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SOP Title:	Applying to Use Human Tissue in Research
Effective Date:	26/06/2023
Preceded by:	*1.0*
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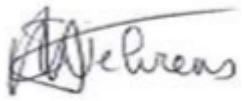
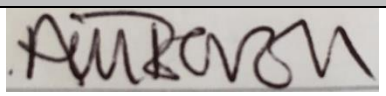
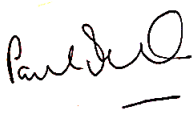
Review Date:	26/06/2026

Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Sophie Wehrens	RIGO Officer		17/12/2019
Approved By:	Ferdousi Chowdhury	Head of RIGO		17/12/2019
Version 2.0	Name	Role	Signature	Date
Revised by:	Marie Bovell	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 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 the common law for consent, material transfer agreements, transportation prohibitions and health and safety standards. The University therefore has in place a governance framework to ensure the use of human material for research is in accordance with the necessary legislation and meets ethical and governance standards.

This governance framework complements the Ethics for Teaching and Research Policy, and the Ethical and Governance reviews undertaken by the University Ethics Committee (UEC) and Research Integrity and Governance Office (RIGO). This SOP describes how to apply for approval to use human tissue in your project and should be read alongside the Ethics Guide

2. SCOPE

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

All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must comply with this SOP and apply for use before commencing their project, this includes for the use of samples in method development or when providing a service e.g. pathology or sample analysis.

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.* They are responsible for ensuring that conditions of the license are complied with by all those who are working with human material.

3.2. The Persons Designate (PD) *assist DIs 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 supporting and directing those wishing to work with human tissue to ensure that they follow the guidance within this SOP.

3.3. The Research Integrity and governance Office (RIGO) are responsible issuing Favourable Ethical Opinion on behalf of the UEC and acting as Sponsor on behalf of the University. RIGO maintain records of all ethics and governance applications including documents specifically relating to the use human tissue.

3.4. The Principal Investigator (PI) is responsible for ensuring all required approvals are in place before commencing research.

3.5. **All individuals working with human tissue** and material must ensure that they adhere to this SOP. It is the responsibility of all individuals to report any problems or concerns in relation to collection of tissues to the Person Designated (PD) and the Research Integrity and Governance Office (RIGO).

4. PROCESS

4.1. The Principal Investigator (PI) for a study, must apply for an ethics review, either through the University Ethics Committee or the NHS Research Ethics Committees.

4.2. As part of the UEC submission or their application for the University to Sponsor NHS research, the PI must submit a Human Tissue Governance application form (HTGov AF) using the template found on the RIGO website and a Human Tissue Risk Assessment (see section 5) together with the study protocol and the other documents listed in table 1 in the column that most closely matches the source of their samples and type of study.

New ethics/governance application				Collaborating as part of a study that has ethics review at another institution
Samples collected for this study		Samples collected as part of a previous study	Samples obtained from a biobank/commercial source	
Samples from non-NHS patients	Samples from NHS patients			
SAGE & EGA	IRAS	SAGE & EGA	SAGE & EGA	SAGE & EGA
Protocol	Protocol	Protocol	Protocol	Protocol
Participant consent form (blank)	Participant consent form (blank)	Participant consent form (blank)		Participant consent form (blank)
		Confirmation that the donor for each sample gave consent for future use	Confirmation that the donor for each sample gave consent for future use	
Participant information sheet	Participant information sheet			Participant information sheet
Participant recruitment material	Participant recruitment material			
HTGov Form	HTGov Form	HTGov Form	HTGov Form	HTGov Form
Risk assessment	Risk assessment	Risk assessment	Risk assessment	Risk assessment
MTA (if samples not collected at UoS)	OID (including MTA)	MTA (if samples not held at Surrey)	MTA / agreement with commercial provider	MTA
				Collaboration Agreement

Figure 1: Documents required for ethics and/or Governance review and application for sponsorship of NHS research. Additional documents may also be requested depending on the individual study protocol, but these represent the minimum documents required.

4.3. As part of the Governance review a member of RIGO and other appropriate persons will review the HTGov AF and Human Tissue RA to ensure the proposed work complies with the HT Act and in accordance with the HTA Codes of Practice and any other appropriate (legal) frameworks.

4.4. The review considers all the documentation that has been submitted and includes but is not limited to:

- Detailed information on the human material being used
- Consenting and withdrawal process
- Researcher status of training in human tissue research including consent
- Understanding and implementation of the relevant SOPs and other instructions
- Suitability of the premises, facilities and equipment
- Sample tracking and accountability
- Arrangements for transfer/destruction of material on completion of research
- Risk assessments

4.5. The PI must address all queries raised during the review process before any approval to commence can be given by RIGO and/or ethics committee.

