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Title: PRODUCTION AND CONTROL OF STANDARD OPERATING PROCEDURES APPLIED TO ACTIVITIES INVOLVING HTA LICENSABLE MATERIAL

Location: CBE Laboratories

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1. PURPOSE

To describe the procedure for the preparation, review, approval, distribution and revision of Standard Operating Procedures (SOPs) relating 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 persons involved in managing SOPs relating to the governance, storage, use and disposal of HTA licensable material under the University's HTA licence for research, 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 may also be applied to control changes relating to other Controlled Documents that support the CBE Quality Management System.

3. RESPONSIBILITIES

3.1. The departmental Quality Manager (dQM) shall ensure that local level SOPs are prepared, reviewed, revised, approved and issued according to this SOP.

3.2. The dQM shall ensure that local level SOPs are subject to regular reviews (at least 2-yearly) and to a system of document/version control

3.3. The dQM shall ensure that all local level SOPs are aligned with Loughborough University procedures applied to the control of HTA licensable material under the University's HTA License Compliance Quality Manual.

Written by: P.Hourd/C.Kavanagh Date: 26/01/16 Reviewed by: C.Kavanagh [signature] Date: 04/12/2023	Reviewed by: R.Thomas [signature] Date: 13/12/2023	Approved by: M. Gleeson Date: 29/01/2016 Review Approved by: K Coopman [signature] Date: 13/12/2023

3.4. The dQM shall ensure that local procedures applied to the control of HTA licensable material do not conflict with any other part of the CBE Quality Management System.

3.5. The departmental Person Designate (dPD), on behalf of the CBE Safety and Quality Compliance Committee, is responsible for the review of all SOPs applied to activities involving HTA licensable material.

4. REFERENCES

The Human Tissue Act (2004) and HTA guidance and Code of Practice E

The University HTA Licence Compliance Quality Manual

The CBE Quality Manual

5. PROCEDURE

5.1. Document Control

5.1.1. A Document Register shall list all active and approved Controlled Documents, including SOPs and associated forms.

5.1.2. All current Controlled Documents, including SOPs shall be held as 'Read-Only' documents within a designated and secure electronic folder on the CBE LEARN page.

5.1.3 Editable word versions of all Controlled Documents and associated forms must be retained in a locked folder as a password protected document to prevent unauthorised editing.

5.1.4. An electronic archive of all revised Controlled Documents should be retained.

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5.1.5. The electronic system shall be backed up regularly as part of the Loughborough University server support which allows recovery in the event of loss of documents.

5.1.6. An original 'wet ink' signed hard copy (Master Copy) of all current Controlled Documents, including SOPs, must be maintained in a secure location. Scanned signed versions should be stored electronically.

5.2. Creation of new procedures

5.2.1. Once the need for a new SOP is identified, the title should be allocated a number according to the local HTA SOP numbering convention and logged in the document register by the dQM.

5.2.2. Each SOP must be produced with a standardised format and content using the available template (HTA-QS-FORM/002).

5.2.3. New SOPs should be written by competent individuals that have current knowledge and experience of the designated task.

Note: For some procedures, it may be necessary to allow a period of training and familiarisation prior to the writing of an SOP. In these circumstances, the SOP should be written within two months of the procedure's first use.

5.2.4. New SOPs should be forwarded to the dQM together with any forms, templates or supporting documents. The dQM shall forward the SOP to the dPD for review.

5.2.5. Once the SOP has been reviewed it should be forwarded to the DI (or Responsible Person designated by the DI), together with any forms, templates or supporting documents, for approval.

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5.2.6. Once the SOP has been approved for implementation, the dQM shall issue a Document Change Note (DCN) and the final numbered Master Copy of the SOP for the appropriate wet ink signatures and date.

Note: The dPD and the DI should sign and date the front page of the SOP in the space provided. The author should sign and date all pages of the SOP in the space provided.

5.2.7. The SOP shall be issued with the date the document was approved. The effective date and the review date (set at a minimum of 2 years) are entered in the footer of each SOP.

5.2.8. The dQM shall make an electronic version of the new SOP available on the CBE LEARN page and update the Document Register to include the SOP version number, approval and review date and the authorised holder or location(s) of the document.

5.2.9 All individuals registered for working with HTA licensable material shall be alerted by the dQM (by email) to any new version of a SOP that is produced and approved for implementation.

5.2.10. All individuals registered for working with HTA licensable material undertake training and maintain a Personal Training Record (PTR), in accordance with CBE/HTA-RM-SOP003. A SOP sign-off form is provided as part of the PTR and all those registered must complete the form to confirm they have read the relevant SOP and understand how to apply it to their research before performing the procedure.

5.2.11. When all activities associated with the issue of the new SOP have been completed the DCN should be closed.

5.3. Planned review and revision of existing procedures

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5.3.1. Each SOP shall be subject to regular review and updating as necessary or as a minimum, every 2 years.

