PROCEDURE

Metro South Health Research Biorepositories- Strategic Oversight Committee and Compliance

PR2017/99
Version No. 3.0

PURPOSE

The Metro South Health (MSH) Research Biorepository Strategic Oversight Committee, in collaboration with the Metro South Research, is responsible for oversight of the MSH Research Biorepository Governance Framework, including all policies, procedures and supporting documents (if applicable). The Strategic Oversight Committee is also responsible for providing recommendations to relevant decision-makers in relation to addressing breaches of or non-adherence to relevant regulations, guidelines and frameworks. This procedure outlines the roles and responsibilities of the MSH Research Biorepository Strategic Oversight Committee and MSH research biorepository compliance requirements.

NOTE: Responsibilities of the MSH Research Biorepository Strategic Oversight Committee may be undertaken by the MSH Research Committee. The MSH Research Committee may convene an extraordinary MSH Research Biorepository Strategic Oversight Committee if/when required.

OUTCOME

Whilst research biorepositories must be operated in accordance with the MSH 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 MSH or Queensland Health (QH) employees whose usual reporting line is through a MSH facility or service (including visiting medical officers, visiting health professionals, students and researchers) who operate or access, or who propose to establish or access, a research biorepository that includes biospecimens collected, processed or stored within MSH facilities.

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 MSH Research Management and Research Biorepository procedures.

KEY PRINCIPLES

The following key principles guide MSH employees in the administration of the MSH Research Biorepository Strategic Oversight Committee and compliance in the collection of biospecimens from MSH patients/participants. The way in which individual MSH research biorepositories put these principles into operation may be scaled in relation to the research biorepository's size of operations.

- The MSH Research Biorepository Strategic Oversight Committee must uphold the principles of the MSH Research Biorepository Governance Framework to ensure equity in all operations.
- All MSH Research Biorepository Strategic Oversight Committee members must act ethically and encourage observance of those standards in others.

Queensland Government

- An effective Strategic Oversight Committee is one that facilitates the efficient discharge of the duties imposed by law on an organisation and adds value to the context of MSH's circumstances. This requires that the MSH Research Biorepository Strategic Oversight Committee be structured in such a way that it; has proper understanding of, and competence to deal with, current and emerging issues and can effectively review and challenge the performance of management and exercise independent judgement.
- All MSH research biorepositories are responsible for establishing an effective system of risk management, internal control and auditing.
- It is vital for each MSH research biorepository to safeguard its own integrity in financial reporting to ensure each research biorepository provides a factual and truthful representation of the collections' financial position.
- All breaches, complaints and research misconduct issues, in relation to research biorepositories, must be managed appropriately and in accordance with principles outlined in this procedure.
- The MSH Research Biorepository Governance Framework is considered as being comprised of 'living documents' which require periodic review and adapted to reflect scientific, technical and management progress.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Human Rights Act 2019 (Qld)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*

To the extent an act or decision under this document may engage human rights under the *Human Rights Act 2019*, regard will be had to that Act in undertaking the act or making the decision. For further information on the *Human Rights Act 2019* see: https://www.qhrc.qld.gov.au/

Regulation

- Transplantation and Anatomy Regulation 2004 (Qld)

Statements, papers and guidelines

- Australian Stock Exchange (ASX) Corporate Governance Council: Corporate Governance Principles and Best Practice Recommendations
- International Society for Biological and Environmental Repositories (ISBER): Best Practices: Recommendations for Repositories Fourth Edition
- National Health and Medical Research Council (NHMRC):
    - Australian Code for the Responsible Conduct of Research 2018
    - Biobanks Information Paper 2010
- 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
- World Health Organisation (WHO): Common Minimum Technical Standards and Protocols for Biological Resource Centres Dedicated to Cancer Research

MSH policies, procedures, manuals and frameworks

- Metro South Health Research Management Policy (PL2017/55)
- Risk Management Policy (PL2018/62)
- Risk Management Procedure (PR2018/97)
- Management of Conflict of Interest Policy (PL2014/38)
- Management of Conflict of Interest - All Staff Procedure (PR2016/66)
- Finance Management Practice Manual (FMPM)

RESPONSIBILITIES

Executive Management

Must ensure all research biorepositories established in MSH are consistently operated in accordance with collaborative, harmonised, clear and detailed publicly available policies, procedures and Standard Operating Procedures (SOPs).

