procedure](#).

## PROCEDURE DETAILS

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**Procedure Number**

PR2017/98

**Procedure Name**

Metro South Health Research Biorepositories –  
Governance, Oversight and Management  
Procedure

**Policy Reference**

PL2017/53

Metro South Health Research Biorepositories  
Policy

**Supersedes**

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02 July 2018

**Effective From**

02 July 2018

**Date of Last Review**

05 July 2018

**Date of Next Review**

02 July 2021 (within the next 3 years)

## ATTACHMENT 1 - Application

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### 1.0 International, national and state regulation, accountability and best practice principles

Research biorepositories are regulated by a number of international, national and state laws, legislation, ethical guidelines, instruments, codes, guidelines institutional requirements and standards. Metro South Health has a statutory obligation to ensure all research biorepositories, which collect biospecimens from Metro South Health patients/participants, are managed scientifically, legally and ethically appropriately.

#### 1.1 Legislated requirements

Research biorepository practices must ensure that access is consistent with state legislation regarding privacy and biospecimens including but not limited to:

- The *Transplantation and Anatomy Act 1979 (Qld)* regulates the removal and use of tissue in certain circumstances including for the purpose of transplantation. The *Transplantation and Anatomy Regulation 2004 (Qld)* and *Transplantation and Anatomy Act 1979 (Qld) - Explanatory Notes* provides additional information relevant to the removal and use of tissue.
- *Information Privacy Act 2009 (Qld)* and *Information Privacy Regulation 2009 (Qld)* sets out a series of principles with which organisations must comply when collecting, storing or using 'personal information' — that is, information or opinions about a named or identifiable person. It regulates how Queensland government agencies, including Metro South Health, must manage personal information and provides a right for individuals to apply for access and amendment of their personal information. Metro South Health must comply with the Australian Privacy Principles. These privacy principles include rules about the transparent management of personal information in the collection, use, anonymity, quality, security, access and disclosure of personal information. They also provide conditions under which personal information may be transferred outside of Australia and rules regarding contracted service providers.
- The *Hospital and Health Boards Act 2011 (Qld)* gives effect to the principles and objectives of the national health system and hospital and health services. It applies to the collection of confidential information (including public and private hospital data) regarding users of the health system (Part 7 Confidentiality).
- The *Public Health Act 2005 (Qld)* aims to protect and promote the health of the Queensland public by preventing, controlling and reducing risks to public health and collecting and managing particular health information, and establishing mechanisms for health information held by a health agency to be accessed for appropriate research.

Metro South Health is also required to comply with Federal laws, codes and institutional requirements that exist in Australia:

- *Privacy Act 1988 (Cth)* outlines how most Australian Government agencies, all private sector and not-for-profit organisations with an annual turnover of more than \$3 million, all private health service providers and some small businesses (collectively called 'APP entities') must handle, use and manage personal information. The Australian Privacy Principles (APPs) are contained in schedule 1 of the Act.
- The *Therapeutic Goods Act 1989 (Cth)* details the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The meaning of a 'biological' is also included under Section 32A *Therapeutic Goods Act 1989 (Cth)*. This is particularly relevant when reviewing sections of the *Transplantation and Anatomy Act 1979 (Qld)* which pertains to research biorepositories.



It is important to note that not all research biorepositories require Therapeutic Goods Association (TGA) approval unless collected biospecimens are intended for transplantation (eg) blood transfusions or eye donations. Biospecimen collections for research purposes do not require TGA approval.

- The *Gene Technology Act 2000 (Cth)* the Gene Technology Regulations 2001 (Cth) protects the health and safety of people and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with Genetically Modified Organisms (GMO).
- The *Defence Trade Controls Act 2012 (Cth)* regulates dealings in certain goods, services and technologies.

## 1.2 Other mandatory requirements

Additionally, national statements and codes, which have been enshrined in legislation, exist to assist with implementing legislative principles including but not limited to:

- The National Health and Medical Research Council (NHMRC), National Statement on Ethical Conduct in Human Research ('National Statement') sets out specific guidelines regarding ethical review of proposed access to and use of biospecimens and associated personal information including pathways for low and high-risk review.
- The NHMRC, the Australian Code for the Responsible Conduct of Research 2018 ('the Code') articulates the broad principles that characterise an honest, ethical and conscientious research culture. It establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.
- The Gene Technology Ethics and Community Consultative Committee, National Framework of Ethical Principles in Gene Technology 2012, is a set of principles which Australian scientists and researchers are expected to abide by when dealing with gene technology and Genetically Modified Organisms (GMOs) at all times. It is a means to encourage ethical conduct in gene technology — in particular — where it relates to human health, the environment, genetically modified organisms and products.

