PROCEDURE

Metro South Health Research Biorepositories – Quality Management System (Assurance and Control)

PR2017/110
Version No. 3.0

PURPOSE

The purpose of a Metro South Health (MSH) research biorepository is to supply biospecimens and their associated data in a form that meets specific quality criteria and is provided in compliance with all necessary regulatory and statutory obligations. Therefore, a Quality Management System (QMS) that includes Quality Assurance (QA) and Quality Control (QC) programs must cover the full spectrum of a research biorepository's operations. The implementation and maintenance of a QMS contributes to the long-term sustainability of research biorepositories in MSH. These systems support the delivery of high-quality services to end user communities and in doing so sustain the business, utility and research viability of collections. This Procedure outlines the requirements for implementing a research biorepository QMS enabling assurance and control in MSH.

OUTCOME

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

This procedure applies to all MSH or Queensland Health (QH) employees whose usual reporting line is through a MSH facility or service (including visiting medical officers, visiting health professionals, students and researchers) who operate or access, or who propose to establish or access, a research biorepository that includes biospecimens collected, processed or stored within MSH facilities.

Failure to comply with this procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other MSH Research Management and Research Biorepository procedures.

KEY PRINCIPLES

The following key principles guide MSH research biorepositories in their establishment of a QMS which encompasses QA and QC programs. 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.

- Existing collections of samples are often of very significant value for research purposes. With increasing numbers of samples being collected, stored and available for research and the use of research biorepositories, there is an emphasis on optimising use and ensuring the quality of these samples. In addition, the use of public monies for the collection of samples and research means there is a duty to ensure that samples are used optimally for the benefit of society; and that duplication of effort is minimised, therefore it is important that nomenclature detail surrounds all samples, and the quality of each samples is known in order for their use to be optimised.
- The research biorepository Custodian must ensure clear, detailed, publicly available Standard

Operating Procedures (SOPs) are in place to ensure samples and data are subject to proper quality control and quality assurance measures at every stage of its processing pertaining to the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, dissemination, use, auditing, annotation and destruction of samples and/or data to ensure high standards of quality in all research biorepository holdings.

- Research biorepository laboratory equipment and infrastructure must be appropriate to ensure proper collection, processing, storage, quality control and distribution of biospecimens and computer/informatics infrastructure must be appropriate to enable each research biorepository to collect, store and share data in an efficient and secure method.
- MSH research biorepositories must have appropriate QA and QC programmes regarding equipment temperature, maintenance, calibration and repair, staff training, SOPs, data management and record keeping, and adherence to quality standards.
- QA processes such as routine audits and quality control analysis must be performed to ensure that integrity and quality of the collection is maintained.
- All MSH research biorepositories (including diagnostic pathology archives) must have processes for ensuring the quality and ongoing integrity of biospecimens and security associated patient information.
- Standards for the collection, processing and storage of samples for research must be proportionate, practical, realistic and achievable.

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

- 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

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

RESPONSIBILITIES

Executive Management

Ensure collaborative, harmonised, clear and detailed publicly available policies, procedures and 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

The MSH Research Biorepository Strategic Oversight Committee consists of personnel with appropriate skills and qualifications, as well as lay or patient/participant representation. The responsibilities of the MSH Research Biorepository Strategic Oversight Committee in relation to the QMS are clearly defined and their place within the organisational structure of the tissue resource must be clear, ensuring appropriate accountability and governance. Please see Governance, Oversight and Management Procedure (PR2017/98) for more information.

Custodian/Principal Investigator – responsible officer

Ensure the research biorepository's QMS which encompasses QA and QC programs is in compliance with the MSH Research Biorepository Governance Framework and appropriate for the type of biospecimens collected. The Custodian must take responsibility and/or appoint a quality and internal compliance manager whose duties include:

- Administering and monitoring an efficient and up-to-date QMS.
- Reporting and advising on quality matters.
- Representing the research biorepository on quality matters when dealing with users, suppliers and outside bodies.

Research biorepository manager

The research biorepository manager has responsibility and authority implement an appropriate QMS which encompasses QA and QC programs on behalf of the research biorepository and report any matters which require action to the Custodian.

