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Document	**Quality Manual for Governance in the Acquisition, Use, Transport, Storage and Disposal of Human Tissue**
Version Number: 6.0	**Effective date: 11 September 2024**
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Version	**Date**	**Change** *(where existing documents have been revised, specific changes and the reasons for the changes are stated in individual document control sheets within the Quality Manual)*
1.0	02/12/15	**N/A**
2.0	27/09/16	• **Revised:** HT3: Obtaining consent for use and storage of human tissue • **Revised**: HT6: Import and Export of human tissue. • **Revised appendix:** Participant Information Sheet • **Revised appendix:** Consent Form • **Revised appendix:** Human Tissue Risk Identification and Assessment Form • **Added appendix:** Human Tissue MTA Request Form (Including Import & Export) • **Revised appendix:** HT.SOP 5: Dealing with fault with -80°C freezer • **Revised appendix:** Human Tissue Disposal Form • **Added appendix:** Evaluation of competence in seeking consent • **Added appendix:** Consent Training Checklist for Student Research • **Revised**: Appendices numbers and SOP numbers so they are in order in which they appear in the Quality Manual • **Revised:** Outdated website links
2.1	20/01/17	• Reformatted using Word template to make it easier to update. • Revised HTMSC membership with new members. Also now in accordance with the University Quality Management Handbook
3.0	2/05/18	• **Revised:** 10.1 Policy and Procedure for Governance

		• **Revised:** 10.2 Policy and Procedure for Identifying Relevant Human Tissue Research Projects • **Revised:** 10.3 Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue • **Revised:** 10.4 Policy and Procedure for the Safe Handling of Human Tissue • **Revised:** 10.5 Policy and Procedure for Local Transport of Human Tissue • **Revised:** 10.6 Policy and Procedure for the Import and Export of Human Tissue • **Revised:** 10.7 Policy and Procedure for Records and Audit • **Revised:** 10.8 Policy and Procedure for the Storage of Human Tissue • **Revised:** 10.9 Policy and Procedure for the Disposal of Human Tissue • **Revised:** 10.10 Policy and Procedure for Reporting Adverse Events • **Revised:** 10.11 Policy and Procedure for Complaints Regarding Human Tissue • **Revised:** 10.12 Policy and Procedure for Training Regarding Human Tissue • **Revised:** Outdated references to old Codes of Practice • **Revised:** Hyperlinks • **Revised appendix:** Human Tissue Audit Report Form • **Added appendix:** HT.SOP 7: Procedure for Storage at Room Temperature • **Added Appendix:** HT.SOP 8: Disinfection • **Revised appendix:** Human Tissue Management Sub-Committee (HTMSC) Members
3.1	27/07/18	• Updated to include the General Data Protection Regulation (GDPR) 2018 and the Data Protection Act 2018.
4.0	12/04/19	• **Updated link:** 3.1.1. The Statement of Primary Responsibilities of the Board of Governors • **Updated:** Policy/ guidance documents relating to ethics, 3.3.3 • **Updated:** Waste contractor, 10.9.4.7 • **Revised appendix:** Participant Information Sheet • **Revised appendix:** Consent Form • **Revised appendix:** Human Tissue Risk Identification and Assessment Form • **Revised appendix:** Human Tissue Audit Report Form • **Added appendix:** Human Tissue Tri-Annual Audit Report Form • **Revised appendix:** HT.SOP 8: Disinfection
		• **Added appendix:** HT.SOP 9: Procedure for the use of human tissue samples away from designated storage areas • **Updated appendix:** Human Tissue Management Sub-Committee (HTMSC) Members
4.1	15.07.19	• **Added information** regarding the use of primary human cells, 10.2.3.3 & 10.2.3.5.
5.0	18.02.20	• **Minor format and grammar changes** • **Revised:** Outdated website links

		• **Update:** Name and terms of reference for University Research & Innovation Committee. • **Update:** Ethics process encompassing SRECs • **Update:** Role of Licence Holder Contact • **Revised:** 10.1 Policy and Procedure for Governance • **Revised:** 10.2 Policy and Procedure for Identifying Relevant Human Tissue Research Projects • **Revised:** 10.3 Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue • **Revised:** 10.4 Policy and Procedure for the Safe Handling of Human Tissue • **Revised:** 10.5 Policy and Procedure for Local Transport of Human Tissue • **Revised:** 10.6 Policy and Procedure for the Import and Export of Human Tissue • **Revised:** 10.7 Policy and Procedure for Records and Audit • **Revised:** 10.8 Policy and Procedure for the Storage of Human Tissue • **Revised:** 10.9 Policy and Procedure for the Disposal of Human Tissue • **Revised:** 10.10 Policy and Procedure for Reporting Adverse Events • **Revised:** 10.12 Policy and Procedure for Training Regarding Human Tissue
5.1	12.04.21	• **Revised:** Human Tissue MTA Request Form. Sign-off section added
6.0	11.09.24	• **Revised:** 3.3.1. Additional clarification on submitting ethics applications for research involving human tissue. • **Revised:** 10.12 Policy and Procedure for Training Regarding Human Tissue. • **Update:** 10.4. Statement regarding risk assessment added to policy and procedure number. • **Addition:** 10.3 Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue. Additional point added regarding ethical extension terms. • **Update:** 10.7. Additional information added regarding the requirement to obtain documentary evidence that non-compliances have been rectified. • **Update:** 10.7.4.9. Additional information added regarding a new requirement for self-audit by people storing tissues under the HTA license, including addition of a new Appendix 22 Researcher Tissue Sample Self Audit Report Form. • **Updated:** 10.11.3.1. Contact information for the research office. • **Addition:** 11.22 added – Researcher tissue samples audit report form. • **Addition:** Added HT. SOP 10 Emergency gas response procedure. • **Revised:** Appendix 2 participant information sheet. Changes to statements regarding export of human tissue & updates to main contact for the research office. • **Updated:** Appendix 5. MTA Request form for Cells of Human Origin (including import & Export). Title changed to a more appropriate title. Additional questions added to the form • **Revised:** Appendix 17 Adverse Event Report – Definitions of severity added in accordance with a HTA minor shortfall adjustment needed. • **Revised:** Appendix 18 Human Tissue Training Record for Researchers

		working under the University's Human Tissue Authority Research License. Revised name change and additional points added to initial statement. • **Addition:** Added Appendix 24 Primary cell cultures vs. cell Lines. • **Addition:** Appendix 27. Guidance Notes: Transport of biological materials including import and export.

Edge Hill University

Quality Manual

for Governance in the Acquisition, Use, Transport, Storage and Disposal of Human Tissue

Version 6.0

Contents

1. Acknowledgements

1.1. The University acknowledges and wishes to thank colleagues at Kingston University for their guidance and support in the development of this Quality Manual, and for their advice on the design and implementation of governance arrangements for work under a Human Tissue Authority license. In particular, we would like to thank Dr Alan Seddon.

2. Background

2.1. The *Human Tissue Act 2004* (*HT Act*) was introduced following a parliamentary review of the legislation and regulatory framework regarding the removal, use and storage of human tissue. This parliamentary review was informed by the findings of a number of inquiries and investigations into the unauthorised removal and retention of human organs at Bristol Royal Infirmary, Alder Hey Children's Hospital, and other organisations.

2.2. The *HT Act* came into force on 1 September 2006. It makes consent a fundamental principle that must underpin the use and storage of human tissue. The *HT Act* provided for the creation of the Human Tissue Authority (HTA) to act as the regulator of these activities and to protect public confidence by licensing all organisations that store and use human tissue for a range of scheduled purposes including research, patient treatment, post-mortem examination, teaching, and public display.

2.3. The *HT Act* grants the HTA the power to set standards (or directions) to establishments undertaking activity that is covered by the *HT Act*, including general directions to establishments to take into account changes in policy and legislation. The HTA has produced seven codes of practice (COPs) in order to provide guidance and to lay down expected standards for each of the sectors it regulates. These codes are:

- *Code A – Guiding principles and the fundamental principle of consent*
- *Code B – Post-mortem examination*
- *Code C – Anatomical examination*
- *Code D – Public display*
- *Code E – Research*
- *Code F part one – Living organ donation*
- *Code F part two – Deceased organ and tissue donation*
- *Code G – Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation*

2.4. The COPs most directly relevant to the current work of Edge Hill University are A and E.

2.5. The *HT Act* does not contain a definition of research but for the purposes of what falls within the HTA's remit, the following definition from *HTA Code E (Research)* applies:

2.5.1. *"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".*

2.6. The HTA also endorses the definition provided by the Department of Health and the Welsh Assembly Government, which is as follows:

2.6.1. "Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods".

2.7. For all work that is covered by the *HT Act*, the University must demonstrate that it meets licencing standards published by the HTA. These relate to the:

1. **consent** provisions of the *HT Act*
2. **r**egulatory requirements for **governance and quality systems**
3. **traceability** of tissue samples
4. regulatory requirements for **premises, facilities and equipment**.

2.8. Edge Hill University's human tissue quality management policies are set out in this quality manual. These policies are intended to ensure our compliance with the *HT Act* and with the standards and guidance set down by the HTA via its codes of practice and other directions. By bringing these policies together into a single document the University seeks to create a clear statement of how any and all work requiring the acquisition, use, storage, or disposal of human tissue must be performed and governed. **All staff using or storing human tissue for research must read this manual carefully and adhere to it.** No such work should be undertaken without authorisation from the University's **Designated Individual** (see policy and procedure *HT1*).

2.9. Whilst this quality manual brings together a number of pre-existing policies and procedures, many of them are new and it is therefore particularly important that all staff take time to familiarise themselves with this document and review it regularly.

3. Edge Hill University Governance Framework

3.1. The Board of Governors

3.1.1. The Statement of Primary Responsibilities of the Board of Governors is available for inspection online.

3.1.2. The role of the Board includes setting and maintaining oversight of the educational character and mission of the University, overseeing its financial viability, financial probity and the effective use of resources, and making key

policy decisions about the running of the University.

3.1.3. The Board of Governors of Edge Hill University is responsible for the strategic direction of the University. The Board comprises both lay and appointed members. The Vice-Chancellor is an ex-officio member of the Board. The Chair of the Board, and Pro-Chancellor, is elected from the lay governors.

3.1.4. The Board of Governors sets strategy on the advice of the Vice-Chancellor and carries overall responsibility for the University. The Vice Chancellor is responsible for all aspects of the operation of the University and is assisted in the discharge of his duties by members of Directorate, including Deputy Vice Chancellor and Pro Vice-Chancellor and University Secretary.

3.2. University Research & Innovation Committee

3.2.1. The University Research and Innovation Committee is responsible to Academic Board for assuring the standards and quality of research and knowledge exchange activity undertaken by staff and students. Its Terms of Reference are:

3.2.2. To monitor research and knowledge exchange activity across the University.

3.2.3. To monitor submissions to research councils and other bodies for funding and evaluate their success and make recommendations on the development of future submissions.

3.2.4. To develop, implement and evaluate the University's quality framework for research degrees including the training and support of students and the appointment, training and support of supervisors.

3.2.5. To review and monitor the work of the University Research Institutes and approve any recommendations or proposals put forward.

3.2.6. To review and monitor the business of its Sub-Committees and approve any recommendations or proposals put forward.

3.2.7. To monitor the effectiveness of the Committee on an annual basis.

3.2.8. To ensure that equality considerations are taken into account in the conduct of the committee's business.

3.2.9. To give due regard to any academic risks which fall within the remit of its Terms of Reference as delegated from Academic Board.

3.2.10. To review and prepare the University for the Research Excellence Framework

3.2.11. Key relevant University documents are:

- *Code of Practice for the Conduct of Research* (ratified March 2014, updated September 2019)
- *The Code of Practice for the Investigation of Research Misconduct* (ratified March 2014, updated September 2019)

3.2.12. Staff and students involved in research are required to read these documents, as well as *The Concordat to Support Research Integrity* published by Universities UK.

3.3. University Research Ethics Sub-Committee

3.3.1. The University Research Ethics Sub-Committee seeks to:

- Meet the obligations, responsibilities and duties of an institution committed to best practice and performance in its knowledge creation, development and exchange activities, and their outputs in relation to the wider community and society
- Recognise that ethical concerns are at the core of the University's community and culture and to inculcate them throughout
- Propagate ethical conduct as central to the work of the University in the pursuit of its knowledge creation, development and exchange activities and the outputs of all such work (by both staff and students).

URESC has the responsibility to oversee the procedures for ensuring good ethical practice in research and knowledge exchange. It oversees the functioning of the five subject research ethics committees (SRECs) to satisfy itself that the Research Ethics Policy (REP) is being adhered to. Before any research involving licensed activity is undertaken, an ethics application must be submitted to and approved by the relevant SREC. All projects involving human tissue must be submitted to the Science Research Ethics Committee (ScREC), or the Health Research Ethics Committee (HREC) if the ethics application is to be subsequently submitted to a National Health Service Research Ethics Committee. High risk projects and all those relating to our policy on researching sensitive material will be subject to an enhanced review, carried out by URESC with assistance from members of the ScREC and HREC as appropriate.

Key University documents relating to the ethical conduct of research are:

- *Research ethics policy* (ratified April 2020)
- *URESC Ethical Guidance for Undertaking Research with Babies, Children, and Young People* (ratified 2019 and updated September 2023)
- *URESC Ethical Guidance for Undertaking Research with Vulnerable Adults* (ratified January 2019 and updated January 2023)
- *URESC Ethical Guidance for Undertaking Research with Edge Hill University Students* (ratified March 2019)
- *Research Data Management Policy* (ratified October 2017)
- *Research Data Management guidance* (updated June 2018)
- *Research Risk Assessment Guidance at Edge Hill University* (ratified January 2020 and updated 2024)
- *Health-related findings guidance* (ratified 2019)
- *Being a participant in/subject of your own research* 2021-2024

4. Research Office

4.1. The Research Office supports the development and implementation of the University's research strategy. It is responsible for the co-ordination of the University's submission to the Research Excellence Framework (REF), the management of the University's Research Investment Fund, the development and implementation of strategies for enterprise and knowledge exchange, and supports academics involved in externally funded research (pre and post award). The Research Office supports the work of the University Research Committee and University Research Ethics Sub-Committee.

5. The Graduate School

5.1. The Graduate School was established in April 2010. It works with academic departments and Academic Registry to, inter alia, provide advice and guidance to postgraduate research students, academic staff and administrators on regulatory matters. It provides both generic and bespoke development opportunities and training for postgraduate research students throughout their studies. The Graduate School also undertakes routine and annual monitoring of the progress of students' research, working with academic departments to ensure appropriate support is available whenever required. It also arranges for the annual induction of new research degree supervisors and annual training of all research degree supervisors.

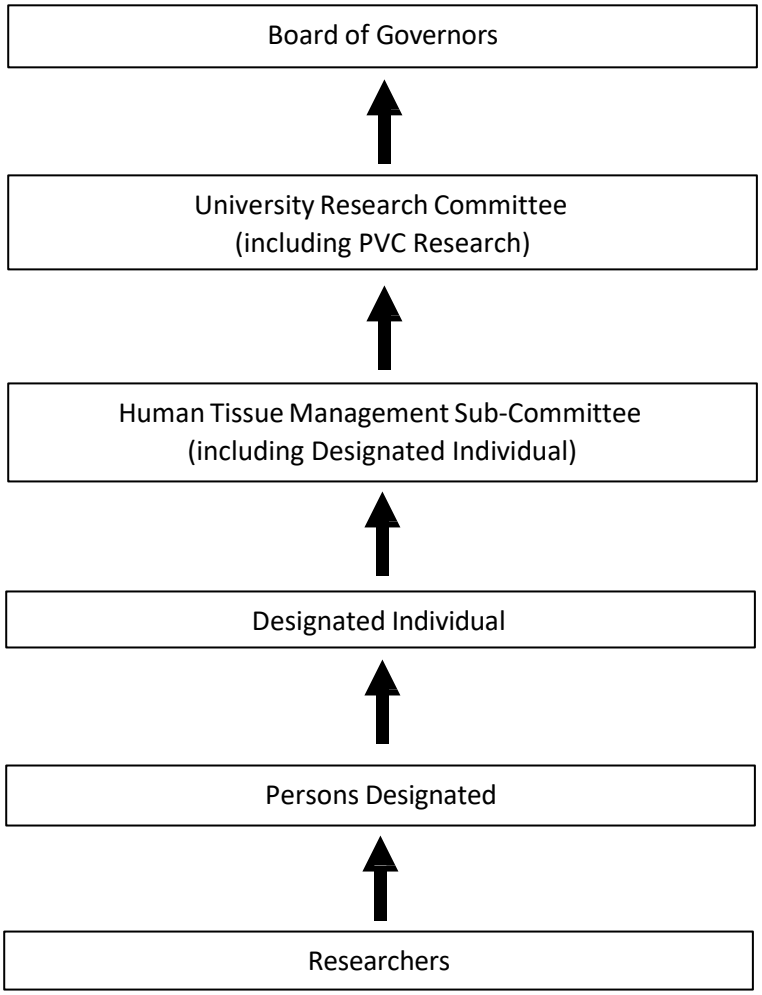
5.2. Key relevant University documents are:

- Research Student Handbook
- Research Degree Regulations

6. Human Tissue Governance Structure

6.1. It is vital that the University's structured system of governance provides clear lines of reporting, responsibility and accountability in regards to any and all matters falling under the *HT Act*. The roles and responsibilities of staff and students within this structure are defined in the sub-sections above and in the relevant documents available via the links provided.

6.2. Each individual statement of 'policy and procedure' in the following sections also includes an introductory statement that defines its scope, how it should be applied, and indicates those responsible for following it. The figure overleaf provides an overview of the reporting lines for research involving the use or storage of human tissue.



7. Human Tissue Management Sub-Committee

7.1. The University has established a Human Tissue Management Sub-Committee to support the work of the Designated Individual. It meets three times per year.

The Terms of Reference of the Human Tissue Management Sub-Committee are:

- To establish, review, and revise policies and procedures to ensure Edge Hill University conducts its business in accordance with the requirements of the Human Tissue Act (2004) and associated codes of practice.
- To monitor activity under the University's Human Tissue Research Licence.
- To monitor compliance with the conditions of the University's Human Tissue Research Licence, and policies and procedures detailed in the University's Human Tissue Quality Manual, including the review of internal and Human Tissue Authority audits.
- To establish the provision and monitoring of training and support given to Edge Hill University staff and postgraduate students working under the University's Human Tissue Research Licence, as well as members of the University Research Ethics Sub-Committee, Science Research Ethics committee, and Health Research Ethics Committee.

- To review any adverse events relating to the handling or storage of human tissue and implementing changes in policy or procedure where appropriate.
- To receive reports from the Science Research Ethics committee, Health Research Ethics Committee, and the University Research Ethics Sub-Committee on ethics applications received that involve human tissue.
- To make available the minutes of the Human Tissue Management Sub- Committee meetings to persons conducting research involving human tissue.
- To monitor the effectiveness of the Committee on an annual basis.
- To ensure that equality considerations are taken into account in the conduct of the Committee's business.

7.2. The membership of the Human Tissue Management Sub-Committee is as follows:

Chair	Designated Individual
Secretary	Research Institutes
Ex-officio	Designated Individual
	University Biological Safety Officer
Appointed	Research Office representative
	Persons designated
	An academic representative of every department using human tissue
Elected members	Not applicable
Student representation	Not applicable
External representation	Not applicable

8. Designated Individual and License Holder

8.1. The Designated Individual and License Holder are key functional roles identified by the *HT Act*. Both play key roles relating to work under the *HT Act*.

8.2. The Designated Individual has primary responsibility to secure:

1. that suitable practices are used in undertaking work involving the use and storage of human tissue;

2. that other persons using and storing human tissue are suitable; and

3. that the conditions of the HTA license are complied with.

The Designated Individual is assisted in his role by Persons Designated.

8.3. Edge Hill University holds a license corporately. The License Holder's Contact receives the minutes of the HTMSC meetings and is in direct contact with the Designated Individual to monitor the operation of and compliance.

9. Edge Hill University Human Tissue Authority License

9.1. The University holds a Human Tissue Authority License (license number 12632).

9.2. The license authorises the storage of relevant material that has come from the human body for use for a scheduled purpose, as defined in Schedule 1, Part 1 of the *Human Tissue Act 2004*.

9.3. The licensed activity should be undertaken only at the licensed premises specified below (the Licensed Premises) and under the supervision of the Designated Individual:

9.4. Edge Hill University

St Helens Road

Ormskirk

West Lancashire L39 4QP

9.5. License Holder's Contact: Lynda Brady, University Secretary and Pro Vice Chancellor (Student Experience)

9.6. Designated Individual: Prof Adrian Midgley, Professor of Clinical Exercise Physiology

9.7. A copy of the first page of the license (the certificate), describing the activity, must be displayed at the licensed premises in a position in which it can be read easily by persons who are involved in the carrying out of the licensed activity or who may wish to do so.

10. Policies and Procedures

Edge Hill University

10.1. Policy and Procedure for Governance	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Minor text amendment	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Update:** Removal of barcode reader and amendment to reflect multiple label printers now in use, section 10.1.5.2	Human Tissue Management Sub-Committee	2 February 2021
6.0	• Revised text regarding training associated with human tissue. Section 10.12	Human Tissue Management Sub-Committee	11 September 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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10.1.1. Scope

10.1.1.1. 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.

10.1.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.1.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.1.2. Governance arrangements

10.1.2.1. Edge Hill University is committed to ensuring that it complies with the *HT Act* and that all of its work involving relevant material meets the standards and guidance set by the HTA. In order to achieve this the University has put in place a clear division of roles and responsibilities with well-understood lines of reporting and accountability. We also have identified those groups and individuals with advisory functions and those required to maintain oversight of all activity encompassed by the *HT Act*.

10.1.2.2. The University's governance framework is described in Section 2 of this quality manual. The University Board of Governors receives an annual report on all activity encompassed by the *HT Act* from the University Research Committee, who are supported in their duties by the Research Office (RO). The RO also supports the work of the University Research Ethics Sub-Committee (URESC) who in turn support the Science Research Ethics Committee (ScREC) and Health Research Ethics Committee (HREC).

10.1.2.3. The Graduate School provides advice, guidance and signposting to postgraduate research students, academic staff and faculty administrators on regulatory matters arising from the work of postgraduate research students.

10.1.2.4. Together, the License Holder's Contact and the Designated Individual play key roles in the management and direction of work undertaken within the scope of the *HT Act*. They form a link between the top tier of management (the Board of Governors) down to the members of staff and students performing that work.

10.1.2.5. The **License Holder's Contact**, as University Secretary and Pro- vice Chancellor for Student Experience, is a member of the University Directorate and therefore part of the University's senior management team. The License Holder's Contact and the Designated Individual communicate directly, working together to monitor operations and to ensure compliance with the terms of the University's HTA License.

10.1.2.6. The **Designated Individual** is ultimately responsible for implementation of the requirements of the *HT Act* and under whose supervision licensed activity is authorised to be undertaken. The Designated Individual has the primary (legal) responsibility under section 18 of the *HT Act* to ensure that:

- Suitable practices are used in undertaking licensed activity
- Other persons working under the license are suitable to do so, and that
- All conditions (standard and non-standard) of the license are complied with.

10.1.2.7. **Human Tissue Management Sub-Committee (HTMSC).** The Designated Individual is assisted in his duties by the HTMSC to review policy and quality management effectiveness and receives any reports of activity performed under the license. These reports include the identification of new Persons Designated, updates on training plans and training records, any adverse events, notification of new projects requiring and receiving appropriate ethical approvals, notification of such projects commencing and ending, and progress reports on the same. The HTMSC also receive reports and advises upon preparation for, performance of and findings of internal and external audits or inspections of quality systems, premises, facilities and equipment. The HTMSC also considers the development of training and guidance to staff and students on seeking and securing appropriate consent for research involving licensed activity.

10.1.2.8. **Persons Designated** are nominated by the Designated Individual, and when nominated in a notice to the HTA, are considered to be a person to who the license applies and, as such, a person to whom the authority conferred by the license extends. Duties include ensuring that staff and students across the University comply with the *HT Act* and conditions of the license and that all work meets the standards set by the HTA. Like the Designated Individual, Persons Designated are able to direct other people in relation to the *HT Act*, including how and why they need to follow all of the procedures agreed by the Designated Individual to comply with the *HT Act*.

