PROCEDURE

Metro South Health Research Biorepositories – Operational Arrangements

PR2017/101
Version No. 3.0

PURPOSE

By making available biospecimens, data and information of guaranteed identity and quality, Metro South Health (MSH) research biorepositories serve an essential infrastructure function for scientific investigation, research and development. This procedure describes operational arrangement requirements for all research biorepositories 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.

KEY PRINCIPLES

The following key principles guide MSH research biorepositories in their operational arrangements. 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.

- A MSH research biorepository must develop a strategy for its long-term sustainability. Adequate and reliable resources might include government support, MSH resources, income from services and private support.
- Where applicable, patients/participants should be provided with the opportunity to communicate with representatives of the research biorepository or its designees to discuss its scope.
- Each research biorepository must have a plan to ensure that its key holdings are appropriately dealt with in the event that the biorepository ceases operations. Ideally, this would include arrangements to have biospecimens remain available for research.
- All personnel involved with a MSH research biorepository must be aware of and comply with policies, procedures and Standard Operating Procedures (SOPs) contained within the MSH Research Biorepository Governance Framework for quality management and compliance purposes.

- Custodians of research biorepositories must strive towards best practice in Quality Assurance (QA) with an aim to ensure; authenticity of biospecimens and databases, assurance of long-term stability and quality control of cell cultures, cell lines and genetic constructs, accuracy of the data collected and supplied and expertise in research biorepositories is raised and shared amongst other Custodians and personnel.
- It is optimal that all those involved in MSH research biorepositories have necessary skills and knowledge and a clear understanding of the processes and policies that define the running of a compliant, efficient and successful program.
- In cases where research biorepositories are made accessible to the broad scientific community, establishing access fees and cost recovery mechanisms are appropriate. Varying fee structures can be applied for access depending on the nature of the biospecimen collection and should take into account public investment in the development and maintenance of such collections.
- MSH research biorepositories must utilise consistent naming conventions and definitions. This is essential for communication and comparability, for assuring quality and avoiding unnecessary duplication.
- The collection, processing, handling, storage, transfer and destruction of biospecimens and data must be conducted in a manner that protects the privacy of the patients/participants and the confidentiality of their biospecimens and data.
- Custodians should encourage appropriate access to and use of biospecimens, data, and information with a view to sharing benefits which may include, as applicable, building resource capacity or expertise including in non-MSH employees.

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
- 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
- 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)
- 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 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

Systematically review and audit all MSH research biorepositories' operations whilst biospecimens are attained from MSH patients/participants.

MSH Human Research Ethics Committee (HREC)

Ethically review and approve MSH research biorepository Human Research Ethics Applications (HREA) and associated documents (eg Research Protocol, Participant Information Consent Form (PICF) and supporting documents) when required.

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.

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 (QMs) and that they are understood and kept informed of any amendments.

Laboratory technician/technologist assistant/clinical personnel

Familiarise themselves with documented 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

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE – OPERATIONAL ARRANGEMENTS

STEP 1: Custodian

A Custodian for the research biorepository must be nominated at the time it is created. Responsible custodianship requires careful planning and transparent policies to ensure the long-term physical integrity of the biospecimens while maintaining the privacy and confidentiality of research patients/participants. Research biorepositories may also have a person appointed as a director who is responsible for budgetary and operational arrangements.

STEP 2: Infrastructure and facility considerations

The Custodian and/or director must ensure that all premises, facilities and equipment are fit for purpose and suitable for the ongoing operations of the research biorepository. Additionally, work health and safety must be considered and compliant with provisions outlined in Emergency Preparedness and Work Health and Safety Procedure (PR2017/108).

STEP 3: Qualifications, education and training

All personnel of the research biorepository must be appropriately qualified and be given relevant education and training applicable to the relevant facility and/or laboratory.

STEP 4: Funding

The Custodian and/or director must ensure the research biorepository is sustainably funded and that appropriate procedures are in place for financial gain, income generation, incentives, cost recovery/offset and royalties (where applicable).

STEP 5: Standard Operating Procedures (SOPs) - operational procedures

The Custodian and/or director must ensure SOPs appropriate for the safe, efficient and effective operations relevant to the biorepository are documented and are available to all personnel involved in its functions. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) and Standard Operating Procedures (SOPs) Procedure (PR2017/11) for more information.

STEP 6: Commercial research

Where applicable, the Custodian and/or director must ensure patients/participants are informed that commercial products may arise from research conducted using the research biorepository during the informed consent process.

An example of suitable wording is as follows; 'While your sample may contribute to research that has a commercial benefit, for example the development of a new technology, you will not be entitled to receive a financial return.' Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.

STEP 7: Benefit-sharing and intellectual property

The Custodian must ensure there are SOPs in place pertaining benefit-sharing and where appropriate, the Custodian should ensure there is a system where benefit-sharing agreements can be negotiated before a research project begins.

The Custodian must also inform the patients/participants of any legal or intellectual property rights that might be material to their participation at the time of consent.

STEP 8: Acknowledgement and publication

The Custodian must ensure researchers using the research biorepository are provided with detailed guidance on the manner in which it wishes to be acknowledged.

Researchers must acknowledge in publications, presentations, and where relevant, patents filed, the research biorepository resources they have used.

STEP 9: Internet

The Custodian and/or director must ensure their research biorepository is registered on the Metro South Research internet page by contacting the person listed on the site.

