PROCEDURE

MSH Research Biorepositories –Disposal, Lab/Fridge Merge and Closure

PR2017/105
Version No. 3.0

PURPOSE

MSH is committed to the highest standards and practices in the operation of tissue banks, biobanks, tumour banks and biospecimen collections ('research biorepositories') for research purposes. This procedure describes MSH research biorepositories processes for disposal, lab/fridge merge and closure.

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 implementing processes for disposal, lab/fridge merge and closure. 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.

- Custodians must plan for a research biorepository's possible discontinuation and should have a suitably detailed Standard Operating Procedure (SOP) setting out the manner in which the biospecimens and data that it holds will be dealt with in the event of its discontinuation.
- The Custodian must ensure there are SOPs in place pertaining to the destruction, disposal and transfer of biospecimens and data in an appropriate way, consistent with the principles of consent and privacy. In some circumstances the destruction, disposal and transfer of biospecimens may also take into consideration cultural heritage and/or religious beliefs known or disclosed by the patients/participants and their representative groups.
- MSH research biorepositories must ensure the destruction of information and data is in a manner not permitting its recovery.

- The Custodian must ensure there are SOPs in place relating to the demise of the research biorepository, where the resource no longer meets a continued scientific need and an unforeseen demise, such as the end of its funding, including the manner in which the samples and data that it holds will be dealt with in the event of its demise.
- Where a research biorepository of scientific value can no longer be supported by its current operators, efforts should be made to transfer the biospecimens and data to another research biorepository or another entity.
- Once a research biorepository is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the biospecimens should be disposed of in an appropriate manner, consistent with the principles of consent, privacy and confidentiality.
- Biospecimens must be disposed of in accordance with legislation and regulation applicable to the disposal of human materials and biohazardous waste.

LEGISLATION OR OTHER AUTHORITY

Legislation

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

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

Regulation

- Transplantation and Anatomy Regulation 2004 (Qld)

Statements, papers and guidelines

- Canadian Tissue Repository Network: Policies and Standard Operating Procedures
- Government of Western Australia: Guidelines for Human biobanks, genetic research databases and associated data
- International Society for Biological and Environmental Repositories (ISBER): Best Practices: Recommendations for Repositories Fourth Edition
- National Health and Medical Research Council (NHMRC): Biobanks Information Paper 2010
- Organisation for Economic Co-operation and Development (OECD): Guidelines on Human Biobanks and Genetic Research Databases

MSH policies, procedures, manuals and frameworks

- Metro South Health Research Management Policy (PL2017/55)
- Risk Management Policy (PL2018/62)
- Risk Management Procedure (PR2018/97)
- Finance Management Practice Manual (FMPM)
- Disposal of Surgically Removed Human Tissue/Limbs Work Instruction 01720/v6/11/2015

RESPONSIBILITIES

Executive Management

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

Metro South 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 MSH Research Biorepository Governance Framework.

MSH Research Biorepository Strategic Oversight Committee

Provide an appropriate Governance Framework within which all MSH research biorepositories operate.

Custodian/Principal Investigator – responsible officer

Ensure the research biorepository's processes for disposal, lab/fridge merge and closure not only supports individual and institutional interests, but 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 disposal, lab/fridge merge and closure for MSH 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 MSH patients/participants are performed in accordance with the MSH Research Biorepository Governance Framework and applicable SOPs.

SUPPORTING DOCUMENTS

Attachment 1 - Application

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE - DISPOSAL, LAB/FRIDGE MERGE AND CLOSURE

STEP 1: Legacy Plan

The Custodian must ensure there is a Legacy Plan in place for a situation where the MSH research biorepository no longer meets a continued scientific need. Please see Establishment of a Research Biorepository Procedure (PR2017/100) for more information.

STEP 2: End date consideration

The initiators of the research biorepository or the Custodian must ensure a possible end date for the MSH research biorepository is considered.

STEP 3: Destruction of information

The Custodian must ensure the destruction of information and data is in a manner not permitting its recovery.

STEP 4: Standard Operating Procedures (SOPs)

The Custodian must ensure there are SOPs in place relating to the demise of the research biorepository including the manner in which the samples and data will be dealt with.

Step 5: Disposal

MSH research biorepositories must ensure SOPs are implemented for the lawful and respectful method of disposal of biospecimens.