10.1.2.9. **Staff** and **students** who undertake work under the *HT Act* are responsible to ensure that:

- All work is conducted in accordance with the *HT Act* and associated HTA codes of practice;
- They undertake the required training as stipulated in the University's *HT12: Policy and Procedure for Training Regarding Human Tissue*;
- All relevant approvals for research are in place;
- Research is conducted in accordance with the University's policies and

procedures stated in this quality manual;

- Appropriate and valid informed consent is obtained for the removal, storage and use of relevant material in accordance with the *HTA Code A (Guiding Principles and the Fundamental Principle of Consent) and the University's HT3: Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue*;

- All tissue samples are handled, stored, and disposed of in accordance with the University's *HT4: Policy and Procedure for Safe Handling of Human Tissue*, *HT5: Policy and Procedure for Local Transport of Human Tissue, HT8: Policy and Procedure for Storage of Human Tissue, and HT9: Policy and Procedure for Disposal of Human Tissue;*

- All stored tissue samples and associated records are available for audit at all times in accordance with the University's *HT7: Policy and Procedure for Records and Audit*;

- They complete their own internal audits of stored tissues samples relating to ethically approved research; in accordance with the University's *HT7: Policy and Procedure for Records and Audit*;

- Transport and transfer of relevant material is undertaken in accordance with *HT5: Policy and Procedure for Local transport of Human Tissue* and *HT6: Policy and Procedure for Import and Export of Human Tissue*; and

- Adverse events are reported as soon as practically possible to the Designated Individual, or his representative, in accordance with *HT10: Policy and Procedure for Reporting Adverse Events*.

10.1.3. Policy development and review

10.1.3.1. All statements of policy and procedure will be kept under review and will reflect good practice. All documents will be reviewed annually, although the Designated Individual, License Holder's Contact, or Board of Governors may require a review at any time.

10.1.3.2. All relevant statements of policy and procedure will be reviewed immediately after any adverse incident has been reported, any reports received under the University's *Code of Practice for the Investigation of Research Misconduct* or *Policy on Whistleblowing,* or after receiving any complaint. All such reviews will be carried out under the direction of the License Holder's Contact.

10.1.3.3. Human tissue (HT) policies and procedures currently in place are:

- *HT1. Governance*

- *HT2. Identifying Relevant Human Tissue Research Projects*

- *HT3. Obtaining Consent for Use and Storage of Human Tissue*
- *HT4. Safe Handling of Human Tissue*
- *HT5. Local Transport of Human Tissue*
- *HT6. Import and Export of Human Tissue*
- *HT7. Records and Audit*
- *HT8. Storage of Human Tissue*
- *HT9. Disposal of Human Tissue*
- *HT10. Reporting Adverse Events*
- *HT11. Complaints Regarding Human Tissue*
- *HH12. Training Regarding Human Tissue*

10.1.4. Reporting

10.1.4.1. Mechanisms are in place to deal with complaints from research participants, researchers, research users and other parties in a fair and timely manner.

10.1.4.2. Mechanisms are in place for the reporting, investigating and documenting of any adverse events (defined and described in *HT10*).

10.1.4.3. Mechanisms are in place to ensure that all relevant research projects are reported to the Designated Individual so that he or she may ensure that all work may proceed, will be performed by suitable people, and will comply with the *HT Act* and conditions of the University's HTA License.

10.1.4.4. Mechanisms are in place to ensure that the Designated Individual can perform an audit of all areas in which relevant material will be stored to ensure its traceability and integrity, including that all relevant material continues to be held with consent. Mechanisms are in place to ensure that the Designated Individual can perform a detailed and structured inspection of the premises and facilities used for licensed activity.

10.1.4.5. Mechanisms are in place to ensure that the HTMSC can disseminate its policy reviews, quality effectiveness measures and reports, audit and inspection findings and any other reports to the relevant university committees. The HTMSC will report directly to the University Research Committee.

10.1.5. Standardisation

10.1.5.1. Wherever possible, standard templates should be used for most

activities encompassed by the *HT Act*, including those of obtaining consent, traceability, and completing risk assessments. All staff should notify and seek support and authorisation from the Designated Individual before planning to undertake any research involving the use or storage of human tissue.

10.1.5.2. The University uses Pro-curo Enterprise sample inventory and tracking software, along with label printers, to help ensure that all samples are stored, used and disposed of in accordance with the terms of the consent under which they were taken, and to ensure the integrity and traceability of all samples at all times. No samples should be stored, taken out of storage, or disposed of without being recorded in this sample inventory and tracking software by an appropriately trained person.

10.1.5.3. Standard templates, and all statements of policy and procedure, are to be agreed centrally and in consultation with the HTMSC.

10.2. Policy and Procedure for Identifying Relevant Human Tissue Research Projects	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Minor text amendments Additional sub section (**10.2.3.5**) regarding primary cells.	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Update:** Ethics process encompassing SRECs, 10.2.7.2 & 10.2.7.3	Human Tissue Management Sub-Committee	2 February 2021

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.2.1. Scope

10.2.1.1. 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.

10.2.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.2.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.2.2. General considerations

10.2.2.1. 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 Appendix 1) for a scheduled purpose under the *HT Act* must be conducted in accordance with the *HT Act* and the directions and guidance laid out in the HTA's codes of practice.

10.2.2.2. Relevant material must be obtained, stored and used with appropriate consent (unless there are exceptions available under law). All research involving relevant material should be conducted in accordance with the conditions of ethical approval, and with the knowledge and direction of the University's Designated Individual.

10.2.2.3. It is therefore important to identify all projects that **may** involve any one of the following procedures: removal, use, transport (including import and export), storage and disposal of relevant human tissue (relevant material).

10.2.3. Identifying relevant material

10.2.3.1. Section 53 of the *HT Act* provides the definition of relevant material, defining it as "… material, other than gametes, which consists of or includes human cells".

10.2.3.2. This definition is intended to be, and should be understood to be, comprehensive.

10.2.3.3. The HTA has produced a supplementary reference list of human tissue considered relevant material as it relates to the *HT Act*. This list is reproduced in Appendix 1 of this quality manual. A summary of different classifications of relevant material is given below.

- **Specifically identified relevant material:** This includes material like bodily

organs and tissues, consisting largely or entirely of cells, and clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone.

- **Processed material:** Processed material that has been rendered wholly and always acellular is not regarded as relevant material. Under this category plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are to be regarded generically as relevant material; while plasma or serum, for example, will not.

- **Bodily waste products (including excretions and secretions):** The HTA considers that bodily waste should normally be regarded as relevant material and advises that all researchers should assume that it is relevant material. In cases where a researcher believes that material intended for a scheduled purpose is actually acellular, the researcher would need to consult the Designated Individual.

- **Cell deposits and tissue sections on microscope slides:** Cell deposits or tissue sections on microscope slides are considered to constitute relevant material. This is because such deposits or sections are likely to contain whole cells, or are intended to be representative of whole cells.

- **Primary human cells:** Primary human cells that have not divided in culture are relevant material (i.e. passage 0).

10.2.3.4. Under the *HT Act* relevant material excludes embryos outside the human body and hair and nail from the body of a living person. As noted above, processed material in which human cells are rendered wholly and always acellular are not classified as relevant material. The presence of a single human cell, however, is sufficient for material to be regarded as relevant material.

10.2.3.5. Cell lines or primary cells that have divided at least once in culture, are not classed as relevant material under the *HT Act*. Primary cells that begin the process of replication on the day that they are transported to EHU (i.e. are transferred from their storage vial into culture) and divide within 7 days do not need to be stored under the HTA license.

10.2.3.6. Any person unsure of what may constitute relevant material should refer to (Appendix 23 Primary Cell Cultures vs. Cell Lines) and/or discuss it with the Designated Individual.

10.2.4. Schedule purpose

10.2.4.1. It should be concluded that any research project involving the use or storage of relevant material for a schedule purpose is subject to the *HT Act* and the relevant HTA codes of practice. Scheduled purposes are defined in Schedule 1, Part 1 of the *HT Act*. Schedule purpose 6 is particularly relevant to the University's HTA License: '**Research in connection with disorders, or the functioning, of the human body**.'

10.2.5. Exemptions

10.2.5.1. There are a number of exemptions from the requirement to store human tissue under a HTA license. These are where:

- Tissue from a person who died more than 100 years ago is being stored for research;
- Human tissue is in storage pending transfer elsewhere providing it is held for no more than 7 days (the HTA taking the view that such storage is incidental to transportation);
- Human tissue is being held during processing with the intention to render the tissue acellular, providing that this processing takes place as soon as possible and the tissue is rendered acellular no later than 7 days after arrival on campus (the HTA viewing such storage as analogous to the incidental to transportation exemption above); and
- Tissue is stored for a specific research project approved by a recognised research ethics committee. Where there is approval for a specific research project from a suitability recognised research ethics committee (REC), relevant material does not need to be stored under a HTA license. Please note that the University Research Ethics Sub-Committee (URESC) is not a recognised REC for this purpose. Where such an approval expires, and there is no further approval pending, the tissue must be stored under the University's HTA License.

10.2.6. Consultation

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

10.2.7. Audit

10.2.7.1. All projects that fall within the *HT Act* should be notified to the Designated Individual. Researchers should notify the Designated Individual before applying for ethical approval.

10.2.7.2. All projects involving human tissue must be submitted to the Science Research Ethics Committee (ScREC) or Health Research Ethics Committee (HREC).

10.2.7.3. The University's HTMSC will be formerly notified by ScREC and HREC of all projects involving the use or storage of human tissue. The HTMSC should maintain a record of all approved projects that involve the use or storage of human tissue and monitor their progress.

This policy and procedure is current to the guidance given in the HTA Code of Practice E

Research (Code of Practice and Standards and Standards and guidance) dated April 2017.

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

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Removal of the statement that permission to import or export human tissue will be withheld. • Information added on multi-stage consent. • Section added relating to training and assessing competence in seeking consent. • Responsibility for ensuring complete and accurate records changed from Designated Individual or his representative to the principal investigator of each study.	Human Tissue Management Sub-Committee	27 September 2016
3.0	• Minor text amendments • Addition of a new sub-section (10.3.2.5) detailing the consent requirements when using and storing tissue from the deceased. • Additional information added to scope of consent, outlining the requirement to respect any conditions that the donor may state when dealing with generic consent and also conditions that the researcher is not legally able to impose. • Removal of sentence stating that '*it is not envisaged staff or students at Edge Hill University will have any requirement to store and use relevant material from a dead body'* to provide guidance for staff who do wish to use such tissue. • Addition of a hierarchy of people who may offer consent, should the donor not be able to do so. • Additional sentence regarding recording details of communication difficulties with donors. • Deletion of the sentence stating that written consent was not an essential	Human Tissue Management Sub-Committee	23 January 2018

Version number	Revision	Authorised by	Date
	requirement, replacing it with a sentence explaining that consent is always required though not necessarily in the form of written consent. • Addition of a new title, *'What systems should be in place when seeking consent to use and store HTA relevant samples from Edge Hill University staff or students for research?*' and relevant information. • Additional paragraph relating to the consent exemptions for education or training. • Addition of a new subsection (10.3.7.3) advising how to deal with samples when a donor withdraws their consent for a study. • Addition of a new subsection (10.3.7.7) stating that 'Donors should be informed if the research is known or likely to involve genetic testing or the use of human tissue in animals.'		
5.0	• **Update:** Ethics process encompassing SRECs, section 10.3.4 • **Updated link:** 10.3.7.10	Human Tissue Management Sub-Committee	2 January 2021
6.0	• **Additional content:** Text amendments added regarding Ethical approval**.** • All research that uses human tissue must be conducted with appropriate ethical approval. • An extension is required for continuation of collection of new human tissue and analysis of human tissue for the same purpose for which ethical approval had originally been obtained. • An extension is not required for the analysis (e.g., statistical analysis) of data from tissue samples that have already been analysed. • A new ethics application is required for a study using the same human tissue samples (providing these are suitable, appropriately collected, and consented for such further use) but for the analysis of outcomes that were not included in the original ethics application.	Human Tissue Management Sub-Committee	30 January2024

Version number	Revision	Authorised by	Date
	• Any limitations regarding the purpose and timeline that accompany the consent, collection, and analysis of human tissue samples should be observed. • The requirements stated above are separate to the consent process that needs to be completed in order to collect the samples in the first place, which should outline the purposes for which the human tissue is being collected and, if applicable, the relevant timeline.		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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10.3.1. Scope

10.3.1.1. The *Human Tissue Act 2004* (*HT Act*) covers England, Wales and Northern Ireland and provides the legal framework under which human tissue may be stored, removed, used and disposed of. The *HT Act* established the Human Tissue authority (HTA) to regulate activities concerning the removal, use, storage and disposal of human tissue.

10.3.1.2. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.3.1.3. The principle of consent for the removal, storage and use of human tissue is central to the *HT Act*. It is vital that all staff engaged in work with human tissue fully understand the need for consent and the procedures for gaining appropriate and valid informed consent.

10.3.1.4. The University Research Ethics Sub-Committee (URESC) has agreed that any research involving human participants should be subject to an appropriate level of ethical scrutiny in order to protect participants, researchers, and the University.

10.3.1.5. This statement of policy and procedure is not intended to, and does not, override any part of the guidance and procedures outlined by URESC. It is intended solely to provide additional information on the consent and ethics procedures for any researcher who wishes to proceed with the use or storage of relevant material for a scheduled purpose, as outlined in the *HT Act*.

10.3.1.6. As noted below, the direction in this quality manual applies mainly to consent for the use and storage of relevant material from the living.

10.3.2. General considerations

10.3.2.1. The consent provisions of the *HT Act* relate to (and vary between) the purposes for which material might be removed, stored or used.

These purposes are the 'scheduled purposes' set out in Schedule 1 of the *HT Act*. These scheduled purposes include **research in connection with disorders, or the functioning, of the human body**.

10.3.2.2. Under the *HT Act* and the *HTA Code of Practice A (Guiding Principles and the Fundamental Principle of Consent)*, consent is required to:

- Store and use dead bodies
- Remove, store and use relevant material from a dead body
- Store and use relevant material from the living: the definition of relevant material applies to material such as bodily organs and tissues, bodily waste products (including excretions and secretions, even if they contain only a single cell) and cell deposits and tissue sections on microscope slides.

10.3.2.3. The *HT Act* and HTA codes of practice set out different consent requirements for the use and storage of tissue from the deceased and the living. At present, it is not envisaged that staff or students at Edge Hill University will have any requirement to store and use dead bodies, or remove, store and use relevant material from a dead body.

10.3.2.4. The direction in this quality manual applies mainly to the storage and use of relevant material from the living. Tissue from the living means tissue taken while the person was alive, and this definition persists after their death. **Any person who believes they have a requirement to remove, store, or use relevant material other than that from the living should contact the Designated Individual before planning any such work.**

10.3.2.5. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose) without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to do an activity, or that Section 1 of the HT Act does not apply.

10.3.2.6. The giving of consent is a positive act and consent must be valid. This consent should also be appropriate for the intended purpose and respected by all those removing, storing, using, or disposing of the tissue.

10.3.2.7. Consent may be generic or specific. For research, the HTA Code of Practice A states that it is good practice to request valid generic consent as this avoids the need to obtain further consent in the future.

10.3.2.8. Consent can be enduring or time limited. Consent can be withdrawn.

10.3.3. Consent requirements

10.3.3.1. As set out in the HTA codes of practice, the principle of consent underpins the *HT Act*. *Code of Practice E* states that the following issues are central to the application of the consent provisions of the *HT Act*:

Is consent required?: In broad terms it should always be assumed that consent is required for the use or storage of tissue from the living, unless exceptions available under the *HT Act* apply. Please see guidance below.

Appropriate consent: Appropriate consent is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative, or (in the absence of either of these) the consent of a person in a qualifying relationship with them immediately before they died.

Valid consent (what is it and how should it be obtained and evidenced?): The giving of consent is a positive act. 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. Obtaining valid consent presupposes that there is a process in which individuals, including their families where appropriate, may discuss any issues fully, ask questions, and make an informed choice. To facilitate this, potential participants should be given the Participant Information Sheet at least 24 hours before meeting them to discuss the research. This is a minimum requirement and the amount of time given should be proportionate to sensitivity of the topic being researched and the level of risk and other participant burdens involved.

Scope of consent: Consent may be specific or generic. Specific consent applies to storage and use of tissue for a defined project. Generic consent typically only applies to research. If conducting research on samples of tissue, it is ***good practice to request generic consent*** because this avoids the need to obtain further consent in the future. Researchers must ensure that any generic consent is also valid consent. If the intention is to store the tissue for an as yet unknown research purpose or as part of a research tissue bank then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of.

If a donor expresses objections to specific types of research with the generic consents, these must be respected, and donors should be provided with information about how future research will be approved within the scope of the consent they have given. A donation may not proceed if a donor places conditions on their consent that cannot be met or guaranteed. However, no material should be removed, stored or used for a scheduled purpose under a form of consent that seeks to impose restrictions on the class of the beneficiary of the scheduled purpose. This includes any restriction based on a beneficiary's sex, sexual orientation, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2010). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010.

Duration of consent: Consent may be enduring or time-limited. Enduring consent remains in force until such time that it is withdrawn. Time limited consent expires after a specific date.

Withdrawal of consent: Whether it is specific or generic, consent may be withdrawn at any time. The withdrawal of consent cannot be effective where tissue has already been used.

10.3.3.2. The HTA's *Code of Practice A* identifies, and provides direction on, how to comply with the consent requirements of the *HT Act*. It also identifies good practice. This code of practice states that before deciding whether to proceed with the removal, storage, or use of tissue for any scheduled purpose (including research), the following should be considered:

Does the activity require consent?

It should always be assumed that consent is required for storage and use of tissue from the living, unless exceptions available under the *HT Act* apply. These exceptions should be reviewed carefully before making a decision to ensure that they do indeed apply. Please contact the Designated Individual if you are in any doubt.

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.

Who may give appropriate consent?

As noted above, appropriate consent is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with them immediately before they died. Those in a qualifying relationship are found in the HT Act in the following order (highest first) and a representative lower down the list may not override the wishes of a person higher up the list:

- Spouse or partner (including civil or same sex partner). The HT Act states that, for these purposes, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship
- Parent or child (in this context a child may be of any age, but must be competent if under the age of 18, and means a biological or adopted child)
- Brother or sister
- Grandparent or grandchild
- Niece or nephew
- Stepfather or stepmother
- Half-brother or half-sister
- Friend of long standing

A person may be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, decline to deal with the matter or are unable to do so, for example, because they are a child or lack capacity to consent. In such cases, the next person in the hierarchy would become the appropriate person to give consent.

Where there is a conflict of consent between those accorded equal ranking in the hierarchy, such as brother and sister, the *HTA Code A* states that the consent of one of those persons is sufficient for the procedure to go ahead providing this is discussed sensitively with all parties involved.

An executor is not automatically classified as a nominated representative and would need to be specifically appointed to this role in line with the requirements of the HT Act.

Not all adults whose human tissue may be used in research have the capacity to consent themselves. Any researchers who may have a requirement to remove, store and use tissue from adults without the capacity to give consent should contact the Designated Individual before taking any other steps. Where permission to proceed is granted such researchers must follow the guidance issued to them.

For activity involving children please refer to guidance below.

Has sufficient written or verbal information been provided for the person giving consent to make a properly considered decision?

Appropriate information on the activities for which consent is being sought must be provided. This information may be provided in the form of leaflets, information sheets, or may be contained within the consent form. Information should always be provided in an appropriate format or language.

The University requires its staff and students to use the approved standard documentation for the informed consent process (please see Appendices 2 and 3), unless the use of alternative documentation has been agreed with the Designated Individual.

All such documentation should make reference to the *HT Act* and the role of the HTA. It should be reviewed before use to ensure that it is consistent with the HTA *Code of Practice A*.

All subjects should be given opportunities to discuss the activities for which consent is required with the researchers and any other employee they consider relevant (e.g. the Designated Individual or Persons Designated).

Has the information been given in an appropriate format?

Where appropriate, participant information sheets and informed consent forms must be provided in a variety of formats. These include braille versions and translations of documents into languages other than English. Where expertise does not exist within staff employed by Edge Hill University, independent interpreters (Capita Translation and Interpreting, Oldham, UK) should be used.

Any difficulties in communicating with the person whom you seek consent from (for example, because of language, literacy or hearing difficulties) that are met should be recorded including an explanation of how these difficulties were overcome.

How will the consent be given and recorded?

The *HT Act* does not specify the format in which consent should be given for the use of human tissue in research. As the HTA notes in its *Code of Practice A*, the information required and the manner in which consent is obtained and recorded may vary depending on the particular circumstances.

Written consent does serve as good evidence of consent. However, a signature on a form does not, alone, make the consent valid unless an appropriately informed person who has the capacity to agree has given it voluntarily.

A system or protocol should be in place to ensure that the process followed is correct and the decision has been properly recorded.

It is good practice for the participant and the witness (i.e. the person taking the consent) to sign two copies of the consent form. The participant retains one copy and the researcher retains one copy.

When is written consent required?

To ensure that the removal, storage or use of any tissue is lawful, it is important to establish clearly that consent has been given, although this consent does not specifically have to be in writing. However, it is good practice to get written consent for any activity that requires consent.

Is consent required for more than one purpose?

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 this reason it is good practice for researchers to seek generic consent.

Researchers may wish to use a multi-stage consent process in which more than one consent form is used. In a two-stage consent process, for example, the first form might be used to seek consent relating to the specific objectives of the study in which the participant is being enrolled. A second form might be used to obtain general consent for the use of the tissue in future investigations where the objectives are currently undefined. This allows patients who do not wish to provide general consent to still be consented and enrolled in the study.

Any special wishes or restrictions expressed by the tissue donor should be documented on the consent form and a system put in place to ensure that the tissue is used in accordance with these wishes.

If a child is involved, are they competent to consent and have they expressed any particular wishes or views?

Under the *HT Act* a child is a person under 18 years of age. Children may consent to the storage and use of their tissue if they are competent to do so. However, the HTA advise that it is good practice to consult the person who has parental responsibility for the child.

If a child did not make a decision, or was not competent to do so, the *HT Act* is clear that the appropriate consent will be that of a person with responsibility for the child. The consent of only one person with parental responsibility is necessary.

If an adult lacks capacity to consent, how should the provisions of the Mental Capacity Act 2005 (MC Act) be applied?

The *HT Act* does not specify the criteria for considering whether or not an adult has capacity to consent. Under the *MC Act*, efforts should be made to provide information that is appropriate in terms of culture and language when assessing capacity. A person aged 16 and over is considered by the *MC Act* to be unable to make a particular decision if they are unable to do one or more of the following:

- understand the information given to them that is relevant to the decision;
- retain that information long enough to be able to make the decision;
- use or weigh up the information as part of the decision-making process and
- communicate their decision by any means.

It is not envisaged that Edge Hill University staff or students will have any requirement to remove, store, or use tissue from adults who lack the capacity to consent. Where any such requirements are identified these should be discussed with the Designated Individual before any other steps are taken.

What systems should be in place when seeking consent to use and store HTA relevant samples from Edge Hill University staff or students for research?

The University requires that researchers 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 with regard to exposure to potential infectious risks) and donors (such as where their health status precludes donations). In consideration of these issues, the University may seek separate employment law or other legal advice when considering whether or not to approve research that involves their staff or students as donors.

What are the exceptions to the consent provisions of the HT Act?

The consent requirements of the *HT Act* do not apply retrospectively and therefore it is not legally necessary to have consent to store or use material from the living or deceased that was already held at the time the *HT Act* came into force (1 September 2006). Under the *HT Act* such material is referred to as *existing holdings.*

Irrespective of the date on which tissue was donated for research, if more than 100 years have elapsed since a person's death, consent to undertake research on their tissue is not required under the *HT Act*.

For research, the consent provisions of the *HT Act* do not apply to imported material. 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 human tissue without the written permission of the Designated Individual.** Please see *HT6: Policy and Procedure for the Import and Export of Human Tissue* for further guidance.

For education or training, the consent provisions of the *HT Act* do not apply to material taken from the living. Consent is required under the common law on removal of tissue from the living. 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 this 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 outlined in this policy and procedure.**

Beyond the above general exceptions, the use and storage of any relevant material needs consent from the donor unless **ALL** of the following circumstances are present:

- the tissue is from a living person;
- the researcher is not in possession, and is not likely to come into possession, of information that identifies the person from whom it has come; and
- the material is used for a specific research project with ethical approval from a suitably recognised research ethics committee (note that Edge Hill University's URESC is not a suitably recognised committee for this purpose).

In order to satisfy the first of these requirements, the HTA's codes of practice state that data about the tissue do not have to be permanently or irrevocably unlinked from the identity of the donor - it can be pseudonymised (for example, where a system of coding is used).

With regard to the second of these requirements, the HTA advise that, although there may be

occasions when a clinician involved in research may also have access to a secure database that would allow the identification of a sample used in research, provided that the material is not identifiable to the researcher (e.g. it is coded by a laboratory accession number) **and** the researcher does not attempt to link the sample to a patient, the sample will be regarded as non- identifiable.

As noted above, Edge Hill University's URESC (and all sub-committees) is not a suitably recognised research ethics committee (REC) for the purposes of this consent exception. Only RECs established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments.

Is DNA analysis likely to be involved?

In most circumstances it is an offence to hold material with the intent of analysing DNA without qualifying consent.

