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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 *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' (RM) as defined by the HTA. They must be followed by all researchers working with material that has been transferred to holding under the UoL HTA Research Licence, including samples collected from projects with University Ethics and Integrity Committee approvals (UEIC). This SOP should also be used for transferring tissue as part of a Health Research Authority/ Research Ethics Committee (HRA/REC) ethically approved research project.

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 SOP *HTA-A1008*, particularly if samples are sent outside UoL premises.

Purpose and Scope

All human tissues and cells classified as RM can only be transferred to other institution(s) and third parties under the terms of consent and ethics of a study.

In line with the HTA's policy on traceability, the transfer of RM must be tracked. If human tissue is transferred between establishments, consideration must therefore be given to safety, and minimising the likelihood 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:

DI	Designated Individual
FFPE	Formalin Fixed Parafin-Embedded
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
REC	Research Ethics Committee
RED	Research and Enterprise Division
REGI	Research Governance Ethics and Integrity
RM	Relevant Material
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester
WHO	World Health Organisation

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. Any transfer of samples must be within the remit of consent, ethical, governance, and documentation requirements.

It is the responsibility of the HTA Monitoring officer to ensure that due diligence checks are undertaken for the transfer of samples, particularly where they are being sent off-site (outside of the UoL). In addition, the HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and changes to the HTA codes of practice for Research.

It is the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and ensuring relevant documents are filed in their HTA PD Masterfiles.

All researchers (UoL staff, students and external visitors) collecting, storing or using human tissue for research under the UoL HTA Research Licence are accountable to the PD for their area and the DI for undertaking work in compliance with this

document. In compliance with the Research Licence issued by the HTA, the UoL expects all persons operating on the University sites to comply with the HT Act, and comply with all Codes of Practice issued by the HTA and relevant University wide and/or local SOPs.

All persons undertaking any role in the transport chain should be properly trained to carry out their responsibilities to the required standards. They must appreciate the risks involved and have an understanding of the relevant regulations. Records of transportation and delivery should also be retained as evidence. It is recommended that the transfer of sample process is audited on occasion by each department to ensure departmental compliance.

Procedure to follow

The transfer of samples will differ depending on the type of samples to be transferred. 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 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.

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. I.e. 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.

External Sample Transfer Procedure -Outgoing

All human tissues and cells classified as RM can only be transferred to and from another institution(s) and third parties under the terms of (i) MTA; or (ii) an agreement containing relevant MTA provisions; or (iii) as part of a project with current ethics approval that allows for such transfer.

Where material is transferred as part of an active project with NHS REC approval* (granted by the HRA/REC) 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) Contracts Team must be consulted to determine whether an MTA is required, and all MTAs must be signed by an authorised signatory from the RED Contracts Team. Please refer to the MTA checklist in *HTA-A1008* SOP.

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

The PD and the researcher responsible for transferring or receiving transferred RM 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. 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). If disposal, arrangements for disposal must also be outlined in the participant information sheet. Please refer to the MTA checklist in SOP *HTA-A1008* for a more comprehensive overview of details that should be addressed within a contract.

Any queries relating to the transfer of RM should be directed to the RED Contracts Team in the first instance.

External Sample Transfer Procedure -Incoming

Where RM is going to be sent to UoL under the governance of a contract, there is a requirement for the RM to be documented and for certain checks to be undertaken before the samples can be received on site. This process should be followed for samples that are under REC approvals, samples from Research Tissue Banks (RTBs) and licenced material (RM held under another institutions licence). There should be a corresponding internal sample application form (SOP HTA A1005-Appendix 1) form completed by the research team outlining the details of the samples that they will receive.

On transfer of human tissue samples where further advice is sought by the RED contracts team, the HTA Monitoring Officer will;

- Check the terms of the consent given by the research participants, ensuring consent for their donated sample to be sent to collaborators or other researchers and if they consented for use in future ethically approved projects.
- 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.

Internal Samples 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 (SOP HTA-A1012-Appendix 1) and for the transfer of internal study materials a record should be completed (SOP HTA-A1012-Appendix 2).

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).* Copies of the transfer documents (SOP HTA-A1012-Appendix 1) and (SOP HTA-A1012-Appendix 2) should be kept in the departmental PD Master File as documentary evidence.

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