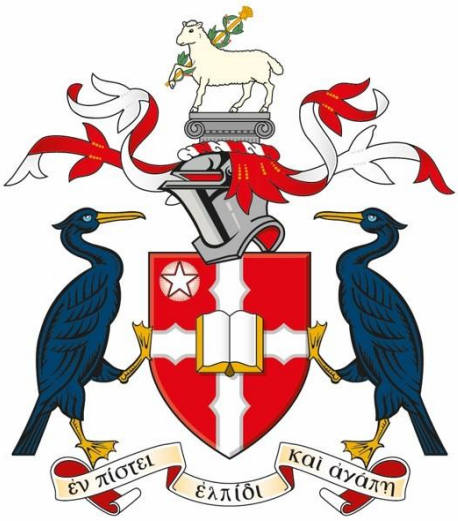


LIVERPOOL HOPE UNIVERSITY

Est. 1844

Human Tissue Research Policy

Responsibility for Policy:	PVC Research
Approved by and date:	University Council on 9th April 2025
Frequency of Review:	Every five years
Next Review date:	9th April 2030
Related Policies:	Research Ethics Policy
Minor Revisions:	
EIA:	Not Required

1. Introduction

Liverpool Hope University (LHU) staA and students engaged in research, education, or training activities involving human tissue must comply with all relevant legal and ethical standards. Failure to adhere to these requirements is strictly prohibited and may constitute a criminal oAence.

The purpose of this Policy is to ensure LHU compliance with the Human Tissue Act 2004 (HT Act) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The HT Act established the Human Tissue Authority (HTA) which regulates the removal, storage, use and disposal of human tissue for research, education, training, and other medical purposes. This policy does not cover all aspects of the HT Act as it relates to research.

2. Research involving human tissue

Researchers working on human tissue are expected to follow best practice on handling, transport, storage, and consent as described by the HTA website guidelines (see here). The HTA considers research to be a study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.

Human organs and other tissue covered by the HT Act are described as “relevant material” and a list of examples can be found on the HTA website (see here).

All research involving the removal or storage of “relevant material” requires ethics approval either via an HTA licensed University Ethics Committee or an NHS Research Ethics Committee (REC). However, most research conducted at LHU involves materials classified by HTA as 'non-relevant’. Non-relevant materials are defined as:

1.1. Materials that have been divided or created outside the human body.

1.2. Materials that have been treated, processed, or lysed through a procedure intended to render them acellular, including instances where freezing or thawing is conducted with the intent to make the material acellular.

This classification is subject to updates. Researchers should regularly consult the HTA website for the most current information.

LHU does not hold a license from the HTA therefore activity involving human tissue is restricted and ethical approval cannot be granted for research other than in very limited and proscribed circumstances as set out below.

The LHU Faculty Ethics Sub-Committee may approve research that involves the removal use and storage of materials considered non-relevant under the HT Act.

Collaborative research, for example with the NHS, may have received approval from a recognised REC and the LHU may be able to conduct some defined aspects of the research without a license in accordance with the REC approval.

3. Consent

It is always required, to seek participants fully informed consent for the research involving relevant and non-relevant materials. Consent must be obtained from a living individual who has the capacity to provide valid consent, and consent must be given voluntarily. For further guidance on conducting research involving adults who lack the capacity to consent, refer to the Health Research Authority website and the provisions of the Mental Capacity Act and its Code of Practice.

Example 1

Psychology students are being asked to provide a saliva sample as part of a study exploring the link between stress and working memory capacity. A whole saliva sample will be collected, immediately analysed for cortisol levels, and then disposed of approximately five minutes after collection. Prior to participating in the study, students were given information about the nature and purpose of the research. They were also informed of any material or significant risks associated with the sample collection process, how the sample will be used, and any potential risks or implications of its use .

Conclusion: The conditions necessary for providing valid and voluntary consent are in place.

4. Storage of Human Tissue

The storage of human tissue for research purposes is licensed by the HTA. LHU does not have an HTA license to store human tissue. Hence LHU researchers must think carefully about whether they are storing human tissue in the ordinary usage of phrase “storage”. The HTA does not set a minimum or maximum timeframe that equates to storage, but a series of examples are provided that help clarify what is likely to be considered storage and therefore require a license.

Example 2
A whole blood sample is taken, and this is then immediately sampled for blood lactate levels in the plasma, then the sample is disposed of about five minutes following the sample being taken.

Conclusion: No storage of relevant material for research would be taking place.

Example 3
A whole blood sample is taken and this is then immediately processed for various tests that day, some of which includes testing directly on the cells themselves. All samples are disposed of when the tests are complete, later that day.

Conclusion: No storage of relevant material for research would be taking place.

Example 4
A whole blood sample is taken and made acellular immediately, and only serum is retained for research.

Conclusion: No storage of relevant material for research would be taking place.

