

PROCEDURE

Metro South Health Research Biorepositories – Access and Applications for Samples

PR2017/106
Version No. 2.0

PURPOSE

Metro South Health is committed to promoting adherence to the highest ethical standards and practices in the release of biospecimens for research purposes. The purpose of this procedure is to outline general principles that can be used to ensure that access to and applications for biospecimens are equitable, ethical, peer reviewed and efficient.

This procedure applies to major ethical, legal and practical considerations that arise in the process of releasing tissue samples/biospecimens from the 'Custodian' (research biorepository) to the researchers requesting samples from the Metro South Health research biorepository.

OUTCOME

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

This procedure applies to:

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

Failure to comply with this procedure may amount to research misconduct on the part of the responsible individual. This procedure must be read in conjunction with other Metro South Health Research Management and Research Biorepository procedures. Additionally, this procedure applies to the major business planning considerations that are applicable to research biorepositories in Metro South Health.

KEY PRINCIPLES

The following key principles guide Metro South Health employees and researchers in access to and applications for samples from Metro South Health research biorepositories. The way in which individual Metro South Health research biorepositories put these principles into operation may be scaled in relation to the research biorepository's size of operations.

- Research biorepositories must only supply biospecimens to other research biorepositories and public or private institutions for research purposes only. In exceptional circumstances processed samples may be used for medical (prognostic/therapeutic) purposes.
- Access to biospecimens and data should be based on objective and clearly articulated criteria and must be consistent with the patients/participants' informed consent.
- Custodians must require that access requests include a scientifically and ethically appropriate research plan.
- A mechanism of rapid peer and/or stakeholder review must be in place to set up priorities as to how collected biospecimens should be allocated to qualified recipient investigators. Preferably, this process is coordinated by the research biorepositories manager and chaired by the Custodian.
- Biospecimens that are required for clinical care must not be made available for researcher use.
- The proposed research project and use of biospecimens must be consistent with patients/participants' consent, research purpose and permitted use of biospecimens.
- Although research biorepositories have the right to establish priorities for access to biospecimens, in principle, research biorepositories must commit themselves to providing equal right of access to researchers.
- Biospecimens and data should only be transferred when the recipient has adequate standards in place regarding privacy and confidentiality.
- Given the potentially finite nature of some biospecimens, review committees and personnel must formulate criteria for prioritising applications for access to the biospecimens.
- Except when required by law, the research biorepository must not make accessible or disclose patients/participants' biospecimens or data to third parties (eg law enforcement agencies, employers, insurance providers) for non-research purposes.

LEGISLATION OR OTHER AUTHORITY

Legislation

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

Regulation

- Transplantation and Anatomy Regulation 2004 (Qld)

Statements, papers and guidelines

- Canadian Tissue Repository Network: [Policies and Standard Operating Procedures](#)
- Government of Western Australia: [Guidelines for Human biobanks, genetic research databases and associated data](#)
- International Society for Biological and Environmental Repositories (ISBER): [Best Practices: Recommendations for Repositories Fourth Edition](#)
- National Cancer Institute: [Best Practices for Biospecimen Resources](#)

- National Health and Medical Research Council (NHMRC): [Biobanks Information Paper 2010](#)
- Organisation for Economic Co-operation and Development (OECD)
 - [Best Practice Guidelines for Biological Resource Centres](#)
 - [Guidelines on Human Biobanks and Genetic Research Databases](#)
- World Health Organisation (WHO): [Common Minimum Technical Standards and Protocols for Biological Resource Centres Dedicated to Cancer Research](#)

Metro South Health policies, procedures, manuals and frameworks

- [Metro South Health Research Management Policy \(PL2017/55\)](#)

RESPONSIBILITIES

Executive Management

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

Centres for Health Research

Support Custodians in the establishment and operation of a research biorepository through the provision of guidance and support when interpreting principles and provisions contained within the Metro South Health Research Biorepository Governance Framework.

