Standard Operating Procedure **CBE/HTA-PR-SOP006**

Title: ACQUISITION, TRANSFER AND TRANSPORT OF HTA LICENSABLE MATERIAL

Location: CBE Laboratories

1. PURPOSE

To describe the procedure for the acquisition, transfer and transport of HTA licensable material from or to other organisations for storage and use in research.

2. SCOPE

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all individuals involved in the acquisition, transfer and transport 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 SOP covers the management of Material Transfer Agreements for the acquisition and transfer of HTA licensable material through collaborative research with other HTA licensed organisations in England, Wales or Northern Ireland or through commercial arrangement. This SOP also covers the import/export of HTA licensable material for research purposes.

Relevant material may be acquired from, or transferred to, another organisation, research institution, collaborator on a research project, a tissue bank or a commercial supplier of material for storage and use in research. This SOP does not apply to exempted materials (eg transfer of samples as part of a specified study with recognised REC approval), although it may be used to manage the acquisition and transfer of all human material in accordance with good practice.

3. RESPONSIBILITIES

3.1. The departmental Quality Manager (dQM) shall ensure that this SOP is aligned with the University procedure for the transfer and transportation of HTA licensable material and that it does not conflict with any other part of the CBE Quality Management System.

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: 28.01.2018 Review approved by: Karen Coopman Date:13/12/2023

3.2. The PI or Person Responsible (as delegated by the PI, and appropriately trained), as custodian of the material, and the departmental Person Designate (dPD) are responsible for authorising the acquisition or transfer of HTA licensable material.

3.3. Individuals proposing to acquire or transfer HTA licensable material are responsible for completing the 'Authorisation to Acquire or Transfer of HTA Licensable Material' Form prior to any acquisition or transfer of HTA licensable material.

3.4. It is the responsibility of the PI or Person Responsible, as custodian of the material, to ensure that the Procuro sample register is updated following the acquisition or transfer of HTA licensable material. The PI must ensure that any individuals delegated these responsibilities are suitably trained to undertake the tasks.

4. REFERENCES

The Human Tissue Act (2004) and HTA guidance and Codes of Practice E
The University HTA Licence Compliance Quality Manual
The CBE Quality Manual

5. PROCEDURE

5.1. Acquisition HTA Licensable Material

5.1.1. Before any planned acquisition and subsequent transfer/storage of HTA licensable material the PI or Person Responsible should liaise with the dQM to:

- agree the work and storage areas to be used,
- arrange any cleaning or maintenance of the facility,
- confirm arrangements for sample tracking and storage monitoring,

- arrange for back-up storage facilities with researchers as part of contingency planning,
- set-up a project specific master file to manage records and documents required associated with procedures for the acquisition, use, transport, storage and disposal.

5.1.2. In advance of the date for receipt of any HTA licensable material to be transferred into the CBE, the PI or Person Responsible must ensure the following are completed and approved:

- Authorisation to Acquire or Transfer HTA Licensable Material Form (refer to Section 5.10),
- Biological Risk Assessment,
- Material Transfer Agreement (MTA) or other appropriate legal agreement.

5.2. Acquisition and transfer HTA licensable material from an external organisation within England, Wales and Northern Ireland

5.2.1. Check (using the link below) to ensure that the external organisation from which the HTA licensable material will be acquired and transferred from is operating in accordance with the HTA, including the status and any additional conditions of any HTA Licences or other relevant accreditation held https://www.hta.gov.uk/professional/establishments

5.2.2. If a researcher wishes to receive HTA licensable material from an external organisation, they **must** ensure that an MTA (or other appropriate legal agreement) is provided by the sending organisation.

Note: The Contracts Team and/or the DI (or deputy DI or PDs) will advise on MTAs received from other organisations.

Note: Complete the 'Checklist for HTA relevant materials' & submit to the LU Designated Individual .

Note: If MTA is required there are 'Outward' and 'Inward' MTA forms.Please only fill in the sections of the MTA document that are relevant to your transfer.

5.2.3 For HTA material, the Principle Investigator (PI) must fill out the HTA checklist for HTA relevant Material.

5.2.4 If MTA is required (based on the checklist) an MTA needs to be submitted. Once the MTA has been agreed it will be signed by the authorized signatories of both organisations i.e. the PI and DI of the recipient and originator organisation.

5.2.5 Ensure any and all relevant signatures have been obtained.

5.2.6 Address any feedback and return the form to the recipients above if necessary, until any queries are addressed.

5.2.7 Once completed, the Fully Signed MTA + signed Checklist + Appendix will be emailed with a Contracts Case Reference Number to the PI, and cc'd to Jacqueline Green (j.a.green@lboro.ac.uk).

