University HTA Licence Compliance Quality Manual

This document together with a set of specified procedures represents the Quality Management System for the control of Human Tissue Authority (HTA) licensable activity. This system is compliant with the Human Tissue Act (2004) and HTA standards and guidance.

Version History

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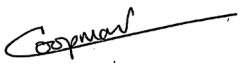
Approved by	**Prof Karen Coopman**

Signed:  **Date: September 2025**

Authorisation and Document Control

The Quality Manual and Standard Operating Procedures (SOPs) will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual is Chair of the HTALSC and has overarching authority for the Quality Management System. Any revisions to documentation will be communicated to staff members by the appropriate Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, Quality Manager or their Supervisor immediately.

Security Statement

This document is the intellectual property of Loughborough University and as such, must not be circulated outside of the University without the written approval from the University Quality Manager and the Designated Individual for the HTA Licence.

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1 Purpose and Scope

The University has an international reputation for research and teaching in the biological sciences. The University acknowledges its responsibilities to adhere to all applicable regulatory and licensing standards connected with research and teaching that involves the acquisition, storage, use and disposal of human tissue. Procedures are in place to ensure the University meets the Health, Safety and Environmental requirements associated with such activities.

This document describes the policy and procedures relating to the acquisition, use, storage and disposal of human tissue at Loughborough University for the purposes of research to comply with the requirements of licensing in accordance with the Human Tissue Act (2004).

These procedures apply to all relevant research carried out within Loughborough University, which is currently limited to activities within the School of Sport, Exercise and Health Sciences (SSEHS), Centre for Biological Engineering (CBE), Department of Chemistry and School of Design & Creative Arts, as well as the storage of skeletal material held within SSEHS for the purposes of teaching anatomy. Research in the biological division of the SSEHS is dedicated to advancing knowledge and expertise in the areas of sport performance; health, physical activity and the prevention of chronic disease; and physical activity and education. Research in the CBE is more focussed on developing cell-based therapies (although no human application is carried out) and the Department of Chemistry is primarily focussed on development of analytical techniques that help us interrogate human samples. Research in the School of Design & Creative Arts is dedicated to environmental ergonomics research by advancing knowledge and expertise in the areas of sport and occupational performance, health, and the prevention of chronic disease.

The University does not intend to use tissue for donor selection or human application, or to distribute human tissue. The scope of research within the University is kept under review and this quality manual and accompanying documentation must be updated to reflect any changes.

2 Legislation and Regulation

The Human Tissue Act (2004) provides the regulatory framework for the acquisition, use, storage and disposal of human tissue for research. An establishment must hold an appropriate licence for the activity that it is engaging in. The provisions of the licence will vary in accordance with the activity. Therefore, it is essential that the appropriate codes of practice are adhered to.

Loughborough University holds a research license, licence number - 12577

- The HTA is currently the competent authority enforcing this legislation and requires the storage of ‘relevant material’ from either the living or deceased to be regulated through licensing, subject to certain exceptions as below:

- HTA Code of Practice and Standards E: Research- Annex B and C.

- ‘Relevant material’ held for a specific research project approved by a ‘recognised’ ethics authority[1]* for the duration of the project.
- ‘Relevant material’ procured from a HTA licensed tissue bank, provided that its intended use is for research which falls in the category of approval of the tissue bank from which it was acquired.
- ‘Relevant material’ intended for transportation or awaiting processing to render it acellular, providing that the duration of storage is a matter of hours or days and certainly no longer than a week.
- ‘Relevant material’ from a deceased person, if more than 100 years have elapsed since the person’s death.

Within the Human Tissue Act ‘relevant material’ is limited to material which consists of or includes human cells (see Materials considered to be relevant under the Human Tissue Act (2004)). Relevant material includes: human bodies, internal organs and tissues, skin and bone, bodily waste, cell deposits, tissue sections, plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process). Storage of materials such as serum and plasma are not subject to licensing, however since they are obtained from ‘relevant material’ they are subject to the consent requirements of the Human Tissue Act and HTA policies and guidance.

DNA (as opposed to the ‘bodily material’ from which it originates) is not considered to be ‘relevant material’ under the Human Tissue Act. ‘Bodily material’ differs from relevant material as it includes hair, nails and gametes. Holding ‘bodily material’ with the intention to analyse its DNA without qualifying consent is an offence unless a specific exemption has been granted by the HTA.

The consent requirements of the Human Tissue Act are not retrospective. This means it is not necessary to obtain consent for material held when the Human Tissue Act came into force on 1 September 2006. This does not affect the necessity for a licence to store such material.

3 Policy

HTA licensable activity should be carried out to the highest standards in accordance with current legislation and national and local ethical and clinical guidance including:

- HTA Codes of Practice and Standards with particular reference to Code of Practice A; Guiding Principles and the Fundamental principle of Consent ; Code of Practice and Standards E, Research.
- General Medical Council guidance on the ethical considerations relating to seeking patients’ consent

[1]* Established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments or an ethics committee recognised by United Kingdom Ethics Committee Authority to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials Regulations 2004). N.B. Loughborough University Ethics Review Sub-Committee does not satisfy this criteria.

- Medical Research Council which provides practical help with legislative and good practice requirements
- Health Research Authority on the use of human tissue in research
- UK Clinical Research collaboration which provides regulatory and governance advice
- Loughborough University Ethics Review Sub-Committee (ERSC)
- Loughborough University ERSC Guidance for Investigators

Compliance with these standards involves all staff that work with human tissue, who are individually responsible for the quality of their work, continuously striving to improve the quality of the research environment and adhere to best practice. To achieve and maintain the required level of quality assurance Loughborough University HTALSC will:

- Operate a Quality Management System to integrate the organisation procedures, processes and resources for the control and management of HTA licensable activity.
- HTALSC will report to Loughborough University Ethics Committee (LUEC) annually.
- Set quality objectives to implement and maintain the system.
- Ensure that appropriate staff and students are familiar with the system.
- Ensure that appropriate staff and students who may be involved in the use of human tissue are trained appropriately and this is recorded.
- Ensure that appropriate staff, equipment, and resources are available to run the system.
- Ensure that data collected from researchers is held confidentially, used only for monitoring research activity, and is not shared with other organisations without the agreement of the researchers and in-line with the Licence.
- Undertake internal audits of the system to monitor compliance and continuously improve the quality of the system.

4 Governance Framework

4.1 Key Roles and Responsibilities

Licence Holder (LH) – Loughborough University
Contact: Mr Richard Taylor, Chief Operating Officer

Designated Individual (DI) Professor Karen Coopman, Professor of Biological Engineering: K.Coopman@lboro.ac.uk

Persons Designated (PD) – Prof Owen Davies, Senior Lecturer in Molecular and Regenerative Biomedicine: O.G.Davies@lboro.ac.uk.

Dr Jim Reynolds, Reader in Analytical Chemistry (Department of Chemistry): J.C.Reynolds@lboro.ac.uk

Prof Rob Thomas, Professor of Manufacturing for Cell and Gene Therapies (CBE, School of Mechanical, Electrical and Manufacturing Engineering): R.J.Thomas@lboro.ac.uk

University Quality Manager and Research Governance -	Sidrah Khan, Head of Quality and Policy (Research and Innovation office): s.khan@lboro.ac.uk
Departmental Quality Managers –	Mr Tony Goodall, Technical Resources Manager (dQM) (SSEHS): T.Goodall@lboro.ac.uk Dr Calum Greenhalgh, (Department of Chemistry): C.Greenhalgh2@lboro.ac.uk Carolyn Kavanagh:C.L.Kavanagh@lboro.ac.uk (CBE, School of Mechanical, Electrical and Manufacturing Engineering) : Matthew Maley, (School of Design & Creative Arts)
Research Governance –	Sidrah Khan (Research and Innovation) s.khan@lboro.ac.uk
Human Tissue Act License Sub Committee –	Membership includes: DI (Chair), QM, PDs, dQMs, Secretary (Research Governance Officer), Research & Innovation Office, University Biological Safety Officer, representative from Loughborough Design School.
Section HTA Senior Management Team –	PD, dQM, representatives from academic and technical staff who use the laboratories. One per School. Loughborough Design School staff will work under the SSEHS HTA Senior Management Team.
Principal Investigator –	Nominated for each study involving human participants or human tissue

4.1.1 **Corporate Licence Holder (Loughborough University)**

The licence holder, with the consent of the DI makes the HTA licence application. They have the right to apply to the HTA to vary the licence which enables them to substitute another person as the DI and allows the establishment to cover circumstances where the DI is unable or incapable of overseeing the licensable activities.