Queensland professional codes of conduct pertaining to research also apply to the governance of research biorepositories including but not limited to:

- The Queensland Biotechnology Code of Ethics outlines general principles pertaining to integrity, beneficence and non-maleficence, respect for persons, respect for the law and system of government, justice and care and protection of animals.

## 1.3 Best practice aspirations

Additionally, national guidelines exist to assist with implementing best practice principles including but not limited to:

- The National Health and Medical Research Council (NHMRC), Biobanks Information Paper 2010, identifies best practice in regard to the standardisation of research biorepository policies, practices and procedures based upon national and international literature.
- The Australian Stock Exchange (ASX) Corporate Governance Council, Corporate Governance Principles and Best Practice Recommendations develops and delivers an industry-wide, supportable and supported framework for corporate governance.

- Other Australian State Guidelines such as, Government of Western Australia Department of Health, Guidelines for Human Biobanks, Genetic Research Databases and Associated Data 2010, New South Wales 'A Comprehensive Review of Cancer-related Biobanks in New South Wales October 2009, 'The Royal College of Pathologists of Australasia Biobanking Guideline' and/or ALRC Report 96 'The Protection of Human Genetic Information in Australia', allows for benchmarking of overarching governance and regulatory frameworks against Queensland and Metro South Health frameworks.
- Australian professional codes of conduct where these overlap with stakeholders' activities (eg Medical licensing bodies and societies).
- Other requirements from funding agencies/organisations/foundations and host institutions may also be delineated and comprise additional external accountability factors (eg annual reporting, creation of advisory boards) that should be incorporated into the internal governance of the research biorepository.

Examples of relevant international regulation and guidelines that apply to Metro South Health research biorepositories include the following:

- The Organisation for Economic Co-operation and Development (OECD), OECD Guidelines on Human Biobanks and Genetic Research Databases 2009, provides principles and best practices for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases.
- The OECD, Best Practice Guidelines for Biological Resource Centres, are intended to serve as a target for the quality management of collections, and are meant to provide guidance for those that seek to improve the quality of biological resource centres. Achieving the levels of quality associated with full compliance with these best practices should be regarded as the pinnacle of success.
- The OECD, 'G20/OECD Principles of Corporate Governance' (2015) outlines principles to assist in evaluating and improving legal, regulatory and institutional frameworks for corporate governance.
- The International Society for Biological and Environmental Repositories (ISBER), Best Practices for Repositories, outlines best practices for the management of all aspects for the management of specimen collections and repositories.
- Medical Research Council (MRC) Ethics Series, Use of Human Samples in Medical Research, provides information on high-level ethical principles and provides more detailed guidance to ensure these principles can be achieved in practice.
- National Cancer Institute (NCI), Best Practices for Biospecimen Resources, is based on extensive research and expert input into the state of NCI-funded biospecimen resources and the quality of biospecimens used in cancer research. The NCI Best Practices outline the operational, technical, ethical, legal and policy best practices for NCI-supported biospecimen resources.
- The World Health Organisation (WHO), International Agency for Research on Cancer (IARC) Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research, includes guidelines and recommendations for biobanks not only in high-income countries but also in low- and middle-income countries (LMICs). The recommendations are based on validated and/or evidence-based guidelines.
- International standards and similar governance frameworks to assist with benchmarking and delineating best practice; 'P3G Biobank Tool Kit and Lifespan' and the 'Canadian Tissue Repository Network'.

## 2.0 Metro South Health Research Biorepository Compliance Matrix

The Metro South Health Research Biorepository Compliance Matrix ([Attachment 3](#)) illustrates a quality system by which Metro South Health research biorepositories are directed and managed. The matrix provides a cogent construct for evaluating how individual research biorepository responsibilities fit in with Metro South Health's governance, oversight and management responsibilities. It also includes attributes that contribute to effective governance and tools for addressing governance risk (ie Metro South Health Research Biorepository Strategic Oversight Committee).

