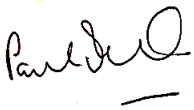
SOP Ref:	UOS_HT_SOP_08
SOP Title:	Transportation of Human Tissue
Effective Date:	26/06/2023
Preceded by:	*1.0 (Formerly UOS_HTA_ SOP_07)*
Version Number	*2.0*
Review Date:	26/06/2026

Approval History				
Version 1.0 (SOP7)	Name	Role	Signature	Date
Written By:	Chris Bradley	UoS Biological Safety Officer		13.03.2020
Approved By:	Ferdousi Chowdhury	Head of RIGO		13.03.2020
Version 2.0 (SOP9)	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		03.05.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The Human Tissue Act (HT Act) requires organisations transporting relevant human tissues to ensure the safety and security of the samples in transit. Biological samples including human tissues being transported on the public highway (e.g., between campuses or being sent to collaborators) must additionally comply with Dangerous Goods Legislation requiring them to be properly labelled and packaged and those being transported by air must also adhere to International Air Transport Association (IATA) requirements.
These requirements encompass the packaging and labelling used and the training and competence of the personnel packaging the samples.
This standard operating procedure (SOP) is based on the HTA Codes of Practice, Dangerous Good Legislation and IATA standards and describes the University's requirements for transporting human tissue samples.

2. SCOPE

This SOP applies to all projects (including Research Ethics committee (REC) approved studies) transporting any type of primary human tissue including material that is considered relevant by the HT Act, any non-relevant human material, and any human biological fluids. All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must ensure that if they wish to transport human tissue samples into or out of the University that they have read and met all the requirements outlined in UOS_HT_SOP_07 (Transfer of human tissue into and out of the University, including import and export) including having a Material Transfer Agreement (MTA) or equivalent agreement in place, before arranging transport following the guidance in this SOP.

3. RESPONSIBILITIES

3.1. The Designated individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* They are responsible for ensuring that all samples are transported by approved methods and fully documented to reduce the risks of sample loss or damage.

3.2 The Persons designate (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for assisting the DI in checking that all samples are being transported appropriately, that appropriate documentation is being sent and logged and samples are being checked on departure and arrival.

3.2. The Principal Investigator (PI) is responsible for ensuring that they and all persons who are packaging samples on their behalf (except approved couriers) have read and understood this SOP and that appropriate packaging and labelling is used. They are responsible for using approved couriers and keeping full documentation of the transportation as detailed in UOS_HT_SOP_09 Human Tissue Records Management including checking and acknowledging

receipt, integrity, and accuracy of any samples on arrival or ensuring such confirmation is received when sending samples to a third party.

3.3. All individuals transporting or arranging for transport of human tissues and material must ensure that they adhere to this SOP. This includes ensuring samples are safely and securely packaged to prevent damage and loss of sample integrity. They should report any problems or concerns relating to sample transport to the PI who should then report it as detailed in UOS_HT_SOP_11, Human tissue adverse event and incident reporting.

4. PROCESS

4.1. Primary containers for unfixed or unmounted tissues

4.1.1. Blood and tissue samples should not be stored in glass for transportation, unless the type of sample being transported absolutely requires this such as in the case of the blood cell preparation tube CPT that is required for PBMS isolation. In this case the tube should be packaged in a padded absorbent tube holder, sleeve or pouch before being sealing in the secondary, waterproof box required for all samples.

4.1.2. Except in the case of clinical samples, being transported to or from a hospital or local medical laboratory, no personal identifiers of the donor should be on or in the packaging. However, a shipping log of the samples must be included using sample codes, so that the samples can be tracked between locations.

4.2. Mode of transport

4.2.1. **On foot:** human tissue samples may be carried on foot by researchers from collection to a laboratory for immediate processing or for transfer between different University of Surrey laboratories.

4.2.2. **Estates, Facilities and Commercial Services (EFCS) porter service** can be used to transfer samples between venues within the University of Surrey. Full documentation is required for this transportation including a dangerous goods transport document.

4.2.3. **Personal vehicles** can only be used if:

- The vehicle is insured for business use and the vehicle's insurer have been informed and have confirmed in writing that they are aware human tissue samples are being carried. Evidence will need to be provided to RIGO who will check with the University Insurance Officer that adequate cover is in place before permission is given for the use of any vehicle for transporting human samples.
- The tissues are in secure packaging and labelled according to Section 4.6.

- Samples packaged in dry ice are in a separate compartment to the driver to reduce exposure to carbon dioxide (CO_2) gas (the boot of most cars is not usually a separate compartment). Dry ice containing packages cannot otherwise be carried in personal vehicles.

