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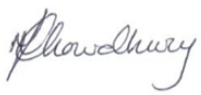
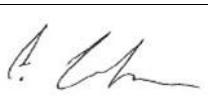
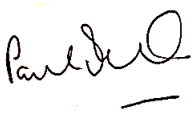
Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Ferdousi Chowdhury	Head of RIGO		06.02.2020
Approved By:	David Sampson	Vice-Provost R&I		10.02.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Paula Huckle	RIGO Manager		07.06.2023
RIGO approval:	Gill Fairbairn	Interim Director, R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The University of Surrey (the University) supports research involving the use of human tissue samples and provides an internal governance framework to ensure researchers conduct their work in accordance with legislative and ethical standards.

This quality manual sets out the University's internal governance and operational framework for research involving human tissue samples.

The Human Tissue Act 2004 (HT Act) applies to England, Wales, and Northern Ireland and came into force on 1st September 2006. The HT Act provides the legislative framework for the removal, storage and use of human organs and tissue from the living and the deceased for scheduled purposes, which includes research.

Human tissue that is regulated by the HT Act is termed 'relevant material'. Relevant material is considered as 'material, other than gametes, which consists of or includes human cells. According to the HTA, the fundamental guideline in determining relevant material is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material.

The Human Tissue Authority (HTA) is responsible for regulating the activities under the HT Act through licensing premises, providing Codes of Conduct and guidance, and conducting inspections of premises. Human tissue samples considered as relevant material can only be stored and used for research purposes if held under an HTA licence or, alternatively, with approval from an NHS Research Ethics Committee (NHS REC).

Other standards and regulations may apply to human tissue samples that are considered non-relevant material. For example, the HT Act sets out provisions regarding the analysis of DNA and the use of gametes for research must adhere to the Human Fertilisation and Embryology Act which is regulated by the Human Fertilisation and Embryology Authority.

It is therefore important that the University has a governance infrastructure in place to assess the use of all human tissue samples to ensure compliance with the relevant regulations and standards. The standard operating procedures (SOPs) listed within this quality manual form part of the governance infrastructure and provide instructions on the University processes. SOPs and associated forms can be accessed via the Research Integrity and Governance Office (RIGO) webpage.

2. SCOPE

This quality manual and associated documents apply to all University of Surrey staff, students and visitors when acquiring, storing, using and disposing of human tissue samples for research purposes under the auspices of the University on or off site. Researchers must abide by the processes set out in these documents and co-operate with audits as required.

For the purpose of this quality manual, human tissue sample refers to any type of human material, including material that is considered relevant by the Human Tissue Act; nonrelevant human material; human DNA and RNA; human biological fluid and human-derived cell lines. This includes, but is not limited to, blood or blood derivatives (plasma, serum, buffy coat etc.), blood spots, cytospins, bodily excretions such as urine and faeces, saliva, tissue blocks, sections or slides, fresh frozen or fresh tissue samples and fixed samples (formalin, glutaraldehyde etc).

This SOP does not apply if you are receiving established cell lines from a source that can be verified (e.g., from a reputable commercial supplier or collaborator, where the provenance of the cell lines can be demonstrated to be in line with the original consent of the primary material) but does apply if you are generating cell lines directly from a primary source.

If in doubt as to whether the type of sample(s) being used falls under the requirements of this quality manual, individuals should contact Rigo@surrey.ac.uk.

3. RESPONSIBILITIES

3.1 Corporate License Holder Contact (CLHc) *is a nominated contact for the organisation, in a position of sufficient seniority to change the Designated Individual (DI) if required.*

3.2. 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.*

3.3 The Persons Designated (PD) *assist the DI in ensuring compliance with HTA standards*. The University of Surrey has at least five PDS; a hub PD, and four satellite site PDs. See 5 below for details of the licensed sites. Details of the PDs can be found on the University webpage.

3.4. The University's Human Tissue Research Operations Group (HTROG) is the governing body that is responsible for correct implementation of this and associated SOPs to ensure researchers are compliant with policies, procedures, relevant ethical and professional standards and statutory or regulatory requirements. This encompasses all aspects of acquisition, storage, use and disposal of human tissue at the University of Surrey, including samples held under the HTA licence, samples held under NHS-REC approval and any human material falling outside the scope of the HTA licence and NHS-REC approval. The University Biological Safety Officer, as a member of the HTROG, is responsible for ensuring all health and safety matters are identified and that any risks are mitigated. The HTROG reports formally to the Research Integrity and Governance Committee and the DI via the hub PD and the Head of RIGO.

