



LSHTM Policy for Research with Human Tissue

Document Type	Policy	
Document owner	Designated Individual for LSHTM (currently the Head of Research Governance and Integrity)	
Approved by	ITD Health and Safety Committee	
Approval date	5 February 2021	
Review date	5 February 2023	
Current Version	6.1	
Amendments	6.1; 14/07/2021	Minor clarification not requiring approval
	6; 05/02/2021	Bi-annual update, approved by the ITD Health and Safety Committee
	5.2; 10/04/2019	Reviewed at Policy Advisory Board 18/03/2019. Minor formatting
	5.1; 10/01/2019	Approved by Lab Safety Cmte
	5.0; 10/12/2018	Updates following HTA inspection
	4.0; 21/02/2018	Bi-annual update
	3.0; 01/09/2015	Bi-annual update
	2.1; 06/12/2013	Bi-annual update
	2.0; 05/12/2011	Annual update
	1.0; Sept 2010	Removed as part of the Safety Manual. DI changed to Quality & Governance Manager
Related Policies & Procedures	Good Research Practice policy LSHTM SOP on human tissue	

1. Introduction and Scope	2
2. Purpose	2
3. LSHTM Licence	2
4. Ethical approval for human tissue research projects	2
5. Designated Individual (DI)	3
6. Person Designated (PD)	3
7. LSHTM management arrangements	3
8. Material covered by the Act	3
9. Material collected overseas	4
10. Consent	4
11. Records Management	5
12. LSHTM Human Tissue Register	6
13. Audit	7
14. Adverse events	7
15. Risk Register	7
16. Training	7
17. References & Links	8



1. Introduction and Scope

This policy details the procedures that must be undertaken by all staff and students who are collecting, using or storing human tissue for research purposes in the Keppel Street building, LSHTM. This includes research projects where material is collected outside of the UK and sent or brought to Keppel Street. Further details are provided in the LSHTM SOP on human tissue.

The policy is considered good practice for research where human tissue is collected, used or stored outside of the Keppel Street building.

2. Purpose

The Human Tissue Act 2004 (the HT Act) regulates the removal, storage and use of human tissue, from both the living and deceased, for 'Scheduled Purposes', including research. The Human Tissue Authority (HTA) is the regulatory body responsible for ensuring compliance with the HT Act.

This policy details compliance with both the Act, as well as more generally, on handling and storing all human material at LSHTM.

3. LSHTM Licence

From 1 September 2006, the HTA has been responsible for issuing licences for the storage and use of human tissue, including for research purposes, in accordance with the HT Act.

Organisations holding human tissue described must be licensed if the tissue is stored and used for research purposes. LSHTM has a licence which covers the storage and use of human tissue for research purposes in the Keppel Street building only. No human tissue may be stored outside of the Keppel Street building.

LSHTM's holding of such a licence does not obviate the need for Principal Investigators (PIs) to obtain relevant ethical approval for their work and ensure that human tissue is not retained unnecessarily.

4. Ethical approval for human tissue research projects

All projects using human tissue, regardless if 'Relevant Material' or not, must obtain research ethics approval from the LSHTM ethics committee prior to starting the project. This includes proof-of-concept studies, early phase studies, unfunded research projects, research using healthy volunteer blood samples, research on stored material as well as research on material transferred to Keppel Street. Other ethics approvals may also be required, eg from the NHS or in-country ethics committees.

Researchers must ensure donor consent and records management comply with the requirements set out in this document, with further details provided in the Good Research Practice policy and applicable Standard Operating Procedures (eg LSHTM-SOP-005 on Informed Consent).



5. Designated Individual (DI)

The Designated Individual (DI) is the person under whose supervision the licensed activity is authorised to take place. The DI is responsible for ensuring that:

- suitable practices are used in undertaking the licensed activity;
- the other persons who work under the licence are suitable, and
- the conditions of the licence are complied with.

The DI is currently the Head of Research Governance and Integrity, in the Research Governance and Integrity Office. (RGIO)

6. Person Designated (PD)



disposal or distribution/transferral of material. According to LSHTM guidelines on record management, research data must be retained for 10 years after the end of the study.

The approach to Records Management is designed to enable the traceability of human tissue stored at LSHTM. From 1 February 2021, records for all new human material arriving to Keppel Street must be stored in LORIS (Laboratory Organisational Research Information System). Previously stored material will be added to LORI



17. References & Links

RGIO:

Good Research Practice policy: <https://www.lshtm.ac.uk/research/research-governance-integrity/research-governance>

Human Tissue information: <https://lshtm.sharepoint.com/Research/Research-Governance/#>

Standard Operating Procedures: [https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-\(sops\).aspx](https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx)

Working with human tissue online training: <https://open.lshtm.ac.uk/enrol/index.php?id=13>

LORIS Guidance: <https://lshtm.sharepoint.com/Research/Research-Governance/Human-Tissue/Pages/LORIS.aspx>

Other LSHTM:

LSHTM Records Management Policy: <https://lshtm.sharepoint.com/Services/Information-Management/Pages/records-management-policy.aspx>

Information on Records Management at LSHTM: <https://lshtm.sharepoint.com/Services/Information-Management/Pages/records.aspx>

Other Links:

Human Tissue Authority: <https://www.hta.gov.uk/>

HRA use of human tissue in research: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/>

MRC e-learning: Research and Human Tissue legislation: <http://www.ecmcnetwork.org.uk/events/training/mrc-e-learning-research-and-human-tissue-legislation-online>

MRC Human Tissue legislation summaries: <https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/>