Title: RECEIPT AND STORAGE OF HTA LICENSABLE MATERIAL

Location: CBE Laboratories

1. PURPOSE

To describe the procedure for receipt, labelling, tracking and storing HTA licensable material for research to ensure the traceability, integrity and security.

2. SCOPE

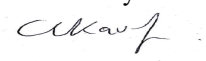
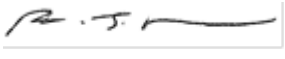
As part of the CBE Quality Management System (QMS) for research, this procedure applies to all persons involved in the receipt, labelling, tracking and storage of HTA licensable material under the University's HTA licence for research, in accordance with the requirements of the HTA legislation, the HTA Codes of Practice and the University's HTA Licence Compliance Quality Manual.

This SOP applies to all HTA licensable material placed in storage within designated temperature controlled storage units (incubators, fridges, freezers and LN2 cryostores) in all laboratories under the CBE Quality Management System . This includes temporary storage of relevant material incidental to transportation or material prior to processing that will render the material acellular or otherwise non-relevant (eg when cells in culture no longer contain original cells), even if it is held for less than 7 days prior to being processed or transferred to another establishment.

3. RESPONSIBILITIES

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

3.2. The Principal Investigator (PI) or Person Responsible (as delegated by the PI, and appropriately trained), as custodian of the material, is responsible for ensuring all licensable material is received, labelled, stored appropriately and entered on the CBE Procuro database

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

in accordance with the requirements of this SOP. The PI must ensure that any individuals delegated these responsibilities are suitably trained to undertake the tasks.

3.3. The dQM shall ensure that the labelling on all storage units used for HTA licensable material is accurate and up-to-date (including any contact names and numbers in the event of an emergency or adverse event), and aligns with the details held on Procuro sample register.

3.4. The dQM is responsible for ensuring that the records of holdings within the CBE are reviewed annually and crosschecked with appropriate consent, research protocols or material transfer agreements along with the location of the storage.

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. Pre-receipt and tracking of materials (including cell cultures)

5.1.1. All HTA licensable material must be logged under a project file on the Procuro database register prior to or at least within 48h of receiving the material. This will generate a unique identification code to ensure traceability of each specimen.

Note 1: The unique identification number is only generated when the log is created in Procuro. It is recommended that the log is created before receipt of the incoming material. If the quantities are unknown, extra spaces should be generated, which can deleted later if not required. This

will ensure that sufficient unique identification numbers are available for each sample to be logged.

Note 2: Samples are stored under a Project Name which must be created by the responsible authority for managing the database.

5.1.2. Liaise with the responsible authority for managing the database to set-up the Procuro register to record the details for each sample of material in the relevant database fields of the register. This will first create the 'Project' Information requiring the following:

- Project Title (must be unique),
- Project Principle Investigator and contact details,
- Research Project/Study Reference number (*to be used on all documentation relating to the project*)
- List of individuals who will have access to samples and information related to the project,
- Project expiry date (indicating whether sample will be retained or destroyed at the end of the project).

5.1.3. The following fields shall be used to track HTA licensable material throughout the procedure described in this SOP:

- Unique sample identifier (generated by Procuro),
- Specimen type/format and tissue site,
- Date of receipt and source/provider,
- Storage location – building/room/unit,
- Material Transfer Agreement (MTA) & Risk Assessment reference numbers,
- Consent details, as applicable (including where the written consent is held),

- Dates and details of sample processing (indicating if material is rendered non-relevant),
- Sample transfer, transfer location and date,
- Date and method of disposal,
- Reason for disposal.

5.1.4. As described in the following sections, the Procuro database register must be updated by individuals responsible for samples when samples are moved from one storage location to another or when samples are disposed of (e.g. at the end of a project/study).

5.2. Receipt and inspection

5.2.1. On receipt, inspect the primary and secondary packaging to ensure that the physical integrity of the material has been maintained during the transportation (including any temperature maintenance requirements).

5.2.2. Check the accompanying paperwork to verify that the administrative requirements specified in the biological risk assessment and/or the MTA has been received.

5.2.3. Check the labelling to verify the identity of the samples. Check that the correct samples have been received and the expected number of samples accounted for.

5.2.4. If there are there are discrepancies between the samples received and those expected or other administrative non-conformance or anomaly during transport, inform the provider and initiate corrective action.

5.2.5. If the material(s) is found to have been compromised during transfer, inform the provider and initiate an investigation following the local adverse event reporting procedure for HTA licensable material.

Note: Any material without appropriate ethical approval and legal agreements, etc. in place will be held under the University's HTA licence in the designated, secure storage units within the CBE under the control of the dQM. Access to or use of the samples shall be prohibited until all appropriate documentary evidence is available.

5.3. Labelling

5.3.1. If possible, label each sample of HTA licensable material (and their derivatives) with a unique code for identification purposes and to ensure traceability. The unique sample number must not contain donor/patient identification.

NOTE: It is **CRUCIAL** that any key information (lot numbers/batch numbers etc) on stored samples is transcribed exactly into Pro-curo to ensure we can cross-reference.

NOTE : Please use the specific labels available for use on frozen samples if required.

NOTE: Please write on vials with lab marker legibly or use specific labels for cold storage. Label **each** vial not just the bag/box..

5.3.2. Each coded label must be securely affixed to the sample container, be in a legible condition and suitable for the storage conditions in which the sample is to be held.

5.3.3. All individual, uniquely identifiable samples must be stored in an orderly and consistent manner and be easy to locate in designated storage units. Individual samples should be grouped in trays/racks to prevent loss/ mix-ups or damage when removed. The location of each sample within a tray (sample position number) should be recorded according to local procedures.

