# Human Tissue in Research

## HTA-CORE-SOP-Transportation

### 1. Purpose

The Human Tissue Authority (HTA) requires that an establishment have in place appropriate documented procedures for the transport of human tissue, which protect both the tissue and any individuals involved in transportation.

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff and students involved in research covered by the Human Tissue Act (HT Act) understand the procedures and mechanisms for the transportation of human tissue.

Acquisition of human tissue usually takes place within a clinical site e.g. hospitals, although it can take place on Swansea University's (SU) research sites. Tissue collected at a clinical site may require transportation to SU and academic collaborative studies can also require the transport of tissues to other organisations. This SOP sets out guidelines and procedures for the transport of human tissues to and from SU, locally, nationally or internationally.

### 2. Scope

This SOP applies to all SU staff and students involved in research projects intending to use human tissue considered relevant material under the HT Act. However, it can be applied to any type of human tissue sample, including material that is not considered relevant under the HT Act, human DNA and RNA, acellular human biological fluid, and human-derived cell lines.

The SOP must be used in concordance with the HTA Codes of Practice and all other relevant University policies and SOPs.

Human-derived samples may contain harmful pathogens so for transport purposes is considered a potentially 'Infectious Substance' and classified as a Biological Substance, Category B. This SOP only provides transport procedures and requirements for **Category B**. Refer to section 4.4. for more details.

Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) that have their own procedures and requirements should not be handled in accordance with this SOP.

## 3. Roles and Responsibilities

All SU employees and students are responsible for reading and following this SOP if they are involved in collecting, using or storing human tissue for research.

The Designated Individual (DI) is responsible for the implementation and supervision of this SOP and the practices herein.

The Human Tissue Governance Officer (HTGO) is responsible for ensuring that this SOP remains fit for purpose.

## 4. Prerequisites for safe and HTA-compliant transportation

### 4.1 Criteria for Transport of Human Tissue between Organisations

Transport of relevant material between two organisations within Wales, England and Northern Ireland for research is permissible where both organisations hold a HTA licence or where one of the following exemptions applies:

a) Transportation of the material is covered by project-specific NHS REC approval.
b) The tissue is being held (not analysed) at an organisation without a HTA license for no longer than 7 days before transportation to an organisation with a licence or covered by a project-specific NHS REC approval.
c) The receiving organisation renders the tissue acellular within 7 days of receipt and the distributing organisation holds a HTA licence or is covered by project-specific NHS REC approval.
d) The tissue is distributed from a Research Tissue Bank (RTB) located on HTA-licenced premises and/or holds generic HRA REC approval.
e) The tissue is distributed from an accredited Health Board in Scotland, as part of the NHS Research Scotland (NRS) Biorepository Network to a HTA licence organisation.
f) The tissue is not relevant material.
g) The tissue is more than 100 years old.

Evidence of an HTA licence or exemption must be in place before tissue is transported from SU premises.

*Note: Research tissue banks based in Scotland do not need a HTA licence and are not governed by HTA. The NRS biorepositories are accredited by an independent expert panel using criteria comparable to and adopted from those for research tissue bank licensing in England, Wales and Northern Ireland by the Human Tissue Authority.*

### 4.2 Assurance of Donor Consent Required

You can only transport human tissue to other researchers if you have donor consent in place for the transportation of their tissues to a 3rd party.

This applies whether you are sending the tissue to somewhere inside Wales, England and Northern Ireland or exporting it outside of Wales, England and Northern Ireland – including Scotland.

If consent is not in place, consideration should be given to the feasibility of approaching donors for consent to transportation. If this is not feasible but the study has HRA REC approval for tissue transportation, the tissues may be transferred as long as they were obtained from the living and are anonymised.

When receiving human tissue from other researchers you should assure yourself that the tissue was collected ethically and with donor consent for all activities you intend to carry out as part of the research study at SU sites.

You should ask for a copy of their ethical approval and a copy of a blank consent form used for the study. If the latter cannot be acquired, assurances by the distributing establishment must be made within a legally binding Material Transfer Agreement (MTA).

### 4.3 Material Transfer Agreements

Before any human tissue, considered relevant material or not, is transported between organisations, a Material Transfer Agreement (MTA) must be in place.

It is customary that the tissue 'provider' also provides the MTA. If you are sending tissues, please contact a member of the Research Engagement & Innovation Services (REIS) Contracts Team to provide you with a template MTA.

All MTAs with SU must be reviewed by the HTGO before they are signed, and all University MTAs are signed by an authorised representative of the Contracts Team.

Only an authorised signatory may sign an MTA on behave of SU**. MTAs must not be signed by PIs or researchers.**

### 4.4 Risk Management

The process for transportation of human tissue should be detailed in project-specific local 'Sample handling' SOPs, adhering to the SU Health and Safety policies. A proper risk assessment of these transport processes must also be documented.

