UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1006 UoL

University of Leicester Ethics Projects (UEIC) HTA Samples

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

Ethical Committee approval is required to safeguard researchers conducting research studies and to protect the rights, safety, dignity and well-being of research participants. Ethical approval facilitates and promotes ethical research that is potentially beneficial to participants, scientific knowledge and understanding. It ensures that research is conducted to a high ethical standard, with integrity and in accordance with good research governance and legal requirements.

All studies that involve human participants, their tissue, and/or their data, are required to obtain a positive opinion from an appropriate research ethics committee (REC). The majority of medical and social care research will fall under the NHS Governance Arrangements for Research Ethics Committees. Where research involves patients or their identifiable data, approval by the Health Research Authority (HRA) and an NHS REC is required. Other projects concerning human participants or their samples (for example healthy volunteers recruited from staff and students and human samples from other sources) might not fall under the remit of an NHS REC but must still be approved in accordance with the University's Code of Practice (CoP) for Research. Ethics approval must always be sought before the project begins.

This SOP should be read in conjunction with the University of Leicester (UoL) Research Ethics Policy and the *Research Code of Conduct*, which sets out the University's commitment to research integrity.

2.0 Purpose and scope

The purpose of this SOP is to ensure that HTA-relevant material that is collected from UoL staff and students through the University of Leicester Ethics and Integrity Committee (UEIC) are reported under the UoL HTA Research Licence 12384, this includes imported samples.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HTA	Human Tissue Authority
ICF	Informed Consent Form
NHS	National Health Service
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
RGO	Research Governance Office
SOP	Standard Operating Procedure
UEIC	University of Leicester Ethics and Integrity Committee
UKECA	United Kingdom Ethics Committee Authority
UoL	University of Leicester

Where samples are coming to UoL as part of a UEIC approved project. Any applicable agreements should be filed within the local PD Masterfile folder for inspection purposes.

3.0 Procedure

Human biological samples collected as part of a study with an active favourable opinion from an HTA-recognised REC does not require reporting under the remit of the UoL HTA Research Licence.

For the purposes of the Human Tissue Act, recognised RECs include RECs within the Research Ethics Service of the all four UK countries i.e., any ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA) under the Clinical Trials Regulations or any Research Ethics Committee (REC) recognised by the health departments in England, Wales or Northern Ireland to advise on the ethics of research involving Human Tissue (NHS RECs).

All research approvals are obtained through the Research Management System. These include UEIC approvals. This procedure must be followed for all research projects which collect HTA-relevant or non-relevant human material that does not meet the requirement for review by an NHS REC. Any material that is to be stored for longer than 7 days must be declared on the PD tissue register so that all relevant material is accounted for. This is because HTA-relevant material collected through UEIC-approved projects are not exempt from being reported on the licence, whereas projects with NHS REC ethics are exempt.

Where samples are coming into UoL for UoL ethics projects, it's the HTA Monitor's responsibility to request and review participant Information Sheets (PIS) and Consent forms that were used to obtain the samples. This is to ensure the appropriate due diligence is undertaken on the documentation, in addition, to ensuring the samples will be used within the terms of consent that they were collected with. Please see the full list of relevant and non-relevant samples on the HTA website.

Please refer to HTA-A1005-UoL if samples are being imported from outside England Wales and Northern Ireland.

3.1 Application

HTA-relevant material collected with approval from a non-recognised REC (e.g., UEIC) must be stored under the UoL HTA Research Licence. The researcher must therefore complete UoLHTAISA001 (Appendix 1 to HTA-A1005-UoL) and return this to HTAenquiries@leicester.ac.uk for assessment by the HTA Monitor and the DI before the study commences.

This application can be completed in conjunction with applying for your UoL ethics approvals. If the application is not completed in conjunction with the ethical approval, the application must be submitted before the collection of samples can commence.

3.2 HTA Compliance visit

If the area being proposed for the storage of HTA-relevant material is a new area, the HTA Monitor and the DI for the HTA Research Licence will visit the area to ensure that

the premises are suitable for the activities as authorised by the licence (if applicable) and in keeping with the HTA Codes of Practice.

3.3 Sample Collection and Consent

Where samples are being collected from any UoL staff and students on UoL premises e.g., blood samples, throat swabs, urine etc. they should only be collected in rooms which meet the relevant criteria for infection prevention and control. For advice and guidance contact *Health and Safety Services*.

It is a HTA requirement that all samples are obtained with informed consent from the donor. Informed consent can only be taken by individuals that have up to date *informed consent training*. Individuals without up-to-date training will not be able to take informed consent for the research project until this training is completed. In addition, the individual taking consent should be aware of any issues posed by the specific study or studies for which samples are being collected, and ideally independent of the study/laboratory.

The individuals obtaining the samples must be appropriately trained, and all relevant vaccinations for working in laboratories must be up-to-date.

3.4 Due Diligence

For samples being brought onto UoL premises (this includes samples coming from England, Wales and Northern Ireland or imported samples) as part of a UEIC project, due diligence must be undertaken regarding the provenance of the samples to ensure they were collected with the appropriate consent for the purposes of research. Due diligence will be conducted by the HTA Monitor, specifically for HTA-relevant material, and will ensure the storage and use of the material will i) be compliant with the HTA requirements, and ii) in keeping with the terms of the consent they were collected with. As a minimum, the HTA Monitor will require a copy of the participant information sheet (PIS) and the informed consent form (ICF) relating to the sample collection. There may be circumstances where further information / documentation might be requested, this is on a case-by-case basis.

3.5 Agreements

For all samples that are being brought into UoL from an external organisation, an agreement must be in place to govern the transfer of the samples between the two organisations (Please see HTA-A1008-UoL – Contracts for the transfer of HTA-relevant material). On the receipt of a sample application form, the HTA Monitor will request a copy of the contract that will govern the transfer of the samples. Copies of these must to be stored in the PD HTA Masterfile's for internal audit and HTA auditing purposes.

3.6 University Ethics and Integrity Committee (UEIC) Ethical Approval

If the UoL is not the lead organisation for the research and ethical approval has been granted by another institution's ethics committee, an application must also be made via the Universities Research Management System including a copy of the external

organisation ethics approval letter attached. This is to ensure the appropriate oversight of the research being conducted at UoL. This is not needed if there is approval from a recognised NHS REC, only where it is a non-recognised (e.g., University / overseas) REC approval.

The University has a number of RECs that consider applications for approval. This is to ensure that any governance issues relating to the work can be addressed appropriately, before the research can commence. Please do not undertake your research until your project has been approved by the appropriate ethics committee.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator or delegate	Application for approvals via Research Management System / completion of UoLHTAISA001 (appendix 1 to HTA SOP A-1005)if applicable. Ensuring tracking and traceability is maintained.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO.	Ensure SOPs are updated with regulatory or changes in HTA legislation. Expert reviewer on the Universities Research Management System. Due diligence on documentation received.
Ethics Officers	UEIC Committee	Review UEIC projects via Research Management System. Offer UEIC advice. Committee approval.
Person Designated (PD)	Person Designated (PD)	Ensuring any sample collections are added to the PD reports, where applicable. Ensure copies of appropriate documents are in the PD Masterfile's.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding	28/11/2024 

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes • Research Management System for reviews and approvals. • Further clarity around RECs for approvals under the HT Act. • Addition around samples being reported on the appropriate PD reports. • Removal of appendix 1 and instead refer out to Appendix 1 to HTA SOP-A1005 which is the same document.