PROCEDURE

Metro South Health Research Biorepositories – Standard Operating Procedures (SOPs)

PR2017/11
Version No. 3.0

PURPOSE

Standard Operating Procedures (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' for Metro South Health (MSH). SOPs form part of the research biorepository internal governance structure. SOPs in MSH provide written guidelines for aspects of the research biorepository and promote quality and consistency in the collection of biospecimens and data across MSH. They also ensure compliance with applicable regulations and guidelines and facilitate education and training of research biorepository personnel.

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. 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 the development of SOPs for the collection of biospecimens from MSH patients/participants. The way in which individual MSH research biorepositories put these principles into operation may be scaled in relation to the research biorepository's size of operations.

- SOPs are controlled documents designed to give instructions for performing routine and essential processes, to ensure that they are performed consistently and in a manner upholding MSH research biorepository quality and integrity.
- A research biorepository must create a series of SOPs which makes a clear quality statement and describes the roles and responsibilities of personnel within and connected to the research biorepository's operations and infrastructures in compliance with regulatory and work health and safety obligations.
- SOPs must reference all the processes which are required to ensure that Quality Assurance (QA) and Quality Control (QC) objectives are fulfilled.

- SOPs must give detailed instructions showing how specific tasks are to be carried out. The aim is to document the tasks at a level that will allow an individual repeating the task to achieve equivalent results.
- SOPs must be developed on a risk proportionate basis (ie focussing on risks which are identified as critical).
- Regular audits should be carried out to ensure that the MSH Research Biorepository Governance Framework and research biorepository SOPs are followed and effective.
- Existing research biorepository collections may require audits for authentication (ie the process by which biospecimens are characterised up to a defined level using appropriate technology to establish a conclusive basis for accepting material as genuine).

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
- Organisation for Economic Co-operation and Development (OECD)
    - Best Practice Guidelines for Biological Resource Centres
    - Guidelines on Human Biobanks and Genetic Research Databases
- 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

- MSH Research Management Policy (PL2017/55)

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

Review relevant SOPs to ensure they are consistent across all MSH research biorepositories.

MSH Human Research Ethics Committee

Ethically review MSH research biorepository Human Research Ethics Applications (HREA) and associated documents (eg Research Protocol, Participant Information and Consent Form and Curriculum Vitaes) 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. Write, revise and update technical, administrative and organisational SOPs.

Research biorepository manager

Undertake regular self-audits against the MSH Research Biorepository Governance Framework to identify gaps in quality management at different levels of a collection (technical, training, management etc). Write, revise and update technical, administrative and organisational SOPs.

Laboratory technician/technologist assistant/clinical personnel

Familiarise themselves with documented protocols 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. Write, revise and update; technical, administrative and organisational SOPs.

Researchers

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

SUPPORTING DOCUMENTS

Attachment 1 - Application

Attachment 2 - Standard Operating Procedures Index

Attachment 3 - Standard Operating Procedure Template

Attachment 4 - Example Standard Operating Procedure

Attachment 5 - Standard Operating Procedures Review Records

Attachment 6 - Standard Operating Procedures Distribution Record

Attachment 7 - Standard Operating Procedure (SOP) Checklist

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE — Standard Operating Procedures (SOPs)

STEP 1: Establishment of SOPs

The person responsible for quality management in the research biorepository is responsible for ensuring that all documentation is correctly written and updated. The Standard Operating Procedures Index (Attachment 2) must be consulted when drafting research biorepository SOPs.

STEP 2: Standard Operating Procedure Template

The MSH Standard Operating Procedure Template (Attachment 3) must be used when drafting all research biorepository SOPs. Research biorepositories may refer to Attachment 4 - Example Standard Operating Procedure for guidance in developing relevant SOPs.

STEP 3: Amendment sheet

When a SOP is created or updated it must be distributed utilising an amendment sheet conducive to appropriate consultation.

STEP 4: Approval

Alterations must be signed and dated by the person responsible for the Quality Management System (QMS). The Custodian, director and/or the individual responsible for the quality management program must approve all SOPs and associated process validation studies prior to implementation. Upon implementation, all SOPs should be followed as written, and any deviations from written SOPs should be clearly noted. Effectiveness of quality management program should be evaluated on a routine basis.

