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| **Human Tissue in Research****HTA-Template – Master Site File** |

1. **Purpose**

It is the responsibility of the Principal/Chief Investigator to ensure all records of the collection, use, storage and disposal of human tissue considered relevant material (as defined by the Human Tissue Act 2004), are regularly checked for completeness, legibility and accuracy.

The purpose of this template is to support Swansea University (SU) staff in collating all documents and maintaining updated records relating to the storage of relevant material, into one clear and logical master site file.

1. **Scope**

This template can be used by any SUstaff or student undertaking a research study involving the collection, use, storage and disposal of human tissue.

Biobanks and collections of Relevant material are stored on Swansea University premises under it’s HTA Research Licence should also refer to this site file structure to support accurate record management.

1. **Instructions:**
* Delete this cover page.
* Review Template section Headings and tailor the template by adding or removing additional sections.
* Refer to HTA-CORE-SOP-Management of Records for guidance on what records your master file should contain.
* Either save a digital version of your tailored template or print the tailored template and place it into a ring bind folder.
	+ If you saved a digital version, you must then add all the required records into the tailors section also in a digital format.
	+ If you have printed the sections you can also contact the Human Tissue Governance Officer for a ring bind folder.

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# Study Information

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| Study Title: |
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| Study Reference Numbers (IRAS / NHS REC / HTA Licence: |
|  |
| Location of Facilities: |
|  |
| Chief Investigator / Principal Investigator: |
|  |
| Study Start Date: |
|  |
| Study Expiry Date: |

If a collection or project has transfer custodianship to another individual within the department or to another organisation. This history should also be evidenced in this section.

# Regulatory Approval Documentation

Examples of document that should be filed in this section:

* Evidence of favourable opinion and all approved documentation, including submission and any amendments must be readily available.
* Or justification and evidence for not seeking Recognised NHS ethical approval.
* The PI must record and monitor the end date of approval to ensure no breach of the HT Act once approval lapses due to the retention of relevant material beyond the REC end date.

# Risk Assessments

Examples of documents that should be filed in this section:

* A project-specific RA should be carried out by a PI or assigned staff member and maintained with reviews as required.
* Risk assessment(s) should cover risk to the human tissue and address and mitigate failures in, Consent, Storage, Handling, Traceability, Transport, Security, Facilities and Disposal.
* [HTA-Template-Risk Assessment](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/).
* Other SU RA templates can be found [here](https://myuni.swansea.ac.uk/living-in-swansea/health-and-safety/postgraduates/policies-and-procedures/laboratory-safety/#biological=is-expanded).
* Your records must show evidence of risk assessment review (or planned review).
* References to local SOPs that have been developed, read and followed to support risk mitigation.
* Evidence of staff/students having read risk assessment and contingency plans.
* Separate RA for the various research Lab activities carried out within the project can also be utilised and maintained.
* Contingency Plans

# Research Team

Examples of document that should be filed in this section:

* List of members of the research team involved in study activities (Staff and Students) e.g. [Delegation Log](https://qp.swansea.ac.uk/QPulseDocumentService/Documents.svc/documents/active/attachment?number=STU-AD-TMP-019)

# Training records

Examples of document that should be filed in this section:

* Records of HTA-specific training e.g. GCP and Human Tissue in Research. Refer to [HTA-CORE-SOP-Human Tissue Training](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).
* Documented evidence of all the Swansea University’s Quality Manual and HTA Core SOPs as being read and understood by all researchers using human tissue. To achieve this request a ‘Read and Understood Form’ from the Human Tissue Governance Officer.
* Evidence that any local HTA SOPs have been read.
* General Induction is provided by the University.
* Local induction from School/Unit.
* Health and Safety training.
* Protection and Confidentiality.

# Standard Operational Procedures (SOPs)

Local SOPs for Safe Handling of the Tissue Samples (controlled and reviewed). Process of collection – persons responsible and locations.

* Procedures for checking imported sample numbers against the record provided by the sender.
* How to anonymise the samples.
* How to use a standardise labelling format for all samples.
* What processing steps are needed before storing the samples.
* How to access your sample log and what details must be added to the log for each sample.
* How you will record sample disposal (e.g. use of a sample log column and/or [Disposal Record Form](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/))
* How to record storage temperature. (e.g. T-scan or other). Refer to [HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).
* How to calibrate or carry out maintenance of relevant equipment if required by staff or students/How to record a calibration/maintenance check.

Link to all up-to-date [Quality Manual and HTA-CORE-SOP](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) are available online.

# Consent and Participant Information

Examples of document that should be filed in this section:

* Each consent form signed by project participant, detailing:
	+ Who gave and who took consent, the date of consent and the version number of the consent form.
	+ What the individual consented to.
	+ Whether the consent is project-specific or for future use in research.
	+ Donor decision for all options presented in the consent.
	+ Restrictions of tissue use stipulated during consent.
* Copy of Patient Information Sheet (PIS).
* Copy of Pro-forma.
* Screening and Enrolment Log (if applicable).
* Welsh Translation of PIS & Pro-forma

Where a 3rd party has obtained consent and collected samples e.g., biobank, clinician, external organization, the following document that should be filed in this section:

* If the consent records are held at a different location(s) details of a named contact at the establishment.
* Documentation with assurances that custody of consent records lies with another organization.

This could be party of and Material Transfer agreement and should be filed under the next section “Material Transfer Records”.

* Copy of ethical approval that is or was in place at the time of consent.
* Evidence that the new use of the relevant material is within the original donor’s consent;
	+ Copy of 3rd party Patient Information Sheet (PIS).
	+ Copy of blank Consent form from 3rd party
* Ethical approval and appropriate consent are in place to contact the donor or relatives of the deceased to use the relevant material for purposes outside the original consent, where applicable.

# Material Transfer Records

Examples of document that should be filed in this section:

* Copy of all MTAs in place for the transfer of relevant material.
* Copy Service Level Agreements (SLAs), and Organisation Information Document (OID), if applicable.
* [HTA-FORM-Importation Justification](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) form for importing from outside the UK.
* Tissue Transfer logs. E.g. [HTA-FORM-Tissue Transfer Record](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)
* Chain of Custody records.
* Agreements with couriers, if applicable.
* A record of the conditions of storage while under the custodianship of the external researchers.

# Disposal records

Examples of document that should be filed in this section:

* Sample Log with each sample’s disposal documented ([HTA-Template-Sample Log](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)).
* [Disposal Record Form](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)

# Maintaining and Monitoring Records

Examples of document that should be filed in this section:

* Service certification/invoices records for equipment involved in study activity (e.g. Tissue Culture Hoods, Centrifuges, Incubators).
* Temperature monitoring logs available.
* Freezer / Fridge Validation records.
* Freezer maintenance records available (Maintenance logs / IAuditor records)
* Refer to [HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).

# Audit Records

Examples of document that should be filed in this section:

* Self-Traceability Audit Forms
* HTGO Compliance Audits
* Research Governance Compliance Audits

# Adverse Event Records

Examples of document that should be filed in this section:

* Copy of Adverse Event Form submitted to Human Tissue Governance Officer
* Copy of Corrective & Preventative Action Forms

# Archive

* Superseded SOPs
* Superseded Risk Assessments
* Superseded Patient Information Sheets
* Superseded Consent forms