University of Wolverhampton

Policy for Use of Human Tissue for Research

1.0 Terms of Reference

The purpose of this document is to detail the University Policy for Use of Human Tissue in Research in line with the requirements of the Human Tissue Authority (HTA). The aim of this Policy will be to ensure University compliance with the Human Tissue Act 2004 and ethical considerations in relation to research using human tissue. This Policy is an integral part of the University research governance arrangements.

This is not a guide covering 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 and storage and consent as described by the Human Tissue Authority. Detailed guidelines on the regulatory requirements and codes of practice are available from the Human Tissue Authority website at:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

2.0 Human Tissue Act

The Human Tissue Act 2004 covers England, Wales and Northern Ireland. It established the Human Tissue Authority 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 giving 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.

3.0 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:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

4.0 Storage of Relevant Material at University of Wolverhampton

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. 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 currently 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. NRES) 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 (eg 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.

5.0 Acquisition and Importation of New Relevant Material at University of Wolverhampton

New human tissue samples may be acquired as part of an NHS REC- approved project or from a REC-approved Research Tissue Bank. If you are a collaborator on a project using human tissue being led by another institution and for which UOW is not a sponsor, it is essential that you are aware of the content of any ethics application submitted to an external REC. It is your responsibility to ensure that your research has appropriate ethical approval. You should lodge a copy of the external REC application with your Faculty REC.

If you are a collaborator on a project which has received external REC approval and you wish to transfer human tissue samples to UoW you will need to apply to your Faculty REC for approval to carry out the research at UoW and append a copy of the external REC application and decision documents and any Material Transfer Agreement.

Tissue samples taken from healthy volunteers with informed consent, including employees and students, may also be used for research as long as 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.

6.0 Obtaining Appropriate Ethical Approval for Research

All research projects involving human tissue must be approved by a UoW Faculty REC. Projects using tissue taken from consenting healthy volunteers who have not been identified because of their use of NHS services do not need NRES approval as long relevant material is rendered acellular as detailed in Section 4.0 and Appendix B. All other projects using human tissue need project-specific NRES 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/

7.0 Disposal of Relevant Material at University of Wolverhampton

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

8.0 Governance and Traceability of Human Tissue Samples at University of Wolverhampton

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.

8.1 Lines of Responsibility:

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

UoW REC

Have ultimate accountability for Human Tissue Research across the University.

Act as an assurance group for Human Tissue Research.

Faculty REC

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 approved project information to the Dean of Research for inclusion on the Human Tissue Research project register

Dean of Research

Accountable for all human tissue research conducted within the University

Maintain register of all human tissue held at UoW

Provide advice and support to staff and students on all aspects of the human tissue research process

Maintain a suite of templates to support the human tissue research process

Ensure amendments and changes to HTA and IRAS policies and procedures are disseminated

Faculty Associate Deans for Research (Chair of Faculty RECs)

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

Principal Investigator

Ensure that all aspects of the human tissue research process are adhered to (including approval)

Carry out human tissue research within University

Act as a mentor to students participating in human tissue research

Faculty HTA Compliance Officer

In each Faculty, the 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.

Maintain the register of human tissue held within the Faculty.

Execute annual audit of human tissue in their custody.

8.2 Register of research projects using human tissue

The Dean of Research will maintain a register of all research projects for which human material is stored at UoW. This register will included details of the project title, Faculty REC approval number, NRES 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.

Appendix A

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/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004#sthash.YFIofFhV.dpuf

Appendix B (NOTE these are examples from the new draft code for research)

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 <u>would not</u> 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 only holding of cellular 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 <u>would</u> 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

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:

1. a) a confidential coding system, so that donors cannot readily be identified by their colleagues;
2. 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;
3. c) donors of samples with desirable biological characteristics should not be unfairly targeted;
4. d) donation thresholds should be established, and donation quantities monitored, such that donors do not donate excessively;
5. 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 with regard to exposure to potential infectious risks) and donors (such as where their health status precludes donations).