The Sheffield Biorepository

Standard Operating Procedure: Audit

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The University Of Sheffield.

1. Background

This document has been produced in accordance with The Human Tissue Act (2004). It should be read in conjunction with the Biorepository SOPs, HTA Standards and the Human Tissue Authority's (HTA) Codes of Practice. The Human Tissue Act must be followed by all researchers working under the University's Research Licence and those transferring HTA relevant material as part of an ethically approved research project.

The purpose of this Standard Operating Procedure is to set out the procedure for conducting audits of the HTA licenced facility. The main aim of an audit is to ensure that all licensed activities related to human tissue, including consent, transportation, storage and disposal are conducted in accordance with the Human Tissue Act (2004) and that internal systems for compliance are effectively in place.

To comply with the HT Act it is necessary to ensure that there is a clear and robust audit trail from the collection of human material, through processing, storage, use and distribution, to final use/disposal. All human material acquired by University staff and students and any external individuals for storage under an HTA licence must be recorded and its use, distribution and disposal accounted for. These audits therefore aim to provide reassurance to the Designated Individual, Faculty Executive Board and support researchers to identify any gaps in compliance and enable solutions to be implemented to meet regulatory standards.

2. Audit Plan

The HTA Licensing Standards state that there must be a documented schedule of audits covering licensable activities. Audit should examine compliance against the four HTA standards:

Consent
Governance & Quality
Traceability
Premises, Facilities and Equipment

All collections of relevant material stored under the HTA research licence must be audited regularly in line with the approved audit schedule and reports will be tabled at the HTA committee.

Audits can be conducted on a scheduled basis or on a risk assessment basis and triggered where a failure has been reported. These audits can be either be targeted at certain aspects of the licencing requirements, or may be a more general audit to ensure that the group is working within the regulations.

Standard audit forms are available and must be used to record findings.

Records of all Audits will be kept on file.

Any non-compliance must be recorded on the audit form and any corrective actions. Corrective actions must be assigned to an individual and be given a target date for completion. Completion of any actions must be reported to the HTA committee or signed off by the DI.

3. Associated Documents

	Document	Document Reference
1	STH Researcher Informed Consent Policy	A106
2	Audit Checklist: Consent	FORM 007
3	Audit Checklist: REC	FORM 006
4	Audit Checklist: Biorepository	FORM 005
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