4.1.2 **Designated Individual (DI)**

The Designated Individual is the person under whose supervision the licensed activity is authorised. They have the primary (legal) responsibility under the Human Tissue Act to ensure:

- Suitable practices are used in undertaking the licensed activity
- Any other persons who work under the licence are suitable
- The conditions of the HTA licence are complied with

It is noted that any change in DI must be formally agreed with the HTA but that under exceptional circumstances (e.g. short-term ill health) the HTA allow arrangements to be made which authorise the PD(s) to oversee the day-to-day activities of the license. In the case of Loughborough University, each PD will become responsible for their area in this instance.

4.1.3 Persons Designated (PD)

The Persons Designated role is to support the DI in operational tasks; however, they cannot relieve the DI of their statutory responsibilities.

4.1.4 University Quality Manager (QM)

The University Quality Manager is responsible for oversight of the University level Quality Management System documentation.

4.1.5 Departmental Quality Manager (dQM)

The departmental Quality Manager is responsible for the day-to-day management of the Quality Management System within the Schools and to make sure that in conjunction with the DI and PDs they manage the internal auditing process. The dQMs will ensure that any local documents comply with the University Quality Management System and can refer to the QM for advice and support in this. In addition, the dQM in SSEHS assumes the responsibilities normally undertaken by the principal investigator of a study, for the storage and use of skeletal material held for teaching anatomy within this School.

4.1.6 Research Governance

The research governance of HTA will reside in the Research and Innovation Office with Sidrah Khan leading and a member of RIO supporting. The role is responsible for advising on HTA related matters, administrating the HTASLC governance meeting and for auditing HTA activities across the university.

4.1.7 Section HTA Senior Management Teams

Each Section (i.e. SSEHS, CBE or Chemistry) HTA Senior Management Team (SMT) is responsible for the management and maintenance of the laboratories within that Section with regards to HTA compliance. The School Senior Management Team of the School in which the laboratory resides (Dean, ADRIs, and Ops manager) have ultimate responsibility for ensuring that the laboratories conform to and are compliant with current legislation and University Health and Safety Policies including the Quality Management System and HTA. It is the responsibility of the Section HTA Senior Management Team to liaise with or make representation to the School Senior Management Team if changes are needed, with support of the DI as necessary.

4.1.8 Principal Investigator

The Principal Investigator is the person responsible, individually or as the leader of a team, for the conduct of a study. They are responsible for ensuring the research is conducted in accordance with legal requirements and University Policies including the Quality Management System. The Principal Investigator is responsible for sample integrity and participant welfare, including following appropriate procedures, record keeping, and reporting any adverse events. They may report any issues directly to the HTALSC.

4.1.9 Hierarchy of Governance

The DI will communicate with the HTA regarding the licence on behalf of the License Holder (Loughborough University). The HTALSC will meet bi-annually but may be convened by the Chair (DI) at any time should the need arise. The Committee reports to Loughborough University Ethics Committee (LUEC) which is responsible for all ethical issues relating to the University. LUEC

meets three times a year, and delegates responsibility for all ethical applications and issues relating to human participants to the Ethics Review Sub-Committee (ERSC). The ERSC meets twelve times each year. LUEC reports to The Council and The Senate annually. The DI interacts with the ERSC to ensure that ethics proposals capture all required information on key HTA matters such as consent.

The Section HTA Senior Management Teams are responsible for ensuring the laboratories within the School meet the requirements of staff and the University, with regards to compliance with the Human Tissue Act legislation and working with their School Senior Management Teams. These teams report to the HTALSC. The PD and dQM who sit on the HTALSC and on the Section HTA Senior Management Team, have additional operational responsibilities associated with the Quality Management system as outlined above. Each individual member of staff has responsibility for their own work and work of their students, including identifying non-compliant practices and recording these instances such that corrective action can be taken.

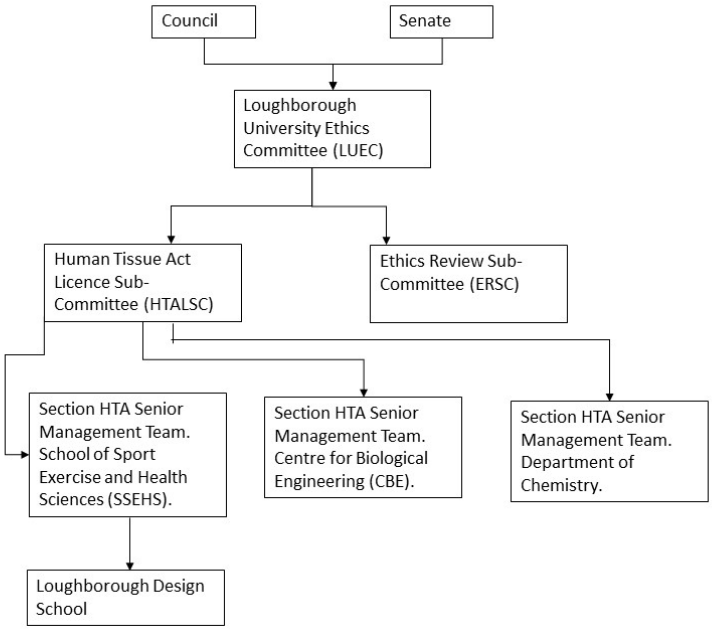

Figure 1: The Governance Structure for The Quality Management System.

5 Organisation and Design

5.1 Control of HTA licensable activity

Human tissue stored under the University HTA licence will be subject to a high level of control at all points, from acquisition through to disposal. Samples will be stored in appropriate facilities to ensure the continued high quality of the sample, that there is restricted access to them and ensure that they are used legitimately.

