UNIVERSITY OF LEICESTER

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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

This document has been produced in accordance with *The Human Tissue Act (2004)*. It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', *HTA Standards* and the Human Tissue Authority's *(HTA) Codes of Practice*. The Human Tissue Act must be followed by all researchers working under the University's Research Licence and those transferring HTA relevant material as part of an ethically approved research project.

Purpose and Scope

The purpose of this SOP is to set out the procedure for conducting audit of HTA licenced areas within UoL. The main aim of audit is to ensure that all licensed activities related to human tissue, including consent, transportation, storage and disposal are conducted in accordance with the *Human Tissue Act (2004)* and that internal systems for compliance are effectively in place.

To comply with the HT Act it is necessary to ensure that there is a clear and robust audit trail from the collection of human material, through processing, storage, use and distribution, to final use/disposal. All human material acquired by UoL staff and students and any external individuals for storage under the HTA licence must be recorded and its use, distribution and disposal accounted for. These audits therefore aim to support researchers to identify any gaps in compliance and enable solutions to be implemented to meet regulatory standards.

Definitions:

CAPA	Corrective Actions, Preventative Actions
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
HTGC	Human Tissue Governance Committee
PD	Persons Designated
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

The HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation or changes to the HTA Codes of Practice for Research. In addition, consent audits will be undertaken by the HTA Monitoring Officer.

It's the responsibility of the Persons Designated (PD) to assist the DI in implementing and adhering to the governance processes. The PDs will be involved in interdepartmental sample audits to ensure each sample has a valid consent form.

All researchers involved in research should ensure that all samples are collected with the appropriate consent and that the consent forms are retained as per University requirements. Full traceability for each sample is also required to be maintained for audit purposes.

Procedure to follow

To ensure compliance with the HTA standards it is a requirement that there be a documented schedule of audits to be undertaken. An audit schedule will be drafted on an annual basis to include consent audits, sample audits, traceability audits and to ensure the Premises, Facilities and Equipment comply with the HTA standards.

Audit plan

The HTA Licensing Standards state that there must be a documented schedule of audits covering licensable activities. Audit should examine compliance against the four HTA standards:

- Consent
- Governance and Quality
- Traceability
- Premises, Facilities and Equipment

All collections of relevant material stored under the HTA research licence must be audited regularly.

A schedule of audits will be defined by the REGI Office distributed to all PDs. This will define the minimum number and type of audit that must be completed by each

laboratory. The laboratory can perform more audits in addition to those scheduled if this thought to be beneficial. Dates for audits may be subject to change, and may be updated throughout the year based on any staff changes, resource or change in processes.

A defined set of audits must be performed by each PD/ Dept/laboratory storing material (i.e. self-inspection).

HTA Research licence audits:

- *Consent audit (Forward)- SOP HTA-A1019 Appendix 1*
- *Consent audit (Reverse)- SOP HTA-A1019 Appendix 2*
- *Traceability audit (Forward)- SOP HTA-A1019 Appendix 3*
- *Traceability audit (Reverse)- SOP HTA-A1019 Appendix 4*
- *Use/Disposal audit- SOP HTA-A1019 Appendix 5*
- *Training audit- SOP HTA-A1019 Appendix 6*
- *Document control audit- SOP HTA-A1019 Appendix 7*

Audits can be conducted on a scheduled basis or on a risk assessment basis and triggered where a failure has been reported. These audits can either be targeted at certain aspects of the licensing requirements, or may be a more general audit to ensure that the group is working within the regulations.

Standard audit forms are available from the REGI office and must be used to record findings.

Standard audits (as defined above) can be supplemented with additional audits, if required and appropriate as determined by the laboratory PD. Records of additional audits should be kept in the PD Master File.

Departmental Self-Inspection

Departments must conduct self-inspection audits according to the *(audit schedule - SOP HTA-A1019 Appendix 8)* drawn up by the REGI Office. Self-inspections must be conducted using the standard audit forms and must be stored in the PD Master File.

Any non-conformance must be recorded on the audit form together with corrective actions. Corrective actions must be assigned to an individual and be given a target date for completion.

The PD or appropriate delegate must perform an audit follow up and check corrective action has been completed. When confirmed, the audit can be closed.

The REGI office will periodically check all audit forms for accuracy, completeness and effectiveness of corrective actions.

Internal Audit

The REGI Office or HTA Monitoring Office will perform internal audits on a random basis to monitor performance and improve the audit processes at least annually for each department. However a suitably trained individual may be asked to escort the auditor and help conduct these audits under certain circumstances.

In advance of the audit, the REGI Office will send the auditees e.g. PD, departmental contact, departmental manager and local researchers (not exclusive to these roles) an audit agenda, detailing the proposed structure for the audit. Auditees will be also be provided with a list of documents/information required for the audit.

It is the responsibility of the auditees to book a room that is suitable to conduct the audit, which is free from distractions, and has space to examine documents.

On the day of the audit, the audit will commence with an opening meeting, chaired by the REGI Office to go through the audit agenda for the day, and requirements of staff. There will also be the opportunity to highlight any proposed changes to the agenda (e.g. if any members of staff are off sick/unavailable, or certain aspects have to be rescheduled).

The (*internal audit check-list - SOP HTA-A1019 Appendix 10)* will be used to facilitate the audit. See *SOP HTA-A1019 Appendix 9 for a copy of the HTA Licensing Standards).*

Following completion of the audit, there will be a closing meeting to summarise the audit activities, to recognise good practice and discuss any observations and possible corrective actions.

An internal audit report will be issued within fifteen (15) working days of the audit detailing the inspection observations to the PD, departmental manager and any researchers involved in the audit. Where the report may take longer (e.g. due to further investigations, or follow up audits), this will be communicated with the auditees.

Where-ever possible, references will be provided to the HTA Standards that each observation relates to, and recommendations provided for a course of action.

Audit findings will be categorised as follows:

Critical shortfall	A shortfall which poses a significant risk to human safety and/or dignity or is in breach of the Human Tissue Act 2004 or associated directions Or - A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

Major shortfall	A non-critical shortfall that • Poses a risk to human safety and/or dignity, or • Indicates a failure to carry out satisfactory procedures, or • Indicates a breach of the relevant codes of practice, the Human Tissue Act, and other professional and statutory guidelines, or • Has the potential to become a critical shortfall unless addressed Or - A combination of a number of minor shortfalls, none of which is major in its own right, but which together could constitute a major shortfall and should be explained and reported as such.
Minor shortfall	A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards/good practice.
Other	Where a shortfall has not been identified, but areas for improvement have been identified, leading to the auditor providing advice to the auditee on improvements.

Internal audit reports will not be shown to outside agencies unless required as part of regulatory inspections.

The auditee should respond to any report observations within twenty (20) working days of receiving the audit report, with an action plan for any corrective/preventative actions required, and expected completion dates.

Where complex observations require a more detailed response, or in agreed exceptional circumstances, a longer period (e.g. twenty-five (25) working days) may be assigned, with the agreement of the REGI. In the event of a response not being issued within four (4) weeks, a position statement, detailing the reasons why and the expected time frame for completion should be forwarded to the REGI. Once agreed with the REGI, actions will be added to the Corrective Actions, Preventative Actions (CAPA) table.

On completion of all corrective and preventative actions, the audit will be considered complete.

External Audits

External audit planning and responses to findings (e.g. by the Human Tissue Authority) will be led by the DI and REGI Office.

When an external audit has been announced, a meeting of the Human Tissue Governance Committee (HTGC) will be arranged at the earliest opportunity in order to plan and prepare for the audit.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N