PROCEDURE DETAILS

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MSH Research Biorepositories – Operational Arrangements Procedure

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ATTACHMENT 1 - Application

1.0 Ownership, custodianship and the gift relationship

1.1 Ownership

Legally and ethically, a clinician, researcher or organisation cannot own a human body or a sample of that human body, once it has been removed from a person. MSH however has an obligation as an organisation to assume organisational responsibility for collections of biospecimens collected from MSH patients/participants. This responsibility extends to collections which; are held within our facilities or assets; contain materials which have originated from MSH patients/participants and/or are accessed by staff within our employment. Research biorepositories and their associated data are valuable assets for MSH therefore organisational responsibility consists of a number of important, interdependent characteristics. MSH organisational responsibility provides greater security for collections and better assurance that patients/participants' rights will be protected. These characteristics are reflected in the following principles:

- **Community benefit** – MSH is responsible for ensuring overall social, ecological and economic benefits to research for all MSH research biorepositories. The use of information derived from research biorepositories will often help individuals or plan for the future and make better decisions. When the community uses information already collected, it may save significant time and money resulting in encouraging the wider use of research biorepository information. These benefits are apparent in social, ecological or economic areas, often in combinations.
- **Access** – MSH is responsible for implementing consistent biospecimen access principles recognising legal and commercial parameters. This may include intellectual property rights, privacy, security or commercial advantage limitations.
- **Accountability** – MSH is ultimately accountable for the research biorepository and its data. MSH may delegate the role of custodianship of a research biorepository to a Principal Investigator, researcher, clinician, initiator and/or MSH employee. The delegation of custodianship makes it easier to deal with changes in individual circumstances of the research team. While an individual, for example a Principal Investigator, may have day-to-day responsibility for management of a collection of biospecimens, MSH considers that it is more appropriate for formal responsibility to rest with institutions/organisations rather than with individual researchers.
- **Disclosure** – MSH is responsible for declaring the standard/specification to which the research biorepository is operated and associated data is maintained.
- **Maintenance** – MSH is responsible ensuring the maintenance of all of collections, that it funds, where biospecimens are attained from MSH patients/participants.
- **Quality Assurance (QA)** – MSH is responsible for substantiating the quality of samples derived from research biorepositories.
- **Self-assessment** – MSH will undertake assessments of research biorepositories under their mandate.

1.2 Gift relationship

MSH requires that samples of biospecimens donated for research are treated as donations, although there will sometimes be conditions attached. In this way, a 'gift relationship' between research

patients/participants and researchers can be promoted, highlighting the altruistic motivation for participating in research. It is important that the patient/research participant understands and agrees to the proposed use(s) of the donated material where this is known, and what would happen to any intellectual property rights generated from the donated biospecimen, to avoid any uncertainty or detriment to the research participant.

1.3 Custodianship

MSH considers that the role of employees involved in the collection, storage and distribution of biospecimens as 'Custodians' of that sample thus taking on certain responsibilities as part of that role. A Custodian for the research biorepository must be nominated at the time it is created. This could be the initiator, an individual researcher, Executive Director of a relevant Hospital or Head of a Department or Division. If the service/facility responsible for creating the research biorepository is the nominated Custodian the authority should be delegated to a responsible individual. The Custodian may or may not be the same person as the research biorepository manager. Additionally, the role of the Custodian may be shared amongst a MSH operational and a professional lead (ie a Director, however primary responsibility must lie with one responsible individual).

Current Australian legislative, regulatory and ethical systems should be considered when determining who the nominated Custodian should be. Consideration should be given to circumstances where the Custodian of the research biorepository may change through unforeseen circumstances (eg change of government) and the affects this may have on the research biorepository. MSH understands that custodianship inherently brings with it the right to determine what happens to a collection in accordance with legislation and the expectations of the patient/participant. This includes responsibility for:

- safekeeping of samples
- control of the use of samples
- transfer to third parties (if applicable)
- subsequent maintenance
- eventual disposal (if required) (ie after the original research project funding is finished).

The Custodian may delegate and document responsibility for the implementation of SOPs to suitability qualified members of staff and provide them with defined responsibilities and authority. Participants must be clear who will be responsible for custodianship of the sample and control of any personal or confidential data related to it and under what circumstances custodianship can be transferred to a third party (if applicable).

1.4 Investigator financial conflicts of interests

The regulations governing extramural research contain examples of conditions or restrictions that might be imposed by an awardee institution to manage Investigator financial conflicts of interest, which includes public disclosure of a significant financial interest. The responsibility of conflicts of interest management rests with the awardee institution as described in the regulations. Awardee institutions and Investigators should adhere to institutional and MSH policies governing conflicts of interests Management of Conflict of Interest Policy (PL2014/38) and Management of Conflict of Interest – All Staff Procedure (PR2016/66).

1.5 Institutional financial conflicts of interests

Institutional financial conflicts of interests should be considered and managed as appropriate. Any known or likely financial benefit to the institution or research biorepository should be disclosed accordingly, for example on the research biorepository internet site or in a clear and concise manner in a brochure that accompanies the informed consent document.

1.6 Non-financial conflicts of interests

Non-financial conflicts of interests should be identified and managed to the extent practicable. An example of a non-financial conflict of interest includes situations in which the individual managing the research biorepository is also a researcher seeking access to biospecimens. In cases where non-financial conflicts of interests are unavoidable (eg small biospecimen collections), research biorepositories should manage the conflicts of interests by adhering to MSH policies and procedures and, if deemed necessary, publicly disclosing the conflicts of interests; for example, via the resource's internet site or written materials. Please see MSH Management of Conflict of Interest Policy (PL2014/38) and Management of Conflict of Interest – All Staff Procedure (PR2016/66) for more information.

2.0 Management and staffing

Running a research biorepository requires appropriate staff for biospecimen processing and storage and for data management. The job description, tasks and reporting system of all supervisory and technical staff involved in the research biorepository must be documented. This is of particular importance in instances where the staff involved in the research biorepository also performs other tasks within the institution (eg pathology service or service activities in molecular biology). Personnel must have adequate educational background, experience and training to ensure that assigned tasks are performed in accordance with the research biorepository's established SOPs. Research biorepository management must ensure that any conflict of interest involving its personnel are disclosed and suitably managed.

2.1 Director

The director is the person with overall responsibility for management of the research biorepository. The director must be qualified by training and experience to direct and manage the scope of activities conducted by the research biorepository. The director and Custodian role may be undertaken by the same employee.

