UNIVERSITY OF LEICESTER

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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.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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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
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Background

This document has been produced in accordance with 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.

Purpose and Scope

This document provides guidance for Designated Individual (DI), Persons 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	Persons Designated
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

The DI is accountable to the HTA for research tissue stored under the authority of the University Licence.

The PDs are accountable to the DI and responsible for assuring that this SOP is observed in respect of human tissue for which they have responsibility and which is stored under the authority of the University Licence. This includes making all staff that collect, store or use human tissue aware of this SOP. In addition, the PD and HTA Departmental contacts will undertake a minimum of two traceability audits per year.

All staff and students and any external individuals staff collecting, storing or using human tissue for research under the University HTA Research Licence are accountable to the relevant PD(s) and the DI for undertaking work in compliance with this document. They must also work in conjunction with relevant University wide and/or local SOPs.

Procedure to follow

Meticulous record keeping is essential. Clear records management and quality management systems must be established and disseminated to all personnel involved with the collection, storage and use of human tissue.

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 tissue and cells must be in place ensuring that the end-of-use of human tissue and cells is clearly documented.

Proper records and documentation for all samples and relevant material must be kept from collection to transfer, use and disposal. This should include:

- When the material was acquired, from where and by whom;
- Details of who gave consent;
- 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;
- The current location of the tissues held under the Licence (see also label *Template Freezer/Cryovessel Notice SOP HTA-A1020 Appendix 1*);
- If tissue is transferred elsewhere, when, by whom and to whom;
- Details indicating whether the material is exhausted (either due to analysis or disposal);
- Details of freezer, fridge or cryovessel cleaning, decontamination or defrosting (see *Cleaning Log SOP HTA-A1020 Appendix 2;Defrosting Log SOP HTA-A1020 Appendix 4*);

- Details of equipment calibration, validation, maintenance and monitoring;
- 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.

Data collected in the course of research must be retained for an appropriate period (please refer to the *research retention of records* on the REGI Office webpages), to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities.

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 human tissue should be retained for at least 6 years (for a non-CTIMP) or 25 years (CTIMP) after completion of the study. Where samples are being transfer to either a Research Tissue Bank (RTB) or transferred to the HTA licence, the consent forms must be retained until the samples are either depleted or destroyed.

There must be a documented record of the nature of each sample and it's precise location until it has been transferred, used up or disposed of, or is no longer classed as 'relevant material' under the HT Act.

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* 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 with can be found in *Human Tissue Training Checklist (SOP HTA-A1020 Appendix 3)*.

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

Compliance of Records

Recommended sample logs are reviewed by the PD and HTA Departmental Contacts on a regular basis to ensure HTA standards are met. Recommended laboratory leads are identified by the PD in each department. The lead will be responsible for planning a minimum of two traceability audits a year. The lead will work with PDs and HTA Departmental Contacts to ensure sample traceability covers collection through to disposal. The local lead is responsible for supplying a schedule of the inspections to the PD. The audit schedule and audit findings shall be stored in the HTA Masterfile file.

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