PROCEDURE

Metro South Health Research Biorepositories – Establishment of a Research Biorepository

PR2017/100
Version No. 3.0

PURPOSE

Metro South Health (MSH) is committed to enhancing research biorepository capacity within the Health Service. The creation of a research biorepository specifically for research purposes, no matter the size, requires careful consideration and planning to ensure that the collection follows best practice from the outset. This procedure describes the processes required to establish a research biorepository in MSH.

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.

This procedure relates primarily to newly established research biorepositories. Custodians of existing biospecimen collections must consider provisions outlined in this procedure if they indent to merge resources and biospecimens with other collections or establish a new collection. Whilst past research biorepository practices may not be fully compliant with contemporary best practice, all provisions outlined in this procedure are as relevant to the future activities of research biorepositories in MSH. Additionally, this procedure applies to the major business planning considerations that are applicable to research biorepositories in MSH.

KEY PRINCIPLES

The following key principles guide MSH employees in establishing a research biorepository. 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.

- Biospecimens are essential for translational clinical research. Collections of stored and well annotated biospecimens and their derivatives represent considerable investment of time and resources and in many cases, are irreplaceable.

- Daily and long-term responsibilities essential for efficient biospecimen collection and operations can be diverse and include organisational considerations, space planning and functional design, resource development, evaluation and solidification of infrastructure requirements, constant and consistent review of operational issues, and regular resource evaluation. When executed and practiced in harmony, all of these factors can dramatically improve success in managing and operating a high-quality, highly utilised, and valuable resource.
- Research biorepository planning, prior to establishment and throughout its operation, is a valuable activity for new and existing research biorepositories to review their objectives and practices. It also serves to create a formal document that can be used as a reference for the existence of the research biorepository and as a communication tool for various stakeholders.
- The purpose, both current and for the foreseeable future, of the research biorepository must be clearly formulated and communicated.
- The operators of the research biorepository must ensure that sufficient professional staff and resources are available to operate effectively.
- The operators of the research biorepository must develop a strategy for ensuring its long-term sustainability, which also addresses the event that funding is terminated or its nature changed.
- In the establishment of a new research biorepository, the Principal Investigator and/or Custodian should consider which relevant stakeholders, including the general public, should be consulted.
- As Custodians of these valuable materials, research biorepositories have a responsibility to strive for public confidence, standardisation of processes, enabling high quality research, financial stability and sustainability.
- MSH research biorepositories are expected to employ sound business practices to maximise their ability to secure adequate funding to maintain the research biorepository, in accordance with the research biorepository's overall mission.

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

- 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
- 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

MSH policies, procedures, manuals and frameworks

- Metro South Health Research Management Policy (PL2017/55)
- Risk Management Policy (PL2018/62)
- Risk Management Procedure (PR2018/97)
- Finance Management Practice Manual (FMPM)

RESPONSIBILITIES

Executive Management

Ensure collaborative, harmonised, clear and detailed publicly available policies, procedures and Standard Operating Procedures (SOPs) are in place for the establishment of all MSH research biorepositories.

Metro South Research

Support Custodians in the establishment of a 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

Review and approve all Research Protocols, Financial Plan and Sustainability Strategies, Resourcing Plans, Legacy Plans, Terms of Reference, Patient Information and Consent Forms (PICFs) and standard Operating Procedures (SOPs) prior to progression to the MSH Human Research Ethics Committee (HREC) for ethical review.

MSH Human Research Ethics Committee

Ethically review Human Research Ethics Applications (HREAs) and associated documents (eg Research Protocol, PICF and Curriculum Vitaes) prior to the establishment of a MSH research biorepository.

Custodian/Principal Investigator – responsible officer

Lead the development of documentation required for MSH Research Biorepository Strategic Oversight Committee and MSH HREC review. Ensure a Research Biorepository Internal Governance Structure is in place for the management and oversight of the collection in compliance with the MSH Research

Biorepository Governance Framework. This may include writing, revising and updating technical and organisational SOPs.

Research biorepository manager

Write, revise and update organisational and administrative SOPs and provide assistance to the Custodian in developing documentation for MSH Research Biorepository Strategic Oversight Committee and MSH HREC review.

Laboratory technician/technologist assistant/clinical personnel:

Write, revise and update organisational and administrative SOPs and provide assistance to the research biorepository manager in developing documentation for MSH Research Biorepository Strategic Oversight Committee and MSH HREC review.

