PREMISES AND EQUIPMENT FOR THE STORAGE OF PATIENT SAMPLES

Purpose and Scope

This SOP outlines the procedure to be followed by all groups collecting under the auspices of the NRS BioResource, to ensure that premises and equipment used for the storage of patient samples are fit for purpose.

Responsibilities

All groups and researchers collecting human tissue for research purposes under the NRS BioResource approval.

References

Human Tissue (Scotland) Act 2006
Human Tissue Act 2004
HTA Codes of Practice
MHRA recommendations on the control and monitoring of storage and transportation temperatures of medicinal products.

Definitions

SOP – Standard Operating Procedure DI – Designated Individual for Tissue
R&D – Research and Development NRS – NHS Research Scotland
NRS BioResource – Formerly SAHSC BioResource

Documentation

QP-TGU-A-SAMSTOR – Storage of samples for research
QP-TGU-A-MANREC – Management of records

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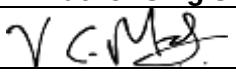
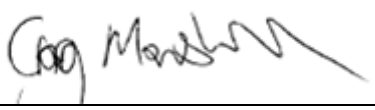
Author:		**Date:**	16-Jan-2021
Authority for issue:		**Date:**	16-Jan-2021

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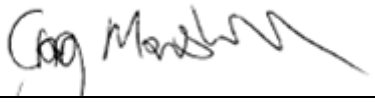
Quality checked:		**Date:**	16-Jan-2021

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1 INTRODUCTION

- This document outlines the procedures that should be followed to meet the requirements for premises and equipment used in the storage of patient samples.

- This SOP will ensure that the required standards for security and maintenance of facilities are met. There is a need for established procedures to ensure that the storage conditions are appropriate, maintained consistently over the period of storage and that adequate monitoring, protection and contingency arrangements are in place to ensure that material is not compromised.

- They must be followed by all staff and researchers collecting and/or using patient samples under the approval held by the NRS BioResource. This SOP should be read in conjunction with QP-TGU-A-SAMSTOR

2 HAZARDS AND PRECAUTIONS

N/A

3 PROCEDURES

3.1 General Principles

Patient samples should be stored securely, in line with health and safety guidelines and current good practice on:

- Security of storage areas and containers [e.g rooms and buildings, freezers, fridges and other storage containers];

- Traceability, including information about risk. Records should detail the location of the materials;

- Health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to others. Cleaning and maintenance of storage is also included in this category.

- Patient samples can be stored in a variety of ways, depending on the type of material being stored and the requirements of the researcher (See SOP for Storage of samples for research - QP-TGU-A-SAMSTOR)

- Consideration must be given to ensuring that patient samples, consumables and records are stored securely and appropriate precautions taken to minimise the risk of damage, loss, theft or contamination.

- The head of the research group is responsible for ensuring that samples are stored in a manner and location suitable for the tissue type and its preservation.

- The head of the research group is also responsible for ensuring that, where applicable, any critical storage parameters are recorded and monitored to ensure they are being met. For example, if the samples need to be stored at -80°C, this should be recorded and the temperature of the freezer monitored to ensure it meets this specification.

3.2 Premises and storage facilities

- Access to the premises storing patient samples must be restricted to authorised persons in order to preserve the integrity of the collection and its records

- Patient samples must be stored in an area that is locked/secure at all times when not in use.

- Storage facilities (i.e. freezers) should be clearly labelled as containing human tissue samples.

- Freezers and other storage facilities should be locked, with access restricted to designated members of staff

3.3 Methods of Storage

- Human Tissue must be stored using recognised methods as per standard practice and guidance and labelled accordingly. See SOP for Storage of samples for research - QP-TGU-A-SAMSTOR

- The appropriate label must convey what the specimen is.

- Labels should not contain patient identifying information.

- Storage records should be maintained for traceability. See SOP for Management of Records for more information (QP-TGU-A-MANREC).

- If a storage unit is used for both human tissue and other material, the human tissue should be stored separately and be clearly labelled as such.

- Documented storage parameters, where applicable, will form part of the internal audit schedule and so they should be created, retained and provided to the NRS BioResource Manager upon request.

- Calibration and maintenance of storage units must be in line with manufacturer's guidance. Records of calibration, monitoring of storage conditions and maintenance should be kept. Records of cleaning, including any cleaning schedules, should be maintained. See MHRA recommendations on the control and monitoring of storage and transportation temperatures of medicinal products.

- A risk assessment relating to the storage of patient samples should be made and should cover, as a minimum, what will be done in the event of failure of storage provision, consideration of what emergency/contingency procedures should be in place, and details of possible alternative storage.

- Any adverse event or 'near-miss' involving the storage of human tissue should be reported in NRS BioResource management.

- If available, local School, departmental or project SOPs should be followed.

3.4 Routine Cleaning

- Procedures for cleaning premises and equipment, as well as any protective equipment and clothing (PPE) required.

- The head of the research group is responsible for ensuring that there are appropriate cleaning procedures in place for any area or equipment where patient samples are stored or used for research.

- If available, local School, departmental or project SOPs should be followed.

- A routine cleaning regime for all forms of storage is necessary, but the method and interval between cleaning will vary greatly with different locations, storage conditions, sample type and containment.

- A Maintenance Log is required for each storage facility (i.e. each fridge, freezer etc will need its own log) in which all cleaning and maintenance actions are recorded. Cleaning procedures form part of the audit schedule so this should be stored locally and available for inspection.

3.5 Routine Maintenance

- The appropriate level of routine maintenance necessary for each storage facility will vary greatly with different equipment.
- The head of the research group is responsible for ensuring that equipment is regularly maintained, in an appropriate manner, and in accordance with risk assessment.
- If available, local School, departmental or project SOPs should be followed.
- Maintenance must be undertaken by competent staff and may require a maintenance or service contract.
- Arrangements for routine maintenance should be stored locally and available for inspection at audit.

3.6 Adverse Events

- Problems with storage facilities are likely to occur from time to time, and systems need to be in place to deal with these so that the stored material is protected and preserved.
- A procedure should be established for dealing with spillages and contamination and documented.
- Procedures for alerting staff to equipment failure and accidental disconnection should be in place and contingency plans for repair /replacement of storage equipment and alternative storage should be established.
- The head of the research group is responsible for preparing their own contingency plans, depending on how the relevant material is stored and what would happen to it if it were destroyed due to e.g. equipment failure.
- The requirements will be dependant on local factors and types of equipment but are likely to employ alarm systems and arrangements for moving samples to alternative storage locations.
- Any adverse event or ‘near-miss’ involving the storage of patient samples or human tissue should be reported to the NRS BioResource Management.

3.7 Equipment failure

- Wherever possible, equipment should be on a service contract to help minimise equipment breakdowns and act as preventive maintenance.

- In the event of equipment failure, the relevant service engineer should be called. The local Laboratory Manager will advise on this.
- In the event of a freezer failure, do not open the freezer until alternative storage of tissue or reagents has been arranged.
- If possible, alternative freezer capacity within the building should be identified in advance as part of a risk assessment.
- In the event of failure of other equipment e.g. mictrotome, ensure that the instrument is taken out of use until a repair has been carried out.
- Place a clearly written sign on any faulty equipment that is awaiting repair. Indicating that it is faulty and should not be used.
- Following repair by a service engineer, a record of the repair and any re-calibration carried out should be maintained.

3.8 Record Keeping

Records of cleaning, calibration, monitoring of storage conditions and maintenance should be kept and maintained according NRS BioResource SOP for Management of Records (QP-TGU-A-MANREC).

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