University of Leicester Research Governance Office

Human Tissue Act Policy

Policy on Compliance with the Human Tissue Act

Version 2.0

Effective Date: 01 December 2024

1.0 Background

The Human Tissue Act 2004 ('The HT Act') sets out the legal framework for the collecting, storing or using and disposal of human tissue. The HTA Act applies to all "relevant material", defined as "material other than gametes, which consists of or includes human cells, but excluding a) embryos outside the human body, or b) hair and nail from the body of a living person". This includes "residual" tissue following clinical and diagnostic procedures and also covers blood, blocks and slides.

2.0 Purpose

The procedures outlined in this policy must be followed by all University of Leicester staff, students and any external researchers working under the University's Research Licence (licence number 12384) and those who may wish to retain tissue at the end of an ethically approved research project.

3.0 Roles and Responsibilities

The Registrar of the University of Leicester is the HTA Licence holder.

The Designated Individual (DI) – has statutory responsibility under Section 18 of the Human Tissue Act. The DI for research is accountable to the HTA for human tissue handled under the authority of the University's licence for research and is responsible for making relevant University staff aware of this policy.

The HTA Monitor or delegate within the RGO is accountable to the DI and will assist him/her in the adherence to the University Research Licence and to this policy.

Persons Designated (PD) – to assist the DI in ensuring that HTA activities are conducted properly within their area. To advise researchers working with human tissue in their area on the procedures and systems they must follow to comply with the HT Act

All staff collecting, storing or using and disposing of human tissue for research under the University HTA Research Licence are accountable to the relevant PD(s) and the DI for undertaking work in compliance with this policy. In compliance with the research licence issued by the HTA, the University expects all persons operating on University sites to comply with the Human Tissue Act and its subsequent amendments, and to comply with all Codes of Practice issued by the HTA and relevant University wide and/or local Standard Operating Procedures (SOPs).

4.0 Material Covered by The Human Tissue Act 2004 – 'Relevant Material'

Within the HT Act, human tissue is referred to as 'relevant material' and this is defined as 'material that has come from a human body and consists of, or includes, human cells. Under the Act, "relevant material" means material, other than gametes, which consists of or includes human cells; the fundamental principle being, 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.

References to relevant material in the Act *do not* include:

- embryos outside the human body, or
- hair and nail from the body of a living person.

The Human Tissue Authority has furthered defined 'relevant material'.

For further information, see the HTA Code of Practice Code E: Research.

5.0 Collection, Storage and Use of Tissues for Research

5.1 Consent

Consent is a fundamental requirement for the collection of tissue and DNA from human participants.

Human tissue samples collected from the living after 1st September 2006 for research purposes must be taken with fully informed consent, with the following exception:

Tissue from the living may be stored for use and/or used without consent, provided that

- Research is ethically approved by a recognised REC and
- Tissue is anonymised (no patient identifying data is available to the researcher).

This is a legal exemption; a recognised ethics committee may still require researchers to seek consent if it is deemed appropriate or necessary for a particular project. The purpose of this exemption is to permit use of relevant material surplus to diagnostic and therapeutic purposes. It should be primarily used in retrospective analyses of, for example, pathology archival material; it should not be used to circumvent need to seek consent in prospective studies where intent to use for research is known at the point of tissue collection. Consent must be sought in these circumstances.

Anonymisation of samples does NOT mean:

- they must be permanently and irrevocably unlinked; linking can be made through a third party where necessary.
- the person holding the samples cannot themselves carry out the research. If members of the clinical team take part in the research, links may be retained to the relevant clinical or patient records, but they must not contain information giving direct patient identification.

Research using samples collected before 1st September 2006 may be used without consent provided there is approval to do so by a recognised REC.

Where consent is not legally required under the HT Act, it is still considered good practice to obtain it wherever practicable.

For specific use in a defined project, project-specific patient information sheets (PIS) and informed consent forms (ICFs) should include adequate information as to the nature of the tissue samples being taken and the subsequent use of the material. The project, including all PIS and consent forms, must be approved by an approved ethics committee (see section 5.2).

For further information, see the HTA Code of Practice Code A: Consent and University HTA A1014 UoL on Consent Recording and exemptions

5.2 Ethics

There is a statutory requirement for ethics approval for research involving use of and/or storage of relevant material and DNA. Where this involves patient samples, this can only be given by a ‘recognised’ ethics committee/authority.

These are:

a) NHS - Research Ethics Committee (REC), established under and operating to the governance arrangements issued by the Department of Health.

b) An ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004

Samples collected under a recognised REC approval do not fall under the remit of the HTA Research Licence.