SUPPORTING DOCUMENTS

Attachment 1 - Application

Attachment 2 - Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan Template

Attachment 3 - Establishment of a Research Biorepository Checklist

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE – Establishment of a Research Biorepository

STEP 1: Research Protocol

Develop a research biorepository/research project Research Protocol (to include: vision, goals, objectives, aims, hypothesis and purpose of research biorepository; need and current status of research biorepository practices; summary of ethical issues; how biorepository will be evaluated for success; description of how research data is collected, stored, used and discussed in compliance with National Statement; criteria for sampling and participation selection). Please see MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113) and the attached Research Protocol template for more information.

STEP 2: Undertake consultation

Consultations must be carried out with diverse stakeholders, groups and communities. The Custodian must clearly indicate to those consulted how their input may influence the establishment and/or future aims of the research biorepository.

It is important to note that this requirement may be scaled based on the size and scope of the proposed research biorepository. For example, a research project specific collection may only require consultation with MSH, Translational Research Institute (TRI) and University stakeholders. Whereas a population based or community research project may require extensive consultation with community groups, especially if patients/participants are considered ‘vulnerable’ or if cultural sensitivity issues have been identified. Regardless of the level of consultation, details of consultation and engagement must be articulated and included as part of the Research Protocol as an attachment.

STEP 3: Research biorepository Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan

Develop and maintain a Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan that defines the research biorepository's overall financial, budgetary resourcing and legacy strategy. The cost for biospecimen collection, processing, storage and distribution can be considerable and it is important for research biorepositories to develop a Financial Plan and Sustainability Strategy for the expected lifetime of the biospecimen storage and handling activities.

Custodians are encouraged to utilise the Research Biorepository Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan Template contained within Attachment 2. However, dependent on the size of the collection, financial plans and sustainability strategies, resourcing plans and legacy plans may be scaled down and included as part of the Research Protocol.

Research biorepository plans and strategies should be reviewed on a regular basis and adjusted as needed. Please see Operational Arrangements Procedure (PR2017/101) for further information.

STEP 4: MSH Strategic Research Biorepository Strategic Oversight Committee

Table the Research Protocol and associated plans/strategies with the MSH Strategic Research Biorepository Strategic Oversight Committee for consideration and review. The Custodian must receive approval from the MSH Strategic Research Biorepository Strategic Oversight Committee prior to proceeding with a HREA and Site Specific Assessment (SSA) and prior to the establishment of a research biorepository in MSH.

Please see MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Management - Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

STEP 5: Research biorepository internal governance structure

Develop research biorepository internal governance structure documents including but not limited to:

- research biorepository Management and Scientific Review Committee/s Terms of Reference (if applicable)
- research biorepository PICF if not utilising MSH PICF
- SOPs.

During resource development it can be helpful to review current procedural and regulatory standards and determine which are pertinent to the resource operations. Custodians must aim to:

- familiarise themselves with the current best practice documents to determine initial base standards for resource development, operations, management, evaluation, and expansion
- orient employees and adjunct teams to current best practice documents and published standards
- incorporate best practices and current relevant standards into resource SOPs with an emphasis on supporting evidence-based practices

STEP 6: MSH HREC

Complete a HREA and SSA in accordance with MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Management - Research Governance (Site Specific Assessment) Procedure (PR2017/116). Submit the application and relevant

documents such as the Research Protocol, PICF and Curriculum Vitaes to the MSH HREC for ethical review. Receive approval from the MSH HREC and research governance authorisation.

Step 7: MSH Strategic Research Biorepository Strategic Oversight Committee

Notify the MSH Strategic Research Biorepository Strategic Oversight Committee when MSH HREC and research governance authorisation has been received and collection has commenced.

STEP 8: Commence operations

Procure equipment and staff in accordance with Research Protocol and strategies outlined in the Research Biorepository Financial Plan and Sustainability Strategy, Resourcing Plan and Legacy Plan.

STEP 9: Self-audit, review and compliance

Utilise Attachment 3 - Establishment of a Research Biorepository Checklist to aid in self-auditing, review and compliance.

STEP 10: Metro South Research internet site

In consultation with the Metro South Research, the Custodian must ensure applicable information on the research biorepository is made publicly available and easily accessible to stakeholders, including participants and the general public on the Metro South Research internet site.