The director must implement MSH policies and procedures and is responsible for all operations, including compliance with current national, state and local regulations. Depending upon organisational structure of the research biorepository, the director may have other responsibilities in collaboration with the Custodian including (but not limited to):

- Ensuring that the research biorepository operates within budget.
- Ensuring that the research biorepository has adequate funding for operations which may require the development of cost-recovery strategies to ensure the research biorepository's short and long-term financial stability.
- Ensuring that adequate SOPs are in place for access to the biospecimens stored in the research biorepository and that requests for biospecimens are met in a timely fashion.
- Serving as a liaison to key users and ensuring confidentiality of data.
- Ensuring that SOPs and best practices are in place and in general use.

2.2 Personnel supervision

The Custodian and/or director must construct and maintain an organisational chart that delineates the functional relationships within the research biorepository. Candidates for the supervisory and technical staff must be approved by the Custodian and/or director. The Custodian and/or director must also approve and maintain job descriptions and document staff responsibilities in accordance with the MSH

Human Resources polices and procedures. The Custodian and/or director should ensure that personnel responsible for performing research biorepository activities are adequate in number and experience, and are assigned responsibilities commensurate with their capabilities. The Custodian and/or director should assign to a specific position the responsibility for ensuring the protection of biosecurity, data and privacy whose responsibility it is to ensure internal compliance with the MSH Research Biorepository Governance Framework.

The Custodian and/or director is also responsible for developing and reviewing employee training programs in consultation with the research biorepository manager and must ensure that the research biorepository is in alignment with all federal, state and local requirements.

2.3 Quality Management System (QMS)

The Custodian and/or director must ensure that a Quality Management System (QMS) is in place to ensure that operations follow the research biorepository's Research Protocol and SOPs and comply with applicable requirements of governmental and regulatory organisations. The Custodian and/or director should require regular, documented, internal reviews or audits to ensure compliance with SOPs and regulations and satisfy end-user requirements. Where possible a deputy should be appointed to serve in the absence of the person responsible for quality management. The person responsible for quality must have direct access to the Custodian on all matters concerning quality. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

2.4 Contracted laboratory services

Research biorepositories that contract for laboratory services must retain records pertaining to the name and address of the contracted facility, the name and contact information for key personnel at the location where the services are being provided, documentation of the inclusive dates of the contract period and copies of the contract as well as any accompanying documentation. The scope of work for all contract services should be clearly articulated and adhere to the MSH Contract Management Framework.

2.5 Outsourcing services

Careful planning during the development phase is critical to research biorepository quality and cost-efficiency. Where internal resources are not sufficient to provide all necessary expertise, either during development or as a research biorepository evolves, a research biorepository may seek assistance from qualified external experts and consultants. Consultants should have documented successful experience (similar to that which would be sought for internal staff) in the area for which they are retained.

Research biorepository consultants may provide expertise in areas such as strategic planning, equipment selection and decisions surrounding automation, SOP development, vendor selection, grants and cost recovery, contract management, quality assurance and regulatory affairs. Similarly, the research biorepository may have contractual relationships with other institutions or service providers that provide access to facilities or services not available at the parent institution. In all of these situations, the director should have clear documentation of the relationships, expectations, and responsibilities.

2.6 Research biorepository manager

Research biorepositories should be adequately staffed, and the personnel selected for these tasks must have an appropriate level of specialised training. The research biorepository should be placed under the overall supervision of a biological resource or research biorepository manager with sufficient training, experience and seniority to fulfil the scope of the activities of the research biorepository.

The manager is responsible for operations, including compliance with current regulations and the MSH

Research Biorepository Governance Framework. Additionally, research biorepository managers are responsible for:

- Establishment of proper SOPs for the sound operation of the research biorepository.
- The respect of ethical rules (ie National Statement Section 3.4 – Chapter on Human Biobanks) and their ethical considerations.
- The implementation and surveillance of quality control.
- The application of the decisions of the Research Biorepository Management Committee and/or Scientific Review Committee regarding control, access to and use of biospecimens.
- The publication of general information on the activities of the research biorepository and research results obtained by using the biospecimens.

Many biospecimens are initially collected for clinical purposes. Their transfer into a research biorepository environment for research purposes and distribution need specific management (eg quality control, traceability and management of consent).

2.7 Technical staff

Technical staff are responsible for the implementation of SOPs as established by the management of the research biorepository. The manager has a critical role in receiving, processing and answering requests for access to stored biospecimens. All persons having access to a research biorepository are bound by a duty of professional secrecy (code of conduct in which there is a requirement to maintain confidentiality). Persons with access to confidential data are contractually bound to code of conduct obligations. Rights of access must be managed, traced and limited to authorised persons.

A pathologist or his/her designee, such as a pathology assistant or another individual with applicable training and judgment, should be involved in collecting and processing anatomical pathology biospecimens, including surgical and autopsy tissue and body fluids. It is important that a pathologist determines which biospecimen, or portion thereof, is necessary for complete evaluation and which is excess (remnant tissue) that may be provided to the biospecimen resource for research purposes. The involvement of a pathologist in this process is crucial in order to ensure that patient care is not compromised.

3.0 Qualifications and training

The Custodian and/or director must ensure that appropriate resources are available for personnel to discharge their responsibilities towards the MSH Research Biorepository Governance Framework. The management of the research biorepository must have the qualifications, training and experience requisite to carry out the research biorepository’s mandate.

Custodians and/or directors must employ professional and technical staff with the appropriate competency to carry out their duties effectively and safely. Employees may be engaged at many levels of experience and qualification but they should not be allocated to any piece of work without expert training, or until training appropriate to the job is completed and they are proved competent.

