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 study may be subjected to audit to ensure accurate record management.

3. Roles and Responsibilities

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place for the management of records related to the use of human tissue in research and that these processes are adhered to.

The Person(s) Designated (PD) carries the role of directing others in relation to the HT Act. As part of this role, they can reasonably assist the DI in implementing procedures to ensure compliance with the HT Act and HTA licensing requirements.

The Principal Investigator (PI) of each research project is responsible for ensuring that quality records are captured, maintained and destroyed in line with this SOP. The PI should ensure all records discussed in this SOP are regularly checked for completeness,

legibility and accuracy. The use of a site master file is recommended to collate all relevant HTA documentation.

It is the responsibility of individual researchers to support the PI in ensuring that tissue-related records are stored and archived securely and appropriately.

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

4. HTA Licencing Standards

The HTA assesses all licenced establishments against a number of 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 a key process to evidence 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 the 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

In addition to the guidelines detailed in the SOP, all research teams must also ensure that their projects are compliant with all SU record management policies before the commencement of any research project using human tissues.

Records relating to human tissue that contain confidential or protected personal information must be kept secure at all times and accessible only to authorised individuals.

All confidential personal information must be processed in accordance with the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR).

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 – must be saved on SU's OneDrive Business through SU staff/student accounts and be password protected. 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. All documents are stored securely on the Microsoft Cloud infrastructure and are geographically located at data centres within the European Union. All documents even if deleted can be recovered for up to 90 days.

Patient-identifiable information must not be held on personal devices and must not be removed from the secure storage environment.

Staff and students should take reasonable steps to protect the security of their usernames and passwords, including not making them available for use to other individuals. Staff and students remotely accessing human tissue-related electronic records should ensure that they are viewed securely and privately.

After the research has been completed, given all data is analysed and final publication of findings has been made and the related human tissue samples are used/disposed of, all confidential named patient/participant data (e.g. consent documentation) collected during an investigation should be destroyed or completely anonymised.

If further recourse to identifiable information is anticipated, it should be kept for as long as such a need may exist where this is permissible under data protection laws.

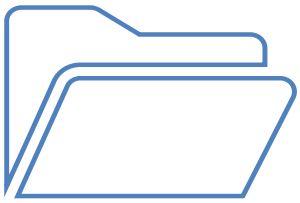
6. Procedure

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 the 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 (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 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.
- Columns to log withdrawal (even if withdrawal is not anticipated).
- Columns to log disposal (even if disposal is not anticipated).

6.2 Master Site file

The Master Site file should be used to house all other documents relating to the acquisition, storage, use and disposal of human tissue. The following listed headings are suggested as file sections (Refer to the HTA-Template-Master Site File):

1. Study Information
2. Regulatory approval documentation
3. Risk Assessments
4. Research Team
5. Training Records
6. Standard Operating Procedures (CORE HTA SOPs and local project-specific)
7. Consent and Participant Information
8. Material Transfer Records
9. Disposal Records
10. Maintenance and Monitoring Records (calibration & servicing of equipment)
11. Adverse Events and Incidents
12. Audit Records
13. Archive

6.2.1 Study Information

- Study Title
- Study Reference Numbers (IRAS / NHS REC / HTA Licence
- Location of Facilities
- Chief Investigator / Principal Investigator

6.2.2 Ethical and Research Governance Approvals

Documents required:

- 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.

6.2.3 Risk Assessments

Documents required:

- HTA-Template-Risk Assessment.
- Risk assessment for transport of samples (between campuses or to/from external organisations)
- Other SU RA templates can be found here.

- A project-specific RA should be carried out by a PI or assigned staff member and maintained with reviews as required.
- Risk assessment 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.
- Your records must show evidence of risk assessment review (or planned review).
- Documented contingency plans in case of failure of storage area & equipment, including location of backup storage equipment. Refer to the HTA-Template-Contingency Plan.
- RA should make 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 RAs for the various research lab activities carried out within the project can also be utilised and maintained.

6.2.4 Research Team

- List of members of the research team involved in study activities (Staff and Students) e.g. Delegation Log.

6.2.5 Staff Training

Documents required:

- Records of HTA-specific training e.g. GCP and Human Tissue in Research. Refer to HTA-CORE-SOP-Human Tissue Training.
- 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.

6.2.6 Standard Operating Procedures (CORE SOPs and local project-specific)

The current version of the HTA Core SOPs are available and readily accessible to all staff, students and visiting workers online.

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. All local SOPS should be documented, in plain language and ideally in a standard format to ensure clarity, consistency and accuracy. Where there is more than one approved technique for any given procedure within the organisation, clear records should be kept of which were used.

Local SOPs should address the project-specific handling of samples, such as:

- 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)
- How to record storage temperature. (e.g. T-scan or other)
- How to calibrate or carry out maintenance of relevant equipment if required by staff or students/How to record a calibration/maintenance check.

There should be evidence that SOPs are reviewed regularly (every 6-12 months) and when procedures change, they should be version-controlled and moved to the archive section of your site file in line with the Swansea University HTA-CORE-SOP-SOP.

6.2.7 Consent Records and Patient Information Sheet (PIS)

Documents required:

Blank copies of the latest ethically approved consent forms and associated patient information sheets must be readily available and all previous versions in the archive section of your site file.

The PIS should detail how the material will be used in the study. The participant consent records must be captured and maintained as required for the collection, storage, use and disposal of relevant material.