The risk assessment should cover all activities involving the handling and transportation of human tissues taking into consideration:

- Risk to the tissue samples.
- Risk to individuals handling the samples.
- Handling of heavy containers.
- Appropriate biohazard labelling of containers.
- Harmful preservative/fixative reagents.

For further information on risk assessing the handling and transportation of human tissue refer to HTA-CORE-SOP-Risk Management. All individuals involved in the transfer of a particular consignment of tissue should have the opportunity to contribute to the risk assessment.

### 4.5 Traceability documents

To be HTA compliant, relevant material and human tissue held under an approved REC study for research must be traceable from collection to disposal including records of transport. Such records should include:

- Where the tissue was transported to.
- When the tissue was transported (date of dispatch and date of receipt).
- How much tissue was transported.
- Contact details for the person responsible for dispatch and receipt.
- Ensure all Sample Log databases and Disposal Logs are up-to-date.

You should utilise the HTA-FORM-Tissue Transfer Record to ensure proper sample traceability.

### 4.6 Understanding Transport Regulations of Biological Substances

There are international regulations on the transportation of dangerous goods by air, sea, road, rail or inland waterway, that apply to the transport of human tissue.

You must first know which biological substances category your human tissue samples fall into. This will then determine how your samples must be packaged and what labelling must be displayed on the packages.

#### *4.6.1 Classification*

The transportation of biological substances is divided into the following categories:

***Category A***: 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 or animals. This definition is supplemented by an indicative list of pathogens, which include HIV and hepatitis B viruses (but not hepatitis C virus), when in the form of cultures but does not encompass specimens from patients suspected of having these infections.

***Category B:*** any infectious substance that does not meet the criteria for inclusion in category A. These are assigned UN 3373 - BIOLOGICAL SUBSTANCE, CATEGORY B. This would include specimens from patients with known or suspected HIV, HBV, HCV or SARS-CoV-2 infections.

There are some 'Exempt Human Specimens', defined as "Patient specimens for which there is minimal likelihood that pathogens are present." (Dangerous Goods Regulations, 3.6.2.2.3.8).

However, it is best practice to consider all human-derived samples as ***Category B, Biological Substance***. Therefore, this SOP only describes the packaging and labelling requirements for the transport of a ***Category B, Biological Substance***.

As ***Category A*** poses a significant risk to anyone handling the substance, if you are unsure or think your sample might fall into this higher category you must contact your Health & Safety Advisor and HTGO for appropriate transportation advice.

### *4.6.2 Packaging Requirements for Category B*

All biological substances, Category B must be posted in packaging that complies with the 'Triple packaging system' as described below:

***Primary receptacle*** - a primary watertight leak-proof receptacle containing the specimen.

***Secondary packaging*** - a second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). The sample receptacles should be packaged with enough absorbent material to absorb all fluid in case of breakage. Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage.

***Outer packaging*** - secondary packaging is placed in outer shipping packaging with suitable cushioning material. The outer packaging must be rigid, it protects contents from outside influences, such as physical damage, while in transit. The completed package should be capable of successfully passing the drop test at a height of 1.2 m.

### *4.6.3 Labelling of requirements Package containing Category B*

All biological substances, Category B packages must be labelled with a UN3373 mark illustrated below. The UN3373 mark must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm, the width of the line must be at least 2 mm, and the letters and numbers must be at least 6 mm high. The proper shipping name 'BIOLOGICAL SUBSTANCE, CATEGORY B', in letters at least 6 mm high shall also be marked on the outer package adjacent to the diamond-shaped mark.


BIOLOGICAL SUBSTANCE, CATEGORY B

## 5. Procedure

Each Human Tissue sample should be labelled with a unique sample identification and an up-to-date sample log should be maintained at all times to facilitate traceability of the tissue. Unique sample identification procedures should be included in local SOPs for the handling of tissues.

### 5.1 Transport between Laboratories

- Human material can be stored in various appropriate primary specimen receptacles, these receptacles should have secure lids and be tightly sealed when transporting samples between laboratories.

- All primary specimen receptacles should be clearly labelled with their unique ID using a permanent marker. They should never be carried directly in gloved hands, pockets or loose inside bags.

- The primary receptacles should then be placed in a larger suitable spill proof container e.g., a taped polystyrene box or another sealable sample box. A suitable container should be made of materials that can be easily disinfected in the case of spillage. Use of sample racks should be used to hold the samples in an upright position to help prevent them from being damaged upon transfer.

- If samples are temperature sensitive, cool packs, ice or dry ice can be added to the secondary spill proof container. **Never use liquid nitrogen.**

- Researchers should be wearing full personal protective equipment as appropriate for the handling of these tissues. However, when exiting a lab researchers should remove either both gloves or just on one hand to allow their un-gloved hand(s) to open doors outside of the lab, thereby reducing the chances of contaminating door handles.