Where samples are collected only from healthy volunteers, a University Ethics Committee may be able to give approval. These samples require reporting under the remit of the HTA Research Licence. For use of relevant material and DNA without consent in research; the samples must be anonymised to the researchers, and the study must have approval from a recognised REC.

5.2.1 Approvals

Approvals must be obtained via the Universities Research Management System: Infonetica. This allows researchers to obtain all the appropriate approvals required for their research and the appropriate reviews by the Research Governance Office (RGO).

All investigators must ensure that a favourable ethical opinion has been granted by a recognised REC where an HTA exemption is being utilised or where patient tissue is involved. Where samples are being collected from staff and students the University of Leicester Ethics Committee (UEIC) approvals can be obtained for any research projects that obtain human tissue solely from healthy volunteers.

University Ethics Investigators must apply for approvals via the Universities Research Management system; Infonetica to ensure their project is registered on the Universities database and to obtain any approvals before any work on their project begins.

5.3 Coding of Samples

Human tissue samples collected for research purposes should have a unique identifying code. Sample tracking software incorporating barcode labelling technologies may be used by individual labs to record all data related to the storage and use of human tissue samples (e.g., Open specimen, Freezer works etc). Alternative password protected databases/spreadsheets and records systems may also be used. All samples logged on laboratory databases/spreadsheets must be assigned a unique Item ID number to facilitate traceability and audit. No patient identifiable data should be stored on laboratory databases or printed on sample labels, thus maintaining patient anonymity.

Samples arriving from other collecting centres may already be coded – they do not need to be coded again but should be logged into laboratory databases and assigned a unique Item ID. The code assigned by the original collector can be entered into the database to allow linking to clinical data.

If necessary, researchers collecting, using or storing tissue for in-house research projects or clinical trials should meet with the RGO before their research begins to devise the best way to code and track their samples.

5.4 Record Keeping

Traceability is a legal requirement. Proper records and documentation for all tissues must be kept from collection to transfer or disposal. This should include:

- When the material was acquired and from where;
- Details of who gave consent;
- Exactly what the consent relates to, and any restrictions on use stipulated during the consent process;
- The uses to which the material is put whilst in the establishment's care and any processes applied to it;
- The current location of the tissues held under the Licence;
- If tissue is transferred elsewhere, when and to whom;
- Details indicating whether the material is exhausted (either due to analysis or disposal);
- Any details of disposal. This may include details of when, why, where and how disposal is undertaken, and the person(s) undertaking and authorising disposal and should document the date, method and reason for disposal.

There should be a documented record of the nature of each sample and its precise location until it has been transferred, used up or disposed of, or is no longer classed as 'relevant material' under the HT Act.

Records should not include names and should conform to all other relevant legislation (e.g., the Data Protection Act/General Data Protection Regulation) and agreed procedures (e.g., as outlined in any ethical approval).

Information should be stored in a systematic manner, which allows access and use (for example by following SOPs) by other parties for auditing purposes or in the event of the custodian being unable to maintain the records. It is the responsibility of the researcher to ensure that all sample records are accurate and up to date.

Data collected in the course of research must be retained for an appropriate period, to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities.

The University of Leicester's policy with respect to data is that unless ethical/professional/local or funding body guidance requires otherwise, research results should be archived in a durable form that is immune to tampering and falsification for a minimum of 6 years after the date of publication. Data should be stored for a minimum of 25 years where it relates to a clinical trial governed by the Medicines for Human Use (Clinical Trial) Regulations.

Sample records will be subject to mini audits undertaken by the PDs on a quarterly basis and upon application to be transferred to the HTA research licence by the HTA Monitor.

5.5 Storage

All relevant material not covered by a recognised REC approval can only be stored in accordance with the University HTA Research Licence in a licenced building. All relevant material should be stored in line with current good practice incorporating adequate:

- Security;
- Traceability, including information about risk. Records should detail the location of the materials;
- Health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to staff or others.

Withdrawing patient samples from their primary site of storage should be carried out only by the responsible scientist / custodian of those samples for the purpose of conducting sample analysis or re-analysis. When the responsible scientist removes patient samples for the purpose of analysis, details of the withdrawal should be recorded. If the samples are transferred to a new location either on a university site or elsewhere, this information must also be recorded.

Tissue banks and other retained samples should be reviewed regularly. If retention is no longer appropriate then samples should be destroyed.

5.6 Material Transfer Agreements (MTA); Tissue Transfer, Import and Export

For material transferred within England, Wales and Northern Ireland, a relevant agreement setting out the terms for the transfer of tissue samples should be in place prior to material being sent out or received.

All human tissues and cells classified as relevant material can only be transferred to and from other institution(s) and third parties under the terms of (i) an MTA; or (ii) an agreement containing relevant Material Transfer Agreement (MTA) provisions; or (iii) as part of a project with current ethics approval that allows for such transfer.

