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.

As part of Swansea University governance internal audits of all human tissue whether considered relevant material or not, held under an HTA licence or Research Ethics Committee (REC) approval, will be carried out regularly.

The Human Tissue Governance Officer (HTGO) 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 PI/CI to arrange internal audits for tissue held under Research Ethics Committee (REC) approval.

2. Scope

The scope of this SOP covers all research involving human tissue undertaken by staff and students of Swansea University.

The objectives of the internal audit are to:

- Ensure that those involved in using human tissue are appropriately trained.
- Ensure appropriate consent has been established for human tissue used in research activities.
- Ensure that Core and local SOPs are followed during the handling and processing of tissue.
- Ensure that sample tracking at all stages of human tissue handling, from collection to disposal, are documented and an accurate trail can be provided an for each sample of tissue.
- Ensure that mechanisms are in place to protect the integrity and safety of the tissue during processing, storage and transportation.
- Ensure that processes are in place to manage adverse events involving human tissue and that these are in line with the core SOP.
- Suggest actions for improved compliance and agree on timescales for completion.

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 HTA Governance Officer and for operational oversight of the management of deficiencies in compliance.

The Person(s) Designate (PD) are responsible for assisting the HTGO 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 audit.

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

The HTGO 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.

On-site audits will be conducted using an Internal Audit Form and will involve both a desk-based review of all related documentation (e.g. Master site file) and a 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, laboratory manager or PD, as appropriate. The HTGO 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.

On the day of the audit, the auditor will meet with the nominated representative to discuss the audit and describe the audit activities. If an audit has previously been carried out, the findings and progress of identified actions will be reviewed.

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 Section 3, Part 1 of the HTA-FORM-Internal Audit.
- 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 form.

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 HTA-FORM-Internal Audit, Section 3, Part 2.
- 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

The HTGO will liaise with the DI and relevant PDs to produce a draft report of the audit activity. If the audit identifies that a standard is not being met, this will be reported as either a 'Critical', 'Major' or 'Minor' shortfall.

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
- 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.

Where the audit highlights areas of non-compliance or possible improvement, the HTGO, in liaison with the DI where required, will determine how the identified shortfalls will be addressed.

The HTGO (or alternative auditor) and a representative of the study/collection under audit will agree on each action and timescale for completion/implementation.

The representative of the study/collection under audit must then submit a Corrective and Preventative Action (CAPA) plan and review their study/collection Risk Assessment for the completion of corrective actions.

The HTA Governance Officer will liaise by email or meet with a representative of the study or department under audit to ensure that the report is accurate and to ensure the submitted CAPA is appropriate.

As each action is completed, the completion date and person completing the action should be documented and the information should be available to the auditor. 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.

4.4 Audit Closure

On completion of all actions arising from the audit, it will be considered closed and will be archived by the HTGO 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.

5. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

6. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

7. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/2015	Updates front page and footers, removal of appendix to standalone audit tool	1.0	Lisa Wakeman
3.0	01/09/2016	Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Addition to definitions	2.0	Lisa Wakeman
4.0	18/04/2018	Amendments to reflect revised HTA Codes of Practice and Standards Updated sector standards information	3.0	Lisa Wakeman
5.0	10/11/2023	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

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