**5.2 Transport between licenced Swansea University buildings & campuses.**

- Transportation of human material between university-licenced buildings or campuses must follow all the procedures detailed in 5.1.
- The secondary spill proof container should be placed inside a third outer container, strong enough to withstand the shocks and loadings normally encountered during transport with the appropriate labelling i.e., Infectious Substances, Category B.

For best practice please use medical bags that comply fully with UN3373 and P650 guidelines e.g., Insulated Pathology Sample Carrier or Blood In Transit Medical Carrier (Image below).


Transportation of hazardous biological material by public transport e.g., tube, bus or passenger rail is prohibited**.**

When employees use their private car on university business, employees should ensure that their car insurance coverage extends to business use.

- Cryogenic gases **must never** be transported in private cars.
- The material must never be left unattended during transport.
- Clear instructions for action in an emergency must be available during the transfer e.g. risk assessment.
- The driver must be aware of the contents of the consignment but not of any personal information therein.

SU has comprehensive motor insurance coverage for all staff and students who need to hire a vehicle on official University business or who need to drive a university-owned vehicle and have been authorised to do so. Details on how to gain this authorisation can be found on SU's webpage **'Motor Insurance Advice'**.

### 5.3 Transport to/from an organisation inside the UK.

If your human tissue samples are temperature sensitive and you need to use Dry Ice or Liquid Nitrogen coolant, please skip this section and follow the procedure outlined in Section 5.4.1 instead.

#### 5.3.1 Sending Human Samples

When sending human tissue samples to another organisation you must ensure each sample is clearly labelled with a unique sample identification number.

You must then complete the HTA-FORM-Tissue Transfer Record, email a digital copy of the form to the Recipient and also print a completed form hard copy to put inside the packaging. This will facilitate your legal responsibility for accurate traceability of human tissues from sender to receiver.

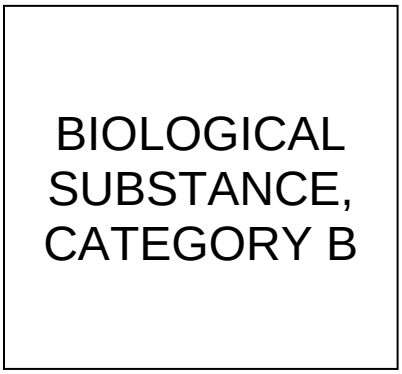
The Post Office will allow UK postage of BIOLOGICAL SUBSTANCE, CATEGORY B providing:

- The total sample volume/mass in any parcel must not exceed 50ml/50g.
- Packaging that complies with Packaging UN3373 Instruction 650.
- Dry Ice & Liquid Nitrogen is prohibited.

You must then package and label your samples in the following way, ensuring that the packaging meets the 'Triple packaging system' requirements described in **Section 4.6.1.**

a) All **primary receptacles** should be held in an upright position using racks.
b) The primary specimens in their racks must then be placed into a sample box (**secondary packaging**).
c) Add enough absorbent material inside or outside the sample box (e.g. cotton wool).
d) Place Secondary packaging into the third **outer packaging** (e.g. polystyrene box), with suitable cushioning material.
e) Refrigerated cool packs can be added between the secondary and outer packaging to keep sample cool.
f) Add the printed copy of your completed HTA-FORM-Tissue Transfer Record inside the outer packaging. The paper should be placed in a waterproof bag and if possible taped to the outside of the secondary container.
g) The outer packaging should be placed inside a tight-fitting cardboard box, with a minimum dimension of 100 mm x 100 mm.

h) Add the following **labelling** to the cardboard box:


i) Add your contact details, return address and telephone number.
j) Add receiving party's contact name, address and telephone number.

See Appendix A for examples.

k) Update your 'Sample Log' database to show which samples have been transferred to external party.

### 5.3.2 Receiving Human Samples

Once an MTA is in place confirm with the person responsible for dispatch:

a) Which courier they are using.
b) When the tissue will be transported.
c) How much tissue will be transported.
d) Request a digital record of all the samples that will be sent, including details of tissue types and their unique sample identification number.
e) The sample record provided should be cross-referenced upon the physical arrival of the tissue.

If the received tissue samples appear damaged or mislabelled, this is considered an Adverse Event. The providing party must be informed and an Adverse Event Report must be submitted to the HTGO.

f) Inform the providing party of the date of receipt at SU, via email and/or completion of a HTA-FORM-Tissue Transfer Record.
g) If storing samples before conducting research, create a Sample Log database for all samples you have accepted (see HTA-CORE-SOP-Storage).

