Human Tissue in Research

HTA-CORE-SOP-Management of Records

1. Purpose

Accurate and complete records of the collection, use, storage and disposal of human tissue must be kept in compliance with the licensing requirements of the Human Tissue Authority (HTA). Principal Investigators (PIs) and custodians of human tissue collections must ensure their holdings are fully documented.

This SOP will detail what records and other documentation staff and students involved in human tissue research must retain and how to manage these records in a clear and systematic approach.

2. Scope

This SOP details the legal requirements for the management of records relating to the collection, storage, and use of human tissue considered relevant material under the Human Tissue Act (HT Act). This SOP should be utilised as best practice by all Swansea University (SU) staff and students involved in research projects using and storing any type of human-derived tissue samples considered relevant material or non-relevant under the HT Act.

The HTA require regular submission of holdings of tissue collections held under an organisation's research licence, similarly, studies with HRA Research Ethics Committee approval must also maintain robust record keeping. Collections stored under the HTA research licence and REC-approved studies may be subjected to audit to ensure accurate record management.

3. Roles and Responsibilities

Designated Individual (DI):

- Ensures appropriate procedures are in place for managing records related to human tissue research.
- Has overarching responsibility for compliance with the Human Tissue Act and HTA licensing standards.

Human Tissue Compliance Manager (HTCM):

- Supports the DI in implementing and monitoring procedures.
- Maintains and reviews all HTA CORE SOPs to ensure ongoing alignment with HTA guidance.
- Supports researchers and PIs in implementing record management processes.

Persons Designate (PDs):

- Support the DI in implementing and monitoring procedures.
- Provide local oversight of records and storage practices within their area of responsibility.

Chief / Principal Investigator (CI/PI):

- Ensures all tissue-related records are created, maintained, and retained in line with this SOP.
- Regularly reviews records for completeness, accuracy, and legibility.
- Maintains a Master Site File and oversees local documentation practices.

Researchers (Staff and Students):

- Support the PI by keeping tissue-related records up to date and securely stored.

4. HTA Licencing Standards

The HTA assesses all licenced establishments against several licensing standards. The standards are grouped into four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE).

Good management of records is key to evidencing how an establishment is meeting the licensing standards.

Records of Consent – evidence of a process for seeking and gaining consent, including documentation and information used to support consent, and evidence that staff involved in consent are suitably trained and equipped for the task.

Governance and Quality – demonstration of a suitable governance framework using version-controlled documentation, risk management, staff training, audits and suitable systems to deal with adverse events.

Traceability - records should evidence the point of tissue collection, receipt and the final destination whether entirely used in testing/processing, disposed of or transferred. Methods of record keeping can be electronic or paper-based and should be maintained securely in locked, or password-protected storage.

Premises, facilities and equipment - demonstrate that they are safe, secure and clean with records of a system for ongoing monitoring and servicing.

5. Ensure the Security of Records

All research teams must ensure compliance with Swansea University's record management policies before the commencement of any research project using human tissues.

- **Confidential or identifiable data** (e.g. Consent forms) in accordance with the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR).
- Such records must be kept **secure at all times** and accessible only to authorised individuals.

5.1. Storage Requirements

Paper records – must be stored in a **locked facility** when not in use. When in use, they must be under the direct supervision of the research team.

Electronic records – **Saved on SU OneDrive Business accounts**, password protected, and accessible only to authorised team members. Personal devices must not be used to store identifiable information.

All documents are stored securely on the Microsoft Cloud infrastructure (i.e. OneDrive) as they are geographically located at data centres within the European Union, and all documents, even if deleted, can be recovered for up to 90 days.

- All passwords should be restricted to authorised individuals within the research team. Passwords should be changed regularly, and personal computers should be password-locked when unattended.
- Staff and students remotely accessing human tissue-related electronic records should ensure that they are viewed securely and privately.

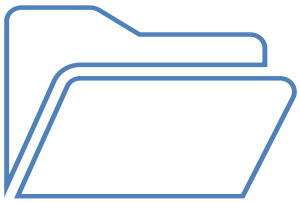
6. Procedure

Ensuring compliance with the HT Act requires the generation of several documents relating to the acquisition, storage, use and disposal of human tissue. All relevant documents detailed in this SOP should be stored and maintained electronically or paper-based and should be maintained securely in locked, or password-protected storage.

It is recommended that at the start of your study, you create:

Tissue Sample Log

And



Master Site File

6.1 Tissue Sample Log

A key record for evidencing traceability is a complete and accurate sample log of donated material and associated products, refer to the HTA-Template-Sample Log.

