	Title: External audit	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_R10	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 6		Review Date March 2026




**SOP R10:HTA RESEARCH LICENCE
EXTERNAL AUDIT**

Disclaimer

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Out of date documents must not be relied upon and should be destroyed.

6	Sept 2024	City merge, review (Sec 4.1,4.3) & formatting	AS/PM	HTLRG
5	March 2023	New DI	AS	HTLRG
5	Sept 2022	New DI, Add PD & Review	AS	HTLRG
4	April 2021	Amend annual audit date	AS	PL
4	August 2020	Review (Section 3.1 & 4.3)	AS/PL	HTLRG
3	March 2018	Reviewed & Amended (New Author)	AS	PL
3	July 2017	Reference to HTA codes updated	PL	HTLRG
3	July 2017	Reviewed and PD contact details	PL	HTLRG
2	5/12/2016	Update contact list	AS	PL
2	10/10/2016	DI change details	AS	MF
2	17/03/2016	Issues for use	GC	HTLRG
1	30/10/12	Issued for use	GC	HTLRG
0	02/10/12	Issued for discussion	GC	
Rev	Date	Amendment	Approved by	Authorised by

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1. Purpose/Background

1.1 This SOP outlines the arrangements for auditing the records and materials held by St George's, University of London (SGUL) under the Human Tissue Authority (HTA) Research Licence 12335.

2. Scope

2.1 This SOP covers the audit procedures for HTA Licence 12335, which governs the archiving and storage of relevant material at CSGUL.

2.2 The audit will consist of verifying that the paper and electronic records accurately correspond to each item of relevant material held at CSGUL.

3. Responsibilities

3.1 The responsibility for ensuring that audits are carried out in accordance with this SOP lies with the Governance Manager in the Joint Research Enterprise Services (JRES), under the general direction of the Licence Holder.

3.2 The responsibility for detailed arrangements for each audit, including liaising with the Governance Manager to identify an appropriate auditor, rests with the Designated Individual under the licence.

4. Procedure


4.1 The audit will be conducted annually between January and April.

4.2 Audits will be carried out by an experienced researcher from another university or similar institution. The Designated Individual will nominate the auditor, and the Human Tissue Licence Review Group (HTLRG) will approve the nomination annually.

4.3 A random sample of four paper records held by the Persons Responsible (PRs) of the NCRI, CGRI, I & I, and PHIR Institutes will be selected. Checks will be conducted to verify that the corresponding electronic records exist in the respective Divisions and on the HTA database. The associated relevant material and, where applicable, sectioned items must also exist and match the records held.

4.4 A random sample of three electronic records held by the Designated Individual will be selected. Checks will be conducted to verify that the corresponding paper and electronic records exist in the Division and on the HTA database, and that the associated relevant material and, where applicable, sectioned items exist and match the records held.

4.5 A random selection of one sample of relevant material and two sectioned items will be made. Checks will be conducted to verify that the appropriate paper and electronic records exist, are complete, and match the items held.

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4.6 The auditor will be required to submit a written report to the Licence Holder and Designated Individual within two weeks of completing the audit, detailing the findings and making recommendations for action where appropriate.

5. Related Documents

5.1 HTA Licence 12335: Licence for the storage of relevant material for scheduled purposes.

5.2 SOP HTA – GEN1v6: Creating Standard Operating Procedures.

5.3 SOP HTA – GEN2v6: Human Tissue Licence Review Group.

6. References

6.1 Human Tissue Authority Codes of Practice:

- Code A: Guiding principles and the fundamental principle of consent.
- Code B: Post-mortem examination.
- Code C: Anatomical examination.
- Code E: Research.
- Code F: Donation of solid organs and tissue for transplantation.
- Code G: Donation of allogenic bone marrow and peripheral blood stem cells for transplantation.

7. Amendment of SOPs

7.1 If, in the course of applying this document, the user identifies a modification that would improve this document, please bring the suggested changes to the attention of the Person Designated (PD) so that amendments can be reviewed and implemented.

8. Contacts DIs and PDs

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