Research Support Office

Policy on the Disposal of Human Material for Research Purposes

Reference: HTA002

<table>
<thead>
<tr>
<th>Author</th>
<th>Date of Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Blaylock (Human Material Governance &amp; Quality Officer)</td>
<td>14/06/17</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approved on behalf of ratifying committee</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janet Risk (Designated Individual - Human Tissue Act)</td>
<td>28/06/2017</td>
</tr>
</tbody>
</table>
Document Control

<table>
<thead>
<tr>
<th>Issue Date</th>
<th>28/06/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date</td>
<td>28th June 2017</td>
</tr>
<tr>
<td>Review Date</td>
<td>28th June 2019</td>
</tr>
</tbody>
</table>

Distribution:

This document is controlled using Workbench and is made available on the University of Liverpool Human Material Governance web pages.

Please note that the web version of this document is the only version that is maintained. This document is uncontrolled when printed and as such, may not necessarily contain the latest updates and amendments.

Document History can be viewed on Workbench

Review Process Prior to Sign Off

<table>
<thead>
<tr>
<th>Name of Group/Department/Specialist Committee</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Material Oversight Committee – Version 1</td>
<td>14th June 2017</td>
</tr>
</tbody>
</table>
1. Introduction

The Human Tissue Act (HT Act (2004)) is a legal framework which regulates the ‘removal, storage, use and disposal of human bodies, organs and tissues’\(^1\). The Act came into effect on the 1\(^{st}\) September 2006 and was amended in July 2014. It applies to England, Wales and Northern Ireland. The HT Act (2004) established the Human Tissue Authority (HTA) to regulate all activities concerning the removal, storage, use and disposal of relevant human material. Relevant human material is defined as material other than gametes, which consists of or includes human cells\(^2\).

As human tissue is a valuable resource it must be treated with due care and respect. The generosity and rights of the donors must be acknowledged and taken into consideration at all times. Any disposal procedure implemented must recognise the nature of the material being handled, the sensitivities of feelings of donors or their relatives (particularly of the bereaved) and the need for clarity when providing information.

Accordingly the HT Act (2004) states that there must be a clear and sensitive policy for disposing of relevant human material and disposal must be documented.

This Policy has been produced in accordance with The Human Tissue Act 2004. It should be read in conjunction with the University of Liverpool (University) ‘Policy on the Use and Storage of Human material for Research Purposes, The University Human Material Code of Practice and the Human Tissue Authority’s (HTA) Code of Practice A paragraphs 13,25,143,151\(^3\) and Code of Practice E paragraphs 127-130\(^4\).

The University is responsible for ensuring that appropriate procedures are put in practice and that staff and students work to the standards set by the HTA.

2. Scope

This policy applies to all staff involved in research activities utilising human material. Staff, students, and other individuals acting under the auspices of the University must ensure compliance with the requirements of the HT Act (2004) at all times.

They must comply with any reasonable requests made by the Sponsor (University or NHS R&D), the University Designated Individual and their delegates to fulfil the requirements of this.

The HT Act (2004) makes significant distinction between tissue removed from the living and the dead. It must be emphasised that the status of the tissue at the time it was removed from the individual determines the requirements for disposal. This also applies to existing holdings, materials obtained prior to the implementation of the Human Tissue Act on 1\(^{st}\) September.

University Staff and Students responsible for the disposal of human material should abide by this policy, The University Policy and Code of Practice for the Management of Hazardous Waste (SAO010) and disposal Standard Operating Procedures (SOPs) in place for their local environment.

---


3. Procedure

3.1 Disposal - Considerations

Where sample disposal is required, staff should be aware of the ethical considerations and requirements under the HT Act (2004). Material should always be disposed of with due respect for the wishes of the donor and consideration should be taken relating to religion, culture, beliefs and what the donor has consented to.

Disposal information should appear on the patient/participant information sheet provided during the study consenting process.

