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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1006-UoL

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

Ethical Committee approval is required to safeguard researchers conducting the study and protects the rights, safety, dignity and well-being of research participants. Ethical approval facilitates and promotes ethical research that is potentially beneficial to participants and scientific knowledge and understanding. It ensures that research is conducted to a high ethical standard, sound 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. The majority of medical and social care research fall under the NHS Governance Arrangements for Research Ethics Committees (REC). Where research involves patients or their identifiable data, approval by an appropriate NHS REC is required. Other projects concerning human participants that do not fall under the remit of NHS REC must be approved in accordance with the University's Code of Practice for Research. Ethics approval must be sought before the project begins.

To identify which approvals your project requires, refer to the *Research Approval Pathway Flowchart*.

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.

Purpose and Scope

The purpose of this SOP is to ensure that Relevant Material samples that are collected from UoL staff and students through the University Ethics and Integrity Committee (UEIC) are reported under the UoL HTA research Licence.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HTA	Human Tissue Authority
ICF	Informed Consent Form

MTA	Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.
NHS	National Health Service
PI	Principle Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UHL	University Hospitals of Leicester
UoL	University of Leicester

Roles and Responsibilities

The seeking and obtaining of all necessary approvals is the responsibility of the researcher (all staff and students including staff visiting from other institutions either undertaking or supervising research at or for the University)

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment to establish/ensure systems are in place to comply with the HTA codes of practice. This includes ensuring that the premises used for storing material are complaint with the HTA licence requirements.

It is the responsibility of all Researchers (UoL staff and students) to familiarise themselves with the Research Ethics Policy and observe the principles and procedures to embed good ethics practice in all aspects of their work before commencement of and during the conduct of research. Researchers should seek advice on ethical approvals from the appropriate *Departmental Ethics Officer(s)* or *Research Ethics Committee* members. Formal submission for ethical approval must be obtained before the work can commence.

It is the responsibility of the HTA Monitoring Officer for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and ensuring that all applicable changes are reflected in this SOP. Where samples are coming into UoL for UoL ethics projects, it's the HTA Monitoring Officers responsibility to ensure Participant Information Sheets (PIS) and Consent forms are obtained for samples from a due diligence perspective. In addition, the HTA Monitoring Officer is

registered approver on the UoL ethics system, and where HTA sample advice is required, the UoL ethics application can be escalated upwards.

Departmental Ethics Officers and Research Ethics committee members are responsible for ensuring that ethics advice is given regarding the collection of relevant samples and ensuring that the applicants are aware of what needs reporting to the HTA Monitoring Officer as licenced material. If relevant material is being collected and stored (e.g. blood samples are being stored for longer than 7 days), it is the researchers responsibility to ensure an application to transfer the samples to the licence are followed. This is to ensure that storage of the material is within an appropriately monitored freezer and that tracking and traceability of the sample and its processing pathway is maintained for audit purposes.

It's the Persons Designated (PD) responsibility to ensure that all signed copies of the HTA application forms and copies of Material Transfer Agreements (MTA) or other agreements that govern the transfer of samples are in the HTA PD Masterfiles.

Procedure to follow

This procedures must be followed for all research projects which include obtaining relevant material which do not meet the requirement for review by a non-University Ethics Committee (e.g. collected in the NHS), where the samples are going to remain as Relevant Material (un-processed) for 7 days or more. Where Relevant Material collected from UoL ethics projects is to be stored for 7 days or more they are require to be registered on the UoL tissue registers so that all Relevant Material is accounted for. This is because Relevant Material collected through University ethics approved projects are not exempt from being reported on the licence, where projects with NHS REC ethics are exempt.

Please see the full list of relevant and non-relevant samples that can be found on the *HTA website*.

If samples are being sourced outside England, Wales and Northern Ireland, this SOP should be read in conjunction with *SOP HTA-A1005.*

Application to the HTA monitoring Officer and Designated Individual

If the material is going to be stored for longer than 7 days as Relevant Material (i.e. whole blood, or the original cells e.g. PBMCs, platelets, saliva e.t.c.) The researcher must complete *SOP HTA-A1006 Appendix 1* and return this to htaenquiries@leicester.ac.uk for assessment by the HTA Monitoring Officer and the DI.

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.

This form is required to be completed for any Relevant Material that is to be imported into any UoL premises, this includes areas that are embedded within University Hospitals of Leicester NHS trust (UHL), as part of an UEIC approved project.

HTA compliance visit

Upon completion, if the area being proposed for the storage of Relevant Material is a new area, the HTA Monitoring Officer and the DI for the HTA Research Licence will conduct a HTA licencing regime, which involves ensuring that the premises are suitable for the activities as authorised by the licence (if applicable).

The DI has to ensure that the areas used for storage are suitable and that there are systems in place to ensure the integrity of the samples can be maintained in line with HTA licencing.

Sample Collection

Where samples are being collected from any UoL staff and students on Uol premises i.e. 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. This should be undertaken only by individuals that have up to date *informed consent training*. Individuals without up to date training, will not be unable to take informed consent for the research project. 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 taking the blood must be appropriately trained in phlebotomy and needle stick injury (Hep B status should be managed as appropriate).

Due diligence

Where applicable, for all samples being brought into the UoL as part as internal ethics projects (for example) samples as part of a collaboration, sourced from an

external RTB the HTA Monitoring Officer will require a copy of the participant information sheet (PIS) and the informed consent form (ICF) from which the samples were obtained to ensure due diligence has been undertaken and that those samples can be used for the purposes of research. Dependant on the request, additional study specific information may be required, such as a copy of the IRAS form and protocol (if applicable).

Agreements

For all samples that are being brought in from outside of UoL, an agreement must be in place to govern the transfer of the samples between the two organisations. Please see *SOP HTA-A1008.* On the receipt of a sample application form, the HTA Monitoring Officer will request a copy of the contract that will govern the transfer of the samples as copies of these will be required to be stored in the PD HTA Masterfiles for internal audit and HTA auditing purposes.

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 *UoL ethics system* and a copy of the external originations ethics approval letter attached. An application through the UoL ethics approval system would be required to ensure there is oversight of the research taking place. This is not needed if there is approval from a recognised NHS REC, only where it is a non-recognised (e.g. University) REC.

The collection of samples must have some form of ethical approval for the collection of them. Therefore for imported materials, it is essential to get ethical approval from a research ethics authority or a local equivalent in the source country before the research takes place. The HTA Monitoring Officer may require copies of these which would form part of a due diligence process.

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.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N