Additionally, the research biorepository manager must inspect and approve biospecimen handling, processing and storage practices, as well as discontinue processing and/or release of biospecimens when errors warrant. A research biorepository must have a clear SOP and create a system for reporting, documentation and follow-up of any deviation, incident or failure and personnel must be trained and encouraged to report deviations. The research biorepository manager is responsible for implementing both audits and accreditation processes.

Laboratory technician/technologist assistant/clinical personnel

Research biorepository personnel must possess sufficient educational background, experience and training to assure that assigned tasks are performed in accordance with the MSH Research Biorepository Governance Framework and applicable SOPs.

SUPPORTING DOCUMENTS

Attachment 1 - Application

Attachment 2 - Quality Assurance and Quality Control Implementation and Auditing

Attachment 3 - Quality Control Considerations for Specific Types of Biospecimens

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE - QUALITY MANAGEMENT SYSTEM (ASSURANCE AND CONTROL)

STEP 1: SOPs

The Custodian must ensure SOPs on contents are developed specifically for the research biorepository. Please see Standard Operating Procedures (SOPs) Procedure (PR2017/111) for more information.

STEP 2: Specified type of data and samples

The Custodian must ensure it is specified which type of data and samples will be collected. This must be justified on the basis of the scientific objectives and purposes of the research biorepository.

STEP 3: Patient/participant confidentiality

The research biorepository must have a QMS process that maintains patient/participant confidentiality.

STEP 4: Tracking of holdings

The research biorepository's holdings must be maintained through a system that allows all the biospecimen, data and any other information to be tracked. Please see Databases, Tracking, Records and Documentation Procedure (PR2017/109) for more information.

STEP 5: Comply with governance framework

The Custodian must ensure the OECD Best Practice Guidelines for Biological Resource Centres or other relevant guidelines are followed in relation to quality control and quality assurance. Please see Attachment 2 - Quality Assurance and Quality Control Implementation and Auditing and Attachment 3 - Quality Control Considerations for Specific Types of Biospecimens for more information.

PROCEDURE DETAILS

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Quality Management System (Assurance and Control) Procedure

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

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

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

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05 July 2024 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Quality Management System (QMS)

One of the biggest risks related to research is maintenance of quality. Poor quality can lead to the waste of valuable samples (eg storage at an incorrect temperature or the use of misidentified cell lines) can lead to inaccurate research results or the inability to reproduce research results, all of which are a betrayal of a patient/participants' trust.

QMSs using defined standards will allow researchers to demonstrate that samples are 'fit for purpose' for their own uses and, where applicable, provide assurance that the samples are fit for the purposes of other potential studies or collaborations. The requirements of a standard will be balanced against the likely uses of the samples. As an example, samples for human application and treatment (not covered by this procedure) will need to meet higher standards than samples for use in research. This is reflected in the available standards and licensing requirements.

Research biorepositories must be able to carefully track each of the biospecimens that are received, processed and distributed from the facility. Accuracy and timeliness are critical to ensure their effective future use. Systems must be established to verify that all biospecimens are handled appropriately. Such systems involve SOPs which are accurate descriptions of tasks performed and may involve the verification activities by more than one research biorepository technician or by a supervisor. When manual processes are followed, double checking of records may be required to ensure that appropriate steps have been taken.

Every MSH research biorepository must have a QMS or adhere to the MSH QA program (if applicable). The QMS program must describe the research biorepository's commitment to its QA and QC programs and describe approaches for ensuring that the requirements of the QA and QC programs are met.

If it is not possible to have a formal Quality Management System with dedicated staff, then processes must be in place to review SOPs and records to assess the efficacy and quality of research biorepository operations. This review must be conducted at least on an annual basis.

1.1 Quality Assurance (QA)

QA is an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, assay, item or product is of the type and quality needed for the project. QA measures should be in place for the collection, processing, storage, handling, transfer and destruction of the biospecimens and data.

