Human Tissue in Research

Standard Operating Procedure for HTA SOPs

1. Purpose

This Standard Operating Procedure (SOP) defines the required format, structure, and governance process for all SOPs within the Human Tissue Authority (HTA) Quality Management System (QMS) at Swansea University.

It defines the procedures required for the creation, approval, implementation, review, revision, distribution, suspension, and archiving of Standard Operating Procedures (SOPs) related to the acquisition, storage, use, or disposal of human tissue under the Human Tissue Act 2004.

It applies to both the HTA Core SOP suite, and any local SOPs developed to support research activities involving relevant material at Swansea University.

2. Scope

This SOP is integral to Swansea University's Quality Management System (QMS) for the governance of human tissue research activities carried out under the HTA research licence.

It applies to:

- All **HTA Core SOPs** are maintained centrally under the University's HTA licence
- Any **local SOPs** developed for **study**- or **collection**-specific procedures involving the acquisition, storage, use, or disposal of **relevant material** under the Human Tissue Act 2004

However, it is considered **good practice** to apply the same standards to **all SOPs** involving human tissue, including those relating to **non-relevant material**.

SOPs should be created wherever a standardised process is required to ensure compliance with regulatory, ethical, and institutional requirements. This includes both generic processes and project-specific procedures directly linked to relevant material.

Local SOPs that relate to relevant material must follow the procedures outlined in this SOP. The format and structure of these SOPs should follow the HTA-TEMPLATE-SOP to ensure consistency, traceability, document control, and change control compliance.

3. Roles and Responsibilities

This SOP applies to all SU staff and students who collect, use or store human tissue for the purpose of research.

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place for the storage of samples for research, and that these processes are adhered to. The DI is responsible for authorising all core HTA SOPs in research in compliance with the HTA requirements.

The Person(s) Designated (PDs) direct 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 Chief / Principal Investigator (CI / PI) is responsible for understanding and following the SU's Core HTA SOPs. They have a responsibility to attend and update HTA-related training as required and ensure a training log of training is maintained.

The Human Tissue Compliance Manager (HTCM) is responsible for drafting, writing and periodic revision of Core HTA SOPs and for ensuring they remain fit for purpose in relation to legislative and regulatory requirements and operational changes.

4. Procedure

All SOPs within the HTA Core SOP suite follow the standardised format defined in this document.

Any additional local SOPs developed to support the acquisition, storage, use, or disposal of relevant material under the Human Tissue Act (2004) must also adopt this format. This ensures that all SOPs — whether core or local — are aligned with Swansea University's Human Tissue Quality Management System (QMS) and inspection-ready for HTA audits.

To ensure this compliance, teams are strongly encouraged to use the ***HTA-Template-SOP*** available on the Human Tissue Governance Teams channel and the Swansea University HTA website.

This standard format includes built-in mechanisms for:

- **Document control** – including the use of unique identifiers and archiving procedures (Section 4.8), allowing SOPs to be tracked, verified as current, and audited when required.

- **Change control** – supported by version tracking, a formal review and amendment process (Section 4.2), and signatory authorisation (Section 4.5), ensuring changes are properly reviewed, approved, and implemented.

If a team chooses to develop an SOP using their own format — for example, in collaborative studies where Swansea University is not the lead organisation, or where an established internal template already exists — they must ensure that **all elements detailed in Appendix A**, and **all procedural requirements described in this SOP**, are fully implemented to comply with document control and change management standards.

4.1 Version Number

All Core HTA SOPs or Local SOPs must have a version number and date to ensure that the current document is in use.

To ensure appropriate change control all SOPs should utilise the following format. Version N.n where N represents a finalised document and n represents draft versions.

When reviewing an SOP, the following procedure for changing version numbers will be used:

- Assign each new, approved and finalised document a major version number e.g., 1.0.
- When taking a document for revision or as a draft, assign a new minor version e.g., 1.1.
- During the review cycle assign each new revision of the draft the next minor version number e.g., 1.2, 1.3 etc.
- Upon approval of the document assign the next major version e.g., 2.0.
- Assign initial pre-approved drafts with version number 0.1 to allow revision and development of the first version to be tracked.

A chronological record of changes and version numbers must be maintained in a table at the end of each SOP.

