Human Samples in Research Standard Operating Procedure 7
Training

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Revision Chronology:	Effective date:	Reason for change:
HSR SOP 7_V1.02	13 December 2010	Clarification of University policy – QMS applies to all human samples. Creation of the role of Administrative Officer, Deputy DI and changes to the role of PD. Reorganisation of Biological Sciences to form the School of Life Sciences. Revision of requirement to register every three years.
HSR SOP 7_V1.03	10 January 2012	Changes in staff, room numbers and external links.
HSR SOP 7_V1.04	25 February 2015	Changes to University governance structures relating to human samples.
HSR SOP 7_V1.05	TBC	Clarification of University policies and review in preparation for HTA inspection in 2019.
HSR SOP 7_V2.0	TBC	Revisions linked to changing to risk-based approach, change of DI and move to Q-Pulse electronic quality management system.
HSR SOP 7_V2.1	24 February 2024	Links Updated

Training

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand human tissue training requirements including maintaining a Personal Training Portfolio (PTP). Training covers the storage and use of human samples for research, the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System for the governance, acquisition, storage, use and disposal of human samples for research.

2. Background

This SOP forms part of the University's Human Samples in Research Quality Management System (QMS). All research involving human samples at the University of Warwick must comply with this Quality Management System.

The University requires that all human samples defined as relevant material by the HTA and held at the University for Research shall meet the standards of quality management set out in its standard operating procedures. For the avoidance of doubt, this includes any cellular human material, regardless of whether it has current REC approval, unless it is a cell line that has been passaged at least three times. A risk-based approach will be applied.

This SOP has been produced in accordance with the HT Act which came into force on 1 September 2006, and should be read in conjunction with the HTA's *Code of Practice* documents:

Code of Practice A: Guiding principles and the fundamental principle of consent
https://content.hta.gov.uk/sites/default/files/2020-11/Code%20A.pdf
Code of Practice E: Research
https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf

3. Procedure

3.1 Responsibilities

The Registrar (as the Licence Holder's Representative) and the Designated Individual (DI) are responsible for ensuring that appropriate procedures are in place, and that staff and students involved in research using human samples are appropriately trained.

The Principal Investigator (PI) is custodian of the samples. PIs have a responsibility to attend training, (even if they do not work in the lab on a regular basis) and for ensuring that their team members, including visitors who are working on human material, attend training, follow the appropriate procedures, and comply with the University's Human Samples in Research Quality Management System. PIs are also responsible for ensuring that their staff are appropriately qualified and trained for their research roles.

Staff and students working with human tissue are responsible for undertaking human tissue training and following the Standard Operating Procedures. They are also responsible for ensuring the accuracy and completeness of PTPs and flagging their ongoing personal development needs.

Persons Designated (PD) are responsible for attending training, assisting the DI in ensuring human tissue awareness and compliance with the Standard Operating Procedures.

The Head of Department is responsible for ensuring that members of their department are operationally compliant with the processes and procedures for working with human material.

The Human Samples Steering Group (HSSG) is responsible for approving all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the Quality Management System, will require approval by the HSSG.

The University has delegated responsibility for the regular review of HTA SOPs to the Human Tissue Act Designated Individual (HTA DI) and Research Governance Team in Research & Impact Services (R&IS).

The DI has a duty to ensure that all those working on human material are suitably trained. Individuals involved in any aspect of human tissue use should check their training requirements with the University's Research Governance Team at hta@warwick.ac.uk. Staff and students working on human material should:

- register as an individual working with human samples;
- undertake the appropriate training as provided by the University;
- receive and maintain awareness of training support materials;
- have access to advice and guidance;
- understand and adhere to the University's Quality Management System;
- comply with the requirements of the related policies and Standard Operating Procedures (SOPs);
- maintain a Personal Training Portfolio (PTP) to record related training and development activities undertaken (see Appendix 1). The PTP may be held in hard or soft-copy format.