1.2 Quality Control (QC)

QC is the system of technical activities that measures the attributes and performance of a process, assay, item or product against defined standards to verify that the stated requirements are fully met. The QC process also confirms the authenticity of a collection's holdings (eg reference strains and cell lines).

2.0 Quality standards

A variety of systems have been devised to allow for confidence and reproducibility in research biorepository practices. Each system described in this section has been developed to ensure that good practices are in place, complete with careful documentation and traceability. While each of the standards described below are resources for repositories, there are costs involved in the attainment of each standard and all the standards may not be appropriate for every repository.

The Custodian should ensure the 'OECD Best Practice Guidelines for Biological Resource Centres' or other appropriate guidelines are followed. These provide technical and practical best practices applicable for, amongst others, hygiene, equipment, storage conditions such as temperature, packaging of materials being provided, and quality audit.

2.1 Current Good Practices

Current Good Practices (cGP) are regulatory guidelines that should be interpreted by the research biorepository to fit its particular circumstances. cGP may be preclinical (Good Laboratory Practice, or GLP), clinical (Good Clinical Practice or GCP) or manufacture (Good Manufacture Practice or GMP). cGP may be more relevant to large corporate research biorepositories, but academic and other small research biorepositories may wish to aim toward cGP guidelines to instil confidence in the implementation of their SOPs. Generally, these standards are interpreted as follows:

- The facility is in a secure, locked area with limited access for unauthorised persons.
- Personnel should be trained in all processes being undertaken and successful completion of such training is documented with evidence of updates, if required, on a periodic basis.
- The facility is subject to internal QA audits and/or site visits by external clients and agencies as appropriate. The agencies that would audit vary by local, state, national or international regulations.
- Policies and procedures are documented in SOPs that are approved by appropriate personnel and are changed or updated only under strict document control rules.
- Records are maintained with respect to the purchase of new equipment, maintenance and repair activities, as well as equipment disposal. Examples of information tracked may include but are not limited to the name and model number for the equipment, name of manufacturer and contact information, serial number, date of acquisition, maintenance and repair, etc
- Records should also be maintained for critical materials and reagents used by the research biorepository. Examples of information tracked may include, but not be limited to; the item name, company from which the item was purchased, date of purchase, expiration date and all related Material Safety Data Sheets (MSDS).
- Deviation reports are produced for all events that fall outside SOPs.

2.2 Best practices

Best practices reflect a consensus body of recommendations made by individuals working in and with research biorepositories. These practices are not binding but rather reflect the knowledge and experience of this community. Best practices go above and beyond standard recommendations and may be cost-prohibitive in some cases. Research biorepository management and other staff should decide which practices to adopt that best support their particular circumstances.

2.3 International Organisation for Standardisation (ISO)

- ISO9001 was created through the International Organisation for Standardisation (ISO). ISO is a worldwide federation of national standards with headquarters in Geneva, Switzerland. The organisation was founded in 1946 to develop a common set of standards for manufacturing, trade and communications organisations.
- ISO9001:2000 Requirements of Quality Management Systems - a system standard, not a product standard. Its primary purpose is to provide organisations with useful internationally recognised models for operating a quality management system. Specifies requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide products that meet customers' and applicable regulatory requirements.

- ISO/IEC 17025:2005 Quality Systems for Testing and Calibration Laboratories - provides general requirements for producers of reference materials including tests and/or calibrations, and sampling. ISO/IEC 17025 covers the use of standard methods, non-standard methods, and laboratory-developed methods. This standard incorporates key requirements of ISO9001:2000.
- ISO /IEC 15189:2007 Medical Laboratories- includes particular requirements for quality and competence. Specifies requirements for quality and competence particular to medical laboratories.
- ISO Guide 34:2000 General Requirements for the Competence of Reference Material Producers - provides the general requirements that a reference material producer should demonstrate if they are to be recognised as competent to carry out the production of reference materials. References ISO/IEC 17025 as a normative document.