4.2.4. **Public transport** must not be used by researchers to transport human samples although participants may bring their own samples by public transport.

4.2.5. **Couriers** are the preferred method of transport for transfer of samples to another institution. The local PD should be consulted for a list of approved couriers. When couriers are used for samples assigned to Category A (see 4.5.2) the courier must be checked to make sure they have the appropriate clearance for transporting this category of samples. It is also important that category A sample transport is discussed with the high containment lab manager and Biosafety Officer before any samples are transferred.

4.3. Packaging for unfixed tissue or unmounted fixed tissues

4.3.1 Sample shipping boxes for transportation must be compliant with UN PI650 (Category B biological agents) or UN PI620 (Category A biological agents) both of which require three levels of packaging for diagnostic liquid and solid samples:

1. The primary receptacle – containing the sample.
2. The secondary packaging – this will contain the primary receptacle(s) and sufficient absorbent material (not required for solids), to soak up any spillage that occurs. Any cold packs or dry ice used must be placed outside of this packaging.
3. The outer packaging i.e., that seen by the delivery driver must have one surface of at least 100mm x 100mm. This packaging must have passed the drop test from a minimum height of 1200mm for UN PI650 and the met the full UN performance test standards for UN PI620.

4.3.2 The selection of packaging must be appropriate for the type of specimens:

- **Liquid specimens or samples in liquid,** both primary receptacles and secondary packaging(s) are required to be leak proof. Absorbent material should be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging.
- **Solid specimens not in liquid**, the primary receptacle(s) and secondary packaging shall be sift-proof (i.e., have minor and major flaps that overlap).

4.4. Packages requiring coolants.

4.4.1. Chilled items: Use of wet ice (frozen water) is not recommended to keep items chilled even in leakproof packaging. Pre-refrigerated or frozen cool packs are a more a suitable alternative.

4.4.2. Frozen items: When it is essential items stay frozen, they should either be transported on an excess of dry ice (e.g., 10kg for same day shipping, 20Kg for international) or in cases where samples are especially precious via a dry shipper courier to avoid risk to sample integrity if delays occur, especially if they need to pass through customs. When using dry ice, UN PI954 should be followed, which includes:

- All dry ice must be placed between the secondary and outer packaging and not within the secondary packaging itself.
- Secondary packaging is placed inside a polystyrene shipping container with the dry ice. Voids are filled with cushioning material to stabilise the contents during transport and separate the primary receptacle from direct contact with the dry ice.
- The lid of the polystyrene box must not be completely sealed to allow venting of CO_2 gas evolved from the dry ice.
- The polystyrene box is placed into an outer cardboard outer box for added strength.
- The packaging should be designed to permit the release of carbon dioxide gas
- The packaging should be designed to prevent the build-up of pressure that could cause rupture.

4.5. Transport categorisations

4.5.1 Category exempt: Human tissue samples for which there is a minimal likelihood of pathogens present are not subject to ADR requirements, although if they are packaged in dry ice, they will still be subject to UN PI954 regulations for dry ice. Such samples include:

- Samples treated to neutralise or inactivate any pathogens present.
- Samples fixed and mounted on microscope slides.
- Dried blood spots collected by applying a drop of blood to absorbent material.
- Faecal occult blood screening samples.
- Specimens which are known not to contain pathogens following testing.

4.5.2 Category A (UN 2814): An infectious substance which is carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans and animals. Some human tissues will fall into this category based on:

- medical history and symptoms
- endemic local conditions
- professional judgement on source material
- individual circumstances

Before transporting tissues that meet the requirements for Category A the Biological Safety Officer must be contacted to discuss security requirements.

4.5.3 Category B (UN 3373): Samples from humans or animals where there is a likelihood of infectious agents being present must be assigned a minimum of Category B (an infectious substance but which is not Category A).

4.5.4 Summary of classifications

Table 1: Summary of UN Transportation categories

UN Category	UN Class	Category	Additional Information
UN 2814 Infectious substances, affecting humans	6.2	Category A if agent causes permanent disability, life-threatening or fatal disease to otherwise healthy humans and animals; otherwise Category B	Can include tissue samples suspected to contain an infectious agent.
UN 3373 Biological substance, category B	6.2	Category B infectious substance that does not fit criteria for Category A.	Includes human blood, tissues or organs, preparation of blood products.
UN Exempt	N/A	N/A	Samples in a form that any pathogens present have been neutralised or inactivated such that they no longer pose a hazard to health. Or human samples that don't pose a health risk.

4.6. Package labelling. All packages containing human tissues must be fully labelled before leaving University sites. The labelling required will depend on what is contained and the method of transport, with increased labelling being required for air transport for example.