Disposal arrangements and disposal routes should be discussed as part of the consenting process and any specific wishes should be recorded.

Whilst it is preferable that all material collected for the purposes of a particular study follow the same disposal procedure, specifically requested exceptions should be considered carefully on a case by case basis, to determine that the method is legal and feasible. The potential benefits of obtaining the sample may be outweighed by the inconvenience and or expenditure incurred by specific disposal requests. This may be a consideration for study exclusion.

Any material collected with a specific disposal request must be clearly identifiable (flagged) as requiring special disposal arrangements.

This also applies to material sourced from a third party where requirements related to disposal are detailed in an agreement such as a Material Transfer Agreement (MTA).

3.2 Disposal - When

This policy applies to circumstances where it is necessary to dispose of human material collected for research purposes when:

- The patient has withdrawn consent for use.
- The consent or ethical approval for a study/project indicates that samples must be destroyed once the study/project ends.
- The sample integrity has been compromised.

It is however, now considered best practice for human material with appropriate consent, to be stored or gifted to Research Tissue Banks (RTB) (“biobanks”) for future research projects⁵.

3.3 Disposal – Method

The disposal method required is dependent on whether material:

- Was obtained from the living or the deceased (Appendix 9.1).
- Is identifiable
- Is an existing holding
- Has any predefined specific disposal arrangements

⁵ https://www.hta.gov.uk/faqs/research-faqs#faq13784
Material from the living

It is generally acceptable to dispose of material collected from the living by incineration unless there are donor-specific wishes for disposal. There is no need to bag individual samples separately however, donated material should be bagged separately from other clinical and laboratory waste before entering a common waste stream.

Material from the deceased

Tissue from the deceased can be disposed of by incineration, cremation or burial, depending on material type, and wishes of the donor.

If there are no specific disposal requests in place for material donated from the deceased then the normal disposal route for non-recognisable human material for your Institute, building or department can be followed.

Anatomical waste

Anatomical waste (body parts or other recognisable anatomical items) must be disposed of in line with the UK government Health technical memoranda management and disposal of healthcare waste (HTM 07-01). This may require slight variation to your normal local disposal route for human material.

Existing holdings

Material collected prior to implementation of the HT Act (2004) should follow the route directed by the status of the donor on collection i.e. living or deceased.

Fetal Tissue

If there is a requirement to use fetal tissue as part of a research project, then further guidance on how to respectfully and lawfully dispose of this material can be found within the HTA web pages.

Imported Material

Unless stipulated otherwise, imported material would follow the same disposal arrangements as material sourced from England, Wales and Northern Ireland.

Any specific requests made regarding disposal during consenting process must be carried out. This may include, for example, the return of material to the country of origin.

3.4 Confidentiality

Confidentiality should be maintained at all times and any identifiable information must be removed from samples prior to disposal.

---

3.5 Disposal – Documentation

Human Material Records

The University of Liverpool requires Chief/Principal Investigator and collection custodians to maintain appropriate records and documents for all material they receive.

Information documented should include details of:

- When and where the material was acquired
- Consent stipulations
- Intended use of the material
- Details of any movement/transfer of the material (to/from whom and where)
- Disposal details

The University of Liverpool requires disposal details to include completion of the Human Material Disposal Form FORMHTA002.

4. Roles and Responsibilities

4.1 Designated Individual for research

The Designated Individual (DI) for research will be responsible and accountable for compliance with the Act and maintaining the appropriate Licence from the Human Tissue Authority. The Designated Individual for research has ultimate responsibility to decide on the best course of action for any human material related incident if a solution cannot be found.

4.2 Designated Individual for anatomy

The DI for anatomy will be responsible and accountable for compliance with the Act and maintaining the appropriate Licence from the Human Tissue Authority.