STEP 5: Storage

All SOPs must be readable and stored in a place where they can easily be located by authorised personnel. They must be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering.

STEP 6: Document management system

Research biorepositories must have a document control program/document management system in place which monitors updates and version control of each SOP. This may be in the form of an electronic/automated document management system or an operational based document control program which utilises tools contained within Attachment 5 - Standard Operating Procedures Review Records and Attachment 6 - Standard Operating Procedures Distribution Record to monitor and record SOPs creation/amendment.

STEP 7: Review

The Custodian must anticipate that over its lifespan there will be a need to review and modify its research protocol/s and SOPs. A process must be in place for undertaking such review and modification as alterations to any SOPs must not be made unless agreed upon by the person responsible for the quality management system. Attachment 5 - Standard Operating Procedures Review Records and Attachment 6 - Standard Operating Procedures Distribution Record should be utilised when undertaking the review process.

STEP 8: Self-audit, review and compliance

Utilise Attachment 7 - Standard Operating Procedure (SOP) Checklist to aid in self-auditing, review and compliance.

PROCEDURE DETAILS

Procedure Number
PR2017/11

Procedure Name
MSH Research Biorepositories — Standard Operating Procedures (SOPs) Procedure

Policy Reference
PL2017/53
MSH Research Biorepositories Policy

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05 July 2024 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Requirement for evidence-based SOPs

To have confidence in research results, it is critical that all reagents be fit-for-purpose and quality-controlled for use in the assay. SOPs should be reproducible with standard reference material (where possible), and control biospecimens that provide a range of anticipated assay values should be utilised. Biospecimens that have been poorly handled are likely to provide erroneous test results because of the molecular changes resulting from the handling process.

It is impractical and currently not possible to consider the development of assays to measure the stability of every cellular component within biospecimens. To that effect, SOPs that optimise the general stability of biomolecules under certain environmental conditions are recommended. Should a particular biomolecule be of interest, it is important to perform some type of analysis to ensure that the storage and handling conditions implemented will allow for accurate determinations of that biomolecule.

1.1 Document management system

Each research biorepository must develop SOPs that state policies and describe relevant processes in detail. Additionally, a document control program/document management system and policies for governing, modifying, or revising SOPs should be at each research biorepository. All SOPs should be reviewed on a periodic basis or whenever significant changes in practices, procedures, technology, law, or regulation necessitate an update. The SOPs should be well structured and undergo a rigorous approval process.

Upon implementation, all SOPs should be followed as written. Current copies of SOPs should be stored in designated locations and available to personnel at all times. Personnel should review new and revised SOPs prior to implementation; reviews and associated trainings should be recorded. Generally, especially for larger research biorepository which have the personnel to support a more comprehensive QMS, an electronic document control system should be implemented.

2.0 QMS

A QMS sets out the standards being worked toward and how MSH operates in order to achieve the standard; this information can be captured SOPs. A QMS might include how the sample is collected and transported, how it is processed and stored, how links with associated health data are maintained and how any risks to quality are managed.

Using a quality system ensures optimal quality and use of samples, facilitation of sharing and collaboration, and management of collections in line with donors' expectations and wishes. Please see Quality Management System (Assurance and Control) Procedure (PR2017/110) for more information.

2.1 Developing new or revising previously issued SOPs

Every MSH research biorepository must develop SOPs in standardised written formats that are incorporated into a catalogue for use by the research biorepository. These SOPs must be utilised to ensure that all samples are appropriately and consistently collected and stored so that they may be effectively disseminated for subsequent uses. Personnel must be trained in the use of the SOPs which must be reviewed on a regular and routine basis or in response to accidents, incidents and failure to conform to the Quality Assurance (QA)/Quality Control (QC) system.

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

Individuals well versed with the procedures or methods being described should be recruited to draft or assist in drafting new or revised SOPs. All MSH research biorepository SOPs must follow the standard format (see Attachment 3 - Standard Operating Procedure Template and Attachment 4 - Example Standard Operating Procedure); the word “draft” should be added to the header. For major revisions to previous SOPs, the major SOP version number must be incremented by one (eg 1.0 becomes 2.0). For minor revisions to previous SOPs, the minor version number must be incremented by 1 (eg 1.0 becomes e1.1).