PROCEDURE DETAILS

Procedure Number
PR2017/100

Procedure Name
MSH Research Biorepositories – Establishment of a Research Biorepository Procedure

Policy Reference
PL2017/53
MSH Research Biorepositories Policy

Supersedes
Version 2.0

Procedure Author
Erica Wright, Manager, Research Development, Metro South Research, Metro South Health

Portfolio Executive Director
Professor John Upham, Chair, Metro South Research, Metro South Health

Approving Officer
Professor John Upham, Chair, Metro South Research, Metro South Health

Approving Date
05 July 2021

Effective From
05 July 2021

Date of Last Review
05 July 2021

Date of Next Review
05 July 2024 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Business planning considerations

Many factors contribute to the decision to develop and run a research biorepository. In practice, the process often starts from the willingness of medical doctors and scientists to develop a resource useful for diagnosis, prognosis and research purposes. However, initiating a research biorepository must not only rely on individual action but also requires a clear commitment by the institution/s. It also needs to ensure that collections are developed within appropriate legal, ethical, clinical, scientific and technical guidelines to provide historical continuity in specimen and record keeping. Finally, the research biorepository should ensure that the materials stored by the research biorepository can be made available for research.

1.1 Objectives

MSH research biorepositories must be operated throughout their existence with integrity, transparency, accountability and respect for human rights and freedoms. A research biorepository must be established, governed and managed in accordance with applicable domestic law, guidelines, international instruments and the MSH Research Biorepository Governance Framework.

The objectives of all MSH research biorepositories, regardless of the size of operations, must be:

- to provide a resource for research that is valued by society and conducted within applicable laws, regulations and ethical frameworks
- to ensure the collection, storage, transfer, access, use and disposal of patients/participants' samples and data are scientifically, legally and ethically appropriate
- to secure the sustainability of the collection, the protection of participants' privacy, the confidentiality of data and, ongoing public trust and involvement.

1.2 Purpose

Research must respect the patients/participants and be conducted in ways that uphold human dignity, fundamental freedoms and human rights. To ensure that the research biorepository will be governed by the overarching principles of transparency and accountability, when proposing to establish a research biorepository, including all research project specific biospecimen collections, the Custodian must clearly identify, define and articulate its current and future purpose/mission (ie primary focus of research it supports) and proposal for operational scope.

When establishing a research biorepository, the Custodian must develop criteria for sampling and participant selection to ensure that the type of samples and data contained in the research biorepository are representative of the targeted population and are scientifically appropriate for its intended use. Consideration must be given to maximising flexibility in the design to enable future collaboration and cooperation, especially in regard to database compatibility and interfaces.

Research biorepositories can be any of the following, or a combination thereof:

- Cross-sectional - biospecimens and data collected from a population, or a representative subset, at a specific point in time (ie clinical trials).

- Longitudinal - correlational research project that involves repeated observations of the same variables over long periods of time, often many decades (ie empirical research project of people with a common characteristic such as cancer or disease).
- Large-scale - a National or State-wide collection, a research biorepository which stores large numbers of samples operated by a dedicated laboratory and/or a central collection a collecting biospecimens from a wide variety of patients/participants.
- Disease/cancer-specific - a collection focused on the collection and storage of targeted samples such as leukaemia and lymphoma, head and neck cancer or prostate cancer.
- Population based - a prospective biobank (focused on the research project of the development of common, complex diseases over time, and mainly based on blood/ nucleic acids collection).

The research biorepository Custodian must determine which services are to be provided and that the appropriate infrastructure is in place to provide them in such a way as to ensure that high quality biospecimens will be available for future research efforts. Consideration might also be given from the start to whether the biospecimens in the research biorepository could be used for non-research purposes such as clinical genetic services, law enforcement, insurance, legal actions and identification.

1.3 Recruitment

The type of research biorepository defines the recruitment process and plan. Relevant considerations include the population and the types of individuals to be asked to participate, as well as any cultural sensitivities that these decisions might raise. Consent requirements are always of paramount importance in the recruitment process, and are particularly challenging where children are to be recruited.

The population from which it is intended to collect samples and information needs to be determined before the research biorepository is established. For large-scale population research biorepository the need for the collected resources to be representative both of the population under research project and the diversity of populations is important. Whilst this may not be practicable from a research perspective, best practice still requires recruitment from as widely generalisable a population sample as possible. Recruitment arrangements need to guard against research bias.

There is also an importance of collecting biospecimens from populations with demographic characteristics and diversity that are appropriate to the scientific goals of the research. The nature of the population under study influences the types of research that can be undertaken. Population diversity has a major influence on research biorepository design. Research biorepositories containing samples from more diverse populations (like Australia) favour association studies to examine population distribution of genetic variants and their association with disease.

Recruitment strategies will depend on the nature of the research biorepository; whether, for example, there is a particular disease focus, or if the research biorepository is intended as a more general resource for research.

Relevant considerations include whether people who lack the capacity to consent, including children and ‘protected adults’, will be included and if they are, what special protections are to be in place. For those research biorepositories with a particular disease focus, the relevant population will be affected patients/participants and family members, and recruitment may be through referral by health professionals, invitation by genetic registry staff, or self-referral. Research biorepositories must have SOPs to address these matters.