The Metro South Health Research Biorepository Compliance Matrix defines the role of the Metro South Health Research Biorepository Governance Framework ([Attachment 2](#)) and the Metro South Health Research Biorepository Strategic Oversight Committee and delineates duties and responsibilities of individual research biorepositories to assist in preventing duplicated efforts and overlooking critical issues. The matrix also assists with the execution of core processes by providing structure to policies, procedures and SOPs.

Additionally, it provides the Metro South Health Research Biorepository Strategic Oversight Committee with a structured way to collaborate with individual research biorepositories and management on specific issues with minimal risk of confusion and loss of productivity. Lastly, the matrix assists in clarifying roles and responsibilities in fulfilling Metro South Health objectives from a corporate governance perspective.

### 2.1 Corporate governance principles

The Metro South Health Research Biorepository Compliance Matrix and Metro South Health Research Biorepository Governance Framework Policies and Procedures are administered in the spirit of:

- the Ten Essential Principles outlined in the 'Principles of Good Corporate Governance and Best Practice' published by Australian Stock Exchange (ASX) Corporate Governance Council
- the Six Essential Principles of the 'OECD Principles of Corporate Governance'.

## 3.0 Governance

All research biorepository professional personnel, researchers and partners must carry out their activities in accordance with legal requirements and ethical principles. Additionally, the Custodian must establish clear responsibilities to ensure that this is accomplished.

Metro South Health considers management as dealing with the day-to-day activities of the research biorepository, while governance involves oversight of operational matters, technical and legal issues, and research biorepository security, access and demise.

As key governance principles are transparency and accountability, Metro South Health governance structures ensures that:

- the rights and well-being of the patient/participant prevail over research interests
- the operators of the research biorepository have in place oversight mechanisms to ensure that the governance, management, operation, access to, use of and discontinuation of the research biorepository complies with legal requirements and ethical principles.

### 3.1 Metro South Health Research Biorepository Governance Framework

Metro South Health research biorepositories must all abide by operational governance and quality assurance procedures contained within the Metro South Health Research Biorepository Governance

Framework in the collection, processing, storage, security, retrieval and transfer (including appropriate Material Transfer Agreement) of biospecimens and associated patient/participant information.

The Governance Framework influences how the objectives of Metro South Health are set and achieved, how risk is monitored and assessed and how performance is optimised. Clear ongoing operational governance arrangements for research biorepositories are also included as part of the Metro South Health Research Biorepository Governance Framework, including when there are laboratory mergers, changes of ownership or closures or when research funds are exhausted or National research collaborations cease.

The following documents are included as part of the Metro South Health Research Biorepository Governance Framework:

- Policy — The Metro South Health Research Biorepositories Policy has been issued to influence and reflect Metro South Health's strategic direction pertaining to tissue banks, biobanks, tumour banks and biospecimen collections in Metro South Health.
- Procedure — A series of procedures have been developed which describe the process for particular research biorepository practices. Metro South Health procedures also include guiding principles to assist in establishing the direction for each required process.
- Terms of Reference — Attached to the [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#) is the Terms of Reference which describes the purpose, scope and authority of the Committee.

The Centres for Health Research and Metro South Health Research Biorepository Strategic Oversight Committee are responsible for maintaining the Metro South Health Research Biorepository Governance Framework.

Principles outlining Metro South Health's expectations relating to the conduct of research are provided as part of the Metro South Health Research Management Compliance Framework. Please see the [Metro South Health Research Management Policy \(PL2017/55\)](#) and Research Management Compliance Framework for more information.

### **3.2 Research biorepository internal governance structure**

The Custodian and/or director of a research biorepository in Metro South Health must implement a research biorepository internal governance structure which includes relevant documents such as:

- Research Protocol
- Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan
- Terms of Reference for Research Biorepository Management and Scientific Review Committees
- PICF
- SOPs.

The research biorepository internal governance structure ensures the rights and well-being of the patients/participants and the common good prevail over the research interests of the Custodian and users of the research biorepository.

The research biorepository internal governance structure must be approved prior to the establishment of the research biorepository by the by the Metro South Health Research Biorepository Strategic Oversight Committee. Please see [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#) for more information.