2.4 Clinical and Laboratory Standards Institute (CLSI)

Different standards have been published by the CLSI which, although developed for clinical laboratories, may also be relevant to research biorepositories. Relevant CLSI standards include the following:

- CLSI H3-A6 Procedures for the collection of diagnostic blood biospecimens by venepuncture; approved standard-sixth edition.
- CLSI H18-A4 Procedures for the handling and processing of blood biospecimens for common laboratory tests; approved guideline-fourth edition.
- CLSI MM13A Collection, transport, preparation and storage of biospecimens for molecular methods; approved guideline.
- CLSI AUTO8-A Managing and validating laboratory information systems; approved guideline.

2.5 Quality management of samples and data

The quality control processes applied to the databases, sample tracking and auditing must maintain patient/participant confidentiality. The research biorepository's holdings must be maintained through a system that allows all the samples, data and any other information to be tracked. To foster the interoperability of systems and facilitate the scientific exchange of data and samples, the Custodian must ensure the samples and data are collected, processed, handled and stored in a manner consistent with internationally accepted technological standards and norms.

2.6 Accreditation processes

All MSH research biorepositories must operate under an appropriate quality assurance and accreditation framework including external quality assurance program participation (where applicable). MSH research biorepositories may be accredited in accordance with diagnostic laboratory National Pathology Accreditation Advisory Council (NPAAC) standards and international standards.

2.7 Authentication and quality checks of biospecimens

The research biorepository must perform regular authentication tests as well as determine the stability of some key features, growth requirements, and methods of maintenance and/or preservation as appropriate to the biospecimen maintained, using appropriate technology. This information should be recorded. These records should be retained and can be used as a base line when in-storage maintenance checks are performed of for validation after preservation restocking. Where possible the identity of the biospecimen should be confirmed after receipt by a competent person employed by the research biorepository. The biospecimen should be checked again by these competent persons before (if there are additional transfers of the biospecimen before it is preserved) and after preservation. This step may include identity, purity or property check of the biospecimen performed by the depositor. A

maintenance place (ie a scheme for periodic control of the preserved material) should be in place for each item stored. Several aspects determine the frequency of the maintenance checks (eg the type of biological material, the preservation method, turnover of material etc) The maintenance check should be appropriate to the biospecimen and be laid down in the domain specific criteria.

2.8 Method and process for quality checks

All methods and processes should be subject to an in-sure quality checks. For example, the product should be checked for fitness for purpose (ie a sample should be selected from a preserved batch and appropriate stability checks carried out). Such checks should be included in the individual documented SOPs.

3.0 Auditing

3.1 Operational audits

Tracking and auditing of biospecimens is critical. A high-quality inventory must be employed so that every sample can be tracked and audited. All records pertaining to sample retrieval, use, or removal must be maintained to facilitate tracking. Regular audits for the inventory system must be performed and primarily directed at prevention of non-conformances as well as detection, corrective action and process improvement implementation. The timing, scope and outcome of these audits must be documented.

3.2 Annual audits

MSH research biorepositories must be subjected to regular audits. Audits cover the implementation of all SOPs that govern the operations of the research biorepository. Audits may be done on a quarterly, semi-annual or annual basis, or in response to a non-compliant incident, accident or a change/deviation in procedure required in the light of new information or alterations to ethical, regulatory or health and safety issues. A designated individual, as identified by the Research Biorepository Management Committee, familiar with the specific work being reviewed but not directly involved in that work will be responsible for each audit. For this function the individual must be someone who is not directly supervised by the Custodian (eg they must report to a separate department or division responsible for quality assurance). A meeting of all audit staff, research biorepository personnel and line management should be held annually to review the audit reports, enquires and complaints received and discuss potential improvement in SOPs and monitoring. The results of the review should be recorded and the person responsible for quality is responsible for implementation of actions prescribed.

4.0 Quality control

Quality check SOPs must be incorporated as part of each process carried out by the research biorepository. In addition, it is necessary to adopt quality control procedures to address the quality of the research biorepository on a general basis. The following aspects must be taken into account:

- Staff training: the competency of staff to perform tasks according to SOPs should be checked on a regular basis (eg annually).
- Infrastructure and equipment maintenance: a preventive maintenance plan should be adopted. Equipment usage should be monitored through logbooks reporting daily operations and incidents.
- Safety and contingency plans: alarm systems and alarm response procedures should be tested on a regular basis (as defined by the research biorepository); detailed debriefing should be held after any incident to identify possible preventive actions and to improve emergency responses. In large facilities, it is recommended to run safety exercises. Location of alternate equipment that

can be used in ‘emergency’ situations (ie due to equipment failure should be sought, recorded and used in safety exercises).

