Guidance Notes for the Use of Human Tissue in Research and Teaching

The *Human Tissue Act 2004* (*HT Act*) provides the legal framework under which human tissue may be stored, removed, used and disposed of. It identifies activities undertaken with human tissue that are lawful with appropriate consent and authorisation, and those circumstances in which consent is not required.

Human tissue must be treated, used, stored and disposed of with respect. All work involving use or storage of human tissue that is considered relevant material (*see table 1*) for a scheduled purpose (e.g. Research) under the *HT Act* must be conducted in accordance with the *HT Act* and the directions and guidance laid out in both the HTA's codes of practice and the Edge Hill University (EHU) Human Tissue Quality Manual.

Any staff or student planning research that involves the use or storage of human tissue should consult the Designated Individual (DI) or persons designated (PD) for advice on whether the research is required to be conducted under the *HT Act* or the University's HTA licence.

All staff working with human tissue should complete the HTA training that is provided by the DI. Heads of departments and those members of staff who sit on ethics committees that receive applications involving the use of human tissue are strongly advised to attend this training.

This guidance document has been produced to highlight some of the information contained in the Human Tissue Quality Manual and should be read IN ADDITION to the EHU Human Tissue Quality Manual and the relevant codes of practice. Policies and procedures addressed in this document are those of consent; storage; records and audit; transport, import and export and reporting adverse events.

The Human Tissue Quality Manual includes the following policies and procedures, and ALL MUST BE ADHERED TO-

10.1. Policy and Procedure for Governance

10.2. Policy and Procedure for Identifying Relevant Human Tissue Research Projects

10.3. Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue

10.4. Policy and Procedure for the Safe Handling of Human Tissue

10.5. Policy and Procedure for Local Transport of Human Tissue

10.6. Policy and Procedure for the Import and Export of Human Tissue

10.7. Policy and Procedure for Records and Audit

10.8. Policy and Procedure for the Storage of Human Tissue

10.9. Policy and Procedure for the Disposal of Human Tissue

10.10. Policy and Procedure for Reporting Adverse Events

10.11. Policy and Procedure for Complaints Regarding Human Tissue

10.12. Policy and Procedure for Training Regarding Human Tissue

1. Consent

It should be assumed that consent is always required for the use or storage of human tissue. It is an offence under the *HT Act* to use human tissue for any purpose for which has not been consented by the donor. If consent has been given for the use of human tissue for a specific purpose, separate consent would be required for any other purpose.

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, understands the nature of the activity in question and, where appropriate, the risks involved. Potential participants should be given a Participant Information Sheet (an example of which can be found in the HTQ manual) at least 24 hours before meeting them to discuss the research. Where staff or students require relevant material from a dead body for use in teaching or research, the Designated Individual should be contacted before any other steps are taken. A donation may not proceed if a donor places conditions on their consent which cannot be met or guaranteed.

For education or training, the consent provisions of the *HT Act* do not apply to material taken from the living, however, consent is required under the common law. The University requires that human tissue taken from the living for use in teaching is handled, transported, stored and disposed of as relevant material in line with the Policy and Procedures outlined in the Human Tissue Quality Manual. The consents obtained for the use of this tissue in teaching need relate only to its removal and not to its use and storage. **Relevant material from the deceased is not exempt to any of the consent requirements of the *HT Act*.**

Consents under the *HT Act* are not required if the tissue is approved by a recognised Research Ethics Committee (REC). Edge Hill University's URESC is not considered to be a recognised REC meaning consent is still required for relevant material to be used for research, even if the project uses tissue from the living and the researcher is not in possession, and not likely to come into possession, of information identifying the participant.

All staff and students involved in seeking consent for the use and storage of relevant material must undertake formal consent training provided by the Designated Individual or nominated representative. This training must be completed before seeking consent from research participants.

Further detail about the consent provisions of the HT Act can be found in the EHU Human Tissue Quality Manual (10.3 Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue) and *HTA Code A (Guiding Principles and the Fundamental Principle of Consent) and Code E Research (Code of practice and standards and Standards and guidance).*

2. Storage Requirements

Tissue should only be stored in designated areas and should not be stored alongside animal tissue or chemicals which may threaten the integrity of the sample. The location of the designated area should be discussed with the Designated Individual or Persons Designated.

Storage vessels should have sufficient storage capacity and documented contingency plans should be in place in case of failure in the storage area.

All staff should have regard to issues of security. Human tissue should not be stored in areas to which members of the public have access. Storage vessels containing human tissue should be locked

securely. All stored samples should be clearly labelled as biohazards to prevent and minimise risk of contamination from inadvertent opening or touching.

Technical staff should develop policies on equipment maintenance, informed by the instructions from the original equipment manufacturer. Temperature alarms should be regularly tested and manually challenged periodically to ensure that they are operating as expected

Storage conditions should be monitored, recorded and acted on when required. The required temperatures of storage facilities should be maintained. Any issues with abnormalities in storage temperature readings should be reported to the relevant staff and/ or the DI.