Each employee associated with the research biorepository must have a documented job description with specific delegated tasks and defined responsibilities. Research biorepository personnel must understand the responsibilities of research biorepositories as the “Custodians” of biospecimens for research purposes and be appropriately qualified by education, training and experience to perform his or her task in an efficient, professional and ethical manner and assume their responsibility for the proper conduct of the program. Custodians and/or directors must also ensure that personnel are knowledgeable about its

goals and purpose and are made aware of their duties to protect the privacy of patients/participants and the confidentiality of data and biospecimens.

3.1 Qualifications

Research biorepository personnel must possess sufficient educational background, experience and training to assure that assigned tasks are performed in accordance with the research biorepository's established SOPs. Additionally, research biorepository personnel should have appropriate professional qualifications that meet recognised standards, education, and training and should be assigned responsibilities commensurate with their capabilities. Technical staff are responsible for adherence to policies and SOPs as established by the Custodian and/or director. Duties of each staff member should coincide with written job descriptions. Staff should demonstrate competency in operations for which they have received training and to which they are assigned. Authority and reporting relationships for each member of the staff should be clearly described.

3.2 Training

Adequate knowledge of MSH research processes, related regulations and guidelines are essential to; safeguarding the interests of the patient/participant, achieving program goals, maintaining program compliance, data and biospecimen integrity and overall quality assurance. MSH research biorepositories must provide induction and training for all research trainees. This training should cover research ethics, work health and safety, and environmental protection, as well as technical matters appropriate to the discipline.

All research biorepository personnel must be adequately trained to perform the tasks required by their particular position description. Proper training is important to ensure quality in biospecimen handling and forms an integral part of the research biorepository's quality system.

Support for training is essential for adequate implementation of certain tasks and in some cases, might require additional resources or time away from regular responsibilities to ensure that the training required is achieved in the most effective manner possible.

3.3 Training program

Every individual who enters the research biorepository for the purpose of performing work must be trained in the particular functions or tasks which they are asked to complete. Custodians must ensure that personnel receive appropriate and timely training (for example on technical matters, applicable law and ethical principles), in order to ensure knowledge and practice are kept up to date. Such training should also address the management of conflicts of interest and communication with patients/participants and the public.

Training must be task and location specific and be designed for the particular position that is expected to carry out the work. Training should involve instruction in the use of any equipment used and involve appropriate quality control and quality assurance practices. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

Training must be designed to meet the needs of the personnel working at the collection. The scope, detail and content of the training should reflect the particular responsibilities of each site or individual. Training must be designed to include general issues such as:

- the moral and ethical issues associated with the use of biospecimens in research
- the MSH Research Biorepository Governance Framework and regulatory requirements that must be complied with
- best practices for record keeping and reporting

- security regarding issues of privacy and confidentiality
- implementation of new technologies or practices
- SOP or Research Protocol review
- tissue and information release (material release) and
- material handling (tissue and information processing and storage).

Training must also be designed to include site-specific issues that may include:

- facility security and procedures
- Work Health and Safety (WHS)
- technical procedures and processes relevant to operations at the site (eg deriving biospecimens products such as DNA, RNA, protein and tissue microarrays)
- maintaining records, updating inventories and databases.

Training for some functions may be provided by departments outside of the research biorepository (eg maintenance staff, equipment vendors, infection control, professional air transport regulatory trainers, Human Resources or the Translational Research Institute) but research biorepository staff must make sure that all individuals who enter the research biorepository follow required safety and other policies in performing their particular tasks. Training must be in a language with which the employee is conversant and the level of training must be appropriate to the employee's level of comprehension.

Academic or other institutional training, in the form of courses, may be available. The syllabus of such courses should be reviewed for correspondence with particular training needs and decisions made accordingly. Examples of areas covered by such courses may include legal aspects, management and financial aspects, cellular and molecular biology, statistical aspects, or Quality Assurance (QA).

Research biorepository staff should be asked to review any written procedures for which they are responsible prior to the commencement of their "hands-on" training. A written record indicating that the employee has read the pertinent SOPs must be kept in the employee's training file. This record should include the title of the SOP, the employee's initials, and the date upon which the SOP was read. It is preferable that a short test be administered to personnel concerning the material that is presented for the employee's review. Such training should be reviewed annually.

To ensure quality of research biorepository activities, employee performance should be routinely monitored to identify needs for additional training between regular training intervals. Staff should be informed when first hired that routine monitoring of employees' performance is a part of regular practices for ensuring quality and is applicable to all research biorepository staff.

Research biorepositories must consider implementing SOPs by which they can assess and evaluate whether or not the personnel have achieved the learning outcomes of the training component. Tools used for training such as policies, procedures and/or SOPs must be updated in a timely manner so as to accurately reflect current practice. Training must be carried out in line with the frequency required by legislation, regulation, guidelines practice and reviewed annually. Training should form an integral part of the research biorepository quality system and should be part of its SOPs.

MSH employees must keep current in their area of expertise. This could include attending relevant seminars, conferences, continuing education courses and keeping professional certification updated. Personnel coming in contact with patients/participants and patient information must be trained in maintaining privacy and confidentiality.

Pathology trainees and pathologists must have access to relevant training in biobanking and a trained scientific and administrative workforce is necessary to operationally support research biorepository

activities.

Authorisation to use specialist equipment must be documented in all personnel's training records. For example, new employees should not be allowed to use autoclaves, centrifuges, freeze-drying equipment, cryopreservation facilities and safety cabinets until they have been trained in their use and are proved competent. Research project specific collections must ensure that personnel associated with the collection meet the above requirements.

3.4 Trainers

The trainer is an employee who regularly performs the SOPs in question, has completed the training program previously and is skilled in explaining the elements of the task. The trainer is responsible for assuring that the trainee understands each process and task. For special areas of training (eg human subjects protection, privacy, safety), personnel with special expertise may provide the training. Experts via audio-visual methods including web-based technologies may also provide training. This approach may permit employees to complete special areas of training at their own pace when time can be scheduled based on the employee's daily activities.