PROCEDURE DETAILS

Procedure Number
PR2017/105

Procedure Name
MSH Research Biorepositories –
Disposal, Lab/Fridge Merge and Closure 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 Disposal

MSH research biorepositories must ensure SOPs are implemented for the lawful and respectful method of disposal of biospecimens. MSH research biorepositories must also ensure the method of disposal of samples is explained to the patients/participants prior to collecting informed consent, particularly for retained tissue samples. The research biorepository's discontinuation plan, normally written at its establishment and included as part of the legacy plan, should include details as to the appropriate disposition or destruction of the biospecimens and data where the research biorepository no longer meets a continued scientific need. Please see Establishment of a Research Biorepository Procedure (PR2017/100) for further information.

1.1 Withdrawal of consent

Under national and international ethical guidelines all research patients/participants, including those providing biospecimens and information for a research biorepository, have the right to withdraw their consent without penalty or explanation. This right extends to family members of patients/participants who have deceased.

This right of withdrawal is a fundamental principle; however, there are limitations to implementing that right of withdrawal in the context of research biorepositories, and potential patients/participants and/or their families (where applicable) need to be made aware of these. In particular, the possibility of withdrawing completely may depend on the timing of the request for withdrawal, whether the biospecimen has been distributed and used for research purposes, or if results are in the public domain or have been published. It may also depend on the nature of IT systems which might not allow complete deletion of personal data. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.

Whilst unused biospecimens can be returned to the research biorepository and withdrawn from the resource, processed biospecimens and the research data generated from them cannot be withdrawn. In these circumstances, individually identifiable information needs to be removed from the data and patients/participants reassured that confidentiality and protection of their biospecimens and data will continue. Withdrawal of consent need not be an 'all or nothing' matter; there may be options for withdrawal, which can be outlined to the potential patient/participant when seeking consent. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.

1.2 Retention of data in the case of withheld or revoked consent

Publication of data imposes a requirement that researchers and the MSH research biorepository retain source data or records. For cases of withheld consent, all case related information and data held (electronically or on paper) by the research biorepository must be removed or destroyed. For cases of revoked consent, all case related information and data must be limited or destroyed.

Guidance from the MSH Human Research Ethics Committee (HREC) should be used in the management of case related biospecimens and data accrued, that cannot be destroyed as it may already be engaged within a research protocol. In some cases, such material may be used as anonymous donor/tissue without information about the clinical characteristics and with MSH HREC approval.

1.3 Cultural sensitivity in the disposal of biospecimens

Cultural sensitivity is imperative in biobanking, including the collection, use and disposal of biospecimens. Some groups regard certain types of biological material as having a special status, particularly where it is removed post mortem, and as deserving of special treatment in its use and disposal.

When research focuses on a particular community, populations, ethnic and/or social groups consideration must be given in relation to any wishes about the method of disposal. The method of disposal must be recorded at the start of the research and taken into account at the time of disposal. This caters for the needs of diverse cultural groups that have specific beliefs about the use and disposal of their biospecimens. Whilst such issues are most likely to be addressed during the consent process, this may not always happen; for example, where research biorepositories are formed using existing collections. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.

2.0 Culling of collections

Culling is the process of reviewing and eliminating selected biospecimens or an entire collection either by destruction or by transfer to a new Custodian. This action may be needed periodically due to storage space constraints and/or the need to control costs. Other reasons for culling may include consent issues, regulatory changes, Research Protocol modifications and/or compromised biospecimen integrity.

SOPs must be established for culling or transfer of collections when biospecimen resources have fulfilled their original purpose, are no longer suitable for their intended purpose or if patients/participants request the withdrawal of their biospecimens.

These SOPs must be clearly described and openly available, as appropriate, to users and potential users of the biospecimen collections. Research biorepositories should remember that there are costs for culling associated with retrieving biospecimens from their environmental storage containers as well as costs involved with the destruction or transfer to a new Custodian.

The best time to plan for the culling of a collection is prior to the acquisition of any biospecimens as part of the Legacy Plan. The value of biospecimen collections must be reviewed on a regular basis.

2.1 Audits

Research biorepositories, in consultation with the Research Biorepository Management and Scientific Review Committee/s, should identify which samples should be stored that have value for research.

