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 |
|---|---|---|---|---|
| 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 |
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## Background

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 procedures represent good practice for the handling of all tissue samples and other types of 'relevant material' as defined by the HTA. They must be followed by all researchers working under the University's HTA Research Licence and those transferring tissue as part of an ethically approved research project. The procedures outlined in this document represent best practice for the handling of all research tissue samples on University premises in accordance with the *Human Tissue Act 2004*.

To comply with the HT Act it is necessary to ensure that there is a clear and robust audit trail from the collection of human material, through processing, storage, use and distribution, to final use/disposal. All human material acquired by university personnel for storage under a HTA licence must be recorded and its use, distribution and disposal accounted for.

## Purpose and Scope

The purpose of this SOP is to ensure that sample coding and tracking requirements are maintained as part of sample management.

Definitions:

| | |
|---|---|
| DI | Designated Individual |
| HTA | Human Tissue Authority |
| MTA | Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes. |
| PD | Persons Designated |
| REGI | Research Governance Ethics and Integrity |
| SOP | Standard Operating Procedure |
| 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. There must be a robust coding and tracking process for all relevant material held under the UoL research licence.

It is the responsibility of the HTA Monitoring Officer to ensure that this SOP remains fit for purpose taking into consideration any changes in legislation or changes to the research Codes of Practice.

It is the responsibility of the PD to assist the DI in implementing and adhering to the governance processes for which they have responsibility for.

All researchers involved in collecting, storing, or using human tissue for research are accountable to the PDs and the DI for undertaking work in compliance with this document. It is the researchers responsibility to assign a unique traceable code to each sample of tissue, and for the tracking of individual samples and there derivatives throughout all the stages of receipt, storage, use, and disposal/return of the remaining sample.

There are multiple methods for storing the coding and tracking information, from excel databases to paper records, to more sophisticated sample tracking software. Please ensure you use a tracking and coding system that is best for your needs.

### Sample Tracking Software/Laboratory Databases

Paper records, password protected (encrypted) databases and records systems must be used by individual laboratories to record all data related to the storage and use of human tissue samples. All sample tracking systems and laboratory databases must be available for audit by the DI and the REGI office.

All sample tracking systems and databases must provide a full audit trail of sample storage, use, transfer, and disposal to ensure compliance with HTA regulations. Disposal must include the date, method, and reason for disposal. Sample tracking software is a robust alternative to spreadsheets and paper records. Its use is encouraged wherever possible e.g. Open Specimen. An example of a paper sample tracking log is shown *SOP HTA-A1013-Appendix 1*.

### Sample coding and tracking

An audit trail must be maintained when tissue is collected. When samples enter the collection, the PD/researcher should record all aspects of their storage, use and fate. The sample should be anonymised by assigning a unique number/identifier that is linked to the original information kept securely in the licensed premises. All

subdivisions of the sample should be identified with reference to the master sample but should ensure each subdivision is unique in its own right.

Samples must be labelled appropriately for the storage conditions. Printed adhesive labels should be used wherever possible or the use of a permanent lab marker pen if adhesive labels are not available. The writing on the tubes must be legible and clear to all that may read it. Ensure permanent pen/marker is used when completing handwritten labels i.e. avoid loss though exposure to moisture and care should be taken were solvents are involved as these can remove permanent pen markings.

Where limited space is available (i.e. Eppendorfs) please ensure the most pertinent information is on them (such as: Study Number, Unique Identifier, Date and Sample type).

Information recorded for each sample should include:

- Sample type
- Unique sample identifier
- Date of collection
- Custodian of the sample
- Whether project specific use / future use / both (based on participant consent)
- Collection centre / providing establishment or organisation (applicable if the study is multi-centre study and samples are coming to us at the end of the study/samples transferred to us via MTA /collaboration agreement)
- Details of any ethics approval for use i.e. ethics number date of ethical approval expiry.
- Any specific details regarding what type of analysis can be undertaken with the materials i.e. DNA analyses or MTA/collaboration agreement restrictions on use.

No personally identifiable data should be printed on the sample container.

When material is used, transferred, or disposed of, this information must also be recorded either using paper records, sample tracking software or password-protected databases.

A log of all material stored must be maintained by the PD or custodian of the collection. This data will be audited and checked against the stored material for accuracy.

Records of transportation and delivery should be kept including any agreements with courier or transport companies and recipients of relevant material.

## Departmental Sample Log Audits

It is recommended that departments audit their own sample logs on a regular basis to ensure all data is kept up to date and error free *(refer to SOP HTA-A1019).*

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) |
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| Date | Name | Department | Received Y/N |
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