During the training period, the trainer demonstrates, explains and reviews the standards to be followed in conducting the processes. The trainer should provide appropriate feedback, as necessary, on the trainee's performance of the process. The trainer should supervise the trainee in all tasks contained in the SOP until the training phase has been completed. Upon successful completion of the training phase and after the appropriate documentation has been completed, the trainer should ask the trainee if they are comfortable conducting the process without supervision or if they feel that additional training is needed. After the training has been completed, the trainer should be available to answer questions when the task is being performed by the trainee for the first few times.

3.5 Training coordinator

Each research biorepository should have an individual responsible for training who is responsible for all aspects of training. The individual maintains the research biorepository's SOPs and coordinates with the supervisor responsible for that particular procedure when any revisions are needed either due to the expiration of the SOP or for technical reasons.

The training coordinator closely coordinates issues related to training in safety with Human Resources and with other individuals responsible for specific areas of research biorepository SOPs (eg shipping and handling). The training coordinator is responsible for monitoring, training and maintaining appropriate training documentation of all employees. The training coordinator maintains records of employees to be trained in each required area, tracks the time of their periodic updates of training, informs the employees of potential times of training and ensures the training is completed according to the required timeframe.

The training coordinator closely coordinates documentation of training and educational activities with personnel who maintain employee records, as needed. Updated training of personnel should be conducted on a periodic basis.

3.5 Frequency of training

Training and repeat training should be conducted in accordance with applicable regulations and also in accordance with the needs of the particular tasks and positions held by research biorepository staff. Training for regular research biorepository tasks should be implemented before employees are asked to perform those particular tasks and repeat training should be performed according to a defined schedule described by SOPs. Supplemental training (sometimes in conjunction with "corrective actions" or a protocol change) may be required following the evaluation of particular incidents in order to prevent their recurrence or to enhance staff performance.

3.6 Cross-training

MSH research biorepositories may find it advantageous to implement a system of cross-training. Cross-training is the practice in which employees are trained in a variety of processes and individuals are able to perform each of these at any time requested. Cross-training alleviates staff burn-out, reduces staff turnover, offers opportunities for advancement and allows for coverage of key activities if staffing levels change either on a temporary or a permanent basis. Also, since some tasks require repetitive motion, cross-training may minimise physical strain among those performing those particular responsibilities.

3.7 Training documentation

Once the training is complete, a written record of the completed training should be made that includes the trainee's signature as well as the trainer's signature. Electronic signatures should be used for documentation of any electronic training that is received.

3.8 Training records

A training file should be maintained for each research biorepository staff member and should include, but may not be limited to the following:

- Position description that includes the job title and responsibilities, as well as the educational experience required to perform the specified task.
- Resume.
- Example of the employee's signature and initials.
- Copies of any certificates documenting that the employee has had specialised training. This should include training in shipping, safety, and applicable regulations.
- Documentation that an employee has read and understands all SOPs pertinent to the employee's responsibilities.
- Documentation of analytical results obtained by a particular staff member to demonstrate proficiency in specified technical tasks. This should include results of reproducibility and/or quality control results.

The training file should be kept in the research biorepository and be available for Quality Assurance (QA) or client review. The training file should be archived according to the research biorepository's SOPs after the employee is separated from the organisation. If an employee moves from the research biorepository to another department within MSH, the employee's training file should be transferred to the new department.

4.0 Infrastructure and facilities

An environment must be provided which is conducive to handling authenticated materials appropriate to the organism domain and to facilitate the acquisition, maintenance and provision of biospecimens and its services. It is the responsibility of the research biorepository manager to check that the accommodation is clean and well-lit and that usual aseptic techniques are followed. Appropriate protective clothing must be Work Health and Safety (WHS) procedures followed.

The Custodian and/or director must outline the premises and processes (including all areas under the responsibility of the research biorepository) used for the specific operational of the collection. These areas, as well as the environment and equipment in the premises, must be in conformity will all relevant provisions contained within the MSH Research Biorepository Governance Framework.

Appropriate areas are required for the specific operation of a research biorepository in MSH. The activities that must be accommodated are as follows:

- receipt and storage of the initial biospecimen

- preparation, regeneration, handling and processing of samples
- biospecimen storage area and back-up or safety duplicate collection (the duplicate collection should preferable be in a remote building or alternative site)
- supply, deliver/sales (kept separate from incoming accessions)
- decontamination and cleaning of equipment
- biospecimen disposal area.

Other areas associated with the research biorepository should be structurally sound, unobstructed, clean and free from laboratory materials. Construction and refurbishments must meet appropriate national regulations and work health and safety policies (eg to the containment level appropriate for the risk (hazard) group of the organisms worked with). If major building, renovation, repair or dirty work is necessary in research biorepository laboratories, normal activities must be suspended until the building, renovation, repair or dirty work is completed.

Appropriate arrangements for site security must be made to ensure hazardous organisms cannot be released to unauthorised users. Please see Facility, Equipment, Storage and Security Procedure (PR2017/103) for more information on security and work health and safety requirements. The minimal requirement is to restrict access to the research biorepository to authorised staff or those accompanied by them. Research biorepositories housing hazardous biospecimens must pay particular attention to security and where appropriate ensure the premises is fitted with security devices.

4.1 Business planning

Business planning can provide justification for financial and institutional commitment and quantification of start-up and sustainability costs.

Business planning should be integrated into all aspects of operations, research biorepository management, and evaluation. Custodians and/or directors must aim to establish a documented annual business plan developed with department staff input and aligned with the vision and mission of the resource.

Business plan items should be specific, measurable, actionable, relevant, and time bound. The resource business plan should also include a formal continuity plan that addresses all possible operational disruptions, including disaster planning. If the resource functions as a service centre, the business plan should address issues related to service and revenue generation.

4.2 Maintenance and inspection

Cleaning and decontamination SOPs must be documented. Building must be cleaned on a regular basis. Cleaning of organism containment areas and specialist equipment must be performed by authorised and trained staff using appropriate personal protective equipment following documented processes.