4.2 Effective date

All Core HTA SOPs will be issued with the date of the next review and approval by the DI and the effective date included on the document. Local SOPs must also be issued with the date of the next review and be approved by the CI / PI.

This information must be displayed in a **Document History Table** within the SOP. This table is located at the end of all CORE HTA SOPs.

4.3 Risk Assessment linked to SOPs

All procedures involving the acquisition, storage, use, and disposal of human tissue must be risk assessed in line with HTA requirements.

A HTA-specific Risk Assessment (RA) must be completed using the HTA-Template-Risk Assessment, which is available online. This template is pre-populated and should be amended by the CI / PI to reflect the specific risks associated with their study or collection. The HTA RA must address risks to the integrity of the human tissue and ensure respect for the donor is maintained throughout the research process.

In addition to the HTA RA, separate biological or laboratory-based risk assessments must also be completed to address risks to staff or students handling the tissue. Multiple RAs may be required depending on the nature of the research activities or analysis performed. These health and safety assessments must comply with Swansea University's Health and Safety Policy and should identify risk reduction measures for each task or process.

All SOPs must reference the RAs by title and ensure these are included or accessible within the project's Master Site File.

4.4 Review and Amendments of SOPs

SOPs are working documents and are subject to regular review. HTA SOPs will be amended in the light of changes to legislation, HTA regulatory requirements and Codes of Practice and other advisory information.

University Core HTA SOPs will be reviewed every two years as a minimum. Individuals involved in tissue use for research may request a revision of Core HTA SOPs at any time if a deficiency or potential improvement is noted. Requests should be made in writing to the HTCM or the DI.

Local SOPs should be reviewed by the research team and approved by the CI / PI. The minimum period between review should be defined when the document is created. Relevant amendments should be made whenever necessary.

4.5 Author and Approval

Swansea University's Core HTA SOPs written for the governance of human tissue in research shall be developed by the HTCM and approved by the DI. Core SOPs will not be deemed effective until approval from the DI has been received. Approval will be considered received upon signature by the DI.

For all Core HTA SOPs, this will be shown in a document history table at the end of each document.

For local SOPs, the author will be primarily responsible for writing and updating a specific research project or tissue collection and this will be approved by the CI/PI. If the CI/PI is the author, the HTCM can review and approve SOPs.

4.6 Distribution of SOPs

Approved current versions of Core HTA SOPs will be available for download on the Human Tissue Governance Teams User Group or the Swansea University HTA website. Whenever the Core SOP suite is updated, a notification will be posted in the Teams channel and on the website.

Researchers working under the HTA human tissue in research licence are responsible for ensuring they are referring to the most current version of each SOP. Once a new version is released, all relevant staff and students must:

- Read the updated SOPs
- Update the study/collection Read & Understood Form.
- If printed and you are maintaining a paper Master Site File, retain copies of previous versions in the Master Site File, clearly **marked as superseded** or moved into an **archive section** of your folder.

Where local SOPs are developed to cover study-specific or collection-specific procedures involving relevant material, the CI/PI is responsible for ensuring these SOPs are distributed to all relevant team members and are included in the project's Master Site File. These local SOPs should be added to the **version control log** and updated as needed.

All team members must be made aware of the latest local SOPs and be able to access the current versions. Read & Understood records should be maintained in line with the procedure for Core SOPs.

4.7 Suspended or Obsolete SOPs

If a Core HTA SOP is suspended or made obsolete, the HTCM will notify relevant individuals by posting in the Teams channel and on the website with the following information as a minimum:

- SOP name, identifier and version number
- Date the SOP was suspended or marked obsolete
- A brief explanation for the change

e.g. ***SUSPENDED as of 15 Oct 2025.*** *Temporary withdrawal pending revision, or permanent withdrawal without replacement*

Local SOPs that are suspended or have become obsolete during the study must be:

- Stored in an **Archive** folder
- Clearly labelled with a **cover sheet** indicating **"SUSPENDED"** or **"OBSOLETE"** and **i**nclude a **short statement** that provides:
    - The date the SOP was suspended or withdrawn
    - The reason for status change (optional but recommended)
    - Whether a replacement SOP is expected

e.g. ***OBSOLETE as of 15 Oct 2025.*** *This SOP has been permanently withdrawn. No replacement is planned.*

4.8 SOP archival

Obsolete Core HTA SOPs will be archived by the HTCM as required.