Metro South Health Research Biorepository Strategic Oversight Committee

Review and approve all Research Protocols and SOPs which provide clarification around access to and applications for samples from Metro South Health research biorepositories

Custodian/Principal Investigator – responsible officer

Ensure the research biorepository's processes for access to and applications for samples not only supports individual and institutional interests however also ensures that high quality biospecimens will be available for future research efforts.

Research biorepository manager

Write, revise and update organisational and administrative SOPs pertaining to access to and applications for samples from Metro South Health research biorepositories.

Laboratory technician/technologist assistant/clinical personnel

Research biorepository personnel must possess sufficient educational background, experience and training to assure that assigned tasks pertaining to the collection of biospecimens from Metro South Health patients/participants are performed in accordance with the Metro South Health Research Biorepository Governance Framework and applicable SOPs.

SUPPORTING DOCUMENTS

Attachment 1 - [Application](#)

Attachment 2 - [Application for Samples Form](#)

DEFINITIONS

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

PROCEDURE - Access and Applications for Samples

STEP 1: Centres for Health Research internet page

The Custodian must register the research biorepository on the [Centres for Health Research internet page](#) and provide relevant contact details for the collection. Registration on the Internet Site will enable researchers to contact relevant personnel to discuss opportunities for access and specific application processes.

STEP 2: Standard Operating Procedures (SOPs)

The Custodian must ensure there are SOPs in place pertaining to access to and applications for all samples and data from the research biorepository prior to accepting or reviewing applications from researchers. The Custodian must make publicly available its access processes as well as a catalogue of the resources accessible for research purposes (if applicable).

Step 3: Third party access to samples

The Custodian must ensure patients/participants are informed whether or not samples and data will be accessible to third parties or law enforcement agencies and if there are legal requirements to do so.

The Custodian must ensure patients/participants are informed about all the legal requirements to provide access to research biorepository samples or data to third parties or law enforcement agencies. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

Step 4: Application process

Researcher application

As part of applicable SOPs, the Custodian must implement an applicable 'Application For Samples Form' which requires the researcher to provide relevant details to enable a detailed review of the request.

The researcher must be advised of fees and charges to access samples. This enables the researcher to consider costing implications as part of the application process. Custodians must ensure that any stratified access or fee policies are fair, transparent and do not inhibit research.

Clinical requests

From time to time, clinical requests to access research biorepository samples in order to complete diagnostic tests that may have been missed at the outset may occur. This may happen days/weeks/months/years after the initial collection date. It is important however to identify as much as possible what is required for clinical need as opposed to research investigation.

Custodians must implement a SOP for requests where samples, required for clinical need, can be withdrawn by the treating clinician for investigation of a clinical problem and this may also pertain to trial cohorts depending on the research biorepositories operation.

STEP 5: Review of researcher application requests

The research biorepository must implement mechanisms to review applications for access to biospecimens and/or data, appropriate to the size of the research biorepository, which meets the following requirements (at a minimum):

- mechanism for appropriate administrative review of the application for biospecimens and/or data
- mechanism for appropriate scientific peer review of the application for biospecimens and/or data
- processes for prioritisation of applications
- processes for complaints/revision of denied requests.

STEP 5: National and international access

If a Metro South Health research biorepository intends to enable national and international access to biospecimens and data additional provisions and processes must be implemented. International researchers who request access to samples or data must have a collaboration agreement with the Custodian.

STEP 6: Prior to release of biospecimens and data

Mechanisms must be employed to ensure that researchers are not inadvertently provided access to potentially identifying data. Additionally, the Custodian must ensure samples and data collected for health research purposes are not accessible to or disclosed to third parties for non-research purposes.

STEP 7: Provision of access

Researchers must be provided access only to coded biospecimens and data contained within a Metro South Health Research Biorepository unless determined otherwise by the Metro South Health Human Research Ethics Committee (HREC) and where provision can be made in accordance with requirements of relevant legislation.

STEP 8: Material Transfer Agreement (MTA)

The terms of access for researchers to the whole or a part of the database(s) of the research biorepository should be set out in an access agreement. Users of data should sign confidentiality agreements when access pertains to data that are not publicly available.

