Standard Operating Procedure **CBE/HTA-PR-SOP007**

Title: DISPOSAL OF HTA LICENSABLE MATERIAL

Location: CBE Laboratories

1. PURPOSE

To describe the procedure for the disposal of HTA Licensable Material to ensure that the material used for research is disposed of responsibly and with due care and respect.

2. SCOPE

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all individuals involved in the 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 includes material no longer required for use or stored for any research activity (a scheduled purpose); surplus material from processing, material whose integrity/quality has been compromised or where the MTA dictates that material must be destroyed at the end of the research project or as a result of an annual review of records of holdings.

3. RESPONSIBILITES

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

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 disposal of HTA licensable material.

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by C.Kavanagh Date: 08/12/2025	Reviewed by: R.Thomas Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Review approved by: K Coopman Date: 09/12/2025

3.3. Individuals proposing to dispose of HTA licensable material are responsible for completing the 'Authorisation to Dispose of HTA Licensable Material' Form prior to disposal 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 disposal of any material. The PI must ensure that any individuals delegated these responsibilities are suitably trained to undertake the tasks.

3.5. 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. If any samples have reached the date due for destruction and no additional consent has been obtained to retain the samples, the dQM shall liaise with the PI, to ensure that are disposed of in an appropriate manner.

4. REFERENCES

The Human Tissue Act (2004) and Code E: Research | Human Tissue Authority

The University HTA Licence Compliance Quality Manual

The CBE Quality Manual

5. PROCEDURE

5.1. Once HTA licensable material has been identified for disposal, the 'Authorisation to Dispose of HTA Licensable Material' form' must be completed and submitted to the PI (or Person Responsible) and dPD for approval in advance of the proposed date for disposal.

Note: This is to ensure that disposal is undertaken in accordance with any conditions of donor consent or ethical approval or as defined in the material transfer agreement (MTA).

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

5.3. Once authority to dispose of the material has been obtained, check the Biological Risk Assessment and/or MTA for the material(s) and/or any other available documentation to determine the appropriate route and method of disposal.

5.4. Unless otherwise specified, the HTA licensable material should be disposed of as clinical waste for incineration in accordance with current waste legislation and local waste procedures.

5.5. Wherever practicable, HTA licensable material should be collected in separate containers/bags marked for disposal of HTA Licensable Material to ensure that the material is kept separate from non-human and other laboratory clinical waste.

5.6 Ecoloc sharps boxes should be used for the disposal of tubes/vials containing residual amounts of blood.These are for HTA use only and will be labelled. Once these are 2/3 full they will securely locked and transported using secondary containment to the Holywell Park Waste Compound and placed in the designated area for Ecoloc boxes awaiting collection from the external contractor. Pro-curo must be updated and HTA-PR-FORM-012 Authorisation to Dispose of HTA Licensable Material must be completed before disposal occurs if you are disposing of reasonable amounts of blood in the vials which is still classed as HTA Relevant at that point.

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5.7. The HTA licensable material should be transferred to the designated, secure storage area in the CBE prior to treatment (as applicable) and disposal.

5.8. On the day of collection, the clinical waste shall be placed in the large clinical incineration bin (which should be kept locked at all times) and transferred to the waste cage in the Holywell Park Courtyard for collection by the University external contractor.

5.9. In accordance with local procedures for storage and tracking of HTA licensable material, the following information must be recorded in the relevant fields of Procuro sample register for each sample of material (identified by its unique identifier):

- Date of disposal
- Date of sterilisation, autoclave ID, cycle number (as applicable)
- Consignment note number (as applicable)
- Person responsible for disposal
- Storage location prior to storage
- Method of disposal (route and place *eg virkon sterilisation then sink*)
- Date of sterilisation, autoclave ID, cycle number (as applicable)
- Amount of material disposed of
- Reason for disposal

5.10 Records of consignment/transport should be copied and retained in the relevant project specific master file.

5.11. When disposal of HTA licensable material is being undertaken at the end of a project the PI or Person Responsible should inform the organisation from which the material originated if this is

required as part of the MTA. When this is the case, a written record (eg email, letter) must be retained in the relevant project specific master file.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. Authorisation to Dispose of HTA Licensable Material Form – HTA-PR-FORM/012

6.2. Data entry into the ProCuro electronic database after every procedure

6.3. Specified documented records related to waste consignment

6.4. Written record of confirmation of disposal to provider (as applicable)

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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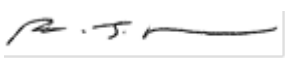
SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4th December 2017 by C.Kavanagh	N/A No change	No Amendments required 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 required Minor editorial only including revision details	1.0 New version not required.
1.0	April 2021 By C.Kavanagh		Added this section : 5.6 Ecoloc sharps boxes should be used for the disposal of tubes/vials containing residual amounts of blood.These are for HTA use only and will be labelled. Once these are 2/3 full they will securely locked and transported using secondary containment to the Holywell Park Waste Compound and placed in the designated area for Ecoloc boxes awaiting collection from the external contractor.	2.0
2.0	6th December 2021 by C.Kavanagh	N/A no change	No Amendments required	2.0
2.0	4th December 2023 by C.Kavanagh	N/A No change	No Amendments required	2.0
2.0	8th December 2025 by C.Kavanagh	N/A no change	No Amendments required	2.0

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by C.Kavanagh  Date: 08/12/2025	Reviewed by: R.Thomas  Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Review approved by: K Coopman  Date: 09/12/2025

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SOP Withdrawal Date:	

Document Control

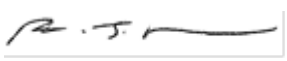
The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their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

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by C.Kavanagh  Date: 08/12/2025	Reviewed by: R.Thomas  Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Review approved by: K Coopman  Date: 09/12/2025