Metro South Research

Support Custodians in the operational arrangements of each research biorepository through the provision of guidance and support when interpreting principles and provisions contained within the MSH Research Biorepository Governance Framework.

MSH Research Biorepository Strategic Oversight Committee

Provide an appropriate Governance Framework within which all MSH research biorepositories operate. Undertake all roles and responsibilities as outlined within the MSH Research Biorepository Strategic Oversight Committee Terms of Reference (Attachment 2).

MSH Research Committee

The MSH Research Committee may undertake all responsibilities and functions of the MSH Research Biorepository Strategic Oversight Committee as outlined within MSH Research Biorepository Governance Framework documents.

From time-to-time, the MSH Research Committee may convene an extraordinary MSH Research Biorepository Strategic Oversight Committee to discuss significant changes and/or impacts to research biorepositories in MSH.

MSH Human Research Ethics Committee (HREC)

Ethically review MSH research biorepository human research ethics applications and associated documents (eg Research Protocol, Participant Information and Consent Form (PICF) and Curriculum Vitaes) when required. Review complaints and investigate of complaints. Recommends or ensures that ethical resolution is achieved.

Custodian/Principal Investigator/responsible officer

Ensure the research biorepository is operated in accordance with the MSH Research Biorepository Governance Framework to ensure consistency in; organisational requirements (sustainability, management and training), premises and equipment maintenance/access, document management, data and informatics, media and reagent preparation (where applicable), accession, preservation,

maintenance and supply of deposits and quality audit and review. Where possible, develop sustainable funding strategies for their research biorepository. Initiates investigations of complaints where required.

Research biorepository manager

Undertake regular self-audits against the MSH Research Biorepository Governance Framework to identify gaps in quality managed at different levels of a collection (technical, training, management etc). Ensure that personnel have access to quality manuals and that they are understood and kept informed of any amendments. Accepts and handles complaints.

Laboratory technician/technologist assistant/clinical personnel

Familiarise themselves with documented protocols and processes and comply with the MSH Research Biorepository Governance Framework and SOPs for the relevant collection at all times. Work with other personnel to develop further information linkage and capacity building to improve appropriate compliance with the MSH Research Biorepository Governance Framework. Work towards the main objective of a research biorepository which is to provide high quality, biospecimen resource collection services to the public.

Researchers

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

SUPPORTING DOCUMENTS

Attachment 1 - Application

Attachment 2 - MSH Research Biorepository Strategic Oversight Committee Terms of Reference

Attachment 3 - MSH Research Biorepository Complaint Form

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE – STRATEGIC OVERSIGHT COMMITTEE AND COMPLIANCE

STEP 1: MSH Research Biorepository Strategic Oversight Committee

The MSH Research Biorepository Strategic Oversight Committee is established and coordinated by the Metro South Research under the auspices and direction of the Executive Director, PAH-QEII Health Network, MSH.

Note: Functions of the MSH Research Biorepository Strategic Oversight Committee may be undertaken by the MSH Research Committee unless further advised.

STEP 2: Compliance with legislation

The MSH Research Biorepository Strategic Oversight Committee, with assistance from the Metro South Research, reviews the MSH Research Biorepository Governance Framework to ensure legislative compliance and Health Service-wide risk mitigation.

The *Transplantation and Anatomy Act 1979 (Qld)* Annual Compliance Self-Assessment Screening Tool is completed by the Metro South Research and the research biorepository manager for review by the Executive Director, Medical Services, Princess Alexandra Hospital.

