UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1025 UoL

Retaining Analysed Samples and Data

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

Researchers are expected to retain the original, raw data from their research for data verification purposes. Retention needs to meet the requirements of the University, funders and journals where the work is published, as appropriate. The UoL has derived a Research Data Retention Flowchart

This SOP will outline the requirements for retaining analysed samples and data beyond the scope of the original research, to ensure that all obligations for the retention of data and samples are met. Please refer to the data retention flow chart for ease.

2.0 Scope

The purpose of the SOP is to ensure that research samples and the data generated from them are retained for the appropriate timescales.

Definitions:

CI	Chief Investigator
CTIMP	Clinical Trials of Investigation Medicinal Products
DI	Designated Individual
HTA	Human Tissue Authority
PD	Persons Designated
PI	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester

3.0 Procedure

This will depend on funder, journal and local UoL policies. Research data and the accompanying samples should be kept for the longest period required by any of these bodies.

3.1 Sample Studies

All samples and data e.g., immunohistology stained tissue slides, can be retained for verification processes. Where samples have been collected from NHS REC approved research studies, the samples can be retained for 12 months for data verification purposes only, after that time, if they are not being retained for future research, the remaining samples should be disposed. Consideration should be given to any funder

and editorial boards as they will have their own policies and requirements, so please ensure you familiarise yourselves with these requirements.

3.2 Clinical Trials of Investigation Medicinal Products (CTIMPs)

Where the samples and data are part of a CTIMP study. The study data including any personally identifiable information must be retained for 25 years.

3.3 Non-CTIMPs

The data and analysed samples from projects that are not part of a CTIMP should be retained for at least 6 years after completion of the project as per UoL policy (provide link), but longer if stipulated by the funder, or journal where the data have been published.

3.4 University Ethics Projects

Data and associated analysed samples from projects that are approved through the University Ethics Pathway, including those that go through the University Ethics and Integrity Committee (UEIC), should be retained for 6 years after the study ends.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator (CI) / Principal Investigator (PI)	Chief Investigator (CI) / Principal Investigator (PI) or their delegate	Responsible for ensuring that their samples and data is stored for the appropriate time frames as outlined within this SOP. Ensure samples are retained for 12 months post closure of NHS REC approved studies, in line with HRA guidelines.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensures SOP is updated to reflect any regulatory changes
Designated Individual (DI)	Designated Individual (DI)	Ensures suitable practices take place within the licenced establishment.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	Human Tissue Act Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding (Designated Individual) 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes • Addition of data flow diagram hyperlink • Clarity around holding samples for data verification from NHS REC studies.