- Unfixed fresh (i.e. non-preserved or non-processed) human biological samples and biofluids present a potential biohazard. This risk will be minimised by only using tissue from participants known not to be in high-risk groups (according to the World Health Organisation criteria).
- Stored samples will be coded with a unique identifier and no information directly revealing the identity of the participant will be present on the stored sample. Where samples are coded by Loughborough University access to information linking the code and the participant identity will be controlled.
- The University may anonymise samples or receive anonymous samples, where the consent process included information regarding the planned anonymisation of samples or the study including the anonymisation process has been approved by a 'recognised' ethics authority[1]*.
- Appropriately qualified and trained staff, in compliance with current health, safety and environmental regulations, will manage the stored samples.
- Samples will be tracked and traceable from acquisition to complete use, anonymisation or destruction.
- Unless otherwise regulated by law, the University will classify human tissue samples as gifts, the acquisition, storage, use and disposal of which are conditional and subject to prior consent from the donors.
- The Principal Investigator, or dQM in the case of skeletal material used for teaching anatomy, will act as custodian for the samples.
- HTA licensable human tissue samples under the custodianship of the University will have a chain of custody to include a record of use. This will provide assurance that they were used according to the informed consent and enable the University to trace the sample (up to the point of use, anonymisation or destruction), should a donor withdraw consent.
- Contingency plans are in place regarding the planned location of storage in the event of facility or appliance failure at each of the 3 sites across campus:
    - SSEHS – back up generators are in place which can be deployed
    - Dept of Chemistry – samples to be transferred to SSEHS
    - Centre for Biological Engineering – a spare -80C freezer is in place or samples will be transferred to SSEHS. A back up generator is also in place which can be deployed when required.
- Material transfer agreements for samples acquired either through collaborative research or commercial arrangement will include safeguards to ensure the sample collection and chain of custody complied with the Human Tissue Act and HTA policies and guidelines.
- The HTALSC will carry out bi-annual risk assessments to review the Quality Management System status with reference to future development and/or changes in research activity and scope within the University (and update the system to reflect such activity).
- Remote working arrangements during COVID-19 and moving forward:
    - Provision will be made to hold licence meetings virtually to enable all staff to participate even if working remotely.
    - During extensive University closures, dQMs will make arrangements with their Operations manager and/or security to ensure that buildings where HTA material is stored continue to be monitored and temperature monitoring of relevant fridges/freezers is continued.
    - Staff in sections 4.1.1- 4.1.6 will continue to be available for HTA related matters as per their normal working patterns by phone, e-mail or alternative system (e.g.

TEAMS) unless specific alternative arrangements have been made (e.g. in case of illness).

5.2 Documentation and Version Control

The Quality Management System is outlined within this document, the Quality Manual. The actual processes and controls applied are described in a series of university level SOPs. Generic forms are available for transportation of human tissue, consent, and complaints processes. All the documents are controlled and available for staff on the University network.

All documentation relating to the Quality Management System is revised and reissued as necessary and all obsolete versions removed from the network, where the latest versions are available. Responsibility for the control of documentation lies with the University QM. All changes are reviewed and approved by the HTALSC. All appropriate staff will be informed when documents are updated by email. Master copies will be retained and archived by the University QM to document changes.

5.3 Consent Process

5.3.1 Requirement for Consent

In the Human Tissue Act consent is the central tenet of lawful removal, storage, and use of 'relevant material'. The Human Tissue Act specifies whose consent is required in all relevant circumstances and there are different consent requirements which apply when dealing with tissue from the deceased and tissue from the living (see Schedule 1, Human Tissue Act). The consent requirements of the Human Tissue Act are not retrospective. This means it is not necessary to obtain consent for 'relevant material' held when the Human Tissue Act came into force on 1 September 2006. Whatever the date the tissue was donated for research, if more than 100 years have elapsed since a person's death, consent to undertake research on their tissue is not required.

The University does not intend to acquire consent for use of 'relevant matter' from the deceased and therefore this is not addressed. The Quality Management System includes a process to update/add procedures and documentation required due to changes in the scope of the University's activities.

Tissue from the living may be stored for use and/or used without consent for education or training relating to human health (including training for research into disorders, or the functioning, of the human body). See Annex B -. Code of Practice A: Guiding Principles and the Fundamental principle of Consent

'Relevant material' from the living may be stored for use and/or used without consent for research purposes, provided that:

- The researcher is not in possession, and not likely to come into possession, of the information that identifies the person from whom it has come (N.B. Data about the tissue does not have to be permanently or irrevocably unlinked), AND
- The research is approved by a 'recognised' ethics authority[1]*. N.B. The University Ethics Review Sub-Committee (ERSC) is not, for the purpose of consent exception, considered to be a 'recognised' research ethics committee.

In ALL other circumstances informed consent is required before 'relevant material' may be stored or used for research purposes. Consent is normally required to use identifiable patient data in research and in general, obtaining consent is preferable to developing complex systems for keeping samples unlinked.

Informed consent is usually required for DNA analysis however there are circumstances in which non-consensual DNA analysis may be performed to obtain information for scientific or medical purposes. Consent for DNA analysis and the offence of non-consensual DNA analysis).

5.3.2 Valid Consent

The Human Tissue Act does not generally give details of when and how consent should be sought or of what information should be given. However, consent underpins much of the remit of the HTA and guidance on these issues is provided in the Code of Practice A; Guiding Principles and the Fundamental principle of Consent, including guidance on the closely related issues of communication and consultation with individuals, and where appropriate their families, which must support the consent process.

For consent to be valid it should be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. To make an informed choice, the person should understand; what the activity involves, and where appropriate, what the risks are. There should be an opportunity for individuals, including their families where appropriate, to discuss the issue fully and ask questions. Consent is only valid if proper communication has taken place and particular consideration should be given to individuals whose first language is not English, or individuals who have language, literacy or hearing difficulties.

5.3.3 Capacity to Consent

Children may consent to the storage and use of their tissue if they are 'competent' to do so. A child who has sufficient intelligence and understanding to enable them to fully understand what is involved is considered to be 'competent' to give consent according to previous case law (Gillick case). In these circumstances it is good practice to involve the person who has parental responsibility in the decision-making process, however, it should be emphasised the decision to consent must be the child's. Information about a 'competent' young person should only be disclosed to the person with parental responsibility for the child with the child's consent and it is essential to make sure that the child has not been unduly influenced by anyone else. Where a child is not 'competent' to give consent, and has not made a decision either way, a person with parental responsibility as defined under the Children Act (1989) may give consent on their behalf.

If an adult is competent, only they are permitted to give consent. The Human Tissue Act (2004) does not specify the criteria for considering whether an individual has capacity to consent. Under the Mental Capacity Act (2005) a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

- Understand the information given to them that is relevant to the decisions
- Retain that information long enough to be able to make the decision
- Use or weigh up the information as part of the decision-making process
- Communicate their decision by any means

Full guidance on how the Mental Capacity Act defines capacity and how it should be assessed is given in Chapter 4 of the Mental Capacity Code of Practice.

Research involving adults who lack the mental capacity to consent themselves may be beneficial to them or others in similar conditions. It is therefore important that these adults are given the opportunity to participate in such research, however certain safeguards need to be in place. For detailed information about research involving adults who cannot consent, refer to the Medical Research Ethics guide. Their participation needs to be agreed by someone who is independent of the study and who can assess the potential participant's interests in accordance with current legislation and guidance. This person may be a relative, a carer or an independent representative. Studies involving adults who lack the capacity to give informed consent must have ethical approval from an 'appropriate body' recognised by the Secretary of State under the Mental Capacity Act. NHS RECs and the HRA Social Care REC are recognised as appropriate bodies. The University ERSC is not recognised as an appropriate body.

5.3.4 Scope of Consent

Consent may differ in its scope. According to the code it is good practice to request generic consent for research, thus avoiding the need to obtain further consent in the future. It is still important however that consent is valid. If the intention is to store the tissue for an as yet unknown research purpose or as part of a tissue bank for research then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of. Consent may be enduring or time-limited.

If there is a desire to use previously collected tissue for research outside the scope of the original consent and/or ethics committee approval, the Principal Investigator should request new ethics approval prior to commencement of the research. The ethics approval will normally be conditional of new/updated consent from the participants.

5.3.5 Withdrawal of Consent

Participants have the right to withdraw their consent to the use of their sample(s), and have their sample(s) destroyed, until such time as the sample(s) has been fully used or anonymised. Withdrawal should be discussed at the outset when consent is being sought and the practicalities of withdrawing consent and the implications of doing so made clear. Withdrawal of consent cannot be effective where tissue has already been used. If someone withdraws consent for samples to be used in any future projects, the sample(s) should be destroyed, but this does not mean that information and research data should be withdrawn from any existing projects. Researchers should implement a consent withdrawal template and follow the withdrawal of consent process as outlined in relevant university or School local level SOP's.