4.6. Once all queries have been addressed and all the requirements have been met a 'Favourable Ethical Opinion' (UEC) or a 'Letter of Sponsorship' (NHS) will be issues.

4.7. Researchers must not buy, receive, collect, or use any tissue before they have received either the UEC FEO or the HRA and/or NHS approval and the letter of sponsorship for NHS research and all members of the research team have completed training as detailed in UOS_HT_SOP_03. The whole process and steps that must be followed are summarised in the flow chart in appendix 1 and the submission and review process in appendix 2.

5. HUMAN TISSUE RISK ASSESSMENT

5.1. All researchers must carry out a Human Tissue Risk assessment (RA) to identify the potential risks to their samples and submit this document as part of the application to either the UEC or for sponsorship of NHS research. This is in addition to any data risk assessment requested.

5.2. A Human Tissue RA template; UOS_RIGO_template_012_human tissue risk assessment, is available on the RIGO website, https://research.surrey.ac.uk/ethics already populated with a set of potential risks. For each risk the PI should assess the likelihood and severity with the existing control measures in place and determine if the residual risk is; not significant, low, medium or high. They should then determine whether further action is required to reduce the risk further.

5.3. These risks cover:

- Consent and withdrawal of consent
- Sample Integrity (damage or loss of tissue due to storage conditions)
- Traceability (loss of tissue due to poor traceability in storage or transit)
- Security (access to samples or associated documentation such as consent forms)
- Disposal (maintaining disposal records and health safety requirements)
- Transport

5.4. The researcher should add any additional risks they perceive to their specific samples at the end of the form and assess these in the same way.

5.5. The Human Tissue RA must be signed by the person filling it in. Where this person is an undergraduate/postgraduate taught or PhD student or early career researcher (ECR) the form should be additionally countersigned by their supervisor.

5.6. When a high residual risk is identified within the assessment the form will be reviewed by the University's Human Research Operations group (HTROG).

5.7. The RA must be reviewed immediately after an incident and at least every 3 years by the researcher to ensure it is still fit for purpose. If any changes to the RA are required, these must be reported to RIGO immediately and a new updated RA provided.

5.8. The researcher is also responsible for ensuring that they have in place suitable H&S risk assessments covering the methods they will be using for working with their samples. These should cover risks to the worker rather than the samples and should be discussed and reviewed by the local H&S advisor but are not reviewed as part of the application to use human tissue.

6. OBTAINING SAMPLES FROM COMMERCIAL SOURCES

6.1. Before obtaining Human Tissue from an external commercial supplier the researcher must check that the consent form used by the company covers use of the samples in research. A blank copy of the consent form used should also be requested and stored in the study documents folder as detailed in UOS_HT_SOP_09.

6.2. The researcher should check if there is a framework agreement in place or whether the supplier is on the list of the University's preferred, approved or punch-out suppliers provided on the internal Procurement webpages. This should be done in line with the Purchasing Policy and Procurement Manual. Any questions relating to approved or preferred suppliers and how to purchase must be directed to the Procurement team.

6.3. Where a supplier is not listed and a listed suppler cannot be used instead a request to add the company should be made by completing the New Suppliers Form via the Procurement webpages.

6.4. The researcher should contact the Research Contracts team as detailed in UOS_HTA_SOP_07, to check whether an MTA or other agreement needs to be in place prior to receipt of the tissue and ask them to check and sign the commercial agreement. Researchers must not under any circumstances sign the commercial agreement themselves.

6.5. The commercial agreement and MTA or equivalent document when required should be submitted as part of the application to the UEC.

6.6. No order should be placed until the researcher has received a 'Favourable Ethical Opinion' (UEC) letter.

7. ASSOCIATED DOCUMENTS

UOS_RIGO_Template_10 Human Tissue Governance Application Form V1.0
UOS_RIGO_template_012 Human Tissue Risk Assessment Form V1.0
Ethics for Teaching and Research Policy
Ethics Guide

8. REFERENCES

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

9. 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.