- Assessment of biospecimen quality, electronic records and storage location: it is recommended that up to 1% of the biospecimen content of the biobank be checked annually. This check should include
    1. the physical verification of the biospecimen location and of the durability of the storage vessels
    2. the verification of annotations and data records,
    3. in the case of collections that are not being actively exploited, the verification of the biological quality of the biospecimens (extraction and analysis of DNA, RNA and other biomolecules as appropriate).
- Quality control results must be recorded and made available for examination upon request by internal or external auditors.

Please note: once a research biorepository employee deemed competent after training, if a future ‘audit’ or other work processes or staff note a non- conformance, then a formal ‘non- conformance’ protocol should be enacted for the employee. The non-conformance would include acknowledgment of issue, re-training and future audits. Subsequent non-conformance in the same area would lead to more formal work performance evaluations, detailed in Professional Development Plans and potential HR processes.

4.1 Validation of sample processing methods

Validation is the process by which a method or assay is ensured to be fit for purpose. This may be done within MSH or by a number of partners cooperating on a systematic and formalised validation exercise. MSH research biorepositories should use validated processing methods for their biospecimens. Processing methods may be validated for the intended purpose either by the research biorepository itself or by a third party. For the purpose of processing method validation, the research biorepository can use scientific literature, feedback from the end users, and/or laboratory quality control results. Technical training is also part of the validation of processing methods.

The research biorepository must list the circumstances requiring new validation measures to be taken (eg new technicians, reagent lot changes, instrument changes, biospecimen type changes). Each processing method will be validated for a specific intended end use or for a group of intended end uses. If no relevant scientific literature is available, the research biorepository may have biospecimen research performed to assess the potential impact of the most important pre-analytical variables, following recommendations on biospecimen research.

4.2 Pre-analytical variations and standards of samples

Features of biospecimen quality; including structure of proteins, function of enzymes, level of metabolites, gene expression levels, DNA methylation status, cell viability, microorganism viability can be affected by the specific procedures followed during sample collection, transport, processing and storage. Whilst it is highly unlikely MSH research biorepositories will have access to pre-collection details vivo pre-analytical variations may be recorded. In vivo pre-analytical variations include the patient’s clinical condition, timing of collection (eg pre-operative, post-operative), medication, diet, stress, circadian rhythms or the non-human biospecimens environmental niche/type of habitat, host, axenic state, season of collection and microbial phase variation which are difficult to control and standardise and should be considered as part of the inter-individual variation of the collection. These variations should be noted whenever possible and appropriate (ie origin of collection site, transport arrangements, time from collection to storage, prior treatment and prior testing etc). In vitro pre-analytical variations include the type of collection tube, pre-centrifugation delay and temperature, centrifugation details for biological fluids, warm and cold ischemia times for solid tissues, type of sampling, type and time of

fixation, time delay before placing into long-term storage, type of long-term storage and exact protocol of cryopreservation and of restoration for environmental biospecimens. These elements should be tracked in an appropriate manner.

4.3 Validation of QC methods

Each QC method must be assessed by the research biorepository or by the external laboratory performing the assays, for its accuracy and precision. Proficiency Testing Programs using Reference Materials should be followed, when available/required. A research biorepository seeking to join a proficiency scheme, should choose a reference lab recognised as a leader in the biorepositories field, this external QC testing gives further confidence to researchers selecting the biorepository for their research samples.

5.0 Records management

Every MSH Research biorepository must develop and maintain a records management system that permits detailed records to be made concurrently with the performance of each step in the collection, processing and distribution of biospecimens. Records maintained may include but are not limited to: training documents, standard operating procedures, protocols, SOPs, informed consent documentation, processing records, testing, equipment maintenance, audit/review documents, biospecimen storage location information, sample distribution, and quality control activities. Records should be created and maintained in a manner that allows steps to be clearly traced and ensure sample chain of custody. Security systems should be adequate to ensure the confidentiality and security of all stored records. Access to records should also be on a “need to know” basis.