5.3.6 Other Relevant Legislation

It is important to be aware that in addition to the consent provisions of the Human Tissue Act (2004) the common law duty of confidentiality, the Data Protection legislation and Freedom of Information Act must be adhered to. In addition, when transporting HTA relevant material between organisations under the conditions set out in the Material Transfer Agreement (MTA), also be aware that the carriage of dangerous goods and use of transportable pressure equipment regulations (2009) must also be adhered to.

The University will comply with all applicable laws and regulations on privacy and personal data protection. Data protection laws do not apply to information generated from, or attaching to, tissue samples that are anonymous at the point of receipt by the University, or if they are subsequently anonymised by the University.

Samples of HTA licensable material and derived data will be coded and de-identified, or anonymised, in order that either no, or a controlled minimum number, of university staff will have access to information required to identify an individual participant with a particular sample. In order to protect the participant, any use or processing of the samples and their derived information, either within or on behalf of the University, will be subject to rules of confidentiality, equivalent to those required of healthcare professionals.

Transfer of data to third parties for research purposes will only be possible where informed consent allows and when allowed by law. The consent process should include written informed consent that the participant accepts the University may seek intellectual property protection relating to research results conducted using their donated samples and that the University may seek to publish the results in conjunction with the results from other participants, provided that no individual participant will be identifiable.

Samples of HTA licensable material acquired from third party companies and/or academic laboratories require Material Transfer Agreements (MTA's) to include measures to ensure the collection process, anonymisation (if relevant) and the chain of custody complied with the requirements of the Human Tissue Act.

Transfer of HTA relevant materials between organisations within the UK or overseas will take place in accordance to the guidelines set out by the HTA. Material shall not be sent to a non-licensed establishment with the exception of overseas transfer as the HTA do not legislate overseas. In this instance all local rules and regulations should be adhered to. In the instance of LU being in receipt of material, consent forms or a sample consent form, shall be requested to evidence that informed consent has taken place. In addition, it is only permitted to utilise university approved modes of transport. There are currently 4 couriers on the university purchasing books which are listed within HTALSC/SOP 003 (see manual appendices) and also includes guidance on processes for transport of relevant materials via post.
When acquiring samples directly, the University will not pay donors for their human tissue sample(s) but will follow usual practice of payment of financial compensation for participation in studies as approved by the ERSC.

Details of the University's approach to Freedom of Information requests and Data Protection Policy can be found here Lboro: Freedom of Information and here Lboro; Data Protection Policy respectively.

5.4 Acquisition and Use

Research involving the acquisition of HTA licensable material requires ethical approval. The University ERSC has a process to approve research involving the acquisition of samples from volunteers. Research involving the acquisition of 'relevant material' from NHS patients, is normally conducted in collaboration with one of the NHS Trusts and requires approval from a 'recognised' ethics authority established under, and operating to the standards set out in, the governance arrangements issued by the UK Health Departments, see the Health Research Authority website for details.

Skeletal material held by the SSEHS for the purposes of teaching anatomy should not be used for the purposes of 'public display', but only to teach individuals as part of a pre-determined programme of education and training.

Samples of HTA licensable material will be subject to strict control to ensure:

- That the research undertaken is ethically acceptable and respects the rights of the participants
- That the research undertaken provides good quality samples and reliable scientific information
- That biosafety is not compromised
- That there is full traceability of samples

After acquisition, some samples will be used immediately and destroyed, used up or rendered acellular. Some may be stored on receipt and others may be used repeatedly from storage. All HTA licensable activity will comply with the conditions specified in this Quality Management System.

The use and storage of HTA licensable material will:

- Comply with all relevant legislation, regulations and University policies including appropriate SOPs
- Comply with the consent given and any conditions of ethical approval
- Respect the rights and sensitivities of the participants
- Ensure the quality and integrity of the samples
- Provide secure storage of the samples and derived information
- Maintain the integrity of the chain of custody

5.5 Storage

5.5.1 Definition of Storage

The Human Tissue Act does not define the term storage. Neither does it give any minimum or maximum term for storage of human tissue for research. Therefore, the HTA considers storage to be when tissue is kept for any period of time for the purpose of research, subject to the exceptions below:

- Where in storage pending transfer elsewhere, providing it is held for a matter of hours or days and certainly no longer than a week.
- Where human tissue is being held whilst it is processed with the intention to render the tissue acellular (e.g. extract DNA or RNA, or other subcellular components that are not 'relevant material'), providing the processing takes a matter of hours or days and certainly no longer than a week.
- Material that is created outside the human body and is for the purpose of research that does not involve any application of tissues or cells into humans. (N.B: Cell cultures are 'relevant material' if they contain cells that were created inside the human body e.g. if the culture contains original cells from a biopsy or blood sample. It will be up to PIs to provide evidence of at what point their cell cultures no longer contain any primary cells. This can be in the form of a significant body of literature or experimental data.

5.5.2 Control of Storage

All HTA licensable material must be stored appropriately for the integrity of the sample and intended analysis, in line with health, safety and environmental guidelines, and recorded. SOPs must be followed and risk assessments of the storage provision made. All wet samples stored under the HTA licence will be stored in category II laboratories and all skeletal material used for the teaching of anatomy stored in such a way that it is not exposed to view by the public. Access to all laboratories in which human tissue is stored under the HTA licence will be restricted and a code of conduct put in place to ensure that samples are treated with appropriate dignity and respect.

EVERY sample stored under the HTA licence must be individually labelled with a unique identifier and full details of the sample recorded on Pro-curo including:

- Unique identifier (matching sample label)
- Research study
- Tissue type
- Date of collection/receipt from other establishment and where it came from
- Storage location
- Dates of sample processing
- If relevant, information regarding transfer to and from other locations
- Date for sample to be disposal

This information should be cross referenced with a unique identifier database. These databases should be kept separately and University guidance in respect of security, access and back-up of records followed. Any supporting documentation such as receipts, analysis results and consent forms should be kept separately.

As of September 2016, it is expected that all samples, from all departments that are designated HTA relevant are logged in the Pro-curo Sample Inventory Database. It is also advised that samples held under NHS ethics are also logged on the Pro-curo Database, as when their consent expires, the samples automatically transition on to the LU HTA licence. Good working practise from the onset will prevent non-compliance.

5.5.3 Duration of Storage

The planned duration of storage of HTA licensable material will be specified in the consent form. The duration of storage, which is usually finite, should be defined in the study protocol which was submitted to the ERSC. At the completion of the specified period the samples should be destroyed, unless new ethical approval and consent have been secured to extend the storage period. Due to constraints on the physical space available it is advised that samples are stored for no longer than 3 years from the study completion date. It is neither practical nor acceptable to request extended durations for sample storage.

Holdings of HTA licensable material must be reviewed annually and cross-checked with appropriate consent and research protocols. Any samples found with expired ethics will be quarantined for 7 days whilst the PI is informed, and records are re-checked. After this period, if ethics approval is not in place, samples will normally be disposed of without question. It is the responsibility of the research groups to ensure that they are managing their samples appropriately. This will be checked at random during the internal audit.

5.6 Transportation

No 'relevant material' may be transported from one establishment to another unless both establishments are subject to an appropriate HTA Licence, the tissue has been obtained from a HTA licensable tissue bank or is part of a project with ethical approval from a 'recognised' ethics authority (see note on page 1).[1*]

The licence status of an establishment can be checked on the HTA website under Find an establishment.

Each sample of HTA licensable material must be tracked and recorded from collection to disposal. Appropriate modes of transport, suitable routes and arrangements with people involved must be planned and arranged in advance. A risk assessment of the transportation must be made prior to transportation. University SOPs must be followed as to packaging and containments, labelling and documentation, transportation methods and the use of third-party carriers.