The University will maintain a register of all individuals working with human samples, which will be saved in the 'HTA Master Log' folder in the 'HTA' folder on the M: drive and will be maintained by the Research Governance Team in R&IS. Registration is a requirement irrespective of an individual's experience of working with human samples at the University or elsewhere.

Researchers are required to complete the training as an induction before starting work with human tissue at Warwick and every four years thereafter. Retraining may be required earlier following a significant change to the HT Act, a significant change to the University's Human Samples in Research Quality Management System, or it is deemed appropriate by the DI.

The University's HTA Licence covers not only research activities, but other activities including teaching using human material are also managed through this licence.

Training sessions are open to all staff and students even if they are not directly working with human material.

3.2 Policies

The HT Act applies only to material considered 'relevant' (see hhttps://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004), however, the University of Warwick applies the standards in its Human Samples in Research Quality Management System to the acquisition, storage and use of all human samples. The University has established a risk-based approach with three tiers which covers all types of human material, as follows:

- **Tier 1:** HTA relevant material (defined by HTA at https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials)
- **Tier 2:** Human-derived non-relevant material (such as serum)
- **Tier 3:** Low risk non-relevant material (such as established human cell lines that have been passaged at least three times, samples where there is no possibility of intact human cells being present, breath samples)

Material considered 'relevant' by HTA is always in Tier 1 of the University's Quality Management System. Material not considered relevant by HTA is in Tiers 2 or 3.

3.3 How?

3.3.1 Registration

Registration is an important means by which the DI can identify all those working with human samples and communicate effectively with them, to provide effective training, advice and guidance. Failure to register or attend the appropriate training and briefings may result in a research project being delayed, halted by the University, or in a researcher being unable to undertake research using human samples.

Staff who require access to training should contact hta@warwick.ac.uk. New starters and visitors will be referred to the training coordinator via hta@warwick.ac.uk by the appointing manager or administrative lead when their intention to import or use human material is identified.

Staff and students will be notified of relevant training sessions by the training coordinator in R&IS.

Registration comprises the following steps:

1. Submit a paragraph regarding your proposed use of human material and your relevant background qualifications and any experience using human material to hta@warwick.ac.uk

2. Attend the training session: *Research using Human Samples – Knowing your Responsibilities.* This must be attended prior to any research using human samples. Training sessions run regularly via TEAMS.
3. Complete the Medical Research Council (MRC) e-learning module: *Research and human tissue legislation*, which is free to access and available at: https://bygsystems.net/mrcrsc-lms/course/index.php?categoryid=1
   A copy of the MRC Certificate available on completion of the e-learning module must be sent to the DI and must also be kept in the Personal Training Portfolio.
4. Read HTA Codes of Practice A and E, available at: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation
5. Complete registration by submitting a *Working with Human Samples - Registration of Individual Researchers* Form (see Appendix 2) to hta@warwick.ac.uk for authorisation by the DI. The authorised copy will be returned to the researcher and should be filed in the Personal Training Portfolio. A copy will be held by the DI, for the purposes of audit by the University (see SOP 8 'Audit') and HTA inspection.

The date of registration is taken as the date the researcher attends the training session with the DI (although registration is not complete until the DI has authorised the *Working with Human Samples - Registration of Individual Researchers* Form.).

Additional training sessions and briefings will be notified to registered staff and students and advertised widely in the University as required. Additional information may also be made available through the University's intranet and distributed to those registered users of human samples (e.g. if HTA guidance or legislation changes, existing SOPs are updated or new SOPs developed).

Individuals must also undertake training in laboratory techniques and health and safety policies and procedures, appropriate to their work with human samples.

It is an individual's responsibility to remain up-to-date with training and guidance available in the University and to maintain their competence in this field.

3.3.2 Personal Training Portfolio (PTP)

All individuals working with human samples will establish a Personal Training Portfolio (PTP) folder, as part of the registration process set out in this SOP. They are responsible for maintaining a complete and up-to-date PTP that should be available to their line manager, the DI, Internal Audit or the HTA for inspection.