Purpose built research biorepository databases or any other type of inventory record keeping (eg excel, access), used to hold confidential patient/participant records for a research biorepository should be held on Queensland Health or MSH server. This negates risk of possible intrusion by third parties via non-secured access to Queensland Health patient records held in a research biorepository. Similarly, any log in access to biorepository databases should be limited to biorepository personnel only.

Any outside interrogation (enquiries) by researchers needs to be set up through a third portal so that only summary data is held, with no access to the actual database and actual patient info/data which is protected behind firewalls. Thus confidentiality of patient information could not be breached even if third portal is hacked (one way access which can be updated daily, weekly, monthly etc).

All communication between client browser and data base server needs to be via a secure socket connection (HTTPS) which ensures all data is encrypted across the internet, again to ensure patient/participant confidentiality. Please see Databases, Tracking, Records and Documentation Procedure (PR2017/109) for more information. In some cases, it may be necessary to either destroy or remove biospecimens at the request of study patient/participants. Under these circumstances, a discard process should be implemented where the sample is discarded and all records are e appropriately amended to indicate that the biospecimen is no longer part of the collection and the information management system should be adequately updated to reflect this event. Please see Disposal, Lab/Fridge Merge and Closure Procedure (PR2017/105) for more information.

Paper files containing confidential patient/participant or client information should be stored in locked, fire and water proof enclosures with controlled access. Research biorepository freezers should be locked after hours to prevent entry by non-associated personnel.

5.1 Template forms and spreadsheets

A research biorepository may develop a variety of forms to allow for effective record keeping. Uniform systems of documentation improve consistency in the tracking and monitoring of research biorepository activities. Examples of effective forms include those to monitor equipment operations and repair, incident reports and activity checklists. Templates may also be developed to facilitate repetitive data entry into a biospecimen database; allowing for files to be translated into a compatible format for the research biorepository's database. Forms or spreadsheets to record the most important pre-analytical variations that may affect the quality of the biospecimens are particularly important. Forms should have a unique number and a distinct title and include the date that the version of the form was created (ie version tracking). All biorepository forms should be able to be tracked (ie active or archived template records kept for the life of the biorepository).

5.2 Record corrections and/or changes

Corrections or changes in a hard copy record should be made in ink with a single line drawn through the altered text. Corrections should be initialled and dated by the individual making the correction or change. Changes in electronic records should be noted and tracked. Changes tracked should include the name of the individual making the change, the time and date at which the change was made and the reason for the change. Dates should implement a format that is unambiguous such as ddmmyyyy, where d stands for day, m stands for month and stands for year. It is recommended a Template Corrections Form is implemented by the research biorepository which is then kept as part of each patient/participants research biorepository record and notes any change to hard copies or electronic copies.

5.3 Archival system

A research biorepository may develop a system for archiving records that are not needed as a part of daily activities that the research biorepository requires to be maintained. This system should be accessible for audits and inspections. The system should meet all regulatory requirements for storage and access.

5.4 Security

Electronic records should be backed up daily on a network or remote secure server. Arrangements should be established with an off-site data security company that retrieves and stores all critical data at a remote location. Computers operated by research biorepository staff should be password protected and should make use of automatic timeout mechanisms that lock the computer (eg screensaver). Permission levels should be created for staff at different operational levels as well as for users who are not research biorepository staff, where this access is allowed. Please see Databases, Tracking, Records and Documentation Procedure (PR2017/109) for more information.

5.5 Availability for inspection

Records should be readily accessible for inspection by authorised personnel from regulatory agencies and QA personnel. Access to privacy records or confidential client information should be restricted to specified research biorepository staff members that are permitted to allow access for inspectors from regulatory agencies and other appropriate auditing groups. Please see Databases, Tracking, Records and Documentation Procedure (PR2017/109) for more information.