5.3.2. For SOPs which have reached their review date, the dQM shall issue an uncontrolled copy of the SOP clearly marked “UNCONTROLLED DOCUMENT. NOT FOR OPERATIONAL USE”, to the ‘Author’ for review.

5.3.3. If no changes or insignificant changes are required e.g. editorial changes, the ‘Author’ shall notify the dQM that no update or that only minor editorial changes are required. The dQM shall update the SOP accordingly and complete the SOP Version History Form at the back of the SOP stating that the SOP was reviewed and that no changes or that minor editorial changes were made.

5.3.4. If significant/substantial changes to the document are required the initiator of the change should submit a Document Change Note (DCN) to the dQM.

Note: To ensure that document changes are controlled and a log of change requests is maintained, each change request should be given a unique “change control” number. .

5.3.5. On receipt of the DCN, the dQM should assess the request based on the perceived need for change, feasibility, risk, impact (e.g. potential training requirements) and any other information provided by the change initiator. Where further information is required this should be requested.

5.3.6. The dQM shall complete the revision history table at the back of the SOP and assign a new version number to the revised SOP before forwarding the SOP to the dPD for review.

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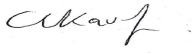
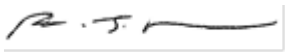
Written by: P.Hourd/C.Kavanagh Date: 26/01/16 Reviewed by: C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 13/12/2023	Approved by: M. Gleeson Date: 29/01/2016 Review Approved by: K Coopman  Date: 13/12/2023

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5.3.7. Once the revised SOP has been reviewed it should be forwarded to the DI (or Responsible Person designated by the DI).

5.3.8. Once the SOP has been approved, the dQM shall re-issue the new version Master Copy of the SOP for the appropriate wet ink signatures and date.

Note: The dPD and the DI should sign and date the front page of the SOP in the space provided. The author should sign and date all pages of the SOP in the space provided.

5.3.9. The revised SOP shall be issued with the date the document was approved. The effective date and the review date (set at a minimum of 2 years) are entered in the footer of each SOP.

5.3.10. The dQM shall make an electronic version of the revised SOP available on the CBE LEARN page and update the Document Register to include the SOP version number, approval and review date and the authorised holder or location(s) of the document.

5.3.11. All individuals registered for working with HTA licensable material shall be alerted by the dQM (by email) to any significant/substantial changes to an existing SOP (e.g. as a result of major changes to the legislation, or HTA regulatory practice).

5.3.12. All individuals registered for working with HTA licensable material undertake training and maintain a Personal Training Record (PTR), in accordance with CBE/HTA-RM-SOP003. A SOP sign-off form is provided as part of the PTR and all those registered must update the form to confirm they have read the revised SOP.

5.3.13. When all activities associated with the issue of the revised SOP have been completed the DCN should be closed.

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5.3.14. Superseded versions of the SOP must be removed from circulation. Superseded versions should be retained and archived in a secure location.

5.4. Unplanned revision of existing procedures

5.4.1. If errors or omissions are identified at any time by a user or any other person, they should bring this to the attention of the dQM immediately.

5.4.2. To request changes to any HTA SOP, users must submit a Document Change Note (DCN) to the dQM in accordance with this SOP.

5.4.3. On receipt of the DCN, the dQM should assess the request based on the perceived need for change, feasibility, risk, impact (e.g. potential training requirements) and any other information provided by the change initiator. Where further information is required this should be requested.

5.4.4. The dQM shall complete the revision history table at the back of the SOP and assign a new version number to the revised SOP.

5.4.5. Once the changes are made, the document should follow the review, approval and release process as described for revised SOPs (Section 5.3).

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. HTA-QS-FORM/002 - SOP template

6.2. HTA-QS-FORM/003 - Document Change Note (DCN) template

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6.3. Records of notification for issue new/revised SOPs

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

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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 changes	No Amendments made Minor Editorials only including revision details.	1.0 New version not required.
1.0	2nd December 2019 by C.Kavanagh	N/A No Changes	No Amendments made. Minor Editorials only including revision details.	1.0 New version not required.
1.0	6th December 2021 by C.Kavanagh	N/A No Changes	No Amendments made. Minor Editorials only including revision details.	1.0 New version not required.
1.0	4th December 2023 by C.Kavanagh	N/A No changes	No amendments made. New revision date only.	1.0 New version not required

SOP Withdrawal Date:	

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Standard Operating Procedure **CBE/HTA-QS-SOP001**

Title: PRODUCTION AND CONTROL OF STANDARD OPERATING PROCEDURES APPLIED TO ACTIVITIES INVOLVING HTA LICENSABLE MATERIAL

Location: CBE Laboratories

Document & Change Control

A 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.

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