4.3 Outside support services and supplies

Any support services used by the research biorepository must be of adequate quality to sustain confidence in its activities. Supplies should be sought from reputable companies with, where possible, proven quantity of products. Preference should be given to services and supplies covered by certification schemes. Where no independent assurance of quality support samples is available, the research biorepository is responsible for confirming the quality of vital biospecimens. Copies of purchase orders must be held on file and records of suppliers and standing orders etc should be maintained for a minimum period of five years.

5.0 Cost management

Appropriate models of research biorepository sustainability should emphasise accessibility to biospecimens and data and sustainability of the research biorepository within a framework that maintains public trust. These models should account for potential loss of funding (ie a Legacy Plan should be in place). However, in order for research biorepositories to operate effectively for the fulfilment of their mission, it is critical that they have sufficient financial support to allow for proper functioning. The financial support available may vary depending on the type of institution with which the research biorepository is affiliated, whether it receives public or private funding, and how much of the operational budget the research biorepository itself will be asked to cover in order to remain operational. For example, some research biorepositories may have part of their budgets covered by medical facilities or universities in which they are located.

Regardless of the funding source, research biorepositories must be able to capture their costs in labour, materials and supplies, equipment, equipment support and facilities. It is only when these costs are known that accurate budgets can be prepared and sources for needed funding can be identified. Failure to accurately capture costs may lead to the early termination of programs.

Research biorepositories should develop a business plan based on their objectives and strategy and based on known and estimated costs. Research biorepositories should ensure that costs are captured effectively in order to support sustainability strategies. This plan should be reviewed regularly in order to account for changes in governance, organisational structure, labour, materials and supplies etc.

In addition to annual budget plans, research biorepositories need to have long term projections for sustainability. To ensure continued operations without compromising quality, specific plans for five (5) years and beyond should be developed to anticipate long term costs and revenues.

5.1 Sustainable funding considerations

The collection of biospecimens is a costly activity that is not self-sustaining. Diagnostic biospecimen archive management including storage facilities, information technology, accreditation, biospecimen retrieval, ancillary processing and pathologist validation is a significant cost to MSH.

Historically long-term storage of formalin-fixed, paraffin embedded tissue was funded from pathology service fees; however, the scale, complexity and cost of supplying the demands of health and medical research greatly exceed the funding available. In addition, most supplementary diagnostic testing of archival biospecimens is not funded in Australia.

Research biorepositories, external to pathology practices, depend on funding from philanthropy, industry sponsored clinical trials, government infrastructure grants, research grants and some service cost recovery.

Where archival biospecimen retrieval, ancillary processing, pathologist review +/- supplementary testing is required for research purposes, the direct and indirect costs (including the administrative burden of storage facility searching, verifying consent and other documentation and data integrity) must be factored into the research funding model and be allocated to the entity that incurs those costs; be it a diagnostic pathology service or stand alone or networked research biorepository.

The funding model must include allocations for quality and accreditation of the facility and contingency funding for unexpected outcomes such as termination of the research or closure of the laboratory/research biorepository.

Well executed biobanking requires dedicated human resources including access to diagnostic pathologists, whose work is traditionally reimbursed via case-based episodes.

Models for reimbursement of workload related to biobanking are essential.

5.2 Identifying and defining costs

Developing an accurate assessment for the costs to support a research biorepository can be complex and depend on possible overlapping functions undertaken in the research biorepository setting. Cost assessments should be developed in cooperation with others involved with the financial management of MSH. Cost information for facilities, equipment and labour may be available from current and historical records. Where possible, information should be obtained from within MSH determine current rates for overhead or indirect costs, facility costs (eg costs for space, Heating Ventilation Air Conditioning (HVAC), utilities and labour) equipment depreciation and maintenance. In determining charges for access to research biorepository resources, it may be necessary to decide whether to distinguish between scientific and commercial access, and whether non-commercial users should have free access or be subject to lower charges than commercial users.

Critical costs for effectively initiating and developing a research biorepository should be considered. For example, costs should be assessed for facilities, staffing (eg payroll, benefits, training), administrative costs (eg support, office equipment, supplies), monitoring equipment (eg environmental monitoring systems, oxygen monitoring systems, pagers, cell phones), inventory management software and licenses, laboratory and specimen processing supplies (eg barcode scanners, buffers, reagents, chemicals, disposables, disinfectants, laboratory safety supplies, personal protective wear) and storage supplies. The actual costs to be considered will depend on the function of the research biorepository. For example, under some circumstances costs for collection should be included, whereas in others only the costs for receiving and storing the specimens should be considered, since the repository may only serve as an intermediate storage facility. Likewise, costs for specimen testing may or may not need to be considered depending on the mission of the research biorepository. Whatever charge structures for cost recovery are ultimately implemented, these arrangements must be recorded and reported in a way that is transparent and publicly available; for example, on a website.

5.3 Cost analysis

Once all costs are accurately defined, it will be important to look at work processes and the ability to optimise work flow. Plans should be developed to share equipment with other, related activities, if possible. A variety of solutions may be possible to reduce labour costs while still performing the work of the research biorepository with high precision and quality.

Routine research biorepository activities should be examined to determine if automation may be incorporated to more rapidly process specimens with high accuracy. While automation typically requires an up-front expenditure of greater funds, reduction in labour and facility costs over time may result in lower overall costs.

Automation strategies range from the simple to the complex, such as scanning bar-coded labels when samples are received or pulled from storage containers, versus automated entry and withdrawal of specimens from freezers. The former example is much less costly to implement than the latter, but both may be effective long-term cost reduction strategies.

Costs should be regularly reviewed to examine the actual costs (eg equipment purchase, repair and maintenance) versus the cost of acquiring new equipment that may be less expensive, more efficient, operate with fewer repairs etc.

