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

SOP HTA-A1012 UoL

Transport of Human Biological Samples

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*. These 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 with HTA-relevant material that is held under the UoL HTA Research Licence, including samples collected from projects with University Ethics and Integrity Committee approvals (UEIC).

This SOP must be used when transporting all human biological samples, whether this is part of a NHS Research Ethics Committee approved research project or for any HTA-relevant material held under the UoL HTA Research Licence.

This SOP should be read in conjunction with UoL policy on the Transportation of Dangerous Goods *UHSP-38* and the *World Health Organisation (WHO) Guidance for regulations for the transport of infectious substances* and in addition to HTA-A1008-UoL, particularly if samples are sent outside UoL premises.

2.0 Scope

Human biological samples can only be transferred to other institution(s) and third parties under the terms of the consent and ethics of a study and must have an appropriate agreement in place for the transfer.

In line with the HTA's policy on traceability, the transfer of HTA-relevant material must be tracked. If human tissue is transferred between establishments, consideration must be given to safety, and minimising the risk of theft, damage, or loss during transport. In addition, data should be carefully controlled during transfer to protect donor confidentiality.

Therefore, a formal arrangement should define how the human tissue and any associated data is protected, any potential contamination risks associated with the material, and who is responsible for disposal if applicable (Code E, Research Disposal Section). For external transfers this would usually require a Material Transfer Agreement (MTA) or research collaboration agreement, and for internal transfers, an email communication between investigators and the PDs for the relevant areas, summarising the formal arrangement.

Definitions:

CI	Chief Investigator
DI	Designated Individual
FFPE	Formalin Fixed Paraffin-Embedded
HBA	Hazardous Biological Agents
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 her own research purposes.
PACs	Pre-Award and Contracts Team
PD	Person Designated
PI	Principal Investigator
REC	Research Ethics Committee
RED	Research and Enterprise Division
RGO	Research Governance Office
RTB	Research Tissue Bank

SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester
WHO	World Health Organisation

3.0 Procedure

The conditions for the transfer of samples will differ depending on the type of samples to be transferred. Where the samples are being transferred across site, this should be in line with the approval of an appropriate Hazardous Biological Agents (HBA) form approved from safety services.

The majority of samples are classified as Category B substances (UN3373) as these are human materials, collected directly from humans including but not limited to, excreta/secreta, blood and blood components, tissue and tissue fluid swabs, and parts of bodies being transferred for research.

Regardless of whether the transfer of samples is externally (outside of the UoL) or internally (to another UoL location) the packaging of the samples must comply with the transfer of category B samples.

The packaging should consist of three components. These are

- A leak proof primary receptacle(s)
- A leak proof secondary packaging: and
- An outer packaging of adequate strength for its capacity, mass and intended use.

For samples that include liquids, there should be absorbent material in sufficient quantity to absorb the entire contents, located between the primary and secondary receptacle(s), to ensure that during transport, any release will not result in liquids reaching the outer packaging.

If there are multiple fragile primary receptacles, they would be individually wrapped or separated to ensure there is no contact between them, which could cause the sample to leak.

3.1 Methods of transfer

There are a number of different methods of transfer for the samples from one site to another, these include:

- Shipment of goods using a courier.
- Shipment of goods by University Staff i.e., staff vehicle (the member of staff must have business use insurance and must have undertaken driver awareness training),
- Shipment of goods by foot. Transportation should use couriers or other vehicle transport. However, where justified (short distances) the physical carrying of a parcel is allowed. e.g., from the RKCBS to the UoL Main Campus.
- Shipment of goods via Royal Mail (UK Only) (please see biological substances and Human or animal samples section from Royal Mail - prohibited and restricted items). Diagnostic specimens including urine, blood, and faeces can be sent in certain quantities. FFPE blocks can be sent via the Royal Mail. Samples shipped using Royal Mail should use the appropriate tracking service. The link to the Royal Mail prohibited and restricted items can be found *here.*

Important: Public transport should not be used to transport dangerous goods, in particular hazardous biological materials and dry ice.

3.2 External Sample Transport Procedure

All human biological samples classified as HTA-relevant material can only be transferred to and from other institution(s) and third parties under the terms of (i) an MTA; (ii) an agreement containing relevant MTA provisions.

