UNIVERSITY OF LEICESTER

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

SOP HTA-A1005 UoL

Import and Export of HTA-Relevant Material

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.

NB: Paper copies of this document may not be the most recent version. The definitive version is held on the RGO, HTA SOP webpages.

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 (CoP)*.
The importation and exportation of HTA-relevant material requires to be documented where it is to be used 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, but storage of the material for research once it is imported requires it to be held under a HTA licence, unless there is a specific exemption that applies (more details below).

2.0 Scope

The purpose of this SOP is to ensure that all UoL Staff students and collaborators 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 such as Gametes 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
CoP	Codes of Practice
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 research materials between two organisations, when the recipient intends to use them for their own research purposes.
PD	Persons Designated
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
RGO	Research Governance Office
SLA	Service Level Agreement
SOP	Standard Operating Procedure
UoL	University of Leicester
WHO	World Health Organisation

3.0 Procedure

This SOP outlines the procedure required 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.

3.1 Consent Requirements under the HT Act

Although consent is the fundamental principle of the HT 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. A copy of the PIS and ICF should be obtained for due diligence purposes

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 ensure 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, an SLA should be in place that demonstrates that there is a record of the consent.

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

3.2 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. Ethical approval using human material is needed for all research and consultancy undertaken by UoL Staff and Students wherever research involves human participants or raises ethical issues.

Infonetica is the UoL Research Management System. It can be used to register your research and obtain any reviews of approval your project may require. Please ensure an application is submitted for review under the new system. This will ensure the appropriate approvals are sought.

Where NHS REC approval is required, application to the IRAS system…

Where NHS REC approval is not required / applicable, please refer to UoL RGO webpages for further information. Please also refer to HTA-A1006-UoL.

In addition, importers should satisfy themselves, with due assurance from their partners abroad, that any material intended for import is sourced in accordance 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.

3.3 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 NHS REC-approved project, or for one of the following purposes:

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

3.4 Import and Export Records

Before any human tissue is imported, authorisation must be obtained from the DI by the completion and the submission of Appendix 1. The form should be submitted to the HTA Monitor 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 authorisation 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

3.5 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 Advice Service (0845 01090000).

3.6 Tissue Identifications and traceability

A donor ID system must be implemented by any researcher that wishes to import or export HTA-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 process have a clear audit trail so that it is clear where that by-product has been derived from. For example, if you are processing blood to serum, but choose to keep the blood cells rather than discarding them, you would need to ensure that it is clear that they are a by-product

of the processing, but are being kept for possible further use. This also applies to DNA, RNA and other non-cellular by products, so there is a clear link to the original sample.

3.7 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 use or disposal of the last consignment. Similarly, the CI/PI should retain their copy 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 must 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.

3.8 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 2021-2022. Both documents should be read in conjunction with this SOP. The following numeric identifiers may be applicable, and 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 signed before the transfer takes place.

3.9 Disposal

Unless stipulated by the sender of any donor requirements, disposal of the imported material should meet the requirements of the HT Act and HTA Codes of Practice. The disposal should comply with the disposal SOP HTA-A1004-UoL, unless there are contractual obligations to return the materials to the sender. Please refer to the agreement to ensure there are no further contractual obligations to considered before the material is disposed.

3.10 Adverse Events

Any adverse event that arises from the importation or exportation of material should be reported and handled as set out in the adverse events SOP HTA-A1022-UoL.

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.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief / Principal Investigator (CI/PI)	Chief / Principal Investigator (CI/PI) or delegates	Ensuring application to import / export relevant material is adhered to. Engaging with PAC team for appropriate contracts are put in place via Work Tribe Ensuring project is registered on the Universities Research Management System. Ensuring tracking and traceability of materials is maintained.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Due diligence on documentation. Providing expert review on the Universities Research Management System. Ensuring SOP remains fit for purpose taking into consideration any changes in legislation and/or CoP.
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place within the licenced establishment. Act as gatekeeper for imported tissue.
Person Designated (PD)	Person Designated (PD)	Ensuring imported samples are logged on their PD reports once approved.

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.

NB: Paper copies of this document may not be the most recent version. The definitive version is held on the RGO, HTA SOP webpages.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes • Addition of Universities Research Management System. • Update to WHO guidelines for transportation

NB: Paper copies of this document may not be the most recent version. The definitive version is held on the RGO, HTA SOP webpages.