3.5. Research Integrity and Governance Office (RIGO) is responsible for overseeing the governance infrastructure supporting human tissue research. This includes reviewing applications for the use of human tissue, maintaining a register of all research projects using human tissue, maintaining central records for training, risk assessments, incidents, adverse

events or deviations. RIGO is also responsible for supporting the University Ethics Committee and the ethics review process

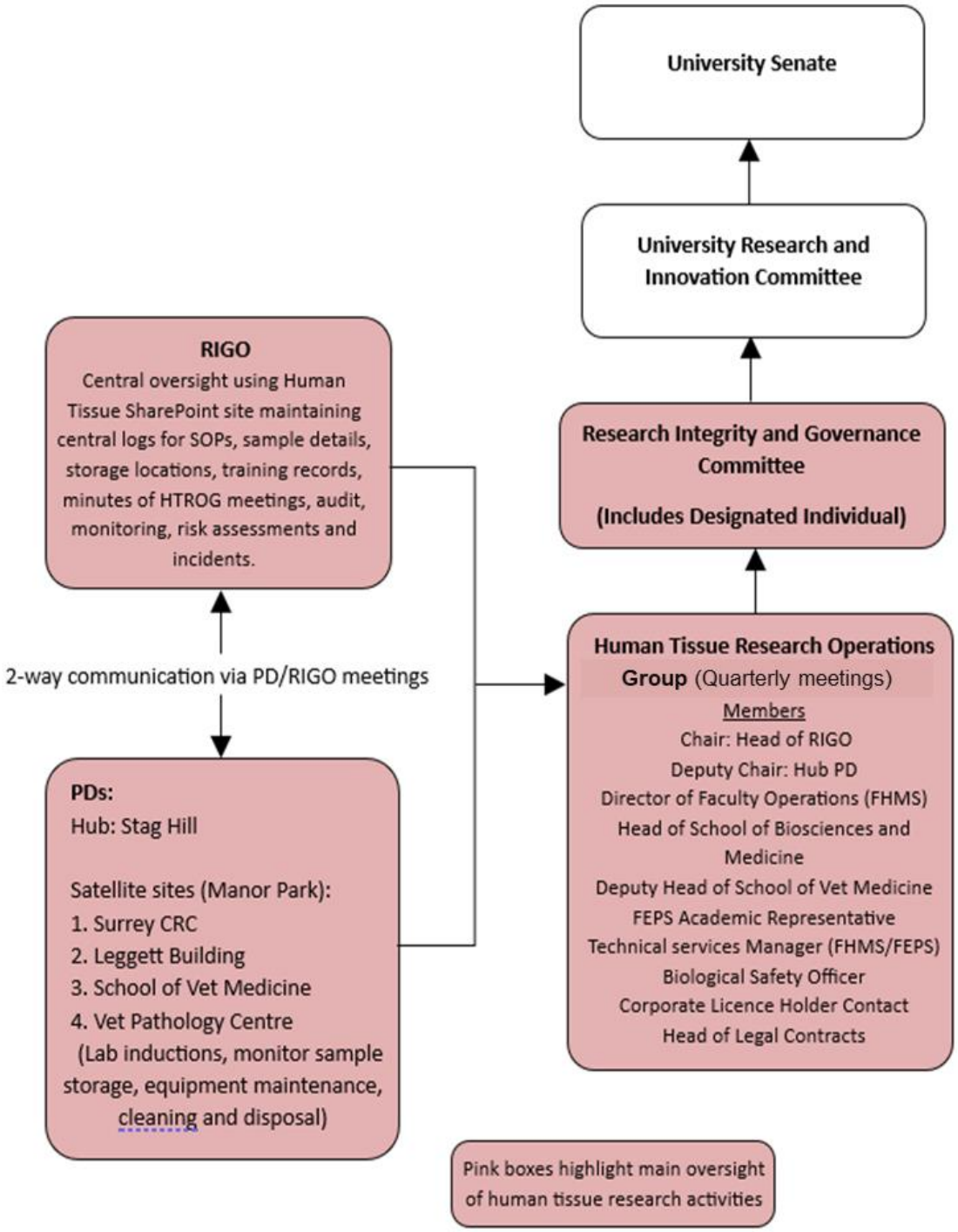
3.6. The research Contracts Team are responsible for drawing up, negotiating and signing legal agreements related to the use of human tissue, such as material transfer agreements (MTAs) and equivalent documents including service agreements from commercial suppliers.

3.7. The Principal Investigator (PI), or student supervisor, is responsible for ensuring that they and their team/students perform research with human samples in accordance with the required standards. They are responsible for ensuring studies conducted under the auspices of the University using human tissue samples do not commence until they have received all the necessary approvals and are registered centrally with RIGO through completion of a Human Tissue Governance Application Form which should be submitted as part of an ethics and governance application (details of the processes can be found in the SOPs listed within this manual).