Such qualifying consent is required to analyse DNA, subject to certain exceptions and these must be carefully reviewed before making any decision. A consenting donor should be informed that their tissue could be used for DNA analysis and made aware that this may reveal significant results (e.g. a family genetic condition).

10.3.4. Ethical approval and consent

10.3.4.1. The HTA's remit does not include ethical approval of research involving human tissue. Ethical approval must be sought using the guidance provided by the National Research Ethics Service and Edge Hill University's Research Ethics Policy.

10.3.4.2. As detailed above, research using relevant material can only be performed where there is appropriate consent (subject to the exceptions outlined above).

10.3.4.3. For any project involving participants who are identified as a result of their past or present use of the NHS, application for ethical approval must be made to the NRES and a favourable opinion must be received.

10.3.4.4. All projects that require Health Research Authority (HRA) approval must be submitted to Edge Hill University's Health Research Ethics Committee (HREC).

10.3.4.5. Suitably recognised RECs (i.e. those established under and operating to the governance arrangements issued by the UK Health Departments) will accept all applications involving the use of relevant material. Only these RECs can give the consent required to take advantage of the consent exception available under the *HT Act*.

10.3.4.6. Edge Hill University's ethics committees are not, for the purposes of the consent exception, considered to be a recognised REC. As such, consent is still required for relevant material to be used for a scheduled purpose for research projects approved by ScREC or HREC, even if it uses tissue from the living and the researcher is not in possession, and not likely to come into

possession, of information identifying the participant.

10.3.4.7. Relevant material for a specific research project approved by a suitably recognised REC (or where approval from such a REC is pending) can be stored on the premises without a HTA license. Where the ethical approval is not by a recognised REC (including Edge Hill University's URESC/ ScREC/HREC), relevant material should be held under the governance of both the University's HTA License and that ethical approval.

10.3.4.8. Tissue received from an approved tissue bank can be stored during the life of the relevant research project without the need for a HTA license, subject to certain requirements. If these requirements are not met, specific project approval from a suitably recognised REC will be required or, alternatively, the samples will need to be stored under the University's HTA License. On completion of research using tissue from a REC approved research tissue bank the individual researcher must transfer the tissue back to the tissue bank, or apply for specific project approval from a suitable REC, or dispose of the human tissue.

10.3.4.9. Any staff member, student, or researcher seeking to obtain tissue from such a tissue bank must first contact the Designated Individual.

10.3.4.10. URESC has agreed that any research involving the use or storage of human tissue should be subject to University ethical scrutiny and approval and should therefore be referred to ScREC or HREC by departmental research ethics committees. ScREC or HREC, with occasional input from URESC, will be responsible for scrutiny and approval of all aspects of the ethics application, not just aspects relating to the use or storage of human tissue.

10.3.4.11. All applicants seeking ethical approval from ScREC or HREC should complete an online application via the Haplo system.

10.3.4.12. Participant information sheets and consent forms used for research involving human tissue should follow the same format as the templates given in appendices 2 and 3. Researchers are permitted to adapt the consent form template to better serve their requirements, but only where this is necessary, e.g. where multi-stage consent is implemented.

10.3.4.13. All research that uses human tissue must be conducted with appropriate ethical approval.

10.3.4.14. An extension is required for continuation of collection of new human tissue and analysis of human tissue for the same purpose for which ethical approval had originally been obtained.

10.3.4.15. An extension is not required for data analysis (e.g., statistical analysis) of data from tissue samples that have already been analysed.

10.3.4.16. A new ethics application is required for a study using the same human tissue samples (providing these are suitable, appropriately collected, and consented for such further use) but for the analysis of outcomes that were not included in the original ethics application.

10.3.5. Storage of consent forms

10.3.5.1. All completed consent forms must be stored on the University's Y-drive and be directly linked to the samples for which consent was taken from within the Pro-curo Enterprise sample inventory and tracking software. Ensuring complete and accurate records is the responsibility of the Principal Investigator of each study.

10.3.6. Training and assessment of competence

10.3.6.1. 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. The Designated Individual or his representative must assess the competency of all staff or students in seeking consent and provide a written report, highlighting aspects of good practice and areas for development. Refresher training and assessment of competency in seeking consent should be undertaken by each researcher every 3 years.

10.3.6.2. Those seeking consent should have a good understanding of both the activities for which they are seeking consent and the intended use of the tissue. Such staff should be in a position to answer questions that may be asked. It is recommended that all those seeking consent and intending to use human tissue for research seek to anticipate questions that may arise and prepare answers.

10.3.7. Other consent considerations

10.3.7.1. An individual's medical history, status, or lifestyle may have a bearing on whether they should consent to participate in a study. An application for ethical approval should always state whether consent is being sought from apparently healthy volunteers, or those with specific medical conditions.

10.3.7.2. If a series of tissue samples are to be collected over a period of time, or extra tissue sought, the donors should be reminded of their right to withdraw from the study (including the withdrawal of their consent for continued storage and future use of their tissue). Where appropriate, donors should be asked to sign another consent form.

10.3.7.3. If a donor gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled purpose, such as research, this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent

has been withdrawn. In addition, if a donor withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects. The implications and practicalities of withdrawing consent should be made clear; for example, withdrawal of consent cannot be effective where tissue has already been used.

10.3.7.4. Seeking consent can be a sensitive issue and consent should be sought in a suitably private environment where the potential research participant can be made comfortable and put at ease. This will help ensure participant confidentiality, provide an environment where the potential participant feels he or she can ask questions, and facilitate fully informed consent.

10.3.7.5. If human tissue is to be collected by hospital staff who are not registered or employed by Edge Hill University, it is good practice to have a system that sets out the responsibilities of the parties involved and the procedure for recording consent. This ensures that only appropriately trained staff obtain valid consent.

10.3.7.6. Donors should be told if their samples will or could be used for research involving the commercial sector. They should be given appropriate information on the range of activities and researchers that may be involved.

10.3.7.7. Donors should be informed if the research is known or likely to involve genetic testing or the use of human tissue in animals.

10.3.7.8. The HTA advises that it is good practice to ensure that donors are given adequate information before providing consent if there is any possibility that their samples will be exported for use abroad.

10.3.7.9. Donors should be informed and should understand that their samples are to be used for research purposes only and not for therapeutic procedures (unless applicable).

10.3.7.10. It is important for all those involved in research to be aware that in addition to the consent provisions of the HT Act they will need to adhere to other legal requirements, including the General Data Protection Regulation (GDPR), 2018 and the Data Protection Act, 2018. Principal investigators should ensure that they understand and adhere to University guidance on data protection under the GDPR and the Data Protection Act, 2018.

Principal investigators must ensure that an appropriate legal basis for processing personal data is identified and that the appropriate safeguards are in place. Principal investigators leading projects that involve human tissue must pay particular attention to the possibility that their work may involve the processing of special category personal data, which includes (but is not limited to):

- data which reveal racial or ethnic origin

- data concerning health (the physical or mental health of a person, including the provision of health care services)
- data concerning sex life or sexual orientation, or
- genetic or biometric data processed to uniquely identify a natural person.

Where a project does involve the processing of special category personal data it will be necessary to identify a further legal basis for this processing. Edge Hill's view is that the most appropriate legal basis to rely upon when processing special category personal data for research purposes is Article 9(2)(j) i.e. where the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Reliance on this article requires Edge Hill to ensure that the processing meeting the public interest test and that appropriate safeguards are in place. Other articles may be more appropriate in exceptional cases. Please contact dataprotection@edgehill.ac.uk and research@edgehill.ac.uk if further advice is required.

This policy and procedure is current to the guidance given in the HTA Code A Guiding Principles and the Fundamental Principle of Consent and Code E Research (Code of practice and standards and Standards and guidance) dated April 2017.

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

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments • Additional sub section (10.4.2.3) relating to regular completion and updating of safety documents. • Adjusted prevalence rates based on figures given on the HSE website 2017 for HBV and Public Health England report for HIV given in 2015. • Addition of Biological Safety Officer as a point of contact • Additional sub section (10.4.3.4) stating that a BioCOSHH form should be completed for work with relevant material. • Additional section (10.4.3.6) listing risk assessments to consult/ complete relating to the premises, practices and procedures connected with licensed activities.	Human Tissue Management Sub-Committee (HTMSC)	23 January 2018
5.0	• **Addition:** Reference to COVID-19 pandemic, section 10.4.3.6 • **Update:** Vaccination requirements, section 10.4.4 • **Update:** Responsibility, section 10.4.5.2 • Addition: Droplets to 10.4.5.13 • **Deletion:** Removal of example disinfectants replaced with a link to SOP 8, Procedure for Disinfection, 10.4.5.13	Human Tissue Management Sub-Committee (HTMSC)	2 February 2021

Version number	Revision	Authorised by	Date
6.0	• **Addition:** Statement regarding risk assessment.	Human Tissue Management Sub-Committee (HTMSC)	11 September 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.4.1. Scope

10.4.1.1. 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.

10.4.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.4.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.4.2. General considerations

10.4.2.1. Human tissue should be taken from participants who are not known or suspected to be infected by hazardous pathogens. However, **all** human tissue samples **must** be considered to be potentially infectious and handled with extreme care.

10.4.2.2. Following appropriate safety measures at all times when handling tissue samples is the only way to minimise the potential risks associated with human material.

10.4.2.3. The University requires that risk assessments, BioCOSHH forms, standard operating procedures (SOPs) and other documentation relating to the safety of both personnel and the human tissue should be completed and reviewed regularly.

10.4.2.4. Risk assessments should be reviewed annually, or sooner where changes in relevant legislation, guidelines, or policy and procedures warrant a review that is earlier than the annual review date.

10.4.3. Threats and risks

10.4.3.1. When working with human tissue and bodily secretions there are significant threats from blood borne agents such as Hepatitis B virus (HBV) and Human Immunodeficiency Virus (HIV). The UK has an estimated prevalence rate between 0.1 and 0.5% for HBV and 0.16% for HIV within the general population. However, prevalence varies considerably within high and low risk groups. Other pathogens could also be present, and it is important to take these into account.

10.4.3.2. Infection by blood borne pathogens is usually by direct contact with human tissue including blood. The main routes of infection normally arise from percutaneous contamination, either by punctures, cuts, or abrasions.

10.4.3.3. As of January 2020, researchers must also take into account the risk of human material containing severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) which gives rise to COVID-19. Risk

assessments should take into consideration it's prevalence in the population at the time of collection and ensure that any work with participants and human samples is in accordance with government and University legislation, policies and guidance.

10.4.3.4. Researchers should consult the Biological Safety Officer (BSO) before designing any research involving subjects whom they believe may fall into high-risk groups.

10.4.3.5. A BioCOSHH form should be completed for work involving the use of relevant material and submitted to the BSO for approval.

10.4.3.6. The following resources should be consulted:

- *Blood-borne viruses (BBV)*
- *Management of Needlesticks, Sharps and Body Fluid Procedure*

10.4.3.7. The following risk assessments relating to the premises, practices and procedures connected with licensed activities should also be consulted/ completed:

- *receiving and/or storing specimens without appropriate consent documentation;*
- *storing or using human tissue after consent withdrawal;*
- *storage failure or other damage affecting human tissue quality for useful research;*
- *loss of human tissue;*
- *sample mix-up or loss of traceability;*
- *transport of specimens to and from the establishment ;*
- *security arrangements;*
- *incorrect disposal.*

10.4.4. Before starting work, researchers should:

- Ensure risks to health and safety from handling human tissue are assessed using both a BioCOSHH Risk Assessment and Risk assessment form. Templates can be downloaded from the University web pages or are available on request from the BSO. Risks to the integrity of human tissue samples also should be assessed using the University's *Human Tissue Risk Identification and Assessment Form* shown in Appendix 4.
- Give general consideration to the nature and source of the human tissue,

the types of pathogens that could be present, and likely incidence given the source (e.g. a particular patient or service user group and/or general population). This is primarily the responsibility of the Principal Investigator, but should be discussed with all staff undertaking the activity, the BSO and the Designated Individual.

- Ensure that they are working only in the agreed and designated working area and that they follow procedures that will avoid the possibility of percutaneous inoculation. Biohazard signs must be displayed and access restricted only to authorised users.

- Ensure that they are familiar with a practiced protocol for any procedure being undertaken, to be sure that the procedure will proceed as expected and does not produce any unforeseen contamination risks.

- Ensure that they are familiar with standard operating procedures (SOPs) drawn up for that particular laboratory.

- Ensure that there are arrangements for the safe decontamination and/ or disposal of human tissue, the decontamination of potentially contaminated surfaces, and disposal/cleaning of laboratory ware. Only trained staff must dispose of contaminated clinical waste. All areas must be carefully decontaminated before access to areas is allowed to any cleaning and maintenance staff, or engineers.

- Ensure that, if the risk assessment has deemed it necessary, all team members working with human tissue samples have been offered a HBV vaccination course with confirmed antibody response.

- Ensure that there is an agreed procedure to follow in the event of an accident occurring, how to report it and record any adverse events. All staff have a duty to inform other laboratory workers of the nature of the work they are intending to undertake.

- Ensure that they have read or completed the relevant risk assessments that relate to the premises, practices and procedures connected with licensed activities.

10.4.5. General Safety Guidelines when handling human tissue

10.4.5.1. Human tissue should only be collected by personnel competent to do so. Competency is regarded as possessing sufficient knowledge, training, and experience to conduct the procedure safely and efficiently.

10.4.5.2. It is the responsibility of the PI to assess the competence of individuals undertaking work under the University's HTA License and to arrange suitable training where appropriate.

10.4.5.3. The use of laboratory glassware or other sharps should be reduced to a

minimum. Disposable plastic ware should be used wherever possible. Tubes should be capped and sealable. Damaged/ cracked equipment should not be used.

10.4.5.4. Contact with human tissue must be avoided. Staff must wear suitable gloves at **all** times and discard punctured/ damaged gloves immediately. Open wounds, cuts and abrasions should be covered with a waterproof dressing.

10.4.5.5. Hands must be washed immediately after handling human tissue.

10.4.5.6. Laboratory coats or protective overalls should be worn when handling human tissue in the laboratory and removed before leaving the laboratory.

10.4.5.7. The process and analysis of relevant material must be undertaken on designated work surfaces. These will be demarcated using biohazard tape and, where possible, appropriate signage.

10.4.5.8. Sharps are only to be handled by a competent member of staff (and if at all possible should be avoided totally). Only disposable sharps that do not require the manual fitting of blades should be used.

10.4.5.9. Eating, chewing, drinking, smoking, storing of food, and applying cosmetics must not take place in the laboratory.

10.4.5.10. Mouth pipetting must not take place.

10.4.5.11. All staff working in the laboratory should avoid contact with any mucosal surfaces such as eyes, nose and mouth e.g. rubbing your face with your hand.

10.4.5.12. The work area should be cleared of any unnecessary equipment before handling human tissue.

10.4.5.13. EC approved eyewear should be worn whilst handling human tissue. If the procedure is likely to generate an aerosol or droplets, a microbiological safety cabinet (class 2) should be used for which the airflow has been checked in the past 12 months.

10.4.5.14. Contaminated glassware must be disinfected either by being immersed in a solution effective against viruses (See HT. SOP 8: Procedure for Disinfection) for the minimum time period stated by the manufacturer or autoclaved.

10.4.5.15. Discarded syringes, needles, cartridges, broken glass and other sharp instruments must be disposed of in yellow sharps bins with orange lids.

10.4.5.16. Contaminated plastics must be disposed of via procedures set out in this manual or decontaminated either by being immersed in a solution effective against viruses for the minimum time period stated by the manufacturer or autoclaved.

10.4.5.17. Spillages should be wiped immediately and the area disinfected using a solution effective against viruses. Contact time should reflect the minimum time period stated by the manufacturer.

10.4.5.18. The above are guidelines and should be used in conjunction with specific protocols, SOPs, BioCOSHH risk assessments and risk assessments.

10.5. Policy and Procedure for the Local Transport of Human Tissue

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments • Additional situations were tissue is expected to be imported to the University from an external source. • Addition of specified countries involved and requirements of the MTA. • Additional information regarding the mental capacity of donors and the use of transport companies/ courier service. • Additional section titled *'Traceability'* and detailing what steps must be undertaken to ensure a robust audit trail	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Rewording :** Heading and BP2, section 10.5.3. • **Removal**: reference to mental capacity of volunteers, section 10.5.3. Already covered under consent.	Human Tissue Management Sub-Committee	2 February 2020

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.5.1. Scope

10.5.1.1. 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.

10.5.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.5.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.5.1.4. This policy and procedure is intended for use in the transport of human tissue within the campus (for example, between the Wilson Centre and the Biosciences Building) and transport from a location external to the campus to the campus. This latter situation is expected during research involving fieldwork, when collaborating with researchers in other institutions and when members of staff join or leave the University.

10.5.2. General considerations

10.5.2.1. Wherever possible the transport of human tissue within the Ormskirk campus of the University, or from locations in the local area, should be avoided or minimised. This means that there is a presumption that samples should be taken on campus in a suitable environment and stored where taken rather than moved from one location to another, unless there is clear justification.

10.5.2.2. Where human tissue is transported locally, consideration must be given to minimising the likelihood of theft, damage, loss, or other adverse events.

10.5.2.3. A decision on how the human tissue is to be preserved, on any potential contamination risks associated with it will be managed, and who is responsible for it during transport and on arrival, should be made before tissue is collected.

10.5.2.4. 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* (Appendix 5) and email it to the Designated Individual. Consideration must be given to minimise the likelihood of theft, damage or loss during transport. The MTA should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable. Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.

10.5.3. The following should be in place before transportation between establishments:

- Confirmation that the appropriate human tissue storage destination areas are available and accessible.
- Each sample to be transported must be linked to a unique reference number that is made available to the receiver to ensure that traceability of relevant material is maintained during transport.
- Appropriate packaging. In the case of unfixed tissue this should consist of a primary break resistant and leak proof container that is robust and legibly labelled, with a secondary watertight container to hold the primary container. These containers should be placed in a larger case of absorbent material such as a polystyrene box that is suitable for the containment of refrigerants e.g. dry ice or water ice. Fixed tissue such as that on microscopic slides should be placed in a primary container and enclosed in a secondary container that consists of absorbent material. Support should be provided inside the packaging to prevent the contents from moving. All containers should be secured by packaging in a sturdy outer casing that includes hazard information and an emergency contact number.
- Appropriate modes of transport and a suitable route.
- Familiarity with the appropriate human tissue preservation procedure and a check for the availability of refrigerants e.g. dry ice or water ice.
- A contact number for a suitable member of Edge Hill University staff and/ or the receiver in case of emergency.
- Ensure that the transport of samples complies with the consent provisions for said samples.
- If using a courier or transport company, ensure that they are aware of the transport requirements and emergency contact information. Agreements with the courier or transport company, including documentation and email exchanges, should be stored by the University.

10.5.4. Collection of samples at a site different to the storage site

- If required, ensure that the volunteer, patient or person in a qualifying relationship to the donor (*see section 10.3.3.2*) has read and understood the relevant participant information sheet and signed the consent form.
- Undertake the appropriate preservation procedure for which a risk assessment will have been conducted.
- Appropriately label human tissue containers with a unique reference number and label the outer packaging with an emergency contact number.

- Ensure that the appropriate protection and decontamination procedures are followed.

- Ensure that all packaging is undamaged and does not have the potential to leak.

- Do not open any human tissue containers again until you are in a suitably controlled Edge Hill University laboratory environment.

10.5.5. Transportation between establishments

10.5.5.1 A system must be in place to ensure the integrity and the traceability of relevant material is maintained during transport.

- Double check the packaging and labelling.
- Never leave the human tissue unattended during transport.
- Follow this policy when using personal or hire vehicles.
- Follow your route directly without any deviation, delays, or distractions.
- If using a courier or transport company, ensure that the samples are tracked and that any adverse events or deviations from the agreed transport requirements are recorded and reported to the emergency contact.

10.5.6. On arrival at Edge Hill University

- Ensure that the human tissue collection containers are securely stored, labels in place, and containers are externally decontaminated. Use appropriate protection.

- Contact a Person Designate or the Designated Individual to arrange storage and update the University's sample inventory and tracking records, including details of the origin, storage location, use and provenance of human tissue samples collected (consulting *HT7: Policy and Procedure for Records and Audit*).
- Ensure that all consent forms, relevant patient information and any transport documentation have been given to a Person Designate or the Designated Individual so that they can be scanned and electronic copies stored within the sample inventory and tracking software or that these documents have been uploaded to the Y drive.

- Report any adverse events e.g. material lost or material quality compromised during transportation and any accidents to the Principal Investigator and the Designated Individual.

- If using a courier or transport company, ensure that the samples are signed for by a member of staff trained to deal with HTA relevant samples and that the above procedures are followed.

10.5.7. Transport from Edge Hill University

10.5.7.1. If transport of any human tissue is made from Edge Hill University to another establishment within England, Wales or Northern Ireland, Edge Hill staff agreeing to that transfer must review the original consent provisions to ensure compliance. A material transfer agreement should be set up. A HTA license is not required to transport human tissue but the receiving establishment should either have a HTA license or the project for which the tissue will be used must have favourable approval from a recognised research ethics committee. Refer to *HT3* for a definition of what is a recognised research ethics committee with respect to the *HT Act*. Anyone wishing to transport human tissue from Edge Hill University to another establishment should, in the first instance, complete a *Human Tissue MTA Request Form* (Appendix 5) and email it to the Designated Individual.

10.5.8. Traceability

10.5.8.1 A coding and records system must be in place to facilitate the traceability of human tissue that ensures a robust audit trail. This includes that the following is undertaken

- Ensure that each sample has been assigned a unique code.
- Add each sample to the University register for imported material, which will include information about when and where the tissue was acquired and received, the consent obtained, the sample storage location, the use to which any material will be put, when and where the material was transferred and to whom, the members of staff associated with the tissue and the details of transport and delivery.
- If transporting material to a different establishment in England, Wales or Northern Ireland, ensure that records of transportation and delivery, agreements with the courier or transport company and any agreements with recipients of relevant material are kept for a minimum of 5 years.

This policy and procedure is current to the guidance given in the HTA Code E Research (Code of practice and Standards and Standards and guidance) dated April 2017.

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

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	Removal of text stating a request for import or export of tissue will normally be denied.	Human Tissue Management Sub-Committee	27 September 2016
3.0	• Minor text amendments • Deleted sentence stating that the University does not encourage the import or export of human tissue. • Additional sentence stating that the University will consider the import and export of human tissue outside of the UK. • Additional sub section (10.6.2.5) regarding the integrity of imported tissue. • Additional sub section (10.6.2.6) regarding provisions that must be in place before the export of tissue outside of the UK.	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Removal**: BP1, section 10.6.2.8. Information incorporated into BP3 (Now BP1).	Human Tissue Management Sub-Committee	2 February 2021

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.6.1. Scope

10.6.1.1. 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.

10.6.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.6.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.6.1.4. This policy does not only relate to the import or export of human tissue for human application, which is covered by the HTA's regulatory remit, but also the *Human Tissue (Quality and Safety for Human application) Regulations 2007*.

10.6.2. General Considerations

10.6.2.1. Standards and guidance concerning the import and export of human tissue are detailed in *HTA Code E Research (Code of Practice and Standards and Standards and guidance).*

10.6.2.2. Under the *HT Act* human tissue may be imported for use in research projects. The consent provisions of the *HT Act* do not apply if human material is imported. However, the HTA considers that it is good practice for researchers and the Designated Individual to ensure that mechanisms are in place in the source country for obtaining consent for the storage, use, and export of samples given.

10.6.2.3. The import and export of relevant material is not a licensable activity under the *HT Act*. However, the storage of such material once it is imported may be licensable if it is stored for a scheduled purpose, as defined by the *HT Act*.

10.6.2.4. The University will consider the import of human tissue from countries outside of the UK if researchers can demonstrate that the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within England, Wales and Northern Ireland. For the purposes of the *HT Act*, this extends to human tissue originating from Scotland (or procured from Scotland), where the use of human tissue is governed by a different legal framework.

10.6.2.5. Researchers should be able to document the integrity of material imported from countries other than England, Wales and Northern Ireland. Although the consent provisions of the HT Act do not apply to imported tissue, the University requires that researchers can document that appropriate consents have been obtained.

10.6.2.6. If tissue is to be transported to a location outside of England, Wales and Northern Ireland, material should be transported and subsequently procured, used, handled, stored and disposed of in accordance with the consent that has been given. This includes providing donors with adequate information when obtaining consent, to the effect that their samples may be exported for use abroad.

10.6.2.7. **No member of staff or student should instigate the import or export of human tissue without the written permission of the Designated Individual.**

10.6.2.8. Where permission is granted to import or export material:

- Imported and exported material should be procured, used, handled, stored, transported and disposed of in accordance with the consent under which it was given.
- Tissue imported from Scotland or outside of the UK, should be treated in the same way as tissue originating from participants in England, Wales and Northern Ireland.

