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

SOP HTA-A1013 UoL

Coding and tracking of HTA-specimens

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 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.

2.0 Scope

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

Definitions:

CI Chief Investigator
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
PI Principal Investigator
RGO Research Governance Office
SOP Standard Operating Procedure
UoL University of Leicester

3.0 Procedure

Sample coding and tracking play an important role in the management of all samples. 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.

3.1 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 HTA-relevant material. All sample tracking systems and laboratory databases must be available for audit by the DI and the RGO.

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 (Sample tracking log, Appendix 1).

3.2 Sample coding and tracking

An audit trail must be maintained when tissue is collected. When samples are held under the UoL HTA Research Licence, it is the CI/PIs responsibility to ensure that samples are appropriately tracked with oversight from the PD for that area. All aspects of their storage, use and fate must be documented. 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. As an example, if the original sample is 101 and you made 3 aliquots of that sample, any sub divisions would be labelled as 101.1, 101.2, 101.3.

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 where solvents are involved as these can remove permanent pen markings.

Where limited space is available (i.e., Eppendorf's) please ensure the most pertinent information is included (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
- Researcher / Custodian of the sample
- 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)

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 CI/PI of the collection. The specimen collections should be included on the PD reports that are submitted to the HTGC meeting. These reports must list HTA-relevant material and contain information about sample related studies that are under current ethical approval. 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. Please refer to the imports and exports SOP for further info on retaining transportation information.

3.3 PD mini audits

Every quarter the PDs will conduct mini audits of randomly picked studies. These are inter-departmental audits which include vertical audits focussing on the traceability of specimens to

their storage location, to ensure sample logs are accurate, and that the records of consent are fully traceable for specimens that are being stored.

4.0 Responsibility

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensuring appropriate unique identifiers are used for sample collections. Ensuring accurate storage logs are maintained and that collections are registered on appropriate PD reports. Ensuring traceability is maintained where samples are relocated, used up or disposed.
Person Designated (PD)	Person Designated (PD)	Ensuring PD report is accurate.
Research Governance Office (RGO)	HTA Monitor	Ensuring SOPs remain up to date.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place in the licensed 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	• Administrative changes • Addition of the PD mini audits • Removal of some sample information requirements, so reflective of current practice