- Sample ID reference. This should be unique and coded so that it links to the donor if necessary and approved during the ethics application process (it should not include the donor's personal details)
- ID reference for any sample splits, aliquots or sections, which should be unique and link the split/aliquot/section to the original sample ID.
- Sample type (if more than one is stored/used).
- Date of receipt and details of where it came from.
- Date sample labelled, if different from date of receipt.
- Exact storage location including building, room, unit, shelf, box and position, if applicable.
- Details and dates of processes applied to the sample.
- Column to log withdrawal
- Column to log disposal

6.2 Master Site File

To support consistency, traceability, and audit-readiness, all human tissue studies should use the following folder structure when setting up a Master Site File. This folder must be accessible to the research team and stored securely.

Recommended Folder Headings (A–M):

A. Study Collection Information
B. Approval Documentation
C. Risk Assessments & Contingency
D. Training Records
E. Local SOPs
F. Study Documents
G. Legal Agreements
H. Sample Log and Transfer Records
I. Maintenance
J. Quality Assurance
K. Study Reports
L. Amendments
M. Archive

To support compliance, a **Template Digital Master Site File** has been developed for use by all SU research teams.

This digital file should be adopted by all staff and students working under the HTA licence or who are carrying out research activities that fall under the Human Tissue Act (2004). i.e. IRAS / NHS REC-approved studies involving relevant material.

The template is designed to accommodate a wide range of human tissue studies and collections. Not all folders or documents will apply to every study. You should **tailor the site file** to reflect your specific study and delete irrelevant folders/files.

This digital site file is pre-structured according to the (A–M) folder system. Each subfolder contains a Word document titled "**GUIDANCE**", which outlines the records to be retained as evidence of compliance. Where appropriate, up-to-date **HTA Forms and Templates** are also included to **be amended to reflect your study**.

Hard Copy Master Site File:

If you choose to create a hard copy of the Master Site File, follow the A–M folder system and refer to the "**GUIDANCE**" documents in the digital version to ensure the correct records are retained for compliance.

6.2.1 Ethical and Research Governance Approvals

Documents required:

- Evidence of favourable opinion and all approved documentation, including submission and any amendments must be readily available.

Alternatively, and if appropriate, 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.

6.2.2 Risk Assessments

All studies should have a customised version of the HTA-Template-Risk Assessment.

The risk assessment (RA) should address and mitigate failures in Consent, Storage, Handling, Traceability, Transport, Security, Facilities and Disposal. Refer to HTA-Core-SOP-Risk Assessment for more information.

A project-specific Health and Safety RA(s) should be carried out by a PI or assigned staff member and maintained with regular reviews as required. However, separate RAs for the various research lab activities carried out within the project can also be utilised and maintained.

RA(s) should make references to local SOPs that have been developed, read and followed to support risk mitigation. There should be evidence of staff/students having read RAs and contingency plans.

Your records must show evidence of RA review (or planned review).

Studies storing relevant Mamerial must have documented contingency plans in case of failure of the storage area & equipment, including the location of backup storage equipment. Refer to the HTA-Template-Contingency Plan.

6.2.3 Research Team

There must be a list of members of the research team involved in study activities (Staff and Students). Utilise the ResGov_FORM_Staff Delegation log_nonCommercial_V3 found in the **Template Digital Master Site File** subfolder **'A. Study_Collection Information'.**

6.2.4 Staff Training

Refer to HTA-CORE-SOP-Human Tissue Training.

6.2.5 Standard Operating Procedures (CORE and local project-specific)

The current versions of the HTA Core SOPs are available and readily accessible to all staff, students and visiting workers online. Your site file should either include a link to the digital SOPs or contain printed copies if you are maintaining a hard copy site file.

Any local SOPs stored in the Site Folder should be related to the study or collection and should be approved by the CI/PI. In your Master File, you should add all your up-to-date local SOPs and protocols for all routine methods that involve the collection, use, storage and disposal of human tissue. The current version should be available and readily accessible to all staff and students within the research team. See the GUIDANCE notes for examples of the local SOPs you should maintain in your **Digital Master File**. Utilise the available HTA-TEMPLATE-SOP to ensure your local SOPs meet compliance standards e.g. structure and are version-controlled, reviewed regularly.

6.2.6 Consent Records and Patient Information Sheet (PIS)

Each site file must contain:

- **Blank copies** of the latest ethically approved **Consent Form** and **Participant Information Sheet (PIS)**.
- **Archived versions** of any previous consent form and PIS versions.

6.2.6.1 Completed Consent Records

Completed consent forms must:

- Be stored **separately** from sample logs to protect identifiable data (e.g. use a separate restricted-access folder or physical location).
    - Digital copies must be **password-protected**, stored outside the Digital Master Site File, and set to **'View Only'** access for research staff.
    - Paper forms must be stored **in a secure, locked facility**.

