MANAGEMENT OF RECORDS

Purpose and Scope

This SOP outlines the procedure to be followed by the Tissue Governance / Lothian NRS BioResource staff and researcher groups collecting under the auspices of the BioResource, to ensure the appropriate management of records relating to the collection, storage and use of patient samples.

Responsibilities

Tissue Governance / Lothian NRS BioResource staff and all research groups 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
NHS Lothian Data Protection Policy
University of Edinburgh Data Protection Policy
General Data Protection Regulation (GDPR) and Data Protection Act 2018

Definitions

SOP – Standard Operating Procedure DI – Designated Individual for Tissue
R&D – Research and Development

Documentation

COPY		Tissue Governance shared drive
Location of Copies		ACCORD website

Authorising signatures

Author:		**Date:**	
Authority for issue:		**Date:**	
Quality checked:		**Date:**	

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Quality checked	Frances Rae	Date	12-Mar-2019

Staff Review Form for Standard Operating Procedures

I have read and understood the above Standard Operating Procedure

Name	Signature	Date

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1 INTRODUCTION

This document outlines the procedures that should be followed to ensure good record keeping processes are in place to capture and manage records on the removal, storage, use and disposal of human tissue in accordance with current best practice. They must be followed by all staff and researchers collecting and/or using patient samples under the approval held by the Lothian NRS BioResource.

These will ensure that there is a clear and robust audit trail from the collection of patient sample, through processing, storage, use and distribution, to final use or disposal. Meticulous record keeping is essential.

2 HAZARDS AND PRECAUTIONS

N/A

3 PROCEDURES

3.1 Record Capture and Creation

3.1.1 Traceability and Audit Record

A full traceability trail must be maintained and documented for the storage and movement of all patient samples from receipt to end use, disposal or distribution.

There should be systems in place to ensure that all records relating to this are able to be located

Groups responsible for human tissue collections must ensure that their holdings are fully documented. As a minimum, the following information on each sample should be kept in a record keeping system:

- Sample ID reference. This code should be unique to the donor and sample. It **must not** include donor personal details.
- Tissue type (if more than one stored/used)
- Date of receipt and details of where it came from
- Date sample labelled
- Consent details (if required) and location of the consent form
- Storage location
- Details and dates of processes applied to the sample
- Date the sample was used and, if relevant, exhausted
- If relevant, details and dates of any transfers out to and back from other locations on a temporary basis.

- Date and method of disposal. This could be transfer to another location or destruction using approved procedures.
- Reason for disposal.

The system for recording this information should be proportionate to the activity being carried out. Ideally, the information should be in electronic format (spreadsheet or database) but if the collection is small a paper-based system would be acceptable.

3.1.2 Other records

Principal investigators must ensure that the following records are created and maintained where required:

- Records of consent (where required), recording who took consent; what the consent related to; location of consent form
- Records of human tissue use and movement, e.g. receipts; transfer documentation; laboratory log books;
- maintenance, cleaning and calibration of equipment records
- risk assessment records
- records of tissue destruction: receipts; laboratory log books;
- records of adverse and serious adverse events, including 'near misses';
- local SOPs and quality management documentation
- system for labelling human tissue

This list is indicative and not exhaustive.

3.2 Records Security and Maintenance

3.2.1 Secure storage

- Records and records management systems containing confidential and/or protected personal information must be kept secure at all times.
- Records relating to patient samples and tissue should only be accessible to authorised personnel.
- Any paper records must be stored in a locked facility when not under the direct supervision of a member of the research team.
- The security of the locked facility will be dependent upon the type of data involved in the study. For example any manual research data should be stored in a locked office however if the data is personal data, additional

security measures need to be taken, for example locked cabinet, locked office with restricted key access.

- Access to records stored on a computer should be controlled by passwords and, where appropriate, access to individual files/databases should also be password protected.

- Passwords should be known only to authorised individuals and changed at regular intervals.

- PCs should be locked when left unattended.

3.2.2 **Electronic Storage**

- Electronic records containing confidential and/or protected personal information must not be stored on non-NHS computers without Caldicott approval.

- Electronic records containing confidential and/or protected personal information should not be accessed via remote access or synchronisation facilities which copy the data and store them locally on the machine/device from which it is accessed.

- Electronic records containing protected personal information must not be transferred or stored off site using removable media without prior, formal approval from Caldicott Guardian.

- Only NHS Lothian-issue, encrypted storage media or devices may be used for this purpose. These must be stored securely when not in use and disposed of in line with NHS Lothian policies. The material should be deleted as soon as possible.

- Provisions for the maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data must be in place.

3.2.3 **Back up of electronic records**

- Procedures should be in place to ensure back up of electronic records and records management systems.

- These must be backed up regularly and ideally kept in a secure area on the NHS or University of Edinburgh systems which are backed up nightly.

- All personal information must be stored, handled and disposed of in accordance with the General Data Protection Regulation (GDPR),the Data Protection Act 2018 and with the NHS Lothian Data Protection Policy, and where applicable, the University of Edinburgh Data Protection Policy.

3.3 Retention of records

- Records must be retained indefinitely after the transfer, use or disposal of the human tissue as an audit trail to demonstrate that any or all processes complied with legal and regulatory requirements, applicable best practice and with the conditions of consent given by the donor.

- Any intention to dispose of these records must be discussed with NRS BioResource management and approval given prior to doing so.

3.4 Archiving

- Once the research project has finished paper and electronic records should be archived in such a way as to ensure that they remain reliable and accurate throughout the retention period.

3.5 Record Destruction

- At the end of the retention period hard copy records should be destroyed in a confidential manner either through the NHS Lothian or University of Edinburgh confidential waste service or using local shredding facilities.

- Any electronic equipment used should be wiped before disposal under the guidance of NHS Lothian eHealth.

- A record of destruction should be completed in line with the procedures or guidance provided.

Document Review History

Review date	Version	New Version	Reviewed by
21-Oct-2015	1.0	1.1	Frances Rae
Summary of changes			
Name of Bioresource changed to NRS Section on Traceability and Audit record, should changed to **must not contain include donor personal details.**			
Review date	**Version**	**New Version**	**Reviewed by**
12-Mar-2019	1.1	1.2	Craig Marshall and Frances Rae
Summary of changes			
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