LSHTM Policy for Research with Human Tissue

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Related Policies & Procedures	Good Research Practice policy LSHTM SOP on human tissue	

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. *The licence covers the storage of human material from all ethically approved research activity and staff do not need to apply for separate licences.*

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)

The Person Designated (PD) assists in the governance of the activities authorised by the licence. The DI has identified several Persons Designated to help direct activities under the licence. Activities include: administrating the human tissue tracking system (LORIS), organising regular audits of the tissue stores, and acting as liaison between research staff and PIs and the RGIO.

The PDs are currently the Research Facilitator - Human Tissue, based in the RGIO, as well as the ITD faculty lab managers.

7. LSHTM management arrangements

Compliance with the HTA Licence will be monitored jointly by the Research Governance and ITD Health and Safety Committees. In addition, the DI attends the Ethics Committee to support members in understanding and knowing the legislation to ensure safe review of studies. The ITD Health and Safety Committee has a regular agenda item on human tissue activity at LSHTM.

The DI is responsible for reviewing this policy every two years, to be reviewed and approved by the ITD Health and Safety Committee.

8. Material covered by the Act

'Relevant Material' is material which consists of, or includes, human cells. Relevant material, as defined in the HT Act, require oversight by the RGIO to ensure compliance with the HT Act. All human material must comply with the LSHTM policy, regardless if 'relevant' or not, thus full documentation covering the entire lifecycle of the material, from collection through processing and finally to storage or disposal, must be retained for all human material.

Relevant material includes material such as whole bodily organs and tissues, consisting largely or entirely of whole cells, clearly identifiable and regarded as such and specifically the following:

- whole blood
- urine
- faeces
- conjunctival swabs
- PBMC
- primary human cell cultures
- skin biopsies

Where material is processed specifically to render the material acellular, for example with plasma and serum or blood spots on filter paper where the desiccation process will lyse cellular membranes, the HTA would rely on an assurance that the process in question to render the material acellular had

been carried out appropriately, with documentation available to demonstrate the activities undertaken.

Material that has been fixed to preserve the cellular structure, eg through plastination or use of formalin or other fixative substances, are considered relevant material.

Bodily waste should normally be regarded as relevant material, unless a process has been applied to remove the cells (eg spinning it and retaining only the supernatant).

Material that is not considered relevant material may still be covered by the HT Act under the provisions for ensuring appropriate consent is in place. **Regardless if the material is relevant or not, LSHTM treats all human material the same**, ie LSHTM ethics committee approval is absolutely required for the use of all human material including DNA, RNA, urine, plasma, serum, etc in a research project. All human material must be stored in compliance with the HT Act and must be logged appropriately on the dedicated system (LORIS). All human material transferred to LSHTM Keppel Street must have an accompanying Material Transfer Agreement (MTA) signed by the DI. The sole difference with relevant material and non-relevant material is that the HTA are less likely to interrogate during inspection holdings of non-relevant material.

Researchers should contact the DI or PDs where further clarification is required.

9. Material collected overseas

All human tissue stored at Keppel Street is subject to UK licence arrangements and therefore imported material stored at Keppel Street **must** comply with these policies and procedures. Overseas projects with samples that will not be imported to the UK are encouraged to adopt the approach as far as practicable as part of good research practice.

LSHTM applies a consistent approach to obtaining consent from participants involved in UK and overseas studies; therefore informed consent **must** be obtained from donors involved in overseas studies as part of good research practice.

Material transferred to the UK must include details of the transfer in the informed consent form, and must have an MTA in place signed by the RGIO detailing the transfer prior to material arriving at Keppel Street.

10. Consent

The principle of obtaining appropriate consent from those donating tissue is fundamental to the HT Act. The RGIO have developed Standard Operating Procedures, guidance and templates which detail the consent requirements consistent with the extant legislation.

10.1 General principles

Human tissue which is removed/stored/used for *research* purposes must be supported by appropriate consent from donors (or other appropriate person). This applies to both UK and overseas studies. Consent for diagnostic purposes is not sufficient in itself for tissue to be used for research purposes. All human tissue used in research must have clear informed consent for the tissue to be used specifically for research. Further information can be found on the RGIO SOP on informed consent.

Records must be retained of each donor's (or legal representative's) consent. Written consent ***must*** be obtained where possible and where it is not possible, a detailed explanation of the reasons must be provided and a record of appropriate consent documented. Verbal consent may be used only with approval from the ethics committee.

Consent must also be obtained to retain human tissue samples for unspecified use after the conclusion of the original research project. Researchers are advised to acquire generic and enduring consent, if required, from donors (or another appropriate person) at the outset. Human tissue samples must be disposed at the conclusion of a research project where donor consent is project specific and does not contain generic and enduring consent.

Use of stored human tissue that does not have generic and enduring consent will usually require that the participant be re-consented for the new research project.

Consent exemptions (ie where unlinked anonymised tissue is to be used in a research project) may apply, but only where:

- the tissue will be from living participants, **and**
- the tissue will be anonymous to the researcher, **and**
- the project has approval from an NRES (National Research Ethics Service)/UKECA (United Kingdom Ethics Committee Authority) recognised Ethics Committee, **and**
- the project has approval from the LSHTM Research Ethics Committee, **and**
- the project has been approved by the DI.