The first version of a SOP is always 1.0. Authors must develop/revise associated attachments, as applicable and revise the version date and update the research biorepository index as necessary (eg for new SOPs added).

Where possible, it is advantageous for all MSH research biorepositories to share their quality practices to ensure commonalities for biospecimen integrity and associated data. The Metro South Research coordinates a central catalogue of SOPs on behalf of MSH.

2.2 Review and approval of SOPs

SOPs must be reviewed regularly (at least every two years or when policy, procedures or methods change) to ensure the current policy, Pprocedure and/or method for performing the process is described. A system should be in place to document the revision number and date of release of the revised document.

The author must circulate the draft SOPs to the applicable reviewers (MSH Research Biorepository Strategic Oversight Committee, management associated with the research biorepository, personnel and other identified staff representatives — eg SOP users) for comments. The author must incorporate the comments, revise the draft version date and circulate the revised draft SOP to the research biorepository director and/or Custodian.

The director or Custodian must review the final draft SOP for accuracy and completeness and for compliance with regulations, guidelines, standard practice and the MSH Research Biorepository Governance Framework. In some circumstances, this may involve MSH Human Research Ethics Committee (HREC) approval of amendment. Also, the reviewer must note whether change in SOP will require amendment to other administrative documents (ie Research Protocol), especially any applicable Privacy Impact Assessments.

The research biorepository must obtain approval (from a SOP authorised signatory) of the final SOP. The effective date is added to the front page (the date that the final signed-off SOP is scheduled to be implemented). “Draft” is removed from the header.

2.3 Format and content of SOPs

The author must write the SOP using the formatting and styles (eg Arial) as shown in the Standard Operating Procedure Template (Attachment 3). Heading and footer information as shown in the SOP template must be completed. The effective date refers to the date that the approved SOP is to be implemented.

A Standard Operating Procedure Index must be created to list all approved SOP, separating them into logical categories (Attachment 2). The example below separates the SOPs into categories corresponding to the general flow of the research biorepository’s operations.

Combining the abbreviated SOP category with the series number creates the SOP number. The original list of SOPs may contain gaps in the numbering sequence in order to accommodate new SOPs in logical order.

SOP categories and numbering system

SOP category	Category (xx).Sub-category (xx).SOP number (xxx)
General institutional requirements of a research biorepository	00.000
Administration	01.001
Patient/participant recruitment and management	02.001
Records management and documentation	03.001
Facilities management and operations	04.001
Quality Assurance (QA)	05.001
Safety	06.001
Training	07.001
Material handling and documentation	08.01.001
Materials request and release	09.001

For new SOPs, personnel must assign the next consecutive number in the appropriate category. Content will be divided into sections shown in the SOP template. For revisions to previously issued SOPs, authors must include a summary of and rationale for the revision. Although SOP attachments may be reviewed, revised and approved separately from the SOP, attachments must be stored with the applicable SOP. The SOP Index may also contain sub-categories if necessary, as shown above for category 08 — Material Handling and Documentation.

2.4 Essential components for SOPs

SOPs serve as the description of how tasks pertaining to research biorepository operations should be handled by staff assigned to those specific responsibilities. SOPs allow for uniformity and reproducibility in biospecimen handling. SOPs should be written by an individual or group of individuals with experience in successfully performing the processes described and should be managed in an appropriate document management system.

Draft SOPs must be reviewed by the Custodian and/or MSH Research Biorepository Strategic Oversight Committee (when required) before they are finalised.

Essential features of a SOP are included in the following list of components:

- Title — a unique name which captures the essence of the practice described.
- Number — a unique number that can be used for easy reference.
- Date — date the process was first introduced as well as the date of the most recent version.

