Standard Operating Procedure **CBE/HTA-MI-SOP009**

Title: SELF-INSPECTION AUDIT OF RESEARCH ACTIVITIES INVOLVING HTA LICENSABLE MATERIAL

Location: CBE Laboratories

1. PURPOSE

To describe the procedure for internal self-inspection audit and monitoring of processes and practices related to the acquisition, storage, use and disposal of HTA licensable material for research.

2. SCOPE

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all individuals involved research activities under the University's HTA licence, in accordance with the requirements of the HTA legislation, the HTA Codes of Practice and the University's HTA Licence Compliance Quality Manual. This procedure covers internal self-inspection audits of research project activities involving HTA licensable material, which may also include audits of local governance procedures and management processes. Inspection reports arising from these audits will serve to facilitate internal reporting and internal level audits by the University as well as to demonstrate commitment to improving quality systems as part of the local Quality Management System.

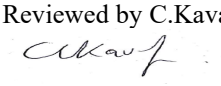
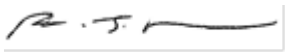
3. RESPONSIBILITIES

3.1. The departmental Quality Manager (dQM) is responsible for planning and scheduling internal (CBE but with support of regulatory officer) self-inspections.

3.2. The dQM shall ensure that inspections are completed on schedule, appropriate remedial action is undertaken and that records are kept of the inspections.

3.3. All individuals engaged in research involving HTA licensable material have the responsibility to maintain and make available all appropriate and required records/documentation for internal self-inspection audit.

4. REFERENCES

Written by: P.Hourd/C.Kavanagh Date:26.01.2016 Reviewed by C.Kavanagh  Date: 08/12/2025	Reviewed by: R.Thomas  Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Approved by: Karen Coopman  Date: 09/12/2025

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The Human Tissue Act (2004) and https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice/code-e-research

The University HTA Licence Compliance Quality Manual

The CBE Quality Manual

5. PROCEDURE

5.1. Self-inspection audit schedule

5.1.1. Internal self-inspection audits shall be conducted by the dQM, the dPD and/or a suitably trained individual(s). It is preferable that the selected inspectors are independent from those having direct responsibility for the inspected activity.

5.1.2. Internal self-inspection audits should be conducted at least once a year but the frequency may be increased or decreased on a risk basis at the discretion of the dQM or dPD (e.g. following a rise in relevant adverse events, an area where poor practice may be suspected, change in regulations etc).

5.1.3. These inspection audits should be typically targeted to test and verify certain aspects of the HTA licencing requirements. The inspection should involve a desk based review of paperwork and/or a laboratory based review of the facilities and equipment. Inspection may cover one or all of the following quality indicators for example:

- Adherence to local procedures
- Accuracy of records and risk assessments
- Ethics and consent documentation

- Security
- Completeness of data and documentation, including training records, sample register
- Storage facilities (including temperature monitoring/storage failure alarms)
- Material tracking & traceability
- Transfer & transportation arrangements for HTA licensable material
- Disposal arrangements for HTA licensable material
- Equipment maintenance

5.2. Conducting the Inspection

5.2.1. The self-inspection audit should commence with an opening meeting with key staff involved and chaired by the auditor.

5.2.2. The first step in the inspection process should be to review minutes of the last three CBE Team Lab, HTA & safety Committee meetings and any findings from previous inspection reports to identify any outstanding actions for assessment during the inspection.

5.2.3. The inspection team should use an inspection checklist and report form for completing the inspection to ensure a structured inspection process.

Note: The checklist is only the basis for an inspection and inspection teams should not confine themselves solely to these points when carrying out an inspection.

5.2.4. The inspection team should then agree on the areas and routes for inspection and any specific tasks delegated to individuals in the team.

5.2.5. While conducting the inspection, inspectors shall seek objective evidence demonstrating whether the inspected activities conform to the requirements of one or more of the four HTA

standards; (1) Consent, (2) Governance & quality, (3) Premises, Facilities and Equipment, (4) Disposal.

5.2.6. The inspection audit may include a sample traceability inspection, selecting a sample of HTA licensable material at random from the CBE's tracking system, and retrieving these in the laboratory (record-to-sample test), followed by a reverse audit, selecting samples at random from the storage unit, and finding these in the sample tracking system (sample-to-record test).

5.2.7. Where possible, for samples selected during the sample traceability inspection, associated documentation eg consent forms should also be inspected.