Failure to comply with **all** of the above exemptions will mean that the tissue **cannot** be used in research.

PIs must confirm to the DI at the start of each new project via the online LSHTM ethics submission (LEO) that they have read and understood LSHTM's Standard Operating Procedure on Informed Consent and have/will disseminate the information to all project staff responsible for seeking consent and/or taking human tissue samples. PIs must also maintain a list of all authorized staff delegated the responsibility for seeking consent and/or taking human tissue samples.

10.2 Consent training

All PIs and associated staff involved in the informed consent process should undertake relevant training in this area. Further details of LSHTM training for working with human tissue can be found in section 16.

10.3 Consent feedback (essential for UK studies and encouraged for overseas studies)

PIs should provide the contact details of the DI to all relevant project staff so they are able to provide feedback/concerns about the consenting process.

PIs must ensure that donor consent forms include contact details to enable donors to provide feedback/concerns to the DI about the consenting process. (Use email address RGIO@lshtm.ac.uk or agree suitable alternative with the DI, e.g. telephone no).

11. Records Management

PIs must ensure up to date records are maintained in accordance with these policies and procedures. Records must be maintained for so long as material is stored and used (i.e. project duration and post project where relevant). In addition, records must be retained for audit purposes following the

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 LORIS on an ongoing basis. Further information on LORIS can be found in the guidance document available on Sharepoint.

Records must be available for scheduled or unannounced inspection and auditing by the HTA and by the DI. Note that maintaining only hard copies of records would not be considered good practice due to the probability of permanent and irretrievable loss of the record. It is recommended that until all records are added to LORIS, if hard copies are used, an electronic back-up be initiated.

LORIS ensures that relevant details of all samples collected for the project are maintained, such as:

- quantities and types of material
- ethics reference numbers
- template participant consent (or evidence of qualification for consent exemption)
- when and where samples obtained
- procurement
- receipt of human material
- location and type of storage facility
- transportation and delivery
- referencing/coding details
- processing and storage
- use material put to
- distribution/transferral
- date of disposal (where relevant)

There must be a clear coding/labelling system which assigns a unique reference number to each human tissue sample and the products associated with it. The reference number must allow each human tissue sample to be both identified within the context of the specific project and the wider environment of LSHTM's specimen collection. A description of the coding/labelling system must be retained with research records.

Additional information on managing human tissue samples can be found in the relevant Standard Operating Procedure.

12. LSHTM Human Tissue Register

The DI/PD will maintain a register of all human tissue stored at LSHTM (i.e. Keppel Street), which will be updated at least annually until such time that LORIS contains records for all human material held at LSHTM. The register will detail:

- quantities, types and location/storage facility of material stored;
- the PI and the person storing the material;
- confirmation of project approval from LSHTM Ethics Committee (and NRES/UKECA recognised Ethics Committee if required);

Applications to the Ethics Committee must confirm as to whether the project involves the taking of human material. In addition, where samples are to be stored at Keppel Street under LSHTM's HTA licence, the project will require a signature from the DI before it can be submitted for ethical review.

The DI/PD will review the application and maintain relevant details on the RGIO database.

13. Audit

The DI/PD will undertake regular audits of material stored at Keppel Street. In particular the DI/PD will focus on the traceability of samples. A typical audit will review the quantities and types of material stored, the location of the storage facility, who has provided consent and review any available consent forms. The DI/PD will also audit adherence to LSHTM policies and procedures, in particular, consent and management records.

The DI or PD will undertake 1-2 audits per annum depending on the result of the RGIO risk assessment.

Major findings from these reviews will be reported to the ITD Health and Safety Committee and if required due to the seriousness of a finding, the Research Governance Committee.

14. Adverse events

An adverse event concerning the removal, storage and use of human tissue for research purposes is defined as the unexpected or unexplained loss of Relevant Material (as a result, for example, of freezer failure or theft), the unintentional retention of material, or material not supported by appropriate consent.

Any such incident must be reported to the DI as soon as it is detected. The DI will be responsible for investigating the matter and making a report to the ITD Health and Safety Committee and Research Governance Committee and HTA, as appropriate.

15. Risk Register

The DI will maintain a risk register covering the practices and processes concerning the removal, storage and use of human tissue for research purposes, which will be reviewed annually, and circulated to the ITD Health and Safety Committee for their information

Project-specific risk assessments are undertaken by the PI in line with relevant LSHTM policies (e.g. safety policies). Where appropriate, risk assessments should identify risks and mitigating action relating to the removal, storage and use of human tissue.

16. Training

Online training entitled “working with human tissue” is available to all staff and students. This training is mandatory for all PIs, students and associated research and laboratory staff working on human tissue stored under LSHTM’s research licence. This is a condition of ethics approval, with certificates required to be uploaded to the online ethics system for verification. The training module contains sections on the legislation governing human tissue research in the UK, governance, quality systems, SOPs and informed consent.

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

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/