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Human Tissue Act
SOP - Audit

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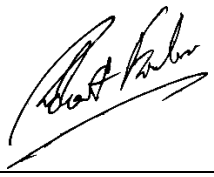
Reviewed: Dr Georgios Giamas **Designation:** Designated Individual School of Life Sciences **Reviewed:** Dr Robert Fowler **Designation:** Persons Designate School of Life Sciences	**Signature**  	**Date** 11/09/2017 11/09/2017
Authorised By: UoS HTA Coordination Group	Authorisation not sought due to minimal changes	

Version	Date	Reason for Change
2.0	30/01/2013	Minor text change required by HTA. Change to reflect increase in audit frequency as requested by HTA
3.0	28/07/2014	To reflect merger of BSMS and SoLS practices for UoS
4.0	04/08/2017	Update to reflect changes to DI

1.0 Purpose

This standard operating procedure outlines the general criteria for annual internal auditing.

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2.0 Introduction

All processes associated with the HTA collections require regular internal auditing in order to evaluate the validity and reliability of the current systems. The focus of the internal audit is to ensure that all activities related to human tissue, including consent, transportation, storage and disposal are conducted in accordance with the HTA Codes of Practice and that internal systems for compliance are effectively in place.

External Audit

- The School of Life Sciences will comply with any external audits required by funding bodies, regulatory bodies and/or host organisations.
- If external agencies are involved, a confidentiality agreement will be required, signed by all participating auditors and Sussex University, on behalf of School of Life Sciences.
- No patient or sample related paperwork will be removed from School files
- Audit reports should remain commercially in confidence

Internal Annual Audit

The School of Life Sciences and BSMS will implement internal audits on a quarterly basis to ensure adherence to protocols, completeness of data etc. At least two people from the HTA Committee will visit each collecting site at a pre-arranged time.

The objectives of internal audit are to:

- determine whether or not the tissue is covered by the license;
- ensure the premises and equipment used for the storage of human tissue is compliant with HTA guidance and requirements;
- ensure that essential documentation relating to all aspects of the human tissue are held by the department/unit;
- ensure that SOPs are being followed during the handling/processing of tissue;
- ensure that an audit trail is in place from receipt of sample to disposal;
- ensure that the health and safety of staff are protected;
- identify any problems and suggest solutions;
- ensure that those involved are fully trained and experienced and that staff have received the appropriate level of training

Procedure

Each audit visit will comprise of a face to face review. This will over the annual cycle comprise checking records to ensure they are accurate, complete and legible; a process review to ensure staff are adhering to SOPs; and a traceability audit to ensure that the establishment can trace specimens from donors consent, or point of receipt if supplied by a third party, to storage, use or disposal.

Details of the procedure to be followed during internal audit may differ for each audit visit and may depend on project type, however, an indication of elements likely to be covered are listed below:

- review local file of documentation as set out in the HTA Audit Checklist (see below), to establish what is held and where there are gaps that could be filled;
- discuss adverse event reporting system and any adverse events that have occurred, including remedial action taken;
- inspect storage facilities;
- ask a member of staff to demonstrate how the tissue is handled/processed, ensuring that all relevant SOPs are followed;
- conduct a trial of traceability system/record keeping to ensure that tissue samples can be traced from receipt to disposal and vice versa

    - Horizontal audit: Information for each of the numbers regarding type and number of samples, location, diagnosis etc will be supplied to check the presence and completeness of data and samples.
    - Vertical audit: sample location will be checked against records and records checked against location.

- A sample of paper pathology reports will be compared to the electronic record to ensure accuracy
- A number of H & E slides and their associated paraffin blocks will be examined to check labels have not been transposed
- discuss training needs;
- interview the PI if necessary to establish:
    - whether staff involved in human tissue activities have the appropriate experience and training and whether they are familiar with HT Act and HTA Codes of Practice;
    - if informed consent procedures are followed and records held;
    - the record management and retention process;
    - whether risk assessments have been carried out;
    - if there are any issues/ queries that they would like guidance on.
- have a final meeting to discuss findings of audit.

An audit report will be drafted within one week of audit date with action points and completion target dates. This report will feed into the School HTA committee which will be held within one month of the audit visit as well as the next tabled School Management committee. The report will then be made available to all staff.
Completion of action points will be followed up and signed off by the DI. In the event of an unsatisfactory audit, the audit will be repeated 3 months later.

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Audit of Documentation
General
• Standard Operating Procedures (SOPs) relating to licensed activities Note: including control system to ensure that latest versions are being used.
• Disposal records
• Complaints log
• Sample consent forms and evidence of consent if samples are collected by a third party
• Risk assessments of premises and activities Note: in addition to risks to individuals, an assessment of risk to the tissue samples should be conducted e.g. in relation to storage and transport of sample.
• Service Level Agreements (SLAs) relating to transport and third parties, (these will be checked against actual samples imported/exported)
• Agreements with third parties Note: evidence of ethics approval if applicable
Equipment
• Equipment Logs
• Maintenance records / contracts for equipment
• Evidence of Equipment Validation and Calibration
• Adverse events / incidents log(s)
• Evidence of corrective and preventative actions (CAPAs) for incidents and quality non-compliances
Training Records
• Induction programme for new staff [including register/record of attendance]
• Training records for staff, including mandatory training and CPD