5.7 Disposal

> HTA licensable material should normally be disposed of in accordance with SOPs on completion of the research, or occasionally where consent has been withdrawn. Such disposal must be in accordance with the guidance set out in the Code of Practice and Standards E, Research.

The HTA recognises that what is sensitive and what is feasible at local level needs to be considered. Although it is lawful to dispose of tissue which has come from a person's body in the course of research as waste, it is good practice to dispose of human tissue respectfully. Where practical, it is preferable for samples to be bagged separately from other clinical waste.

For research using HTA licensable material:

- Participants will be informed about disposal procedures during the consent process.
- Where tissue samples remain at the end of the period of storage agreed during the consent process they will be destroyed unless further consent and ethical approval is obtained to extend the storage period.
- Human tissue will be disposed of in a sensitive manner.
- Appropriate methods of destruction of samples and arrangements with people involved will be planned, arranged in advance and risk assessments made and regularly reviewed.
- Samples will not normally be returned to the participant, and this will be made clear during the consent process.
- Samples may be destroyed due to lack of quality or stability.
- The Principal Investigator of a study, or dQM in SSEHS in the case of skeletal material held for teaching anatomy, are responsible for recording the destruction of a sample.

5.8 Distribution

The University will not normally distribute HTA licensable material but may transfer such material for research purposes. For example, samples of cells may be sent to commercial entities or collaborators for testing that is not carried out in house (e.g. mycoplasma testing, karyotype

analysis). Following completion of the relevant MTA checklist by the study PI, A Material Transfer Agreement (MTA) will be completed by both parties to maintain the same principals as specified in the acquisition of HTA relevant material:

- That the research undertaken is ethically acceptable and respects the rights of the participants
- That the research undertaken provides good quality samples and reliable scientific information
- That biosafety is not compromised
- That there is full traceability of samples.

5.9 Images

The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the Human Tissue Act. However, the HTA requires suitable practices are carried out and endorses the guidance on images provided by the General Medical Council in its publication Making and Using Visual and Audio Recordings of Patients.

5.10 Training

All staff and students involved in HTA licensable activity must undertake Human Tissue Licence training. This will include the University mandatory online learning modules and assessments, e-learning and assessment provided by MRC and Laboratory Inductions provided at local School level. dQm's will also signpost researcher to relevant local SOP's as additional training. All such training is compulsory and renewed every two years or as necessary. Line managers are responsible for identifying and making recommendations on the training needs of their staff and for ensuring that employees are suitably qualified and experienced to undertake their duties and responsibilities effectively. All staff and students are encouraged to ensure that they request further training if they feel they are not sufficiently trained for their role. It is each member of staff's responsibility to maintain records of training and competencies and Principal Investigators to ensure students have completed all mandatory training before undertaking research activity with human tissue.

5.11 Adverse Incident Reporting

In the event of an adverse incident, a report must be filed, and any corrective action taken should be recorded. The report should be filed with the dQM and if the incident involves HTA licensable activity it should be referenced in the audit report. If the accident/ incident involves a person(s) the University Form to report an accident, near miss, a case of occupational ill-health or dangerous incident involving a person must also be completed and forwarded to the University Health and Safety Office. Forms are available through a web portal on the Health and Safety website.

When reporting an adverse incident ensure that as much relevant detail is included, and the reports are completed in a timely manner. Staff are encouraged to report any HTA Licence non-compliance issues. Any concern regarding research misconduct or malpractice should be reported to the appropriate Associate Dean (Research & Innovation), who will then notify the PV(C)R or

Chief Operating Officer if it is felt there is a case to be considered, according to the University's Research Misconduct Policy which also makes reference to the University's Whistleblowing policy.

All staff are encouraged to suggest improvements to avoid recurrence of the incident.

5.12 Complaints Procedure

All complaints received relating to HTA licensable activity should be sent directly to the DI, unless the complaint relates to the DI in which case it should be addressed to the Licence Holder contact. All complaints will be dealt with individually and with sensitivity. On receipt of a complaint an investigation will be initiated as soon as possible with a view to resolving in a reasonable timescale, normally within six weeks (dependant on the nature of the allegation). The DI may delegate responsibility for leading the investigation to the PD if appropriate and will report to the Departmental Quality Managers and the Research Governance Officer to ensure all incident and compliance reporting is completed.

5.13 Non-compliance with the University Human Licence

All individuals undertaking research with human tissue at the university have a responsibility to ensure they are compliant with requirements of both the University HTA Licence and HTA codes of conduct and in accordance with HTA (2004)

In the event of non-compliance, the shortfall should be reported and corrective action requested as per the categories below:

> Critical non-compliance: a shortfall which poses a significant risk to human safety and/or dignity, or is in breach of the HT Act 2004 must be reported immediately to the study PI and copied to the University DI and university dQM for further investigation and action. Depending on the nature of the non compliance, the use of the relevant material may be suspended with immediate effect.
>
> Major non-compliance: A failure to carry out expected standards of good practice should be reported to the study PI and to the University dQM in the first instance for further investigation and action. The individuals involved must respond and undertake requested corrective action within 5 working days and with corrective action clearly documented with any issues escalated to. If no response is received within 5 working days this should be reported to the university DI.
>
> Minor non-compliance: A shortfall which indicates a departure from expected standards or good practice and should be reported to a Senior Technician. The individuals involved must respond and undertake required corrective action within 10 working days with corrective action clearly documented and any issues escalated to the local PD and university dQM in the first instance. Audit and Management Review

6 Audit and Management Review

6.1 Internal Audit

HTA-style forward and reverse traceability audits to be carried out 6 times per year and will include checking of consent forms. It is suggested that these are held in Feb, April, June, August, October and Dec.

- To be carried out within each Section by the dQM/PD or Regulatory Compliance personnel a minimum of 4 times per year. In addition, a minimum of 2 external audits will be carried out by the DI, university dQM (or their delegate) and Strategic Scientific Development Officer or the dQM/PD team from another Section.

- Where practical (i.e. based on the number of projects within a Section), 4 different projects and 10 samples will be inspected at each audit.
- At one of the 'external' audits each year, temperature monitoring and freezer/liquid nitrogen maintenance records will also be checked.
- Records of audits will be brought to each HTAL subcommittee meeting to discuss best practice.

It is recognised that in exceptional circumstances, such as those caused by the COVID-19 pandemic of 2020 (prolonged University closures and majority of staff working from home), the auditing schedule may be amended to reflect staff availability with agreement of the DI.

6.2 External Audit

The HTA may carry out inspection site visits in relation to Human Tissue Act licensable activity. In the majority of cases due notice will be given, however, occasionally an inspection site visit may be unannounced. The powers of the HTA to inspect are set out in the Human Tissue Act – Schedule 5.

6.3 Management Review

The HTALSC will review the suitability and effectiveness of the Quality Management System annually, or as deemed necessary by the DI.

This review will consider:

- Whether the Quality Management System is achieving its function of ensuring that research using 'relevant material' is being carried out to the highest standards in accordance with current legislation and national ethical and clinical guidance.
- Cases of non-compliance and any recommendations of corrective action.
- Any complaints received and evaluated whether the response was appropriate.
- Any systemic weaknesses and evaluate possible improvements.
- The effectiveness of any previous corrective actions.

- Any documentation that has reached its review date.
- That the Quality Management System as described in the documentation covers the scope of any planned research within the University.