STEP 3: Establishment of a research biorepository

Review and approve all Research Protocols, Financial Plan and Sustainability Strategies, Resourcing Plans, Legacy Plans, Terms of Reference, PICFs and SOPs prior to progression to a relevant HREC for ethical review. Please see Establishment of a Research Biorepository Procedure (PR2017/100) for more information.

STEP 4: Decision-making

The MSH Research Biorepository Strategic Oversight Committee may make recommendations to decision-makers as required.

STEP 5: Auditing

Each MSH research biorepository is responsible for conducting regular first-party audits. Second-party audits may be conducted by the MSH Audit and Risk Management Unit. In the future, the MSH Research Biorepository Strategic Oversight Committee may be responsible for conducting 'second party assessments' on a regular basis (ie annually).

STEP 6: Annual reporting

MSH research biorepositories must submit reports to relevant bodies, such as MSH finance committees, when required/requested.

STEP 7: Breaches, complaints and research misconduct

All patient/participant complaints must be managed in compliance with applicable MSH policies and procedures. Complaints related to research misconduct, for example a complaint regarding a university/institution, may be managed in accordance with Research Management - Research Complaints and Misconduct Procedure (PR2017/124). In the absence of an applicable procedure the complaint must be managed in accordance with the principles outlined in this procedure.

Any breaches, complaints and allegations of research misconduct which involves a MSH employee must be reported to Human Resources and/or Manager, Staff Complaints and managed in accordance with Employee Complaints Procedure (WS.E.PR.1.3), Reporting Corrupt Conduct Procedure (WS.E.PR.1.1) and Public Interest Disclosure (PID) Procedure (WS.E.PR.1.2).

In addition to the above, the Research Biorepository Management Committee must also be informed of all complaints received in relation to the research biorepository. If the complaint is not resolved to the satisfaction of the complainant, the complaint may be escalated to the MSH Research Biorepository Strategic Oversight Committee for advice if/when required.

The threshold for escalation in relation to breaches, complaints and/or research misconduct is to be determined on a case by case basis by the Custodian and the Research Biorepository Management Committee. If escalated to the MSH Research Biorepository Strategic Oversight Committee, the Committee may make recommendations to relevant decision-makers for appropriate action.

PROCEDURE DETAILS

Procedure Number
PR2017/99

Procedure Name
MSH Research Biorepositories – Strategic Oversight Committee and Compliance Procedure

Policy Reference
PL2017/53
MSH Research Biorepositories Policy

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05 July 2024 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Governance

Guidance must be provided on governance and operation of research biorepositories and associated databases (including human genetic research databases). In essence, governance refers to the optimal operation of research biorepositories according to prescribed and published standards, including open review and recording to ensure best practice. Please see Governance, Oversight and Management Procedure (PR2017/98) for more information.

1.1 Legislative and regulatory requirements

On an annual basis Department of Health and MSH will commission reviews to ensure all research biorepositories are operating in compliance with relevant legislation. Annual Compliance Self-Assessment Screening Tools may be distributed to research biorepository managers for completion and certification. The Executive Director, Medical Services, Princess Alexandra Hospital is the appropriately qualified health service employee who has responsibility to ensure MSH is compliant with the *Transplantation and Anatomy Act 1979 (Qld).*

1.2 MSH Research Biorepository Strategic Oversight Committee role

Oversight of research biorepositories by independent bodies may be required, given the particular ethical issues associated with large-scale banking of biospecimens, its linkage with genetic, medical and genealogical information, and the associated layers of complexity.

The MSH Research Biorepository Strategic Oversight Committee ensures the rights of stakeholders are considered and respected in implementing the MSH Research Biorepository Governance Framework. The Strategic Oversight Committee enables key stakeholders to discuss legal and ethical practices and (in some circumstances) make decisions regarding the operations of all research biorepositories in MSH. Please see Attachment 2 for the MSH Research Biorepository Strategic Oversight Committee Terms of Reference.

