Bournemouth University

Medical Sciences Department

Human Tissue Facility

SOP title:	Internal audit of human tissue authority licensed premises, facilities and equipment
SOP Reference:	BU-HTF-PRO-003
Version number: 0.1	Date: June 2019
Effective from:	Review date:

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Amendment log

Version:	Date	Amendment(s):

Abbreviations:

SOP: Standard operating Procedure

HTA: Human Tissue Authority

CoP: Code of Practice

CI: Chief Investigator

MTA: Material Transfer Agreement

CAPA: Corrective Actions/Preventative Actions

ID: Individual Designated

PD: Person Designated

QAM: Quality Assurance Manager

Purpose: The purpose of this SOP is to describe the procedure for the internal auditing of premises licensed by the Human Tissue Authority at BU. An auditing process is required in order to ensure that the premises, facilities and equipment used for work in relation to human tissue are fit for purpose and comply with the required licensing standards.

Scope: This SOP is intended for BU researchers or students whose activities involve collecting, storing using and disposing of human tissue or primary human cells.

1. **Introduction:**

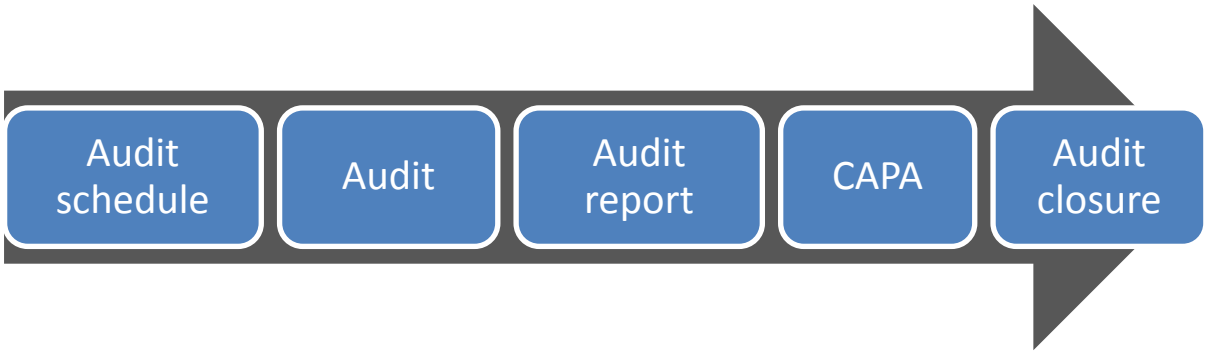
The Human Tissue Act (20014) provides the legal framework for the regulation of activities involving the removal, storage, use and disposal of human tissue [(1)] The HTA licenses premises to undertake such activities and sets out standards that establishments are expected to meet to ensure compliance with the Human Tissue Act. One of the conditions for licensing is the presence of a documented system of audit covering licensable activities, and including how findings will be addressed, who is responsible for follow up actions and the time frames to complete these actions (GQ2) [(2)]

Human tissue repositories should be subjected to regular audits. Audits cover the implementation of all SOPs that govern the repository. Audits may be done periodically, or in response to a non-compliance incident, accident or deviation in procedure. The auditor should be an individual familiar with the specific work being reviewed but not directly involved with that work, and shall be clearly defined in the facility's organisation chart [(3)]

If the audit findings cast doubt on any aspect of the facility's operations, timely corrective actions should be taken. Records shall be maintained of the areas audited, audit findings and any corrective actions arising from them. The facility shall assess and record the effectiveness of any corrective actions implemented [(4)]

2. **Procedure**:

The format of the internal audits is set out as follows:



2.1 **Audit schedule**

The PD will liaise with the human tissue governance team to determine the schedule for the audits, including date, time and venue. Any additional personal that may need to be present will also be identified. A mutually convenient day will be arranged with the team/area to be audited, who will be advised and sent a copy of the auditing template.

Frequency

TBC

Locations subject to inspection

TBC

2.2 Audit process

The objective of the audit process is to determine whether operations related to research using human tissue comply with the required standards. It will therefore require inspection of the following (though not necessarily at the same time):

- Local documentations, procedures and risk assessments
- Security and access controls system
- Environmental controls and health and safety
- Storage facilities (including monitoring ad tracking systems)
- Transportation arrangements
- Disposal arrangements
- Equipment maintenance and training
- Data storage systems (paper and electronic)

2.3 Audit report and findings

Following an audit, the auditing team will prepare a report within XXX weeks of completing the audit. A template for the audit report can be found XXXX

The audit report will include:

- A list of the issues identified
- A list of corrective actions to be taken to address the issues identified and a time scale for completion.
- In the event of serious findings, the above steps will be implemented followed by a date to conduct a follow-up audit.

- In the event that corrective action(s) is/are not completed in time for the re-audit, the license holder will be notified and all human tissue act –related activities may be suspended until all actions are completed.