10.6.3. Procedure

10.6.3.1. The import or export of human tissue should only ever take place with the approval and involvement of the Designated Individual.

10.6.3.2. For export, service level agreements should be in place to ensure that the exported tissue is used in accordance with the consent given.

10.6.3.3. Some or all of the following will need to be in place (with precise requirements determined by the Designated Individual):

- A materials transfer agreement (MTA) between the source organisation and the end user of the tissue.
- Policies and procedures which clearly evidence how informed consent was obtained, including safeguarding of the confidentiality of all information.
- Approval from a research ethics authority or the local equivalent in the source country.
- A quality management system should be in place, including standard operating procedures, and stating the final destination (and user) of tissue.
- Details of the imported tissue should be entered into the University's human tissue sample inventory and tracking software, including the recording of the reasons why the decision was made to import. These details should include details of when the imported material was acquired and where from, the uses to which it will be put, when the material was exhausted, transferred elsewhere (and to whom), or disposed of.
- Disposal arrangements should meet the requirements applying to material that had been sourced in England, Wales, or Northern Ireland.

- The supplier's record and other documentation of each consignment of imported tissue should be retained by the person undertaking the import for at least five years after disposal of the last part included in the consignment.
- A system to ensure that adverse events, reactions and/or incidents involving imported tissue is investigated.

This policy and procedure is current to the guidance given in the HTA Code E Research (Code of Practice and Standards) paragraphs 98-114 (Import and export), and Research Standards and guidance dated April 2017.

10.7. Policy and Procedure for Records and Audit	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments • Additional sub sections (10.7.2.1 & 10.7.2.2) taken from the new HTA code of practice for Research • Additional information about required details of transport and delivery and the '*calibration, validation, maintenance and monitoring*' of equipment. • Addition of sub section (10.7.3.11) regarding loss of records. • Addition of section (10.7.4.10) stating the requirement to '*include who is responsible for follow-up actions*' and '*timelines*'.	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Addition:** Person(s) Designate to section 10.7.3.10. • **Revision:** Distinction made between internal 'inspection' and the formal 'audit' procedure, 10.7.4. • **Addition:** Individual responsibilities, section 10.7.4.5 • Minor text amendment, 10.7.4.9	Human Tissue Management Sub-Committee	2 February 2021
6.0	• **Update:** Additional information added regarding a new requirement for self-audit by people storing tissues under the HTA license, section 10.7.4.9. • **Update:** Additional information added regarding the requirement to obtain documentary evidence that non-compliances have been rectified.	Human Tissue Management Sub-Committee	30 January 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.7.1. Scope

10.7.1.1. 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.

10.7.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.7.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.7.2. General Considerations

10.7.2.1. Establishments meeting the HTA licensing standards on Governance and Quality Systems will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

10.7.2.2. Establishments meeting the HTA licensing standards on Traceability will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and we expect establishments to take a pro- active approach to assuring themselves of effective traceability throughout the lifetime of their licence.

10.7.2.3. A system should be in place to maintain proper records and documentation for all tissue acquired, stored, used, passed to others, or disposed of within the remit of the *HT Act*. The University uses Pro- curo Enterprise sample inventory and tracking software for these purposes. This software has been developed to facilitate compliance with the *HT Act* and the directions given in the HTA's codes of practice.

10.7.2.4. All staff undertaking any activity involving the acquisition, storage, or use of human tissue that falls within the remit of the *HT Act* **must** use this software only. No alternative approach to the maintenance of records may be used.

10.7.2.5. The standard operating procedure for tracking tissue samples is shown in Appendix 6.

10.7.2.6. The HTA expects all establishments to be committed to maintaining standards and improving quality control. To ensure this, the University's

Human Tissue Management Sub-Committee has adopted and will implement a programme to audit human tissue stored under the university's HTA License and all of the processes related to that storage.

10.7.3. Records

10.7.3.1. When using the University's Pro-curo Enterprise sample inventory and tracking software all required and relevant fields must be completed. These will include:

- The location of relevant material stored under the HTA License (e.g. in which freezer it is stored) and name of the Principal Investigator.
- When the material was acquired or received and where from.
- To what has been consented, including scanned copies of signed consent forms and any ethical approval letters.
- The uses to which the material is put whilst in Edge Hill University's care and any process applied to it.
- Details of any transport and delivery of tissue. This includes records (and copies) relating to the transportation and delivery of material, agreements with the courier or transport company and agreements with the recipients of any material (such as MTAs).
- The time, place, and method of and reason for disposal, including a scanned copy of the certificate of destruction.

10.7.3.2. 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.

10.7.3.3. 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. Bar code labels must be used to ensure that relevant material is given a unique identifier and that this is both legible and indelible.

10.7.3.4. 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 particular project or for broader use in research.

10.7.3.5. 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).

10.7.3.6. All written confidential data must be held securely and in a lockable filing cabinet with access restricted to the Designated Individual and

Persons Designated. Access to the sample inventory and tracking software should be controlled by a system of usernames and passwords, and good password security practices must be followed.

10.7.3.7. The length of time that records are stored remains the University's responsibility and is not regulated by the HTA. All records (written and electronic) should be retained for a least 5 years after the disposal of the last item included in the consignment. Computer records should be backed up securely. No tissue stored under the University's HTA License is expected to be used in human application, but in such an event, records of this tissue must be kept for at least 30 years.

10.7.3.8. 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.

10.7.3.9. 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 and;
- complaints.

10.7.3.10. All records need to be available for inspection or audit at any time by the Designated Individual, Persons Designate, Principal Investigator, or the HTA.

10.7.3.11. 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.

10.7.4. Audit & Inspections

10.7.4.1. Before undertaking any work all researchers should ensure that they have read and understand the relevant 'policy and procedure' statements and are clear of what needs to be identified, recorded, and made available for audit.

10.7.4.2. All researchers should perform regular inspections of record content relating to their samples to check them for completeness, legibility, and accuracy. Using the University's human tissue sample inventory and tracking system, researchers should ensure that the records have been amended when human tissue samples have been processed or disposed of,

so they are no longer registered as stored.

10.7.4.3. Each researcher should follow the guidance and instructions of the Persons Designated (and provide that person with all information requested) for the purposes of record keeping following the standardised procedures. Records must be entered into the

University's human tissue sample inventory and tracking software to ensure that a record of each and every sample is created and populated, that traceability is maintained, that there is an associated record of signed consent forms, and a copy of a favourable opinion or approval letter from an ethics committee.

10.7.4.4. All staff should perform regular inspections of records of their teaching collections to check them for completeness, legibility, and accuracy. Each teaching collection should be recorded using the University's sample inventory and tracking system to ensure that a record of each and every sample is created and populated, that traceability is maintained, and that there is an associated record of

signed consent forms (where applicable). The inspection should also include an assessment of the condition of specimens.

10.7.4.5. An inspection should always be performed when any human tissue needs to be relocated (e.g. transferred to a different freezer). This should be performed by the PI responsible for the samples or a designated member of their research team and the Persons Designate (PD) for the area should be informed.

10.7.4.6. Inspections, in the above case, should check sample labelling and record any losses, damages, inaccuracies, or adverse events (see *HT10: Policy and Procedure for Reporting Adverse Events*). Any inconsistencies or errors should be recorded.

10.7.4.7. The Designated Individual, or their representative, will perform audits of the premises, facilities and equipment, ensuring that the relevant logs demonstrate that good security measures, maintenance programmes, and appropriate risk assessments are in place.

10.7.4.8. The Designated Individual, or his representative, will perform scheduled traceability audits on teaching and research human tissue collections. These can consist of reviews of paper and electronic records, stored tissue, and audit processes, or can be a complete record audit. Random samples will be chosen to ensure proper identification of and matching with the associated records. Entries (covering receipt, use, storage, and disposal) in the sample inventory and tracking software will be inspected. The Designated Individual, or his representative, will match these with the appropriate signed consent records. Any quality issues (e.g. inaccuracies or incomplete records) will be logged and advice given on remedial action at the earliest opportunity.

10.7.4.9. A schedule of required audits is shown below.

Timing	Audit activity
Throughout the year	Each researcher/ collection curator will self-audit and ensure that they have completed the necessary training and have read the current versions of the policy and procedures. Regular audits of samples and consent forms should be completed to check for completeness, legibility, and accuracy.
Twice yearly	Principal investigators are responsible for ensuring a formal audit of tissue samples is completed for each study they are responsible for. A minimum of 20 tissue samples should be audited using a separate audit form for each study. Where the total number of samples for a study or human tissue collection is less than 20, then all samples should be audited. The Researcher Tissue Sample Self Audit Report Form (Section 11.22) that needs to be completed and submitted to the Human Tissue Management Sub-Committee can be found on the University's Y drive. The audit should be completed, and the completed audit form submitted to the secretary of the Human Tissue Management Sub-Committee within 3-4 weeks before the March and September committee meetings.
Yearly	The Designated Individual, or his representative, will perform an audit of the premises and facilities, and traceability of teaching and research human tissue collections (Section A-B of the Human Tissue Audit Report Form). The audit should be completed, and the completed audit form submitted to the secretary of the Human Tissue Management Sub-Committee within 1-2 weeks before the March committee meeting.
Yearly	The Designated Individual, or his representative, will conduct traceability audits on teaching and research human tissue collections. The audit will consist of reviews of paper/ electronic records, stored tissue, and/or general audit processes (Sections A-F of the Human Tissue Audit Report Form). The audit should be completed, and the completed audit form submitted to the secretary of the Human Tissue Management Sub-Committee within 1-2 weeks before the September committee meeting.

10.7.4.10. Audits conducted by the Designated Individual, or his representative, should include who is responsible for follow-up actions and the timeframes for completing these

10.7.4.11. Documented evidence should be obtained and recorded to confirm that non-compliances have been rectified.

This policy and procedure is current to the guidance given in the HTA Code E Research (Code of practice and standards and Standards and guidance), dated April 2017.

10.8. Policy and Procedure for the Storage of Human Tissue	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments • Addition of sub section (10.8.2.4) detailing requirements of storage from tissue imported from outside of England, Wales and Northern Ireland. • Additional sub section (10.8.2.6) regarding storage of tissue during processing. • Additional information for clarity as to what human tissue does not need to be stored under a HTA license. • Additional sub section (10.8.2.9) providing information for surplus material. • Additional information regarding xenografts. • Additional sub section (10.8.3.3) detailing the requirement to maintain the temperatures of storage facilities. • Addition of sub section (10.8.3.8) regarding the requirement to monitor and report abnormalities in temperature.	Human Tissue Management Sub-Committee	23 January 2018
5.0	• **Addition:** Reference to SREC, 10.8.2.11	Human Tissue Management Sub-Committee	2 February 2021

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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10.8.1. Scope

10.8.1.1. 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.

10.8.1.2. The Human Tissue Authority (HTA) regulates activities concerning the removal, storage, use and disposal of human tissue. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the HTA, established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.8.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.8.2. General considerations

10.8.2.1. The *HT Act* does not define the term 'storage', nor does it give any minimum or maximum term for storage of human tissue for research – the HTA considers storage to occur whenever tissue is kept for any period of time for the purpose of research, education and training.

10.8.2.2. When seeking to store relevant material all members of staff and students must have regard to both the consent provisions of the *HT Act* and the licensing requirements of the HTA.

10.8.2.3. Storage of relevant material needs consent unless there are specific exceptions that apply. Please see *HT3* for more detail about consent for storage.

10.8.2.4. The consent provisions of the HT Act do not apply to material imported from outside of England, Wales and Northern Ireland, however, it is good practice for there to be mechanisms in place to provide assurance that the tissue is being stored with valid consent. Imported tissue stored for research should be treated in the same way as tissue originating from participants in England, Wales or Northern Ireland. This means that the same exceptions to licensing apply. The University requires that all imported, stored material has material transfer agreements (MTAs) or service level agreements (SLAs) in place to ensure that consent for storage has been obtained prior to import. Specific guidance on import and export of human tissue can be found in section 10.6 of this manual.

10.8.2.5. A HTA license is not required for storage of relevant material held for no more than seven days AND the storage is incidental to transportation.

10.8.2.6. 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.

10.8.2.7. Existing holdings (defined as those held prior to 1 September 2006 when the *HT Act* came into force) require a license for storage. Please see *HT3* for guidance on consent and appropriate holdings.

10.8.2.8. Any relevant material collected from a living person as part of a research project that has ethical approval from a suitably recognised research ethics committee (REC), such as the National Research Ethics Committee (NRES), does not need to be held under a HTA license for the period of time that ethical approval is valid, provided the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come. The University Research Ethics Sub-Committee (URESC) is not a recognised research ethics committee for this purpose. Details of all recognised committees and general information about ethical approval can be

found on the HRA's website.

10.8.2.9. Material that is stored under the above exemptions from the *HT Act*, should only be stored for the duration and or the purpose specified by the recognised REC. Any surplus material at the end of the project should be transferred back to the REC-approved research tissue bank, disposed of according to procedures outlined in the ethical approval or should be stored as material that does not have recognised REC approval.

10.8.2.10. The use of human tissues and cells in animals (xenografts) is not considered a method of storing human tissue or cells and, therefore, does not require a storage licence. However, human tissues and cells being stored prior to the transplant into a recipient species must be stored in line with the *HT Act*.

10.8.2.11. Relevant material with ethical approval from a 'non-recognised' research ethics committee (such as Edge Hill University's SREC, HREC, or URESC) must be stored under the governance of both:

- Edge Hill University SREC/HREC/ URESC approval, and
- A HTA License.

10.8.2.12. Storage is only permitted on the licensed premises (Ormskirk campus) and with the permission of the Designated Individual.

10.8.3. Procedure

10.8.3.1. Human tissue should only be stored when the appropriate consent has been obtained unless there are specific exceptions that apply (see *HT3*).

10.8.3.2. 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. These designated areas will be specific locations within specific -80^{o}C freezers, fridges or cabinets. The location of the designated area should be discussed with the Designated Individual or Persons Designate.

10.8.3.3. Freezers, fridges and cupboards should have sufficient storage capacity and documented contingency plans should be in place in case of failure in the storage area.

10.8.3.4. All stored tissue should be labelled with a unique identifier generated using the University's human tissue sample inventory and tracking system.

10.8.3.5. 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. Freezers, fridges, and any cupboards containing human tissue should be locked securely.

10.8.3.6. All stored samples should be clearly labelled as biohazards to prevent and minimise risk of contamination from inadvertent opening or touching. All samples should be double wrapped or boxed. Health and safety warning labels should be applied to the outside of the storage facility.

10.8.3.7. 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.

10.8.3.8. 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.

10.8.3.9. Standard operating procedures for storage, maintenance, and defrosting -80^{o}C freezers, and for dealing with freezer faults and defrosted samples, are shown in Appendices 8, 9, 10, 11, and 12.

10.8.3.10. Human tissue is an important research resource. However, 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 (see *HT9: Policy and Procedure for Disposal of Human Tissue*).

This policy and procedure is current to the guidance given in the HTA Code E Research (Code of practice and standards and Standards and guidance) dated April 2017.

10.9. Policy and Procedure for the Disposal of Human Tissue

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments. • Addition of sub section (10.9.4.1) advising separation of human tissue and clinical waste. • Addition of sub section (10.9.5.1) regarding full traceability through to disposal. • Additional sub section (10.9.5.4) regarding disposal agreements on an MTA.	Human Tissue Management Sub-Committee (HTMSC)	23 January 2018
3.0	• Updated information to reflect that the University stored material from both the living and the deceased.	HTMSC	2 May 2018
4.0	• Updated waste contractor details	HTMSC	1 May 2019
5.0	• **Update:** To reflect current systems, 10.9.4.2 • **Amendment:** Responsibility shifted to Facilities Management, 10.9.4.9 • **Addition:** Clear designation of responsibilities, 10.9.4.10	HTMSC	2 February 2021

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.9.1. Scope

10.9.1.1. 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.

10.9.1.2. The Human Tissue Authority (HTA) regulates activities concerning the removal, storage, use, and disposal of human tissue.

10.9.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.9.1.4. This policy and procedure relates to the disposal of clinical waste and human tissue that falls within the definition of relevant material (see Appendix 1).

10.9.1.5. This policy and procedure complies with the *Hazardous Waste Regulations 2005*.

10.9.2. General considerations

10.9.2.1. The *HT Act* and the HTA's codes of practice seek to ensure that human tissue is treated with respect and used in accordance with the wishes of donors or their relatives. The HTA's *Code E Research (Code of practice and standards paragraphs 127-130) and Research Standards and guidance* sets out guidance to help establishments undertaking licensed activity develop policies for the disposal of human tissue.

10.9.2.2. Decisions about the disposal of human tissue from the living and the deceased are subject to different considerations. At present, the University stores material from both the living and the deceased.

10.9.2.3. Disposal of surplus human tissue is permitted when the material has come from a person's body in the course of participating in research, or comes from a human body and ceases to be used, or stored for use, for any scheduled purpose.

10.9.2.4. During the informed consent process, individuals must be informed about the duration of which their tissue will be stored and how their tissue it will be disposed of after use. During the informed consent process consideration must be given to individuals whose first language is not English and any other factors that might affect communication, such as sight or hearing impairment, or poor literacy.

10.9.2.5. Attitudes towards disposal may differ between people of different cultures and religions and staff working with human tissue should be sensitive to this. This issue should be discussed in the training given by the

Designated Individual to those working under the HTA License.

10.9.2.6. There are particular sensitivities concerning the use and disposal of human tissue following lost pregnancy that should be taken into consideration. At present, it is not envisaged that staff or students will work with such material. However, if anyone is considering working with such tissue they should consult the Designated Individual before doing so.

10.9.2.7. Existing holdings (defined as those held prior to 1 September 2006 when the *HT Act* came into force) that represent identifiable and unidentifiable tissue taken from the living may be disposed of for incineration. Anyone planning to do this should first consult the Designated Individual.

10.9.2.8. Disposal arrangements for human tissue sourced outside of England, Wales, and Northern Ireland should be followed as though the material had been sourced from England, Wales, and Northern Ireland.

10.9.3. The following should be in place before disposal:

- A clear reason for disposal. Disposal should always be discussed with all staff that may be associated with the relevant human tissue (sourcing it, storing it, and using it or potentially using it for research). The University's human tissue sample inventory and tracking software must be consulted to ensure that there are no particular consent provisions or alternative arrangements for storage or disposal stipulated in the ethical approval attached to the sample, or any material transfer agreements that may exist;
- Arrangements for the secure storage of human tissue and clinical waste on Edge Hill University premises pending collection by the University's designated waste management company;
- Evidence of consideration of any potential contamination risks;
- Consideration to protecting the sample from theft or loss during the disposal process;
- A system for reporting any adverse events arising during the disposal process.
- A completed Human Tissue Disposal Form (Appendix 17)

10.9.4. Disposal

10.9.4.1. It is good practice for excess human tissue and the waste generated from work with human tissue to be bagged separately from clinical waste. Staff and students should make every effort to dispose of unused human tissue and human tissue waste in separate bags/ or containers from those used for animal waste.

10.9.4.2. Designated yellow rigid one-way access containers must be used for storage of excess/ unused human tissue pending collection for disposal by incineration. Human tissue waste can be collected in clinical waste containers/ bags. The containers/ bags must then be stored in a yellow Eurobin that must be held within a restricted access area or locked at all times if outside of a restricted access area, except when access is needed for inserting the smaller containers/ bags.

10.9.4.3. Designated orange bags must be used for the disposal of 'soft' clinical waste such as dressings, swabs and latex gloves contaminated with human tissue that may be treated to render safe prior to disposal. Yellow bags must be used for the disposal of potentially infectious human tissue waste which requires disposal via incineration.

10.9.4.4. Designated yellow sharps bins with orange/ yellow lids must be used for the disposal of sharps, receptacles such as capillary tubes, and any other contaminated material that could puncture the designated bags used for disposal of clinical waste.

10.9.4.5. Liquid human tissue waste (e.g. cell culture aspirate) must be rendered safe before disposal. This can be via sterilisation/ disinfection. Excess/ unused liquid human tissue (e.g. blood) should be disposed of as in 10.9.4.2.

10.9.4.6. Excess tissue (excluding pregnancy remains)/ material from processing may be disposed of as clinical waste unless a different method is agreed and stated in the consents. Where possible, excess tissue/ material from processing should be separated from the general clinical waste but can be stored and transported alongside other clinical waste.

10.9.4.7. Any human tissue that cannot be disposed of as clinical waste (e.g. pregnancy remains) must **not** be stored and transported alongside clinical waste. Separate vessels must be used for the storage of human tissue and clinical waste pending collection for disposal.

10.9.4.8. Human tissue should only be disposed of using the University's designated waste management company. The company Edge Hill University uses for collection and disposal of human tissue and clinical waste is AM Services (8 Penrod Way, Heysham, Morecambe, Lancashire, LA3 2UZ) who sub-contract to Initial, UK (Brunswick Business Park, Liverpool, L3 4BL).

10.9.4.9. The waste management company collects clinical waste for disposal from designated areas in the Wilson Centre and Biosciences Building. Clinical waste waiting for collection for disposal must be stored in one of these designated storage areas in a locked Eurobin. Consult with the relevant laboratory technician to identify the storage location and arrangements for storage.

10.9.4.10. Those who need to dispose of human tissue separately from clinical waste should liaise directly with Facilities Management to ensure the

conditions of the participant consents are met.

10.9.4.11. Facilities management are responsible for arranging a regular clinical waste collection and must liaise with departmental representatives to ensure that the arrangements are sufficient for the output.

10.9.4.12. Laboratory technicians must take care to liaise with Facilities Management to ensure that their waste requirements are clearly communicated. Both Facilities Management and laboratory technicians must ensure that the procedures in place minimise the period of time in which human tissue and clinical waste is stored in the designated storage area prior to collection by the waste management company.

10.9.5. Records

10.9.5.1. The University should be able to demonstrate full traceability for the human tissue for which they are responsible, from consent through to final disposal/ disposition or the material has been used up entirely.

10.9.5.2. The University's human tissue sample inventory and tracking software records must be updated to record the full use or disposal of human tissue, making note of the date, place, method of and reason for disposal.

10.9.5.3. A certificate of destruction, obtained from the waste management company, also should be stored within the sample inventory and tracking software.

10.9.5.4. MTA's for relevant tissue that has been imported or exported should define who is responsible for disposal. If a party other than Edge Hill University is responsible for disposal, there should be assurances in place that the material will be disposed of in accordance with HTA's codes of practice.

This policy and procedure is current to the guidance given in the HTA's Code E Research (Code of Practice and Standards and Research Standards and guidance) dated April 2017.

10.10. Policy and Procedure for Reporting Adverse Events	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2nd December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Minor text amendments. • Additional information regarding improvements to practice and inappropriate disposal.	Human Tissue Management Sub-Committee	23 January 2018
5.0	• Amendment. Section 10.10.4.3, Head of Environment and Safety Management changed to Health and Safety Manager.	HTMSC	2 February 2021

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.10.1. Scope

10.10.1.1. 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.

10.10.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.10.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.10.2. General considerations

10.10.2.1. Human tissue should be treated, used, stored, and disposed of in such a way to minimise or eliminate the occurrence of adverse events.

10.10.2.2. As part of the terms of its HTA License, the University is required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis.

10.10.2.3. All staff working under a HTA Research License must understand what constitutes an adverse event and be aware of the procedure to follow when an adverse event occurs.

10.10.2.4. Effective corrective and preventative actions will be taken where necessary and improvements to practice will be made.

10.10.3. Definition of an 'adverse event'

10.10.3.1. 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.

10.10.3.2. The primary principle of the *HT Act* is the need for appropriate consent. Any removal, use or storage of material without appropriate consent (unless there are specific exceptions applying) should be regarded as a serious adverse event.

10.10.3.3. Other examples of adverse events can include but are not limited to:

- 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 and;
- inappropriate disposal.

10.10.4. Procedure

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

10.10.4.2. The Designated Individual will assess the adverse incident and provide it with a preliminary grading depending on the severity of the incident. The Designated Individual will record the adverse incident in the log (Appendix 18) and any incident regarded as 'severe' will be escalated to the License Holder's Contact (Pro Vice-Chancellor (Student Experience) & University Secretary).

10.10.4.3. Remedial action must be taken immediately if staff, students, visitors, or any relevant material (existing or future holdings) are at risk. Any issues regarding a major injury, fire risk, or other health and safety risk must be reported separately to the University's Health and Safety Manager.

10.10.4.4. The Designated Individual will write a detailed report of the incident and if necessary re-grade the severity of the incident. This report should provide a full description of the adverse event (who, where, when, how) and detail the corrective action that has been taken.

10.10.4.5. The Designated Individual will store the report in the HTA folder on the Y drive and disseminate the report to the Human Tissue Management Sub-Committee who will discuss the action taken, review any relevant policies, and make recommendations as appropriate.