In addition to acting as an independent guardian of the MSH Research Biorepository Governance Framework and advising Executive Management on revision of the Governance Framework, the MSH Research Biorepository Strategic Oversight Committee may also discuss Health Service-wide issues, such matters as:

- recruitment strategies
- consent models
- provision of health information to patients/participants
- recontact for future research projects
- barriers to participation by ethnic minorities
- capacity to consent
- confidentiality and access
- intellectual property.

Monitoring of ethics and governance by the MSH Research Biorepository Strategic Oversight Committee should not be seen as replacing ethical oversight of individual research projects the MSH HREC. It would still be necessary to go through the normal ethical review processes for each proposal for

research involving the use of research biorepository resources. Please see Governance, Oversight and Management Procedure (PR2017/98) for more information.

1.3 Membership and accountability

The MSH Research Biorepository Strategic Oversight Committee may include expertise from diverse relevant fields, as well as representatives from different stakeholder groups. Expertise may be drawn from various medical and scientific specialities such as genetics/genomics, pathology and laboratory medicine, epidemiology, as well as other fields such as law, ethics, informatics and accounting etc. Depending on the nature of MSH collections, representatives might also include non-experts or patient/participant groups.

Members of the MSH Research Biorepository Strategic Oversight Committee may include:

- Directors and Custodians of various MSH research biorepositories
- research biorepository managers and laboratory managers (proxy only)
- representative/s from Metro South Research
- representative/s from the MSH HREC
- representative/s from Pathology Queensland
- relevant experts from various medical and scientific specialities as required.

The oversight structure may also include other roles, performed by individual(s) with the following additional components:

- Public/Participant Advisory Role: This role provides advice to the MSH Research Biorepository Strategic Oversight Committee on all aspects affecting MSH research biorepositories, with specific emphasis on patient/participant concerns.
- Ethics Advisory Role: This role provides advice and if required, oversight in the areas of law, ethics and the public's perception of all MSH research biorepositories.
- Scientific Advisory Role: The role provides advice to the MSH Research Biorepository Strategic Oversight Committee on the general scientific plan for all MSH research biorepositories.

1.4 Responsibilities and functions

The MSH Research Biorepository Strategic Oversight Committee's roles and responsibilities are outlined within the MSH Research Biorepository Strategic Oversight Committee Terms of Reference Attachment 2.

1.5 Risk management

Together with guiding MSH strategy, the MSH Research Biorepository Strategic Oversight Committee is chiefly responsible for monitoring general MSH research biorepository performance and risks. In order for the Strategic Oversight Committee to effectively fulfil its responsibilities, members must be able to exercise objective and independent judgement.

The Strategic Oversight Committee is responsible for overseeing the Governance Framework, which can also be referred to as a risk management system, as it's designed to ensure MSH obeys applicable laws and regulations. Accountabilities and responsibilities for managing risks include:

- Specifying the types and degree of risk that the MSH Research Biorepository Strategic Oversight Committee is willing to accept in pursuit of MSH's goals.
- Managing the risks all research biorepositories create collectively through their operations and relationships.

The MSH Research Biorepository Strategic Oversight Committee is responsible for monitoring the effectiveness of the MSH Research Biorepository Governance Framework and ensuring that each research biorepository's operations, practices and SOPs are in compliance with the Governance Framework.

1.6 Decision-making/ethical decision-making/considerations

Trust is an essential component among those donating, processing and storing the biospecimens, as well as among the Principal Investigators and researchers who use the biospecimens to pursue a scientific endeavour. Efforts must be made to ensure that trust is developed and maintained. Policies and Procedures governing research biorepositories must be transparent and effective lines of communication established among stakeholders and research patients/participants.

