	Title: Internal audit	Author: P. Madhou	Date: 16/04/2025
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SOP R21:HTA RESEARCH LICENCE
INTERNAL AUDIT

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Rev	Date	Amendment	Approved by	Authorised by
1	July 2025	Issued for use	PM	HTLRG
0	July 2025	Issued for discussion	PM	HTLRG

1. Purpose/Background

1.1 This SOP outlines the procedures for conducting internal audits of research groups working under the HTA Research Licence 12335 at City St George's, University of London (CSGUL)

1.2 Internal audits aim to ensure ongoing compliance with the Human Tissue Act (2004), the HTA Codes of Practice, and the university's governance standards.

2. Scope

2.1 This SOP applies to all research groups at CSGUL working with and storing relevant human material under the HTA Research Licence 12335.

2.2 The procedure involves auditing the documentation, storage, and tracking systems for human tissue samples held under the licence.

3. Responsibilities

3.1 The Designated Individual is responsible for the overall coordination of the internal audit process under the direction of the Licence Holder.

3.2 The Designated Individual (DI) is responsible for nominating the research groups to be audited and ensuring completion of audit cycles.

3.3 Research groups are required to cooperate with internal audits and implement corrective and preventative actions (CAPAs) in response to findings.

3.4 The DI is assisted by the Persons Designated (PD) in undertaking the internal audits.

4. Procedure

4.1 Audit Frequency and Selection
- Two research groups will be selected for internal audit each month, following a predefined schedule that takes into account the dates of their last inspection.
- The DI will notify selected groups by email, including:
 - The audit date and time.
 - A sample HTA checklist for preparation.

4.2 Audit Scope and Duration
- The audit will be conducted on-site and will last approximately one hour.
- It will include checks of:
  - Consent and sample documentation.
  - Storage conditions of human tissue.
  - Labelling, tracking systems, and disposal logs.
  - Record accuracy in paper and electronic formats.

4.3 Post-Audit Reporting
- Within a week, the audit team will issue a Corrective and Preventative Action (CAPA) form to the audited group, outlining:
  - Any non-conformances.
  - Required actions to meet HTA standards.
  - Recommendations for best practice.

4.4 CAPA Implementation
- Groups must implement corrective actions within 1–2 months, depending on severity and complexity.

- Evidence of implementation must be submitted to the DI.

4.5 Audit Closure
- The DI reviews the completed CAPA and supporting evidence.
- If all actions are satisfactory, the DI formally closes the audit.
- Records of all audits are maintained for HTA inspection readiness.

5. Related Documents
5.1 SOP HTA – GEN1v6: Creating Standard Operating Procedures
5.2 SOP HTA – GEN2v6: Human Tissue Licence Review Group
5.3 HTA Internal Audit Checklist

6. References

6.1 HTA Codes of Practice:
- Code A: Guiding principles
- Code E: Research

7. Amendment of SOPs

7.1 Suggestions for improvements to this SOP should be submitted to the Person Designated (PD) for review and inclusion in the next update cycle.

8. Contacts DIs and PDs

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