All local SOPs should be retained and archived for the duration of each research study and for as long as the human tissue continues to be stored. All NHS-REC studies should be retained and archived for 10 years following closure.

Superseded local SOPs should be marked as such or placed in an archived section but not destroyed. Superseded SOPs should be available for inspection during an internal audit or external inspection by the HTA. Further guidance is available in HTA-CORE-SOP-Management of Records.

4.9 Audit

Core HTA SOPs and local SOPs will be subject to an internal audit to assess the effectiveness and compliance with the HTA requirements. All Core and local HTA SOPs will be subject to inspection by the HTA.

5. References

HTA Code of Practice E: Research; Code of Practice and Standards

https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

6. Risk Assessment

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

7. 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.

8. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/2015	Amendment to front page, footer and review period. The appendix was removed to create referenced standalone SOP template. Removal of reference to JSOPG	1.0	Lisa Wakeman
3.0	01/09/2018	Post-licence grant review, an amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18/04/2018	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman
5.0	07/02/2024	New Human Tissue Governance Officer revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forwards.	4.0	Bethan R Thomas & DI
6.0	01/10/25	Revision to clarify the scope and purpose of the SOP. Added clear distinction between HTA Core SOPs and local SOPs. Defined format and structural requirements in Appendix A. Expanded guidance on RAs versioning, distribution, authorship, review, approval, and archiving. Introduced Teams-based communication for SOP updates.	5.0	Bethan R Thomas & DI

Author	**Name and role**	Dr Bethan Rhian Thomas Human Tissue Compliance Manager		
	Signature and date	Signed copy held by HTGO 01/10/2025		
Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)		
	Signature and date	Signed copy held by HTGO 6th October 2025		
Effective Date:	01/09/2026	**Next Review Date:**	01/09/2028	

Appendix A

SOP authors are encouraged to use the HTA-TEMPLATE-SOP, which includes all the below in a pre-formatted structure with guidance.

However, if you choose to use your own template, it must incorporate all elements listed here to meet document control and change management standards, as well as the procedural requirements set out in the above SOP.

1. **Document Title**
2. **Unique Identifier (SOP ID)**

Each SOP should be identified by a unique code. Core HTA SOPs will be identified uniquely using the format HTA-CORE-SOP-Title. *e.g., HTA-CORE-SOP- Standard Operating Procedures.* The unique identifier will be displayed on the front page of each SOP.

3. **Version Number** – Including full version history
4. **Effective Date**
5. **Review Date**
6. **Purpose -**Why the SOP exists and what it seeks to ensure?

Provide a description of the intended purpose of the SOP.

e.g., The purpose of this SOP is to ensure all staff and students are aware of the procedure for handling, documenting, labelling and storage of relevant material collected and stored for the [insert title] study.

7. **Scope** – What is covered and what specific scenario(s) it applies to including any exclusions.

An overview of the standard process being defined within the document, establishing the specific aims it is intended to satisfy, how the SOP meets HT-Act requirements and any exclusions and constraints.

8. **Responsibilities** – Roles and responsibilities relevant to this SOP
9. **Procedure** – Clear, step-by-step instructions for the process

This section details the specific steps to be performed when the task or process the SOP intends to describe is undertaken. For technical SOPs, the instructions in this section should be written as clearly and comprehensively as possible. All abbreviations should be defined on the first usage to aid understanding.

10. **Risk Assessment** – Utilise the HTA-Template-Risk Assessment and Biological Health and Safety Risk Assessments.

To comply with HTA standards, you must complete a Human Tissue Risk Assessment, which specifically considers the risks to the integrity of the tissue and the respect for the donor for your specific study or collection.

All procedures involving the acquisition, storage, use and disposal of human tissue must be risk assessed to comply with HTA requirements.

SOPs describing manual, technical and scientific procedures involving human tissue must be accompanied by a biological risk assessment to ensure that any individual undertaking the process is aware of the possible hazards and understands the steps to be taken to minimise them.

The SOP must reference all related Risk Assessment documents and their titles.

11. **Definitions (if applicable)** – Clarify specific terms or abbreviations
12. **References** – Regulatory guidance, policies, or other SOPs referenced
13. **Review and Amendment History** – Log of any changes and version control
14. **Author and Approver Signatures** – Showing who prepared and who approved