10.10.4.6. Remedial advice where appropriate should be circulated to all other staff working under the HTA License and any trends in adverse events noted.

10.11. Policy and Procedure for Complaints Regarding Human Tissue

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Addition of email as a method of responding to complaints.	Human Tissue Management Sub-Committee	23 January 2018
3.0	• Updated: contact for research office.	Human Tissue Management Sub-Committee	30 January 2014
6.0	• Updated: Contact information for the research office, section 10.11.3.1.	Human Tissue Management Sub-Committee	11 September 2024

Note: All human tissue policies, procedures, and standard operating procedures are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes to policy or procedures are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.11.1. Scope

10.11.1.1. 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.

10.11.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.11.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.11.2. General considerations

10.11.2.1. Human tissue should be treated, used, stored and disposed of with respect. All work involving human tissue must be conducted in accordance with the *HT Act* and the directions and guidance laid out in the HTA's codes of practice. Human tissue must be obtained, stored, and used with appropriate consent (unless there are exceptions available under law). All research involving human tissue should be conducted under the appropriate ethical review, and with the knowledge and direction of the University's Designated Individual.

10.11.2.2. Where there are any concerns, mechanisms must be in place to allow complaints to be made and thoroughly investigated. There must also be mechanisms for the results of such investigations to be reported back to the complainant. These mechanisms must be clear and understood by those under their direction.

10.11.3. Procedure

10.11.3.1. 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 OrmskirkL39 4QP
OR email: *research@edgehill.ac.uk* (FAO: Joanne Morris, URESC Secretary)

10.11.3.2. A complaint received will be acknowledged and investigated. The complainant will be informed of any outcome. If the complaint is upheld, appropriate preventative and corrective action will be implemented.

10.11.3.3. A written or email response to complaints will be given within four weeks from the date of receipt of the complaint.

10.11.3.4. If the complaint is not resolved to the satisfaction of the complainant, it may be referred upwards to the License Holder.

10.11.3.5. The University's Designated Individual will make an appropriate record of all complaints raised, the process and outcomes of any investigation, and the actions taken subsequently. All such records will be considered by the University's Human Tissue Management Sub- Committee and submitted to the University Research Committee.

10.12. Policy and Procedure for Training Regarding Human Tissue

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Addition of sub-section (10.12.2.4) stating that training provisions apply to visiting staff • Addition of sub-section (10.12.3.4) regarding '*personal development plans*' • Addition of sub-section (10.12.4.1) detailing when training may need to be updated	Human Tissue Management Sub-Committee (HTMSC)	23 January 2018
5.0	• Addition of SREC to section 10.12.3.11	HTMSC	23 January 2018
6.0	• Addition of point of staff introduction to the designated individual surround the induction process	HTMSC	30 January 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

10.12.1. Scope

10.12.1.1. 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.

10.12.1.2. Most activity involving the storage of human tissue for research and other scheduled purposes falls within the regulatory remit of the Human Tissue Authority (HTA), established under the *HT Act*, and should only be undertaken under the terms of a license from the HTA.

10.12.1.3. This statement of policy and procedure applies to all staff and students whose duties or research include activities encompassed by the *HT Act.*

10.12.2. General considerations

10.12.2.1. Edge Hill University is committed to maintaining the highest standards of quality in teaching and research, and to ensuring that staff and students are competent to undertake relevant tasks.

10.12.2.2. The Designated Individual is responsible for those staff and students who are directly involved in research involving human tissue and must ensure that they are competent by providing appropriate training.

10.12.2.3. The Designated Individual, assisted by Persons Designated, must maintain records of training received by all staff undertaking work covered by the *HT Act*.

10.12.2.4. Training provisions include those for visiting staff.

10.12.3. Training provision

10.12.3.1. The Designated Individual must ensure that all staff and students are competent to undertake work involving the use and storage of human tissue, and that training records are comprehensive, accurate and up-to-date. The training record form for researchers working under the University's HTA license is shown in Appendix 19.

10.12.3.2. Training should cover key issues, including:

- Identifying relevant research projects
- Governance
- Sample and inventory management (including use of the Pro-curo Enterprise sample inventory and tracking software)
- Valid consent

- Safe handling
- Transportation
- Storage and use of storage facilities
- Standard Operating Procedures
- Disposal
- Reporting adverse events
- Data protection and confidentiality.

10.12.3.3. Other training needs will be identified by the Human Tissue Management Sub-Committee. Such training might include, but not limited to, infection control, venepuncture, and cannulation.

10.12.3.4. Staff and students should have personal development plans put in place which will include their training requirements and time frames for completion. These will be reviewed periodically.

10.12.3.5. Staff and students seeking consent for the use of human tissue for research must undertake consent training and have their competency in seeking consent assessed by a member of staff proficient in consent taking. The form used in assessing the competency of staff and PhD student in seeking consent is in Appendix 20 and the form for other students is in Appendix 21.

10.12.3.6. Staff and postgraduate researchers wishing to undertake research involving the use or storage of human tissue, who have not previously done so at Edge Hill University, must be introduced to the Designated Individual. Training should be provided to all such staff as part of an induction process before any licensable activity commences and this training will be documented. Training that is required as part of the staff induction process is stated in Appendix 19.

10.12.3.7. Staff joining the University and bringing with them relevant research projects must bring these to the attention of the Designated Individual by following the policy and procedure outlined in *HT2*.

10.12.3.8. The Medical Research Council (MRC) offers an e-learning module (*Research and Human Tissue Legislation*), which is free to use, and must be taken by all staff before undertaking licensed activity.

10.12.3.9. The Designated Individual should bring any updates in directions and guidance to the attention of all staff undertaking research involving the use or storage of human tissue.

10.12.3.10. All staff and students undertaking research involving the use or storage of human tissue must have access to a copy of this quality manual, and must acknowledge in writing to the Designated Individual that they have read and understood it.

10.12.3.11. The Designated Individual or his representative is responsible for providing appropriate training for members of the University Research Ethics Sub-Committee, Science Research Ethics Committee, Health Research Ethics Committee, and the Human Tissue Management Sub-Committee and maintaining a training record.

10.12.3.12. The Designated Individual is responsible for ensuring maintenance of accurate training records. All completed records must be located in the 'HTA Compliance Documents' folder on the shared 'Y' drive.

10.12.4. Monitoring

10.12.4.1. Training may need to be updated when legislation has changed, new policies or practices have been implemented, different research activities are to be undertaken or a significant period of time has elapsed since research activities have been conducted.

10.12.4.2. The Designated Individual has responsibility for delivering refresher training and reviewing the competencies and any further training needs of persons undertaking research involving the use or storage of human tissue. This process will take place on a continual basis and a formal review will take place during internal auditing. Monitoring of competencies and training needs of staff and students undertaking research involving the use or storage of human tissue will be undertaken by Edge Hill University's Human Tissue Management Sub-Committee.

11. Appendices

Edge Hill University

11.1. Supplementary List of Materials Considered 'Relevant Material'	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 1

Supplementary List of Materials Considered 'Relevant Material'

This list is intended to supplement the HTA's guidance on 'relevant material'.

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that might be considered relevant material. The HTA will review the list periodically and update it as required.

Where a material is not included within the following list, stakeholders should use the information on our website to make their own assessment about whether it is relevant material, seeking advice from us where necessary.

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:

- They have divided or been created outside the human body
- 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.

Although cell damage can be minimised by controlling the rate of temperature change and/or by adding one or more 'cryoprotective' agents, freezing/thawing can cause cell damage such that no whole cells remain. Centrifugation can be used to remove residual platelets from plasma, rendering it acellular, but the effectiveness is dependent on the protocol used. In either case, sufficient validation data (either in-house or published research) should be provided if the techniques are to be relied on to render samples acellular.

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

Material	**'Relevant material' for the purpose of the *Human Tissue Act*?**
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

Notes

* 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).

† 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).

11.2. Participant Information Sheet	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	• Term 'Principal Investigator' now used instead of 'Lead Investigator' and place for name of any student investigator to be included • Philip Bentley now Research office contact for complaints	Human Tissue Management Sub-Committee	27 September 2016
3.0	• Additional headings 'Support; Consent; Health Related Findings' in line with the University Participant Information Sheet template. • Additional information regarding the lawful basis for processing personal data, the University's Privacy Policy and consent.	Human Tissue Management Sub-Committee	1 May 2019
4.0	• Changes to statements regarding export of human tissue. • Updates to Main contact for the research office.	Human Tissue Management Sub-Committee	30 January 2024
6.0	• Changes to statements regarding export of human tissue & updates to main contact for the research office.	Human Tissue Management Sub-Committee	11 September 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder.

APPENDIX 2

Edge Hill University

ST HELENS ROAD
ORMSKIRK
L39 4PE
Homepage: www.edgehill.ac.uk

PARTICIPANT INFORMATION SHEET

Version / date:

Principal investigator:

Student investigator (if applicable):

Title of the research study: *The full title of the study should be provided here.*

Lay title: *A title written in simplified language should be written here. The lay title should provide a lay person with a good indication of what the study is about.*

A paragraph should be included here that is an invitation to ask participants to consider the study and decide whether to participate. The following is an example: "We would like to invite you to take part in our research study. Before you decide whether or not to participate we would like you to understand why the research is being undertaken, why you have been invited to participate, and what participation involves. You will get the opportunity to ask the researchers questions about the study. Please discuss the study with others, such as family and friends, if you wish."

What is the purpose of the study? *This is an important consideration for participants. Provide here a concise description that is easy to understand.*

Why have I been invited to participate? *Briefly explain here why the participant has been invited to participate in the study. State how many other participants will be involved in the study.*

Do I have to take part? *State here that participation in the study is entirely voluntary. State that the participant will be asked to sign a consent form if he or she agrees to participate in the study and that there will be no penalty for not participating.*

What will happen if I take part? *Here, provide an accurate description of what the participants will be expected to do, including a description of the data you will collect from the participant. It should be clear exactly what information will be collected and what it will be used for. State if the participant will be photographed, videotaped, or audio taped and what this will involve. If the study involves an interview or a survey, inform participants that they can skip any question that makes them uncomfortable and they can stop the interview/survey at any time.*

How much of my time will participation in the study involve? *State here an estimate of the total amount of time the participant will be expected to give to the study. If the study includes multiple sessions, also state the amount of time that is required for each session.*

Will I be paid for participating? *State here if any expenses will be given to the participant and when and how the participant can obtain payment. If the project involves multiple sessions or parts, explain how this will affect the payment received if the participant does not complete all that is expected of participation.*

What are the possible disadvantages and risks of participation? *Describe here possible physical, psychological, professional, or personal risks (including possible discomfort or embarrassment) and what controls have been put in place to minimise risks. If pregnancy poses a specific risk then this should be stated. Please note that someone could be pregnant without knowing and, if relevant, this should be highlighted. All risks must be stated, however, it is important to not overstate the risks. If there are no anticipated risks to the participant, then this should be stated.*

Health-related findings: *You should inform the participant if participation could result in a finding that has potential health or reproductive importance to the individual. You will need to establish whether you have a duty of care as a researcher to inform the participant when these health-related findings (HRF) are identified and, if so, whether your duty of care overrides a participant's wishes not to know potentially upsetting information about their own health.*

Edge Hill guidance on HRFs is available but, if you have any other questions, please consult this advice from the Medical Research Council or contact the Biological Safety Officer.

Please remember that your specific discipline or area of study may have additional governance and best practice guidelines, so please consult your local research lead.

What are the possible advantages of participation? *State here the perceived benefits to the participant. Do not overstate the benefits, or include details of payment or credit in this section. If there are no direct benefits to the participant, clearly state this; however, state the benefits to society, or the broader population from which the participant was sampled. Please note that someone should benefit from each research study.*

Will taking part in the study be kept confidential? *State here how you will keep the participant's data private and confidential. This should include details of how the data will be securely stored, who will have access to it and refer to the General Data Protection Regulation (GDPR) 2018 and the Data Protection Act, 2018. Details of how data will be anonymised also should be provided. The following is an example statement: "Your data will be collected, used and stored in line with the General Data Protection Regulation (GDPR) 2018 and the Data Protection Act 2018. Your data will be anonymous, which means that your name will not be linked to your data."*

You should include a 'just in time' notice on your information sheet and consent form that signposts to the University's Privacy Policy. For example: "At Edge Hill, we are committed to respecting and protecting your personal information. To find ways in which we use your data, please see edgehill.ac.uk/about/legal/privacy."

In some studies anonymity cannot be assured and the following sentence might be appropriate: "It may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you." Details of how you will keep participants information confidential during the consent process also should be stated (e.g. consent will taken in a private room).

You will need to understand the lawful basis on which you are seeking the participant's data:

- *Academic research is a public good for current and future generations, so* ***the lawful basis***

  for research data collection is normally that of 'public task' *i.e. the collection of personal data is 'necessary for the performance of a task (research) carried out for reasons of public interest'.*

- *The nature of the personal data you will be collecting may require you to cite a lawful basis*

  other than public task. If in doubt, please contact the University's Data Protection Officer.

- ***You do not need to specify the lawful basis on your participant information sheet*** *– there are limited circumstances in which you would rely on something other than public task – but you will need to be able to explain the reasons for your chosen lawful basis if asked.*

- *Instead of specifying the lawful basis on your information sheet, the University's Data Protection Officer suggests reassuring your participants by* ***including the following text****: ''The University is committed to ensuring compliance with current data protection legislation and confirms that all data collected is used fairly, stored safely, and not disclosed to any other person unlawfully. The University is a data controller and, in some instances, may be a data processor of this data.''*

Special category data brings additional responsibilities. Such data covers race, ethnicity, health, politics, religion, trade union membership, genetics, biometrics, sex life, and sexual orientation. Please contact the University's Data Protection Officer for advice.

While you need to obtain consent for reasons of research ethics, you should not use this as the lawful basis for the purpose of GDPR. Doing so would pose a significant risk to the future of the research because you would have to be prepared to remove an individual's data from your dataset at any point, should they ever withdraw consent.

While some research activity may be exempt from some aspects of the legislation, provided it meets certain criteria such as safeguarding and transparency, you will need to demonstrate why this should apply to the processing of your research data.

Furthermore, if your research falls under the NHS Health Research Authority (HRA), there are additional GDPR requirements for your participant information sheet.

What will happen to tissue samples that I give? *State here what measurements will be taken from the tissue. State if any surplus tissue will be collected above that required for the stated measurements and a description of intended use. If relevant, provide details of procedures in case the analysis of tissue uncovers important information such as results indicative of a medical condition. If tissue is to be stored, state how, where, and for how long, and that the tissue is being stored under the University's Human Tissue Authority License. State who will have access to the tissue and how anonymity will be secured when collecting, analysing, and storing samples. Provide details of how any surplus tissue will be disposed of. State whether samples might be exported for use abroad (this pertains to outside England, Wales, Northern Ireland for the purpose of the governance of human tissue) and whether the commercial section will be involved in the research.*

What will happen to my results? *State here what will happen to the results of the study, such as whether the results will be published. If the results are to be published, state where, such as a scientific journal or government report. Also state whether the results will be presented at a conference or other academic gathering. State that participants will not be identified during any report or other communication, unless prior consent has be obtained to do so. If you plan to share data, you must inform participants to whom it may be released and in what form the data will be published or otherwise shared (for re-use).*

Is this research being funded? *Provide details of any funding agency. If the research has not been funded this should be stated.*

Who has reviewed this study? *Include a statement such as the following: "To protect your interests, all research undertaken at Edge Hill University is reviewed by a research ethics committee. This research study has been reviewed by Edge Hill University Research Ethics Sub- Committee.*

How do I withdraw from the study if I no longer wish to participate? *State here that participation in the study is completely voluntary and that the participant has the right to withdraw from the study at any time without penalty. State clearly that withdrawal of specific consent for the use of tissue cannot be effective if donated tissue has already been used. Where two- stage consent has been use (i.e. separate specific and general consent), highlight that the participant can withdraw general consent without withdrawing specific content. If it is not possible for data to be destroyed (e.g. unlinked-anonymised data) state this clearly. If you are using an audio or video tape, please state that the participant's tape will be destroyed should they decide to withdraw. State clearly how the participant can withdraw from the study during data collection and how to withdraw data after data collection has finished. The description of the withdrawal process should include the contact details of the person who the participant should contact to withdraw.*

FURTHER INFORMATION AND CONTACT DETAILS

If you have questions about the study, contact:

Principal investigator's name here Academic department or faculty name here Edge Hill University Ormskirk, L39 4QP

Telephone: 01695 xxxxxx Email: xxxx@edgehill.ac.uk

If you are unhappy about any aspect of the study, or wish to make a formal complaint, write to:

The Research Office (FAO: Rachel Glayzer, URESC Secretary)
Edge Hill University Ormskirk
L39 4QP

OR email: *research@edgehill.ac.uk (FAO: Rachel Glayzer, URESC Secretary)*

Support

There should also be aftercare support agencies identified for those research projects that carry risk to the participant. The research team should have made contact with such organisations before recommending them wherever feasible. If the research participants are not UK-based, an alternative, local provider of support services should be identified – you should have written confirmation from the organisations that they are willing to provide such a service.

11.3. Consent Form	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	Term 'Principal Investigator' now used instead of 'Lead Investigator' and place for name of any student investigator to be Included	Human Tissue Management Sub-Committee	27 September 2016
3.0	Additional questions asking consent for the storage of data and sharing of data.	Human Tissue Management Sub-Committee	1 May 2019

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 3

Edge Hill University

ST HELENS ROAD
ORMSKIRK
L39 4PE
Homepage: http://www.edgehill.ac.uk

CONSENT FORM

Participant ID:xxxx

Version / date:

Principle investigator: xxxx

Student investigator (if applicable):

Title of project: xxxx

Lay title: xxxx

	Participant initia each point
1. I confirm that I have read and understand the Participant Information Sheet dated xxxx (version x) for the above study	☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily where applicable	☐
3. I understand that this procedure involves the collection and use of blood, urine, saliva, or other human tissue samples for research purposes	☐
4. I agree to the collection, storage, and use of human tissue samples for ethically approved research	☐
5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without recourse	☐
6. I understand that if I have questions or concerns about my rights as a research participant, or about how the study was carried out, I may contact the lead investigator, xxxx (Department of xxxx, Ormskirk, Lancashire, L39 4QP; Email: xxxxxx@edgehill.ac.uk; Tel: 01695 xxxxxx)	☐
7. I understand that data collected about me during my participation in this study will be stored for up to ten years in accordance with the General Data Protection Regulation (GDPR) 2018; the University's policies, guidance and standards; and funder, legislative and ethical requirements.	☐
8. (If appropriate) I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.	☐
9. I agree to take part in the above study	☐

Name of participant	Date	Signature
Name of Person taking consent	Date	Signature

11.4. Human Tissue Risk Identification and Assessment Form

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A. Current version		
2.0	Revisions made to conform with the HTA annual compliance update questions related to assessment of risks to tissue	Human Tissue Management Sub-Committee	27 September 2016
3.0	Risk matrix added to assist in the assessment process.	Human Tissue Management Sub-Committee	1 May 2019

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder.

APPENDIX 4

HUMAN TISSUE RISK ASSESSMENT FORM

Project title		**Risk assessor**		**Date**	

NOTE: When completing this form please ensure you cite relevant sections of the Human Tissue Quality Manual in describing how you are going to control risks. A description of how you will control the six risks already listed in this form **MUST** be provided. Please add other risks to the form as appropriate to your study.

Risk Matrix Used when completing this form

		Severity		
		1 Not in breach of HTA laws, guidelines or University procedures	**2** Breach of University Procedures	**3** Breach of HT licence
Liklihood	**1** Extremely unlikely	1	2	3
	2 Unlikely but potentially likely	2	4	6
	3 Likely	3	6	9

Risk

1-3 – Low Risk

4-6 – Medium Risk – Consider adding additional control measures

7-9 – High Risk – Do not proceed

DESCRIPTION OF RISK	CONTROLS – physical controls and/or systems to reduce risk of adverse incidents	RISK ASSESSMENT		
		Severity	Likelihood	Risk
		(S)	(L)	(S x L)
Examples • Appropriate & valid consent not obtained or records for each participant not properly maintained • Loss of donor confidentiality • Loss of human tissue during transport or storage • Loss of tissue traceability • Storage failure • Accidental disposal of human tissue				

11.5. Human Tissue MTA Request Form (Including Import & Export)

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Human Tissue Management Sub-Committee	**Date:** 27 September 2016

Document Review History

Version number	Revision	Authorised by	Date
1.0	N/A		
1.1	• Added: Has the tissue be procured from the living or the dead? • Added: If the tissue is to be used for teaching please state whether this relates to education or training relating to human health	Human Tissue Management Sub-Committee	27 September 2016
5.0	• Code of practice updated to E	Human Tissue Management Sub-Committee	February 2021
6.0	• Title changed to a more appropriate title. Additional questions added to the form.	Human Tissue Management Sub-Committee	11 September 2024

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The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder.

APPENDIX 5

MTA Request Form for Cells of Human Origin (Including Import & Export)

A material transfer agreement (MTA) must be in place to transfer human tissue between establishments. This requirement applies to all cells of human origin regardless of whether considered relevant material under the Huna tissue Act 2004.

The MTA ensures that the rights and responsibilities of the involved establishments are clearly documented and agreed in relation to the transferred tissue and any derivatives. The tissue transfer must be undertaken in accordance with the Human Tissue Act 2004 and associated codes of practice, and the University's own human tissue policies and procedures.

In accordance with Code of Practice E, published by the Human Tissue Authority, any person wishing to import human tissue should be able to demonstrate that the purposes for which they wish to import such material cannot be met adequately by comparable material available from sources within England, Wales or Northern Ireland, or is for a particular purpose which justifies import.

This form should be used by Edge Hill University staff to request an MTA. Once completed, please email the form to the University's Designated Individual (adrian.midgley@edgehill.ac.uk).

Completion of this form should be undertaken with a word processor. Forms should not be handwritten. Please type 'N/A' for any sections of this form that are not applicable (please do not leave any sections blank).

Person making MTA request	
Job title	
Department	
Email & telephone number	
Line manager	

Has an 'in principle' agreement to transfer the tissue been made? (tick one box. Double-click and choose 'checked' if nothing happens)

Yes ☐ No ☐

Who will be the provider of the human tissue? (tick one box) EHU ☐ Non-EHU establishment ☐

Who will be responsible for providing the MTA? (tick one box) EHU ☐ Non-EHU establishment ☐

What is the proposed date of tissue transfer? (tick box **OR** provide approximate date) As soon as possible ☐ Date: Click here to enter a date.

Tissue Details & Intended Use	
Details of human tissue (type, amount, etc.)	
Is the tissue considered 'relevant material' under the Human Tissue Act 2004?	
Has the tissue be procured from the living or the dead?	
Where did the tissue originate?	
Where is the tissue currently located?	
What is the reason for the transfer request, including intended uses?	**If the tissue is to be used for teaching please state whether this relates to education or training relating to human health**
What is the estimated value of the tissue?	
Is there any cost in acquiring the tissue other than transport costs?	
Details of Non-EHU Establishment	
Contact name and details for non-EHU establishment	
Licence number of non-EHU establishment if within the UK	
Transport Details	
Details of transport	
Responsibility for arranging transport	
Responsibility for transport costs	
Details of any risk assessment relating to the transfer, particularly relating to potential theft, damage, or loss during transport	
Ethical Approval & Consent for Use of Tissue	
Details of ethical approval relating to the tissue	
Statement that copies of completed consent forms will accompany the tissue, or assurances that consent was in place and the intended uses of the tissue are in accordance with wishes of the donors documented during the seeking of consent	
Details of how participant confidentiality will be maintained	
Are you aware of any third party interests in the tissue (e.g. funders or collaborators)?	
Are you aware of any issues relating to publication and/or intellectual property rights?	
Are you aware of any patent issues relating to this tissue?	
Are you aware of any other constraints on the use of the tissue?	
Storage & Disposal Details	
Will the tissue be stored for a set period of time?	
How will the tissue will be stored once transferred?	

Are any additional transfers of the tissue intended if this requested transfer is completed?	
How will any surplus tissue at the end of the permitted use be disposed of?	
Please Provide any other Relevant Information (including justification if requested transfer relates to import of human tissue)	

Sign off

Researcher

By submitting this form, I certify that the above information is, to the best of my knowledge and belief, complete and accurate.

Name:

Signature:

Date: Click here to enter a date.

Once you have completed and signed this form, please return to Biological Safety Officer.

FOR BIOLOGICAL SAFETY OFFICER'S USE ONLY

Are EHU able to handle and store the material safely at the required containment level?	
How should the material be transferred safely?	
What are the arrangements for receiving and storing the material on arrival?	
Any other issues to be addressed?	

I have considered the above issues in consultation with the Researcher and agree that once an MTA has been agreed in consultation with the RO the material is ready to be transferred to/from EHU.

Name:

Signature:

Date: Click here to enter a date.