5.2.8 The Research and Enterprise Office will retain the signed copy of the fully executed MTA. An electronic copy of the fully executed MTA will be sent to each signatory.

5.2.9 To ensure that MTAs are controlled and a register of agreements maintained, each MTA should be issued a unique and sequential reference number which can be entered in the Procuro database. A copy of the MTA should be retained in the project specific master file.

5.2.10 The Research and Enterprise Office will provide notification of clearance to receive the HTA licensable material from the sending organisation.

5.2 Purchasing HTA 'Relevant Material' from commercial suppliers.

5.3.1. In some instances an MTA may not be required but a clear ethical statement or other evidence of appropriate consent should be obtained from the supplier confirming that the materials were sourced using appropriate methods.

Note: The Research and Enterprise Office and/or the DI (or deputy DI or PDs) will advise on MTAs received and the terms and conditions of commercial suppliers.

5.3.2. Documented evidence or other suitable forms of assurance, including the purpose for which the material may be used i.e. research, should be retained in the project specific master file.

5.4. Acquisition and transfer of HTA licensable material from an external organisation outside England, Wales and Northern Ireland (Import of Relevant Material)

5.4.1. The import (and export) of Relevant Material is not a licensable activity under the HT Act. However, if the import is not covered by a project specific NHS REC approval, the material once imported must be stored under a HTA licence unless another exemption applies.

5.4.2. In terms of research, the consent provision of the HTA does not apply to imported material. However, the HTA consider it good practice to ensure mechanisms are in place, which provide assurance that the material is imported with appropriate consent.

5.4.3. To exert a measure of control over the transfer of material and to ensure that it is used within the terms of consent and that an audit trail is maintained, an MTA or other formal agreement should be in place and signed by both establishments (following the procedure described in section 5.2).

5.4.4. In some circumstances, it may be believed that the source organisation is unable or unwilling to provide or enter into a MTA or that the terms of transfer may be covered by another formal arrangement e.g. a research protocol, a collaboration agreement or service level agreement. **In**

these instances, advice must be sought from the DI, (or deputy DI or PDs) or from the Research and Enterprise Office in advance of any transfer to the CBE.

5.5. Transfer of HTA Licensable Material to an external organisation within England, Wales and Northern Ireland

5.5.1. Check to ensure that any consent under which the material was obtained by the CBE permits the material to be transferred and used by other research groups.

5.5.2. Check (using the link below) to ensure that the external organisation to whom HTA licensable material will be transferred to is operating in accordance with the HTA, including the status and any additional conditions of any HTA Licences or other relevant accreditation held https://www.hta.gov.uk/professional/establishments

5.5.3. Complete the Checklist for HTA Relevant Materials & append any relevant documents and submit to the Designated Individual.

5.5.4. Following review, the researcher/PI should submit to the Contracts Office.

5.5.5. The Contracts Team will draft the final MTA based upon the specific nature of the circumstances surrounding the sample transfer and the rights of the organisations and funding bodies involved.

5.5.6. The MTA will then be sent to the recipient organisation, requesting that they either sign two copies and return one to Research and Enterprise Office or summarize any questions or concerns they have regarding the MTA.

5.5.7. Once the terms of the MTA have been agreed, the MTA will be sent to the internal authorized signatories for sign-off. The Research and Enterprise Office will retain the signed copy of the fully executed MTA. An electronic copy of the fully executed MTA will be sent to each signatory.

5.5.8. To ensure that MTAs are controlled and a register of agreements maintained, each MTA should be issued a unique and sequential reference number which can be entered in the Procuro database. A copy of the MTA should be retained in the project specific master file.

5.5.9. The Research and Enterprise Office will provide notification of clearance for transfer of the HTA licensable material.

5.6. Transferring HTA Licensable Material to an external Service Provider within England, Wales and Northern Ireland

5.6.1. If HTA licensable material is to be transferred to an external commercial service provider a MTA and/or Service Level Agreement may be required. This will depend on whether the Service Provider has an HTA Licence or on how long the Service Provider needs to hold the material for the requested service/testing.

5.6.2. Advice should be sought from the dPD or the DI before transferring any HTA licensable material to an external service provider.

5.7. Transferring HTA Licensable Material to other licensed sites within Loughborough University

5.7.1. A MTA is not required for internal transfers between designated areas within Loughborough University; however materials must be transferred in accordance with local Health and Safety procedures.

5.7.2. Materials must be tracked and recorded from transfer to disposal according to existing arrangements for storage of HTA licensable material. The Procuro database register should be updated prior to transfer to record the reason for transfer, the storage conditions and use of the material.