For research biorepository with a more general research focus, recruitment will be more open. It needs to be non-coercive and equitable, and arrangements need to be in place to ensure this. To be 'non-coercive', recruitment needs to be carried out in a way that respects individual freedom of choice. In ensuring equitable recruitment research biorepositories need to be aware of potential barriers to participation, such as those relating to age, gender, ethnicity, social class, residence, employment and language, through location and opening times of recruitment centres and by translation of research project materials.

1.4 Cultural sensitivity

Cultural sensitivity is needed in all aspects of managing a research biorepository, including recruitment. The National Health and Medical Research Council (NHMRC), 'National Statement on Ethical Conduct in Human Research' (2015) ('National Statement') reflects this; for example, the provision on respect includes having due regard for the beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in the research. Also relevant is the requirement for research biorepositories to have SOPs for collection, use, storage and disposal of human tissue in research to have regard to socio-cultural considerations.

1.5 Research Protocol

The research biorepository Custodian must ensure a Research Protocol is developed. The research biorepository Research Protocol must include the following components:

- Description of the vision, goals, objectives, aims, hypothesis and purpose of the research biorepository.
- Description of the need and current status of research biorepository practices in MSH.
- Summary of ethical issues in the milieu specific to the research biorepository and issues relating to public confidence and public relations.
- How the research biorepository will evaluate its success at meeting its objectives, developed in collaboration with all necessary stakeholders (eg milestones; metrics such as the number of cases collected and released).
- Description of how research data will be collected, stored, used and disclosed in compliance with the National Statement.
- Criteria for sampling and participant selection.

A Research Protocol Template has been developed and included as an attachment to MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113).

1.6 Infrastructure and space planning

When planning, it is crucial to fully assess start-up, operational, and maintenance costs for any and all infrastructure. Some favour a centralised model in an attempt to promote harmonisation to achieve standardised, well-annotated, high-quality, robust biospecimen and data research biorepositories. In this regard, it can be helpful for each institution to perform evaluative exercises, for example using the ISBER Self-Assessment Tool.

Infrastructure requirements can vary based on the research biorepository scope and requirements. Infrastructure requirements include but are not limited to the physical laboratory, office, and adjunct and/or satellite space needs as well as requisite informatics, equipment, storage platforms,

telecommunications, and consumables needs. In general, the baseline requirements should aim to include ample space for the following functions, where appropriate, based on the nature and functions of the resource:

- Collection, receiving, tracking, and shipping as needed.
- Immediate and interim processing (eg fine and gross dissection benches).
- Areas to prepare and process blood products.
- Histological preparation.
- Equipment such as safety hoods (laminar flow), centrifuges, freezers.
- Stations for pathology case review.
- Storage for biospecimens, consumables, and related records.
- Office work areas to support data, operational, and end user management.

In addition, some research biorepositories may include areas dedicated to purification of nucleic acids, tissue and cell culture, single-cell suspension, and other specialised laboratory practices.

1.7 Equipment selection and maintenance

Equipment selection complements infrastructure planning and should be considered in parallel with space planning and resource design. Research biorepository management should consider the following factors when selecting equipment:

- Current resources and budget, current and future services, need, frequency of use, vendor options, manufacturing lead time, and cost — including maintenance, delivery, warranty, service contracts, lifespan, eco-friendliness, performance, and efficiency cost savings, along with current and future service provision options.
- Aim to factor depreciation for all capital equipment into the cost-recovery plan when appropriate.
- Utilise resource sharing to defray financial investment in equipment.
- Determine if used/sale equipment is appropriate.
- Consider batching service contracts among neighbouring resources to save money.
- Review calibration and validation instructions.
- Review preventive maintenance summaries and/or equipment log files after and prior to scheduling all maintenance visits as part of the quality management program.

2.0 Consultation

Prior to establishment the Principal Investigator and Custodian of the research biorepository must engage independent members of relevant and diverse communities in decisions about its establishment, governance and use and carry out consultations with stakeholders. The greater the breadth of targeted participants, information and data collected for the research biorepository, the more important that broad consultations be carried out and with diverse groups.

Consultations may assist in communicating information about the nature, purpose and scope of the research biorepository as well as identifying patient/participant needs and concerns. The extent and types of consultations with relevant stakeholders should be based upon consideration of the nature and

design of the proposed research biorepository; the risks involved to patients/participants, their families and to identifiable groups; any particular sensitivities related to the individuals and groups under research project; and the types of research to be conducted with the research biorepository. The Custodian must clearly indicate during any consultation how they will take account of stakeholders' views.