The research biorepository must ensure a formal Material Transfer Agreement is in place prior to the release of samples. The terms of access for researchers to biospecimens and samples collected from patients/participants, should be set out in a Material Transfer Agreement or other agreement appropriate for that purpose. Please see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information

PROCEDURE DETAILS

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Metro South Health Research Biorepositories –
Access and Applications for Samples Procedure

Policy Reference

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02 July 2021 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Biospecimens access and accessibility

Advances in knowledge and discoveries coming from basic and translational research on biospecimens has the potential to contribute to improved care and new treatments. Collaboration between Metro South Health research biorepositories and researchers, and ethical use of resource controlled by the research biorepository, requires harmonisation of Procedures regarding issues such as tissue and data release.

As each Metro South Health research biorepository is independently governed, funded, operated, and is the principal Custodian of its materials, it is vital for each research biorepository to be able to determine its own access priorities to consider the priorities of its local/regional governance, funders and stakeholders. However, each research biorepository must also commit to strive with Metro South Health to make materials nationally or internationally available where possible and feasible after local priorities have been addressed.

Considerations for access for research purposes include:

- from the patient/participant perspective- welfare, respect for human dignity and justice
- from the researcher perspective- scientific freedom and justice
- from the public perspective- welfare (health-care benefits), respect (community consultation) and justice (not being subjected to discrimination and stigmatisation).

Access to biospecimens and data must be based on objective and clearly articulated criteria, and should be consistent with the patients/participants' informed consent. The operators of the research biorepository must require that access requests include a scientifically and ethically appropriate research plan. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

1.1 Accessibility

To support this initiative all Metro South Health research biorepositories should be registered on the [Centres for Health Research internet page](#). Even though some collections may not be shared widely, registration on the Internet Site will foster transparency and enable researchers to contact Custodians to discuss samples contained within the collection.

Metro South Health research biorepositories must ensure they:

- are accessible through transparent access processes to relevant and independently approved research projects that have also passed Human Research Ethics Committee review
- provide publicly accessible information on their collection (such as through the Metro South Health [Centres for Health Research internet page](#))
- provide publically accessible information around how to contact and apply for access
- provide publically accessible information on priorities for determining access and release
- entertain and respond with a decision to all reasonable requests for access
- provide information on their criteria and review processes, as delineated in the relevant SOP

- will have the option, if supplies are adequate, of making samples available to commercially supported research projects that meet scientific and ethical criteria, on a full cost-recovery/offset or similar basis.

Additionally, research biorepositories may make available data describing the biospecimen and its origin and provide electronic catalogues to users through the [Centres for Health Research internet page](#) or through focused, state, national and international networks. Data should also be retained for traceability in compliance with relevant legislation and regulations. The research biorepository should respect a defined update frequency for data publication (on-line or not), in accordance with the flow of available biospecimens. Research biorepositories must ensure the quality and consistency of data sets and provide data to users while ensuring information security, bio-security, protection of intellectual property rights, client information and human dignity. Access to electronic catalogues may be restricted where appropriate.

1.2 Standard Operating Procedures (SOPs)

Access to biospecimens for research purposes is crucial for most fields of cancer research and in particular to genomics, proteomics, metabolomics or molecular imaging. Metro South Health research biorepositories must not serve exclusively to satisfy individual needs or research projects and all efforts must be made to ensure biospecimens and data are available to the wider scientific community.

Prior to releasing and distributing samples to researchers, Metro South Health research biorepositories must have well-established, clear, detailed, publicly available written SOPs in place for governing access to all samples and data and sharing and distributing biospecimens, as well as, processes for determining what constitutes appropriate research use of the biospecimens and data.

Access and application SOPs must be in compliance with existing rules, regulations, Policies, Procedures and applicable laws and must include provisions pertaining to:

- Who has access – for example, public sector researchers only, or both public and private sector researchers.
- How should access be provided.
- Whether access should be free or for a fee.
- What access should be given.
- The purposes for which should access be given.
- Requirements for accessing samples and data. This should be based on objective and clearly articulated criteria considering data security and confidentiality.
- The circumstances under which they would provide access to samples or data to third parties and any legislation that may apply.
- Requirements for the return or destruction (in a manner not permitting, of samples and data provided to third parties at the completion of their research.