5.2.8. Following completion of the inspection, there should be a closing meeting to summarise the inspection activities and discuss any observations and possible remedial/corrective action.

5.3. Post-inspection reporting

5.3.1. An internal inspection report should be completed by the dQM within 4 weeks of the inspection taking place.

5.3.2. To ensure that reports are controlled a register is maintained, each report should be given a unique and sequential number.

5.3.3. The audit report should include:

- A list of identified non-conformities with HTA standards. These should be graded in accordance of severity, i.e. minor, major and critical.
- An assessment of how well HTA standards and guidance has been met. Wherever possible, references should be provided to the HTA Standards that each observation relates to, and recommendations provided for a course of action.

- Where applicable, a list of corrective actions to be taken to ensure compliance and a time scale in which to allow the changes to take place.
- In the event of finding critical non-compliance issues, a date for re-inspection.

5.3.4. The inspection report should be made available to the CBE Team Lab, HTA & safety Committee and to relevant staff impacted, as appropriate. Internal inspection reports will not be sent to the DI unless a critical shortfall has been identified or subject to the discretion of the CBE Team Lab, HTA & Safety Committee.

5.3.5. Inspection findings should be categorised as follows:

Critical shortfall	A shortfall which poses a significant risk to human safety and/or dignity or is in breach of the Human Tissue Act 2004 or associated directions Or - A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

Major shortfall	A non-critical shortfall that : ➢ Poses a risk to human safety and/or dignity, or ➢ Indicates a failure to carry out satisfactory procedures, or ➢ Indicates a breach of the relevant codes of practice, the Human Tissue Act, and other professional and statutory guidelines, or ➢ Has the potential to become a critical shortfall unless addressed Or - A combination of a number of minor shortfalls, none of which is major in its own right, but which together could constitute a major shortfall and should be explained and reported as such.
Minor shortfall	A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards/good practice.
Other	Where a shortfall has not been identified, but areas for improvement have been identified, leading to the auditor providing advice to the auditee on improvements.

5.4. Corrective action, follow up and closure

5.4.1. Corrective and preventative actions (CAPA) resulting from the inspection findings should documented and implemented using the local CAPA procedure (SOP050).

5.4.2. On, or immediately after the due date for implementation of each corrective and/or preventative action, the auditor should determine if the action has been implemented and if it is effective.

5.4.3. When there is objective evidence that the action is effective, the non-conformity checklist and report form shall be closed out. If more work is needed to fully implement the action, a new follow-up date should be agreed.

5.4.4. On completion of all corrective and preventative actions, the inspection will be considered complete.

6. DOCUMENTATION

Title: SELF-INSPECTION AUDIT OF RESEARCH ACTIVITIES INVOLVING HTA LICENSABLE MATERIAL

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The following records are outputs of this SOP:

6.1. HTA-MI-FORM/010 Self Inspection Checklist & Report Form

These records shall be stored on the CBE network and/or stored in the CBE Office or otherwise archived for future review or retrieval.

Written by: P.Hourd/C.Kavanagh Date:26.01.2016 Reviewed by C.Kavanagh Date: 08/12/2025	Reviewed by: R.Thomas Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Approved by: Karen Coopman Date: 09/12/2025

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SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4th December 2017 by C.Kavanagh	N/A No change required	No Amendments Minor editorials only including revision details.	1.0 New version not required
1.0	2nd December 2019 by C.Kavanagh	N/A No change required	No Amendments Minor editorials only including revision details.	1.0 New version not required
1.0	6th December 2021 by C.Kavanagh	N/A No change required	No Amendments Minor editorials only including revision details.Self inspection checklist amended. DCN 0015	1.0 New version not required
1.0	4th December 2023 by C.Kavanagh	N/A No change required	Minor Editorial only including revision details	1.0 New version not required
1.0	8th December 2025 by C.Kavanagh	N/A no change required	Minor editorial only, update of broken links	1.0 New version not required

SOP Withdrawal Date:	

Document Control

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The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their Supervisor immediately.

Security Statement

This SOP is the intellectual property of the CBE within Loughborough University, and as such, must not be circulated outside of the University without the written approval from the dQM and the author.

Acknowledgements

This SOP has been produced with advice and input from colleagues and with reference to Loughborough University School of Sport, Exercise and Health Sciences (SSEHS) SOPs and publically available SOPs used at a number of other UK universities. We also acknowledge the contributions of Andreea Iftimia-Mander to the original draft versions of this SOP.

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