Appendices
(Click the links to be directed to the appendices of interest)

1) Standard Operating Procedures:

- HTALSC_SOP_001 Production and Control of SOPs for the Control of HTA Licensable Material
- HTALSC_SOP_002 Acquisition and Storage of HTA Licensable Material
- HTALSC_SOP_003 Transfer and Transportation of HTA Licensable Material
- HTALSC_SOP_004 Disposal of HTA Licensable Material
- HTALSC_SOP_005 Obtaining Consent-Human Participants
- HTALSC_SOP_006 Withdrawal of consent to use tissue donated for research (HTA)

2) Consent Form for Participation in a Study Involving the Acquisition of HTA Licensable Material
Consent Form Template

3) Anatomy_Laboratory_code_of_conduct

4) University Form to Report an Adverse Incident Involving a HTA Licensable Activity
HTA_ADVERSE_EVENT_FORM

5) Standard Operating Procedure Template SOP Template

6) Material Transfer Pre-approval form/checklist:
https://www.lboro.ac.uk/research/support/collaboration

7) Log of Skeletal Material held by the University Skeletal Material Log

Risk assessments:

HTA Risk Assessment – Inappropriate consent and loss of traceability

Transport of material under a HTA licence

Production and Control of SOPs for the Control of HTA Licensable Material

HTALSC/SOP 001
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
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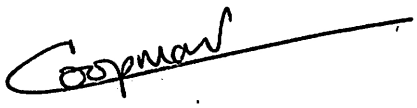
Author (s):	**Mr Tony Goodall** **Dr Donna Bentley** **Dr Jackie Green-Smith**
Approved by:	**Dr Karen Coopman**

Signed:  **Date: Sept 2025**

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has overarching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, QM or their Supervisor immediately.

Security Statement

7 Purpose

To describe the procedure for the preparation, review, approval, distribution, amendment and storage of SOPs. Thus providing written instruction and record of procedures agreed and adopted as standard practice for the purposes of compliance with the University HTA Licence.

8 Scope

This procedure is applicable to all persons writing, using or controlling an SOP which forms part of the Quality Management System for the control of HTA licensable material and should be read in conjunction with the University HTA Licence Compliance Quality Manual.

9 Responsibilities

9.1 The University Quality Manager for the HTA Licence or their designate is responsible for the control of this document.

9.2 The Human Tissue Act Sub Committee (HTALSC) Human Tissue Act Licence Sub Committee The HTALSC reviews policies and procedures specific to the HTA licence. It has ownership of the University HTA licence Compliance Quality Manual

9.3 Review of individual School SOPs associated with the HTA licence, must occur within the that school by the Departmental Quality Manager (dQM) or their Persons designate.

9.4 The current version of all SOPs must be approved by the Designated Individual for the University HTA Licence.

10 References

The Human Tissue Act (2004) and HTA guidance and codes of practice

The University HTA Licence Compliance Quality Manual Loughborough Human Tissue Authority Licence Landing Page

11 Procedure

11.1 An SOP should be written as soon as the need for a standard written instruction arises. For some instructions it may be necessary to allow a period of training and familiarisation prior to the writing of an SOP. In these circumstances an SOP should be usually written within two months of the procedures first use.

11.2 SOPs should be prepared by individuals competent and suitably informed to do so. Where possible this individual should have current knowledge and experience of the task.

11.3 SOPs must include the following:

The author's name
Version number
Effective Date
Review Date
Unique identification number

11.4 SOPs must be reviewed as necessary or a minimum of every two years by the HTA Licence Committee. In addition, if errors or omissions are identified at any time by any member of staff they should bring this to the attention of the Human Tissue Act Licence Sub-Committee, the Designated Individual or University Quality Manager for the HTA Licence immediately.

11.5 Any revisions to the SOP must be agreed and approved by the Designated Individual for the HTA Licence.

11.6 Any revisions to the SOP must then be communicated to staff members by the departmental Quality Manager or their designates within the relevant school

11.7 The current version of the SOP should be made available on the University network and obsolete versions removed and archived

11.8 The Master Copy of the SOP must be filed and older versions retained and archived by the University Quality Manager or their designate.

12 Special Notes

Local level documentation may align with this SOP but it must not conflict with this SOP or any other part of the Quality Management System for the control of HTA licensable material.

13 Documentation

SOP Template

Can be requested by e mailing ssehs.regulatory@mailbox.lboro.ac.uk or accessing the HTASLC MS Teams channel

Acquisition and Storage of HTA Licensable Material

HTALSC/SOP-002
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

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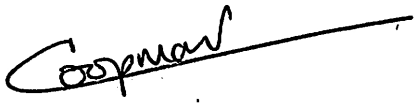
Signed:  **Date: September 2025**

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has over-arching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, QM or their Supervisor immediately.

Security Statement

1 Purpose

To outline the procedure for the acquisition and storage of HTA licensable material on University premises.

2 Scope

This procedure is applicable to the acquisition and storage of HTA licensable material and should be read in conjunction with the University HTA Licence Compliance Quality Manual.

3 Responsibilities

3.1 Any person acquiring directly, procuring, or currently holding human tissue to store, which is licensable by the HTA (see University HTA Licence Compliance Quality Manual for clarification), is responsible for ensuring they are familiar with the procedure and appropriately trained. HTA training is mandatory before undertaking any research activity with human tissue. Training can be requested by contacting the relevant School dQM. The Principal Investigator of the study, or departmental Quality Manager (dQM) (see University HTA Licence Compliance Quality Manual for clarification) in the case of skeletal material used for teaching anatomy, have a responsibility to ensure all those involved in the procedure are appropriately trained. Where possible the use of human bone for teaching should be avoided. It is the responsibility of the technical staff to conduct regular bone audits to ensure any human material used is returned.

3.2 For undergraduates (UG's) it should be noted that these individuals will be working under supervision. In addition the UG's will typically be working with materials such as blood spots, rather than relevant material which is to be stored long term.

3.3 All those involved in working with HTA relevant material must be familiar with the Human Tissue Act (2004) and HTA Codes of Practice and guidance, and have read the University HTA Licence Compliance Quality Manual. For undergraduate (UG) students they should complete the required HTA training for UG students and have an awareness of the core principles of the HTA, with particular reference to; consent, sample integrity, good working practice. PGT's and short-term placement students should complete the required HTA training for postgraduate students. Guidance on the required mandatory training should be made through the relevant School dQM. Relevant mandatory training including Laboratory Inductions must be completed before undertaking any research activity with human tissue at the University.

3.4 The departmental Quality Manager (dQM)/ Regulatory Compliance Manager is/ are responsible for the control of centrally held information stored within a School, including documentation or information held electronically (e.g. within a centrally held database).

3.5 The Designated Individual for the University HTA Licence is responsible for ensuring that the appropriate processes and resources are in place in order that the acquisition and storage of human tissue complies with the Human Tissue Act (2004) and current HTA Codes of

Practice and guidelines. Persons Designated, may be enlisted to help meet these requirements however they cannot relieve the Designated Individual of their statutory responsibilities.

4 References

Human Tissue Act 2004

The University HTA Licence Compliance Quality Manual (Can be accessed via the Human Tissue Act Licence Sub-Committee page). Human Tissue Act Licence Sub-Committee

University Occupational Health Page Occupational health

Hepatitis B and biological agent form (Can be accessed by the LU Health and safety form pages) Health and safety forms

5 HTA local level School SOPsProcedure

Ethical approval must be obtained from the University Ethics Review Sub-Committee (ERSC). The study protocol which is submitted to the ERSC must include the following.

5.1.1 All ethics applications for use of Human Participants (or personal or sensitive data) must be submitted for consideration by the Ethics Review Sub-Committee by way of Loughborough Ethics Online (LEON).