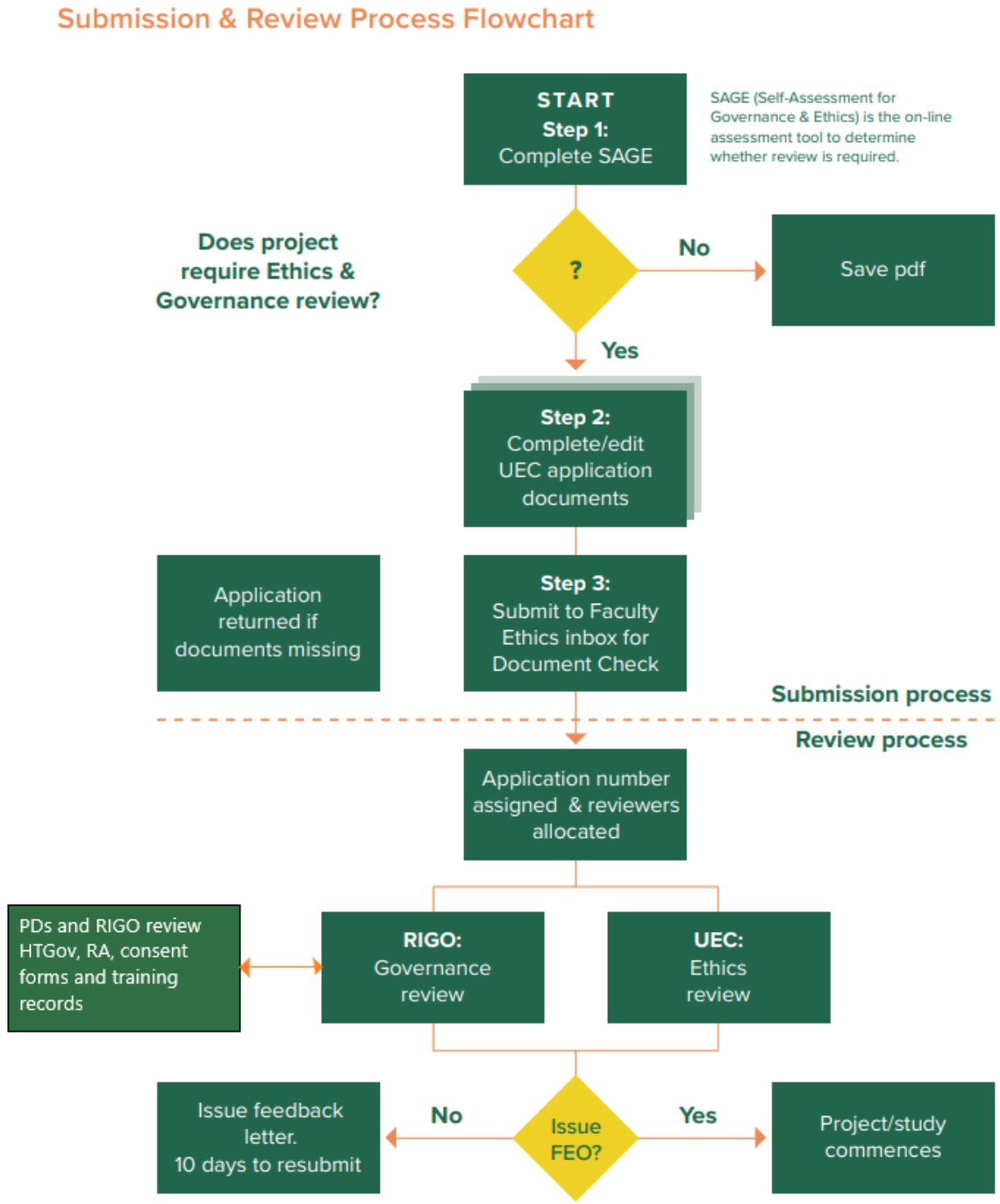
3.8. All individuals working with human samples are responsible for ensuring they follow policies and procedures relevant to their research and for reporting any incidents, adverse events or deviations to the PD for their site and to RIGO. All individuals are responsible for ensuring they complete the required training (UOS_HT_SOP_03) to demonstrate they understand their responsibilities and can conduct their activities compliantly and to the required standard. All individuals must be co-operative during audits and monitoring exercises.

4. GOVERNANCE STRUCTURE

4.1. Human Tissue Research governance and oversight structure



4.2. Application flow chart



4.3. HTA Licence Details

The University holds a HTA license for 'storage of relevant material which has come from a human body for use for a scheduled purpose.'

- University of Surrey HTA licensing number 12365.
- License Holder: University of Surrey
- Licensed Premises: University of Surrey
- The establishment has been licensed since September 2007.

All human tissue samples must be declared through application via the RIGO. Undeclared samples will not be considered as being held under the license. The hub (Stag Hill: main site under the license) consists of the Faculty of Health and Medical Sciences (FHMS) and the Faculty of Engineering and Physical Sciences (FEPS).