It is acceptable to store your sample log document within your Digital Master File as long as it is also password-protected.

6.2.6.2 Corrections to Consent Forms

If an error is made on a consent form:

- Cross through the error with a single line, ensuring it remains legible.
- Sign and date the correction, adding a brief explanation in the margin.
- Do not use correction fluid.
- If in doubt, complete a new form and retain both, adding a note to explain.

6.2.6.3 Lost or Damaged Signed Consent Forms

If **paper** consent forms are lost/damaged during transit or retention (10 years), linked samples must be destroyed, and an Adverse Event form submitted.

For **digital** records, contact IT via the **Service Centre** on your App Dashboard to attempt recovery (files stored in Microsoft Cloud are recoverable for up to **90 days**).

If unrecoverable, all linked tissue samples **must be destroyed** and an **Adverse Event submitted**.

6.2.6.4 Consent Records for the Re-Use of Relevant Material

If you receive relevant material from another organisation or are planning to re-use existing samples in a new project:

The Providing Party must retain:

- Who the material was released by, when and for what study.
- Whether the material was anonymised or linked-anonymised.
- Evidence that re-use is permitted under the original donor consent.
- Any limitations on the use of the material.
- A signed MTA for the transfer of material.

The Receiving Party must retain:

- Contact details of the organisation holding original consent records (if held externally).
- A record of when the material was received and by whom.
- The original Sample ID and any reassigned IDs (if applicable).
- A signed MTA.
- Evidence of original ethical approval was in place at the time of consent.
- Evidence that the new use of the relevant material aligns with the original consent (e.g. copy of blank consent and PIS).
- If re-consent is needed (e.g. for a new purpose), ensure:
    - 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.
    - Appropriate new consent is obtained.

6.2.7 Legal Agreements

e.g. Material Transfer Agreements (MTAs) / Service Level Agreements (SLAs), Non-Disclosure Agreements (NDAs), Organisation Information Documentation (OIDs).

All agreements must be signed by an authorised signatory from Swansea University's Research Knowledge Exchange Contracts Team. Not by staff or CI/PIs.

Request MTA support by completing the MTA Checklist Form: MTA Checklist Form – Fill in form

6.2.8 Sample Log and Transfer Records

It is acceptable to store your sample log in the folder 'H. Sample Log and Transfer Records' as long as it is password-protected.

Documents required:

- Name of CI/PI responsible
- Evidence of:
  - HTA licence of the receiving party if transporting relevant material within England, Wales and Northern Ireland.
  - If importing from an NHS Research Scotland (NRS) Biorepository Network, evidence of their accreditation by Health Improvement Scotland.
  - Or if importing from outside the UK a HTA-FORM-Importation Justification form for importing from outside the UK.
  - Or evidence of an approved NHS-REC covering the transfer to a collaborating organisation.
- Keep a Signed copy of:
  - All related MTAs, SLAs, NDAs, OIDs
  - HTA-FORM-Tissue Transfer Record / Chain of Custody
- Ensure traceability with:
  a) Addresses from where relevant material was sent and received.
  b) Date of transport, including date sent and date arrived if different.
  c) ID numbers for samples sent, the amount of each sample, and the type of sample to be kept by a named recipient.
- All courier documentation (e.g. invoice, tracking reference and chain of custody records) must be retained and kept in the site file.
- Any other Chain of Custody records provided.
- HTA-FORM-Disposal Record for unexpected disposal of relevant material. Refer to the HTA-Core-SOP-Disposal.
- If an MTA requires a researcher to dispose of, rather than return material to the biobank, they must keep auditable records of the date and method of disposal, see next section.

If **transferring tissue from a SU-based Biobank**, all the above-mentioned documents should be recorded in addition to:

- A record of the conditions of storage while under the custodianship of the external researchers.
- If samples not exhausted by the end-user are returned to an SU biobank or disposed of, a record of either of these outcomes must be maintained.

If transferring sample from an expired REC into an SU-based Biobank please utilise the HTA-FORM-Tissue Storage Application.

6.2.9 Tissue Disposal

Within any sample log, there must be a record of disposal for all samples of relevant material. For best practice add a column for disposal to your sample logs, refer to the HTA-Template-Sample Log.

In addition to your sample log record of disposal, any unexpected disposal of relevant material will require the completion of a Disposal Record Form and an Adverse Event Form. HTA-Core-SOP-Disposal. Information that should be recorded in the site file are:

- Reason for disposal.
- Date of disposal.
- Total amount of relevant material to be disposed of.
- Method of disposal (including if the relevant material has been used up in processing or cells have been divided in culture).
- Contact details/information of contact concerning disposal.