The Custodian must ensure the consultations do not inflate the future and potential benefits of the research biorepository itself and of participating in the research biorepository. The following principles apply when undertaking appropriate consultation prior to establishing a research biorepository in MSH:

- Consultations may be carried out using diverse approaches and more than one approach may be used (eg focus groups, surveys, interviews, forums, workshops, public meetings and web-based discussions).
- Consultations should aim to cover a variety of issues, particularly those where concerns have been identified (eg scientific, legal, regulatory, social and ethical issues).
- Consultations should be carried out with diverse stakeholders, groups and communities as relevant for the research biorepository this may include the general public, patient groups, industry, scientists, ethicists, clinicians, researchers and other research biorepositories.
- Consultations must be conducted through appropriate means. The extent and types of consultations with relevant stakeholders should be based upon considerations of the nature and design of the proposed research biorepository, the risks involved to participants and their families and to identifiable groups, any particular sensitivities related to the individuals and groups under research project and the types of research to be conducted with the research biorepository.
- Consultations must cover a variety of topics including the proposed purpose and focus of research. The Custodian should articulate as much as is known about the possible future scope of the research biorepository.
- The Custodian must clearly indicate to those consulted the manner in which their input may influence the establishment and impact on the future aims of the research biorepository.

The MSH Research Biorepository Strategic Oversight Committee may be also engaged to assist in the consultation process. Please see Strategic Oversight Committee and Compliance Procedure (PR2017/99) for more information.

3.0 Scientific and financial feasibility

Given the significant resource implications of establishing and maintaining a research biorepository, the scientific and financial feasibility of the research biorepository be assessed, the scientific need demonstrated, and the financial resources secured prior to establishment.

3.1 Scientific feasibility

The research biorepository Custodian must 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, subject to applicable domestic laws, regulations and ethical guidelines. The research biorepository Custodian must ensure risks to individuals, their families and potentially identifiable populations or groups whose samples and data are included in the research biorepository and used for research are minimised.

3.2 Financial feasibility

MSH research biorepositories are dependent for funding on philanthropy, industry sponsored clinical trials, government infrastructure grants, research grants and some service cost recovery/offset. One important element of research biorepository capacity is financial security of new and existing MSH research biorepositories.

The research biorepository initiator must utilise general business planning principles to develop a Financial Plan and Sustainability Strategy, including a budget estimate, of the anticipated revenues and operating expenses in order to establish sustainable entities. The practical and financial feasibility of the research biorepository should be assessed and the financial resources to support the infrastructure should be secured as early as possible.

The funding model established must give consideration to ensuring the finances will be secured for the lifespan of the research biorepository. Where a research biorepository Custodian foresees private or foreign investment in the research biorepository occurring or commercial or international collaborations being entered into, this must be clearly articulated, communicated (especially to patients/participants) and undertaken in accordance with applicable domestic law and regulation.

Where the Principal Investigator or Custodian foresees attracting private investment or entering in commercial collaborations, this should be clearly articulated and communicated before such collaborations have been established, especially to patients/participants.

For all new collections of biospecimens funded by MSH, researchers and their host institutions must reach agreement with the MSH Research Biorepository Strategic Oversight Committee on specific arrangements for the custodianship and control of use of sample collections (both while the research project is ongoing and after it is finished) before funding is released. It is expected that samples collected with public monies will be fully utilised for research, and so arrangements for maintenance and access, including by other research groups, following the initial funded research project should be made. In some rare circumstances MSH may consider having formal responsibility for custodianship of the collection.

3.3 Financial Plan and Sustainability Strategy

Custodians must make available information on the scientific rationale underlying the research biorepository, and on the scientific and business uncertainties and risks associated with the establishment, operation and use of the collection.

After reviewing the proposed research biorepository's scientific and financial feasibility a Financial Plan and Sustainability Strategy must be developed. The Financial Plan and Sustainability Strategy must:

- include the financial plan and sustainability strategy which includes the financial model that the research biorepository intends to adopt over its lifespan
- be explicit and transparent about the nature and source of its financing/funding
- set out the financial and scientific feasibility of the research biorepository, examining any assumptions made or risks identified with establishing the research biorepository
- ensure that the research biorepository has sufficient professional staff and resources to operate effectively in all aspects and include the proposed organisational structure
- include plans for ensuring the ongoing financial and public support of the samples and data throughout its existence
- include plans to mitigate risks
- include plans to procure or establish a databank/database
- include a business strategy in the event that funding is terminated or its nature changed

- establish and document any planned cost recovery/offset mechanisms (on a regular basis (eg annually) a review should be conducted of the cost recovery processes)
- indicate approval/endorsement from all necessary stakeholders.