Metro South Health must provide access to these Procedures to sponsors, patients/participants and if appropriate, to the general public. Metro South Health research biorepositories must train staff on SOPs related to biospecimen access and utilisation.

1.3 Human Research Ethics Committee (HREC) Review

When investigators/researchers are required to obtain Metro South Health HREC ethical clearance, for the research use of biospecimens and/or data, documentation of such approval must be obtained prior to biospecimen or data distribution.

1.4 Third party access

Metro South Health research biorepositories must ensure patients/participants' samples or data obtained for health research purposes are not accessible to, or disclosed to, third parties for non-research purposes, including to government departments, religious groups, lawyers, insurance providers, employers, or to law enforcement agencies, except where required by law. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

The Custodian must ensure patients/participants are informed if samples and data will be accessible to third parties or law enforcement agencies and the purposes they may be used for, including, if it is for research or non-research purposes.

Where samples or data may be released to third parties the Custodian must ensure consideration is given to the implications for the Custodianship of any data derived from the analyses performed by that third party. Consideration should be given to maintaining patients/participant's privacy and the confidentiality of any released samples and data, particularly where released samples or data can be linked to other data on the same patients/participants. This may require suitable provisions managing the use of the data being included in the terms of Material Transfer Agreements (MTAs) which govern the release of the samples and data from the research biorepository to the researcher. Please see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.

2.0 Application process

The effective sharing of biospecimens and associated data is essential to ensure optimal use and avoid unnecessary duplication of research effort and waste of resources. This should be done with transparency for the patient/participant. Information on access to samples and/or data must be provided to patients/participants prior to collecting informed consent. Please see Metro South Health Research Management - [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

Access should preferably be to derived tissue products (such as DNA, RNA or proteins), tissue sections and associated information rather than direct release of whole tissue in order to maximise the use of each samples; particularly if the research biorepository determines that the tissues requested are rare, available in limited number or that several competing requests have been received for the material in question. Please see [Collection, Processing, Handling and Retrieval Procedure \(PR2017/104\)](#) for more information. The decision to offer access to derived/processes tissues should be made in consultation with the researchers. The Custodian must ensure information is publicly available on the research projects for which samples and data are accessed, and the results of these research projects.

2.1 Application form

Research biorepositories must pay specific attention to the authentication of new clients (first orders from new clients must be received on an application form with the client's official letter head and signed by an authorised person) and of the individual representatives(s). As part of applicable SOPs, the Custodian must implement an "Application for Samples Form" ([Attachment 2](#)) which requires the researcher to provide the following details (at a minimum):

- the scientific validity of the research proposal
- the investigator's and institution's research qualifications
- the investigator's written agreement covering confidentiality
- use, disposition, and security of biospecimens and associated data
- the investigator's written agreement in a Material Transfer Agreement covering publication, sharing of research results, and ownership of future intellectual property
- ethical approval of the proposed research
- the funding level for the project.

Research biorepositories must provide an appropriate and protected follow-up mechanism to maintain adequate authentication.

2.2 Research Plan

A scientifically sound and appropriate research plan must be included in access requests. If applicable to the research project design and research biorepository purpose, the following specific issues are among those to be considered by the research biorepository in access decisions:

- use of standardised, validated research biomarker assay methodology
- statistical evaluation that shows that the study question can be addressed with the samples available and, if applicable, a negotiated arrangement with a clinical protocol coordinating group to provide timely statistical analysis of research project results
- compliance with Research Protocol-specific requirements needed to achieve research project goals before other access is considered
- confirmation that an investigator has defined funding and HREC approval for the research project, if applicable
- agreement that the investigator will publish or provide public information about the research project outcome according to applicable SOPs.