5.3.4. Any external containers (e.g. in sarstedt boxes) should be labelled with the unique project/study code. The labelling must enable the identification of the PI or Person

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Responsible, as custodian of the samples. Consideration should be given to the inclusion of the type(s) of material, the sample number range contained within and the date of acquisition if appropriate.

5.3.5. Transfer the samples to the appropriate designated quarantine storage area and complete the Part A & Part B of the 'Acquisition and Receipt' form according to local procedures.

5.3.6. Submit the acquisition & receipt form together with any received paperwork to the dQM. Release from quarantine shall be subject to approval by the dQM (as recorded in Part C of the 'Acquisition and Receipt' form) before samples can be moved. Update Proc-curo.as required.

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

5.4. Storage and/or processing of material

5.4.1. Non-conforming material that is not approved for release shall be subject to further review to determine whether the material should be:

- Reworked, reprocessed or tested to meet the specified requirements
- Accepted as is
- Returned to the provider
- Destroyed

5.4.2. On approval for release from quarantine, material should be transferred to storage prior to processing or otherwise processed immediately.

5.4.3. Transfer the material to one of the temperature controlled designated storage areas (or designated racks, trays or boxes within these units) for HTA licensable material identified below:

- HTA material incubator (**Inc-HTA**), located in Room CBE/H-XX (variable)
- HTA material -80 Freezer (**80Fre-HTA**), located in Room CBE/H34
- HTA material -20 Freezer (**20Fre-HTA**), located in Room CBE/H30
- HTA material 2-8C Fridge (**4Fri-HTA**), located in Room CBE/H17
- HTA material 2-8c Fridge **(4FRI-HTA),** located in Room T208b (Wolfson School)
- HTA material cryostore (**Cryo-HTA**), located in Room CBE/H31

Note 1: Designated storage units should be labelled to indicate that they contain human samples held under the Loughborough University HTA Licence, and include the licence number and contact details for the custodian of the samples.

Note 2: Storage units containing HTA licensable material are located in rooms within CBE laboratories that are access-controlled (including card-controlled access to the building and the CBE) and accessible only to authorised personnel. Access to T208b is key access only.

5.4.4. If the material is removed from quarantine for immediate processing, any derived material if still identified as HTA licensable material (eg cell cultures still containing original cells) must be labelled, tracked and stored according to this SOP to ensure traceability

5.4.5. Update the relevant fields of the database register with the storage location and/or any actions relating to non-conforming material or details of any processing (indicating if material is rendered acellular or otherwise non-relevant).

5.5. Removal of material from storage

5.5.1. If the material (part or all) is removed from storage for transfer to another organisation or location within the CBE or Loughborough University campus, it must be transferred according to local procedures for the transport of HTA licensable material (CBE/HTA-PR-SOP006).

5.5.2. If the material is removed from storage for processing, any derived material if still identified as relevant material (eg cell cultures still containing original cells) must be labelled, tracked and stored according to this SOP to ensure traceability.

Note: Cell cultures which contain cells that were created inside the human body (eg original cells from a biopsy or blood sample) are considered to be relevant material and are stored under a licence from the HTA. Once cells in culture have divided outside the human body they are no longer considered to be relevant material. Researchers will need to make a judgement (and be able to justify it) as to when cells in culture no longer contain original cells.

Records of storage and use of all cell cultures containing original cells must be maintained by the researcher to ensure traceability.

5.5.3. If the material is removed from storage for disposal (eg at the end of a project/study), it must be disposed of according to local procedures for disposal of HTA licensable material (CBE/HTA-PR-SOP007).

5.5.4. Update the relevant fields of the database register with the dates and details of the transfer, processing (indicating if material is rendered acellular or otherwise non-relevant) or disposal of the material.

5.6. Contingency plans

5.6.1. In the event of a storage unit breakdown, alarm failure or power failure, local contingency arrangements, detailed in CBE/HTA-MI-SOP010, must be activated.

5.6.2. Individuals responsible for responding in the event of an alarm or system failure must follow the local adverse event reporting procedure for HTA licensable material.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. HTA-PR-FORM/007 - Acquisition and Receipt Form

6.2. Specified administrative documents related to acquisition and receipt retained in project specific master file

6.3. 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.

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Standard Operating Procedure CBE/HTA-PR-SOP004

Title: RECEIPT AND STORAGE OF HTA LICENSABLE MATERIAL

Location: CBE Laboratories

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 made Minor editorial only including revision details.	1.0 New version not required
1.0	2nd February 2019 by C.Kavanagh	002	**Added this to section 5.3** **NOTE:** It is **CRUCIAL** that any key information (lot numbers/batch numbers etc) on stored samples is transcribed exactly into Pro-curo to ensure we can cross-reference. **NOTE :** Please use the specific labels available for use on frozen samples if required. **NOTE:** Please write on vials with lab marker legibly or use specific labels for cold storage	2.0
2.0	2nd December 2019 by C.Kavanagh	006	Annual review Updated Scope to say that it includes all laboratories under the CBE Quality Management system. This now includes T208b CL2 lab in the Wolfson School. Added location of HTA storage unit in T208b Added to say label each vial not just the bag/box	3.0
3.0	6th December 2021 by C.Kavanagh		No amendments made Minor editorials only	3.0
3.0	4th December 2023 by C.Kavanagh		Minor editorials only .New review date .	3.0

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SOP Withdrawal Date:	

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 to the original draft versions of this SOP.

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