University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1019 UoL

Auditing HTA-Licenced Areas

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', 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 HTA Research Licence and those transferring HTA-relevant material at the end of an NHS REC-approved research project.

2.0 Scope

This SOP sets out the procedure for conducting an 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 HTA Codes of Practice, and that effective internal systems for compliance are in place.

To comply with the HT Act there must be a clear and robust audit trail from the collection of human material, through processing, storage, use and distribution, to final use/disposal. All HTA-relevant material acquired by UoL staff and students and any external individuals for storage under the UoL HTA Research 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	Person Designated
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 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 end-of-study closure consent audits and sample log audits, traceability audits and to ensure the Premises, Facilities and Equipment comply with the HTA standards.

3.1 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 UoL HTA Research Licence must be

audited regularly.

A schedule of audits will be defined by the RGO and 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 is 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)- Appendix 1
- Consent audit (Reverse)- Appendix 2
- Traceability audit (Forward)- Appendix 3
- Traceability audit (Reverse)- Appendix 4
- Use/Disposal audit- Appendix 5
- Training audit- Appendix 6
- Document control audit- 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 RGO 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.

3.2 NHS REC approved studies reaching End-of-Study

For every UoL sponsored NHS REC-approved study that are retaining HTA-relevant material whether they are being held as a collection pending further ethical approval, or the collection is becoming part of an NHS REC-approved RTB, or samples are to be transferred to become a licenced collection that is retained beyond the life of the original study (as per HTA_A1001_UoL), an end-of-study audit will be performed. For smaller studies (up to 100 participants), a 100% consent audit will be undertaken. For larger studies or where there are >100 participants, a consent audit of 100 or 10% of participants, whichever is the greatest, will be undertaken. Where the future research clause is an optional (Yes / No) clause, a full audit would be required to be conducted, to ensure only samples from those participants that agreed to have their samples used in future research would be retained. Similarly, if there are optional sample-related clauses, these would need to be documented as part of the audit to ensure samples are used in compliance with the consent that they were collected with. There will be corroboration with sample logs to ensure that only samples with the appropriate permissions for future research are retained. Where missing consent forms are identified, research teams are given the opportunity to locate a copy of the consent form. Failure to locate a copy requires sample destruction.

Researchers wishing to retain samples from an NHS REC-approved study to transfer to another NHS REC approved study or to an NHS REC approved RTB but lacking future use

clause should seek ethical approval via an amendment before notifying the HRA/REC of the end of the study (see SOP HTA-1003-UoL).

The audit schedule is generated for this at the end of the year ready for submission for Januarys Human Tissue Governance Committee (HTGC) meeting and is based upon studies that are due to close within that year; some will be subject to change due to changes in end-of-study dates.

3.3 University Ethics an Integrity (University Ethics studies)

Where samples are being collected and retained as relevant material for longer than 7 days, the UEIC study requires reporting on the appropriate PD tissue register. Upon completion of the study, an end of study audit will take place to firm up the remaining numbers of samples and to ensure each sample being retained has a corresponding validly completed consent forms.

3.4 PD mini audits

Every quarter each PD will undertake an audit of a study identified by the HTA Monitor. These will be called the PD mini audits (please refer to Appendix 12 for the audit template. The PD pairings is available in appendix 11). These mini audits will be used to identify shortfalls or increased risk and will be used as a tool to help identify where further HTA audits conducted by the HTA monitor may be required.

The mini audits specifically look at a number of yes/no questions and undertake 6 traceability (3 forward / 3 Reverse) audits and 6 consent audits (3 forward / 3 reverse) to identify potential issues with these areas. The studies chosen will either be suggestions from the PDs or referral by the HTA monitor.

3.5 Internal Audit

The RGO or HTA Monitor 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 RGO will send the auditees e.g., PD, departmental contact, departmental manager and local researchers (not exclusive to these roles) a request to access the study site files. Auditees will 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.

The (internal audit check-list Appendix 10) will be used to facilitate this style of audit. Please refer to the HTA website for the most up to date HTA Research Licence 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 linked 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 RGO. 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 RGO. Once agreed with the RGO, 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.

3.6 External Audits

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

When an external audit has been announced, a meeting of the HTGC will be arranged at the earliest opportunity in order to plan and prepare for the audit. This could be in addition to the quarterly meetings within a year.

4.0 Responsibility

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI) and delegated individuals	Chief Investigator / Principal Investigator (CI/PI) and delegated individuals	Aid in facilitating the audits, ensuring all relevant paper work is available on the day of audit, and appropriate facilities for the audits to take place.
HTA Monitor	HTA Monitor	End of study audits / audit schedule (annually) Mini audit study identification Review of PD mini audits Internal Audit scheduling
Person Designated (PDs)	Person Designated (PDs)	PD mini audits
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place in the licenced establishment

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding (Designated Individual) 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative updates • Removal of departmental self-inspection and Internal audit sections. Addition of PD Mini audits and 2 appendices. • Removal of appendix 8 and 9. Addition of appendix 11 and 12.