Where an 'incoming' MTA (as provided by the supplier) is received or an outgoing MTA is required (when the University is required to draft an MTA for sending University materials), the contract should be investigator initiated via Work Tribe platform. The MTA must be negotiated and signed by authorised representatives of both the sending and receiving organisations before any samples are sent i.e., a fully executed contract The University RED contracts team will keep a record of the signed MTA and will provide the researcher with a copy of this for the researcher's records. Where contracts relate to UoL sponsored studies a copy of the fully executed agreement will be filed within the sponsor folders.

Where material is transferred as part of a project with current ethics approval an MTA is not necessarily required. This would depend upon the contracts that were put in place at the time the study was set up. The Contracts Team must be consulted to determine whether an MTA is required and all MTAs must be signed by an authorised signatory from the Contracts Team. The terms of use of the material including disposal/return at the end of the study must be stated in the ethics submission or approved protocol.

5.7 Transport and Delivery

Whether tissue is being transferred within England, Wales and Northern Ireland or imported from abroad, traceability of tissue must be maintained during transport and delivery. Where samples are coming from Scotland and/or overseas i.e., outside of the Human Tissue Authority's remit, the HMRC may need to be consulted. All samples should have a unique identification code and this should be recorded along with details of transport and delivery. Material should only be shipped using a courier that can ensure that the integrity of the human tissue is maintained (in its suitable storage) for the duration of the transfer. When shipping

materials, confirmation of delivery by the recipient must be obtained and filed for a minimum of 5 years

Documentation relating to transport and delivery should be available for inspection by the HTA and for audit conducted by the RGO. When material is carried by post or courier, the packaging should conform to the international standards for the transport of hazardous clinical material. Guidance for transport of material can be found on the Department of Health website and safety services webpages

5.8 Disposal of Human Tissue Samples Collected for Research

When a REC-approved project is completed, a sample may only be kept if there is consent to do so, i.e., there is a future research consent clause which the participant has agreed to or it was collected before September 1st 2006. Disposal should be handled sensitively. All staff responsible for taking consent for the removal, storage and/or use of human tissue samples for research should be prepared to discuss the issue of disposal with donors or relatives, including an explanation of the options available and responsibilities for any associated costs. Information about disposal must appear on the study information sheet provided for consent purposes and donors must be given sufficient information to allow them to make an informed decision.

Disposal of samples should be logged on any laboratory database/spreadsheet or paper sample log. The date, method and reason for disposal must be recorded for each portion of human tissue. If disposal is other than by local incineration, details of the place of disposal must also be recorded.

Where human tissue samples have been collected and stored as part of a defined research study, with ethical approval, the samples must be either disposed of when approval for the study expires i.e., within the 12 months of notifying the REC of the study closing, or be transferred to the HTA Research Licence or to an appropriate research tissue bank (RTB) if appropriate consent has been obtained to permit this. Disposal of such samples should not be undertaken without prior notification and agreement of the custodian for the study, where this is reasonably practicable and meets the requirements of the HT Act.

Please note: The HTA Research Licence only covers storage, not use. To use stored samples in further research either i) a further REC approval is required, or ii) they must be transferred to a REC-approved Research Tissue Bank.

Where practical, it is good practice for human tissue to be bagged separately from clinical waste, but disposed of within the same incinerator. It is not necessary for each tissue sample to be disposed of individually. Although in some cases it is lawful to dispose of human tissue as surplus, it is good practice to dispose of human tissue respectfully where particular sensitivities arise.

For further information, see the HTA Code of Practice Code E: Research and University SOP HTA A1004 UoL on Disposal of Human Tissue Samples.

6.0 Existing Holdings Removed and Stored Prior to 1 Sept 2006

Holdings of human tissue samples taken from the living, even if those individuals are now known to be dead, can be incinerated in the same way as any other sample of tissue taken from a living person.

Holdings of human tissue samples taken from the deceased should be disposed of in accordance with the University SOP HTA A1004 UoL for the Disposal of Human Tissue Samples.

7.0 Review Record

Date	Version number	Reviewed by	Description of changes (If any)
November 2024	V2.0	A Sutcliffe	1. Administrative updates 2. Reference to approvals system: Infonetica 3. Consent section relocated to 5.1 4. Section 5.2 updated- samples under REC approval and University Ethics updates 5. Examples of sample tracking software 6. Minor disposal update 7. Update to archival dates 8. PD mini audits 9. Work Tribe for contracts 10. HMRC wording for overseas samples 11. Minor changed to section 5.9- End of study expectations and future research clause. 12. Updated tables to accessible versions