2.3 Costs

If the research biorepository has a process of stratified access and fees, this could be based on a number of criteria including the background or affiliation of the researcher (eg private companies could be charged a higher fee than researchers from public universities and public laboratories), the researcher must be notified at the time of application.

The research biorepository access and fee SOPs may be stratified but these should be fair, transparent and not inhibit research. Please see [Operational Arrangements Procedure \(PR2017/101\)](#) for further information.

3.0 Review of biospecimen use requests and applications

Access decisions should be guided by the following general principles, as appropriate:

- Timely, equitable, and appropriate access to biospecimens without undue administrative burden.
- Scientific merit and institutional research qualifications, proven investigator experience with the proposed method, and a research plan appropriate to answer the study question.

- Community attitudes and ethical/legal considerations as primary factors.
- Fair, transparent, and clearly communicated access procedures.
- Appropriate allocation of biospecimens based on the nature of the scientific investigation (eg discovery, prevalence, initial validation and hypothesis testing) and the need for annotation. The level of identifiability of the biospecimens and related transfer documents should be appropriate for the proposed research.
- A mechanism for addressing disputes over allocation decisions.
- An investigator agreement covering confidentiality, use, disposition, and security of biospecimens and associated data.
- The parties' written agreement in a Material Transfer Agreement or other appropriate document.

3.1 Terms of access

Access must be assessed considering: the objectives for the research biorepository; the patient/participant's interest; and to ensure that the proposed uses are scientifically and ethically appropriate and consistent with applicable Legislation, frameworks, policies and procedures.

Metro South Health research biorepositories must have a well-documented and clearly defined process for sharing biospecimens and data, prioritising requests for access to biospecimens and data with limited availability and a mechanism for evaluating competing requests for scarce resources. Requests must be reviewed in a timely manner by qualified individuals.

Requests for biospecimen use must undergo some level of scientific and/or administrative review to ensure proper utilisation. The Custodian must ensure stakeholders, including the general community and researchers, are consulted to formulate criteria for prioritising applications for access to the samples. Generally, separate administrative review and/or scientific peer review committees are convened for large research biorepositories (further information provided below) however it may not be necessary for the Custodian to convene separate committees due to the size and scope of the collection.

Irrespective of the committee structure, the Custodian must implement an equitable review process, designed to ensure rapid turnaround of requests, with minimal administrative burden. The review of researcher requests must be conducted by appropriate personnel who can make determinations regarding administrative and scientific feasibility.

Regardless of the approach, the request process for the research biorepository must be standardised through a common easy to use "Application for Samples Form" and accessible review SOP that is readily accessible to potential researchers. The mechanisms and processes for reviewing applications for access to and use of the research biorepository, including HRECs or other oversight mechanisms, must:

- ensure samples or data are used in a manner consistent with the original informed consent process, including determining when to seek new consent
- review the use of samples and/or data which were consented using a broader or layered format for unspecified future uses, especially in the case of large-scale genetic epidemiology studies
- review the plan for data access and data distribution to make sure it is consistent with the informed consent provided by the patient/participant.

Research biorepositories may develop a distribution strategy that addresses how they will manage possible conflicts between hold and supply activities in cases of rare and/or precious samples as well as for those samples that cannot be replenished.

3.2 Administrative review processes

The research biorepository administrative review process, often referred to as a Research Biorepository Management Committee, must include representation from the academic research community and may also include representatives from lay community, patient advocacy groups and government or industry members.

As part of the review process, the administrative review must evaluate if the research meets release criteria in order to maximise utilisation of the resource. Research evaluation/release criteria must include:

- scientific merit of the request
- experimental or research project design is capable of answering the questions being proposed
- originality and innovative use of materials
- awareness of similar research projects being done or published
- established methodology and ability to complete study within a defined time period
- adequate funding to complete the research project
- potential for research to be published, lead to patents or aid in discovery and development of new therapeutic agents and biomarkers (data to support regulatory submission)
- consideration where tissue samples are scarce and valuable (especially small samples from certain rare cancers).