Where material is transferred as part of an active project with NHS REC approval* (granted by the HRA/REC and therefore not under the governance of the UoL HTA Research Licence) an MTA is not necessarily required as this may be stipulated in another agreement e.g., the Statement of Activities. The Research and Enterprise Division (RED) Pre-Awards and Contracts (PACs) Team must be consulted to determine whether an MTA is required, and all MTAs must be signed by an authorised signatory from the PACs Team. This can be raised via the Worktribe platform. Please refer to the MTA checklist in HTA-A1008-UoL SOP.

*For example: tissue samples collected from individuals enrolled on a study within UoL and then transferred to an external lab for analysis.

The CI/PI or delegate responsible for transferring or receiving transferred HTA-relevant material must keep his or her own records detailing which samples have been transferred, where the samples have been transferred to/from and dates of sample transfer. This should be recorded on laboratory databases or equivalent and any copies of MTAs should be available in the PD Masterfile along with the list of the samples sent. The sender should inform the recipient of what should happen to the samples upon receipt (i.e., sample storage conditions) and following recipient use (disposal or return) which should be detailed within the agreement. If disposal is required, arrangements for disposal must also be outlined in the participant information sheet. Please refer to the MTA checklist in HTA-A1008-UoL for a more comprehensive overview of details that should be addressed within a contract.

Any queries relating to the transfer of HTA-relevant material should be directed to the PACs Team in the first instance.

Where HTA-relevant material is going to be sent to UoL under the governance of a contract, certain checks must to be undertaken before the samples can be received on site (see SOP HTA_A1008 – Import and Export). This process should be followed for samples that are under REC approvals, samples from Research Tissue Banks (RTBs) and HTA-relevant material held under another institution's HTA Research Licence. There should be a corresponding internal sample application form UoLHTAISA001 v1 form completed by the research team outlining the details of the samples that they will receive (see SOPs HTA_A1008 [Contracts] and HTA_A1005 {Import and Export]).

- **Further points:** If the recipient is to use the samples in another project (i.e., not the one that they were collected for), the recipient should give documentary evidence (such as; Integrated Research Application System (IRAS) application form) to the sender that NHS REC approval is in place for the recipient's project.
- Samples should be sent in a coded form, and ensure no identifiable information is sent with the samples. Unless there is explicit consent for transferring identifiable information from the research participant and this has been approved by an NHS REC. If identifiable information is sent subject to these requirements, the recipient must confirm that these data will be treated in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2018.
- In all cases, the sender must keep a record of when the samples were transferred and to whom. For internal transfers a transfer agreement is not required. However, materials should be transferred in accordance with local Health and Safety procedures and packaged accordingly with fully auditable tracking logs.

- In all cases, it must be stipulated that the recipient is not at liberty to send the samples to any other third party.

3.3 Internal Sample Transfer

Internal sample transfer, is the transfer of samples from one UoL satellite site or building to another UoL satellite site or building. For the transfer of archival samples, a record should be completed (Transfer of archival material Appendix 1) and for the transfer of internal study materials a record should be completed (Transfer of internal samples Appendix 2).

3.4 Sample Tracking

Departments must ensure an audit trail is maintained for any material being transferred between two departments, local sample tracking records (e.g., Open specimen, Paper records or bespoke software) should be updated with the details of when and where the samples/tissues were transferred and to whom. (Please refer to SOP HTA-A1013 Coding & Tracking of Human Samples). Copies of the transfer documents (Appendix 1 Transfer of Archival Tissue) and (Appendix 2 Transfer of Internal Samples) should be kept in the departmental PD Master File as documentary evidence.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensuring contracts are raised via the appropriate platform i.e., Work Tribe. Where samples are being transferred across different organisations. Specimen log list detailing the transfer of the specimens, either paper copy, electronic of via tracking / samples logging software.
PACs Team	PACs Team	Drafting of appropriate MTA / or other applicable agreements
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensuring SOP is kept up-to date and in line with any regulatory or legislation updates. Due diligence around the transfer of samples either incoming or outbound transfers.
Person Designated (PD)	Person Designated (PD)	Ensuring PD Masterfile's are kept up to date with the retention of appropriate contracts relating to HTA licenced materteral.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place within 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	• Administrating changes • Referral to Work Tribe for agreements via the PACs team • Referral to approval of Hazardous Biological Agent (HBA) approval via safety services