There are four satellite sites at Manor Park Campus registered under the license:

· the Leggett Building (since September 2007);
· the Surrey Clinical Research Centre (SCRC, since September 2007);
· the School of Veterinary Medicine (since March 2019); and
· the Veterinary Pathology Centre in the School of Veterinary Medicine (since October 2016).

4.4. Standard Operating Procedures

The following list of standard operating procedures covers the full life cycle of human tissue research including acquisition, storage, use and disposal. The SOPs are available on the RIGO webpage and via Q-Pulse. Individuals should read and acknowledge any SOPs assigned to them via Q-Pulse and make sure they have understood and follow the processes described. Training needs will be identified by the PDs/RIGO at the point of review of applications to use human tissue and followed up before any work on human tissue samples can begin.

SOP Number	Topic
UOS_HT_SOP_01	Quality Manual: Human tissue in research: acquisition, storage, use and disposal
UOS_HT_SOP_02	Applying to use human tissue in research
UOS_HT_SOP_03	Training requirements for using human tissue
UOS_HT_SOP_04	Internal audits of HTA licensable activities
UOS_HT_SOP_05	Consent and withdrawal of consent for using human tissue in research
UOS_HT_SOP_06	Collection of human tissue from participants
UOS_HT_SOP_07	Transfer of human tissue into or out of the University including import and export
UOS_HT_SOP_08	Transportation of human tissue
UOS_HT_SOP_09	Human tissue records management
UOS_HT_SOP_10	Human tissue labelling, storage, and tracking
UOS_HT_SOP_11	Human Tissue, adverse event and incident reporting
UOS_HT_SOP_12	Maintenance and monitoring of human tissue storage areas
UOS_HT_SOP_13	Disposal of human tissue samples
UOS_HT_SOP_14	Continued storage of human tissue samples after the end of a study
UOS_HT_SOP_15	Change control

4.5. Central Oversight

RIGO is responsible for maintaining central oversight of human tissue research activities on behalf of the DI. This includes maintaining the following records on a dedicated secure, controlled-access Human Tissue Governance SharePoint site only accessible to the PDs and members of RIGO:

- Agenda and Minutes of HTROG meetings;
- Standard operating procedures and associated forms;
- Applications for the use of human tissue samples;
- Register of research projects using human tissue (including those that store samples under the HTA licence, under REC approval or under other approvals or exemptions);

· Register of training records for individuals using human samples for research;
· Audit records;
· Monitoring records (progress reports and end of study reports);
· Incident, adverse event and deviation records;
· List of storage areas for HTA relevant material; and
· Risk assessments.

RIGO meets regularly with the hub PD to ensure the above records are correct and up to date.

4.6 Monitoring and Audit

4.6.1. All human tissue research will be subject to internal and external monitoring and audit of activities to ensure the processes set out in the SOPs are being followed and that the expected standards are being achieved. A schedule for internal monitoring and auditing will be overseen by RIGO.

4.6.2. Internal monitoring will require all PIs to:
· Provide up-to-date logs of samples when requested or through eLab Inventory
· Provide an end-of-study report regarding remaining samples and whether these will be, destroyed, sent to a third party of an application put in for future storage

4.6.3. Internal auditing will follow the four areas covered by the HTA's licencing standards: Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment

4.6.4. External audits and inspections conducted by external bodies, such as the HTA, will be supported by RIGO and the PDs under the direction of the DI.

4.6.5. Any shortfalls and non-compliance identified by the audits, whether internal or external, will result in a corrective action and preventative action plan (CAPA) and the HTROG will be responsible for ensuring that the actions are completed in a timely manner. Samples will, where necessary be placed under quarantine to prevent their further use until the required actions are completed.

4.6.6 All staff, students and visitors using human tissue samples for research purposes under the auspices of the University, whether on or off site, will be required to cooperate and make themselves available as required for audits.

4.7 Concerns and Issues

Any concerns in relation to the storage and use of human tissue should be referred to the PDs and RIGO and any adverse events or incidents reported using the AE/I reporting form. Details of the issue and any recommended actions will be compiled by RIGO or the PDs for consideration by the DI. It is ultimately the DI who will determine what action, if any, needs to be taken and to determine whether the issue falls under the University's Code of Conduct on Handling Allegations of Research. RIGO will be responsible for maintaining a log.

5. REFERENCES

Health Research Authority: https://www.hra.nhs.uk/ Human Fertilisation and Embryology Authority: https://www.hfea.gov.uk/ 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

6. USEFUL ABBREVIATIONS

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

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.

8. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document	Ferdousi Chowahury	06.02.2020
2.0	Conversion from QM to SOP	Paula Huckle	07.06.2023