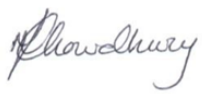
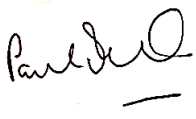
SOP Ref:	UOS_HT_SOP_03
SOP Title:	Training Requirements for Using Human Tissue
Effective Date:	26/06/2023
Preceded by:	*1.0*
Version Number	*2.0*
Review Date:	26/06/2026

Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Ferdousi Chowdhury	Head of RIGO		20.01.2020
Approved By:	David Sampson	Vice-Provost R&I		10/02/2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Paula Huckle	RIGO Manager		07.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The ability to conduct high-quality research to the standards expected by regulatory bodies, funders, and other stakeholders requires comprehensive and effective training. Research using 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 the standards set out in the HTA Codes of Practice to ensure compliance with the HT Act. It is also a requirement to conduct staff training and maintain up-to-date staff training records, including attendance records, inductions for new staff and an assessment of competency.
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.

2 SCOPE

This SOP applies to projects intending to use any type of human sample, including material that is considered relevant under the HT Act; non-relevant human material; human DNA and RNA; human biological fluid; and human-derived cell lines.

All individuals, whether staff, student or visitor, conducting research with human samples under the auspices of the University of Surrey on or off site must follow the requirements set out in this SOP.

3. RESPONSIBILITIES

3.1. The Designated Individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* They are responsible for ensuring that all staff working with human tissue samples are fully trained and follow the University guidance covered in this and the other SOPs.

3.2. The Persons Designated (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for assisting the DI in ensuring that all researchers working with human tissue are fully trained and in giving training in the use of the electronic logging system eLab Inventory.

3.3. The Research Integrity and Governance Office (RIGO) is responsible for delivering the University Mandatory training Session, maintaining the central register of training records and reminding researchers when this mandatory training is due for renewal.

3.4. The principal investigator (PI) is responsible for ensuring that they and all members of their research team are fully trained as outlined in section 4 below before commencing any work with any human tissue and that all samples are fully logged, labelled, used and disposed of in the approved way.

3.5. All individuals working with human tissue are responsible for ensuring that they have read, understand and follow the guidance given in this and other relevant SOPs for all work that they wish to do or support involving human tissue at the University and completed all the training detailed in section 4 of this SOP. They must maintain their own records of training and provide copies to RIGO for their central register.

4. PROCESS

4.1. Training records.

4.1.1 All individuals must keep a personal training log of their role-specific and HTA-related training and attend refresher training every three years.

4.1.2 It is the responsibility of the PI to ensure individual training records are managed at a local level using a systematic and planned approach. This may be achieved through creating a study specific training log (paper and/or electronic).

4.1.3 Documented evidence of role-specific and HTA-related training should be made available when requested for audit purposes.

4.1.4 Copies of all mandatory training certificates should also be sent to RIGO (rigo@surrey.ac.uk) for their central record.

4.2. General mandatory training for everyone: All individuals working with or supporting research involving human tissue samples MUST complete the following two mandatory training courses:

4.2.1. Attend the RIGO run: Use of Human Samples in Research which covers the HTA Codes of Practice for consent (Code A) and research (Code E) and University policies and procedures applicable to all types of human tissue research. The 30-minute session is bookable via RIGO (Rigo@surrey.ac.uk). Following attendance, a certificate of attendance will be provided by RIGO.

4.2.2. Complete the Health Research Authority (HRA) e-learning module: Research Involving Human Tissue ("Module 4" as of April 2023) and accompanying assessment. A pass mark of 80% must be achieved for a certificate to be issued. On successful completion of the assessment, a copy of the certificate should be sent to RIGO (rigo@surrey.ac.uk) as a record of competency.

4.3. Additional mandatory training for those who are taking consent: All individuals involved in taking participant consent or developing the recruitment and informed consent material, including participant consent forms and participant/donor information sheets MUST also complete the two courses below and send a copy of the certificates issued to rigo@surrey.ac.uk as a record of competency.

4.3.1. Global Health Training Centre's Introduction to Informed Consent e-learning module and assessment . A pass mark of 80% must be achieved for a certificate to be issued.

4.3.2. GCP training (https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm).

4.4. Local Lab Induction. Anyone who is working with human tissue samples in a laboratory or clinical area must complete a local induction following FHMS-FOR-136 (Lab induction checklist part B) with a lab manager, PD or other appropriately trained member of staff. Anyone who is unsure who to contact to arrange a lab induction should email HTAlabfacilities@surrey.ac.uk. This training will cover local policies and processes for working in a laboratory environment including:

- Health and Safety (including Control of Substances Hazardous to Health Regulations (COSHH) assessment, good lab practice, chemical and biosafety and disinfection procedures)
- Health and Safety Risk assessments
- Waste management
- Equipment (safe use and training requirements)
- Lone working and out of hours working
- Incident reporting and first aid

4.5. eLab Inventory record keeping training.
Before starting to collect or use any human tissue samples all researchers must obtain a login and attend training on eLab Inventory by contacting HTAlabfacilities@surrey.ac.uk.

This training will include:

- Logging into the system
- System navigation
- Sample storage and adding samples
- Viewing and editing sample details
- Updating the status of samples following use/destruction/transfer to a third party.
- Exporting data
- University expectations on sample labelling and tracking.

[In a few cases where the eLab inventory system does not hold the functionality required for the area (e.g. Surrey CRB), use of excel log sheets stored on a central secure electronic location (e.g. SharePoint) will replace the use of eLab Inventory. Researchers who think that this will apply to their study should still contact the email above to discuss this and to request access to the SharePoint site].

4.6. Standard Operating Procedures (SOPs)

All individuals using human tissue samples are expected to read, understand, acknowledge, and then follow the guidance contained in all the UOS_ HT_ SOPs that they are relevant to their work. These can be found on the RIGO webpage and researchers will also be made copy holders of those considered essential for them to have read via the document management system Q-Pulse. Where necessary, individuals should contact their PD or RIGO for any further training and/or clarification of the processes detailed in the SOPs.

4.7. Commencing Work

Only once all training has been completed and certificates for the courses in 4.2 and 4.3 sent to RIGO 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 three years.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_01-14 RIGO webpage
FOR-136 Lab induction checklist part B

6. REFERENCES

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

7. TRAINING

Individuals involved in research using human samples must read, understand, and follow this SOP.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT act – Human Tissue act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA – Material Transfer Agreement
REC – Research Ethics Committee
UEC – University ethics committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New Document	Ferdousi Chowdhury	21.01.2020
2.0	Major revision	Paula Huckle	07.06.2023