### 5.4 International Import/Export (Temperature Sensitive Samples)

#### 5.4.1 Sending Human Samples

Staff and Students **should not** prepare the outer package of temperature-sensitive human tissue samples when sending to another organisation in the UK or internationally.

Staff or students should contact one of the couriers' companies available registered under suppliers on ABW (e.g. YSDS or Biocair) for a quote.

Within the requested quote specify that the courier should provide the outer 3rd packaging complaint with all UN3373 and P650 guidelines. You will need to provide the courier with the following details:

a) Sample quantities and volume.
b) Your contact details, return address and telephone number.
c) Add the receiving party's contact name, address and telephone number.
d) Temperature requirements e.g. dry ice or liquid nitrogen cooling.
e) If you require temperature monitoring throughout transit.
f) If you require dry ice top-ups to maintain temperature.
g) Any other information requested by the courier to provide an accurate quote.

From the courier's quote raise a Req on ABW.

You must ensure each sample is clearly labelled with a unique sample identification number.

Follow the courier's instructions for packaging your primary specimen receptacles into the outer package they provide.

You must then complete the HTA-FORM-Tissue Transfer Record, email a digital copy of the form to the recipient party and also print a completed form hard copy to put inside the packaging. This will facilitate your legal responsibility for accurate traceability of human tissues from sender to receiver.

Send the completed triple package according to the courier's instructions.

#### 5.4.2 Receiving human tissue from outside the UK.

Although consent is a fundamental principle of the HT Act, the consent provisions do not apply to imported material. That said it is good practice to gain assurance that consent and an ethical review were undertaken in the source country.

The researcher should request evidence of ethical approval and if possible, the consent forms for the imported tissue should accompany the material. If this is not feasible, a blank

copy of the patient information sheet and consent form should be retained by the researcher.

Justification of tissue imported from outside the UK must be documented and sent to the HTGO. Please use HTA-FORM-Importation Justification.

Any researcher planning to import material into the University must demonstrate that comparable material sourced from within England, Wales or Northern Ireland cannot satisfy their requirements. The documented assessment must be available for internal audit and external inspection by the HTA.

Request that the outer packaging of the imported samples shows:

- a 'Contains Human Tissue or Cells' statement and 'HANDLE WITH CARE'
- if the sample contains living cells required for the function of a graft, such as stem cells, the statement 'DO NOT IRRADIATE' should also be added to outer package.
- A statement recommending transport conditions, e.g. keep cool, in an upright position, etc.

Upon physical arrival of the tissue to SU, staff and students receiving human tissue from outside the UK should follow the same procedure as detailed in **Section 5.3.2.**

## 6. Related documents

- HTA-CORE-SOP-SOP
- HTA-CORE-SOP-Risk Management
- HTA-CORE-TEMPLATE-Risk Assessment
- HTA-CORE-SOP-Chain of Custody
- HTA-FORM-Tissue Transfer Record
- HTA-CORE-SOP-Storage
- SU's Biological Safety Policy Arrangements HSA-10126

## 7. References

Health and Safety Executive guidance for Transportation of infectious substances

Department of Transport Guidance for Packaging and transport requirements for patient samples – UN3373

HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

## 8. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

## 9. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

## 10. Document History

| Document History | | | | |
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| **Version** | **Review Date** | **Comment** | **Replaces** | **Reviewed by** |
| 2.0 | 24/10/2015 | Frontpage, hyperlink and footer amendments, removal of MTA template. Addition of courier requirements for exempt specimens | 1.0 | Lisa Wakeman |
| 3.0 | 01/09/2016 | Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Update reference to DRI to REIS | 2.0 | Lisa Wakeman |
| 4.0 | 18/04/2018 | Amendments to reflect revised HTA Codes of Practice and Standards Minor change to consent for transportation. Updated link to current transport regulations. Addition of insurance requirements for use of private vehicles | 3.0 | Lisa Wakeman |
| 5.0 | 13/02/2024 | Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward. | 4.0 | Bethan R Thomas & DI |
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|---|---|---|---|
| **Author** | **Name and role** | Dr Bethan Rhian Thomas<br>Human Tissue Governance Officer | |
| | **Signature and date** | Signed copy held by HTGO | |
| **Approver** | **Name and role** | Professor Catherine Thornton<br>Designated Individual (DI) | |
| | **Signature and date** | Signed copy held by HTGO | |
| **Effective Date:** | 01/04/2024 | **Next Review Date:** | 13/02/2025 |

## Appendix A: Labels for the third Outer packaging:


BIOLOGICAL SUBSTANCE, CATEGORY B

| **Shipper's Details** | **Consignee's Details:** |
|---|---|
| Name: Title, First Name, Second Name<br>Telephone:<br>Return address: | Name: Title, First Name, Second Name<br>Telephone:<br>Return address: |