5.1.2 Details about the procurement or acquisition of HTA licensable material must be provided within the ethics application. This includes laboratory protocols for the acquisition of material directly from human participants This also includes material that is being sourced from another organisation on a material transfer agreement. Descriptions of any planned checks to ensure external organisations/collaborators procedures also comply with the Human Tissue Act should also be included. The best way to do this is to ensure that the organisation that you are receiving/ transferring material to, also has a valid HTA licence. HTA Find an Establishment

5.1.3 Completed pre-approval Material Transfer Agreement checklist

5.1.4 Any risk assessments pertaining to the procedures/ activities that will take place.

5.1.5 Participant Information Sheets. Approved templates are available for download via LEON. Approved templates are available for download via LEON: Templates - LEON - Loughborough Ethics ONline.

5.1.6. Consent Forms or details of the checks in place to ensure that the collection of procured samples complied with the Human Tissue Act. Approved templates are available for download via LEON.

5.1.7. The planned method for disposal of any unused 'relevant material' and the procedures planned in the event of withdrawal of consent.

5.2 The Principal Investigator must ensure that they themselves and other members of their research team are competent in the techniques they will be using, are familiar with the Human Tissue Act, the HTA guidance and Codes of Practice, have undertaken the appropriate training including the University HTA Licence Training course (this must be undertaken prior to commencement of activity involving HTA licensable material and on a bi annual basis thereafter), and have a record of such training and competencies.

5.3 All University staff or students working with unscreened biological matrices for the first time should be referred to occupational health for assessment for fitness to work, in accordance with local and University Health, Safety and Environment Policy including the University Biological Safety Policy, Blood Borne Viruses Policy and Control of Substances Hazardous to Health Policy. The hepatitis B status of staff working with biological matrices should also be checked, and immunisation actioned if needed. Forms can be acquired via the following link; Health and Safety Forms.

5.4 The Principal Investigator must liaise with the departmental Quality Manager/ Persons Designate and departmental technicians regarding the storage, use and disposal of HTA licensable material.

5.4.1 Agree any facilities to be used. If working within the SSEHS E-mail ssehs.regulatory@mailbox.lboro.ac.uk. to book freezer space. If required arrange any maintenance, cleaning, and preparation of facilities necessary. Otherwise, if you are working elsewhere within the University, please contact your departmental quality manager (dQM) to book this.

5.4.2 Ensure that you are aware of the record/labelling system to be used for the samples collected; and the procedure for monitoring the storage of the sample(s) or what to do if you come across a freezer that is in alarm

5.4.3 Ensure user accounts and projects are set up on Pro-curo. If you are based within the SSEHS E-mail ssehs.regulatory@mailbox.lboro.ac.uk to request a Pro-curo account set up and training. For all other University departments please contact your Departmental Quality Manager. All relevant material samples MUST be entered into the Pro-curo database. See local level SOP for your School: Setting up/ Editing Projects in Pro-curo.

5.4.4 In general arrangements will be according to local level SOPs, however where studies have unusual requirements or involve new techniques or facilities a complete risk assessment must be undertaken and specific control measures identified and approved by the Designated Individual or Persons Designated.

5.5 Where applicable University and local level SOPs for your relevant School must be followed.

5.6 Unless the samples were obtained before 1 September 2006 valid consent must be established or obtained for each HTA licensable sample. (NB Samples from a deceased person where more than 100 years have elapsed since a person's death, samples from a HTA licensed tissue bank and

samples which are anonymised as part of a study approved by a recognised research ethics committee may be stored without a HTA licence and do not necessarily require consent)

- 5.6.1 If the samples are to be acquired either through collaborative research with another establishment or commercial arrangement, material transfer agreements must include safeguards to ensure valid consent was obtained prior to the collection of the sample. (See relevant SOP in Appendices to this manual: HTALSC/SOP 003 Transfer and Transportation of HTA Licensable Material

- 5.6.2 If the samples are acquired directly valid consent must be obtained from all participants donating samples. For consent to be valid it should be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question (see relevant SOP in appendices to this manual: HTALSC_SOP_005 Obtaining Consent-Human Participants on), and the planned duration of storage should be specified during the consent process. You must explicitly state when the consent for the samples held is due to expire, and whether consent was given to hold the samples for use in future research. Consideration should be given to the needs of individuals whose first language is not English

5.7 Samples must be stored appropriately for the integrity of the sample and planned analysis, and in line with health, safety and environmental guidelines. The location of storage must be secure and entry controlled. Skeletal material held for teaching anatomy must be stored in such a way that it is not exposed to view by the public and kept secure such that the risk of tampering or theft is minimised.

5.8 Calibration and maintenance of storage units must be in line with manufacturer's guidance. Records of calibration, monitoring of storage conditions, maintenance and cleaning should be kept.

5.9 Every sample must be individually labelled with a unique identifier and if applicable any hazard warnings relating to the medium or preservative (N.B. other information about the sample/study may be included on the label but it must not be possible to identify the donor from such information) and details of the sample recorded including:

Unique identifier (to match sample label)

Research study

Tissue type

Date of collection/receipt from other establishment and where it came from

Storage location

Consent/Material transfer details (including where the documentation is held)

Dates of sample processing

Information regarding transfer to and from other locations (if relevant)

Sample storage disposal date

Reason for disposal

(NB disposal information must be logged on the Pro-curo system at the time of sample disposal).

5.10 If any details which could identify the sample donor are to be retained this information should be crossed referenced with a unique identifier database which should be kept separately and University guidance in respect to security access and back up followed. Any supporting documents such as receipts, analysis etc, must be kept.

5.11 Any adverse incident should be reported to the departmental quality manager and/ or the PD and any corrective action taken should be recorded.

5.12 SOPs supporting additional HTA practices are available within local level school workspaces.

5.13 At the completion of the specified period the samples should be destroyed, it is not good practise to re approach the participant and ask for an extension to the consent period for holding samples. As such, please give serious consideration to how long you will need your samples and seek consent accordingly.

5.14 Holdings must be reviewed by the researcher and cross-checked with appropriate consent and research protocols.

5.15 Individual schools also conduct audits of HTA samples and the associated consent process and paperwork. When you are called to audit, please do engage with your School dQM

5.16 If the audit identifies any storage discrepancies within your sample storage, you must work with the Regulatory Team to amend the discrepancies and bring your sample storage into order. The team will support and advise, however sample storage and traceability is ultimately the responsibility of the Principal Investigator.

6 Special Notes

Local level documentation may align with this SOP but it must not conflict with this SOP or any other part of the Quality Management System for the control of HTA licensable material.

7 Documentation

Transfer and Transport of HTA Licensable Material

HTALSC/SOP-003
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
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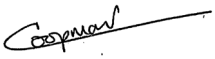
Date of next Review:	**September 2027**
Author (s)	**Mr Tony Goodall** **Dr Donna Bentley** **Dr Jackie Green-Smith**
Approved by	**Dr Karen Coopman**

Signed:  **Date: September 2025**

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has overarching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, QM or their Supervisor immediately.

Security Statement

This document is the intellectual property of the Loughborough University and as such, must not be circulated outside of the University without written approval from the University Quality Manager and the Designated Individual.

1 Purpose

To describe the procedure for the transfer and transport of HTA licensable material for research between different organisations.

2 Scope

This procedure is applicable to the planned transfer (from or to other HTA Licensed organizations) and transport (including transport within the campus) of HTA licensable material should be read in conjunction with the University HTA Licence Compliance Quality Manual.

3 Responsibilities

3.1 Any person transferring or transporting HTA licensable material is responsible for ensuring they have completed the required HTA training before undertaking any research activity with human tissue. All study PIs should must complete the MRC HTA training by accessing: MRC Human Tissue Training : MRC training link is: http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1. All students working directly with human tissue should complete both the HTA MRC training and Loughborough University HTA online training modules. Guidance for required HTA training can be provided by contacting your relevant School dQM.

3.2 Procedural aspects of setting up an MTA are included in the in-house HTA training that is organised by the regulatory team. This training takes place on a bi-annual basis at the very least. Training shall occur more frequently if demand or need is apparent.