- Version Reference — system for tracking version number and/or date to ensure the most recent version is used.
- Department/Division/Staff Covered — individuals to whom the SOP will apply.
- Purpose — brief description of the process(es) described in the SOP.
- Protective Wear — protective equipment that should be worn by staff when performing the process described.
- Equipment — list of the equipment needed to perform the processes. Equipment description may include but is not limited to the name, model, date of purchase, serial number, inventory tracking number, and manufacturer.
- Supplies — all materials and supplies needed to perform the procedure should be recorded. The SOP may direct the user to maintain a record of the vendor, catalogue number, lot number and expiration dates for the materials and supplies utilised.
- Step-by-Step Guidance — the process must be written in specific detail to ensure that it can be repeated in a reproducible fashion to include the order of steps that should be followed, the times allowed for each step (as needed) and the temperatures at which the steps are to be performed.
- Safety — describes any safety steps associated with the procedures and reference any relevant SOPs involving safety.
- References.

2.5 Critical topics for SOPs

All MSH research biorepositories must develop, document and regularly update SOPs in a standardised written format that is readily available to all laboratory personnel. SOPs must specifically cover topics including, but not limited to, processes regarding the following:

- Informed consent: Each research biorepository must have documentation of the informed consent status for each biospecimen. In addition, procedures for obtaining informed consent and protecting the privacy of identifiable human research patient/participants and confidentiality of data should be clearly described, as should procedures to follow in the case of withdrawal of consent.
- Collection, transport, processing and storage of samples and data: Each research biorepository should define, in sufficient detail to allow replication, the procedures associated with biospecimen collection, handling, processing, and preservation for each biospecimen type. This includes detailed descriptions of supplies, equipment, methods, and processing for division of a biospecimen into multiple aliquots. Biospecimen collection and processing should always include the recording of personnel names, dates, and times to accurately record these potential sources of pre-analytic variation:
    - Details of the quality and quantity of the samples and/or data to be collected from the patient/participant or from other sources.
    - Provision of details of the type of sample/s to be collected (eg blood, urine, hair, buccal swab, biopsy material). The types of samples and data collected and stored in the research biorepository must be justified on the basis of the scientific objectives and purpose.
    - Indication of whether there will be direct or indirect links to identifying information and whether additional data will be accessed from MSH, other health data collections or other records such as personal, medical/health, biochemical, life-style, genealogical, family history, genetic,

physiological and other demographic and personal data. The SOP must describe if this data will be linked with, and/or stored in the research biorepository and if the 'linkage key' will be retained. The SOP must take into account ethical and other approval processes required for any secondary use of health and other records, especially when combined with other data.

  - The selection of samples, processes must be developed such that the least invasive approach, associated with the least risk to the patient/participant, should be pursued. Processes to minimise the risk of invasive SOPs must be in place.
  - Indication if immortalised cell lines will be created from the samples collected.
  - Provision of details of the quantity of the samples to be collected and what each sample will be used for and the data obtained from it (eg 60mLs blood to extract DNA and RNA and to test for glucose and haemaglobin levels).
  - Whether results from research carried out using samples or data from the research biorepository should be incorporated into the resource. The SOP must include the standard of quality required for including research results in the research biorepository, what the results will be used for and any conditions for further access to them.
  - The duration of storage of the samples and the data, recognising that the duration of storage may vary according to the nature and the potential uses of the samples or data. Specific conditions may apply for samples and data which form part of an application for market authorisation of a medical product or a medical device.
  - Whether specific types of tests are not allowed to be performed or if specific types of data will not be entered.

- Biospecimen handling including supplies, methods and equipment.
- Laboratory techniques and processes for tests performed in-house and any biospecimen aliquoting or other specimen processing eg tests and quality control.
- Where appropriate, human subjects' protection documentation, including informed consent, privacy and confidentiality protections, and other legal, ethical and cultural issues.
- Where appropriate, access and sharing of biospecimens and associated data. Each research biorepository should have policies for managing records and procedures defining data access, data collection methods, reporting, data Quality Control (QC), and standardised medical terminology.
- Shipping and receiving of biospecimens: Shipping and transportation SOPs must be established to ensure that containers, labels, conditions and methods are optimal for sample protection. This includes packaging specifications to maintain appropriate temperature conditions; wet ice, dry ice, and liquid nitrogen (LN_2) handling; shipment temperature monitoring; shipment regulations for hazardous materials; shipment logs; delivery notifications; confirmation of delivery; shipment feedback mechanisms; and Material Transfer Agreements (MTAs) or other appropriate agreements to cover transfers.
- Equipment monitoring, calibration, maintenance, and repair: Each research biorepository should have procedures to routinely monitor devices that are used for biospecimen storage or preparation. This includes ensuring that equipment is accurately calibrated, that operational settings are routinely recorded, and that scheduled maintenance and repairs are documented. Equipment SOPs and records should also cover associated backup and emergency notification systems.
- Relocation of biospecimens within a research biorepository as equipment and environmental needs warrant.
- Management and governance structure.

