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| **Human Tissue in Research****HTA-FORM-Importations Justification**  |

# Purpose

This form should be used by staff or students who are seeking to import samples considered to be relevant material under the Human Tissue Act 2006 from outside of the UK.

Note: *Research tissue banks based in* ***Scotland*** *do not need a HTA licence and are not governed by HTA. However, 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, t*herefore tissues sourced from *NRS biorepositories* can be treated the same as *HTA licenced organisation*.

Justification of tissue imported from outside the UK must be documented and sent to the Human Tissue Governance Officer (HTGO) along with a [HTA risk assessment](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) for the collection.

# Scope

Any researcher planning to import material into Swansea University must demonstrate that comparable material sourced from within England, Wales or Northern Ireland cannot satisfy their requirements.

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 participant information sheet and consent form should be retained by the researcher.

1. **Instructions**
* Remove this cover page from the document.
* Complete the form
* Send to Human Tissue Governance Officer with a Risk Assessment.

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| **Importation Justification Form** |
| **Principle Investigator Details** |
| Title:  | Name:  |
| Email: Telephone:  | Faculty: School: Building: Room:  |
| **Study Details** |
| Research Study Title |  |
| University REC Reference number |  |
| **Supplier Details**  |
| Name of organisation |  |
| Address  |  |
| Contact name |  |
| Contact email |  |
| Contact telephone number |  |
| **Sample Details** |
| Assurance that consent has been obtained in the source country. | [ ]  Copy of blank consent form used[ ]  Confirmation in writing[ ]  Other:  |
| Evidence of ethics from a Research Ethics Committee (REC) or equivalent in the source country. | Y/NDetails: e.g. Copy of approval letter |
| Sample type(s) |  |
| Sample quantity (for each type) |  |
| What are the specific storage temperature requirements (e.g. 5°-25°C) |  |
| Where will the samples be stored once received? | Faculty: Building: Floor: Room/Lab:  |
| Which storage unit will they be stored in? | Fridge/Freezer ID: (T-scan ID accepted)Other:  |
| **Justification for Import** |
| Please provide reason(s) why the relevant must be imported from outside of the UK:*Reasons can include:** *Accessibility*
* *Quality*
* *Limited timescale for project completion*
* *Infection risk lower*
* *Quality of service*
* *Cost-effectiveness*
* *Scientific/research needs*
 |
| **Health and Safety** |
| A risk assessment is in place covering* Risk to handlers during transport
* Risk to tissue during transport
* Possible infection risk
 | Y/N |
| **Planned Fate of Tissue Samples** |
| The planned fate of the samples: |
| Entirely used up during the delivery of research | Y/N |
| Return to supplier | Y/N |
| Transfer to another organisation, if yes provide details  | Y/NDetails: |
| Retain samples pending application for ethical approval for a new study | Y/N |
| Disposal | Y/N |

I confirm that the information given above is accurate and that the imported tissue will be handled in line with the Human Tissue Act 2007 and Human Tissue Authority requirements.

Print Name...............................................................................................

Signature of Principal Investigator................................................................. Date.........................

**Human Tissue Governance Officer Authorisation**

Print Name................................................................................................

Signature................................................................. Date.........................