UNIVERSITY OF LEICESTER

Paper copies of this document might not be the most up to date version.

The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1025-UoL

Version Number: 1.0

Effective Date: January 2021

Supersedes: N/A

Last Review Date: N/A Next Review Date: Jan 2023

Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
Authoriser	Professor Peter Bradding	Designated Individual		08/02/2021

Background

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* to help researchers decide how long they are required to retain the research data and any personally identifiable data on living individuals for the different types of studies that researchers are involved with.

Samples are often used to generate data required for publication. This SOP will outline the requirements of retaining samples and data beyond the scope of the original research to ensure that all obligations for the retention of data and samples are met.

Purpose and Scope

The purpose of the SOP is to ensure there are clear requirement samples and data retention information that researchers can use as guidance to ensure samples and 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	Principle Investigator
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee

UoL University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

The HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes

It is the responsibility of all researchers, staff and students to ensure samples are retained for data verification processes. Each funder and editorial board will have their own policies and requirements, so please ensure you familiarise yourselves with these requirements.

Procedure to follow

Peer reviewed manuscripts require research that is involving human participants, human material or human data, have been performed in accordance with the Declarations of Helsinki and must have been approved with an appropriate ethics committee (REC). A statement detailing this, including name of the REC that approved the project, and the REC reference number, should be documented in the manuscript. In some circumstances, manuscripts can be rejected by the Editor, if the editor considers that the research has not been carried out within the appropriate ethical framework.

Projects involving Children

Projects involving children, the data and the associated samples should be retained until three years after the youngest participant reaches 18 years old, or 6 years from the project completion, whichever is longer.

In certain circumstances, there is a more appropriate retention period for example where samples specifically have consent for the future use i.e. they will be retained until depleted or destroyed. In this circumstance, the original consent forms must be

retained for as long as the sample is in existence to ensure compliance with the HTA regulations.

Non-CTIMP Projects

Projects that involve adults that are not part of a clinical trial of investigation medicinal products (CTIMP) the data and the associated samples should be retained for 6 years after completion of the project, unless there is a more appropriate retention period, which could be dictated by funder or publisher requirements, or where samples specifically have consent for the future use i.e. they will be retained until depleted or destroyed.

Only samples that have the appropriate approvals to be retained at the end of the research study can be transferred to the UoL HTA research licence or a UoL hosted Research Tissue Bank (RTB). In this circumstance, the original consent forms must be retained for as long as the sample is in existence.

CTIMP Projects

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

Similarly, samples form CTIMPs that have the appropriate approvals to be retained at the end of the research study can be transferred to the UoL HTA research licence or a UoL hosted Research Tissue bank (RTB). In this circumstance, the original consent forms must be retained for as long as the sample is in existence. Once the samples have either been depleted or destroyed, the consent form can then be destroyed.

Projects approved through the University Ethics Pathway

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.

If there are relevant samples from these studies, providing there is the appropriate consent for future use in place, the consent forms are required to be retained for as long as the samples are available to use, until they are either depleted or destroyed.

Once the samples has been depleted or destroyed, the consent form can be destroyed.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N