5.8. Transferring HTA Licensable Material to an external organisation outside England, Wales and Northern Ireland (Export of Relevant Material)

5.8.1. Check to ensure that any consent under which the material was obtained by the CBE permits the material to be exported for use by other research groups.

Note: If the tissue is from the deceased and consent to export is not in place, the tissue must not be exported. If the donor did not consent to their tissue being sent abroad, it can only be exported if further consent is obtained from the donor or if the tissue is from the living and NHS REC approval is obtained to export the anonymised material.

5.8.2. To exert a measure of control over the transfer of material, to ensure that it is used within the terms of consent and that an audit trail is maintained, an MTA or other formal agreement should be in place and signed by both establishments (following the procedure described in section 5.5).

5.8.3. In some circumstances, it may be believed that the recipient organisation is unable or unwilling to provide or enter into a MTA or that the terms of transfer may be covered by another formal arrangement e.g. a research protocol, a collaboration agreement or service level agreement. . **In these instances, advice must be sought from the DI (or deputy DI or PDs) or from the Research and Enterprise Office in advance of any transfer to an external organisation from the CBE.**

5.9. Alternative Arrangements for Transfer

5.9.1. In some instances, it may be believed by the sending or receiving institution that the terms of the transfer of a material may be covered by another formal agreement e.g. a research protocol, a collaboration agreement or service level agreement.

5.9.2. In these circumstance researchers must be confident that the arrangement considers the minimisation of the likelihood of theft, damage or loss during transport, and should define how the human tissue is preserved, and any potential contamination risks associated with it and who is responsible for disposal if applicable.

5.9.3. **In these cases, advice must be sought from the DI (or deputy DI or PDs) or from the Research and Enterprise Office in advance of any transfer of material to or from the CBE.**

5.10. Authority to Acquire or Transfer HTA Licensable Material

5.10.1. An 'Authorisation to Acquire or Transfer HTA Licensable Material' Form must be completed and submitted to PI (or Person Responsible) and dPD for approval in advance of the proposed date for the transfer of any licensable material into or out of the CBE.

5.10.2. To ensure that records of acquisition or transfer of material is controlled a register is maintained, with each form given a unique and sequential number.

5.11. Transport of HTA Licensable Material

5.11.1. Check the pre-approved 'Risk Assessment for transportation of HTA licensable material' to ensure that and risk associated with the planned route and mode of transfer is acceptable and that the intended control measures are adequate for the circumstances of transfer.

5.11.2. If the HTA licensable material is to be transferred by a courier, check that the courier has been approved by the DI and that arrangements are put in place with the courier to ensure the appropriate conditions for transportation of the material.

Transport providers on the University supplier list:

- Diamond dispatch
- CBS couriers
- Biocair (these are expensive - it is advisable you obtain quotes from the other 2 first)

Note: The use of personal vehicles and public transport is discouraged.

