Clinical Directorate Clinical Research Governance Team

Policy

Policy on the Use and Storage of Human Material for Research

HTA001

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Dr Hannah Davies	28/07/2022
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Dr Neil French	08/08/2022

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1. Introduction and Principles

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),** 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 2. Scope and Exemptions).
- 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.
- Studies using human material must be registered with the University Human Material Governance team. Accurate records of all human material and associated data must be maintained for governance purposes.

Wilful failure to meet, or continued negligence in meeting, these policy requirements will constitute a disciplinary matter and could be referred to the University Integrity team.

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.

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 1st September 2006).

- Imported tissue or tissue from a body that has been imported*.

- Surplus Material**.

** Whilst the consent provisions of the Human Tissue Act (2004) do not apply to imported tissue the storage provisions do. Imported Material cannot be stored where a Material Transfer Agreement (MTA) or other formal agreement is not held. The purpose of such agreement is to provide UoL with assurance that the tissue or samples imported were; obtained ethically, in line with the governance requirements of the country of origin, which includes consent.*

*** 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).*

Despite these exceptions 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.

3. Roles and responsibilities

3.1 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.

3.2 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.

3.3 Human Material Governance Team

The Human Material Governance Team are responsible for the day to day oversight of human material activities and act as a central contact point for all users.

3.4 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.

3.5 Person Designate

A Person Designate (PD) is appointed by the DI and acts on their behalf. The University has four PDs, One at each of the four satellite sites; Aintree University Hospital (part of Liverpool University Hospitals

NHS Foundation Trust), Liverpool Women's NHS Foundation Trust, Institute in the Park at Alder Hey Children's Hospital and the University Leahurst Campus.

3.6 Human Material Officer (HMO)

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.

3.7 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.

3.8 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.

4. 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 relevant to their role.

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 internal website 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 must read and understand is this Human Material Policy (HTA001), the University's Code of Practice (HTA003) and attend local training as soon as reasonably possible before undertaking such activities.

If attendance at the local training is not possible prior to onset of activities then completion of the MRC Research and human tissue legislation E-Learning package entitled 'Research and human tissue legislation' must be completed.

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

5. 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 Human Material Governance Team 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 are responsible for assisting in monitoring the storage and use of human material in the departments within their Institute or Faculty.

6. Abbreviations

HMO Human Material Officer

HTA Human Tissue Authority

University University of Liverpool

7. Associated Documents and References

- Human Tissue Act 2004
- Relevant material under the Human Tissue Act 2004
- Health Research Authority
- HTA Codes of Practice;
    - *HTA Code of Practice A: Guiding principles and the fundamental principle of consent*
    - *HTA Code of Practice E: Research and Standards*
- MRC E-Learning Package-Module Human Tissue Legislation
- ICH E6 (R2) Principles of Good Clinical Practice
- University of Liverpool Policies and Procedures
    - ***HTA003*** *Human Material Code of Practice*
    - ***HTA004*** *Human Material Research Quality Manual*
    - ***HTA005*** *Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004*
    - ***HTA006*** *Human Tissue Authority Licence Risk Assessment*
    - ***HTA007****Procedure for Internal Audit of Relevant Human Material*
    - ***HTA008*** *Research Tissue Bank Applications and Documented Procedures Necessary to Ensure Compliance with the Human Tissue Act (2004)*