Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Human Tissue Audits

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Date effective	01 June 2016	**Authors**	Nana Theodorou
Related SOPs	*The Use of Human Tissue in Research (C120)*		
Approved by (name & role)	Dipak Patel Research Manager	**Date:** 25 May 2016	**Signature:**

Standard Operating Procedure: Research Department

Human Tissue Audits

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the Human Tissue Authority (HTA). It outlines the procedures to be followed when Research Department staff audit human tissue studies.

Background

Sheffield Teaching Hospitals NHS Foundation Trust (STH) currently holds a HTA licence for the storage of relevant material for research purposes. Investigators using human tissue for research must adhere to the HTA Codes of Practice, and any updates released. Part of the Act and the Licence is that human tissue audits are performed regularly.

The Codes of Practice provide practical advice to researchers pertaining to legislation and the carrying out of activities which fall under the remit of the Human Tissue Act 2004. There are nine Codes of Practice which are used across all of the Sectors including the Research Sector.

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1. Acronyms

CF	**Consent Form**
CI	**Chief Investigator**
CRF	**Clinical Research Facility**
DI	**Designated Individual**
HTA	**Human Tissue Authority**
PIS	**Participant Information Sheet**
REC	**Research Ethics Committee**
RTB	**Research Tissue Bank**
SOP	**Standard Operating Procedure**
STH	**Sheffield Teaching Hospitals NHS Foundation Trust**

2. Audit overview

In order to comply with the conditions of the HTA Licence, STH Research Department staff conduct human tissue audits on behalf of the Designated Individual (DI). Where possible, Research Tissue Banks (RTBs) are audited at least once every two years and tissue only studies are audited on request or if issues come to light during the running of the study.

2.1 Audit standards

STH has set out a human tissue audit to mirror HTA inspections in terms of the standards to be reviewed, see Table 1.

During the audit, the following HTA standards will be reviewed for compliance:

- Consent
- Governance and Quality Systems
- Premises, Facilities and Equipment
- Tissue Disposal Arrangements

Table 1. Audit visit overview

Standards reviewed	**Audit trail of paperwork**
Consent	How consent is obtained, from whom consent is obtained and who obtains it How consent is recorded Appropriateness of paperwork for obtaining consent Withdrawal of consent Training in consent procedures
Governance & Quality	Policies & procedures in place Governance procedures Systems of quality management & audit Records management (paper, electronic records and security measurements for storing confidential information on tissue donors etc.) Systems for recording adverse events
Premises, facilities and equipment	Review of the premises for sample storage to ensure fit for purpose and maintained in an environment that preserves the integrity of the samples. Contingency plans Condition and maintenance records of equipment Security of premises
Tissue Disposal Arrangements	Policies for disposal of tissue

3. Audit procedure

The audit involves:

- Review of all study related documents and consent forms
- Review of delegation log and staff training records
- Review of the premises and equipment used for the storage of human tissue

- Audit trail for up to 5 randomly-selected tissue samples, including an assessment of records of the trail; more samples may be tracked if the need arises. The trail starts from tissue sample consent to sample storage and vice versa.

3.1 Audit initiation

The HTA Lead will coordinate the audits. An initial email is sent to the Chief Investigator for the selected RTB or tissue study informing them of the intention to audit against the HTA standards. The current STH sponsored RTB list is available from the HTA Lead.

Once the audit date is confirmed, a standard email is sent to the CI and study team with the following documents attached:

- STH Human Tissue Audit visit confirmation letter addressed to the CI
- Copy of the HTA standards
- STH Human Tissue Audit version control document

The Biorepository manager and technician will also be copied into the email if the RTB or tissue study store tissue in the Biorepository. The study team should review, complete and return the Version Control sheet before the audit visit.

Suitable accommodation should be identified and booked by the study team to include space for two auditors to review all documents with photocopying facilities and space for relevant staff to attend a summary meeting. The audit will normally take place in the department where the CI is based.

3.2 Audit conduct

Two Research Department staff will perform the audit including the HTA Lead. The following study team members (as applicable) should be available to answer questions and to attend the summary meeting during the Audit:

- CI or delegated study team member
- Biorepository staff
- CRF staff
- Directorate Research coordinators

The audit will usually last between 4-6 hours. A list of questions has been created and can be used to guide the start of the audit. The auditors base their review on the STH Human Tissue Audit report template.

4. Audit report and findings

When the auditors are satisfied that all documentation and premises have been scrutinised and the audit template has been completed, the audit report should be written as soon as possible after the audit; one of the audit team will write the report for review by the second auditor.

A copy of the draft Audit report should be sent to the CI copying in relevant study team members, usually within a fortnight from the audit date. The CI will be given two weeks to review the draft report and complete the proposed actions column next to the listed shortfalls. Once the draft report is returned to the Auditors by email, a copy

of the final report will be emailed to the CI in a timely manner with a deadline to complete the actions by, usually within 4-6 weeks.

Copies of the Human Tissue Audit visit confirmation letter, Human Tissue Audit Version Control document and STH Human Tissue Audit draft and final reports must be saved on the Research network drive or Alfresco under the specific STH reference number.

If the recommendations made by the audit report have not been implemented by the set date, a reminder will be sent to the CI and if no reply is received within a week, the DI and Research Manager will be notified in writing. The DI will then contact the CI for a progress update and request to complete all outstanding actions.

5. Audit outcome

A summary of the RTB audit findings will be presented at the next scheduled HTA Committee meeting using the STH Human Tissue Audit summary template.

Appendix 1. Associated Documents

	Document	Research Department Network Location	Website	Alfresco	Created by
1	STH Human Tissue Audit email	HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit email.docx	No	Yes	NT
2	STH Human Tissue Audit visit confirmation letter	..\HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit version control document.docx	No	Yes	NT
3	STH Human Tissue Audit version control document	..\HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit version control document.docx	No	Yes	NT
4	STH Human Tissue Audit questions to CI	HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit questions to CI.docx	No	Yes	NT
5	STH Human Tissue Audit report template	..\HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit report template.docx	No	Yes	NT
6	STH Human Tissue Audit summary template	..\HTA Audit\Human Tissue Audit document templates\STH Human Tissue Audit summary template.docx	No	Yes	NT

Appendix 2. SOP revisions and history

SOP number & version	Effective date	Reason for change	Author
THIS SOP			
PREVIOUS SOPs			