Human Tissue in Research

HTA-Core-SOP – Internal Audit

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process of internal audit in relation to the collection, use, storage and disposal of human tissue for research.

Internal audits help ensure compliance with the Human Tissue Act 2004 (HT Act) and the licensing standards set out by the Human Tissue Authority (HTA). They provide evidence of compliance and promote good practice in consent, traceability, governance, premises, and disposal, and ensure corrective actions are identified and implemented.

2. Scope

The scope of this SOP covers all research involving human tissue considered relevant material under the HT Act undertaken by staff and students of Swansea University.

As part of Swansea University governance, internal audits of relevant material held under an HTA licence or Research Ethics Committee (REC) approval will be carried out regularly.

- The Human Tissue Compliance Manager (HTCM) will contact Principal Investigators / Cheif Investigators (PI/CI) to arrange regular internal audits for tissue collections and biobanks held under Swansea University's HTA Research Licence.
- Research Governance will contact CI to arrange internal audits for tissue held under Research Ethics Committee (REC) approval.

3. Roles and Responsibilities

The Designated Individual (DI) has the responsibility for ensuring the development and implementation of a documented system of quality management and audit, conducting internal audits in conjunction with the Human Tissue Compliance Manager (HTCM) and for operational oversight of the management of deficiencies in compliance.

The Person(s) Designate (PD) are responsible for assisting the HTCM in conducting internal audits and for managing plans to rectify deficiencies within their scope of responsibility.

All PI/CI and researchers involved in human tissue research, are responsible for engaging in the audit process for studies in which they are involved, including reviewing deficiencies, identifying and implementing corrective and preventative actions and adhering to associated timelines for rectification and quality improvements arising from the audit.

The HTCM, PDs and DI are responsible for monitoring actions arising from internal audits of human tissue in the University.

The HTCM is responsible for ensuring this SOP remains fit for purpose.

4. Procedure

Internal audits of tissue collections will be undertaken to establish the level of compliance with Swansea Univeristy's HTA Core SOPs, HT Act, HTA standards for the research sector and HTA Codes of Practice.

Audits will be conducted using an Internal Audit Form and will involve both a review of all related documentation (e.g. Master site folder) and an on-site laboratory-based review. The internal audit form will use a set of questions that are generated to evaluate compliance against the HTA standards for research:

- Governance and quality systems
- Consent
- Traceability
- Premises, facilities and equipment (PFE).

As research activities will vary depending on the study protocols, only the relevant sections of the audit will be utilised, and any sections deemed irrelevant will be marked as not applicable.

Audits will be scheduled with either the PI/CI, laboratory manager or PD, as appropriate. The HTCM or an assigned PD will perform the audit. PDs may not audit projects or tissue

collections for which they are responsible, but may be required to audit other departmental collections.

The auditor will meet with the nominated representative to discuss the audit and describe the audit activities.

4.1. Audit Schedule

An internal HTA audit will be conducted every 2 years as a minimum for all tissue collections stored under the university's HTA research licence, unless otherwise agreed with the DI or research groups. Audit duration will vary depending on the size and complexity of the tissue collection.

4.2. Traceability Audit

Traceability will be assessed by reviewing sample consent records, sample logs and disposal records, as well as, a physical inspection of stored human tissue samples.

4.2.1. Record to Sample Location Audit

- Three records from a tissue log (e.g. database, spreadsheet, logbook) will be randomly selected. Where more than one database relates to different sample types, samples will be selected from different databases.
- The sample ID, storage location and the tissue type recorded in the sample log, will be noted in the audit report.
- The auditor will then attempt to find the three stored samples based on the recorded locations and will physically examine them to check the information and sample log match.
- The outcome will be recorded on the audit report.

4.2.2. Sample Location to Record Audit

- Three samples will be selected randomly from different storage locations.
- The exact location of the samples, sample ID and sample type will be noted by the auditor on the audit report.
- The information on the sample will be checked against the sample log.
- The outcome will be recorded on the form.

4.3. Audit Reports and Follow-up

Following each audit, the HTCM (or designated auditor) will produce a live Word document audit report. The report will record:

- Any identified shortfalls

- The corresponding risk category (Critical, Major, Minor, or Other – see definitions below)
- The corrective and/or preventative actions required to address each shortfall.

Each required action will be assigned a responsible person and a target completion date, which will be confirmed in agreement with the relevant representative (e.g. CI/PI, PD, or Lab Manager) for the study or collection.

The audit report will serve as a live working document and will be shared with the representative via the appropriate Teams site or secure SharePoint folder. The representative must use tracked changes or comments to record progress, including details of how and when each action has been completed.

If corrective actions are not completed within the agreed timescale or appear to be unreasonably delayed, the HTCM will raise the matter directly with the Designated Individual (DI) and may escalate concerns to the HTA Sub-Committee.

The auditor may request to undertake a follow-up audit of the area to confirm that the corrective actions have been implemented.

If an audit finding is deemed to be an adverse event, appropriate action should be taken in line with HTA-CORE-SOP-Adverse Event Reporting.

Shortfall Categories:

The shortfall category is based on whether there has been a breach of the legislation, codes of practice or HTA directions, and risks to patient safety, tissue or organ integrity, or public confidence.

The audit shortfalls are categorised as follows:

Critical shortfall	A shortfall which poses a significant risk to human safety and / or dignity of the tissue. Actions known and understood to be in breach of the HT Act 2004 or HTA codes of practice or SU policies. Or A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall.
Major shortfall	• A non-critical shortfall that poses a risk to human safety and/or the dignity of tissue. • Evidence of unintentional breach of the relevant codes of practice, the Human Tissue Act, and other professional and statutory guidelines. • 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.
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.

4.4 Audit Closure

Once all actions have been completed and the HTCM is satisfied that sufficient evidence has been provided, the audit report will be finalised and saved as a closed version. A PDF copy will be issued to the representative for retention in the study's Master Site File.

It will be considered closed and will be archived for inspection by regulatory authorities including the HTA and the MHRA.

4.5 Self-Inspection

In addition to organizational internal audit inspections, it is recommended that research groups conduct regular self-inspections to identify deficiencies in compliance with HTA standards and other regulatory requirements.

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21.09.15	Updates front page and footers, removal of appendix to standalone audit tool	1.0	Lisa Wakeman
3.0	01.09.16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Addition to definitions	2.0	Lisa Wakeman
4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards Updated sector standards information	3.0	Lisa Wakeman
4.1	10/11/23	Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward.	4.0	Bethan R Thomas & DI
6.0	13/01/2026	Reformatting text and clarifying the CAPA process with a live audit report document for tracking and evidencing corrective actions. Updated HTGO tile to HTCM.	5.0	Bethan R Thomas & DI

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