# 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 Principal Investigator (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 HTA governance officer of staff and students who require training.

***The Human Tissue Governance Officer*** 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 PI or Chief Investigator (CI) to ensure individual training records are managed at a local level using a systematic and planned approach. This may 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 Human Tissue Governance Officer (HTGO). Documented evidence of individuals' role-specific training should be made available when requested for audit purposes.

## 5. Training for Human Tissue Research

### 5.1 General Training

All staff at SU are required to:

- Complete the online Statutory and Essential Training Modules – On Canvas
- Familiarise themselves with all SU Laboratory Safety Guidance and Policies.
- Attend Biological Safety User Training – Contact the Scientific Safety Advisor.
- Read and understand all local SOPs and Biological Risk Assessments
- Ensure you understand how to submit via the SU 'Research Ethics Application' portal that also supports SU sponsorship applications, accessed through your Staff Apps under the name 'Ethics: Applicant, and Healthcare Sponsorship'.

**Note**: If tissues involve NHS staff or patients you will need to submit an IRAS ethical application. Link to NHS "Do I need NHS REC Review?" tool.

### 5.2 Mandatory Training - Human Tissue Research

All SU staff and students undertaking research or supporting research activities (this includes handling, analysis, storage and disposal) involving human tissue ***MUST*** complete the following training.

This includes studies that collect human tissue and process the material to render it acellular (non-relevant)**.**

- Read the HTA Codes of Practice for consent (Code A) & research (Code E).
- Complete the National Institute for Health and Care Research (NIHR) - 'Good Clinical Practice (GCP) module'
- Complete the UKRI Medical Research Council (MRC) e-learning module: 'Research and human tissue legislation' and the accompanying assessment.

Module certificates for the abovementioned modules are required when submitting your study for internal ethical approval or sponsorship applications for NHS-REC approval via the SU Ethics App. Only when evidence of completion of the mandatory training has been submitted and your ethical application reviewed and approved can individuals begin to work with human tissue samples.

- All individuals continuing to work with human tissue samples will be expected to attend refresher training every 3 years*. It is the responsibility of the individual to maintain up-to-date training.*
- NIHR offer a 'Good Clinical Practice (GCP) Refresher' module to those who undertook their GCP module over 3 years ago.
- The updated and or refresher certificate must be submitted to the HTGO.

*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*.

### 5.3 Specific Consent Training

If staff and students are involved in a SU-based study which requires the collection of human tissue, including relevant material, from participants ***under the age of 18*** or with **adults lacking the capacity** to provide informed consent must undertake the following online training course in addition to the aforementioned training.

- NIHR - Informed Consent in Paediatric Research (<18 year of age)
- NIHR - Receiving Informed Consent from Adults Lacking Capacity (including Urgent Public Health Studies)

### 5.4 Designated Individual and Person-Designated Training

In addition to the aforementioned training for all SU staff and students, the DI, HTGO and PDs should also complete the Health Research Authority (HRA) e-learning module: "Research involving human tissue" and the accompanying assessment.

### 5.5 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 HTGO 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 | | | | |
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| **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 |
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