Prior to the initiation of collection efforts, the MSH Research Biorepository Strategic Oversight Committee must discuss communication strategies to ensure that expectations are satisfied and transparency and trust can be firmly established. Additionally, research biorepositories must develop and provide to the Committee clear guidance as to what services are provided, the costs for the provision of those services, the hours services are available and contact information appropriate for each category of stakeholder for regular hours as well as for after-hour emergencies. Please see Establishment of a Research Biorepository Procedure (PR2017/100) for more information.

2.0 Auditing

2.1 First-party assessment (self-audit)

First-party audits are often called internal audits. This is where the Custodian or research biorepository manager from the research biorepository itself will audit a process or set of processes in the quality management system to ensure it meets the procedure that MSH has specified. This person can be an employee of MSH or someone hired by the research biorepository to perform the internal audits, such as a consultant. It's important to note that the person conducting the self-audit is acting on behalf of the research biorepository rather than a customer or certification body.

This type of audit is focused not only on whether the research biorepository processes meet the requirements of a standard, but all rules the research biorepository has set for itself.

The audit will look for problem areas, areas where processes do not align with each other, opportunities for improvement, and the effectiveness of the quality management system. By design, these audits can and should be much more in depth than the other audits, since this is one of the best ways for a research biorepository to find areas to improve upon. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

2.2 Second-party assessment (audit)

A second-party audit is when an affiliated MSH area, such as the Audit and Risk Unit or another MSH research biorepository, performs an audit of a research biorepository to ensure that they are meeting the requirements specified in the contract. These requirements may include special control over certain

processes (such as collection or disposal), requirements on traceability of assets, requirements for special cleanliness standards, requirements for specific documentation, or any of a host of other items of special interest to MSH.

These audits will be conducted by the auditors and can be done on-site by reviewing the processes or even off-site by reviewing documents submitted by the research biorepository out of session. In the same manner, such areas may organise training courses aiming to achieve full compliance with best practice guidelines. Such an approach would lead to the transparency of activities among partners and to coordinated capacity building. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

Please note this process does not impact upon the research governance on-site monitoring process which is conducted by the MSH Research Monitoring Office. Please see MSH Research Management - Research Governance (Monitoring) Procedure (PR2017/117) for more information.

2.3 Third-party independent assessment (certification) ISBER, ISO or ACHS

A third-party audit occurs if/when MSH establishes a Quality Management System (QMS) that conforms to a standard set of requirements, such as ISO 9001, and hires an independent company to perform an audit to verify that the research biorepository has succeeded in this endeavour. These independent companies are called certification bodies or registrars, and they are in the business of conducting audits to compare and verify that the QMS meets all the requirements of the chosen standard, and continues to meet the requirements on an ongoing basis. They then provide certification to MSH that they approve. This can be used to give customers of the certified company confidence that the QMS meets the requirements of the chosen standard. There are three types of audits used in this process, called certification audits, maintenance or surveillance audits and re-certification audits. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

The Australian Council of Healthcare Standards (ACHS) is an independent, not-for-profit organisation dedicated to improving quality in health care. The ACHS Council represents governments, consumers and peak health bodies from throughout Australia. If a MSH research biorepository is included as part of the ACHS then the appropriate Patient Safety and Quality Unit must be engaged to ensure compliance in preparation with the review.

3.0 Annual reporting

MSH research biorepositories must submit reports to relevant bodies, such as MSH finance committees, on topics including but not limited to:

- overview and summary of collection
- organisational structure
- Research Biorepository Management Committee structure and highlights
- performance reporting (resource and finance)
- programs and achievements
- financial summaries.

The Custodian of the MSH research biorepository must ensure:

- the general results of research conducted using the research biorepository are made publicly available regardless of outcome
- aggregate results from research using the research biorepository are not limited to academic publications and are made available in easily accessible forms
- an annual progress report and a report at the completion or termination of a research project is released and made publicly available
- annual reports are provided to the HREC of the relevant institution.

The MSH Research Biorepository Strategic Oversight Committee may request annual reports from MSH research biorepositories, when required, for review and make recommendations to MSH Executive Management.

