King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: **Human Tissue Act Compliance Audit for the Research, Anatomical Examination and Public Display Sectors**

Purpose
The purpose of this SOP is to describe the audit arrangements in place to monitor compliance with the Human Tissue Act.

Scope
The scope of this SOP is to describe the different types of audit activity and the annual timetable of these events. The mechanism for reporting audit outcome to persons working under the KCL HTA Licence and Human Tissue Governance Group are also described.

Document Detail	
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Approved By	KCL HTA Governance Committee [20-Nov-2019]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 7/6/2010	1.0	2.0	3	1	Responsibility of DI
2. 7/6/2010	1.0	2.0	4	3.2	DI recommendations following sample audit
3. 6/11/12	2.0	3.0	3	2	Two audits per year to incorporate traceability audits
4.6/11/12	2.0	3.0	3	2.1	External auditor to include HTA DI from another campus
5. 6/11/12	2.0	3.0	4	3.1	Audit reports not to be added to KCL HTA webpage
6. 8/6/15	3.0	4.0	1 & 3 3	Title & 1 2.3	Inclusion of anatomical examination and public display audits Change to minimum of 3 cases checked in traceability audit
7. 11/09/17	4.0	4.1	3	1 2	PD responsibility to correct non-conformance Plan to include traceability audits
8. 20/11/2019	4.1	5.0	3	2 2.2 2.3	(i) Audit frequency and interim audit changed. (ii) Expansion of auditors to include any nominated individual. (iii) Traceability forms used by Research Sector only

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

It is the responsibility of personnel working under a KCL HTA Research, Anatomical Examination and Public Display licence to ensure that:

a) They participate in the KCL HTA audit programme as outlined in this SOP.
b) They comply with the audit recommendations within the agreed timescale.

It is the responsibility of the Persons Designated to:
a) Make local arrangements to facilitate External and Internal HTA audits.
b) Participate in traceability audits and report outcome to the Designated Individual
c) Assist the Designated Individual in addressing issues identified in traceability audits
d) Respond to any points raised during the audit and correct issues within the agreed timelines

It is the responsibility of the Designated Individual to:
a) Review responses and information provided during the audit programme.
b) Ensure that steps are taken to rectify issues identified in audits.
c) Ensure that following each audit a written report is sent to the Person Designated or named individual.

2 Audit Activities

There shall be at least two HTA-associated audits carried out per year; this must include a formal annual audit supplemented by traceability or interim audits.

2.1 Annual KCL HTA Campus Audit:
Led by a HTA Designated Individual (not directly responsible for the campus or sector) or an experienced auditor.
The Lead Auditor will decide which aspects of HTA compliance he/she will audit but a traceability audit must be included. The lead may be advised by the Campus Designated Individual to include potentially non-compliant activities. These may include poor practices identified in a previous audit or those identified as a result of a reported adverse event/incident.

2.2 Interim KCL HTA Campus Audit:
Led by the KCL Campus HTA Designated Individual who may choose to carry out an audit of specific groups where the annual audit has indicated non- or limited compliance with HTA standards or where limited information has been provided. A traceability audit must form part of the interim audit (described in 2.3).

Alternatively, the KCL Campus HTA Designated Individual may arrange for the interim audit to be a traceability audit undertaken by Persons Designated from the same HTA licence sector (described in 2.3).

2.3 KCL HTA Traceability Audit:
Led by the KCL Campus HTA Designated Individual, Persons Designated or Named Individual (at the discretion of the Designated Individual) shall carry out a record to sample and sample to record audit of at least one collection. Where there are multiple collections within a department, the auditor may choose to audit more than one collection.

2.3.1 Record to Sample Location Audit

a) Select a minimum of 3 records from a database/ spreadsheet/ logbook. Selected from different databases when there is more than one and relate to different sample types (eg tissue and blood).
b) Record the collection name sample ID, material format and storage location on the 'Sample Traceability Audit' form (Research Sector only, appendix 1) or highlight specimens on the prosection database (Anatomy Sector).
c) Physically check the sample, to confirm that sample information and record match.
d) Consent form information may also be included in the traceability audit but is not compulsory.
e) Record the outcome on the form or note any discrepancies.

2.3.2. Sample to Record Audit (Research and Public Display Sector)

a) Randomly select a minimum of 3 samples (from different storage locations) record the sample ID and exact location.
b) Check this information against the database/spreadsheet/logbook.
c) Record the outcome on the form

3 Reporting of Audit Activities

3.1 Annual and Interim KCL HTA Campus Audits

a) Audit reports will be prepared for each individual Department/Group.
b) Where appropriate the auditor will make recommendations to improve HTA compliance. Where non-compliant activities are identified, the Auditor in collaboration with HTA Campus Designated Individual, will agree a timetable in which changes in practice must be made.
c) Annual and interim audit reports will be sent to the Person Designated or Named Individual in the first instance to allow them to correct factual detail and comment on the audit outcome.
d) A Person Designated or Named Individual must confirm receipt of an audit report.
e) A summary of the Annual and Interim audit report with recommendations shall be presented to the KCL Human Tissue Act Governance Group.

3.2 KCL HTA Traceability Audit

a) Completed 'Sample Traceability Audit' forms should be sent to the Campus Designated Individual. In the Anatomy Sector, confirmation of a completed audit should be sent to the Designated Individual and any discrepancies noted.
b) Where traceability is shown to be poor the Designated Individual will;
    i. Assess how representative the audit results are.
    ii. With the Person Designated or Nominated Individual implement a programme of improving sample traceability.
c) Information from the forms will be added to a spreadsheet held by the campus DI. The spreadsheet should be used to;
    i. Show trends in audit performance between different groups.
    ii. Monitor audit results of previously identified poor performers.
    iii. Identify groups or tissue collections that require more frequent auditing as practices are changed.

Appendix 1

King's College London HTA Governance Group

Sample Traceability Audit

Name and Location of Group/Lab:

Audited By: Date of Audit:

1. Record to Sample Location Check
Select a minimum of 3 records from a database/ spreadsheet/ log-book. Record storage location and physically check on the sample itself that sample information and record match. Records should be selected from different databases when there is more than one and relate to different sample types (eg tissue and blood).

2. Sample to Record Check
Select a minimum of 3 samples (from different storage locations) record the sample ID and exact location. Check this information against the database/spreadsheet/log-book.

1. Record to Sample

	Collection Name	ID from Record	Type/Format of sample	Location from Record	Does ID on sample match?
1					
2					
3					

2. Sample to Record

	Collection Name	ID on Sample	Type/Format of sample	Location of Sample	Does sample ID and location match with Record?
1					
2					
3					

Please send or e-mail completed form to the Campus Designated Individual.