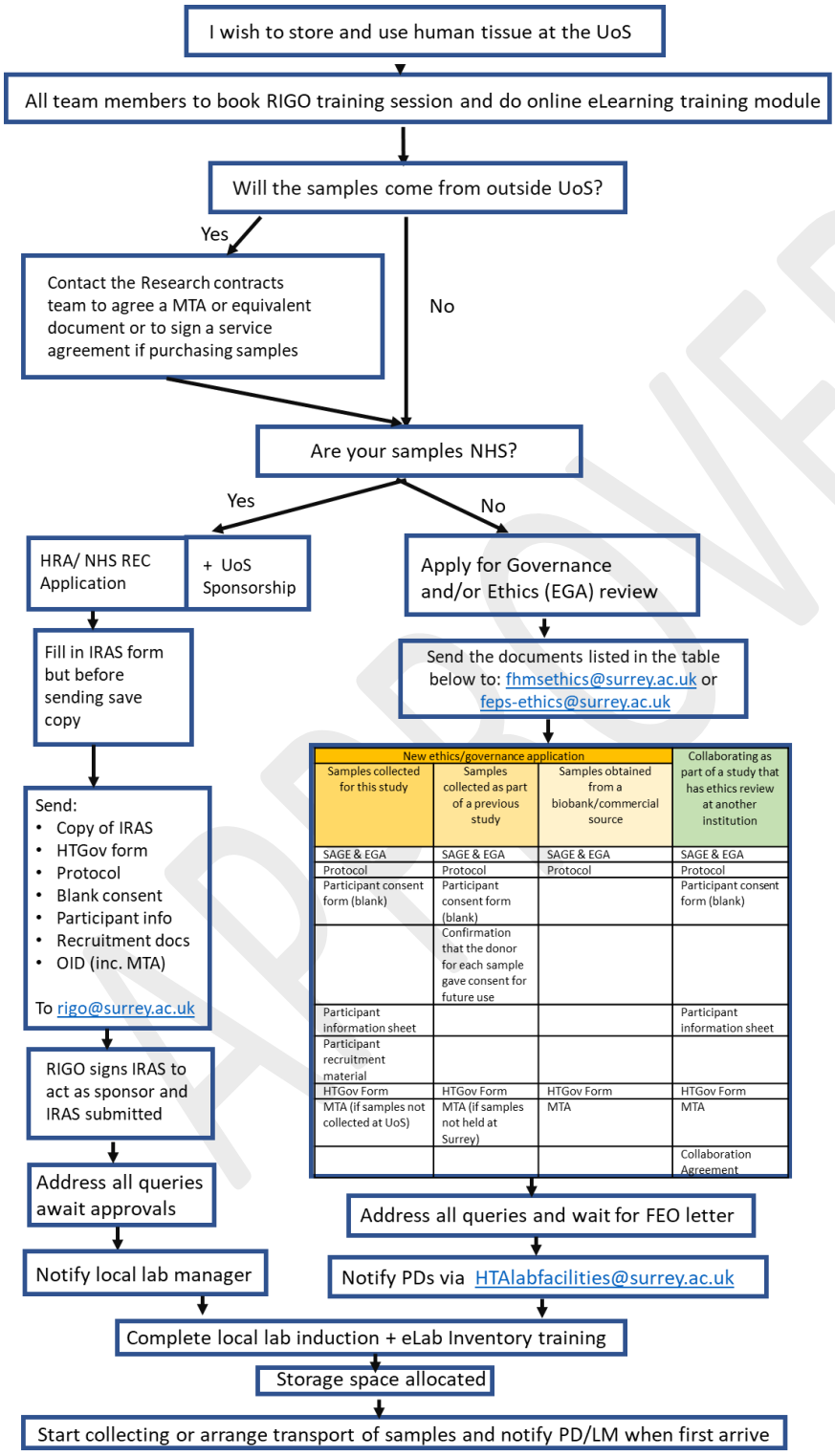
10. USEFUL ABBREVIATIONS

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

11. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document	Sophie Wehrens	17.12.2019
2.0	Major revision Combining UOS_HTA_SOP 001,002&008 into a single document, UOS_HT_SOP_02	Marie Bovell	07.06.2023

Appendix 1: Summary of steps in applying to use human tissue.



New ethics/governance application			
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Participant consent form (blank)	Participant consent form (blank)		Participant consent form (blank)
	Confirmation that the donor for each sample gave consent for future use		
Participant information sheet			Participant information sheet
Participant recruitment material			
HTGov Form	HTGov Form	HTGov Form	HTGov Form
MTA (if samples not collected at UoS)	MTA (if samples not held at Surrey)	MTA	MTA
			Collaboration Agreement

Appendix 2: Submission and review process flowchart