Human Tissue in Research

SOP - Human Tissue Training

1. Purpose

This standard operating procedure (SOP) is based on the HTA Codes of Practice and describes the University's training requirements for conducting research using human tissue samples, both new collections and historical.

The ability to conduct high-quality research to the standards expected by regulatory bodies, funders, and other stakeholders requires effective training.

Research using relevant human tissue that is regulated by the Human Tissue Act (HT Act) requires organisations holding a Human Tissue Authority (HTA) license to demonstrate an effective and suitable training infrastructure as part of their quality and governance systems. This training must encompass up-to-date standards set out in the HTA Codes of Practice to ensure compliance with the HT Act.

2. Scope

This SOP applies to all Swansea University (SU) staff and students involved in research projects intending to use human tissue considered relevant material under the HT Act. However, it can be applied to any type of human tissue sample, including material that is not considered relevant under the HT Act, human DNA and RNA, acellular human biological fluid and human-derived cell lines.

All individuals, whether staff, students or visitors to SU, conducting research with human samples on or off-site must follow the requirements set out in this SOP.

3. Roles and Responsibilities

All staff & students working with human samples must ensure that they adhere to this SOP concerning attending and completing the necessary training for their activities. They are personally responsible for ensuring they undertake the required training for the tasks they are performing, including training requirements at the local level.

The Chief / Principal Investigator (CI/PI) or ***student supervisor*** is responsible for identifying training needs for their team and/or students and for ensuring they complete the required training before commencing any human tissue research-related activity.

The Designated Individual (DI) is accountable to the HTA for ensuring compliance with the HT Act. This includes ensuring systems are in place to demonstrate researchers are appropriately trained.

The HTA Sub-Committee is the governing body overseeing this process.

The Persons Designated (PDs) should support the DI to ensure compliance with the Human Tissue Act (2004) and any subsequent amendments, within their local environment by acting as local ambassadors for the Act. They are responsible for supporting the training of individuals who collect, store or use human samples. This includes but is not limited to informing the ***Human Tissue Compliance Manager*** (HTCM) of staff and students who require training.

The HTCM is responsible for keeping the DI informed of any problems or breaches of this SOP regarding training requirements.

4. Procedure

Individual staff members and students working with human tissue should maintain documented evidence of all role-related and HTA-specific training and development covered in this section.

It is the responsibility of the CI/PI to ensure individual training records are managed at a local level using a systematic and planned approach. This can be achieved by creating a study-specific training log (paper or digital).
Please refer to 'HTA SOP Management of Records' and 'HTA-Template-Training Log''.

In addition, all certificates issued following the successful completion of online training courses outlined in this SOP should also be submitted and kept by the HTCM. Documented evidence of individuals' role-specific training should be made available when requested for audit purposes.

5. Training for Human Tissue Research

All individuals must complete the mandatory training below before commencing work with human tissue. Training certificates must be submitted with the relevant Swansea University Ethics or NHS-REC sponsorship application. Work may only begin once training evidence has been received and ethical approval granted.

General Laboratory Training			
Training	***Provider***	***Link***	***Notes***
Statutory and Essential Training	Canvas	https://canvas.swansea.ac.uk/	
Health and Safety Introduction	Canvas	https://canvas.swansea.ac.uk/	
Health, Safety and Sustainability Introduction to Laboratories	Canvas	https://canvas.swansea.ac.uk/	
Laboratory Safety Guidance and Policies	Swansea.ac.uk	Policies & Procedures - Laboratory Safety	
Biological Safety User Training	Scientific Safety Advisor	Health and Safety Team	
Laboratory induction	Local Technician		In-person arranged locally
Read & Understand Local SOPs and Biological Risk Assessments	Supervisor & Local Technician		Before starting any laboratory work
SU's Research Ethics Application Online System	Microsoft Apps	Research Ethics System	Understand how to submit studies for ethics review

Mandatory Training - Human Tissue Research			
Read HTA Codes of Practice: Consent (Code A) & Research (Code E)	Human Tissue Authority	HTA Codes of Practice	Familiarise with core regulatory codes
Good Clinical Practice (GCP)	NIHR	GCP e-Learning Module	Refresher training every 3 years is required
Research and human tissue legislation & Assessment for England, Wales and N. Ireland	MRC	Research & Human Tissue Legislation e-Learning Module	Refresher training every 3 years is required

Specific Consent Training

Informed Consent in Paediatric Research	NIHR	Paediatric Consent e-Learning	*If working with participants <18 years old*
Receiving Informed Consent from Adults Lacking Capacity	NIHR	Consent from Adults Lacking Capacity e-Learning	*If working with adult participants* lacking capacity

HTA inspections routinely review training records; therefore, all individuals continuing to work with human tissue samples are expected to attend refresher training every 3 years. It is the responsibility of the individual to maintain up-to-date training.

Note: Immunisation - Anyone taking or working on unfixed human tissue products should have a Hepatitis B vaccination and a booster every 5 years. Please contact Occupation Health (OH) to arrange; occupational-health@swansea.ac.uk. It is the responsibility of the PI to ensure staff and students are aware of the requirement to have a Hepatitis B vaccination. It is the individual's responsibility to work with blood to organise their vaccination.

5.1 Designated Individual and Person-Designated Training

The DI, HTCM and PDs are all expected to complete the same mandatory training as other SU staff and students.

As senior, named individuals on the University's HTA licence, the DI, HTCM, and PDs must be familiar with the ethical, legal, and governance requirements for research involving human tissue. The DI will have extensive experience in this area and is responsible for ensuring the competence of all staff under the licence. The HTCM and PDs also hold defined responsibilities and are registered on the HTA portal by the DI.

5.2 HTA Quality Manual and Standard Operating Procedures (SOPs)

All individuals using human tissue samples are expected to read, understand and follow the University's Human Tissue Act Quality Manual and the associated HTA SOPs that are relevant to their activities. These can be found on the University Research Governance HTA QMS webpage. Where necessary, individuals should contact their PD or the HTCM for further training and/or clarification of the processes detailed in the SOPs.

6. Associated Document

- Human Tissue Act Quality Manual
- HTA SOP Management of Records

- HTA TEMPLATE - Training Log

7. References

- Health Research Authority (HRA)
- Human Tissue Act 2004
- Human Tissue Authority (HTA)
- HTA Codes of Practice

8. Risk Assessment

A risk assessment 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. Revision History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/15	Amendments to the front page and footer	1.0	Lisa Wakeman
3.0	01/09/16	Post-licence grant review, an 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. Removal/update of redundant links	3.0	Lisa Wakeman
5.0	30/02/2023	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	28/04/2025	Reviewed SOP, reformatted training into a table and updated training requirement for DI, HTCM & PDs	5.0	Bethan R Thomas & DI

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