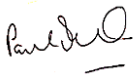
SOP Ref:	UOS_HT_SOP_15
SOP Title:	Change control
Effective Date: **Preceded by:** *1.0 (formerly UOS_HTA_SOP_021)* **Version Number** *2.0* **Review Date:**	

Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Ferdousi Chowdhury	Head of RIGO		31.03.2020
Approved By:	Matthew Purcell	Director of H&S		31.03.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		01.07.2023
RIGO approval:	Gill Fairbairn	Director, Research, Innovation and Impact		26/09/2023
DI approval:	Paul Townsend	DI		28/09/2023

1 INTRODUCTION

The regulations for working with human material are complex and there are several regulations and standards that govern the use of human material including the Human Tissue Act (HT Act), the Human Fertilisation and Embryology Act, the Data Protection Act, the UK Policy Framework for Health and Social Care in addition to other requirements such as health and safety standards. The University monitors these legislations and updates their policies and procedures to ensure continued compliance.

The University has a Human Tissue Authority (HTA) Research Licence and in accordance with this has in place a governance framework to ensure the use of human material for research meets the necessary legislation and ethical and governance standards. This governance framework includes a quality manual and a set of standard operating procedures (SOPs) that set out the procedures that must be followed when researchers intend to use human material for research purposes. It is important that any changes made to the quality manual and SOPs are communicated effectively to the University's researchers.

This SOP describes the change control mechanisms in place for the implementation of new operational procedures and is based on the HTA Code E for Research guidance.

2 SCOPE

All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must follow this SOP in relation to changes to procedures.

This SOP applies to projects intending to use any type of human material including material that is considered relevant by HT Act and any non-relevant human material.

Any project using human material must be registered centrally with the Research Integrity and Governance Office (RIGO) through making an application.

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.* This includes ensuring that appropriate change control methods are in place for updating SOPs and that SOPS are reviewed at least every three years.

3.2. The Persons Designated (PD) *assist the DI in ensuring compliance with HTA standards.* They are responsible for assisting in the SOP review process as directed by the DI and HTROG and for reading any new or revised drafts before they become active and helping to ensure there is an

appropriate change control mechanism in place. They are also responsible for assisting in ensuring that SOPs are read by all those working with human tissue.

3.3. The University's Human Tissue Research Operations Group (HTROG) is the governing body that is responsible for overseeing all human tissue research and is responsible for ensuring that this SOP is implemented and all SOPs are reviewed at least every three years by ensuring that specific members have been allocated documents to review.

3.4. The Principal Investigator (PI), or student supervisor, is responsible for ensuring that all members in their team intending to work with or support research with human tissue have completed mandatory training including the reading of all appropriate SOPS. The PI is also responsible of ensuring any changes to policies and procedures are implemented within their projects.

3.5. Research Integrity and Governance Office (RIGO) is responsible for ensuring all individuals on the central training log are notified of any changes to policies and procedures and for keeping the Designated Individual (DI) informed of any changes to legislation that may require changes to internal policies and procedures.

3.6. All individuals working with human samples are responsible for reading and the Human tissue SOPS relating to their activities before commencing any work and keeping up to date with any new or revised versions that are circulated at a later date.

4 PROCESS

4.1 The governance framework for human tissue research consists of a quality manual and a suite of SOPs. These are considered controlled documents with master word copies held centrally by RIGO.

4.2 SOPs are issued for use as a PDF to ensure they are not adapted by researchers. The PDFs are issued to specific locations by RIGO including the University's RIGO webpage and the Human Tissue Governance SharePoint Site as well as the quality management software system, Q-Pulse, to ensure researchers have access to the latest versions.

4.3 Any printed versions are considered uncontrolled as indicated by the document footer.

4.4 Researchers are directed to the requirements to read the SOPs during the University's mandatory training and as specified in UOS_HT_SOP_03 Training requirements for Using Human Tissue.

4.5 All SOPs will be scheduled for review 3 years from the effective date. A SOP list is accessible to the Human Tissue Research Operations Group which lists the effective and scheduled review date for human tissue SOPs and this group is responsible for allocating the responsibility of performing the 3-yearly review of the SOPS to appropriate members.

4.6 SOPs must be revised earlier if a change to process or correction of an error is needed. This includes any changes suggested as part of a CAPA plan following an adverse event or incident. Minor typographic errors should be corrected at the next review date of the SOP.

4.7 Any changes made must take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.

4.8 The table included in all the SOPS under revision history, must be updated following any revision to include the version number, a brief description of all the changes to the procedure and the effective date of that version.

4.9 The master word copy will be used as the basis for the new version. Any new version will have a 'draft' watermark until approved. Once finalised and ready for issuing, RIGO will change the watermark to 'Approved' and upload to the relevant locations. The superseded word version will be archived by RIGO, changing the watermark of the word document from 'approved' to 'archived'.

4.10 Any new or revised 'draft' SOP will be circulated initially to all PDs for review. Once comments have been received and any necessary changes made, the 'draft' will be sent to a senior member of RIGO and the DI for approval and signature.

4.11 Anyone listed on the central training log held by RIGO will be notified of any updated SOPs and will be required to read and acknowledge these within the Q-pulse system. Any individual not able to access this system should send email confirmation that they have read and understood the SOPs and any updated SOPs to HTAlabfacilities@surrey.ac.uk. Where additional training is required for updated SOPs, the PDs will contact researchers and arrange this.

5 ASSOCIATED DOCUMENTS

UOS_HTA_SOP_003 Training requirements for Using Human Tissue
Research Integrity and Governance Office:
https://surreynet.surrey.ac.uk/academicservices/research-and-innovation-services/research-integrity-and-governance-office

6 REFERENCES

Human Tissue Act: https://www.hta.gov.uk/policies/human-tissue-act-2004
Human Tissue Authority main website: https://www.hta.gov.uk/
Human Tissue Authority Codes of Practice and Standards:
https://www.hta.gov.uk/htacodes-practice-and-standards-0

7 TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue. They must also complete any additional training where required for updated policies and procedures.

8. USEFUL TERMS

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	31.03.2020
2.0	Formatting and numbering changes, for consistency with other SOPs and small changes to content.	Linda McLatchie	01.07.2023