- Biosafety: Each research biorepository should have SOPs covering biosafety, including reporting staff injuries, as well as standard precautions for blood-borne pathogens, personal protection equipment, hazardous material handling, and disposal of medical waste and other biohazardous materials.
- Records management and document control practices. These should include processes regarding the shredding of confidential documentation at the appropriate time.
- QA and QC for supplies, equipment, instruments, reagents, labels and processes employed in sample collection, processing, storage and retrieval.
- Equipment inspection, qualification, maintenance, repair, calibration, upgrading and replacement.
- Maintenance of essential support systems (eg liquid nitrogen (LN_2) supplies, electricity, extra power supply, temperature control system).
  Laboratory tests performed in-house including biospecimen quality control testing. Each research biorepository should have SOPs governing standardised in-house testing procedures and should document the results in associated quality records. This includes tests to assess and control biospecimen quality, such as confirmation of histopathology diagnosis, nucleic acid integrity, or biomarker expression.
- Safety programs including documentation and reporting of staff ergonomics, safety-related incidents, injuries and exposure to potential human pathogens and notifiable animal/plant pathogens and agents under biological control.
- Investigation, documentation and reporting of incidents and near miss incidents, accidents, errors, complaints and adverse outcomes.
- Emergency response procedures.
- Disposal of medical and other hazardous waste.
- Requirements of training programs for research biorepository personnel.
- Training: Each research biorepository should have processes for training of all staff members. Such training should be documented and include policies and procedures to manage corrective actions; to resolve inventory and shipment discrepancies; to monitor all sample storage; and to manage power outages, emergencies, and natural disasters.
- Introduction of new personnel.
- Security: Each research biorepository should have procedures for administrative, technical, and physical security, including procedures for information systems security. Security SOPs and policies should include information on points of contact and designated backup personnel, including names and emergency contact numbers.
- Validation and documentation of the IT system including backup routines.
- Customer relations, forms and agreements.
- Access processes and agreements specific to the research biorepository.
- Risk assessment, audit and review.
- Premises, facilities and equipment.
- Quality control and proficiency testing.

- Storage and retrieval: Each research biorepository should define procedures for the storage and retrieval of biospecimens from a research biorepository, including processes for adding new biospecimens, withdrawing biospecimens, responding to and filling requests, and final disposition of biospecimens.
- Data protection and security.
- What happens when things go wrong: Complaints, anomalies, non-conformities and adverse events and corrective and preventive actions.
- Control of biospecimen collection supplies (disposables and reagents): Each research biorepository should have procedures to ensure that consumable supplies and reagents used for collection, processing, and storage conform to required standards. This includes ensuring purchased supplies are approved, are acquired from approved vendors, meet defined material specifications, and are in good condition for use.
- Biospecimen identification and labelling conventions: Each research biorepository should define procedures for labelling (coding) biospecimens and linking biospecimens to other data sets and patient informed consent.

1.6 Style

Within the SOP each operation in a process must be described as a separate step. Instructions must be explicit enough so that a qualified individual could perform the procedure by following the instructions. Instructions must also be explicit enough so that the SOP may be used as a training tool, and easily referred to for guidance during routine work.

The author must use clear, concise, unambiguous instructions so that the user can understand the requirements. Qualifiers and vague terms such as “usually”, “sometimes”, “normally”, “regularly” or “try to” must not be used.

Flowcharts may be included, as they are an excellent way of communicating the sequential steps of a process. Equipment diagrams and scanned images can also help personnel understand machinery, and are useful aids during hands-on training sessions.