4.3 Person Designate

Person Designate (PD) are appointed and supervised by the DI. The PDs role is to act on behalf of the DI in defined areas of the University. The University has six PDs, four for the satellite sites at Aintree University Hospital NHS Foundation Trust, Liverpool Women’s NHS Foundation Trust, Institute in the Park at Alder Hey and Leahurst Campus. The two other PDs are positioned centrally in the Research Support Office (RSO) and the Institute of Translational Medicine (ITM).

4.4 Human Material Officer

Human Material Officers are appointed by Faculties or Research Institutes within the University to assist in dissemination and collation of information relating to human material. They act on behalf of and are responsible to the DI.

---

https://www.liverpool.ac.uk/intranet/human-material-research-governance
4.5 Individual chief/principal investigator

It is the responsibility of individual chief/principal investigators to ensure that all research staff adhere to this policy. It is the investigators’ responsibility to report all human material related incidents to the Designated Individual. If a researcher is unsure whether something should be classed as an adverse event, their institutional HMO should be contacted for advice.

4.6 All research personnel

It is the responsibility of all research personnel to read and follow the guidance relating to research and human material in this policy and the Codes of Practice, and to report human material incidents. If a researcher is unsure whether something should be classed as an adverse event, their institutional HMO should be contacted for advice.

5. Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>Chief Investigator</td>
</tr>
<tr>
<td>HTA</td>
<td>Human Tissue Authority</td>
</tr>
<tr>
<td>MTA</td>
<td>Material Transfer Agreement</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
</tbody>
</table>

6. Associated Documents and References

- Human Tissue Act (2004)\(^1\).
- HTA Materials considered to be relevant material\(^2\).
- HTA Code of Practice A: Guiding principles and the fundamental principle of consent\(^3\).
- HTA Code of Practice E: Research and Standards\(^4\).
- Government guidance on healthcare waste\(^6\).
- HTA guidance on disposal of pregnancy remains\(^7\).
- University of Liverpool: Policy on the Use and Storage of Human Material for Research Purposes (HTA001)\(^8\).
- University of Liverpool: Human Material Code of Practice (HTA003)\(^8\).
- University of Liverpool: Human Material Research Quality Manual (HTA004)\(^8\).
- University of Liverpool: Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004 (HTA005)\(^8\).
- University of Liverpool: Human Tissue Authority Licence Risk Assessment (HTA006)\(^8\).
- University of Liverpool: Procedure for Internal Audit of Relevant Human Material (HTA007)\(^8\).
- University of Liverpool: Human Material Supporting Documents (SDS001-SDS003)\(^8\).
- University of Liverpool: Human Material Standard Operating Procedure (SOP) Suite\(^8\).
7. Training and Resources

It is important that all individuals utilising human material as part of their research projects have a good understanding of the HT Act (2004) and the HTA codes of Practice\(^1\) relevant to their role.

In addition to the information and references within this HM code, The University conducts regular HTA training courses for Staff and Students utilising human material to ensure compliance. The full course content of which, is available on the University Human Material web page\(^8\) to view all year round.

New members of staff and postgraduate students who intend to collect, store, use and/or dispose of human material on University premises shall attend local training as soon as reasonably possible, or complete the MRC Research and human tissue legislation E-Learning package\(^9\) before undertaking such activities.

In line with Good Clinical Practice (GCP) retraining requirements, human material training shall be repeated every 3 years.

8. Monitoring and Audit

The University requires all staff, students and those working under its auspices to maintain accurate records of human material and to make these available for audit purposes.

An annual return of human material will be requested and must be completed by Chief/Principal Investigators and collection custodians in order to provide the DI and HTA with an overall view of the material being stored on University premises and the purpose of the material storage.

The Designated Individual, Persons Designate and Human Material Officers will continue to audit and monitor the storage and use of human material throughout the year.

\(^{9}\) http://byglearning.co.uk/mrcsc-ims/course/category.php?id=1
9. Appendix

9.1 Disposal Options

Disposal options for human tissue from the living

Disposal options for human tissue from the deceased