5.4 Financial gain/income generation, incentives, cost recovery/offset and royalties

Research biorepositories must not participate in the trading or advertising of tissue which includes buying or enquiring whether a person is willing to sell tissue, selling or enquiring whether as person is willing to buy the tissue and/or advertising the buying of tissue. The sale for profit (in cash or in kind) of biospecimen collected with MSH funding is not acceptable. Full recovery of costs, based on a transparent accounting system is, however, acceptable.

Research biorepositories may require no additional funding, partial funding or complete recovery of costs from specimen collection through the entire life cycle of the specimen. External funding may be obtained through grants, contracts, other private funding mechanisms as well as user fees to cover the partial or full cost of collecting, maintaining and disseminating the biospecimen.

Even research biorepositories that have most of their costs covered may wish to consider a nominal service fee to promote good stewardship and judicious use of resources. Regardless of funding sources, it will be necessary for research biorepository managers to prepare accurate, annual budgets to support orderly research biorepository activities.

SOPs on cost recovery should be determined in advance, as appropriate, with key stakeholders of the research biorepository, potential recipients of the collected biospecimens, and with advocates for the research project patients/participants. Prices should be kept at a "market"-acceptable range in order to allow maximum use of the biospecimen resource.

SOPs on cost recovery and actual expenses and revenue should be reviewed on a regular basis (eg yearly) to ensure the relevance of the projected prices, effectiveness of the costs recovered to accomplish the intention of the cost recovery plan, and to ensure that anticipated usage is being implemented as expected. Regular adjustments are likely to be required.

Services should be provided following business agreements based on quotations that include the length of time during which quotations for products or services will be honoured.

SOPs should be implemented to allow for the timely collection of fees and handling of non-payment. A research biorepository may implement incentive structures to encourage other clinician researchers to contribute to their collection.

5.5 Financial review and financial supervision (ie committee)

On a regular basis (eg annually) a review must be conducted of both the estimated costs and anticipated revenues to ensure they remain current and accurate for every research biorepository in MSH. This reporting may form part of the annual HREC research project review process. Work processes must be regularly reviewed to identify any potential cost savings measures (eg alternate source for lab consumables; more efficient workflows).

NB — prior to implementing any change to a standardised SOP, it is important to test and verify that the proposed change will not create an undesirable effect. Any upgrades to aging equipment or redevelopment of infrastructure should be anticipated and included in the budget.

6.0 Commercial research/working with industry

The National Statement indicates that for commercialisation there should be no trade in human tissue for research purposes, however, where applicable the Custodian must ensure the research biorepository has clearly articulated SOPs that is communicated to patients/participants relating to the commercialisation of its own resources, research results derived from those resources, and/or commercial products, if any, that may arise from research using its resources.

MSH is committed to developing and sustaining close, productive and transparent partnerships with

industry in Australia and beyond. Alignment with industry is important in supporting research which will ultimately benefit human health.

It is important that there is clarity of arrangements for allowing commercial access to biospecimen originally donated for research projects funded by the public or charity sectors. Where possible, patients/participants should know when their sample or products derived from it may be used by the commercial sector, and the potential benefits of this access.

It is also important to let the patient/participant know they will not be entitled to a share of any profits that might ensue, as is also the case for intellectual property rights generated from sample use in the academic sector. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information on Participant Information and Consent Form (PICF) requirements.

It is not appropriate for any one company to be given exclusive rights of access to a collection of samples made with the benefit of public funds. MSH requires arrangements for projects conducted with commercial partners, to be agreed before a project starts and recommends research activities are carried out within an appropriate contractual framework where possible. The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is very dependent on commercial involvement. Access by the commercial sector to biospecimens within MSH research biorepositories must be facilitated if consistent with the goals of the research biorepository. However, no one commercial enterprise should be given exclusive rights of access to the collection.

7.0 Intellectual property and resource sharing

Inventions and data arising from research using annotated biospecimens may have commercial value. As researchers and industry sponsors have sharply increased their demand for properly prepared and clinically annotated biospecimens, some institutions have begun to assert control over biospecimens, associated data, and research findings. The current variability in intellectual property policies at institutions hosting research and research biorepositories may ultimately lead to problems in biospecimen and data access, timely and open publication, sharing of research findings, and establishment of new research biorepositories. Sharing of research data obtained through use of biospecimens and associated research materials (eg derivatives) is essential for the advancement of science. Accordingly, research data and tools generated through the use of biospecimens should be shared in a timely manner and, to the greatest extent possible, in a manner consistent with applicable MSH sharing provisions.

7.1 Benefit-sharing

In recognition that the sharing of knowledge is one of the most important benefits to be derived from research biorepositories, benefits arising from research using the resources of a MSH research biorepository must be shared as broadly as possible with the research community.

Benefits arising from research using the research biorepository’s resources should be shared as broadly as possible, including by the sharing of information, licensing, or transferring of technology or materials. Where appropriate, the Custodian should ensure there is a system where benefit-sharing agreements can be negotiated before a research project begins, especially in the case of population-level studies where there may be vulnerable populations or unique concerns. The Custodian must also ensure a clearly articulated SOP is in place which addresses whether tests or products arising from research

using its resources might be shared with the community and/or the general population, and how such sharing will be affected. The following principles apply to benefit-sharing in MSH:

- The Custodian must ensure the exchange of information and technology is fostered.
- The Custodian must ensure the general results of research conducted using the research biorepository's resources are made publicly available regardless of outcome.
- Reporting of aggregate results arising from research conducted using the research biorepository's resources should not be limited to academic publications. The Custodian must ensure these results are made available in easily accessible forms, including a newsletter or website.
- The Custodian must ensure an annual progress report and a report at the completion or termination of a research project is released to the approving Human Research Ethics Committee and relevant Research Governance Office/r. Such reports should list publications and patents resulting from research on the research biorepository's resources and should be made publicly available.
- Researchers must acknowledge in publications, presentations, and, where relevant, patents filed, the research biorepository resources they have used or relied on.
- The Custodian must ensure researchers using its resources are provided with detailed guidance on the manner in which it wishes to be acknowledged.
- Where appropriate, the Custodian must ensure there is a system where benefit-sharing agreements can be negotiated before a research project begins, especially in the case of population-level studies where there may be vulnerable populations, whole communities, many patients/participants or unique concerns.

