Human Tissue in Research

Standard Operating Procedure for HTA SOPs

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the requirements and procedures for the production, review, approval and distribution of SOPs relating to the acquisition, storage, use and disposal of human bodies, tissues and cells covered by the Human Tissue Act 2004 (HT Act) and as set out in the Human Tissue Authority (HTA) Codes of Practice.

This HTA governance SOP may be used as a template for the development of local SOPs for specific use.

2. Scope

This SOP is integral to the Swansea University (SU) Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples for the Scheduled Purpose of Research as defined in the HT Act.

Organizations which undertake research have a responsibility to ensure the confidence of researchers and the public with regard to the use of human tissue. Under the HTA QMS, all human samples regardless of whether they are from the living or deceased, cellular or acellular or classed as relevant or not under the HT Act should be treated in the same manner in accordance with the obligations and standards set out in the HTA Quality Manual. Refer to the 'HTA Quality Manual' available to download on SU's HTA QMS webpage.

SOPs should be developed wherever there is a need for a standard written procedure. They should be prepared, reviewed, revised, approved and issued as described in this SOP. All core and local human tissue SOPs should be regularly reviewed, version controlled and available for inspection/audit.

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) directs 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 Lead/Principal Investigator 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 Governance Officer (HTGO) 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

Once the need for a standard procedure is identified, an SOP should be written by individuals with the required knowledge and skills to accurately represent the process in question. All local SOPs should be written in accordance with this SOP. Templates are available online. e.g. *HTA-Template-SOP,* this can be tailored as required for local use in specific areas and projects.

4.1 SOP Content:

All SOPs should contain the following information:

- SOP title
- Unique identifier
- Version number
- Effective date
- Chronology of review
- Author
- Signatories of approval
- Total number of pages

4.2 Unique Identifier

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.

4.3 Version Number

All SOPs will be issued with a version number to ensure that the current document is in use. It is good practice to assign a version number to each document using the format 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 will be maintained in a table at the end of each SOP.

4.4 Author and Approval

The author of each SOP should be indicated within the document. For all Core HTA SOPs this will be shown in a table at the end of each document. The author will be primarily responsible for writing and updating the SOP.

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

Local SOPs for specific research projects should be approved by the PI.

4.5 Effective date

All SOPs will be issued with the date of the next review and approval by the DI and the effective date. This information will be displayed in a table at the end of each SOP.

4.6 Purpose

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 preparing, reviewing, and archiving SOPs for compliance with the quality management system and HTA requirements for the management of records in relation to the acquisition, storage, use and disposal of human tissue.

4.7 Scope

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.

4.8 Roles and Responsibilities

This section should identify the main roles and responsibilities of individuals involved in documenting, performing, and supervising an activity detailed in the SOP.

4.9 Procedure

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.

4.9 References

All references related to the development of the SOP and to the principles on which the SOP is based should be documented in this section.

4.10 Risk Assessment

All procedures involving the acquisition, storage, use and disposal of human tissue must be risk assessed to comply with HTA requirements. All risk assessments (RAs) for the acquisition, storage, use and disposal of human tissue, must consider the risks to the integrity of the tissue, the respect for the donor and the safety of the handler.

A RA template with guidance on how to address the risks involved in the acquisition, storage, use and disposal of human tissue for a study involving human tissue is available online, i.e. *HTA-Template-Risk Assessment*.

Additionally, to comply with SU policies all SOPs describing manual, technical and scientific procedures, including those involving human tissue, must also be accompanied by a RA to assess the general health and safety of the personnel carrying out the task or process and detailed steps for risk reduction. This health and safety RA must be performed with consideration of Swansea University's Health and Safety Policy arrangements.

All SOPs must reference all related RA documents and their titles.

4.11 Definitions

This section should be included where an explanation of definitions aids the reader in carrying out the procedure or increases the safety of the procedure described. The definitions listed in each SOP should be concise and applicable to the specific SOP.

4.12 Appendices

Include all information referenced in the SOP text as necessary.

4.13 Review and Amendments

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 HTGO or the DI.

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

4.15 Distribution

Approved current versions of Core SOPs will be available for download on the Swansea University HTA website.

Individuals are responsible for ensuring that they are working with the current version of each SOP. Once a revised version of a Core HTA SOP is available, each individual working under the licence should read the latest version and update the study's ***Read & Understood Form***. Where printed copies of previous versions have been in use, these should be retained and marked as superseded.

4.16 SOP Training

As a minimum training requirement, all individuals working with human tissue are required to:

- Read each Core HTA SOP and document it by using the Read & Understood Form.
- Complete MRC human Tissue in Research and NIIR Good Clinical Practise e-course. These courses must be updated every 3 years as a minimum.
- A study Training log for all staff working with the human tissue and certificate evidence must be available during an internal audit and external HTA inspection.

If required, SOP training can be provided by the HTGO to facilitate a clear understanding of the documented processes related to HTA compliance. Researchers should visit the relevant website regularly to ensure that they are aware of and working on the latest SOPs and guidance documents relevant to their research. Please contact the HTGO for further assistance and advice.

4.17 Suspending an SOP

Should it be deemed necessary to suspend a Core HTA SOP, the HTGO will provide email notification to all relevant individuals with the following information as a minimum:

- SOP name, identifier and version number
- Effective date of suspension
- Brief details of the reason for suspension

4.18 SOP archival

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

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

Superseded SOPs should be marked as such and archived 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.

4.19 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

Author	**Name and role**	Dr Bethan Rhian Thomas Human Tissue Governance Officer	
	Signature and date	Signature held my HTGO	
Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)	
	Signature and date	Signature held my HTGO	
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