Policy for Use of Human Tissue for Research

UNIVERSITY OF WOLVERHAMPTON

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POLICY FOR USE OF HUMAN TISSUE FOR RESEARCH

1. Introduction

The use of human tissue at the University requires that legislation covered in The Human Tissue Act (2004) is observed. The Act aims to provide a legal framework for regulating the storage and use of human tissue from the living, and the removal, storage, and use of tissue from the deceased.

2. The Human Tissue Act

The Human Tissue Act 2004 covers England, Wales, and Northern Ireland. It established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue for research, medical treatment, post-mortem examination, education and training, and display in public, along with approval for organ and bone marrow donations from living people.

The HTA issues licenses for the storage and use of human tissue, carries out inspections on licensed premises and promotes good practice on all aspects of the handling, use, storage, and disposal of human tissue. The Human Tissue Act 2004 made it an offence to store human tissue without a license and/or recognised Research Ethics Committee approval (HTA Code of Practice and Standards guidance - section 14).

3. Purpose

The purpose of this Policy is to ensure University compliance with the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007, in addition to ethical considerations in relation to research using human tissue.

This policy does not cover all aspects of the Human Tissue Act as it relates to research. Researchers working on human tissue are expected to follow best practice on handling, transport, storage and consent as described by the Human Tissue Authority website guidelines at: https://www.hta.gov.uk/guidance-professionals/hta-legislation

4. Principles

The implementation of this policy is in accordance with the University's ARIA staff charter values:

- **Accountable;** we take pride in what we do and how we do it, take responsibility for our actions and operate with transparency and integrity.
- **Resilient;** we have a positive outlook; we are adaptable and recover from setbacks.
- **Inclusive;** we are welcoming, respectful, collegiate and supportive.
- **Ambitious;** we are imaginative, confident, innovative and deliver excellence.

The principles that relate to the collection, storage, and use of Human Tissue for research purposes within the University, are outlined below:

- **Consent** – informed consent is obtained prior to collecting and storing human tissue.
- **Traceability** – a record must be made by all researchers taking a tissue sample.
- **Licensing** – where required by law, all human tissue for research is collected, stored and, when appropriate, used under a licence applicable to that tissue (Licensing | Human Tissue Authority (hta.gov.uk)).
- **Ethical approval** – all research studies collecting, storing, or using relevant materials for research must have Ethics Committee approval in place (Ethics Guidance - University of Wolverhampton (wlv.ac.uk)).
- **Accessing relevant material from the deceased** – removal from the deceased is done in accordance with the appropriate licence and in compliance with the Human Tissue Act.
- **Implementation and monitoring** – all activities involving human tissue in research are conducted within the framework of ratified research policies and procedures (WLV Policies - University of Wolverhampton).

5. Scope

The policy is relevant to any activity involving human tissue that will be used for research purposes.

It applies to all University staff and students engaged in relevant studies or research as well as to visitors, individuals, collaborators, or agents conducting research or other studies in the name of or at the University and/or engaged to conduct research by the University.

6. Human Tissue and Relevant Material

The Human Tissue Act defines human tissue as 'material that has come from a human body and consists of or includes human cells' and is frequently referred to in the Act as 'relevant material'. The Act defines relevant material as human tissue, other than gametes, which consists of, or includes cells. Only relevant material is covered by the Human Tissue Act.

A list of relevant material can be found in **Appendix A** and on the HTA website at: https://www.hta.gov.uk/guidance-professionals/hta-legislation/materials-considered-relevant-material-under-human-tissue

7. Storage of Relevant Material at the University

A licence is required to store relevant human material unless you have ethical approval from the local NHS Research Ethics Committee (NHS REC) for a specific research project (Research Ethics Committee review - Health Research Authority (hra.nhs.uk)). The requirement to hold a licence includes where tissue is being stored for distribution to other researchers or, where tissue samples were collected before 1 September 2006 and were less than 100 years old on that date

(known as existing holdings) or, where tissue samples are imported from outside England, Wales, and Northern Ireland.

The University of Wolverhampton does not hold a Human Tissue Licence. Therefore, no researcher can store relevant material unless one of the following exemptions apply:

- **A research project using relevant material that has been approved by a recognised research ethics committee** (e.g. the Research Ethics Service(RES)) and the researcher cannot identify the individual from whom the material has come. The relevant material may be stored without a license for the duration of the project and at the end of the project, the relevant material must either be destroyed or returned to the licensed premises. A university ethics committee is not considered to be a recognised research ethics committee for this purpose.
- **A research project using tissue provided by a REC-approved bank which has generic ethical approval.** The recipients do not need to store relevant material under an HTA licence during the period of the research project. On completion of the project, the researcher must return tissue to the bank or to an alternative HTA-licensed establishment, apply for project-specific approval by a REC or destroy it.
- **Where relevant material is being held with the intention of processing to render the material acellular** (e.g. extracted DNA or protein lysates) **prior to research**. Tissue may be stored without a licence providing that the processing takes a matter of hours or days and certainly no longer than a week.