Audits of samples held should be undertaken annually as, an audit of collections will identify samples that can be discarded. This ensures the samples stored are of value for future research and that resources are used efficiently.

2.2 Biospecimen destruction

There are a number of circumstances that may influence decisions as to whether or not a collection should be destroyed. Some of the reasons for destroying samples may include:

- When all identifying information has been lost.
- When samples have been compromised by equipment failure.

- When samples have experienced freeze-thaw cycles such that the molecular contents have been compromised.
- When a Custodian has left the organisation and key information regarding the biospecimens has been lost.
- When required by consent, research project design or regulation.
- Lack of use due to 'supply & demand' for that disease type.
- When there is new information about potential biohazards associated with the biospecimen.
- When extra biospecimens were collected or stored in excess of the Principal Investigator's research protocol.
- When the status of a patient/participant changes from 'eligible to ineligible' or their case/control status changes.

In certain circumstances, annual maximum thresholds for each disease (or classification) may be described by the Custodian and (annual) discard processes undertaken to reduce held samples to that level. Custodians may make decisions/determinations in regard to future 'collections' for the disease type (ie are 'old' samples to be continuously replaced with new 'stock' or is remaining stock left to age with no 'new' capture/replacement for a specified period).

MSH research biorepositories must assess and document the destruction of any samples, noting when they are destroyed and for what reason. Custodians must implement a relevant SOP which implements a destruction of sample process and associated form. The 'Destruction Form' must contain:

- the reason for the destruction (eg withdrawal of consent)
- a checklist of the process undertaken on a patient's/participant's biospecimen or data
- space for identification of where data (hard copy or electronic) has been captured (ie within which system/s
- a tick box (signed and dated) which ensures that ALL associated data is deleted and that every time point sample destroyed.

This information can be important to the research biorepository's quality management and may serve as an indicator for the research biorepository of areas that need improvement.

MSH research biorepositories must also consider relevant Hospital and institution specific processes when destroying samples. Please see Disposal of Surgically Removed Human Tissue/Limbs Work Instruction 01720/v6/11/2015 for more information.

2.3 Tracking and records

MSH research biorepositories must have a system in place to track the elimination of collections either through sample destruction or transfer to a new Custodian. The system should include documentation of the history of the collection, what records may accompany the collection and the reason for the culling of the collection.

Administrative review may be helpful to see if there are others within MSH or institution affiliated with the research biorepository that may be able to make use of the collection, providing this is allowed by the consent documentation. Records regarding culling should be included with other archival records for the research biorepository. Please see Databases, Tracking, Records and Documentation Procedure (PR2017/109) for further information.

3.0 Research biorepository closure, merger or change of ownership

3.1 Transfer of a collection

A research biorepository may have a need to transfer a collection to another research biorepository or a Custodian. In this situation, the new Custodian should be made aware of consent and ownership issues related to the collection and all documentation associated with the biospecimens should be transferred. New MSH HREC review will be necessary for new uses for the biospecimens. A Material Transfer Agreement (MTA) will need to be established to document allowable uses for the collection. The cost for retrieving and transporting the collection to the new Custodian should also be taken into account. Please see Material Transfer Agreements, Packaging and Shipping Procedure (PR2017/107) for further information.

3.2 Closure of a research biorepository

The initiators of a research biorepository or the Custodian must ensure a possible end date for the research biorepository is considered. MSH research biorepositories must have plans in place to manage collections, upon expiry of the ethics approval, by considering the following:

- whether samples will be transferred to another research biorepository, including feasibility (ie size of the collection, existence of quality management/assurance protocols, inventory management systems and data)
- whether or not the equipment that is storing the samples is also being transferred
- whether the Custodian will seek further approval from the MSH HREC
- if the samples will be discarded (only appropriate if not of significant value).

In the event that a research biorepository is no longer sustainable, the Custodian must ensure the transfer of the samples and data, in accordance with consent given by patients/participants, and approval undertakings made in relation to data provision, to another initiative or to another entity.

If a transfer is deemed appropriate, a definitive transition plan is required ahead of the scheduled transfer date. Alternative instructions may be required dependent on whether a research biorepository is being handed over in full or part, and if assets are also being transferred.

