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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.

SOP: HTA-A1005-UoL

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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

The import and export of relevant material which has come from the human body for use for scheduled purposes e.g. (research), into/out of England, Wales, or Northern Ireland. When material is coming into England, Wales, and Northern Ireland it is considered to be an import and the opposite (material leaving England, Wales and Northern Ireland) is an export, with regards to the geographical scope of the HTA.

The actual transfer of the material is not considered a licensable activity under the HT Act, however, storage of the material for research once it is imported requires it be held under a HTA licence, unless there is a specific exemption that applies (more details below).

Purpose and Scope

The purpose of this SOP is to ensure that all UoL Staff students and external visitors understand the requirements of the Human Tissue Act (HT Act) regarding the import and export of human tissue for research purposes.

This SOP does not apply to the import and export of human materials that fall outside of the HT Act (Gametes and other cells) that come under the remit of the Human Embryology and Fertilisation Authority (HEFA) and materials that have been processed to become acellular material (certain types of plasma, serum).

Definitions:

CI	Chief Investigator
DI	Designated Individual
DOT	Department of Transport
HT Act	Human Tissue Act
HTA	Human Tissue Authority
IATA	International Air Transport Association
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	Principle Investigator
PIS	Participant Information Sheet

REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
SLA	Service Level Agreement
SOP	Standard Operating Procedure
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. The DI must act as a gatekeeper for any imported tissue and should be satisfied that there is an appropriate agreement in place: either a service level agreement (SLA) or Material Transfer agreement (MTA). This must detail compliance with consent, ethical, governance, disposal and documentation requirements.

It is the responsibility of the HTA Monitoring Officer to ensure that for each sample set imported, that there is the appropriate participant information sheet (PIS) and a blank template of the consent form governing the sample set. In addition, the HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and/or Codes of Practice.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes.

All researchers involved in the import or export of human tissue have the responsibility of assigning 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, and to ensure that all contractual agreements are complied with.

Procedure to follow

This SOP outlines the procedure required to be followed for any relevant material that is either being imported into the UoL from outside of England, Wales or Northern Ireland or that are being exported outside of England, Wales and Northern Ireland.

Consent requirements under the HT Act

Although consent is the fundamental principle of the HTA Act, the consent provision does not apply to imported material. However, the HTA recommend that researchers satisfy themselves that appropriate consent has been obtained in line with the proposed use of the material that has been obtained from the source country.

If samples are to be exported outside of the country, this can only be undertaken in line with the original consent that was obtained at the time of the tissue donation.

Good practice requires that robust processes are in place to evidence that informed consent was obtained from the donor before the acquisition of the sample. If a third party is responsible for the importation of the material, a SLA should be in place that demonstrates that there is a record of the consent.

The HT Act makes it clear that relevant material are not to be exported and re-imported to avoid the consent requirements.

Ethical approval

It is the Chief/ Principal Investigators (CI/PIs) responsibility to ensure that any ethical approvals required have been obtained before the research can commence. Please refer to SOP *HTA-A1006*. UoL Internal Ethics Projects. If your research involves human participants, tissue or data or having an impact on humans but does not involve the NHS, you will require to follow the UoL ethics approval pathway for your research to be reviewed. Please see the *approval pathway* for more information.

In addition, importers should satisfy themselves, with due assurance from their partners abroad, that any material intended for import is sourced constantly with the legal and ethical review requirements in England, Wales and Northern Ireland. It is good practice to ensure approval has been obtained from a research ethics authority or the local equivalent in the source country beforehand.

Imported material exemptions

There are a number of specific exemptions that may apply with regard to imported material. These exemptions include:

- Material taken from the living as intended for diagnostic use

- Under the jurisdiction of the Coroner/Procurator Fiscal.
- Being brought into England, Wales and Northern Ireland for lawful disposal.
- Historic remains/artefacts older than 100 years, imported by museums.

Storage of imported material may be held on unlicensed premises if it has been collected from the living and imported for a specific HRA Research Ethics Committee (REC) approved project or for one of the following purposes:

- Clinical audit
- Performance assessment (e.g. analyser validation)
- Public health monitoring
- Quality assurance

Import and export records

Before any human tissue is imported, authorization must be obtained from the DI by the completion and the submission of SOP *HTA-A1005 Appendix 1.* The form should be submitted to the HTA Monitoring Officer with a copy to the DI. A signed copy must be kept by the CI/PI and given to their local PD to be filed into the HTA PD Masterfile so it is available for internal audit and inspection by the HTA. No material should be transferred until authorization is complete.

The following records must also be retained and kept available for inspection by the HTA:

- Details of transport and delivery
- MTAs with tissue suppliers
- SLAs with courier companies
- A register of the details of the imported tissue
- Suppliers record and consignment documentation

HM Customs & Revenues

Researchers must normally declare imports and exports to the HM Revenue and Customs (HMRC). Further advice can be obtained from the HM Revenue and Custom National Advise Service (0845 01090000).

Tissue identification and traceability

A donor ID system must be implemented by any researcher that wishes to import or export relevant material to ensure full traceability. In some circumstances, there might already be an ID system used for the material being imported. Providing each sample being imported has a unique code (i.e. multiple aliquots need a unique identifier) it is possible to retain and utilise that ID system. When processing the

sample, it is important that any associated by-products, of the processing that are being stored for future use has a clear path so it is clear where that by-product has been derived from. (As an example, if you are processing blood to serum, but choose to keep the blood cells rather than discarding them, you would need to ensure it is clear that it's a by-product of the processing but are being kept for possible further use, similarly, for DNA, RNA and other non-cellular by products, so there is a clear link to the provenance of the original sample).

Retention of Records

The records of each consignment relating to imported/exported bodies, body parts and tissues should be retained for a minimum of 5 years after the disposal of the last consignment. Similarly, the CI/PI should retain their copy of the of the consignment documentation and sample logs for at least 5 years after the disposal of the last item recorded in it.

Should the CI/PI leave the UoL, provisions should be put in place for the samples to be transferred to an alternative custodian or destroyed, in addition to any corresponding paperwork. Copies of such should be maintained in the PD Masterfile.

Transportation

Importation and exportation should be packaged and transported in line with *UHSP-38 transportation of dangerous goods* and *The World Health Organization (WHO) Guidance on regulations for the Transport of Infectious Substances 2017-2018.* Both documents should be read in conjunction with this SOP. The following numeric identifiers maybe applicable, please ensure that any packages have the relevant identifiers on the shipment packaging.

UN3373 is the dangerous goods shipment classification under International Air Transport Association (IATA). Infectious substances frequently include the following: Biological Substance, Biological Products, Patient Specimens and Medical Waste.

Dry Ice is classified by the Department of Transportation (DOT) and IATA as a "miscellaneous" hazard, class 9. UN1845 is the numeric identifier for dry ice assigned to the United Nations (UN) and UN Committee of Experts on the Transport of Dangerous Goods.

Researchers should ensure that a professional courier is used when sending samples internationally. It is the researcher's responsibility to ensure they comply with all of the couriers requirements, and ensure the appropriate contracts are in signed before the transfer takes place.

Disposal

Unless stipulated by the donor of any donor requirements, disposal of the imported material should meet the requirements of the HT Act. The disposal should comply with the disposal SOP *HTA-A1004*, unless there are contractual obligations to return the materials to the sender.

Adverse Events

Any adverse event that arise from the importation or exportation of material should be reported and handled as set out in the adverse events SOP *HTA-A1022*. Investigations will take place into the adverse events arising. Corrective and preventative actions will be implemented as required. Evidence of correct handling of adverse events must be available for internal audit and inspection by the HTA.
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