Please refer to **Appendix B** for examples given by the HTA.

It is expected that unlicensed facilities holding samples for specific studies with REC approval will follow some basic quality standards including:

a) temperature controlled (and preferably monitored) fridges & freezers
b) protection of samples from contamination
c) adequate labelling
d) appropriate documentation (including SOPs covering storage and destruction)
e) system to demonstrate full traceability of sample from collection to destruction
f) appropriate security measures
g) back- up procedures in case of emergency (e.g. power loss, equipment failure

8. Acquisition and Importation of New Relevant Material

New human tissue samples may be acquired as part of an NHS REC- approved project or from an NHS REC-approved Research Tissue Bank. Researchers collaborating on a project using human tissue being led by another institution and for which University of Wolverhampton is not a sponsor, must ensure they are aware of the content of any ethics application submitted to an external REC. It is the researcher's responsibility to ensure that the research has appropriate ethical approval. A copy of the external REC application must be lodged with the relevant University of Wolverhampton Ethics Subject Panel.

Researchers collaborating on a project which has received external REC approval, who wish to transfer human tissue samples to the University must apply to their Ethics Subject Panel for approval. The original external REC application, decision documents and any Material Transfer Agreement should be appended.

Tissue samples taken from healthy volunteers with informed consent, including employees and students, may also be used for research if appropriate ethical approval is obtained. Guidance provided by the HTA for recruiting healthy volunteers is detailed in **Appendix C**.

Imported tissue for research should be treated in the same way as tissue originating from England, Wales or Northern Ireland and the same exceptions to licensing apply.

9. Obtaining Appropriate Ethical Approval for Research

All research projects involving human tissue must be approved by the Life Sciences Ethics Committee.

Projects using tissue taken from consenting healthy volunteers who have not been identified because of their use of NHS services do not need RES approval as long relevant material is rendered acellular as detailed in Section 7 and **Appendix B**.

All other projects using human tissue need project-specific RES approval unless the tissue has been acquired from a REC-approved bank with broad ethical approval for research and the project falls within the specified remit of work.

Further guidance can be sought http://hra-decisiontools.org.uk/ethics/

10. Disposal of Relevant Material

At the end of the research project, relevant material must be transferred to an NHS REC-approved Research Tissue Bank or another HTA-licensed site or destroyed by incineration as clinical waste. This should be managed by the researcher.

11. Governance and Traceability of Human Tissue Samples

The University of Wolverhampton has a framework of governance including designated management roles, controlled documentation, and organised and effective record-keeping. All human material is traceable from receipt to final disposition.

Lines of Responsibility:

The roles and responsibilities identified below are specific to the University Use of Human Tissue for Research Policy.

Committee for Ethics & Research Integrity (CERI)

- Have ultimate accountability for Human Tissue Research across the University.
- Act as an assurance group for Human Tissue Research.

Faculty Ethics & Research Integrity Committee

- Have oversight and maintain a register of all research projects involving human tissue taking place within the faculty (including projects with NHS REC approval).
- Provide advice and support to staff and students on all aspects of the human tissue research process.

Chair of Faculty Ethics & Research Integrity Committee

- Ensure that human tissue research information is effectively communicated across the Faculty/Service Department.
- Ensure that human tissue research processes are embedded and adhered to within the Faculty/Service Department.
- Have oversight at a local level of human tissue research projects.
- Initiate and oversee annual audit of human tissue in the faculty, as appropriate.

Principal Investigator

- Ensure that all aspects of the human tissue research process are adhered to (including approval).
- Maintain a register of human tissue held for each of their projects.
- Act as a mentor to students participating in human tissue research.
- In the case of a study which is being undertaken by a student as part or in fulfilment of an academic qualification, the Director of Studies will take responsibility as named PI.

Faculty HTA Compliance Officer

- In each Faculty, a HTA Compliance Officer (appointed from the technical staff) oversees operational matters involving storage of human tissue according to Faculty Code of Practice for Working with Human Tissue.
- Curate the register of human tissue held within the faculty.
- Execute annual audit of human tissue in their custody, as appropriate.

Register of research projects using human tissue

The register will include details of the project title, Faculty REC approval number, RES approval number, name of the principal researcher and start and finish dates of the project.

Register of human tissue held at University of Wolverhampton

In each Faculty, the HTA Compliance Officer will maintain an appropriate and functional inventory of relevant material used in research projects. This register will include details of the

project title, REC approval number, name of the principal researcher responsible for the samples used in the project, sample receipt dates, specific storage locations, scope of consent, transfer of material to another project (if permitted), dates of audit and date and means of disposal.