1.7 Implementation

The Custodian must review and approve all SOPs and associated process validation studies prior to implementation. MSH SOPs which are able to be utilised across a variety of research biorepositories may be reviewed by the MSH Research Biorepository Strategic Oversight Committee prior to their use and implementation. Upon implementation, all SOPs must be followed as written.

1.8 Distribution and communication

SOPs must be readily available to all research biorepository personnel and other identified staff users.

Research biorepository personnel, management members of the research biorepository, and other identified staff users must be notified of any new or revised SOPs, and the rationale for the SOP or SOPs changes. Ideally, direct users should be notified immediately of new/revised SOPs. The research biorepository manager must provide training on new or revised SOPs. Training attendance must be documented as appropriate to meet MSH requirements. All outdated copies of SOPs and attachments must be retrieved and replaced with updated versions. Outdated SOPs and/or standing operating procedures, appendices and indices must be archived.

1.9 Maintenance

Research biorepositories must institute a review process for all SOPs. SOPs must be reviewed regularly. The SOPs should be reviewed sooner if there are changes to regulations, guidelines, research practice, or MSH Policies and Procedures. Once a SOP is reviewed and approved, the author must complete the SOP Review Record (Attachment 5) and file a copy with the Metro South Research (if required).

If only revisions to an attachment are needed, modifications may be made without revising the SOP. The author may revise the attachment, update the version date, and file a copy with the Metro South Research (if required).

1.10 Modifications and document management

Documents are materials that provide, publish and disseminate information. Each MSH research biorepository must have document control SOPs in place that govern retention and modifications or revisions to SOPs or other documents. Prior to implementation, each modification must be approved by the Custodian and other appropriate individuals. Implementation dates must be recorded for all procedures.

A system must be in place to ensure that only current versions of documents are available for use and that previous revisions are removed when new revisions are issued. Old versions of documents must be removed and archived when new revisions are issued.

1.11 Records

Records ('historical footprints') comprise information compiled as registered and recorded evidence that is permanent and traceable. Records cannot be modified. Record keeping must be formalised and the research biorepository manager must ensure records are stored under secure/safe conditions and made accessible for inspection by authorised internal and external auditors (eg regulatory, work health and safety accreditation inspections).

1.12 Storage

MSH research biorepositories must create and maintain a central SOP file. The following documents must be stored in the SOP file if not recorded in an electronic document management system:

- Standard Operating Procedure Distribution Record (Attachment 6) or electronic audit trail if relevant.
- Final, approved original and revised versions of each SOP.
- One copy of the original and revised versions of each SOP appendix/attachment.
- Original, signed SOP Review Record (Attachment 6).
- Copies of SOP training records from the collection sites (if maintained).

For electronic SOPs, final SOPs must be posted in a format that cannot be altered (eg pdf format). Electronic files must be checked regularly and research biorepositories must ensure only current SOPs are referenced.

1.13 Staff access and review

Current copies of the SOPs must be stored in designated locations and available to research biorepository personnel at all times in a SOP Manual. A complete SOP Manual must be made available at the workbench or in the work area.

Electronic (computerised) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the research biorepository so long as the electronic versions are

readily available to all personnel. New and revised SOPs must be read by the staff prior to implementation. Research biorepositories must implement a system document staff review of the most recent versions of a SOP. Training associated with SOPs must be maintained in a training record.

1.14 Cultural considerations

The Custodian should ensure SOPs relating to contents take into account the different attitudes held by different cultural and religious groups towards samples. Some groups regard particular material as having a special status, particularly where it is removed post mortem and consider special treatment should be provided (eg in terms of the method of disposal).

3.0 Compliance with internal documentation

All staff must adhere to the prescribed SOPs of the research biorepository. Any departures from documented processes must be agreed upon by the Custodian prior to deviation. Written permission and justification must then be included in the relevant records. In the case where a prescribed process is not followed a deviation report is required outlining the specific error and corrective actions that will be taken. If failure has been brought about by a misunderstanding or misdirection, the error must be investigated, rectified and retraining implemented if necessary.