Policy on the Use and Storage of Human Material for Research Purposes

Reference: HTA001

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1. Introduction

The University of Liverpool (University) expects that research and related activities undertaken by its staff and students; on its premises; or in its name, meets the requirements of research governance and research good practice. The University is committed to maintaining the highest standards of respect, care and integrity in regard to its holdings of human material. To ensure high quality research and compliance with legislation, all samples of human material (including nucleic acids, excretions and secretions)\(^1\), must be acquired lawfully, with appropriate consent, and stored, handled, used and disposed of sensitively and responsibly.

The University requires that the removal, use, storage and disposal of human material meet legal and ethical standards. The principles that guide this stance are as follows:

- Consent for the collection of human material is essential in all research activities, as is consent for storage and use with few exceptions (section 9. Consent exceptions).

- The donor (or relatives of the deceased) of human material must be respected in its removal, use, storage and/or destruction. Donations of human material are made with goodwill, under the expectation that the material will be respected and utilised for the advancement of knowledge. Staff, students, and those operating under the auspices of the University must respect the gift of such material in the removal, use, storage and destruction so that its integrity is maintained.

- Records of human material must be accurately maintained and made available to the University for Research Governance purposes.

Wilful failure to meet, or continued negligence in meeting, these policy requirements will constitute a disciplinary matter.

2. Scope and exemptions

This policy applies to the removal, use, storage and/or disposal of all human material (including nucleic acids, excretions and secretions) for research purposes.

The University holds an HTA licence (number 12020) for the storage of human material for use in research. Staff, students, and other individuals acting under the auspices of the University must ensure compliance with the requirements of this licence at all times. They must comply with any reasonable requests made by the Designated Individual and their delegates to fulfil the requirements of this licence.

The Licence does not include the physical collection (i.e. removal from the person) or the use of tissue for research purposes. Staff, students and those working under the auspices of the University must gain ethics committee approval for such activities.

Storage of human material obtained prior to 1\(^{st}\) September 2006 (existing holdings) is not legally required to comply with the consent requirements of Human Tissue Act (2004)\(^2\); however, the University considers it good practice to, where possible, adhere to all of the HTA standards, which include consent, proper storage, accurate record keeping and sensitive disposal.

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\(^1\) https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

\(^2\) http://www.legislation.gov.uk/ukpga/2004/30/contents
The Health Research Authority (HRA)\(^3\) however, do require that NHS Research Ethics Committee (NHS REC) approval is in place prior to the use of existing collections.

3. Procedure

The University is committed to adherence to rigorous procedures for the lawful removal, use, storage and destruction of human material, including bodily fluids.

The HTA’s remit applies to human material obtained less than 100 years prior to the donor’s death. However, the University procedures shall apply to all human material and are underpinned by the following fundamental principles:

- **Existing collections** (i.e. retrospective collections) of human material, including bodily fluids, obtained from 1\(^{st}\) September 2006 onwards must have evidence of consent; or where this was not sought, evidence of ethical approval and anonymisation of material.

- **New collections** (i.e. prospective collections) of human material, including bodily fluids, from living donors must, where feasible, be able to illustrate consent. Consent must be obtained, without exception, in all cases where human material is removed from the deceased.

- Assurances should be sought when sourcing collections from third parties that appropriate consent and ethical approval exists for the collection, storage and use of the material (within the governance framework of the country of origin).

- **New studies** collecting or using human material, including bodily fluids, must gain appropriate ethical approval. Where approval is not facilitated by the Health Research Authority Research Ethics Committee (HRA REC), approval must be gained from a University Research Ethics Committee. Advice should be sought from ethics@liverpool.ac.uk.

- New studies using human material must gain Sponsorship where appropriate, as required according to Good Clinical Practice guidance. This includes accessing material stored in approved Research Tissue Banks (RTB) (“biobanks”). Advice should be sought from sponsor@liverpool.ac.uk.

- Appropriate records of the collection (removal), storage, use and destruction of relevant human material \((\text{including nucleic acids, excretions and secretions})\), for research purposes shall be maintained to ensure compliance with the Human Tissue Act (2004).

- Human material samples \((\text{including nucleic acids, excretions and secretions})\) must be traceable from point of collection, storage to destruction.

4. Roles and responsibilities

4.1 University of Liverpool (University)

The University is responsible for ensuring that appropriate procedures are in place for the storage and use of relevant human material in accordance with the requirements of the Human Tissue Act (2004). The University of Liverpool is responsible and accountable for making sure that its staff work in line with the HTA standards.

\(^3\) [http://www.hra.nhs.uk/](http://www.hra.nhs.uk/)
4.2 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.

4.3 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.

4.4 Person Designate

A Person Designate (PD) is appointed by the DI and acts on their behalf. The University has six PDs, one at each of the four satellite sites; 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 in the Institute of Translational Medicine (ITM).

4.5 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.

4.6 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.

4.7 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

- HRA: Health Research Authority
- HRA REC: Health Research Authority Research Ethics Committee
- HTA: Human Tissue Authority
- University: University of Liverpool
- NHS REC: National Health Service Research Ethics Committee
- NRES: National Research Ethics Service
- RTB: Research Tissue Bank
6. Associated Documents and References

- HTA List of Materials considered to be Relevant Material under the HT Act (2004)\(^1\).
- Human Tissue Act (2004)\(^2\).
- Health Research Authority\(^3\).
- HTA Code of Practice A: Guiding principles and the fundamental principle of consent\(^4\).
- HTA Code of Practice E: Research and Standards\(^5\).
- Good Clinical Practice Guidance\(^6\).
- University of Liverpool: Policy on the Disposal of Human Material for Research Purposes (HTA002)\(^7\).
- University of Liverpool: Human Material Code of Practice (HTA003)\(^7\).
- University of Liverpool: Human Material Research Quality Manual (HTA004)\(^7\).
- University of Liverpool: Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004 (HTA005)\(^7\).
- University of Liverpool: Human Tissue Authority Licence Risk Assessment (HTA006)\(^7\).
- University of Liverpool: Procedure for Internal Audit of Relevant Human Material (HTA007)\(^7\).
- University of Liverpool: Human Material Supporting Documents (SDS001-SDS003)\(^7\).
- University of Liverpool: Human Material Standard Operating Procedure (SOP) Suite\(^7\).

7. Training and Resources

New members of staff and postgraduate students who intend to collect, store, use and/or dispose of human material on University of Liverpool premises shall attend local training as soon as reasonably possible, or complete the MRC E-Learning package\(^8\) entitled ‘Research and human tissue legislation’, before undertaking such activities. In line with 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 led by the Designated Individual in order to gain an overall view of the material being stored on University premises and the purpose of the storage of the material. Persons Designate and Human Material Officers will also be responsible for monitoring the storage and use of human material in the departments within their institute or faculty.

9. Consent Exemptions

There are a number of instances where consent is not required for the storage and/or use of human material for research, however ethical approval is required for its use. These include;

- Existing holdings (relevant material collected prior to 1\(^{st}\) September 2006).
- Imported tissue or tissue from a body that has been imported.
- Surplus Material*.

* Surplus Material: taken from the living for diagnostic purposes and subsequently stored for use in research can be used with consent or without consent if in an unidentifiable form i.e. (anonymised or linked-anonymised).


\(^{3}\) [https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials](https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials)

\(^{4}\) [https://www.liverpool.ac.uk/intranet/human-material-research-governance/](https://www.liverpool.ac.uk/intranet/human-material-research-governance/)

\(^{5}\) [http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1](http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1)