Benefits from research may be shared in different ways including the sharing of financial benefits, information, licensing, or transferring of technology or materials. Information and technology exchange may occur through various ways including: technology transfer, material transfer, licensing, or joint development activities. Benefit-sharing is another important consideration, particularly when dealing with specimens or data from developing countries. Sharing the "benefits" from specimen research is important to ensure that providers of resources are treated in a fair and equitable way.

There are numerous ways that "benefits" can be shared. These include sharing of technology or sharing benefits of research with the research project population or providing security backup of stored specimens in an established research biorepository with quality practices in place. To contribute towards the continued development of MSH research biorepositories as a resource, the Custodian should aim to ensure that general results arising from research conducted using its resources are added back into its database(s). Where the research biorepository has been developed with input from researchers from resource poor settings, it may be appropriate for the users of the resources or the Custodian to identify ways in which those contributors can be supported (eg through the exchange of knowledge or know how to develop research capacity in such settings).

Within a research biorepository's Research Protocol and SOPs, the Custodian must ensure provisions are included that cover benefit-sharing and considers how the sustainability of the research biorepository may be facilitated. Provisions must be included pertaining to:

- Any intellectual property resulting from the research biorepository and whom this applies to, including the researcher, the Custodian and the participant.
- Whether research results will be added to the research biorepository to build it as a resource for research.

- Whether tests or products arising from research using its resources might be shared with the community and/or the general population, and how such sharing will occur.
- Whether or not it intends to commercialise any resources (eg samples, data, information or the database/s), if commercial resources may arise from research, the modalities of such commercialisation and whether patients/participants will derive any benefits from the commercialisation.
- Whether private or foreign investment will be allowed or commercial collaboration in the future.

7.2 Intellectual property

Generally, research biorepositories have no inherent rights to future intellectual property of end-users, such as reach-through rights to inventions made by investigators using samples obtained from the research biorepository. Additionally, biospecimen does not inherently have any intellectual property. However intellectual property can arise from the research utilising the samples and this may be sold or licensed in the usual way. It is important to note that although researchers do not originally own the sample itself, they can come to 'own' the product of work or skill applied to that sample. This may involve intellectual property rights generated from a sample. There may also be intellectual property rights that arise pursuant to research carried out using the research biorepository.

The Custodian must inform the patients/participants of any legal or intellectual property rights that might be material to their participation including:

- to whom the property rights accrue; and
- who will ensure their protection or enforcement, if necessary.

The Custodian must give consideration to existing legislation, regulations, and ethical guidelines on this. Intellectual property rights arising from research using human samples may be sold or licensed in the same way as other intellectual property rights. Before allowing access to samples by either academic or commercial sector researchers, the research biorepository or Custodian of the biospecimens and data should make clear (by contractual agreement) its policies on ownership of intellectual property.

Research biorepositories must have clearly articulated SOPs and indicate to patients/participants whether they and/or the research biorepository retains any rights over the biospecimens and/or data and the nature of such rights as well SOPs regarding intellectual property rights, which should address the rights, if any, of the research biorepository, researchers and patients/participants.

In general, ownership of intellectual property arising out of use of research biorepository resources vests in the investigator creating it or his or her institution, rather than the research biorepository. In some circumstances it may be appropriate for the research biorepository to be a joint owner, depending on the relative levels of contribution.

Research biorepositories may claim joint ownership of intellectual property and a share of revenue from downstream commercialisation when the research is a collaborative endeavour. Research biorepositories tend to support commercial development of research results arising out of the use of research biorepository resources, rather than prescribing limitations on commercialisation.

7.3 Inventorship

Generally, research biorepository staff, as Custodians of biospecimens, will not be considered a priori inventors under patent law for inventions made using materials distributed by the research biorepository. In general, one whose sole contribution to an invention consists of the routine collection, handling,

storage, and disbursement of biospecimens might not rise to the level of “inventor.” Inventorship is determined by patent law and is considered on a case-by-case basis by legal personnel.

8.0 Acknowledgement and publication

Researchers must acknowledge in publications, presentations, and where relevant, patents filed, the research biorepository resources they have used or relied on. The Custodian must ensure researchers using the research biorepository are provided with detailed guidance on the manner in which it wishes to be acknowledged. Additionally, the Custodian must ensure:

- An annual progress report and a report at the completion or termination of a research project is released and made publicly available, such reports should list publications, published patent applications and patents issued arising from research accessing the research biorepository’s resources.
- Aggregate/summary results from research using the collection are not limited to academic publications and are made available in easily accessible forms such as a newsletter or website.
- The general results of research conducted using the research biorepository are made publicly available regardless of outcome.

9.0 Registration on Metro South Research internet site

All research biorepositories which collect biospecimens from patients/participants in MSH must be registered on the Metro South Research internet site. Whilst some collections are project specific they must still be registered to allow visibility and accountability to MSH and the public. Custodians must ensure that patients/participants have access to regularly updated information about the type of research being carried out with the biospecimens and data contained within the research biorepository. The Custodian must ensure that information is made publicly available about any significant modifications to the research biorepository’s research protocols and SOPs and that where these affect the interests of patients/participants, that there are appropriate mechanisms to inform patients/participants about such modifications (if applicable).

Additionally, a research biorepository should publish a catalogue of biospecimens accessible in order to optimise the utilisation of biospecimens and ensure transparency of research biorepository activities. A catalogue should contain a list of available samples associated with a synopsis of the Minimum Data Sheet. Please see Acquisition, Attainment and Recruitment Procedure (PR2017/102) for more information. Prior to publication, sufficient means should be taken to ensure that no individual can be identified from the information provided.