Documents contained within the research biorepository internal governance structure, such as the Research Protocol and PICF, are subject to independent ethical review (this includes but is not limited to existing and future processes for ethical review). Please see Metro South Health Research Management - [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information. Site Specific Assessment (SSA) approval and monitoring and must be administered according to the best practice principles of good corporate governance. Please see Metro South Health Research Management - [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) and [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information.

The research biorepository Custodian must anticipate that the need to modify research biorepository internal governance structure documents (ie the Research Protocol and SOPs) over the lifespan of the research biorepository will arise, and should ensure a process is in place for undertaking these modifications.

The Custodian must ensure approval is obtained from the Metro South Health HREC for modifications that significantly alter the research biorepository's Research Protocol or PICF. Where the Research Protocol or PICF of the research biorepository are significantly modified, the Custodian, in some circumstances must ensure that new consent is obtained from the patient/participant or substitute decision-maker (unless exempted through a waiver of consent authorised by the Metro South Health HREC).

This may also include ensuring a means for patients/participants to be informed about these modifications if modifications differ significantly from the signed PICF. Please see Metro South Health Research Management - [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

#### **4.0 Oversight**

Fundamental to establishing a robust corporate governance structure is determining the roles of management and the oversight bodies. Oversight bodies in Metro South Health (outlined below) may include representatives from medical and scientific specialties including genetics/genomics and epidemiology, as well as other fields including management, law, ethics and finance.

Oversight groups may follow a number of models with different functions including scientific peer-review committees or scientific advisory committees. Review processes, in accordance with applicable laws, including HRECs or comparable oversight mechanisms, should be in place for use in cases where biospecimens or data are to be used in a manner not anticipated in the original informed consent process, including:

- for previously collected biospecimens or data where the use might deviate from the original consent
- for cases where informed consent may not have been obtained at the time of collection
- for determining when to seek re-consent
- for use of biospecimens or data where consent was obtained using a broader or layered format for uses unspecified at the time of collection, especially in the case of large-scale genetic epidemiology research projects.

The individuals selected to be involved in the oversight process should be drawn from diverse areas of expertise of relevance to the nature and purpose of Metro South Health research biorepositories.

Small-scale disease-specific research biorepositories may be adequately and appropriately governed by those who establish them, and oversight of ethical considerations may be adequately dealt with by the Metro South Health HREC, guided by the National Statement.

Oversight of large-scale entities is likely to be somewhat more complex than for the smaller-scale research biorepositories for a number of reasons. Size of itself is not necessarily a factor, however, because the large-scale research biorepositories are generally established to provide access to a greater number of researchers than the smaller research biorepositories; ethical considerations are heightened, particularly with regard to consent and privacy.

Large-scale research biorepositories also tend to be population-based and collect tissue and information from healthy participants, whereas many of the small-scale research biorepositories are disease-specific and source their collections from people whose disease status is already known. An important additional consideration with large scale research biorepositories is that research may reveal the disease status of otherwise healthy individuals. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information regarding incidental findings.

#### **4.1 Metro South Health Research Biorepository Strategic Oversight Committee**

The Metro South Health Research Biorepository Strategic Oversight Committee, in collaboration with the Centres for Health Research, is responsible for oversight of the Metro South Health Research Biorepository Governance Framework, including all policies, procedures and supporting documents (if applicable).

Stakeholders may include leaders at institutional cancer centres, pathology, surgery and bioinformatics departments and leaders in clinical research units, translational research and epidemiology teams. Patient advocates and research participants are also key stakeholders. The Committee is also responsible for addressing breaches of or non-adherence to relevant regulations, guidelines and frameworks. Please see [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#) for more information.

#### **4.2 Research Biorepository Management and Scientific Review Committees**

The Research Biorepository Management Committee is expected to assume responsibility for upholding relevant legal and ethical standards. Research Biorepository Management Committees generally monitor observance of the ethical standards and legal requirements applicable to the handling of samples and data, for instance, the collection and subsequent use of bodily substances, or the processing of the personal data used in each case.

