Title: INDUCTION AND TRAINING FOR HTA COMPLIANCE

Location: CBE Laboratories

1. PURPOSE

To describe the procedure for the provision and documentation of training for individuals (current and new staff and students) involved in activities related to the acquisition, storage, use and disposal of HTA licensable material for research.

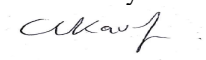
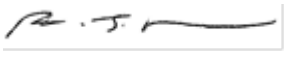
2. SCOPE

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all persons involved in research activities under the University's HTA licence to ensure that they have the necessary knowledge and skills to carry out their roles and responsibilities in compliance with the HTA legislation, the HTA Codes of Practice and the University's HTA Licence Compliance Quality Manual. This training is supplemental to the completion of relevant training in laboratory processes and health and safety policy and procedures set out in the local QMS for research, which is a condition for gaining authorised access the CBE laboratory facilities.

3. RESPONSIBILITIES

3.1. The Principal Investigator (PI) or Person Responsible (as delegated by the PI, and appropriately trained), as custodian of the material, must ensure they are familiar with the HTA Code of Practice on Research, understand and follow the governance policies and procedures in place under the local Quality Management System, attend any relevant training and comply with the conditions of the University's HTA License Compliance Quality Manual.

3.2. The Principal Investigator (PI) or Person Responsible, as custodian of the material, is responsible for identifying the training needs of the staff and students working under their supervision, are appropriately informed and have received the appropriate training prior to commencing any new project or activity under the Loughborough University HTA licence.

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

3.3. The departmental Person Designate (dPD) is responsible for ensuring all staff and students carrying out or overseeing HTA related activities are operationally compliant with the local processes and procedures for working with HTA licensable material.

3.4. Each individual proposing to acquire, store, use, transport or dispose of HTA licensable material must register to undertake training appropriate to their immediate research needs and maintain a personal training file that demonstrates they are competent to perform duties appropriate to their role in each research project. The responsibility for ensuring the accuracy and completeness of ongoing personal development rests with the individual researcher.

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. On request, the PI or Person Responsible should provide details of all new starters to the departmental Quality Manager (dQM) in advance of new staff/students start date.

5.2. Before commencement of any new activity or project involving HTA licensable material, current staff should liaise with the dQM to identify and arrange any training need. This training need shall be informed by completion of a Biological Risk Assessment for the use of the material.

5.3. Any new starters/current staff identified (including those who need a refresher) as intending to acquire, store, use or dispose of HTA licensable material shall be added to a Central Register held by the dQM.

5.4. The register of all CBE personnel involved in work with HTA licensable material shall be submitted to the University Designated Individual (DI) on request.

Note: Training & being added to the register is a requirement irrespective of an individual's experience of working with HTA licensable material either at the University or elsewhere. It is an important means by which the DI can identify all those working with HTA licensable material and communicate effectively with them, to provide effective training, advice and guidance. Failure to register or attend the appropriate training and briefings may result in a research project being delayed, or a researcher being unable to undertake research using human samples.

5.5. Training shall be identified and discussed at an initial meeting with the dQM and the PI or Person Responsible. All individuals will receive a Personal Training Record folder to complete as they progress through the HTA Training program. The training has several elements.

5.6. All individuals must complete the mandatory In-house University HTA training covering the requirements of the HTA .

5.7. All individuals intending to work with HTA licensable material must complete the online Medical Research Council's e-learning course "Research and Human Tissue Legislation" (as a minimum requirement) prior to the commencement of the work. Details can be found at https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1

Certificates of completion of any on-line courses must be retained as proof of completion.

5.8. All individuals intending to work with HTA licensable material must also complete local induction and orientation training. This will include specific in-house training on local procedures and practices for the acquisition, storage, use and disposal of HTA licensable

material, as well as the use of the 'Pro-curo' database software for registering and tracking HTA licensable material.

5.9. All training must be documented in each individual's Personal Training Record folder. Core documents shall include:

- HTA reading (HTA Code of Practice E – Research; LU HTA Quality Manual)
- Record of internal training (eg Certificates of completion of internal training sessions; Certificate of completion of MRC – e-learning module; record of SOP sign-off)
- Record of external training (if applicable)
- Any additional training documentation or other related information
- Training Portfolio Sign-off

Note: If appropriate, eg non-laboratory workers, supervisors, line managers, relevant records may be retained in a HTA Training Master File.

5.10. Researchers are required to update their training at least every 2 years. Retraining may be required earlier if there is a significant change to HTA legislation, to the University's HTA Licence Compliance Quality Manual, or the CBE Quality Manual for example.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. HTA-RM-FORM/005 -Training Record for HTA compliance

6.2. Certificates of training

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: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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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	No major amendments. Minor editorial only including the addition of the revision details and correcting the retraining date from 4 years to 3 years. This is in- line with university guidelines and was a typing error.	1.0 New version not required.
1.0	2nd December 2019 by C.Kavanagh	N/A No Change	No major amendments. Minor amendments only to ensure this is in line with University guidelines including: i)Retraining date is now 2 years ii)the addition of the *Regulatory* E-mail address now used for booking training.	1.0 New version not required.
1.0	6th December 2021 by C.Kavanagh	N/A No Change	No major amendments Minor amendment to MRC link for HTA training.	1.0 New version not required.
1.0	4th December 2023 by C.Kavanagh	DCN0018	5.6 Amended to reflect the changes in format of University HTA training provision .	2.0

SOP Withdrawal Date:	

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

Standard Operating Procedure CBE/HTA-RM-SOP003

Title: INDUCTION AND TRAINING FOR HTA COMPLIANCE

Location: CBE Laboratories

Document Control

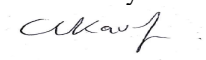
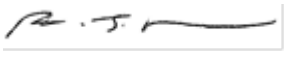
The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their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

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