Additionally, the strategy should consider future collaboration and co-operation, especially regarding database compatibility and interfaces. Appropriate design elements providing for such compatibility and interfaces should be incorporated when creating the databases. The Custodian should consider using standardised approaches for the collection, storage and analysis of biospecimens and/or data to facilitate cross-research biorepository data exchange and sharing across MSH.

4.0 Resourcing Plan

An organisational overview can assist in defining the institutional structural components within and around the research biorepository. An overview typically begins with description of the organisational mandate; its associated goals, mission, and vision; operational scope; and core areas of research support.

The research biorepository Custodian must ensure that appropriate staff and resources are available to preserve/maintain records, data and biospecimens appropriately, and to handle requests for access to data and biospecimens.

Organisational structures may vary according to the nature of the research biorepository. Thoughtful documentation of the resource's organisational structure in relation to its parent institution may help to predict needs, promote incorporation of existing resources, and streamline workflow while increasing communication among stakeholders, management, and end users.

Custodians must seek to define and document their organisational structure in advance of resource planning and/or development. A Resourcing Plan and organisational structure must be clearly defined to encompass at a minimum the following roles and elements:

- Leadership including nominated Custodian.
- Management of operations.
- Contact and access processes.

The specific roles and chains of responsibilities of those involved in the research biorepository's activities should be clearly identified and delineated, including the person(s) responsible for:

- ensuring adherence with the governing requirements of the research biorepository including the legal, financial, ethical, policy, managerial and reporting requirements
- ensuring the security of samples and data particularly the protection of privacy and confidentiality.

As part of operational management, a research biorepository must include components that perform the following roles:

- Custodian- Leader/Director/Principal Investigator/Initiator: This component is responsible overall for research biorepository employees, daily operations of the research biorepository partnership activities and funding and reporting or accountability to institutions or agencies. The individual(s) identified in this role also may be nominated to perform the roles of the Research Biorepository

Manager role (eg for a small/ mono-research biorepository and moderate-sized/oligo-research biorepository). This role may also be divided between a professional and operational manager.

- Research biorepository manager- Operations and/or access management/laboratory manager: This component establishes and oversees standards for the operations of the research biorepository, including SOPs, Quality Control (QC), Quality Assurance (QA), and data protection policies used when handling and storing biospecimens and their derived data, as well as other data from patients/participants. This role will also review performance including patients/participant and biospecimen accrual.
- Research coordinator: This component may be included as part of the research biorepository manager role. This role is responsible for coordinating clinical research including administrative and operational support for clinical research projects.
- Research team: works under the auspice of the Custodian to undertake clinical research utilising MSH research biorepository biospecimens.

This organisational structure, including identification of individual(s) who will perform these roles, may be influenced by external stakeholders (such as the institution in the case of large research biorepositories) and approval will normally be part of ethics review and approval. This structure should be accepted by all those who assume a defined role, should be known to all staff, and also be a matter of public record.

The organisational structure and chart can be a significant tool in supporting existing governance structures through elucidation of roles, responsibilities, chain of command, and requisite reporting relationships. Research biorepositories should develop and publicly display the current organisational chart within the resource. Research biorepositories should provide a copy of the current organisational chart and discuss with every new staff member as part of the orientation process, reviewing the current management of the institution.

The research biorepository can choose to assign the different roles within the structure to an individual, individuals, or committees and this should be based on factors relating to the nature of the research biorepository, including its size, sources of funding, stakeholders, and the number of anticipated users of the research biorepository. This means that for a small research biorepository all roles might be assumed and performed by one individual who accepts all these roles while for a large research biorepository some of these roles might be performed by a Research Biorepository Management and Scientific Review Committee.

4.1 Resourcing and roles

Personnel are an important part of a research biorepository. Descriptions of roles and responsibilities are important for selecting, hiring, and supervising qualified individuals. Personnel involved in research biorepository management and use, including researchers, technicians, nurses, surgeons, pathologists, anaesthesiologists, and assistants should be aware of the purpose and goals of the research biorepository. Research biorepository personnel are encouraged to participate in the research biorepository establishment process in accordance with their professional roles and responsibilities.