4.6.1 Category A labelling: should include a diamond like that shown in Figure 1a, with sides of width at least 2mm thick and of a minimum size of 50mm by 50mm for small packages (100mm x 100mm for large packages) and writing of at least 6mm. The package should also clearly display the UN category number (UN2814), orientation arrows, the name address and contact details of the shipper and consignee and name and contact number of a responsible person.

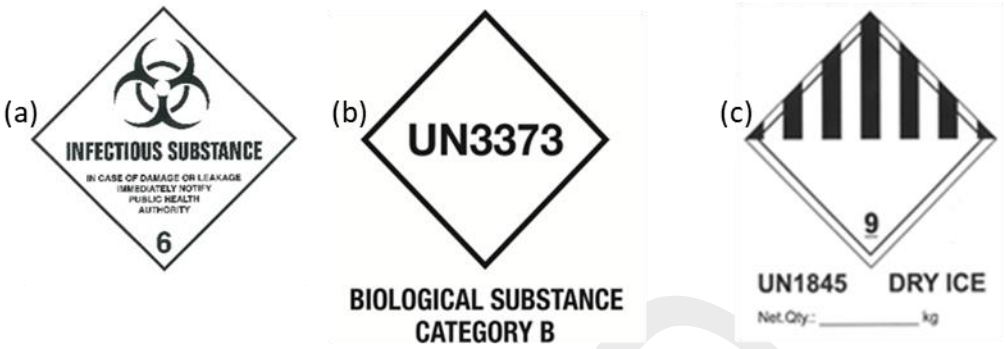


Figure 1: Package labelling for (a) Category A samples, (b) Category B samples and (c) Samples packed with dry ice.

4.6.2 **Category B labelling:** should include a similarly sized diamond containing the UN category (UN3373) and the wording ''Biological substance category B'' underneath in letters of at least 6mm as shown in Figure 1b.

4.6.3 **Category exempt labelling**: should include the words, '' Exempt Human specimen'' on the outer packaging, again in letters of at least 6mm.

4.6.4. **Packages with dry ice:** must also be labelled with a Class 9 diamond shape shown in Figure 1c, with the net weight (kg) added. For air transport it should be labelled as ''UN 1845 DRY ICE'' and for road transport, ''DRY ICE AS COOLANT''.

4.7. Containers for slide mounted tissues.

4.7.1 Tissue sections fixed and mounted on microscope slides must be sent in either slide boxes or mailing cases with separation between individual slides. Slide trays are not appropriate for transportation.

4.7.2 Slide boxes must be placed into rigid packaging with suitable and sufficient padded material to protect the slides from breakage in transit.

4.8. Transfer of samples to couriers

4.8.1 Packages containing human tissue samples must be held securely until collection.

4.8.2 Couriers should be asked to provide some form of receipt or other documentation that the package has been picked up before leaving the University premises.

4.9. Documentation. Whether the samples are being transported to another part of the campus or another institution each completed package should be clearly labelled and accompanied with an itemised list of contents. It is also the PIs responsibility to ensure that they keep a full record of all courier agreements and shipping documents, including evidence of sample dispatch, delivery and safe receipt, documentation of sample checking and the itemised list of the items shipped in the study folder as detailed in UOS_HT_SOP_09, Human tissue records management.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_03 Training requirements for using human tissue
UOS_HT_SOP_07 Transfer of human tissue into and out of the University, including import and export.
UOS_HT_SOP_09 Human Tissue records management
UOS_HT_SOP_10 Human Tissue Labelling, Storage and Tracking
UOS_HT_SOP_13_Disposal of human tissue Samples

6. REFERENCES

Guidance on regulations for the transport of infectious substances 2019 – 2020, WHO 2019
ADR, CDG Regs and Dangerous Goods Safety Advisors, Health and Safety Executive
TRANSPORT OF INFECTIOUS SUBSTANCES UN2814, UN2900 AND UN3373. Guidance note 17/2012 [Rev.7].

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue.

In addition, anyone packaging samples is responsible for either ensuring that they use a reputable courier who will also package the items appropriately or that they have had training with an external training provider approved by UK department of transport and are fully aware and follow the IATA dangerous goods regulations (IATA DGR) and ICAO regulations for air transport.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT act – Human Tissue act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA– Material Transfer Agreement
REC – Research Ethics Committee
UEC – University Ethics committee
UN PI954 – Packing instruction 954 for dry ice

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document (Formally, UOS_HTA_SOP_07)	Chris Bradley	16.03.2020
2.0	Major revision including new number (UOS_HT_SOP_08)	Linda McLatchie	03.06.2023