4.0 Breaches, complaints and research misconduct

Voluntary participation of patients/participants will influence the success of all MSH research biorepository programs. Patients/participants must be assured that their interests and privacy is of primary importance to the management and employees of the research biorepository. If patients/participants have any reason to believe that their rights or interests have been violated, a Procedure must be in place to deal with their complaints.

4.1 Breach of Legislation, policy and procedure

All MSH tissue banks, biobanks, tumour banks and/or biospecimen collections must comply with the MSH Research Biorepository Governance Framework. Breaches may incur the following consequences:

- an informal warning
- a formal warning kept on the employee's file
- termination of employment
- withdrawal of samples
- discontinuation of the provision of biospecimens from MSH patients/participants
- legislative and legal penalties.

4.2 Complaints

MSH has implemented various procedures to assist in the management of a complaint. Any complaints made in relation to MSH employees must be referred immediately to Human Resources and/or the Manager, Staff Complaints.

Custodians and research biorepository personnel must review the complaint to ensure it's managed in accordance with relevant procedures (if required). If the complaint is unable to be managed in accordance with applicable MSH procedures, due to relevance or locality, the below process must be implemented.

Optimally, complaints must be handled:

- in a timely manner
- in a manner responsive to patient/participant concerns

- with quality and thoroughness
- by a neutral individual trained to handle and investigate complaints
- with fairness
- with flexibility.

When a complaint is received the research biorepository manager must assure the patient/participant that the research biorepository is serious about handling all complaints and that there is a process in place to deal with it. Research biorepository personnel should try to resolve the complaint at the time it is received however if personnel are not able to easily resolve complaints/concerns or if personnel feel uncomfortable addressing the complaint, the matter must be referred to the director or Custodian of the research biorepository.

Only if the individual lodging the complaint requests a formal independent review will MSH refer the complaint to the appropriate institutional body: this could include a patient ombudsman and/or the relevant HREC. Please see the Research Management - Research Complaints and Misconduct (PR2017/124) for more information.

For complaints that escalate beyond point of service, it may be required that any or all of the following steps be completed:

- Encourage the patient/participant to submit the complaint in writing (using a form such as the one included in Attachment 3).
- Speak to the person or representative lodging the complaint to confirm the basis of the complaint.
- Collect additional information.
- Write a letter to the patient/participant acknowledging the receipt of the complaint (this acknowledgement should include an explanation of the process for reviewing complaints).
- Conduct an investigation, if warranted and authorised.
- Produce a report outlining the findings of the investigation and the recommendations.
- Write a letter to the individual summarising the resolution and/or summary of the complaint review.
- Inform relevant authorities if there has been a breach of privacy.

The complaint handling process must be documented and include records of:

- the complaint
- the results of the complaint investigation/review
- any communications with the patient/participant
- the resolution and recommendations
- any changes to inventory after the resolution of the complaint.

Complaints may be escalated Research Biorepository Management Committee if relevant for discussion of appropriate resolutions and/or actions to be taken as a result of the complaint. For matters which may affect all MSH research biorepositories, complaints may be escalated to the MSH Strategic Research Biorepository Oversight Committee.

If appropriate, the MSH Research Biorepository Strategic Oversight Committee may make necessary modifications to policies and/or procedures to ensure that the incident precipitating the complaint does not recur in the future.

4.3 Research misconduct

The Australian Code of the Responsible Conduct of Research establishes a framework for dealing with allegations of research misconduct and establishing inquiries to determine whether research misconduct has occurred. Serious misconduct in research can lead to serious penalties, including termination of employment and people who are the subject of such complaints must be entitled to appeal to a higher body through institutional disciplinary processes. Please see the Research Management - Research Complaints and Misconduct (PR2017/124) for more information.

Any breaches, complaints and allegations of research misconduct which involves a MSH employee must be reported in accordance relevant Human Resources policies and procedures.