Upon execution of the MTA it will be the responsibility of the Researcher to make arrangements with the provider for transportation and delivery of the requested material. Any transportation costs will need to be managed by the Researcher's department.

11.6. HT.SOP 1: Procedure for Tracking Tissue Samples	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 6

Standard Operating Procedure (SOP)

HT.SOP 1: Procedure for Tracking Tissue Samples

Introduction

To comply with the requirements of the Human Tissue Act (2004) and Edge Hill University's Human Tissue Authority (HTA) Licence, strict procedures need to be followed for tracking stored human tissue samples. These procedures are to ensure that a full traceability trail is maintained and documented for the storage and movement of human tissue from receipt to end use, disposal, or distribution. This SOP outlines those procedures. This SOP should be read in conjunction with the following Edge Hill University policies and procedures: *HT3. Policy and Procedure for Obtaining Consent for Use and Storage of Human Tissue*; *HT7. Policy and Procedure for Records and Audit*; *HT8. Policy and Procedure for Storage of Human tissue*; and *HT9. Policy and Procedure for Disposal of Human Tissue*.

Edge Hill University Sample Inventory and Tracking System

Edge Hill University has a designated sample inventory and tracking system for the traceability of human tissue stored on its premises. This system includes Pro-curo Enterprise sample inventory software that is installed on the University server, a label printer, and label scanner. A designated desktop computer and the label printer and scanner are located in the Physiology Laboratory on the ground floor of the Wilson Centre. Any person storing human tissue samples on University premises **must** use this sample inventory and tracking system. Anyone who is storing human tissue samples on University premises will be given training on how to use this system and will be issued with a username and password by the Designated Individual. It is the responsibility of principal investigators and custodians of human tissue collections to ensure complete and accurate records are maintained.

Records

There are a number of records that should be kept within the Pro-curo Enterprise software.

Project Information

The DI will register each study or tissue collection within the software and enter the following details:

- **Project title.** A short title for the study or tissue collection.
- **Project sponsor**. This will typically be Edge Hill University.
- **Contact**. The name of the principal investigator or custodian of the tissue collection – this is the person with overall responsibility for the proper conduct of the research, or maintenance of the tissue collection.
- **Address.** Work address and telephone number of the principal investigator or custodian of the tissue collection**.**

Before a study can be registered within the Pro-curo Enterprise software a copy of the ethical approval letter or email **must** be given to the Designated Individual and all human tissue training **must** have been completed according to *HT12. Policy and Procedure for Training Regarding Human Tissue*.

Sample Information

The principal investigator for a given study, or custodian of a given tissue collection, will be responsible for entering and maintaining information in the following fields of the Pro-curo Enterprise software:

- **Sample number**. This must be a sample identifier unique to each sample.
- **Project name.** The name of the study or tissue collection associated with the sample.
- **Sample type**. This will typically be whole blood, plasma, saliva, or urine.
- **Batch number**. This must be an identifier code that is unique to each sample donor and include no personal identifiers.
- **Mass.** The net weight or volume of the sample.
- **Location**. The specific freezer and location within the freezer the sample is stored.
- **Consent date (if applicable).** Date on which consent was taken from the donor.
- **Batch document links.** PDFs of the following scanned documents: Ethical approval letter for the study; completed signed Consent Form, completed Human Tissue Risk Identification and Assessment Form (the latter two forms can found in Appendices 3 and 4 of the Human Tissue Quality Manual).
- **Expiry date**. Date on which consent expires if consent is time-limited.

The Pro-curo Enterprise software will automatically log the date on which each sample was booked into the freezer.

The above list is indicative rather than exhaustive and some projects might require different records and the Designated Individual will discuss any further requirements with the principal investigator or custodian of tissue collection before sample storage for a particular study or tissue collection commences.

Retirement and Disposal of Samples

Stored samples can be retired or disposed of and this information **must** be entered into the Pro- curo Enterprise software if and when applicable. Retired samples are typically samples that are no longer in active service, but still need to be stored in case of retesting, for example. Retired samples are not visible in the software window unless the information is explicitly requested.
Principal investigators need to ask the Designated Individual or Persons Designate to unretire samples. When samples are being disposed of it is the responsibility of the principal investigator or custodian of a tissue collection to complete a Human Tissue Disposal Form (Appendix 11 in the Human Tissue Quality manual), which **must** be signed by the principal investigator /custodian of the tissue collection and Designated Individual before disposal of any stored tissue. It is the responsibility of the Designated Individual and Persons Designated to store PDFs of all scanned images of all completed Human Tissue Disposal Forms within the Pro-curo Enterprise software. The reason for disposal also needs to be selected from the drop-down list with the Pro-curo Enterprise software. The Pro-curo Enterprise software automatically retains records of the full history of all samples that have been disposed of.

Labelling Samples

All individual stored tissue samples **must** be labelled with a label that includes a unique sample number and bar code. All individual tissue samples **must** be securely packaged in a larger container that itself is labelled with a label that includes a unique number and barcode that identifies that container. The designated label printer and barcode scanner **must** be used for labelling and tracking samples. Principal investigators should consult with the Designated Individual or Persons Designated before seeking ethical approval for their research to establish the source of funding to meet label printing and packaging costs.

Other Records

It is the responsibility of the DI to maintain human tissue training records of all staff and students within the University who are storing tissues samples. These records will be kept within the Pro-curo Enterprise software for at least 3 years after the staff member or student has left the University.

Access to records

The Designated Individual and Persons Designated will have access to all records kept in the Pro-curo Enterprise, including completed consent forms, and this should be stated in the Participant Information Sheet given to potential participants during the consent process.
Researchers and custodians of tissue collections storing samples will have access only to records associated with their own studies or tissue collections. It will be the responsibility of the principal investigator or custodian of tissue collections to inform the Designated Individual of which people require access to the Pro-curo Enterprise software. All researchers and custodians of tissue collections, the Designated Individual, and Persons Designated are responsible for ensuring that usernames and passwords to access records maintained in the Pro-curo Enterprise software are not shared with unauthorised users. Computers with access to the Pro- curo Enterprise software **must** be password locked when unattended. All associated paper records containing confidential information **must** be stored in a locked facility when not under the direct possession of the research team, custodian of tissue collections, Designated Individual, or Persons Designated. If electronic records of confidential information are to be transferred using removable media (e.g. laptops, memory sticks, and portable hard drives) the media must be password protected. The transferred records must be removed from the removable media as soon as successful transfer has been completed.

11.7. Human Tissue Audit Report Form	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	New Human Tissue Audit Report Form	Human Tissue Management Sub-Committee	April 2018
3.0	Amended - Key added	Human Tissue Management Sub-Committee	1 May 2019

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 7

Human Tissue Audit Report Form

To be completed by the Designated Individual or his representative. Only parts A, B & G should be completed for triannual audits. All parts should be completed for annual audits.

Any follow-up actions, including who is responsible for them and the timeframe for completion, should be recording in the minutes of Human Tissue Sub-Committee meetings and section G.

Audit type (triannual/annual)	
Audit date	
Person(s) conducting audit	
Signature(s)	

SECTION A – FACILITIES *(all relevant departments)*

Item	Comply?		Comments
Storage facilities locked	Biol		
	Psych		
	Sport		
Freezer socket protectors locked	Biol		
	Psych		
	Sport		
Designated human tissue processing areas properly marked & free from clutter	Biol		
	Psych		
	Sport		
All equipment for sample inventory and tracking present and working properly	Biol		
	Psych		
	Sport		
	Biol		
Storage freezers working properly with little frost build-up	Psych		
	Sport		

Item	Comply?		Comments
Inside of storage areas tidy	Biol		
	Psych		
	Sport		
Alarm monitoring system working			

KEY
RED TEXT – Non-compliance for item BLACK TEXT – Items for discussion

SECTION B – TISSUE SAMPLES

1. Physiology Laboratory – Wilson Centre (-80°C)

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Proof of ethical approval	Proof of consent	MTA (where applicable)	Non-compliance details
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

2. TSH12 Laboratory – Tech Hub (-80°C)

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Proof of ethical approval	Proof of consent	MTA (where applicable)	Non-compliance details
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

3. Hooke Laboratory – Biosciences Building (liquid nitrogen)

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Proof of ethical approval	Proof of consent	MTA (where applicable)	Non-compliance details
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

4. TSH12 Laboratory – Tech Hub (room temperature)

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Proof of ethical approval	Proof of consent	MTA (where applicable)	Non-compliance details
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

5. Bio 102 Teaching Collections – Biosciences Building (room temperature)

Still need to establish the original source of the bone teaching collections and consider disposing of, if not used anymore and the original source cannot be identified.

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Non-compliance details
1					
2					
3					
4					
5					

SECTION C – Y DRIVE RECORDS

Item	Comply?	Comments
Adverse events & corrective action		
Tissue slide & bone collections		
Equipment manuals		
Ethics applications		
HTA compliance updates		
HTMSC meeting minutes		
Blank form templates		
Training		
Internal audit reports		
Tissue transfer requests		
Freezer maintenance log		

SECTION D – TRAINING

NOTE: According to Edge Hill University's human tissue governance, the first wave of refreshing training will need to be started on or before the 14th October 2018 to ensure training is refreshed every 3 years.

Name	Role	Required training completed & up-to-date	Consent competency assessed & up-to-date	Non- compliance details

SECTION E – MISCELLANEOUS

Item	Comply?	Comments
Quality Manual up-to-date		
University human tissue web pages up-to-date		
Copy of human tissue licence displayed in each faculty		
Annual email sent to University staff regarding human tissue governance		

SECTION F – OTHER COMMENTS

SECTION G – ACTION POINTS

Action Point	Named Actor(s)	Action Taken/ Progress Report	Close/ Ongoing	Deadline

11.8. HT.SOP 2: Procedure for Storage in -80°C Freezer	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

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APPENDIX 8

Standard Operating Procedure (SOP)

HT.SOP 2: Procedure for Storage in -80°c Freezer

Booking and prior arrangements

1. All samples must be logged in the University's human tissue inventory and sample management system and have a unique barcode before being stored in the -80°C freezer. **This should be done by a person who has received the appropriate training to undertake this procedure.**
2. One of the University's Persons Designated must be contacted prior to any sample arriving and being stored in a -80°C freezer. This person will ask questions about your samples. Complete and accurate answers must be given.
3. One of the University's Persons Designated will advise on suitable storage containers and correct labelling.
4. The samples and storage containers need to be labelled with unique identification before they are put into the -80°C freezer using the inventory and sample management system.

Access to the -80°C freezers:

1. Access to the -80°C freezers will be restricted to nominated persons.
2. A freezer can normally only be opened at every two hour intervals.
3. If you notice anything wrong with the freezer you must inform one of the Persons Designated or the Designated Individual immediately. Instructions on the use of the freezer will be given by these members of staff.
4. Written approval must be provided from the Designated Individual before any human tissue samples can be stored. A copy of this approval, as part of an approved University Research Ethics Sub-Committee application, must be logged within the University's sample inventory and tracking software by one of the Persons Designated or Designated Individual.

11.9. HT.SOP 3: Procedure for General Maintenance of -80°C Freezer	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 9

Standard Operating Procedure (SOP)

HT.SOP 3: Procedure for General Maintenance of -80°C Freezer

The -80°C freezers are checked on a **monthly** basis with the following being carried out.

1. Use a dry cloth to wipe off loose dust inside and outside the freezer. If the unit is very dirty use a clean cloth soaked with neutral detergent. Then use a dry cloth to wipe off the leftover detergent solution.
2. Air intake grills: brush the grills with a soft brush or vacuum the dust from the grills.
3. Door or lid seal: wipe the door seal with a soft dry cloth.
4. Battery test: Refer to individual user manual.
5. Alarm test: Refer to individual user manual
6. CO_2 back-up system: Refer to individual user manual
7. After an extended period of operation, defrosting may become necessary (see *HT.SOP 3*).
8. Lubrication: Compressors and other mechanical parts are hermetically sealed so do not require lubrication.
9. Clean the frost and ice off the unit once a month. Also, clean the condenser filter once a month.
10. When the control panel shows an alarm signal for Hot Condenser, the alarm flashes. The condenser filter must be cleaned to avoid overheating and improve refrigeration efficiency.
11. Cleaning the condenser filter: Pull off the front grill and pull out the filter screen. Use water to wash the filter screen or alternatively use a Vacuum cleaner. Install the screen back in its original position and close the cover.

11.10. HT.SOP 4: Procedure for Defrosting -80°C Freezer	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 10

Standard Operating Procedure (SOP)

HT.SOP 4: Procedure for Defrosting -80°C Freezer

Defrosting of freezers used for storage of human tissue must only be undertaken by one of Edge Hill University's Persons Designated.

Before defrosting

1. There must be another freezer available where the samples can be stored on the licensed premises.
2. **Check availability of freezer space prior to beginning any removal of samples.**
3. Principal Investigators storing samples and the Designated Individual need to be notified prior to samples being moved.
4. Samples in the freezer need to be checked using the barcodes.
5. The samples must be transferred on ice and in suitable transportation boxes to the new location.
6. Records in the University's human tissue inventory and sample management system must be updated showing the new location of the samples.
7. Principal Investigators storing samples and the Designated Individual need to be informed when this has been completed.

During defrosting

1. A note will be left in the freezer indicating that it is not operational and is being defrosted.
2. Unplug the freezer from the mains/ electrical supply. The temperature display screen will still be active due to the back-up battery, but can be turned off by turning off the battery control switch.
3. Leave the inner and outer doors open.
4. Leave paper towels on the floor to absorb melt water. Ensure adequate health and safety signage regarding slippery floor, etc.
5. Allow the ice to melt.
6. Dry and decontaminate the inside of the freezer. Inner doors and shelves can also be removed for cleaning (following instructions in the manufacturer's operating manual).
7. When defrosting is complete, reassemble doors and shelves and reconnect the freezer to the mains/ electrical supply.
8. Turn the mains/ power switch on and reactive the battery (alarm) switch.
9. Once the temperature reaches -80°C the samples can be checked back in, updating the inventory and sample management system.
10. Principal Investigators storing samples and the Designated Individual should be informed that the process has been completed and that the inventory and sample management system has been updated.

11.11. HT.SOP 5: Procedure for Dealing with Fault with -80°CFreezer

Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Revision to out-of-hours procedures to state principal investigators rather than security staff are responsible for monitoring freezers. Addition of information on 24 hour access to buildings and laboratories	Human Tissue Management Sub-Committee (HTMSC)	27 September 2016

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 11

Standard Operating Procedure (SOP)

HT.SOP 5: Procedure for Dealing with Fault with -80°C Freezer

On campus

1. On hearing the freezer alarm, DO NOT open the freezer.
2. The flashing alarm light cannot be cancelled unless the root cause for the alarm has been rectified.
3. The buzzing alarm can be temporarily silenced for 30 minutes by pressing the alarm silence button but will resume after 30 minutes if the problem is not fixed.
4. Inform one of the University's Persons Designated or the Designated Individual that the freezer alarm has been activated.
5. A Person Designate or Designated Individual should investigate the cause of the freezer fault (e.g. power failure) and seek to rectify the problem as quickly as possible.
6. If the integrity of the stored tissue samples is in doubt, a person designate should switch on the back-up freezer and arrange for the relocation of the tissue samples to the back- up freezer when the storage temperature has been achieved.
7. Relocation of the tissue samples should be undertaken in accordance with the University's *HT5: Policy and Procedure for Local transport of Human Tissue* and *HT8: Policy and Procedure for Storage of Human Tissue*. If tissue samples already have defrosted the University's *HT.SOP 5: Removal of Defrosted Samples from -80°C Freezer* should be consulted.

Off campus remote monitoring

1. During out of office hours, principal investigators (PIs) of studies that involve storage of human tissue under the University's Human Tissue Authority license are responsible for monitoring freezers containing their human tissue samples using the designated remote monitoring system.
2. Each PI will be given access to the remote freezer monitoring system and will be required to notify the Designated Individual of any other persons within the research team that they wish to have access.
3. Each PI must agree to provide an emergency contact mobile telephone number by which he or she can receive text alerts regarding potential issues with the proper functioning of the freezer(s).
4. If a text alert has been received, the PI should consult the online freezer monitoring system (https://www.realtime-online.com/) to identify what might be the problem and to monitor freezer temperature.
5. The PI, or the PI's deputy, should personally investigate the cause of any problem (e.g.

power failure) and seek to rectify the problem.

6. If the integrity of the stored tissue samples is in doubt, the PI, or the PI's deputy, should attend campus to switch on the back-up freezer and relocate the tissue samples to the back-up freezer when the storage temperature has been achieved.
7. Relocation of the tissue samples should be undertaken in accordance with the University's *HT5: Policy and Procedure for Local transport of Human Tissue* and *HT8: Policy and Procedure for Storage of Human Tissue*. If tissue samples already have defrosted the University's *HT.SOP 5: Removal of Defrosted Samples from -80°C Freezer* should be consulted.
8. Principal investigators should report the incident to the Designated Individual, or his deputy, as soon as practicably possible.
9. Principal investigators can delegate tasks to others on their research teams; however, principal investigators bear ultimate responsibility for protecting tissue samples 'out of office hours' for studies for which they are the named principal investigator.

Access to buildings and laboratories

1. If any buildings or laboratories are locked, 24 hour access can be achieved by contacting campus security.
2. Campus security also has a copy of the key for access to the main storage freezer in case the key stored next to the main storage freezer is missing.

Written Report

A written report of all freezer faults should be completed by the Designated Individual, or his representative, using the Adverse Event Report Form shown in Appendix 18 and stored within the University's human tissue inventory and sample management system.

11.12. HT.SOP 6: Removal of Defrosted Samples from -80°C Freezer	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 12

Standard Operating Procedure (SOP)

HT.SOP 6: Removal of Defrosted Samples from -80°C Freezer

1. One of the University's Persons Designated or the Designated Individual inform all Principal Investigators who have human tissue stored in the freezer by referring to the University's human tissue inventory and sample management system as soon as possible.
2. Check the inventory and sample management system to identify types of samples and their location in the freezer.
3. Make an assessment of the integrity of human tissue samples. If in doubt about the integrity of the sample you should save it by placing it in another freezer (recording this in the inventory and sample management system) with a record being made of its condition, e.g. noting whether or not the sample had totally thawed out and the estimated time in that state). The location of an alternative freezer for storing human tissue under the University's HTA License is: **Biosciences Building**.
4. Check and record unique identification codes for each tissue sample removed.
5. Gloves and protective clothing should be worn at all times.
6. Any water on the floor should be contained and mopped up using a hazard spillage kit and paper towels. These should be placed into an orange incineration bag for disposal.
7. Any human tissue samples for which integrity is severely compromised should be identified from the inventory and sample management system and placed into a yellow rigid one-way access container. All samples need to be identified and disposed of in the correct manner (following *HT9: Policy and Procedure for Disposal of Human Tissue*).
8. The inside of the freezer should be wiped dry using paper towels, which must be put into an orange clinical waste bag.
9. The inside of the freezer should then be wiped with paper towels soaked in 70% alcohol, which should then be put into an orange clinical waste bag.
10. Gloves, when finished with, should be put directly into an orange clinical waste bag.
11. Yellow rigid one-way access containers and orange clinical waste bags should be kept in a designated storage area pending collection by the University's designated waste management company.
12. The inventory and sample management system must be updated and the Designated Individual should complete an adverse event report (see *HT10: Policy and Procedure for Reporting Adverse Events*).

11.13. HT. SOP 7: Procedure for Storage at Room Temperature	
Author: Dr Lauren Harkin	**Position:** Biological Safety Officer
Approved by: Human Tissue Management Sub-Committee	**Date:** 2 April 2018

Document Review History			
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The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder Standard Operating Procedure (SOP)

APPENDIX 13

Standard Operating Procedure (SOP)

HT.SOP 7: Procedure for Storage at Room Temperature

Storage of Samples at Room Temperature

1. The location of the designated storage area should be discussed with the Designated Individual or the Person(s) Designated before being stored. Written approval must be provided from the Designated Individual before any human tissue samples can be stored. A copy of this approval must be logged within the University's sample inventory and tracking software by one of the Persons Designated or Designated Individual.
2. The temperature of the room used for the storage of HTA relevant samples must remain between 15°C and 26°C and should be monitored remotely or manually. Any issues with abnormalities in storage temperature readings should be reported to the relevant staff and/ or the DI.
3. Access to the room or the cabinet containing the samples within the room must be restricted to personnel who have received human tissue training.
4. Storage vessels should have sufficient storage capacity and should not contain animal tissue or chemicals that could threaten the integrity of the sample.
5. Storage vessels should be clearly labelled as biohazards to prevent and minimise risk of contamination from inadvertent opening or touching.
6. 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.

Booking and Prior Arrangements

1. All samples must be logged in the University's human tissue inventory and sample management system and have a unique barcode or sample ID before being stored in the designated HTA room and/ or HTA cabinet at room temperature. **This should be done by a person who has received the appropriate training to undertake this procedure.**
2. One of the University's Persons Designated must be contacted prior to any sample arriving and being stored on University premises. This person will ask questions about your samples. Complete and accurate answers must be given.
3. One of the University's Persons Designated will advise on suitable storage containers and correct labelling.
4. The samples need to be labelled with unique identification numbers before they are stored. These numbers should correspond to the sample ID numbers logged in the inventory and sample management system. Storage containers should also be given a unique name/ number that corresponds to that which has been entered into the inventory and sample management system.

11.14. HT. SOP 8: Procedure for Disinfection	
Author: Dr Lauren Harkin	**Position:** Biological Safety Officer
Approved by: Human Tissue Management Sub-Committee (HTMSC)	**Date:** 2 April 2018

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Table of disinfectants replaced with a more comprehensive version.	Human Tissue Management Sub-Committee	1 May 2019

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

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APPENDIX 14

Standard Operating Procedure (SOP)

HT.SOP 8: Disinfection

1. The ideal disinfectant should be broad-spectrum, non-irritating, non-corrosive, and inexpensive.
2. The selection should be based on the effectiveness against the pathogenic agent, the circumstances under which the disinfectant will be used, the type of surfaces being decontaminated and any hazards to human health.
3. The disinfectant of choice should comply with the requirements of the EU Biocides Regulations.
4. A COSHH risk assessment must be completed and the control measures necessary to handle concentrated and working dilutions of disinfectants safely must be identified.
5. The disinfectant of choice should be approved by the Biological Safety Officer as being effective against the micro-organisms present in unscreened human tissues and safe for use.
6. If the disinfectant does not contain a colour indicator, the expiry date should be clearly marked on the container when the working strength solution is prepared.
7. Ideally, organic material should be removed prior to disinfection as this can protect micro-organisms and inhibit disinfectant activity.
8. Disinfectants must remain in contact with micro-organisms at a specific concentration for the time recommended by the manufacturer in order to be effective.
9. Containers of working strength disinfectant should be available in areas where human tissue is processed and where waste is generated.
10. Items placed in discard containers should be completely immersed in the disinfectant and care taken to ensure that air bubbles do not prevent contact with surfaces to be disinfected.
11. If liquid waste is to be decanted to a discard jar the amount of concentrated disinfectant in the jar must allow for dilution to the final working strength.
12. Work surfaces that are contaminated with blood, body fluids or infected cultures must immediately be disinfected.
13. All working surfaces should be routinely cleaned with disinfectant before beginning work and at the end of each working day.
14. There should be control measures in place to avoid any hazards posed by exposure to the disinfectant during decontamination procedures.

Common disinfectants

1. **Alcohols**
    - Alcohols must be diluted (70% ethanol; 60% isopropanol) before use as undiluted alcohol is not an effective biocidal.
    - Alcohols should only be used on physically clean surfaces as they poorly penetrate organic matter, particularly proteinaceous material.
    - Alcohol has a limited effect due to evaporation and therefore should be confined to surfaces with no visible contamination.
    - Alcohols should not be used near flames or equipment likely to generate sparks and should be stored safely.

2. **Peroxygen-based (e.g. Virkon)**
    - A minimum contact time of 1 hour is recommended for complete disinfection.
    - Working solutions of 1% w/v should be used as they have low toxicity and no irritancy.
    - Powdered forms can generate air-borne dust particles which can irritate the eyes and respiratory tract.
    - Virkon solutions should be made fresh every 7 days.
    - Virkon solutions must be replaced if the colour starts to fade.

3. **Chlorine-containing or -generating compounds (e.g. Hypochlorite, Chloros, Presept)**
    - Chlorine-containing or -generating compounds should only be used on physically clean surfaces as they are inactivated by organic matter.

4. **Aldehydes**
    - Formaldehyde and gluterldehyde are not suitable as general disinfectants but may be used for specialised procedures such as the fumigation of microbiological safety cabinets or containment facilities.
    - Their use should be regularly reviewed and consideration given to less toxic alternatives wherever practicable (e.g. hydrogen peroxide).
    - Occupational Exposure Limits (OELs) have been set for both formaldehyde and gluteraldehyde (see HSE Guidance note EH40 Occupational Exposure Limits) and should not be exceeded.