Access should only be approved if the proposed research project is in accordance with the mission and goals of the research biorepository. Distribution, especially against competing demands for biospecimens, must be prioritised in a fair and equitable manner.

Prioritisation of distribution must be conducted by the Research Biorepository Management Committee. The following issues must be considered when prioritising distribution:

- Researchers' affiliation to an institution connected to or supported by Metro South Health research biorepositories may be a priority.
- Geographic location of requesting institution (Metro South Health research biorepositories may have the mandate to meet the needs of researchers from Metro South Health first).
- Importance of the proposed research project to address the mandate of the research biorepository.
- Researchers track record and former collaborations with the research biorepository if relevant.
- Utilisation of the resource is maximised. Consider if the tissue needed for a research project might be obtained from other sources (alternate sources such as prospective or retrospective collections, without associated or outcome data if adequate).

Where there is doubt over whether an intended use of human tissue or data is consistent with the purpose for which consent was given by a patient/participant, legal advice must be sought by the research biorepository Custodian or Human Research Ethics Committee through the institutional or departmental legal service.

Please see [Operational Arrangements Procedure \(PR2017/101\)](#) for more information regarding the Research Biorepository Management Committee.

3.3 Scientific peer review

Access must be granted only after review by an established scientific review process. Considerations may include:

- Scientific merit and potential impact of the proposed research.
- Whether the research use is appropriate to the nature and purpose of the research biorepository.

- Availability of biospecimens of a specific type.
- Adequacy of the research project design and funding.
- Public health benefits and risks of the proposed research.
- Legal and ethical considerations and qualifications of the research team.
- Research environment.

Review must also consider requests for research projects requiring rare biospecimens, biospecimens annotated with large amounts of data and those that require additional processing, pre-analysis or special handling by research biorepository personnel. During evaluation of the proposal it needs to be considered whether the proper expertise has been brought together in the research project and whether the lab is adequately equipped to perform the proposed experiment.

Evidence of scientific peer review and ethical approval is required to demonstrate this.

3.4 Principles for international biospecimen exchanges

National and international access to research biorepository samples and data should be contingent on recipients being subject to law or other binding requirements which are substantially similar to those applicable in this jurisdiction regarding handling, privacy and confidentiality of tissue samples and information.

Many countries have adopted safeguard mechanisms and regulations to ensure the security of biospecimens and associated personal data as well as to protect the right of ownership and intellectual property that may stem from research conducted using biospecimens collected on their national territory.

It is important to develop SOPs which cover international processes to facilitate and oversee human biospecimen exchanges that respect the principles of national and international regulations on human subject research protections. Under such SOPs, studies that meet a number of conditions may be granted a waiver of restrictions on biospecimen exchanges.

Key conditions are listed below:

- The study should be developed in the context of a scientific partnership between scientists and institutions of countries that are “biospecimen providers” and “biospecimen users”.
- The study must have been approved by the relevant institutional and legal ethical review boards in all the countries that are part to the study.
- Personal and individual data accompanying the biospecimens should be anonymised.
- Packaging, shipping and sending should comply with international regulations on the transport of hazardous biospecimens (see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information)
- The involvement of all parties should be regulated by a “Material Transfer Agreement” (MTA) describing the nature of the involvement of each partner, the sharing of intellectual property and authorship, and the measures for proper re-storage or despatching of biospecimen leftovers.
- Such Biospecimen Transfer Agreements should be guided by a principle of shared access to technology, knowledge, training and benefits of research.

When the biospecimen exchange involves countries of different socio-economic status, it is fair to include in the Material Transfer Agreement provisions to ensure that any application deriving from the research performed using the biospecimens should be made available at costs compatible with the resources of the country with the lowest socio-economic status. Access should only be approved with evidence of approval of the proposed research by the Human Research Ethics Committee (HREC).

