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Human Samples in Research

Internal Audit

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Document History

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2.0	21.09.15	Updates front page and footers, removal of appendix to standalone audit tool	1.0	Lisa Wakeman
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4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards Updated sector standards information	3.0	Lisa Wakeman

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 required by the Human Tissue Authority (HTA) standards for the Research Sector. The vision for Swansea University and Abertawe Bro Morgannwg University Health Board (ABM UHB) is that all human samples, whether considered relevant material or not, held under a HTA licence or Research Ethics Committee (REC) approval be governed to the standards set out by the HTA for licensed establishments. To achieve this, scheduled internal audits of research projects and facilities where human material is collected, handled, processed, stored and disposed of will be performed.

The objectives of the internal audit are to:

- Identify where human tissue activities are in breach of the Human Tissue Act 2004 (HT Act).
- Establish whether relevant material is being held and where it is handled and stored.
- Establish whether tissue is being held under a HTA licence or recognized REC approval.
- Ensure that local processes are in place to track all stages of human tissue handling; from collection to disposal and that these processes and associated tracking information are documented and provide an audit trail for each sample of tissue.
- Ensure that SOPs are followed during the handling and processing of tissue.
- Ensure that mechanisms are in place to protect the integrity and safety of the tissue during processing, storage and transportation.
- Ensure that those involved in using human tissue are appropriately trained.
- Ensure that local processes are in place to manage adverse events involving human tissue and that these are in line with the joint core SOP.
- Suggest actions for improved compliance and agree timescales for completion.

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

On occasions, the HTA publishes standalone inspection report summaries and guidance documents. Where these indicate a change of practice or a potential deficiency in the joint HTA quality management system, this SOP will be revised to incorporate changes in best practice.

As this SOP is reviewed the specific audit questions in each of the four sections of the main audit tool (*HTA-07-FORM-Internal Audit 1*) will be revised to ensure that all elements of the HTA standards are audited over time.

2. Background

The HTA standards for the Research Sector provide a governance framework for the regulation of human tissue as set out in the HT Act. Audit trails must be maintained of details of when and where relevant material was acquired, consent obtained, uses to which the material was put, when the material was transferred and to whom and details of disposal. These activities and records form the basis of the internal audit process.

The standards require that, for tissue collections held under a HTA licence, there be in place a schedule of audits covering all aspects of the Research Sector HTA standards including regular audit of record content to check for completeness, legibility and accuracy.

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 conducting internal audits in conjunction with HTA Governance Officer and for managing plans to rectify deficiencies within their scope of responsibility.

All researchers 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 HTA Governance Officer, PDs and DI are responsible for monitoring actions arising from internal audits of human tissue in the University and Health Board.

The HTA Governance Officer is responsible for ensuring this SOP remains fit for purpose.

4. Procedure

4.1 On-site Audits

Internal audits of Departments, Colleges, Schools and specific tissue collections will be undertaken to establish the level of compliance with the joint core HTA SOPs, HT Act, HTA standards for the research sector and HTA Codes of Practice. Where an area undertakes only part of the activities covered by HTA regulation, the relevant sections of the audit will be omitted and marked as not applicable. The intention is to use simple audit tools flexibly to minimize complexity. On-site audits using *HTA-07-FORM-Internal Audit 1* will assess compliance against a set list questions generated from the HTA standards for the research sector (section 2) and an evaluation of sample traceability (section 3). One or both of these elements may be used for the on-site audit.

Audits will be scheduled with either the PI, laboratory manager, PD or departmental R&D lead as appropriate. The HTA Governance Officer and wherever possible the DI or a PD from another area will perform the audit. PDs may not audit projects or tissue collections for which they have HTA compliance responsibility but will be required to audit other departmental collections.

The audit will involve a desk based review of documentation and a laboratory based review of the premises, facilities and equipment, examining compliance against the four HTA standards:

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

4.11 Audit Schedule

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

4.1.2 On-site HTA Standards Audit

On-site audits against the HTA standards for the research sector (*HTA-07-FORM-Internal Audit 1* (Section 2)) will be undertaken for the following:

- Tissue collections stored under the Swansea University / ABM UHB HTA licence

- Individual storage facilities
- Biobanks

4.1.3 On-site Traceability Audit

Traceability audits (*HTA-07-FORM-Internal Audit 1* (Section 3)) will generally be undertaken alongside the HTA standards audit where appropriate.

On the day of the audit, the auditor will meet with the PD or 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.

The audit will then take place to examine compliance against the four categories of the HTA standards for the research sector to reflect the manner in which the HTA will inspect a licensed establishment i.e.:

1. Consent
2. Governance and Quality
3. Traceability
4. Premises, Facilities and Equipment

4.1.3.1 Record to Sample Location Audit

- Three records from a tissue register (e.g. database, spreadsheet, log book) will be randomly selected. Where more than one database relates to different sample types, samples will be selected from different databases.

- *HTA-07-FORM-Internal Audit 1* (Section 3, Part 1) will be used to record the collection name, sample ID, tissue type.

- The sample label will be physically examined to check that the sample information and record match.

- The outcome will be recorded on the form.

4.1.3.2 Sample to Record Audit

- Three samples will be selected randomly, from different storage units if appropriate.

- The exact location of the samples and the sample ID will be recorded on *HTA-07-FORM-Internal Audit 1* (Section 3, Part 2).

- The information on the sample will be checked against the database/spreadsheet/log book.

- The outcome will be recorded on the form.

4.2 Audit Reports and Follow-up

- The HTA Governance Officer will liaise with the DI and relevant PDs to produce a draft report of the audit activity the core Internal Audit tools. 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.
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, 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.
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 HTA Governance Officer, in liaison with the DI where required, will suggest and collate recommendations for changes of practice and/or additional documentation requirements. The HTA Governance Officer (or alternative auditor) and a representative of study/department under audit will agree each action and timescales for completion / implementation. 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 assign timescales for the identified actions in the form of an action plan.

- The HTA Governance Officer, PD and DI will liaise as necessary with the representative of the audited area to monitor the action plan timescales.

- As each action is completed, the action taken, completion date and person completing the action should be documented and the information 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-11-SOP-Adverse Event Reporting*.

4.3 Audit Closure

On completion of all actions arising from the audit, it will be considered closed and will be archived by the HTA Governance Officer for inspection by regulatory authorities including the HTA and the MHRA.

4.4 Self-Inspection

In addition to organizational internal audit inspections by the HTA Governance Officer, DI or other appropriate individual, it is recommended that research groups and support departments conduct regular self-inspection to identify deficiencies in compliance with HTA standards and other regulatory requirements.

5. References

HTA Code of Practice E: Research; Code of Practice and Standards

https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

HTA Summary of Inspections 2006-2008 Research – Department of Health
http://www.hta.gov.uk/_db/_documents/HTA-inspection-research-v3.pdf

6. Risk Assessment

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

7. Definitions

Chief Investigator (CI) – The individual who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the Chief Investigator takes responsibility for the

design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

Designated Individual (DI) – The person who is authorised and who supervises activities under a licence issued by the Human Tissue Authority.

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Authority (HTA) – The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions.

Internal Audit - an independent, objective assurance activity designed to add value and improve organisational operations by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

Person Designate (PD) – A person to whom the licence applies and to whom the authority conferred by the licence extends. Each School operating under an HTA Licence should have at least one Person Designate.

Principal Investigator (PI) – is the appropriately qualified individual at each project site who has responsibility for the conduct of the project at that site.

Standard Operating Procedure (SOP) – Detailed, written instructions to achieve uniformity of performance of a specific function.