Although the research biorepository Custodian is responsible for overseeing the research biorepository program, all personnel have defined roles and responsibilities and should be familiar with this Procedure. It is important to note that roles at some research biorepositories may overlap. The roles and responsibilities should be used as a guide to ensure that personnel are qualified by education and training to accomplish their respective jobs. The Custodian of the MSH research biorepository must:

- Nominate responsible employees; these individuals must have explicit, well-resourced roles to

ensure that these and other research governance expectations are met, and to take part in opportunities to share best practice.

- Ensure that all personnel are knowledgeable about the goals and mission for the research biorepository.
- Be qualified by training and experience to carry out the research biorepository's mandate.
- Ensure that personnel have the appropriate professional qualifications that meet recognised standards, underpinned by experience, skills, up-to-date knowledge, education and training and are assigned responsibilities commensurate with their capabilities.
- Develop and implement employee training programs.
- Ensure all personnel have a clear understanding of their role within the organisation and have access to the appropriate level of information to support their decisions and actions.
- Provide training for employees who are new and have not previously received such training and for experienced staff who need to keep current with new development, new methods, updated equipment or software and evolving regulatory requirements.

Health information and bioinformatics experts are integral to the set up and maintenance of research biorepositories. Ideally there would be a member of the pathology staff given managerial carriage of the research biorepository function within the laboratory/organisation organisational structure. Scientists trained in research biorepositories would take day-to-day responsibility for operational aspects of the research biorepository. This would be backed up by administrative staff and systems, appropriate governance and audit practices.

4.2 Job descriptions and curriculum vitaes

Job descriptions aid in the construction of organisational charts that may be referred to by the Custodian and management when allocating resources or personnel for operation of the research biorepository. They may also be used to ensure that research biorepository personnel are appropriately qualified to perform his or her assigned task.

Curriculum vitaes must be sourced for each person involved with the research biorepository. Curriculum vitaes must be included as part of the HREA to assist the MSH HREC in their review of the research biorepository. Please see MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113) for more information.

5.0 Legacy Plan

In addition to the development of the Research Protocol, Financial Plan and Sustainability Strategy and Resource Plan the Custodian must develop a Legacy Plan in the case that the research biorepository is discontinued. The Legacy Plan must include planning provisions should it become necessary to cull the collection through destruction or transfer of the biospecimens/data. It is vital to document the plan for the culling process and obtain the necessary approvals prior to enacting it, including all applicable governing bodies (eg the governing MSH Research Biorepository Strategic Oversight Committee).

All records pertaining to the destruction or transfer of biospecimen/data must be stored under the same terms and conditions for other archival records of the research biorepository as such data resources may provide platforms for international collaboration research.

When considering how long research data and primary materials are to be retained, the Custodian must take account of professional standards, legal requirements and contractual arrangements. Custodians must retain research data and primary materials for sufficient time to allow reference to them by other

researchers and interested parties. For published research data, this may be for as long as interest and discussion persist following publication. If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

6.0 Research biorepository internal governance structure

The research biorepository custodian must ensure SOPs are in place and compliant with the MSH Research Biorepository Governance Framework. If the research biorepository intends to establish a Research Biorepository Management and/or Scientific Review Committee/s relevant Terms of Reference must also be established. Additionally if not utilising the MSH PICF a research biorepository specific PICF must be developed which is compliant with MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115).

6.1 Standard Operating Procedures (SOPs)

SOPs are detailed written descriptions of how to execute a particular procedure or method. SOPs are based on national and international guidelines and conventions as well as policies and procedures that are considered “best practice” in MSH. The purpose of having documented SOPs is to:

- Provide written guidelines for operational aspects of the MSH research biorepository.
- Promote quality and consistency in tissue and tumour banking and data collection across MSH research biorepositories.
- Ensure compliance with applicable regulations and guidelines.
- Facilitate education and training of research biorepository personnel.

The MSH Research Biorepository Strategic Oversight Committee, Custodian or research biorepository manager can identify the need for new/revised SOPs. The need can arise from the findings of a routine SOPs review or from changes to regulations, guidelines, research practice, or institutional policies.

Individuals well versed with the procedures or methods being described may be recruited to draft or assist in drafting new or revised SOPs. SOPs should follow the standard format and general version control provisions apply (eg the first version of SOP is always 1.0).

SOP developers must develop/revise associated attachments, as applicable and revise the version date. Please see Standard Operating Procedures (SOPs) Procedure (PR2017/11) for more information.

6.2 Review and approval of SOPs

Custodians must circulate draft SOPs to applicable reviewers (ie research biorepository personnel, Research Biorepository Management Committee, research biorepository and/or other identified staff representatives) for comments. Comments must be incorporated and a revised final draft SOPs must be submitted to the Custodian for review for accuracy and completeness and for compliance with regulations, guidelines and standard practice. It is also important for the Custodian to note whether change in SOP will require amendment to other administrative documents, especially any applicable privacy impact assessments. Once reviewed by the Custodian the final SOP is tabled at the Research Biorepository Management Committee. Once approved by the Committee the SOP becomes finalised and is able to be managed by the Custodian and research biorepository manager.