2.4 **CAPA**

The auditee should respond to any report findings within XXX days of receiving the report, with an action plan for any CAPA required, identifying the individual or group responsible for completing the actions and expected completion dates. In exceptional circumstances, the auditee may agree a longer period together with the auditor/QAM and/or the DI.

The auditor/QAM will keep a log of all audit findings and CAPA, with milestones for completion. Where complex observations require a more detailed response, each completed action should be documented, along with completion date and individual completing the action, and the information provided to the auditor. The auditor may also conduct a further audit of the facility to confirm the CAPA has been implemented.

2.5 Audit closure

Once all recommendations have been addressed and the auditing team are satisfied that compliance has been achieved, the team/area audited will be issued with a letter confirming that the audit has been closed out.

3 References

(1) Human Tissue Act 2004: http://www.legislation.gov.uk/ukpga/2004/30/contents

(2) Human Tissue Authority code of practice and standards. Code E - Research: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

(3) International Society for Biological and Environmental Repositories (ISBER). 2012. Best practices for repositories: Collection, storage, retrieval, and distribution of biological material for research. Biopreservation and biobanking. Vol 10; No 2.

(4) National Cancer Research Institute (NCRI)/Confederation of Cancer Biobanks: Biobank Quality Standard, collecting, storing and providing human biological material and data for research, version 1, 2014.

Audit templates for HTA licensed premises:

PREMISES			
	Yes	No	Comments
Are the premises and equipment secure?			
Are the areas covered by the HTL clearly flagged?			
Is access to these areas controlled or restricted?			
Are freezers appropriately labelled to ensure the safety of users?			
Have all staff been instructed on how to report a problem?			
Are working areas for staff, students and visitors safe?			
Are there procedures in place for the cleaning and decontamination of areas and equipment?			
Is suitable protective equipment available for staff and students?			
Are temperature records maintained and auditable?			
Are call out rotas available?			
Are alarms being tested			

regularly?			
Are staff trained and aware of the contingency plans and procedures?			
Are checks and filling of nitrogen Dewars documented?			
Are the facilities compliant with institutional policies such as health and safety?			
EQUIPMENT			
Are maintenance records and service contracts for equipment available?			
Can quality assurance or calibration of equipment be demonstrated?			
Are instructions and training provided for the use of equipment? Is training documented?			

GOVERNANCE AND QUALITY SYSTEMS			
Are all procedures and policies up to date and ratified? Do they cover all licensable activities?			

Has the need for a new SOP or procedure been identified?			
Are staff up to date with training requirements (including visiting staff)?			
Document control system in place?			
Is there an auditable system in place to record risk assessments?			
Is there an auditable system in place to record adverse events?			
Are all documents secure and backed up?			
Is the governance committee holding regular meetings?			
Are document control and review methods in place for SOPs and risk assessments?			

HUMAN TISSUE AUTHORITY MASTER FILE			
Is the master file available for auditing?			
Local structure complete and up to date?			
Copy of HTA license?			

Copy of PD role acceptance document?			
Local staff CVs, job descriptions and training certificates?			
List of local tissue collections?			
Up to date list of HTA quality documents?			
Evidence of staff's familiarity with SOPs and guidance documents?			
List of facilities and equipment up to date?			
List of external MTAs/SLAs and courier records?			
HTL committee meetings minutes available?			
Adverse events records available?			
List of internal audits and outcomes available?			

CONSENT			
Do researchers consent participants themselves?			
If yes, is there evidence of staff training and competency for			

taking consent?			
If not, is there an agreement for consent by a third party (for example MTA)?			
Are signed consent forms present?			
Is the consent procedure documented?			
Is there a procedure for managing withdrawal of consent?			

Is the local documentation in order and up to date?			
Are the areas covered by the HTL secure and access is still restricted?			
Are environmental controls in place and suitable to ensure the health and safety of staff, students and visitors?			
Are the storage facilities in order and fit for purpose?			
Are transportation records and			

service level agreements available and in order?			
Are the local procedures for disposal clear and adhered to by staff?			
Are equipment maintenance records, instructions and training in order and up to date?			
Is electronic data held in a secure, restricted access location?			

Considering the above findings, Are these shortfalls considered:

CRITICAL

A critical shortfall is one which poses a significant risk to human safety and/or dignity, or a significant breach of the HT act.

Also, where there is a combination of several major shortfalls, when none of them is critical on its own.

MAJOR

A shortfall that poses a risk to human safety and/or dignity

A breach of the HTA codes of Practice, the HT act, or other guidelines

Has the potential to become a critical shortfall

Where the local SOPs have not been closely adhered to

Where there is a combination of minor shortfalls, even when none of them is major on its own

MINOR

A shortfall which indicates a departure from expected standards and can be easily corrected.