You must store and maintain all signed consent forms. Signed consent forms should detail:

- 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 that were stipulated during consent.
- Assurances of consent if custody of consent records lies with another organization.

Donor and sample ID link consent forms or other such linked documents (link-anonymised) **MUST be held securely and separately** from any tissue sample log or other sample documents only denoting the sample ID (e.g. pre-forma or questionnaire).

The signed consent or donor and ID-linked documents should only be accessed by authorised personnel. Refer to section *5. Ensuring the Security of Records*.

6.2.7.1 Consent Records for the Re-Use of Relevant Material

Provider of the relevant material for re-use must hold a record of:

- Who the material was released by, when and for what study.
- Whether the material was released anonymously.
- Evidence that the new use of the relevant material is within the original donor consent.
- Any limitations on the use of the material.
- A signed MTA for the transfer of material.

The receiving party of any relevant material must hold a record of:

- If the consent records are held at a different location(s) details of a named contact at the establishment.
- A record of when the material was received and by whom.
- The original Sample ID alongside the new Sample ID should also be available.
- A signed MTA for the transfer of material.
- Evidence 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 e.g. copy of blank consent and PIS or signed document from the provider.
- 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.

6.2.8 Material Transfer

Documents required:

- Name of C/PI responsible for sending and receiving relevant material.
- Evidence of:
    a) HTA licence if transporting relevant material within England, Wales and Northern Ireland.
    b) Or if importing from an NHS Research Scotland (NRS) Biorepository Network evidence of their accreditation by Health Improvement Scotland.
    c) Or if importing from outside the UK a HTA-FORM-Importation Justification form for importing from outside the UK.
    d) Or evidence of an approved NHS-REC covering the transfer to a collaborating organisation.
- A signed copy of all project-related Material Transfer Agreements (MTAs), Service Level Agreements (SLAs), and Organisation Information Document(s) (OIDs) must be recorded and maintained in a site file.

MTAs must be signed by an authorised signatory from Swansea University's Research Engagement & Innovation Services (REIS) Contracts Team. Not by staff or PIs.

- Traceability information relating to samples records must be included in the site file:
    - Addresses from where relevant material was sent from and received.
    - Date of transport including date sent and date arrived if different.
    - ID numbers for samples sent, amount of each sample and type of sample to be sent and kept by the recipient.
    - Utilise a HTA-FORM-Tissue Transfer Record for best practice.
- All courier documentation e.g. invoice, tracking reference and chain of custody records must be retained and kept in the site file.
- 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 *6.2.9 Tissue Disposal*.

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.

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.

6.2.10 Records of Equipment Maintenance

PIs must maintain a record of service inspections and equipment maintenance logs. These records should be retained throughout the study or for the lifetime of the instrument.

If calibration or maintenance of relevant equipment is carried out by research staff or students, local SOPs for their use, calibration and maintenance, together with associated risk assessments, must be documented within the site file.

6.2.10.1 Fridge or Freezer Records

Refer to HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage.
Documents required:

- Documented cleaning and decontamination processes.
- Contingency plans displayed on the storage unit, with name and contact details of the C/PI displayed on the storage equipment. Refer to HTA-Template-Storage Sign.
- Evidence of regular challenges to cold storage alarm system.
- Records of calibration, validation, maintenance and monitoring of equipment used for the project including storage equipment and alarm system.
- Evidence that storage conditions are recorded and monitored, including room temperature storage, e.g. daily temperature log (electronic T-Scan or manual).
- When a freezer is being used for potentially very long-term storage, e.g. in biobanking, data summarised from daily temperature records should be kept for at least the lifetime of the equipment.

- The records of all affected individual samples should be annotated with any temperature deviation beyond 'normal' variance. These details should remain accessible as a component of the sample record, following transfer to a new freezer, for the lifetime of the specimen.

6.2.11 Audit Reports

All records of self-audits, internal audits carried out by the HTGO 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 the HTGO, including where material has been stored and/or used in a way that contravenes the consent.

6.2.12 Adverse events and complaints

PI should complete an Adverse Event Form when necessary, refer to HTA-CORE-SOP-Adverse Event Reporting.

All adverse events and associated corrective and preventative actions must be recorded and added to the site file.

6.2.13 Archiving / Retention

Documents required within the site file:

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

It is a requirement of Swansea University Research Integrity Framework on Research Ethics and Governance that data should be kept for a minimum of 10 years post-study completion.

6.2.14 Disposal of Study Records

The PI must take responsibility for data destruction, and all collected identifiable data will be destroyed at the earliest 10 years post-study completion.

6.2.15 Transfer of Records

When funding for a project ends and there is a potential loss of a leading researcher(s) or if the PI of a study leaves the University, arrangements must be made in advance to support the retention and management of samples and data. This may include the transfer of custodianship to another individual within the department or to another organisation and arrangements should detail provisions for access and eventual destruction.

If there is a transfer of custodianship to another individual within the department or to another organisation, the DI and HTGO should be notified. Transfer of samples to another organisation must be done under a MTA in line with HTA-CORE-SOP-Transportation.

7. Risk Assessment

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

8. 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.

9. 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

Author	**Name and role**	Dr Bethan Rhian Thomas Human Tissue Governance Officer (HTGO)	
	Signature and date	Signed copy held by HTGO	
Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)	
	Signature and date	Signed copy held by HTGO	
Effective Date:	01/04/2024	**Next Review Date:**	08/02/2024