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

SOP HTA-A1020 UoL

Management of HTA Records

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.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

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*.

The management of records are an important source of documentary evidence and should be either retained in paper for within the PD Masterfile or as an electronic version. This is particularly important for freezers holding HTA-relevant material that is reported on the HTA Research Licence.

2.0 Scope

This document provides guidance for the Designated Individual (DI), Person Designated (PD) and staff working under their direction so that they are fully aware of the requirements for management of records relating to the collection, storage and use of human tissue.

Definitions

DI	Designated Individual
HTA	Human Tissue Authority
PD	Person Designated
RGO	Research Governance Office
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

Meticulous record keeping is essential. Clear records must be kept by all personnel involved with the collection, storage and use of HTA -relevant material.

Quality management systems must be established and made available to all personnel involved with the collection, storage and use of HTA -relevant material.

A local system to manage policies for the creation, retention and destruction of records must be in place, together with a system to ensure the accuracy of records.

Where required, SOPs must be written, authorised and made available to all personnel, and a system of SOP document control established.

A coding and record system to facilitate the traceability of HTA-relevant material must be in place ensuring that the sample use is documented right till it is used up.

Appropriate records and documentation for all HTA-relevant material must be kept from collection to transfer, use and disposal. There **must** be a documented record of the nature of each sample and its precise location until it has been transferred, used up or disposed of, or is no longer classed as 'relevant material' under the HT Act.

Recorded information should therefore include:

- When the material was acquired, from where and by whom
- The type of material

- Details of who gave consent (if applicable)
- Exactly what the consent relates to, and any restrictions on use stipulated during the consent process
- The uses to which the material is put whilst in the establishment's care and any processes applied to it
- If HTA -relevant material is transferred elsewhere, when, by whom and to whom reference to SOP HTA-A1008-UoL
- Details indicating whether the material is exhausted (either due to analysis or disposal)
- Any details of disposal. This may include details of when, why, where and how disposal was undertaken, and the person(s) undertaking and authorising disposal. (SOP HTA-A1004-UoL)
- Details of freezer, fridge or cryovessel cleaning, decontamination or defrosting SOP HTA-A1009-UoL
- Details of equipment calibration, validation, maintenance and monitoring; SOP HTA-A1011-UoL

Data collected in the course of research must be retained for an appropriate period (please refer to the *research retention of records* on the RGO Webpages), to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities. Also, SOP HTA-A1025-UoL

The UoL policy with respect to data is that unless ethical/professional/local or funding body guidance requires otherwise, research results should be archived in a durable form that is immune to tampering and falsification for a minimum of 6 years after the date of completion depending on the nature of the study.

It is recommended good practice that records relating to all human samples should be retained for at least 6 years (for a non-CTIMP) or 25 years (CTIMP) after completion of the study. Where samples are transferred to either a Research Tissue Bank (RTB) or the HTA Research Licence, the consent forms must be retained until the samples are either depleted or destroyed.

Clear record systems must be in place to ensure that all adverse events are recorded and action taken as appropriate. Adverse events and Incidents SOP HTA-A1022-UoL must be followed.

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.

Recovery plans for computer back-up of files available from Information Systems must be implemented.

There should also be evidence that staff are appropriately trained in techniques relevant to their work. The HTA training checklist can be utilised in staff training folders which can be found in *Human Tissue Training Checklist Appendix 3*.

All personal information including information relating to staff of students must be stored, handled and disposed of in accordance with the Data Protection Act and General Data Protection Regulation (GDPR) 2018.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigators (CI/PI)	Chief Investigator / Principal Investigators (CI/PI) or delegates	Ensuring appropriate records are maintained at all times for the collection, retention and use of HTA material. Ensuring equipment used to store or use material is appropriately maintained and that maintenance is documented. Ensuring training is maintained.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensuring SOPs remaining up to date and updated in line with any changes in regulations.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices are in place in 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	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	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	• Removal of office address • Mino typographical changes. • Slight update to intro and scope.