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Paper copies of this document might not be the most up to date version.

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.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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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

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', *HTA Standards* and the Human Tissue Authority's *(HTA) Codes of Practice.*

Consent and the wishes of the donor, or their appropriate nominated representatives or relatives have importance when removing, storing, or using human tissue for research purposes. This means that:

- Human tissue, or bodies of the deceased, should be used in accordance with the expressed wishes of the donor or their relatives.
- Donors and their relatives should be given the information they need to make an informed decision that is right for them
- Those seeking consent should do so with sensitivity and appreciation for the particular circumstances in each case.

Purpose and Scope

This SOP should be used as guidance and highlight the importance of consent, which is a legal requirement under the HT Act.

This document aims to provide guidance for the Designated Individual (DI) and Persons Designate (PD), and UoL staff, students and any external individuals working under their direction so that they are fully aware of the procedures needed to ensure that the requirements for consent recording for licensed tissue holdings under the HT Act and HTA Codes of Practice are met.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HT Act	Human Tissue Act
HTA	Human Tissue Authority
ICF	Informed Consent Form
mNCA	Model-Non-Commercial Agreement

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
PD	Persons Designated
PI	Principle Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

The DI is accountable to the HTA for research tissue stored under the authority of the UoL HTA Research Licence. It is the responsibility of the DI to ensure that the licensed establishment complies with the HTA Codes of Practice.

It is the responsibility of the HTA Monitoring Officer for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation or changes to the HTA Codes of Practice.

It's the responsibility of the PDs to assist the DI in implementing and adhering to the governance processes, and for ensuring that this document is observed in respect of human tissue for which they have responsibility for stored under the governance of the UoL Licence. This includes making all staff that collect, store, use and dispose of tissue aware of this SOP.

All UoL staff, students and external individuals collecting, storing, using, and disposing of human tissue for research under the UoL HTA Research Licence are accountable to the relevant PDs and the DI for undertaking work in compliance with this document

Procedure to follow

This SOP should be read in conjunction with the HTA Codes of Practice (A: Consent and E: Research). All samples of relevant material collected on or after 1st September 2006 and stored under the HTA research licence must have been given with informed consent. Only exemptions as described in the consent exemption are permissible.

General Points on Consent

It is the responsibility of the Chief/Principal Investigator (CI/PI) or custodian ('researcher') storing the material to ensure consent has been given and recorded appropriately. For projects with NHS Research Ethics Approval (REC), guidance for drafting Participant Information Sheets (PIS) and Informed Consent Forms (ICF) can be found on the Health Research Authority (HRA) website.

Assurance that consent has been given should be recorded in one of the following ways (in order of preference):

- An ICF signed by the participant, nominated representative or person in a qualifying relationship and retained by the researcher, or,
- The researcher must obtain a signed statement from the provider declaring "all material provided is obtained with informed consent for research".

The giving of consent is a positive act. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

PIS and ICFs should be available in formats appropriate to the situation and language translations available where appropriate.

All staff seeking consent must be suitability trained in taking informed consent with details/certificates of training documented in staff training records. Consent training for non-medics is mandatory. *Please refer to UoL Sponsor SOPs*.

Obtaining Consent

If identifiable tissue is to be used for research, participants must be told about any implications this may have in addition, there should be a specific clause on the ICF for the use of identifiable information. For example, they may be contacted by researchers, given feedback, or be asked for access to their medical records.

Participants must be told whether the consent is generic (i.e. for use in any future research project which has ethical approval) or specific. For any samples to be used beyond the scope of the original research project, there must be a clause in the ICF for the participant to initial, only samples that have this box initialled by the participant can be retained and transferred to the UoL HTA licence. Please refer to *SOP HTA-A1001* for the application process.

Participants must be informed if their samples will or could be used for research in the commercial sector.

Where consent is sought from a nominated representative or person in a qualifying relationship, information of the same level should be provided. However, care must be taken regarding the disclosure of sensitive information such as genetic information or Human Immunodeficiency Virus (HIV) status.

It is a legal requirement that consent is obtained if genetic analysis is to be performed on the bodily material.

Externally sponsored studies

Where materials are obtained from external organisations (i.e. externally sponsored studies), if possible, copies of the original consent forms should be shared with us, particularly if the materials are to be stored beyond the scope of the original research purpose. They should be governed by an appropriate Material Transfer Agreement (MTA), unless the samples are governed by an alternative agreement, such as a model Non-Commercial Agreement (mNCA).

If this is not possible, depending on agreements and what is documented in the original ethics approval, a blank template of the consent form must be shared with us and a consent audit must be undertaken by the study sponsor before the samples are shipped to UoL to ensure the samples were obtained with the appropriate consent, and there is documentary evidence that appropriate consent was obtained.

Research using cadaver material

The HT Act defines appropriate consent by reference to the person who may give consent. If, prior to death, the deceased individual has not indicated their consent to post-mortem examination or removal, storage or use of their material for research, a person in a ‘qualifying relationship’ with them immediately before they died may give consent on behalf of the individual concerned.

Those in a qualifying relationship, outlined below in the hierarchical structure with the highest first:

1. Spouse or partner (including civil or same sex partner)
2. Parent or child (child may be of any age but must be competent if under the age of 18, and means biological or adopted child).
3. Brother or sister
4. Grandparent or grandchild
5. Niece or nephew
6. Stepfather or stepmother
7. Half-brother or half-sister
8. Friend of long standing

Consent only needs to be obtained from one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If the person higher up refuses to give consent, then it is not possible to act on someone further down the list.

Withdrawal of consent

A competent person is entitled to withdraw consent at any time. Withdrawal should be discussed at the outset when consent it being sought. It must be clear that the withdrawal of consent cannot be acted upon where tissue has already been used.

Under such circumstances, no further tests can be done, and the samples must be destroyed, unless held for the purpose of maintaining a diagnostic record, audit or quality control. Existing information obtained from the samples does not have to be withdrawn from the research project but should not be used any further after that point.

If someone withdraws their consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

Research without Consent

An exemption in the HT Act allows tissue to be stored without a HTA research licence is the research project has the appropriate NHS REC ethics approval.

Additionally, consent is not required for tissue which has been taken from a living individual if both the following criteria are met: i) the researcher is not able to identify the person, and ii) the research project is approved by an NHS REC.

The consent provision does not apply to for the use of imported tissue, however the HTA recommends that researchers satisfy themselves that appropriate consent has been obtained. Please refer to SOP *HTA-A1005* for guidance relating to the import and export of materials.

Residual tissue samples from living, competent adults following diagnostic or therapeutic intervention or research can be used for research or education and training without separate consent if these purposes are included within the surgical consent form. In such circumstances where this is applicable, a copy of the surgical consent form would be required to be retained for audit purposes.

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