4.0 Release and transfer

One goal of the Metro South Health Research Biorepository Governance Framework is to develop, assist and harmonise use of standardised mechanisms for release/use of tissues and products to research collaborators by Metro South Health research biorepositories. Metro South Health research biorepositories must ensure that mechanisms are in place to maintain biospecimen and data quality, protect patient/participant privacy and confidentiality and to ensure that biospecimens are shared in a manner that is consistent with the consent and privacy standards under which such biospecimens and data were obtained. Release mechanisms must be designed to promote the goals of the research biorepository (advancing cancer research) as well as safeguarding the interests of the patients/participants.

4.1 Release and transfer of samples

Custodians of the samples bear responsibility for keeping proper records of all uses that have been made of the materials, whether by themselves or others. If release and transfer of material occurs, appropriate Material Transfer Agreement processes must be followed and documented. Please see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.

4.2 Release and transfer of data

Free exchange of scientific data is of paramount importance, and access arrangements for data in non-identifiable form should reflect this. Patient/participant welfare, respect for human dignity, and justice are likely to be less pressing concerns in such circumstances than when access is sought to linked data or tissue. Researchers should only have access to biospecimens or data that are coded or anonymised, such that the patient/participant cannot be identified, and researchers should be required to not attempt to re-identify patients/participants. However, under exceptional conditions, researchers may be provided with access to biospecimens or data that are not coded or anonymised.

Additionally, samples are often more useful for scientific research when accompanied by subject specific data that characterises the sample and its source. Therefore, research biorepositories often provide a set of associated data with each sample to aid with the interpretation and analysis of the scientific user's experimental results. It is important to ensure that such data will be used in accordance with appropriate legal requirements including the Participant Information and Consent (PICF), Research Protocol and other documents governing the research biorepository. In the case of human samples, it is important to protect subject/donor identity and privacy. Whenever possible, human subject's data must have all identifying information removed. The terms of access for researchers to the whole or a part of the database(s) of a research biorepository must be set out in a Data Transfer Agreement. Please see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.

To enable the tracking of data and sample usage, the patients/participant's consent on the type of research for which his/her biospecimens and data can be used should be incorporated into the research biorepository's information management system.

Metro South Health research biorepositories must develop SOPs consistent with applicable laws and regulations including those related to transfer of intellectual property, informed consent, ethical and privacy standards and formal agreements covering specific data sharing arrangements. Please see [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for further information.

4.3 Types of data

Biospecimens and associated data must be distributed without information that could identify the patient/participant, unless identification is absolutely necessary and the human subjects or Human Research Ethics Committee review has granted permission for inclusion of identifying information.

Two kinds of data may be associated with biospecimens: biospecimen-specific data and patient/participant or subject-specific data. Both types may include identifying and non-identifying information.

Biospecimen-specific data is uniquely associated with a particular biospecimen (eg aliquot of tissue, vial of fluid). Examples of biospecimen-specific data include sample quantity (eg volume, weight), quality indicators (eg RIN numbers, ischemic times) and storage conditions (eg stored in media, preservative, paraffin-embedded).

Patient/participant specific data includes clinical or biological data gleaned from existing records (eg diagnoses, treatment history, family history, risk factors, lab results), databases such as patient registries, donor identifiers (eg names, field identifications, health record numbers, species) and exposure data (eg air pollution, geographic particularities, natural and man-made toxic substances, volcanoes and waste dumps). Please see [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for further information.

4.4 Confidentiality

The use of biospecimens and accompanying data is critical for medical research. The public and patients/participants should have confidence that research biorepositories and researchers will use and handle such material with sensitivity and responsibility. It is important to ensure that collections of biospecimens are used ethically and optimally to benefit health and knowledge. Clearly, the process should focus on timely and equitable access to biospecimens and associated data without excessive administrative burden.

Mechanisms must be employed to ensure that researchers are not inadvertently provided access to potentially identifying data, including, for example, by only permitting the querying of the database by research biorepository personnel who return the aggregated results to the researcher or by permitting researchers to query only certain aspects of the data held by the research biorepository. Users of data must sign confidentiality agreements.

Unless strictly necessary as determined by a HREC, researchers should be provided access only to samples and data or information that are coded such that the patient/participant cannot be identified and researchers should be required to not attempt to re-identify patients/participants.