Human tissue should not be stored indefinitely with no prospect of it ever being used. Stores of relevant material should be reviewed on a regular basis and a decision made whether to dispose of material or continue to store it

A HTA license is not required for storing material that is being held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular). The processing of human tissue samples should begin immediately after collection or as soon as samples are received and should not take longer than 7 days.

Further detail about the consent provisions of the HT Act can be found in the EHU Human Tissue Quality Manual (10.8 Storage of Human Tissue) and *HTA Code E Research (Code of practice and standards and Standards and guidance).*

3. Records and Audit

All stored human tissue and associated products must be given a unique identification number and traceability records must be maintained. This must be completed using the University's human tissue sample inventory and tracking system (Pro-curo).

The record created should be linked to signed consent forms that must be accessible within the software. The records must indicate whether consent is specific to a project or for broader use in research.

If samples are split for different purposes the sample inventory and tracking software will allow each batch to be traced to the parent sample (and the consent and ethical approval associated with the parent sample).

All records (written and electronic) should be retained for a least five years after the disposal of the last item included in the consignment. Computer records should be backed up securely.

Any member of staff or student who is about to leave the University, or retire, having stored human tissue under the University's HTA License, should contact the Designated Individual to discuss appropriate arrangements for the continued storage, use, transfer, or disposal of the tissue.

In addition to records of human tissue samples, records of the following should be maintained:

- Risk assessments
- Staff training and competency assessments
- Equipment calibration, validation, maintenance and monitoring
- Adverse events
- Complaints.

There should be provisions in place for back-up/ recovery of in the event of loss of records. The loss of records should be reported as an incident to the DI and effective corrective and preventive actions should be taken where necessary and improvements in practice made.

All staff and students working within the remit of the *HT Act* must provide all information requested by the University's Designated Individual or Persons Designated and must do so in an accurate and timely fashion. All records need to be available for inspection or audit by the Designated Individual, Principal Investigator, or the HTA at any time.

Further detail about the consent provisions of the HT Act can be found in the EHU Human Tissue Quality Manual (10.7 Records and Audit) and *HTA Code E Research (Code of practice and standards and Standards and guidance).*

4. Transport, Import and Export

Anyone wishing to transport human tissue between establishments within England, Wales or Northern Ireland should, in the first instance, complete a *Human Tissue MTA Request Form* and email it to the Designated Individual.

For research, the consent provisions of the *HT Act* do not apply to imported material (material imported from establishments outside of England, Wales or Norther Ireland). Despite this, the HTA consider it good practice to ensure that tissue was obtained with valid consent. **No member of staff, student or researcher should instigate the import or export of primary human tissue without the written permission of the Designated Individual.**

Anyone wishing to import or export human tissue between establishments outside of England, Wales or Northern Ireland should complete a *Human Tissue MTA Request Form* and email it to the Designated Individual. Imported tissue stored for research should be treated in the same way as tissue originating from participants in England, Wales or Northern Ireland.

Further information and requirements can be found in the EHU Human Tissue Quality Manual (Policy and Procedure 10.5 Local Transport of Human Tissue & 10.6 Import and Export of Human Tissue) and *HTA Code E Research (Code of practice and standards and Standards and guidance).*

5. Reporting Adverse Events

Any failure to comply with the *HT Act*, the HTA codes of practice, or the conditions of the University's HTA License constitutes an adverse event. Similarly, loss of or damage to tissue, or the data pertaining to that tissue, should be regarded as an adverse event.

Examples of adverse events can include but are not limited to:

- Removal, use or storage of material without appropriate consent (unless there are specific exceptions applying).
- Human tissue being used for a different purpose than originally intended.
- A breach of donor confidentiality.
- Labelling errors that effectively break the link between tissue and consent records.

- Storage malfunction (e.g. freezer failure or abnormalities in storage temperature readings), or other inappropriate storage that leads to loss of tissue integrity.
- A breach or loss through compromised security arrangements (affecting tissue or data pertaining to tissue).
- Any health and safety incidents.
- Inappropriate disposal.

Any adverse event that occurs under the University's HTA License **must be immediately reported** to the Designated Individual or a Persons Designate in their absence.

Any individual member of staff, student, or member of the public wishing to raise a complaint in relation to the removal, use, storage, or disposal of human tissue at Edge Hill University should write to;

Research Office (FAO: Joanne Morris, URESC Secretary) Edge Hill University
Ormskirk
L39 4QP
OR email: research@edgehill.ac.uk (FAO:, URESC Secretary)

Further information and requirements can be found in the EHU Human Tissue Quality Manual (Policy and Procedure 10.10 Reporting Adverse Events) and *HTA Code E Research (Code of practice and standards and Standards and guidance).*

The current Designated Individual at Edge Hill University is Professor Adrian Midgley.

Table 1. **List of human tissue considered relevant material as it relates to the *HT Act***

Material	**'Relevant material' for the purpose of the *Human Tissue Act*?**
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
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 †	No
Platelets	**Yes**
Pleural fluid	**Yes**
Primary cell cultures (whole explant/biopsy present)	**Yes**
Pus	**Yes**
RNA	No
Saliva	**Yes**
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).