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| **Human Tissue in Research**  **HTA-FORM-Licence Storage Application** |

# Purpose

This form should be used by staff or students wish to store human tissue, defined as relevant material by the Human Tissue (HT) Act 2004 under Swansea University’s Human Tissue Authority (HTA) research licence (ref 12651).

The HTA-FORM-Licence Storage Application should be sent to the [Human Tissue Governance Officer](mailto:b.r.thomas@Swansea.ac.uk) (HTGO) along with several supporting documentation including 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

There are a few different situations where a tissue collection would need to be accepted to be held under the licence and this form must be completed:

* Collections of relevant material established during an NHS Research Ethics Committee (REC) approved research study, with evidence of appropriate and valid consent to store the samples for the future after the end date submitted to IRAS.
* Collections transferred from other premises held under their HTA licence, when a new staff member joins Swansea University (SU).
* Retirement or departure of staff who was responsible for tissue collection held under our HTA licence and custodianship is to be reassigned to another staff member.
* Creation of a Research Tissue Bank (Biobank / Biological Repository).

1. **Instructions**

* Remove this cover page from the document.
* Complete the form.
* Compile all supporting documentation mentioned in [HTA-CORE-SOP- Acceptance of Sample Collections](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/), if applicable.
* Send this form, all supporting documentation, electronic log of samples, training certificates and [HTA risk assessment](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) to the [HTGO](mailto:b.r.thomas@Swansea.ac.uk).
* Once authorisation has been granted a future internal audit date will be established.

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| **Applicant Information:** | |
| Principal Investigator: |  |
| Email: |  |
| Contact email: |  |
| Contact number: |  |
| Location: | Faculty:  Building:  Floor:  Room/Office: |
| Have your storage facilities been subject to internal human tissue governance audits in the past 12 months?  Yes No\* | |
| ***\*If no, then you will have to agree to an audit before permission to store samples under the licence can be granted.*** | |

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| **Supporting Documents submitted with the application form:** | | |
| Copy of IRAS application form, along with any amendments to NHS REC approval | Attached | Unavailable |
| Copy of Ethics approval letter/s  NHS REC or SU REC: | Attached | Unavailable |
| Copy of NHS R&D approval letter | Attached | Unavailable |
| A copy of the participant information sheet/s (all versions): | Attached | Unavailable |
| A blank copy of the consent form/s (all versions): | Attached | Unavailable |
| Material transfer/service agreements: | Attached | Unavailable |
| New study protocol for continued access: | Attached | Unavailable |
| GCP Training Certificate: | Attached |  |
| HTA Training Certificate: | Attached |  |
| A full electronic record/log of samples: | Attached |  |
| HTA Risk Assessment for collection: | Attached |  |

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| **Sample Collection Information:** | | | |
| **Are the samples being transferred to Swansea University from an external location?** | | **Yes (give details)** | **No** |
| **Details:** | | | |
| **Current sample location:** | **Faculty:**  **Building:**  **Floor:**  **Lab:** | | |
| **The proposed storage location**  **(if different to the above):** | **Faculty:**  **Building:**  **Floor:**  **Lab:** | | |
| **Which storage unit/s will they be stored in?** | **Fridge ID (T-scan ID accepted):**  **Freezer ID (T-scan ID accepted):**  **Other:** | | |
| **Has the study/collection previously been approved by NHS REC?** | | **Yes** | **No** |
| **Expiry date:**    **Ref No.:** |
| **Has the study/collection been approved by any SU REC?** | | **Yes**  **Expiry date:**    **Ref No.:** | **No** |
| **Has the study/collection been approved by any other REC?** | | **Yes (give details)** | **No** |
| **Details:**  **If applicable, include the expiry date:** | | | |
| **Where were the samples collected from the donors? (tick all that apply)**  **England, Wales or Northern Ireland**  **Outside England, Wales or Northern Ireland (including transfer from Scotland)**    **Within Swansea University** | | | |
| **Are the samples currently stored in a Research Tissue Bank?** | | **Yes (give details)** | **No** |
| **Details:** | | | |
| **For existing collections (pre-1st Sept 2006), have all donors previously consented to long-term storage for future research?** | | **Yes** | **No** |
| *Blank copies of the donor information sheet and consent form must also be submitted* | | | |
| **If, the original research was undertaken at SU or SU was the NHS REC Sponsor for the previously approved study, are all signed consent forms stored in a secure location on SU premises?** | | **Yes** | **No** |
| **Details:** | |  |  |
| **Reasons for storage under SU HTA Research Licence:** | | **(Tick all that apply)** | |
| Retain samples pending application for ethical approval for a new study. | | | |
| Creation of a Research Tissue Bank. | | | |
| Use tissue samples for educational purposes | | | |
| Other, provide details: | | | |

**Summary sample information**

For prospective collections give targets or estimated numbers.

Detail the number of each sample type, weight/volume to be stored and storage temperature requirements

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| **Prospective summary sample information:** |
| e.g.  biopsy of skin tissue – 5cm diameter – 100 samples – storage at ultra-low temperature -80°C  Fix skin sections in microscope slides – 100 samples – room temperature storage. |

For previously established tissue collections provide a full sample record with any consent opt-outs that apply you may use the table below or provide your own electronic version with your submission email.

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| **Sample Log Record** | | | |  |  |
| ***Sample ID*** | | ***Volume/Grams*** | ***Tissue type*** | ***Storage temp requirement:*** | ***Consent opt-outs*** |
| *(add more row if needed)* | |  |  |  |  |
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| **Additional details/comments:** |  | | | | |

***All up-to-date Core HTA SOPS are available to view and download*** [***online***](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/)***.***

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| **I agree I have read and understood the following core HTA Standard Operating Procedures:** | **Version** | **Signature** |
| SU Human Tissue Act Quality Manual |  |  |
| HTA-CORE-SOP-SOPs |  |  |
| HTA-CORE-SOP-Consent |  |  |
| HTA-CORE-SOP-Storage |  |  |
| HTA-CORE-SOP-Disposal |  |  |
| HTA-CORE-SOP-Transportation |  |  |
| HTA-CORE-SOP-Management of Records |  |  |
| HTA-CORE-SOP-Human Tissue Training |  |  |
| HTA-CORE-SOP-Risk Management |  |  |
| HTA-CORE-SOP-Equipment Management |  |  |
| HTA-CORE-SOP- Maintenance & Monitoring of Cold Storage |  |  |
| HTA-CORE-SOP-Adverse Event Reporting |  |  |
| HTA-CORE-SOP-Internal Audit |  |  |
| HTA-CORE-SOP-Chain of Custody |  |  |
| HTA-CORE-SOP-Acceptance of Sample Collections |  |  |
| HTA-CORE-SOP-QR Code Label |  |  |

I confirm that all information provided above in this form and attached to the submission email, is accurate and that the imported tissue will be handled in line with the Human Tissue Act 2004 and Human Tissue Authority requirements.

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

Signature of Chief/Principal Investigator....................................................

Date.........................

# Authorisation:

Following a review of the information above and all additional requested supporting evidence provided by the applicant, I authorise and accept the aforementioned tissue collection for storage under SU HTA Research Licence:

**Human Tissue Governance Officer Authorisation**

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

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

**Designated Individual Authorisation**

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

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