Personal and medical information relating to the patient/participant and tissue sample must always be treated as confidential. Please see [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for further information.

4.5 Data security

Metro South Health research biorepositories must ensure that the data is transmitted securely, minimising the possibility of interception or unauthorised use, particularly if information is included that could potentially identify individual patients/participants. Metro South Health research biorepositories must instruct data recipients regarding data security measures including the use of password protection and encryption, where appropriate.

Metro South Health research biorepositories that send data to users must carefully consider available data distribution methods. Internet transmission for example, is convenient but requires special consideration of security technologies such as encryption. Security concerns also arise when transmitting data using physical formats (eg disks, tapes).

Data distribution via courier for example, is preferable to standard postal service when use of a reliable tracking mechanism is confirmed. Encryption is recommended when using couriers since there is always the chance of delivery error or interference. Please see [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for further information.

4.6 Publishing and provision of data to biorepositories

In publications that result from the use of biospecimens, the Metro South Health research biorepository must be acknowledged as the source of the biospecimens. Prior to providing the biospecimens, authorship guidelines must be established, so that it is clearly delineated between those cases when the research biorepository is merely serving as a source of biospecimens and those cases when research biorepository personnel actively participate in the research project itself, and therefore should be considered co-authors (eg by providing substantial intellectual input beyond the routine role of the research biorepository, which may include data analysis or manuscript preparation).

Many research biorepositories are required to provide an annual report to funding agencies that describes the outcome of the studies that recipient researchers have performed with biospecimens. For this reason, recipient researchers may be requested to provide the research biorepository with a listing of abstracts, presentations, publications, patent applications, and funding that has been the direct result of using biospecimens from the research biorepository.

Some research biorepositories may ask biospecimen recipients to provide research data on individual biospecimens to the research biorepository (either aggregate findings or individual-level data). The desired data format can range from the abstract of any publication based on analysis of the materials to the publication itself, a data summary, or the complete experimental data set.

Research biorepositories may specify a date by which sample recipients should or must provide data. A standard date may be set (eg twelve (12) months after publication or completion of the research), or a date may be set by the research project. Sample recipients often require time following the completion of research activity for publication of results or for securing intellectual property rights before data can be provided to a research biorepository.

When biospecimens are used in research publications, care must be taken to ensure patient/participant confidentiality. In most cases, de-identified biospecimens are provided to recipient investigators such that coded numbers fully protect the privacy of the patients/participants.

Research biorepositories should create a plan to receive feedback from users to make sure that customers' needs have been satisfied to the greatest extent possible.

Research biorepositories may also request a description of analytical methods used to generate or process the data, including quality control measures. The provision of such data may enhance the value of Metro South Health research biorepositories, depending upon their purpose and nature.

Consideration of a data provision SOP is recommended, particularly when significant biospecimen-specific data is available. Research biorepository administrators must consider whether the research biorepository's purpose would be served by retrieving data generated through analysis of shared materials.

The research biorepository's intended use of data will influence other aspects of its data acquisition practices. Research biorepositories may ask researchers to provide the research biorepository with data derived from individual samples or aggregate research results for a variety of reasons including:

- To document research biorepository value and accomplishments.
- To share data with future researchers who will use aliquots from the same biospecimen, case or patient/participant.
- To conduct further analyses of the data to generate new findings.

5.0 Recording access to research biorepository resources

A major component of good governance arrangements for research biorepositories is a precise and reliable system for recording all requests for access to and release of information and biospecimens. Particular care is necessary where biospecimens are transferred. Please see [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for more information.

Metro South Health requires that formal Material Transfer Agreements (MTAs) are executed prior to transfer. Generally, these MTAs will specify:

- the parties to the transaction
- the biospecimens to be transferred
- conditions on transfer
- destruction or return of residual biospecimens after use
- restrictions on transfer to third parties and trans-border transfer
- intellectual property rights in resultant inventions.

In addition, an important component of most Material Transfer Agreements is that they include a mandated return of research results to the research biorepository, within a given timeframe. Please see [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.