The PTP will contain the following:

- Training Portfolio Sign-off
- Training Log
- Links to HTA Codes of Practice, for example
- Code A: Guiding Principles and the Fundamental Principle of Consent
- Code E: Research

The following documentation should be added to the PTP folder:

- Registration declaration – signed by the DI;
- Certificate of completion of the MRC e-learning module: Research and human tissue legislation;
- Certificate of attendance at, and the presentation from, the *Human Samples Training Session - Knowing your Responsibilities*.

All additional training documentation and other related information, including, for example, a copy of the University's Quality Manual, SOPs and other HTA Codes of Practice may also be held in the PTP.

4. Advice & Guidance

Further advice on training and registration for research with human samples and the provisions of this SOP may be sought from the DI via hta@warwick.ac.uk. The DI may seek advice directly from the HTA when appropriate.

5. Monitoring and audit

Monitoring and audit of training and this SOP will be undertaken, in accordance with SOP Audit.

List of Abbreviations

HTA	Human Tissue Act/ Authority
DI	Designated Individual
PD	Persons Designated
PI	Principal Investigator
R&IS	Research & Impact Services
SOP	Standard Operating Procedure

Templates/Associated documents

Appendix 1: Cover sheet – Personal Training Portfolio
Appendix 2: Registration of individual researchers

Appendix 1

University of Warwick

Working with Human Samples

Cover Sheet - Personal Training Portfolio (PTP)

All staff and students working with human samples at the University of Warwick must maintain a complete record of their ongoing personal development to demonstrate they are competent to perform duties appropriate to their role in each project.

The responsibility for ensuring the accuracy and completeness of each folder rests with the individual member of staff. Folders may be checked periodically for completeness and should be available for inspection by internal or external parties at all times.

Documents to be filed for personal development and training:

- Induction documentation
  - HTA Code of Practice A – Consent
  - HTA Code of Practice E – Research
  - Certificate of attendance at Session 1 (Knowing your Responsibilities)
  - Certificate of completion of MRC e-learning module (https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1)
- Record of training

Appendix 2

University of Warwick

Working with Human Samples
Registration of individual researchers

The University of Warwick maintains a register of all staff and students working with human samples. Registration requires the researcher to undertake training appropriate to their research needs and to maintain a training programme that demonstrates they are competent to perform duties appropriate to their role in each research project. The responsibility for ongoing personal development rests with the individual researcher.

Name of researcher:……

Email: ……

Job title (or degree if student):……

Employer:……

Location of work:……

Telephone contact:……

Lead Investigator for project:……

Title of project:……

Brief details of work involving human samples

Brief details of any previous experience handling human samples

Declaration of Registration

I believe that I have received adequate information, instruction and training to be able to carry out my work with human tissue safely and in accordance with the Human Tissue Act (2004) and the University's Standard Operating Procedures. I will at all times follow the appropriate instructions I have been given and adopt safe working practices.

I have read/attended and understood the following documents/presentations:

- HTA Code of Practice A: Guiding principles and the fundamental principle of consent
- HTA Code of Practice E: Research
- Briefing Session 1 (Knowing your Responsibilities)
- MRC e-learning module
    - https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation

In the event of any situation arising where I am not sure about the appropriate action to take, I will seek advice before proceeding. Where appropriate, I will bring to the attention of my supervisor and/or Lead Investigator any concerns that I have in relation to my work with human samples. If I still have concerns, or where I am Lead Investigator or Person Responsible, I will notify the Designated Individual.

Name: _____

Signed: _____ Date: _____

Lead Investigator or Person Responsible (where applicable)

I confirm that I accept overall responsibility for the involvement of the above-named individual involving human samples that I am custodian for.

Name: _____

Signed: _____ Date: _____

Confirmation of Registration

I confirm that the above-named individual is registered for working with human samples at the University of Warwick.

Name: Geraldine Hartshorne (Designated Individual, HTA Licence #12297)

Signed: _____ Date: _____

All individuals working with human samples are required to update their registration and training at least every 4 years. This registration will be due for renewal on _____