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**Standard Operating Procedure**

**CBE/HTA-QS-SOP002**

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Title: CHANGE CONTROL FOR WORK ACTIVITIES INVOLVING HTA LICENSABLE MATERIAL

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Location: CBE Laboratories

**1. PURPOSE**

To describe the procedure for controlling planned changes relating to processes, practices, facilities and systems involved in 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 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 does not cover unplanned changes which affect the validated or controlled state of a system or process, which should be treated as an Adverse Event and reported according to local procedures.

**3. RESPONSIBILITIES**

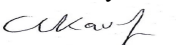
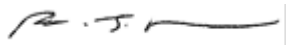
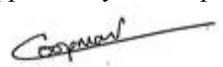
- 3.1. The departmental Quality Manager (dQM) is responsible for the control of planned changes to facilities, systems, processes or practices that may impact CBE activities under the Loughborough University HTA licence for research.
- 3.2. Individuals proposing any change to the facility, a system, process or practice that may affect the research activities under the Loughborough University HTA licence for research must submit a change request according to this SOP before any change is made.

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Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by: C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 13/12/2023	Approved by: M.Gleeson Date: 28.01.2016 Approved by: K Coopman  Date: 13/12/2023
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- 3.3. The dQM is responsible for ensuring that any planned change to CBE systems or processes do not conflict with any other part of the CBE Quality Management System.
  
- 3.4. The departmental Person Designate (dPD), on behalf of the CBE Safety and Quality Compliance Committee, is responsible for the review and approval of all Change Requests relating 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. The initiator of the change should submit a change request to the dQM using the Change Request Note (CRN) form (HTA-QS-FORM/004).

**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. .

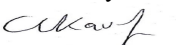
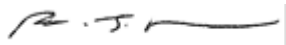
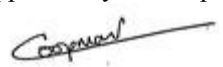
- 5.2. On receipt of the CRN, the dQM, with the process/system owner and the dPD, should assess

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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. Once the change has been approved by the dQM and the dPD, the dQM shall forward the CRN to an appropriate member of the CBE Management Committee for approval to implement.
- 5.4. Once the implementation of the change has been approved, the dQM shall issue the CRN for the appropriate signatures and date.
- 5.5. The requested change should be implemented in accordance with the process agreed in the CRN.
- 5.6. All individuals registered for working with HTA licensable material shall be alerted by the dQM (by email) to any implementation of changes to existing processes or practices.
- 5.7. 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. If training and/or briefing sessions related to the change are provided, this must be recorded in the user PTR.
- 5.8. When all activities associated with implementation of the change have been completed, the CRN should be closed.

**6. DOCUMENTATION**

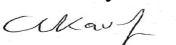
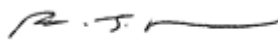
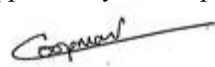
The following records are outputs of this SOP:

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

6.2. HTA-QS-FORM/004 - Change Request Note (CRN) template

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

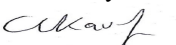
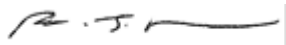
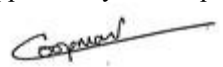
**SOP Version History**

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4 <sup>th</sup> December 2017 by C.Kavanagh	N/A No Change	No amendments Minor editorial only including revision details.	1.0 New version not required.
1.0	2 <sup>nd</sup> December 2019 by C.Kavanagh	N/A No Change	No amendments Minor editorial only including revision details.	1.0 New version not required
1.0	6 <sup>th</sup> December 2021 by C.Kavanagh	N/A No Change	No amendments Minor editorial only including revision details.	1.0 New version not required
1.0	4 <sup>th</sup> December 2023 by C.Kavanagh	N/A no Change	No Amendments . New review date only.	1.0 New version not required

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<b>SOP Withdrawal Date:</b>	
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**Document Control**

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.

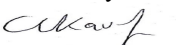
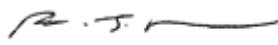
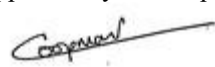
**Acknowledgements**

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.

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