See table 1 for a summary of the biocidal properties of disinfectants by type.

Table 1. Biocidal properties of disinfectants

Disinfectant type	Examples	Active against				
		Bacteria	**Bacterial spores**	**Fungi**	**Viruses**	**Myco-bacteria**
Aldehydes	Horticide (Glutaraldehyde) Formaldehyde Heliphur H*	+	+	+	+	+
Quaternary ammonium compounds (Halogenated tertiary amines)	Microsol 3+ Distel Chemgene	+	-	-	+ (variable effect)	+ (variable effect)
Peracetic acid	Hyperox Kickstart Jet 5	+	+ (At high conc's)	+	+	+
Alcohols	Ethanol IMS Bacillol	+	-	-	+/- (Effective against enveloped viruses only)	+
Chlorine	Sodium hypochlorite (Bleach)	+	-	+	+	+
Active oxygen compounds	Virkon H_2O_2 Ozone	+	+ (At high conc's)	+	+	+

11.15. HT. SOP 9: Procedure for use of human tissue samples away from designated storage areas

Author: Lauren Harkin	**Position:** Designated Individual
Approved by: Human Tissue Management Sub-Committee	**Date:** 15 January 2019

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
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Appendix 15

Standard Operating Procedure (SOP)

HT.SOP 9: Procedure for use of human tissue samples away from designated storage areas

1. Individuals wishing to use samples that are stored in designated areas must have the consent from the person responsible for the samples. This will likely be the Principal Investigator (PI) on the URESC application for research samples.
2. Samples must only be used for what consent has been given for.
   - Research samples should only be used for the projects for which consent **and** ethical approval have been granted.
   - Research samples should only be used within the period that the EHU ethics application is valid for.
   - Samples given consent for use in research **only** must not be used for teaching and vice versa.
3. When being used, the sample's location must be known at all times. This can be achieved by signing the sample out using the software. Using the history record in the software, you can also find out who removed the sample and how long they were out for. ***To sign a sample in/ out of the software:***
   - Move your mouse to the samples panel and select the sample or multiple samples (using Shift or Ctrl) that you wish to sign in/out,
   - Click the right mouse button for the quick access samples menu and click the book in or book out icon, alternatively you can also find the same icons in the "Locations and Samples" ribbon tab within the samples group.

   NOTE: the samples background colour then changes from white to brown.
4. When in use, samples should be handled and transported safely, and users must comply with HT4 (Policy and Procedure for the Safe Handling of Human Tissue) and HT5 (Policy and Procedure for Local Transport of Human Tissue).
5. Samples must not be stored anywhere other than the designated storage areas when not in use. When the procedure for which the samples were signed out for use ceases, samples must be returned to storage immediately and signed back in to the software. Take care to ensure that the sample is returned to the correct storage location, matching that which is recorded in the software.
6. Should you wish to store samples in a different location, you must change the location information for that sample in the software (Please follow the instructions provided in the Pro-curo user manual which is available on the Y drive).
7. Should you wish to dispose of samples after use you must complete a Human Tissue Disposal form and submit it to the Designated Individual. The completed document should be stored in the University's human tissue sample tracking and management system by a Persons' Designated and the software should be updated accordingly.
8. If you have used up all of the sample and no relevant material remains, the records in Pro-curo must be updated to record the full use of human tissue.

11.16. HT. SOP 10: Emergency Gas Response Procedure

Author: Kayleigh Golding	**Position:** Senior Biology Technician
Approved by: Human Tissue Management Sub-Committee	**Date:** 30 January 2024

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version	Human Tissue Management Sub-committee	30 January 2024

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APPENDIX 16

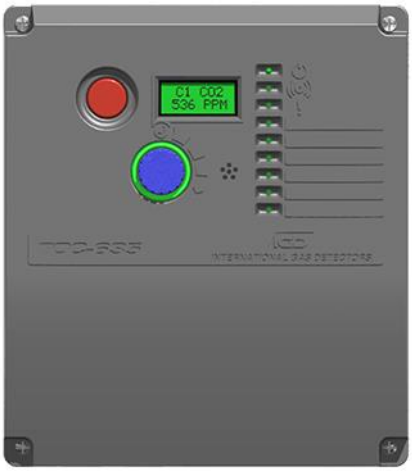
Emergency Gas Response Procedure

Gas Leak/Alarm

- Upon hearing the alarm (higher pitch than fire alarm accompanied by a flashing orange beacon above the door in the affected room), or becoming aware of a gas leak, **NOTIFY** all personnel in the area and **EVACUATE** the laboratory immediately.
- **DO NOT USE** fire alarm stations within the lab as they have the potential to spark.
- **DO NOT USE** electrical equipment or switch the lights on or off.
- **Provide assistance** to those needing additional help in evacuating. Implement Personal emergency evacuation plans (PEEPs) as appropriate (i.e. depending on whether any person subject to a plan is present on site).
- **DO NOT ENTER** a lab in which the alarm is sounding. **If someone is unconscious and the gas alarm is sounding, DO NOT go in to 'rescue' them.** On a phone away from the area, **call the emergency services** and request an ambulance. Explain that there is an unconscious person in a laboratory in which there is a gas leak.
- On a phone outside of the laboratory, **NOTIFY** the head technician on **7227 (internal)/ 01695 65 7227** or BSO on **7241 (internal)/ 01695 65 7241.** If unavailable, notify a trained member of staff from the department (see list of trained personnel below). Inform them if you have called an ambulance.
- **Out of hours** (or in the absence of trained personnel) **NOTIFY** Campus Support on **2222 (internal)** or **01695 584 227,** where the request will be treated as priority.
- **DO NOT RE-ENTER** the area until it has been deemed safe by Andrew Marriot or Matthew Smith.
- Inform line manager (staff) or course tutor (students) at the earliest opportunity and report as a near miss using the online reporting system.
- **IN THE EVENT OF POWER LOSS – EVACUATE THE LAB IMMEDIATELY – contact security as above and in the first instance Andrew Marriott AND Anne Oxbrough AND Clare Strode. DO NOT RE-ENTER** the area until it has been deemed safe by Andrew Marriott or Matthew Smith.
- **All users should only enter the lab if the external panel is green (see below), if red amber or no power – DO NOT ENTER on any circumstances**

Trained Emergency Responder

Name	Contact Number	Extension
Matthew Smith	01695 65 7241	7241
Andrew Marriot	01695 65 7227	7227
Kayleigh Golding	01695 65 7542	7542
Daniel Cosgrove	01695 65 0984	7984
Marie Heaps	01695 65 7374	7374
Priyanka More	01695 65 1590	1590
Richard Heaton	01695 65 1597	1597
Jasmine Morgan	01695 65 4222	4222



Only enter if gas panel is green as above

11.17. Human Tissue Disposal Form	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Spaces added to print names of signatories.	Human Tissue Management Sub-Committee	27 September 2016

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APPENDIX 17

Human Tissue Disposal Form

To be completed by the person undertaking the disposal of relevant material for research. The completed document should be stored in the University's human tissue sample tracking and management system by a Persons 'Designated.

Project Details	
URESC approval number (if applicable)	
Project/collection name	
PI or custodian of collection	
Dates samples collected (pre or post 01/09/2006)	
Description of tissue	
Date and time of disposal	
Type and amount of tissue disposed	
Sample ID numbers	
Reason for disposal	
Method of disposal	
Person responsible for disposal	
Additional details/comments	
Disposal authorised by:	Principal Investigator/ custodian Name: Signed: Date: Designated Individual or his representative Name: Signed: Date:

11.18. Adverse Event Report Form	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
6.0	Definitions of severity added in accordance with a HTA minor shortfall adjustment needed.	Human Tissue Management Sub-Committee	11 September 2024

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APPENDIX 18

Edge Hill University

Adverse Event Report Form

1. Reporting

Adverse event reported to:	**By:**	**Date reported:**
Designated Individual		
Person Designated		

2. Adverse Event / Incident

Date incident occurred	
Location of adverse event	
Summary of adverse event	
Severity/grade of adverse event*	

3. Initial action taken by DI and/or PD since being made aware of adverse event

Corrective	
Preventative	
Date of resolution, if applicable	

4. Any other relevant information

Please provide any additional information relevant to the adverse event

5. Signature

Report completed by:	Signature	Date report submitted:

* Adverse events should be graded as follows:

Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the Human Tissue Authority (HTA) and implemented.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway

Major shortfall:

A non-critical shortfall that:

- Poses a risk to human safety and/or dignity, or
- Indicates a failure to carry out satisfactory procedures, or
- Indicates a breach of the relevant Codes of Practice, the Human Tissue Act 2004, and other relevant professional and statutory guidelines, or
- Has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

11.19. Human Tissue Training Record (Researchers)	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Academic Board	**Date:** 2 December 2015

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		
2.0	Updated to reflect new Codes of Practice	Human Tissue Management Sub-Committee (HTMSC)	April 2018
3.0	Updated to include new revised title and new introductory statement added to the form, with revised sections in the table in regard to training requirements.	Human Tissue Management Sub-Committee	30 January 2024
6.0	Name change and additional points added to initial statement.	Human Tissue Management Sub-Committee	11 September 2024

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APPENDIX 19

Human Tissue Training Record for Researchers

This form should be completed as part of the induction process for any researcher that intends to conduct research under the University's Human Tissue Authority Research License. The researcher should email the completed form to the University's Designated Individual.

1. Personal details

Name	
Position	
Department	
Line manager	
Qualifications/ experience relevant to work with human tissue	

2. Training received relevant to work with human tissue

Training	**Delivered by**	**Date**	**Signature**
Edge Hill University Human Tissue Act training			
MRC online human tissue training (achieved min. 70%)	**N/A**		
Laboratory safety induction			
COSHH training			
Risk assessments training			
Pro-curo software training (state N/A where not applicable)			
Consent seeking competency assessed (state N/A where not applicable)			
Other training (please specify)			

3. Compulsory reading

Document	Date	Signature
EHU Quality Manual for Governance in the Acquisition, Use, Storage and Disposal of Human Tissue		
HTA Code A (Consent)		
HTA Code E (Research)		
HTA Code E (Research Standards and guidance)		
EHU Code of Practice for the Conduct of Research		
EHU Code of Practice for the Investigation of Research Misconduct		
EHU Research Ethics Policy		
EHU Research Data Management Guidelines		
Research Risk Assessment at Edge Hill University		
Concordat to Support Research Integrity		

4. Declarations

Researcher

I believe that I have received adequate information, instruction, and training for me to be able to carry out my work with human tissue safely and in accordance with the *Human Tissue Act 2004 and associated codes of practice,* and the conditions of Edge Hill University's Human Tissue Authority License. I have read and understood the documents listed above. I will at all times follow appropriate instructions and adopt the safe working practices I have been shown. I will bring to the attention of the Designated Individual (or his representative) any concerns that I have in relation to my work with human tissue.

Name	Date	Signature

Designated Individual

This person has satisfactorily completed training for work with human tissue and is deemed competent to undertake work under Edge Hill University's Human Tissue License.

Name	Date	Signature

11.20. Evaluation of competence in seeking consent	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Human Tissue Management Sub-Committee	**Date:** 27 September 2016

Document Review History			
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APPENDIX 20

Evaluation of Competence in Seeking Consent

Preamble

Although consent for the procurement of human tissue from the living is covered by common law, consent for the use and storage of human tissue for research is a statutory legal requirement that needs to be obtained in accordance with the requirements of the Human Tissue Act and as set out in the code of practice on consent published by the Human Tissue Authority. The Human Tissue Authority also sets consent standards for licenced establishments. These standards include that staff involved in seeking consent from research participants must receive training and support in the implications and essential requirements of taking consent.
Specifically, this involves

- Provision of standard operating procedures detailing the consent process (see HT3: Obtaining consent for use and storage of human tissue);
- Evidence of suitable training;
- Maintaining records demonstrating up-to-date training; and
- Competency in taking valid consent is assessed and maintained.

Edge Hill University holds a Human Tissue Authority licence and is expected to meet these licencing standards. In addition to the legal requirements, the provision of consent training, assessment, and feedback is important for the professional development of university staff and students undertaking research with human participants.

It is widely accepted that the consent process should not be regarded as a tick box exercise. The Participation Information Sheet should be a concisely written document that provides basic essential information about participation in a research project. This document should be given to the potential participant an appropriate amount of time (usually ≥ 24 hours) before being consented to the study to allow time for potential participants to properly consider the information and think of any questions they may wish to ask. When consenting participants there normally should be a face-to-face discussion where the person taking consent repeats, explains and reinforces information given in the Participation Information Sheet and allows an opportunity for potential participants to ask questions and express any concerns they might have.

This evaluation form is for evaluating the competencies of researchers in taking consent for research involving the use or storage of human tissue and for providing feedback for development of those competencies. Researchers may wish to use the form as a checklist during the consent process, or for reflecting on their own performance, although the list should not be regarded as exhaustive and some research projects may require additional considerations.

Person taking consent	
Position	
Department/Faculty	
REC approval number if applicable	

Professionalism	**COM***	**Feedback**
Privacy ensured		
Introduces self (name/role)		
Participant placed at ease		
Non-coercive style		
Allows companion present		
Interpersonal & Communication	**COM***	**Feedback**
Conversational manner used		
Avoids reading verbatim		
Appropriate language level		
Attentive & empathic		
Maintains eye contact		
Allows sufficient time for discussion		
Elicits questions effectively		
Questions answered appropriately		
Asks questions to ascertain level of participant understanding		
Consent Process	**COM***	**Feedback**
Participant Information Sheet given to participant ≥24 hours prior to meeting		
Project identified as research		
Explanation of project purpose		
Expected duration of participation, including total time & time for each part		
Explanation of voluntary participation		
Statement to let researcher know of any cultural or religious beliefs that may affect participation		
Explanation of procedures		
Explanation & confirmation that meet inclusion/exclusion criteria		

Risks, discomforts & other burdens		
Potential benefits (participant/others)		
Explanation of how and when any payment/course credits will be made		
Explanation of confidentiality & storage/use/disposal of data		
Procurement/storage/use/disposal of tissue samples		
Explanation of generic consent for possible future use of tissue		
Explanation of procedures for potential health-related findings		
Explanation of withdrawal process, including implications for human tissue		
Explanation of reasons why the researcher may withdraw the participant		
Whom to contact for more information/reporting adverse effects/raising concerns		

Other comments

Observer	
Signature	
Date	

11.21. Consent Training Checklist for Student Research	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Human Tissue Management Sub-Committee	**Date:** 27 September 2016

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APPENDIX 21

Consent Training Checklist for Student Research

Preamble

Unless exemptions apply, under the Human Tissue Act 2004, it is a criminal offence to use human tissue for a purpose for which consent has not been obtained from the tissue donor. As a licensed establishment under the Human Tissue Authority, Edge Hill University is expected to comply with standards set by the Human Tissue Authority. These standards include the provision of consent training and the assessment of the competency of those taking consent for the use of human tissue for research.

Undergraduate and taught postgraduate students typically undertake a project near the end of their degree programme. This project is often regarded as research training rather than research and, therefore, does not fall under the definition of research as it relates to the Human Tissue Act. If the findings from that project are published, or contribute to generalisable knowledge through some other means of dissemination, however, then the Human Tissue Act applies. If a student project is to be regarded as research, the student must undertake consent training BEFORE consenting participants to that project. The competency of the student in seeking consent also must be assessed by an authorised person during the early stages of consenting participants. All studies conducted by PhD students should be regarded as research.

The checklist on the next page states the topics that must be included in consent training for students using human tissue for research.

The student should initial each box if the topic was included in the training and to state that he or she understood the information provided. The student and person delivering the training should then sign and date this form.

Consent Training Checklist	**Student to initial**
Overview of the Human Tissue Act 2004 & penalties for non-compliance	
Role of the Human Tissue Authority	
Edge University's Human Tissue Authority Licence	
When consent is required for research	
Appropriate consent	
Valid consent	
Specific versus generic consent	
Time-limited versus enduring consent	
Health-related findings	
Withdrawal of consent	
Protecting the participant's dignity, confidentiality, privacy, and rights when seeking consent	

Student Declaration

I have received training on the above topics relating to seeking consent for use of human tissue in research and understand the information that has been given to me.

Name: Signature: Date:

Person delivering the training

Name: Signature: Date

11.22. Researcher Tissue Sample Self Audit Report Form	
Author: Prof Adrian Midgley	**Position:** Designated Individual
Approved by: Human Tissue Management Sub-Committee	**Date:** 5 January 2024

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version		

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder.

APPENDIX 22

Researcher Tissue Sample Self Audit Report Form

Every 4 months, researchers are required to audit a minimum of 20 random samples for each of their studies that are storing tissue samples under the University's Human Tissue Authority research licence. Please add more rows to the table below if necessary. Where the total number of samples for a study or human tissue collection is less than 20, then all samples should be audited. The audit should be completed in the first 2 weeks of April, August, and December, and the completed forms submitted to the secretary of the Human Tissue Management Sub-Committee so they can be considered at the committee meetings. A separate audit form should be completed for each study.

Ethical approval code: **Person completed the audit:** **Date of Audit:**

	Sample ID number	Database match storage location	Sample labelled correctly	Required Pro-curo fields completed	Proof of ethical approval	Proof of consent	MTA (where applicable)	Non-compliance details, including corrective and preventative actions
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								

11.23. Primary cell cultures vs. cell lines	
Author: Kayleigh Golding	**Position: Senior Biology Technician**
Approved by: Human Tissue Management Sub-Committee	**Date:** 30 January 2024

Document Review History			
Version Number	**Revision**	**Authorised by**	**Date**
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Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages:
https://www.edgehill.ac.uk/research/human-tissue/

APPENDIX 23

Primary Cell Cultures vs. Cell Lines

Human cells are commonly cultured for scientific research, and they can be classified into two main types:

- **Primary cells:**
  Primary cell cultures are directly isolated from a parental tissue of interest, e.g. fibroblasts extracted from a skin biopsy, and *typically* have a limited lifespan. A primary cell culture that has not undergone subculturing/passaging, and is freshly isolated from human tissue, is P0/Passage 0.

- **Cell lines:**
  Cell lines are primarily characterised by their ability to divide indefinitely, or more so than primary cells. Cell lines can be further classified into the following:

  - **Sub-cultured primary cells** refer to primary cell cultures that have surpassed P0/ Passage 0. Primary cells may be transformed to become an immortal cell line.

  - **Transformed cells** have undergone spontaneous or induced permanent genotypic alterations, *typically* resulting in the ability to proliferate indefinitely (immortalisation). E.g. the HeLa cell line.

  - **Self-renewing cells** are undifferentiated and are capable of differentiation into other cell types, or of indefinite proliferation of the same cell type. E.g. embryonic stem cells. [1]

According to the Human Tissue Authority (HTA), primary cell cultures are relevant material, which is defined as "material, other than gametes, which consists of or includes human cells." However, this differs in relation to cells that have been passaged/sub-cultured, as the HTA state a sample(s) will not be classified as relevant material if "they have divided or been created outside the human body."

Therefore, P0/Passage 0 primary cells are relevant material, whereas P1/Passage 1 primary cells and cell lines are not.

Example scenario:
A laboratory researcher purchases a vial of primary human epithelial cells, specifically bought at P0. As the cells have not yet divided in culture, the researcher must conform to HTA legislation. However, once the researcher has sub-cultured the cells to P1, the cells are no longer relevant material and do not have to comply with HTA regulations.

[1] Segeritz, C. P., and Vallier, L., 2017. Cell Culture: Growing Cells as Model Systems In Vitro. *Basic Science Methods for Clinical Researchers,* 151–172. https://doi.org/10.1016/B978-0-12-803077-6.00009-6.
[2] Sánchez-Romero, N., Meade, P., & Giménez, I. (2016). Microfluidic-Based 3D Models of Renal Function for Clinically Oriented Research. Translating Regenerative Medicine to the Clinic, 315–334. https://doi.org/10.1016/b978-0-12-800548-4.00022-x.

11.24. Guidance Notes: Transport of biological materials including import and export	
Author: Matt Smith	**Position:** Biological Safety Officer
Approved by: Human Tissue Management Sub-committee	**Date:** 11 September 2024

Document Review History			
Version number	**Revision**	**Authorised by**	**Date**
1.0	N/A. Current version	Human Tissue Management Sub-committee	11 September 2024

Note: All human tissue policies, procedures, standard operating procedures, and forms are scheduled for review in April of each year in conjunction with the annual audit, or at any other time changes are necessary.

This is a controlled document. When using this document please ensure that the version is the most up-to-date by checking the University's human tissue webpages: https://www.edgehill.ac.uk/research/human-tissue/

The current version also can be found on the University's shared drive (Y drive) in the 'HTA Compliance Documents' folder.

APPENDIX 24

Contents

1. Material Transfer Agreements

Before you arrange to transport any biological materials between Universities or from a non-commercial source, you must inform the research office and the biological safety officer of your intent to do so. It is likely that a Material Transfer Agreement (MTA) will have to be drawn up and signed by both parties (the sender and the recipient) before any material can be transferred to or from Edge Hill University.

An MTA is a contract that governs the **transfer** of tangible research **materials** between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the **materials** and any derivatives. Materials can include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, plants and other materials with scientific or commercial value.

An MTA offers a number of important benefits to the provider. Such an agreement can:

- give them control over the distribution of the material,
- enable them to restrict the use of the material to non-commercial research,
- reduce their legal liability for the recipient's use of the material, and
- help them gain access to the results of the research, both for information purposes and for commercial exploitation.

If the materials are hazard group II, the Biological safety officer will add them to the Universities hazardous substances list and will require information about their storage on the premises. The biological safety officer will also be able to assist you with the transfer of the materials and offer advice should it be required.

In order for the Research Office to process your request for an MTA, please fill in the relevant Material Transfer Request (MTR) form as below:

- Human Tissue MRF and send to: midglead@edgehill.ac.uk
- Non human tissue MTR form send to: hughesch@edgehill.ac.uk

NB: The non-human MTR is currently being produced by the RO

2. Classification of human and animal samples

2.1 Dangerous Goods

The carriage of dangerous goods by road, rail, inland waterway, sea and air is regulated internationally by European agreements, directives and regulations, and parallel legislation in the UK. If the substance you want to transport does not appear in the sections below, please refer to the government web pages for more information.

2.1.1 Infectious substances

Infectious substances are those materials known or reasonably expected to contain pathogens which can cause disease in humans or animals. They are classified as below:

Class 6 Division 2 (Class 6.2 dangerous goods)
Category A – Capable of causing permanent disability life threatening or fatal disease in otherwise healthy humans or animals when exposure occurs.
Category B – Substance does not meet criteria for inclusion in Category A.

Category A substances must also be marked with a UN specification mark (U above an N in a circle). The UN mark is followed by information on the type of packaging and the class of dangerous goods that the package is suitable for.

NB: Plant pathogens are not regulated by the transport regulations (See section 5).

2.1.2 GMOs

Genetically Modified Organisms (GMOs) that are also infectious substances are transported as infectious substances as above.

GMOs that are not infectious but can modify animals, plants, microbial substances or ecosystems are transported as **Class 9, Miscellaneous Dangerous Goods.**

2.1.3 Dry Ice

Must always be placed in a container which permits the release of gas. Dry Ice is transported as **Class 9, Miscellaneous Dangerous Goods.**

2.2 Exempt Patient Specimens

Exempt patient specimens are samples taken from patients (human and animal) that are unlikely to contain pathogens. They must have been taken directly from the patient (i.e. not cultured) and a professional judgement must have been made that the sample does not contain infectious substances. This judgement should be based on known medical history, symptoms and individual circumstances of the source material and endemic local conditions. Patient specimens include:

- Blood
- Urine
- Human tissues
- Animal tissues

Exempt patient specimens do not require **'**Proper Shipping Names' or 'UN numbers'. Should you be unable to provide the above assurances that the samples do not contain pathogenic agents, they should be transported as infectious substances (2.1.1).

2.3 Non-Infectious Biological agents

The following do not require 'Proper Shipping Names' or 'UN numbers'.

- Antibodies
- Cell extracts
- Protein samples
- Formalin fixed sections
- Non-infectious 'naked' DNA
- Non-infectious GMOs which do not affect the environment

3. Labelling

Diamond hazard labels are used to indicate the class or division of the material. The proper shipping name and UN number must also be displayed on the package. Handling labels can also be used. Markings and labels must be durable and placed where they are visible at all times.

3.1 Example Labelling

Dangerous goods must be labelled with the correct 'Proper Shipping Name' and 'UN number' (4 digit unique ID number).