12. Compliance with the Policy

Failure to comply with this Policy, or any breach of the Ethics Policy or procedures will be taken extremely seriously, and may be construed as misconduct or gross misconduct and dealt with by the **Student Disciplinary Procedures** or **Staff Disciplinary Policy & Procedure,** as appropriate.

The **'Procedures for Dealing with Allegations of Misconduct in Research'** may also be invoked.

13. Exceptions

There are no exceptions to this policy.

14. Data Protection Requirements

When personal data is expected to be used under this policy, staff must adhere to applicable data protection laws. These are outlined in the University's Data Protection Policy and related policies (https://www.wlv.ac.uk/about-us/corporate-information/wlv-policies/). Any use of personal data should be detailed in the relevant privacy notice and processed in accordance with all data protection principles.

For processing activities that may carry high risk; completion of a Data Protection Impact Assessment (DPIA) may be required. This is determined by answering a series of screening questions included in the DPIA template. The Data Protection Team is available to provide assistance and guidance with any part of this process, please contact them via email: dataprotection@wlv.ac.uk.

Please note that whilst the Data Protection Act does not cover aggregate data, it must be ensured that small numbers held within aggregate data sets do not inadvertently identify individuals.

15. Amendments

This Policy was approved by the Academic Board in June 2026. The University may change this Policy at any time, and where appropriate. Where a policy is not due for review, but is found to require updating, it will remain published, unless the reasons for review render it obsolete.

16. Information and resources

This policy should be read in conjunction with:

- HTA Code of Practice and Standards (Research) https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf
- Research Policies, Procedures and Guidelines www.wlv.ac.uk/researchpolicies

- University Ethics Guidance www.wlv.ac.uk/ethics

17. Contact

For general queries regarding Research Policies, Procedures and guidelines contact Jill Morgan, Senior Officer Governance & Integrity, by email: J.Morgan4@wlv.ac.uk

For general queries, please contact the University Corporate Compliance Team via email: compliance@wlv.ac.uk.

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Appendix A – Relevant Materials

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

1) They have divided or been created outside the human body.
2) They have been treated, processed, or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Human Tissue Type	Relevant Material?
Antibodies	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast milk	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines	No
Cells that have divided in culture	No
CSF (cerebrospinal fluid)	Yes
Cystic fluid	Yes
DNA	No
Eggs (ova)*	No
Embryonic stem cells (cells derived from an embryo)	No
Embryos (outside the body)*	No
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates, and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No

Human Tissue Type	Relevant Material?
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non-blood, derived stem cells (i.e. derived from the body.)	Yes
Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material).	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Sebum	No
Serum	No
Skin	Yes
Sperm cells (spermatozoa)*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Sweat	No
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

* While outside the definition of relevant material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA). - See more at: https://www.hta.gov.uk/guidance-professionals/hta-legislation/materials-considered-relevant-material-under-human-tissue

Appendix B – Examples

If there is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells, then no storage licence is required.

a) Examples where a HTA storage licence would not be required:

Example 1
A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not relevant material, the blood does not need to be stored under a HTA licence.

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, only serum being stored for subsequent research.

Conclusion: There is no intention to use or store human cellular material for research, and the holding of the material is temporary (a few days) and for the purpose of obtaining material which does not contain cells.

b) Example where a HTA storage licence would be required:

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, 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 only for 2-3 days, relevant material samples are being stored 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 use of the relevant material (the analysis) also destroys the cells as part of that process, this does not alter the point that prior licensable storage would have taken place.

Appendix C – Recruitment of Employees or Students

The HTA provides the following guidance on the recruitment of employees or students. "Research establishments may wish to seek consent to obtain the equivalent of 'healthy volunteer' blood, or other, samples from their own staff or students. A reliance on this mechanism of donation poses potential risks to staff or students who are also donors; for example, there is a risk of people feeling pressured or coerced to donate.

At a minimum, in addition to meeting all other required regulatory standards, establishments that wish to obtain samples from their staff or students should put systems in place to ensure the following:

a) A confidential coding system, so that donors cannot readily be identified by their colleagues.
b) Donors should be able to withdraw their consent at any time, without any reason, without their decision having any negative effect on their relationship with colleagues or their conditions of employment or enrolment.
c) Donors of samples with desirable biological characteristics should not be unfairly targeted.
d) Donation thresholds should be established, and donation quantities monitored, such that donors do not donate excessively.
e) Where donations are likely to be repeated, appropriate consent should either be sought afresh or reconfirmed, depending on whether the information needed to support the consent process has changed.

In addition, establishments need to consider other risks, such as whether the lifestyle or medical history of the donor has changed since their previous donation. This may be important to protect both research staff (for example regarding exposure to potential infectious risks) and donors (such as where their health status precludes donations).