7.0 MSH Human Research Ethics Committee (HREC)

The Metro South HREC requires particular documents contained within internal research biorepository internal governance structures as part of the Human Research Ethics Application (HREA) process such as:

- HREA - Completed
- Research Protocol
- PICF
- supporting documents.

Please see MSH Research Management - Ethical and Scientific Review of Human Research Procedure (PR2017/113) for more information regarding this process. The research biorepository will be independently monitored for compliance with applicable domestic law, guidelines and international instruments. Please see MSH Research Management - Research Governance (Site Specific Assessment) Procedure (PR2017/116) and Research Management - Research Governance (Monitoring) Procedure (PR2017/117) for more information.

8.0 Information and education

Information regarding MSH research biorepositories should be made publicly available and easily accessible to stakeholders, patients/participants and the general public on governance, oversight and management and should include:

- the ethics approval for the establishment of each MSH research biorepository
- the mechanisms and responsibilities for governance, oversight, management and review of applications for access and use, auditing and redress, and complaint processes
- significant modifications to the Research Protocol or PICF of the research biorepository
- if applicable, the ethics approval obtained for significant modifications to the Research Protocol or PICF of the research biorepository
- key elements of applicable domestic laws, regulations, ethics guidelines and international instruments
- the legislation, regulations and ethical guidelines that all MSH research biorepositories operate under, including how to access information on these, such as the implications for non-adherence
- annual reports of compliance of the research biorepository with applicable domestic laws, regulations, ethics guidelines and international instruments.

Additionally, the research biorepository Custodian should ensure information is made publicly available and is easily accessible to stakeholders, including patients/participants and the general public, on:

- the background and objectives of the research biorepository
- the purpose(s) and scope, both current and future, including the aims and scope of research
- how the research biorepository is set up operationally
- where the research biorepository complies with the best practices in the external guidelines and when it does not, reasons should be provided

- the internal research biorepository internal governance structure and SOPs of the research biorepository, including proposed security and data protection measures, and access policies
- the type of research that will or is being carried out with the samples and data contained within the research biorepository
- the research outcomes resulting from utilisation of the research biorepository, including any health and scientific benefits
- the scientific and business risks and uncertainties associated with the establishment, operation and use of the research biorepository
- any risks for members of the public, particularly public health risks, associated with the establishment, operation and use of the research biorepository
- where possible the nature and source of its financing/funding, especially private or foreign investment, commercial or international collaborations
- financial model information which could include the business plan for both the short-term and the long-term
- the ethics approval obtained to establish the research biorepository
- the proposed duration of the research biorepository
- the name(s) of senior management
- any vested interests and partnerships
- where to find more information on the research biorepository including contact details for a representative who will answer questions from the public.

The MSH Research Biorepository Strategic Oversight Committee may make determinations on what kinds of information must be made public in MSH.

8.1 Metro South Research internet site

The public has a right to know that research biorepositories exist. The Metro South Research Internet Site has been established to enable research biorepository Custodians to publish information to the public which is easily accessible on the existence, purposes, rationale for and operation of their research biorepository.

The Custodian should make information publicly available in easily accessible form detailing its background, purpose, scope, ethical and governance framework, name(s) of senior management, answers to Frequently Asked Questions (FAQs) as well as contact information of a representative who will answer questions from the public.

It is good practice to offer research patients/participants the opportunity to be kept informed about the general results of research projects completed using the samples they have donated, though this may not be appropriate or possible in all circumstances. Such communication with patients/participants acknowledges their contribution, shows respect and supports transparency in research.

Patients/participants could be informed by posting information on research outcomes on the Metro South Research internet site, or by offering them the opportunity to receive a newsletter. When new predictive tests of clinical value become available as a result of the research, where possible, participants/patients should be informed how to access these tests if they wish.

8.2 Education

MSH is committed to promoting and educating research biorepositories personnel to achieve adherence to high ethical standards and practices in the collection and storage of biospecimen research purposes. The Custodian is ultimately responsible for the research biorepository specific staff training, as well as ensuring that he/she has adequately skilled, educated and trained staff to carry out the processes of the program and their tasks. The clinical and technical research biorepository personnel have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their relevant duties. Please see the Operational Arrangements Procedure (PR2017/101) for more information regarding training requirements.