Category A Infectious Substance –
Infectious substance infecting humans UN 2841 Infectious substance infecting animals only UN 2900

Category B Infectious Substance –
Biological Substances, Category B UN 3373

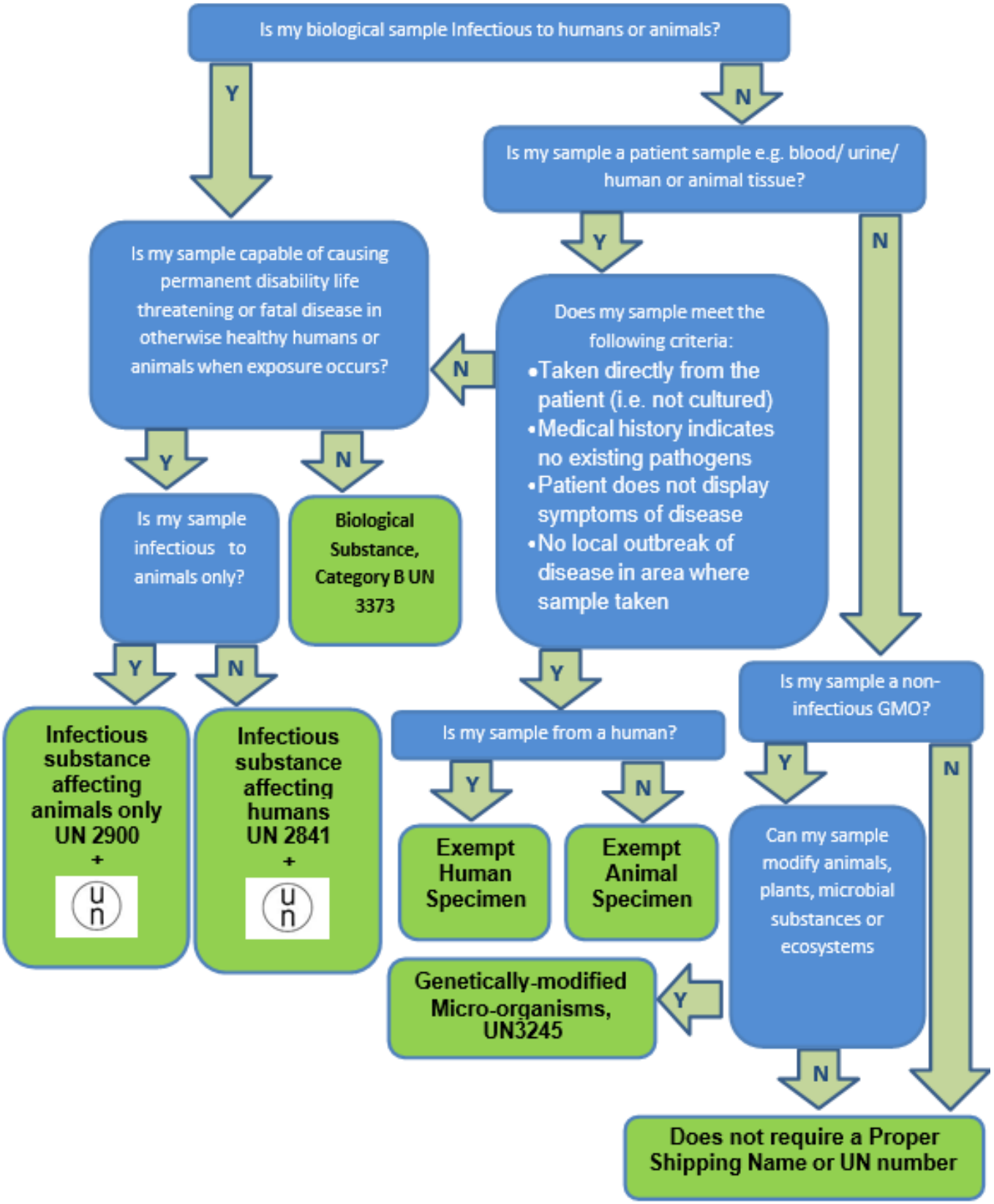
GMOs that are not infectious but can modify animals, plants, microbial substances or ecosystems –
Genetically-modified Micro-organisms, UN3245

Exempt patient specimens Exempt human specimen Exempt animal specimen

Non-Infectious Biological agents
N/A

Dry Ice
Dry Ice, UN1845

How should I Label my Biological Substance?



Proper Shipping Name and UN number	Packing Instruction Road/Air	Label
Infectious substance affecting humans UN2814	620/ 620	
Infectious substance affecting animals only UN2900	620/ 620	
Biological Substance, Category B UN 3373	650/ 650	
Genetically-modified Micro-organisms UN3245	904/ 959	
Exempt Human Specimen	-	**EXEMPT HUMAN SPECIMEN**
Exempt Animal Specimen	-	**EXEMPT ANIMAL SPECIMEN**

4. Packaging

Infectious Substances and exempt patient specimens should have 3 layers of packaging;

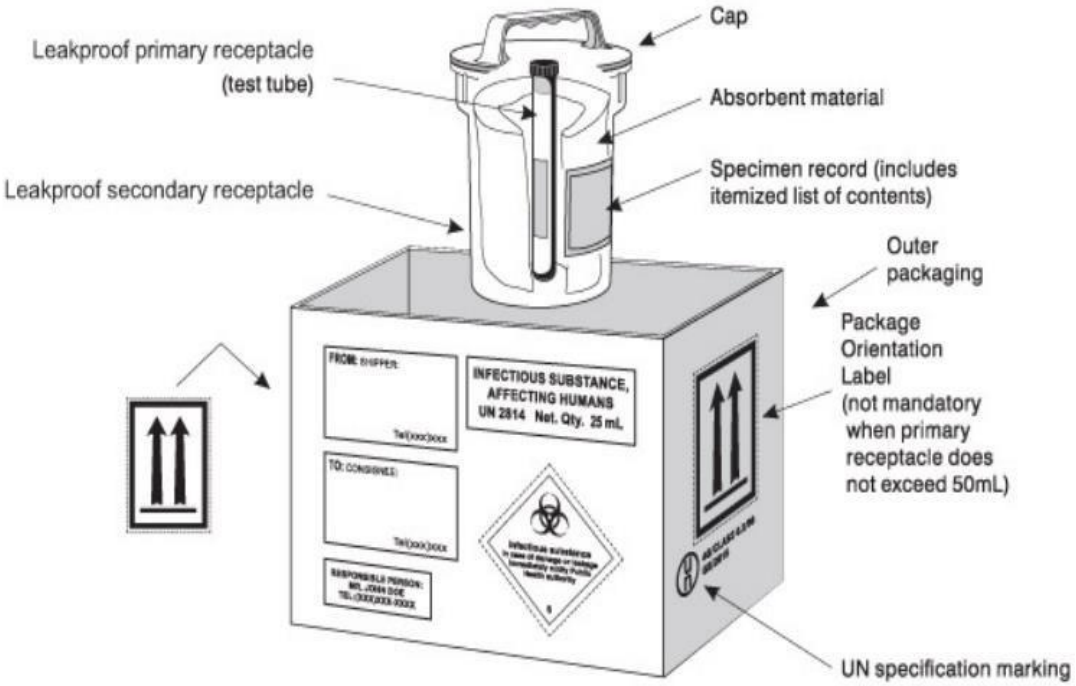
- Leak-proof primary receptacle(s);
- Leak-proof secondary packaging; and
- A rigid outer packaging of adequate strength for its capacity, mass and intended use with at least one surface having minimum dimensions of 100 mm × 100 mm

For liquid specimens there should be absorbent material placed between the primary and secondary packaging that is sufficient to be absorb the entire contents.
Labels should be clear, easily read and placed securely on the packaging.

4.1 Infectious Substances

Example of Packing and Marking for Category A Infectious Substances

(See Packing Instruction 620 for additional requirements)

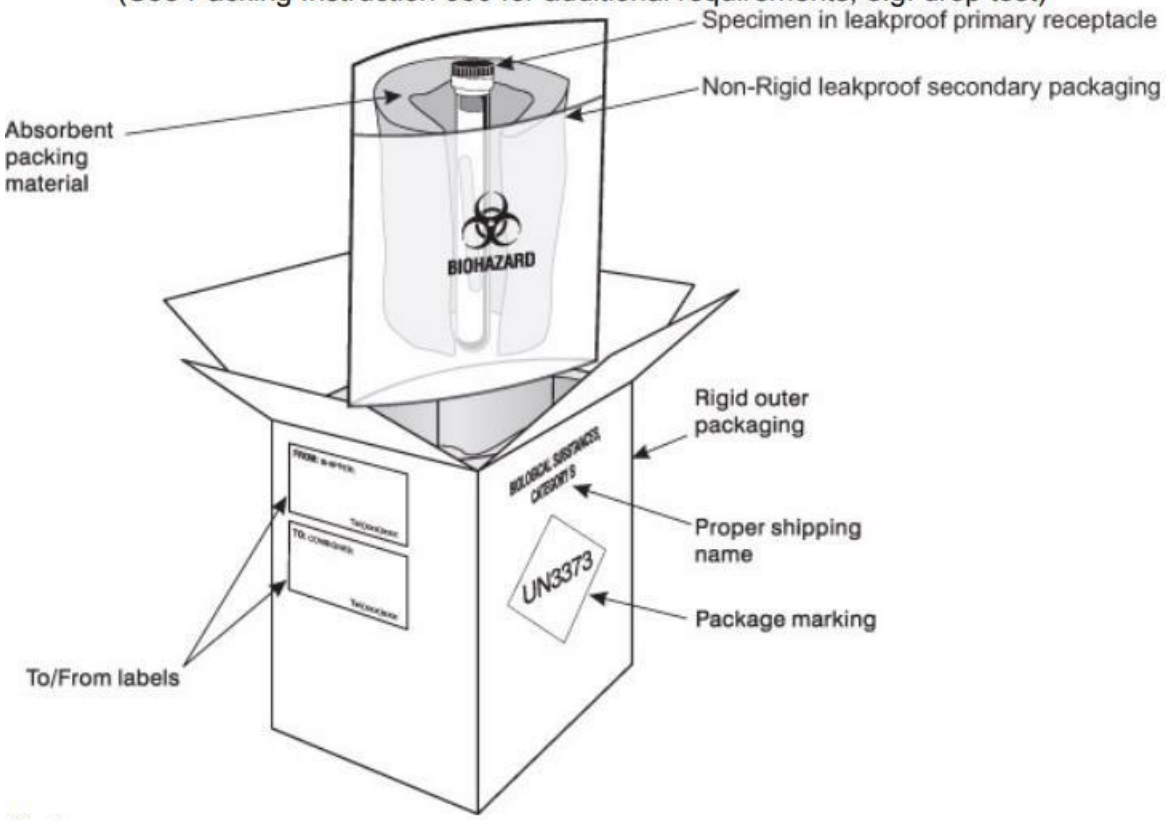


Notes:

1. The smallest external dimension of the outer packaging must not be less than 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Example of Packing and Marking for Category B Infectious Substances

(See Packing Instruction 650 for additional requirements, e.g. drop test)

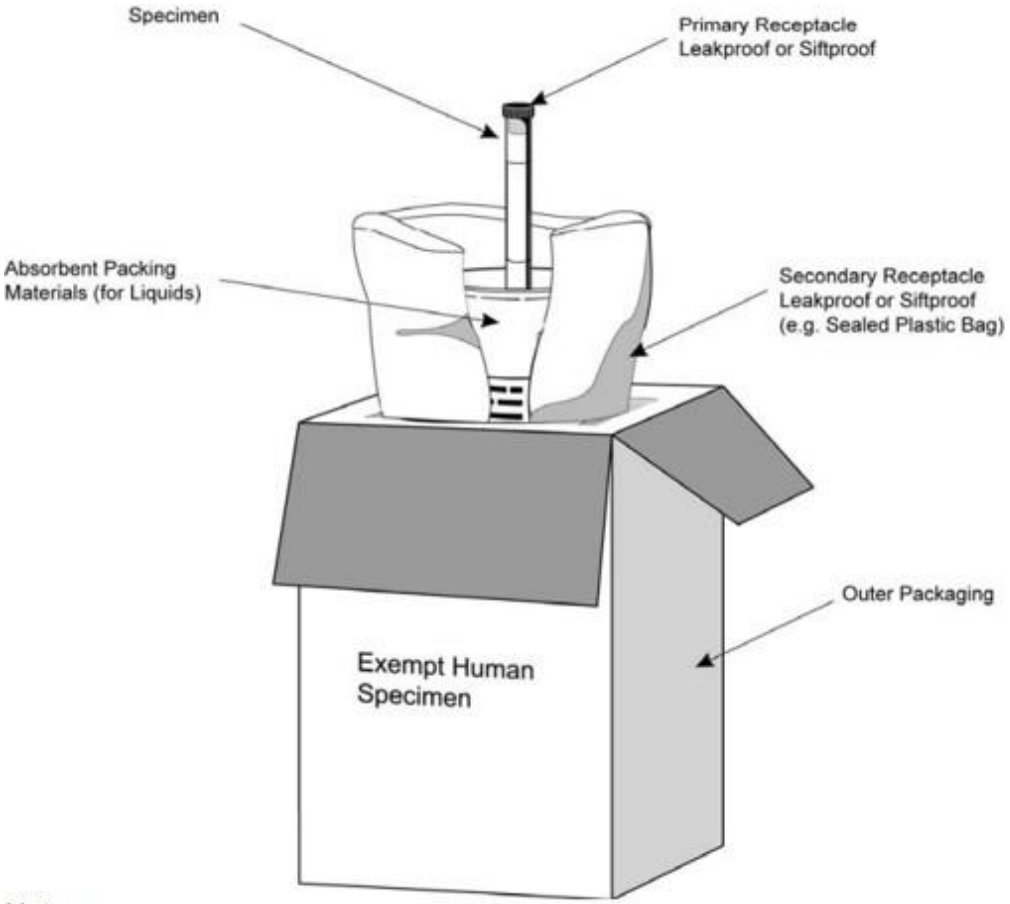


Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

4.2 Exempt Patient Specimens

Example of Packing and Marking for Exempt Specimens



Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The outer packaging must be of adequate strength for its capacity, mass and intended use.

5. Transport

Bio-hazardous materials must not be carried onto an airplane in checked or carry on bags, or on a passenger's person.

The quantity of the dangerous goods will determine if the package can be transported by passenger or cargo aircraft.

Who sets the laws regarding transport?

Air:

- International Civil Aviation Organisation (ICAO)
- International Air Transport Association (IATA)

Road:

- The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)
- The Carriage of Dangerous goods and Use of Transportable Pressure Equipment Regulations 2009

Rail:

- The Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)

Sea:

- The International Maritime Dangerous Goods Code (IMDG code)

6. Importing plants and soil

Plants, fruit, vegetables and plant material (like soil) from outside the EU fall into 3 categories:

- **'unrestricted'** material you can bring to the UK without any conditions
- **'controlled'** material that you can only bring into the UK with a 'phytosanitary certificate' to show it meets the requirements for entry to the EU
- **'prohibited'** material you can't bring into the UK unless you get a scientific research licence or an exception ('derogation') to the rules.

6.1 Controlled material

Controlled plants, fruit, vegetables and plant material include:

- All plants for planting;
- Common fruits (except for bananas and grapes) other than fruit preserved by deep freezing;
- Cut flowers;
- Some seeds and leafy vegetables other than vegetables preserved by deep freezing;

- Potatoes from some countries.

If you're not sure whether the item you want to bring to the UK is controlled, check the list of plant species by import category or contact APHA.

6.1.1 Personal allowance

You can import a total of 5 controlled plants without a phytosanitary certificate, if you're returning from an EU country or Switzerland, Algeria, Egypt, Israel, Jordan, Lebanon, Libya, Morocco, Syria, Tunisia and Turkey and the plants are:

- in your personal baggage
- for your personal use
- not diseased or infected with pests

Otherwise you must follow the procedures in this guide.

6.1.2 Phytosanitary certificates

When importing more than 5 controlled plant species, or if you are importing controlled plants from countries other than those listed in 6.1.1, you must obtain a phytosanitary certificate for each consignment of controlled material that you import, from the plant health authority in the country where your supplier is.

The certificate is a statement from the plant health authority that the consignment:

- Has been officially inspected;
- Complies with legal requirements for entry into the EU;
- Is free from serious pests and diseases.

The inspection referred to in the certificate must take place no more than 14 days before the consignment is dispatched from the inspecting country. The certificate must be signed by someone in the inspecting plant health authority within the same 14 day period. If your consignment includes plants from more than one country, you'll need to get a separate phytosanitary certificate from the plant health authority in each country.

You must have a licence to import, move or keep any plants, parts of plants or seeds listed in Annex III of EU Directive 2000/29/EC.

You may be able to use a licence to bring in plants, parts of plants and seeds which would normally need a phytosanitary certificate or plant passport. You can only do this if you can't get the phytosanitary certificate or plant passport for scientifically justified reasons, eg the plants were collected from the wild - contact the APHA if you want to do this.

Please contact the biological safety officer (lauren.harkin@edgehill.ac.uk) for further information and advice and before applying for a licence.

6.2 Prohibited material

6.2.1 Importing plant pests and pathogens

You must obtain a licence to import, move or keep invertebrate plant pests or plant pathogens which meet any one of the following conditions:

- They are listed in the annexes of EC directive 2000/29/EC;
- They're under statutory control in England, Scotland and Wales or subject to an eradication campaign - contact APHA to check this;
- Defra considers that they're not present in England, Scotland and Wales and are likely to be harmful to plants;
- Defra considers them to be non-indigenous races, strains, populations or clones of indigenous species which could exhibit an increased risk to plant health (eg increased pathogenicity or resistance to commonly used control strategies).

Contact APHA to check if an invertebrate plant pest or pathogen is prohibited.

Please contact the biological safety officer (lauren.harkin@edgehill.ac.uk) for further information and advice and before applying for a licence.

6.2.2 Importing soil

You must get a licence from the Animal and Plant Health Agency (APHA) to import, move or keep soil collected from any country that is not part of continental Europe (except Egypt, Libya, Israel, Morocco or Tunisia), Belarus. Moldova, Russia, Turkey and Ukraine.

You don't need a licence for:

- marine sediments
- pure and unused peat
- pure sand, clay, talc, rocks, volcanic pumice and chalk
- water that isn't contaminated by soil or organic matter

You must have a licence for artificial growing medium that contains any organic matter, unless it's made up entirely of unused peat.

Please contact the biological safety officer (lauren.harkin@edgehill.ac.uk) for further information and advice and before applying for a licence.

6.3 Moving consignments within England and Wales

6.3.1 Sending material to other sites in the UK

You can send licensed prohibited material to other people or organisations in England and Wales, provided the destination site or person has a licence to receive them.

Complete form PHI10 and send it to the APHA - if they approve your plan, they'll send you a written agreement. This written agreement is valid for 12 months, provided the recipient's

licence isn't amended or cancelled in this time. If the recipient changes the terms of their licence you'll have to contact APHA for a new approval.

6.3.2 Receiving material from other sites

You must have a licence to receive prohibited material from other people or organisations in England and Wales. You must also make sure your supplier has a licence and a written agreement from the APHA.

7. Importing animals or animal products

7.1 Importing live animals or animal products from EU countries

Research samples coming from other member states, Switzerland, Norway, Iceland or Liechtenstein do not need to be licenced or authorised but must comply with EU rules on animal by-products. You may wish to include a copy of the facilitation letter with any consignments from EU countries.

7.2 Importing live animals or animal products from non-EU countries

Import conditions for research samples are provided for in the animal by-product legislation. They must be authorised before they are imported. Some general licences and authorisations may need to be read together with a separate amendment notice.

There are multiple APHA General Licences that can be printed from the government website and used to import non-pathogenic animals or animal material/ products into the UK. If you feel that the import meets the conditions of a general licence you will be able to print a copy to travel with the consignment. General licences can be printed for immediate use, do not have an expiry date and can be used multiple times.

7.3 Animal pathogens

7.3.1 Non-specified animal pathogens

In order to move **non-specified animal pathogens** or carriers into the UK from another EU member state. Carriers are non-human living creature which can carry or transmit an animal pathogen. A carrier can also be the tissue, cell culture, body fluid, faeces, carcass, or carcass part of any such creature, if it can carry or transmit pathogens. You must read

You must have an import licence to move **non-specified animal pathogens** or carriers into the UK from a non-EU state. If you would like to import an animal pathogen into England from a country outside the EU, you must contact the BSO in the first instance who will contact APHA at imports@apha.gsi.gov.uk.

Should the BSO believe that your samples for import meet the conditions of the general licence, you will be asked to read the guidance notes and the conditions of the licence to ensure that a general license can be used. Before importing you must complete the declaration template and return it to APHA.

7.3.2 Specified animal pathogens

Specified animal pathogens are infectious agents, such as viruses, bacteria, parasites, including:

- Intact pathogens;
- Pathogens which have been attenuated or genetically modified by any means; and
- Any nucleic acid derived from an animal pathogen listed in Schedule 1 of SAPO which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.

If you plan to work with **specified animal pathogens,** animal products that contain (or may contain) specified animal pathogens or carriers, or if, for any reason, you **cannot** meet the conditions of any of the general licences then you will require a license for the site at which the work will take place as well as a licence for the transport of the material. The department of Biology currently does not possess a licence to work with or possess a specified animal pathogen. You must contact the BSO if you plan to import specified animal pathogens, who will work with you to complete a SAPO1 form and apply to the HSE for a new licence. This will not be a fast process and the department may not be able to provide the correct facilities for the work and so you should plan accordingly.

In addition to a site licence, to import animal products or **specified animal pathogens** or carriers, or if, for any reason, you **cannot** meet the conditions of any of the general licences you will require a license for transport and should please see the IV58 application form and IV59 guidance for completion, and return it to imports@apha.gsi.gov.uk. Please allow at least 15 working days for your application to be processed.

8. Obtaining a licence

If you require a licence to import your samples, please contact the biological safety officer (lauren.harkin@edgehill.ac.uk).

9. Useful Links

- Human Tissue MRF
- Moving Dangerous Goods
- Get a scientific research licence
- List of plant species by import category
- APHA
- Bringing non-specified animal pathogens or carriers into the UK
- The SAPO application process
- General Licences

10. Forms

- IV58: application for an import licence for an animal pathogen/and or carrier
- IV59: notes for guidance on completing the application form to import animal pathogen/carrier
- PHI10

APPENDIX 25

11.25 Glossary

Designated Individual. The person under whose supervision the licensed activity is authorised to carry on.

Human Tissue. Any and all constituent parts of the human body formed by cells.

***Human Tissue Act 2004* (*HT Act*)**. Provides a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified scheduled purposes.

Human Tissue Authority (HTA). The governing body set up to regulate activities that come under the *Human Tissue Act 2004*.

Licensable activity. Any activity specified under Section 16 of the *Human Tissue Act 2004*.

Person Designate. A person to whom the license applies and to whom the authority conferred by the license extends.

Principal Investigator. The scientist who has overall responsibility for overseeing the conduct of a research project.

Relevant material. Any material, other than gametes, removed from the body that consists of or contains human cells.

Schedule purpose. A purpose for which consent is required under the *Human Tissue Act 2004*.

APPENDIX 26

11.26 Useful Resources

1. Human Tissue Authority website

2. *Human Tissue Act 2004*

3. *Human Tissue Authority Code of Practice A (Guiding Principles and the Fundamental Principle of Consent)*

4. *Human Tissue Authority Code of Practice E (Research – Code of Practice and Standards)*

5. *Human Tissue Authority Code E (Research - Standards and guidance)*

6. Medical Research Council guidance for those working with human tissue

7. National Research Ethics Service *Information Sheets & Consent Forms: Guidance for Researchers & Reviewers*

8. Edge Hill University *Research Data Management Guidelines*

APPENDIX 27

11.27 Human Tissue Management Sub-Committee (HTMSC) Members

2024 – 2025

M E M B E R S H I P

	Name	Role	Contact
Chair	Prof Adrian Midgley	Chair	midglead@edghill.ac.uk
Secretary	Victoria Chalmers	Research Support Administrator	victoria.chalmers@edgehill.ac.uk
Ex-officio members	Lynda Brady	Licence Holder's Contact	bradyl@edgehill.ac.uk
	Prof Adrian Midgley	Designated Individual	midglead@edghill.ac.uk
Appointed Members	Adam Jones	Person designated (Sport & Physical Activity)	jonesad@edgehill.ac.uk
	Andrew Marriott	Person designated (Biological Sciences)	marriota@edgehill.ac.uk
	Scott Mosher	Person designated (Health & Psychology)	moshers@edgehill.ac.uk
	Chris Hughes	Research Office representative	hughesch@edgehill.ac.uk
	Dr Craig Bridge	Researchers' representative (Sport & PA)	bridgec@edgehill.ac.uk
	Dr Jane Bradbury	Researchers' representative (FoHSCM)	jane.bradbury@edgehill.ac.uk
	Prof Philip Murphy	Researchers' representative (Psychology)	murphyp@edgehill.ac.uk
	Dr Adjanie Patabendige	Researchers' representative (Biosciences)	patabenda@edgehill.ac.uk