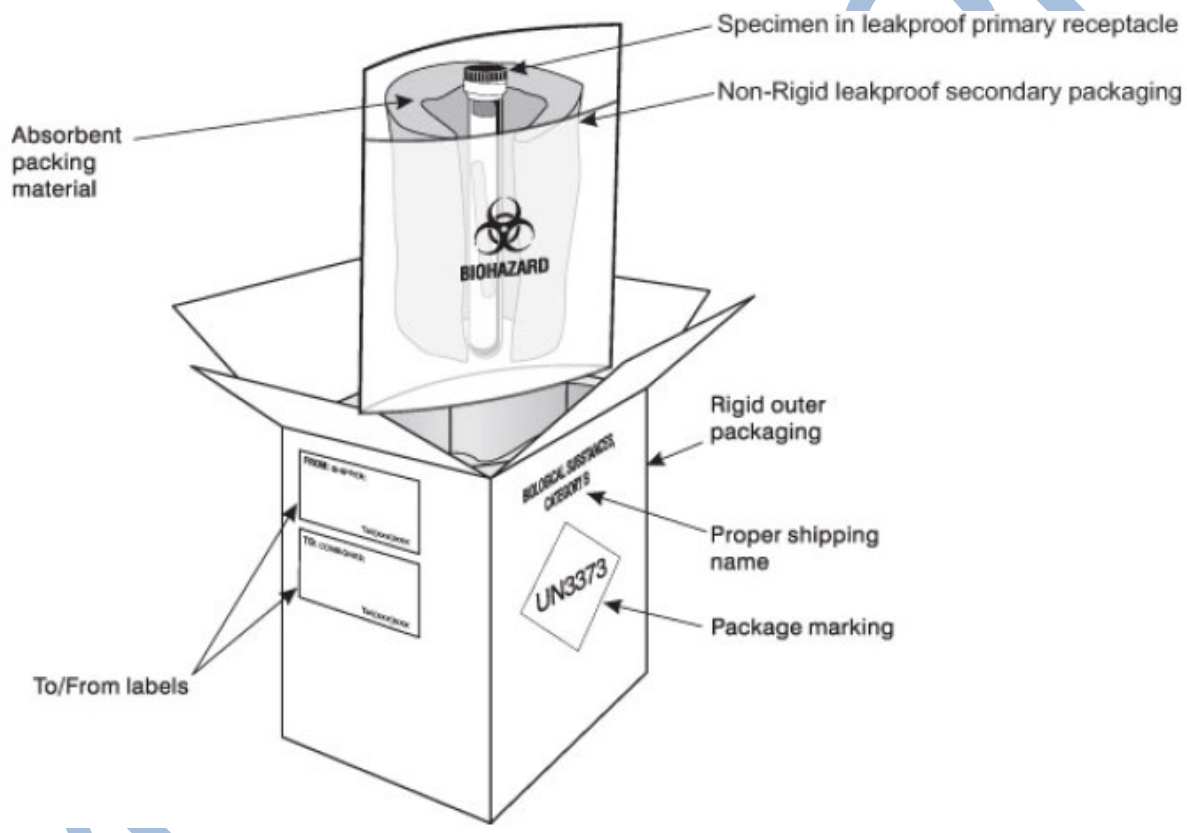
5.11.3. The individual responsible must ensure that the material is contained in a secure, leak-proof and break-resistant container to prevent contamination or exposure to infectious substances, as required under current 'hazardous goods' legislation. The person responsible should refer to the Biological Risk Assessment for the material, which contains information on the required shipping arrangements and packing instructions.

5.11.4. Pack the container into an appropriate secondary container and label with the appropriate approved human tissue sample hazard warning label (see example in Figure 1).

5.11.5. Appropriate documentation should be placed inside the package and should include the following information:

- Description and identification details of the material
- Address of source
- Address of destination
- Details of hazardous contents
- Contact numbers and addresses

Figure 1. Example of Packing and Marking for Category B Infectious Substances (Taken from IATA infectious substances guidance document)



5.12. Tracking transferred HTA licensable material

5.12.1. On completion of the transfer, the tracking record for each sample (i.e. Procuro Database) must be updated with the details of where it went, how much, when it was transported, who was responsible for the transport and receipt of the HTA licensable material and any planned return dates if relevant.

5.12.2. Records of transportation and delivery should be retained as evidence (e.g. signed delivery from courier, emails confirming satisfactory receipt by the receiving institution) in the project specific master file.

5.12.3. Arrangements should be made to ensure that the recipient of the HTA licensable material notifies the CBE when the material has been exhausted, disposed of or dispatched for return. This confirmation and date should be recorded in the tracking database.

5.12.4. Arrangements should be made to alert researchers to when a MTA expires so that any remaining material can be managed in accordance with the terms agreed in the original transfer agreement.

5.12.5. Any adverse and incidents associated with this procedure should be reported to the dQM or dPD and investigated according to local procedures.

5.13. Receipt of HTA Licensable Material

5.13.1. Materials should be only be accepted into the CBE according to local procedures for the management and control of incoming biological material, which ensures the acquisition and safe receipt, identification, quarantine, testing and appropriate disposition of biological materials in CBE laboratory facilities.

5.13.2. Materials should only be stored and used in accordance with the terms and conditions set out in the MTA.

5.13.3. Any adverse and incidents associated with this procedure (eg administrative discrepancies, damage to packaging or to material) should be reported to the dQM or dPD and investigated according to local procedures.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. HTA-PR-FORM/006 Loughborough University MTA template

6.2. HTA-PR-FORM/011 Authorisation to acquire or transfer HTA licensable material form

6.3. Specified documented records related to transport retained in project specific master file

6.4. Data entry into the Procuro electronic database

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	4th 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	2nd 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	6th December 2021 by C.Kavanagh	DCN0014	Updates to the MTA process including information about the outward and incoming forms & who to send for approvals. Updated the link to find establishments.	2.0
2.0	4th December 2023 by C.Kavanagh	N/A No change	Minor editorials only	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: 28.01.2018 Review approved by: Karen Coopman Date:13/12/2023

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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. We also acknowledge the contributions of Amit Chandra and Jen Bowdrey to the original draft versions of this SOP.

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