Example 5
An experiment is conducted over a 6 day period. Whole blood samples are provided by volunteers throughout the sample collection period. All the samples are made acellular by day 7, with only serum being stored for research.

Conclusion: There is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary (a few days) and for the purpose of obtaining research material which does not contain cells. The serum is the material which will be stored for research, and this does not require a HTA licence.

Example 6
A study has received approval from a recognised REC where blood samples are taken during a clinical trial.

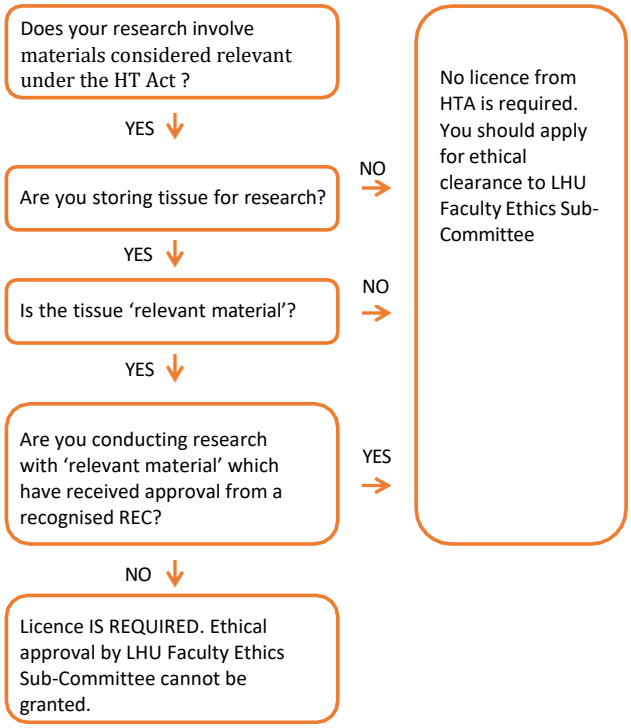
Conclusion: No HTA licence is required to store samples for which REC approval has been obtained (see paragraph 86).

Example 7
Blood samples from healthy volunteers are collected from two groups of participants as part of a research study over a two-day period. After each collection, the samples are stored in a refrigerator and then analysed for research, as a batch, once all have been collected. All samples are used and disposed of within seven days of the first collection. The project involves healthy volunteers and has not been approved by a recognised REC.

Conclusion: Although the storage period is for only 2-3 days, relevant material samples (whole blood) are being stored solely for the purpose of research within the scope of the Act; a HTA storage licence is therefore required. Please note that even if the research destroys the cells, this does not alter the point that prior licensable storage of relevant material for research would have taken place.

5. Ethical Approval

Ethical approval must be obtained from the Faculty Ethics Sub-Committee for studies involving materials considered non-relevant under the HT Act. When seeking ethical approval, the applicant must state what type of material will be collected, stored, used, and disposed. In addition, the applicant must include the output from the REC review tool: [https://www.hra-decisiontools.org.uk/ethics/] to confirm that the research does not require review by a recognised REC. See the flowchart below:



In the application, the researcher needs to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation related to:

a) StaA relevant expertise to perform such research and up to date staA training.
b) Traceability for the human material for which researcher is responsible, from receipt to final disposal/disposition.
c) Appropriateness of premises and facilities to perform activities in safe and secure manner
d) EAective system of risk management and suitable systems to deal with adverse events.

6. Failure to comply with the Human Tissue Act and associated regulatory requirements

The following are examples of oAences under the Act and can result in penalties ranging from a fine to up to three years' imprisonment:

a) Removing, storing or using human tissue without appropriate consent.
b) Storing or using human tissue donated for a specific purpose for another purpose.
c) TraAicking in human tissue for transplantation purposes.
d) Carrying out licensable activities without holding a licence from the HTA

The HTA provides useful information that should be accessed before proceeding with research involving human tissue, including Code A concerning consent and Code E concerning research Practice and Standards, both accessed here: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice

7. Glossary

Term	Definition
Stored incidental to transportation	The HTA defines incidental storage as holding human tissue for a short period. Although the timeframe is not specifically defined, for the purposes of this policy, it should not exceed one week.
Recognised RECs under the Human Tissue Act	In England, RECs are specified under Governance Arrangements for Research Ethics Committees. Universities research ethics committees are not part of the National Research Ethics Service (see here).
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.
Storage	As HTA does not set time period for storage, we encourage researchers instead to consider whether they are actually storing material for research in the normal usage of that term; for example, to think about the context in which they plan to hold relevant material and their intention (see Example 2).
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

8. Other sources of useful information

- Governance Arrangements for Research Ethics Committees (GAfREC)
- Human Tissue Act 2004
- Human Tissue Authority Code E: Research
- Human Tissue Authority Research standards and guidance
- Mental Capacity Act 2005
- NHS Health Research Authority: Mental Capacity Act 2005
- NHS Health Research Authority: Use of human tissue in research