This body should therefore be responsible for ensuring, for example, that patient/participants' expectations, as recorded in their declarations of consent, are complied with; that the relevant conditions of access to the research biorepository are observed; that the limitations on the transfer of materials or data set by the research vocation of the research biorepository and by the declarations of consent are not exceeded; and, finally, that if the research biorepository is closed down, its stored bodily substances and information are not misused. Please see [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) and [Disposal, Lab/Fridge Merge and Closure Procedure \(PR2017/105\)](#) for more information.

Oversight committees often composed of experts from outside the research biorepository, serve to oversee the resource and support transparent and accountable operations while preventing conflicts of interest and balancing competing demands. Care should be taken to define, evaluate, and document any potential Conflicts of Interests (COIs) for any and all members.

The research biorepository Custodian must clearly formulate oversight roles and responsibilities (ie Research Biorepository Management and/or Scientific Review Committees) applicable to their biospecimen collection, in a documented Terms of Reference or as part of the Research Protocol.

Oversight roles and/or Research Biorepository Management and Scientific Review Committees must be established to oversee the processes that govern research access and utilisation of the biospecimens and data in the research biorepository. Research Biorepository Management and Scientific Review Committees must include mechanisms for the following:

- Independent scientific, financial and ethical oversight to ensure that the governance, management and operation of the research biorepository complies with the Metro South Health Research Biorepository Governance Framework.
- Provides strategic guidance, scientific feedback, and advice on resource development to the research biorepository management and stakeholders.
- Supports access to biospecimens for research through assessment of criteria such as scientific rationale, validity of the scientific project, regulatory adherence, potential conflicts of interest and fair biospecimen/data allocation practices.
- Review of applications for access to and use of the samples and/or data.
- Internal auditing to monitor access to and the uses of the samples and data, for adherence with research ethics approvals, access approvals and the research uses agreed to by patients/participants during the informed consent process.

The person responsible for oversight and/or Research Biorepository Management and Scientific Review Committees must submit reports on compliance with applicable domestic laws, regulations and ethics guidelines, and international instruments to the Metro South Health Research Biorepository Strategic Oversight Committee if/when requested.

Research Biorepository Management Committees and/or Custodians are responsible for providing relevant reports which include research biorepository activity (including research projects supported), ethical and regulatory compliance, budget and financial status, and details of complaints/disputes to the Metro South Health Human Research Ethics Committee Office and/or Research Governance Office. Please see [Strategic Oversight Committee and Compliance Procedure \(PR2017/99\)](#) and Metro South Health Research Management - [Research Complaints and Misconduct Procedure \(PR2017/124\)](#) for more information.

#### 4.2.1 Research Biorepository Management and Scientific Review Committee evaluation and assessment

The evaluation process can be a valuable exercise to aid executive decision-making with respect to assessment of future funding needs; overall service quality and effectiveness, customer satisfaction, program results, scientific and financial impact, opportunities for expansion, crucial lessons learned and program success. Evaluation should include the following general topic areas:

##### *Self-auditing, audit preparedness, and clinical research monitoring*

Self-auditing and audit preparedness are cornerstones to support and/or evaluate areas of poor performance as well as success in quality of operations. Audits and surveys may be conducted in relation to monitoring of end-user support for clinical research biorepository efforts.

##### *Strategic and long-range planning, setting benchmarks*

Strategic and long-range planning can help to set a resource roadmap, provide opportunities to fine-tune and reset operational focus, offer proof of concept, provide analysis of resource allocation, highlight crucial lessons learned, accelerate decision-making and resource growth, and increase communication and understanding of resource benefits.

*Quantification of performance, utilisation review, and assessment of continuing research needs of the resource*

Formal quantification of performance justifies the benefit, utility and overall need for the stakeholder's financial investment in the research biorepository.

*Scientific impact of the resource*

Formal analysis of scientific impact can provide evidence of the inherent and extrinsic scientific value and contribution of the resource.

*Risk management*

In regard to business risks, Custodians may choose to highlight that there may be changes over the lifespan of the research biorepository. Examples of areas where change may occur include in regard to ownership of the research biorepository. For instance, over the lifespan of the research biorepository, public enterprises/universities may become privatised or vice versa. The research biorepository may provide information that ownership could change and explain the uncertainties associated with the establishment and operation of the research biorepository to the Metro South Health Research Biorepository Strategic Oversight Committee.