Custodians must consider that the transition or deconstruction of a research biorepository is highly dependent on the age and size of existing holdings especially in relation to the time requirement needed complete the transfer of samples and all related quality assurance material. Consideration of closure needs to be made well in advance so experienced staff with a working knowledge of the research biorepository can be involved in the transfer and handover or destruction process.

Where the demise/discontinuation of the research biorepository results from insolvency, the liquidator will be governed by applicable insolvency law. The initiators of the research biorepository and the Custodian must be aware that the liquidator may be permitted or required to sell the assets of the research biorepository to commercial buyers, subject to any constraints in the patients/participants' consent or under the law. The research biorepository should consider what steps should be taken to provide for this and make information available to patients/participants.

SOPs on the disposal of samples and data at the demise of the research biorepository must consider how samples and data that have been provided to third parties will be managed this includes samples which have been utilised within an approved research project.

Depending on how long the research biorepository has been running the destruction of all data may also be quite difficult given that back-up files may cover a lengthy period (eg 30 years). While the research biorepository will retrieve and destroy as much of the data as possible, there may be circumstances where this is not feasible (eg if pooled samples have been prepared or cell lines have been developed

and disseminated in a non-identifiable form). Information on these conditions should be provided before collecting informed consent. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.

3.3 Relocation of a research biorepository

There are times that require research biorepositories be moved from one site to another. Such situations may be caused by the inability to renew a lease if research biorepository space is leased or possibly because the special requirements have changed, either due to expansion or reduction of the collections housed within the research biorepository. Since many considerations must be made to ensure an orderly transfer of equipment and supplies, planning should begin as early as possible to ensure the effective transfer.

The requirements for the new space should be well documented and complete and should meet the anticipated growth for the period of time for which it will be occupied. Stakeholders and staff should be included in discussions to ensure that all details are attended to and that all training needs are met for handling the collections in the new location.

Move(s) should be planned over a period of time that will allow for effective responses to any challenge that may arise. Empty, cold, environmental equipment for all storage temperatures reflected in the collection to be transported should be operational and stabilised to receive biospecimens in the event of a failure of a particular unit during transit.

Equipment maintenance professionals should be alerted to the date and time of the move to ensure the likelihood of their rapid response. To the greatest extent possible, research biorepository personnel must ensure that shippers, carriers and drivers follow all regulations for movement of hazardous and infectious materials.

A map should be created for the new site that will indicate the location of all equipment and materials that will be transferred prior to the initiation of the move. Planning should include review of current processes to ensure that efficiencies can be incorporated into the new space.

The details of how the relocation is to be accomplished (eg a description of the plan, timelines, roles of staff and contract support) should be documented to ensure that those involved are fully aware of schedules, costs and to ensure that the transition process is carried out effectively and appropriately.

3.4 Established collections

For many old collections, no specific arrangements for Custodianship of samples and management of access will have been put in place. This can present problems when researchers retire or move to a different job, or when there is disagreement over who should be allowed to use the samples.

When a researcher wishes to move samples to a new location, the agreement of the current and the future host institution must be sought, and contributing organisations must be consulted where possible.

The terms of the original consent and Human Research Ethics Committee approval must be reviewed, and amendment sought if necessary. When a researcher leaves an organisation and sample collections are to be retained, MSH and any supporting institutions must ensure arrangements are put in place for future maintenance and management, and that a new person is identified to take on responsibility for the collection.

3.5 Decisions about sustainability and retention of established collections

Established collections of biospecimens can provide a valuable source of samples for research, if they are of known quality and hold links to appropriate data. However, long-term maintenance of sample collections requires resources and it is important that the Custodian assesses periodically whether old samples are still ‘fit for purpose’, taking into account both their scientific value and ethical issues.

The MSH Research Biorepository Strategic Oversight Committee is responsible for making decisions

regarding the sustainability and retention of established collections. Please see Strategic Oversight Committee and Compliance Procedure (PR2017/99) for more information. If samples are no longer of value, they should be disposed of safely, respectfully and sensitively, and in accordance with any legal requirements.

Some old and valuable collections of biospecimens may not have broad and enduring research consent in place. The National Statement on Ethical Conduct in Human Research (2007) ("National Statement") contains waiver provisions which are applicable in this circumstance. Please see MSH Research Management - Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) for more information.