The sample log record of disposal should also be completed if relevant material stored for more than 7 days prior, is rendered acellular to create non-relevant samples.

MaintenanceCIs and PIs are responsible for maintaining records of equipment servicing, inspections, and maintenance. These records must be retained for the duration of the study or, where applicable, for the lifetime of the equipment.

If calibration or maintenance is carried out by research staff or students, local SOPs covering the use, calibration, and maintenance of equipment—along with associated risk assessments—must be documented in the site file.

Temperature Monitoring

Refer to HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage for detailed guidance on cold storage monitoring standards. This includes the use of tools such as

T-Scan and SafetyCulture, which can help determine if additional local documentation is required.

T-Scan, SafetyCulture, and the above SOP should support the following documentation requirements:

- Documented cleaning and decontamination procedures for equipment.
- Clearly displayed contingency plans on each storage unit, including the name and contact details of the CI/PI (see HTA-Template-Storage Sign).
- Evidence of regular alarm system testing and challenges.
- Records of calibration, validation, maintenance, and routine monitoring for all relevant equipment (including storage units and alarm systems).
- Documented monitoring of all storage conditions (e.g. daily temperature logs for cold and room temperature storage, whether electronic via T-Scan or manual).
- For freezers used in long-term storage (e.g. biobanking), daily temperature data should be summarised and retained for the full lifespan of the equipment.

Temperature Deviations

If stored samples experience temperature fluctuations outside the acceptable range, each affected sample must be annotated to reflect the deviation. An adverse event should be reported, and the relevant details must remain accessible within the sample record—including after transfer to a new storage unit—for the lifetime of the specimen.

If T-Scan and SafetyCulture are not available in your local area, please contact HumanTissueResearch@swansea.ac.uk for guidance and support.

6.2.10 Quality Assurance

All records of **audits** carried out by the HTCM or a member of Research Governance, and all external audits, must be kept and be available in the site file.

Refer to HTA-FORM-Self Traceability Audit for the creation of researcher-led sample traceability audits and consent audits.Any shortfalls discovered during these audits should be reported immediately to HumanTissueResearch@swansea.ac.uk including where material has been stored and/or used in a way that contravenes the consent.

6.2.11 Study Reports

Study Reports include:

- HTA-Adverse Event Reports - Refer to HTA-CORE-SOP-AE Reporting.
- Serious Breaches (IRAS)
- Annual Progress Reports (IRAS)
- End of Study Report (IRAS)

7. Retention and Disposal of Study Records

Your **Archive** subfolder in your Master Site File should store:

- Superseded SOPs
- Superseded Risk Assessments
- Superseded Participant Information Sheets
- Superseded Consent forms
- Any other study-related documents that are superseded during study delivery (e.g. questionnaires or pre-forma)

In accordance with the Swansea University Research Integrity Framework on Research Ethics and Governance, **all study-related records must be retained for a minimum of 10 years** after study completion.

The CI/PI is responsible for the destruction of all identifiable participant data, no earlier than 10 years post-study completion.

After 10 years of retention period, all **identifiable participant data (e.g. consent forms)** should be:

- **Securely destroyed** or
- **Irreversibly anonymised**

Unless retention is required by:

- Ethical approval
- Valid consent for future use
- Funder or Sponsor requirements

If future access to identifiable data is anticipated, it may be retained for **as long as necessary**, provided this complies with UK data protection law.

7.1. Transfer of Custodianship of Study/Collection and Samples

When funding for a project ends or if the CI/PI is due to leave the University, arrangements must be made in advance for the ongoing retention and management of human tissue samples and study records.

This may include the transfer of custodianship to:

- Another individual within the department, or
- Another organisation.

Arrangements should:

- Ensure secure storage and traceability of samples and data,
- Clearly define access permissions and responsibilities, and
- Include a plan for eventual disposal or archiving.

If records or tissue samples are transferred the DI and HTCM should be notified and any transfer of samples must be done under an MTA in line with HTA-CORE-SOP-Transportation.

8. Risk Assessment

A RA 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				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21.09.15	Update to front page and footers. Text deletions for obsolete links	1.0	Lisa Wakeman
3.0	01.09.16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards. Amendments to reference to updated NHS guidance on records management	3.0	Lisa Wakeman
5.0	08/02/2024	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
6.0	01/05/2025	Updated SOP to encourage the use of a digital Template Master Site File for good Management of Records and to use the guidance notes in the digital folder to under what records should be kept and maintained.	5.0	Bethan R Thomas & DI

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	Signature and date	Signed copy held by HTGO 01/05/2025	
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	Signature and date	Signed copy held by HTGO *16th September 2025*	
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