#### **4.3 Reviewing, internal compliance and audit**

Metro South Health research biorepositories are responsible for the coordination of internal audit cycles, for example research biorepository processes for managing sample storage may be audited. The independent auditing mechanism should conduct regular and random auditing at appropriate stages including at the end of approved research projects and at the demise of the research biorepository. Please see [Quality Management System \(Assurance and Control\) Procedure \(PR2017/110\)](#) for more information.

Additionally, Metro South Health research biorepositories may also utilise the following to support oversight for their collection/s:

- Adjunct research support teams which may include clinical research coordinators and research project nurses, research assistants, laboratory technicians, bioinformatics professionals, clinical residents and fellows and statisticians.
- An internal support system which may include space planning, financial administration, comptroller, purchasing, environmental services/maintenance, telecommunications, informatics and marketing.
- External support/outsourced roles which may include vendors, consultants, contractors, architects and engineers.

Research projects and research biorepositories may also be monitored in accordance with Metro South Health Research Management - [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#).

#### **4.4 Laboratory safety and biosecurity**

All Metro South Health research biorepositories must establish, or have access to a Committee which discusses laboratory work health and safety, general biosafety and biosecurity issues.

### **5.0 Management**

In Metro South Health, a research biorepository must establish and implement management structures in accordance with the Metro South Health Research Biorepository Compliance Matrix. Please see [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) and [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.



## 5.1 Regulatory

Research biorepositories that provide biospecimens and associated data for research purposes must undergo ethics review and approval by a relevant HREC. Certification and/or accreditation of the research biorepository by an external body may be beneficial for this review process. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

## 5.2 Conflicts of interest

Metro South Health has established systems to ensure that conflicts or potential conflicts of interest are disclosed and that reasonable steps are taken to address and resolve any conflict. These steps include:

- Requiring staff and management to disclose possible conflicts of interest.
- Requiring staff and management to disclose their pecuniary interests (including any business associations, shareholdings, sponsorships, donations, payments or fees).
- In particular cases:
  - determining whether a conflict or perceived conflict of interest exists that might call into question the integrity of the work — or
  - where appropriate, directing or advising an employee to cease involvement in the work or to divest him or herself of external interests that are seen as incompatible with the integrity of the work — or
  - determining that a conflict (or perceived conflict) of interest is acceptable or unavoidable in the circumstances, is not detrimental to the integrity of the work, and is appropriately disclosed.

All conflicts of interest must be declared in compliance with Metro South Health Management of Conflict of Interest [Policy](#) and [Procedure](#) and Research Management procedures. In cases where a conflict of interest exists or may exist, or where the circumstances could give rise to a reasonable perception of conflict, the research biorepository must disclose the circumstances to relevant authorities having oversight of the activity concerned. The relevant authorities include:

- The HREC responsible for approval and/or monitoring of research biorepository activities within the organisation, where the circumstances relate to a matter or matters for which the committee has responsibility.
- An external research funding institution, where the circumstances relate to an activity funded, or proposed to be funded, by the institution.
- A regulatory authority where the circumstances relate to scientific advice or assessments that could be used by the authority to approve or monitor research or product release.
- An editor or producer of a professional journal, publication or media report, where the circumstances relate to scientific advice or assessments proposed for reporting in the journal, publication or media report.
- An advisory board or government authority where the circumstances relate to the provision of scientific advice provided to the board or authority.
- Metro South Health finance (if relevant).

The Metro South Health Research Biorepository Strategic Oversight Committee may be engaged to provide guidance and advice to relevant Custodians and/or Research Biorepository Management Committees prior to or during escalation to relevant authorities.

As a general rule, Metro South Health should disclose to relevant authorities all funding sources associated with research activities (irrespective of whether a conflict of interest may exist or is perceived to exist).

### **5.3 Financial**

All Metro South Health research biorepositories must comply with Metro South Health financial policies, procedures and guidelines the [Financial Delegations Framework](#). Custodians are responsible for presenting at relevant Departmental/Facility/Financial Management Meetings in relation to research biorepository funding, budget and asset management.

### **5.4 Operational**

All Metro South Health research biorepositories must implement operational structures consistent with the size and scope of operations. Roles and responsibilities must be allocated to responsible persons engaged as part of research biorepository operations. Please see [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) for more information.