3.3 The Principal Investigator (PI) of the study has a responsibility to ensure all those involved in working with human tissue are appropriately trained to carry out the work. The PI is also responsible for ensuring that any students working with human tissue are appropriately supervised.

3.4 All those involved in the procedure must be familiar with the Human Tissue Act (2004) and HTA Codes of Practice and guidance, and are aware of the University HTA Licence Compliance Quality Manual

3.5 The Designated Individual for the University HTA Licence is responsible for ensuring that the appropriate processes and resources are in place in order that the transfer and transport of human tissue complies with the Human Tissue Act (2004) and current HTA Codes of Practice and guidelines. Persons Designated, may be enlisted to help meet these requirements however they cannot relieve the Designated Individual of their statutory responsibilities.

3.6 If we are sending or receiving material from an organisation, the following individuals need to be aware of the sample transfer; The Designated Individual, The Research Support Team

Leader (s), The Research Governance Officer (HTA) and the Secretary of the Ethics Review Sub Committee.

3.7 The investigators are responsible for checking that the institution in which the samples will be transferred holds an appropriate HTA licence.

3.8 Investigators preparing material for transfer have a responsibility to ensure that the sample integrity will be maintained for the duration of transport by way of providing suitable and sufficient sample packaging.

3.9 Investigators preparing for sample transfer have responsibility to ensure that any associated regulations for the transport of material are adhered to. Particular attention should be paid to the Transport of Dangerous Goods Act.

4 References

The Human Tissue Act (2004) and HTA guidance and codes of practice

- https://www.hta.gov.uk/
- The University HTA Licence Compliance Quality Manual

5 Procedure

5.1 Ethical approval must be obtained from the University Ethics Review Sub-Committee (ERSC) and/or the relevant permission or approval for the activity secured from any external organisation HTA licensable material is being transferred from or to.

5.1.1 The study protocol submitted to the ERSC must include any checks made to ensure an external organisation to whom HTA licensable material will be transferred to or from is operating in accordance with the Human Tissue Act (2004) and HTA guidance and Codes of Practice. This is, including the status and any additional conditions of any HTA Licences or other relevant accreditation held.

5.1.2 **To check that a partner establishment has a HTA licence, and the type of licence held, use this link HTA Find an Establishment**

5.2 Appropriate arrangements need to be made with the courier concerned. This needs to be organised in advance of the planned sample transfer date. Check with the budget holder that there are funds available to cover the transfer costs, note details of the budget code and consult with the relevant contact in finance with regard to raising a purchase order.

5.3 A complete risk assessment of the transfer and any transportation must be undertaken and submitted to the Designated Individual. This part is a legal requirement and must be signed off prior to approval being granted for the transfer process. The Principal Investigator must ensure that they themselves, and other members of their research team are; familiar with the Human Tissue Act (2004), the HTA guidance and Codes of Practice, have undertaken the

appropriate training including the University HTA Licence Training course (this must be undertaken prior to commencement of activity involving HTA licensable activity and every three years thereafter), and have a record of such training and competencies. HTA training can be requested by contacting your relevant School dQM. University staff or students working with unscreened biological matrices for the first time should be referred to occupational health for assessment for fitness to work, in accordance with local and University Health, Safety and Environment Policy including the University Biological Safety Policy, Blood Borne Viruses Policy and Control of Substances Hazardous to Health Policy. Hepatitis B immunisation status shall also be checked, and immunisation actioned if needs be. Please see the hyperlink to access the Loughborough University Biological Safety Information.

5.4 There must be a Material Transfer Agreement for any planned transfer.

The relevant MTA pre-approval template can be downloaded and further information regarding the process accessible at Research Support

5.5 The MTA forms have also been consolidated such that one transfer form covers the arrangement of transfer for

- HTA-relevant biological material
- Non-HTA relevant biological material
- Chemicals

5.7 The Principal Investigator must review and sign the MTA pre-approval form before forwarding to the DI and University contracts team.

- Ensure any and all relevant signatures have been obtained as outlined on the MTA pre-approval form.
- Address any feedback and return the form to the recipients above if necessary, until any queries are addressed.
- Once completed, the Fully Signed MTA + signed MTA pre-approval form should be emailed with a Contracts Case Reference Number to the PI.
- If you are based in the SSEHS, please forward a copy of the completed MTA and associated details to ssehs.regulatory@mailbox.lboro.ac.uk.
- You should check with your relevant School dQM who the nominated person is within the school to also hold a copy of the signed MTA.
- Make any other relevant arrangements to allow completion of the MTA process, examples include but are not limited to; ensuring an entry for the project that the

samples are associated with have been set up on the Pro-curo database. Ensuring freezer space has been allocated, approved and is available in time for when the samples arrive within your relevant School, and ensuring purchase orders have been arrange for the proposed transfer.

5.6 Guidance on completion of the MTA pre-approval form:

- For HTA material, the sender must fill complete the relevant sections as outlined on the form.
- Send this to Karen Coopman: K.Coopman@lboro.ac.uk to sign. You should also check with your relevant School dQM who the nominated individual to receive a copy of the form.
- Address any feedback and return the form to the recipients above if necessary until any queries are addressed
- Send to the Recipient Institution. The Recipient/ Recipient Scientist must also complete the relevant sections as outlined on the MTA per-approval form.
- Ask for the recipient to return the form to their contact at Loughborough University (LU).
- Await confirmation of approval of transfer from the Contracts Office of LU and authorised signatory of the recipient organisation.
- If you are based in the SSEHS, please forward a copy of the completed MTA and associated details to ssehs.regulatory@mailbox.lboro.ac.uk. If you are based within another School, please check with the dQM, the nominated person to receive a copy of the completed MTA.
- Make any other relevant arrangements to allow completion of the MTA process, examples include but are not limited to; ensuring an entry for the project that the samples are associated with have been set up in Pro-curo. Ensuring freezer space has been allocated and is available in time for when the samples arrive with the relevant Technicians or dQM within the School and ensuring purchase orders have been arrange for the proposed transfer.

5.6.1 If the sample(s) is being received, this must include safeguards to ensure the collection and storage of the sample(s) up to this point has complied with current legislation including the Human Tissue Act (2004). The chain of custody must be maintained and the sample(s) details documented.

5.6.2 If the sample(s) is being transferred from the University this must include arrangements to return the sample(s) or arrangements to inform the University when the sample(s) has been disposed of. Safeguards must be in place to ensure the destruction process complies with current legislation including the Human Tissue Act (2004).

Valid consent must be obtained prior to receipt of or collection of each HTA licensable sample. For consent to be valid it should be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. see your relevant local level School SOP for further clarification).

5.7 Any planned transportation and any risks associated must be specified during the consent process. (NB Samples from a deceased person where more than 100 years have elapsed since a person's death, samples from a HTA licensed tissue bank and samples which are anonymised as part of a study approved by a recognised research ethics committee may be stored without a HTA licence and do not necessarily require consent).

5.8 Samples must be packaged appropriately. Suitable methods of transportation must be in place to maintain the integrity of the sample during transportation in accordance with current legislation and University policies including:

Data Protection and consent under GDPR Guidelines on Consent (GDPR) under Regulation 2016/679

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (2009)

5.9 Samples for transportation must be collectively labelled to include:

- The study (and batch number if applicable)
- The principal investigator of the study
- Period during which the samples were collected
- Details of appropriate storage conditions
- Collection and delivery locations
- Planned time and date of collection and delivery
- Carrier responsible for consignment

- Planned date of disposal if relevant
- The signatures and time and date of receipt of each person in the chain of custody

Samples packaged for transport must be compliant to UN3373, as shown in Figure 1:.

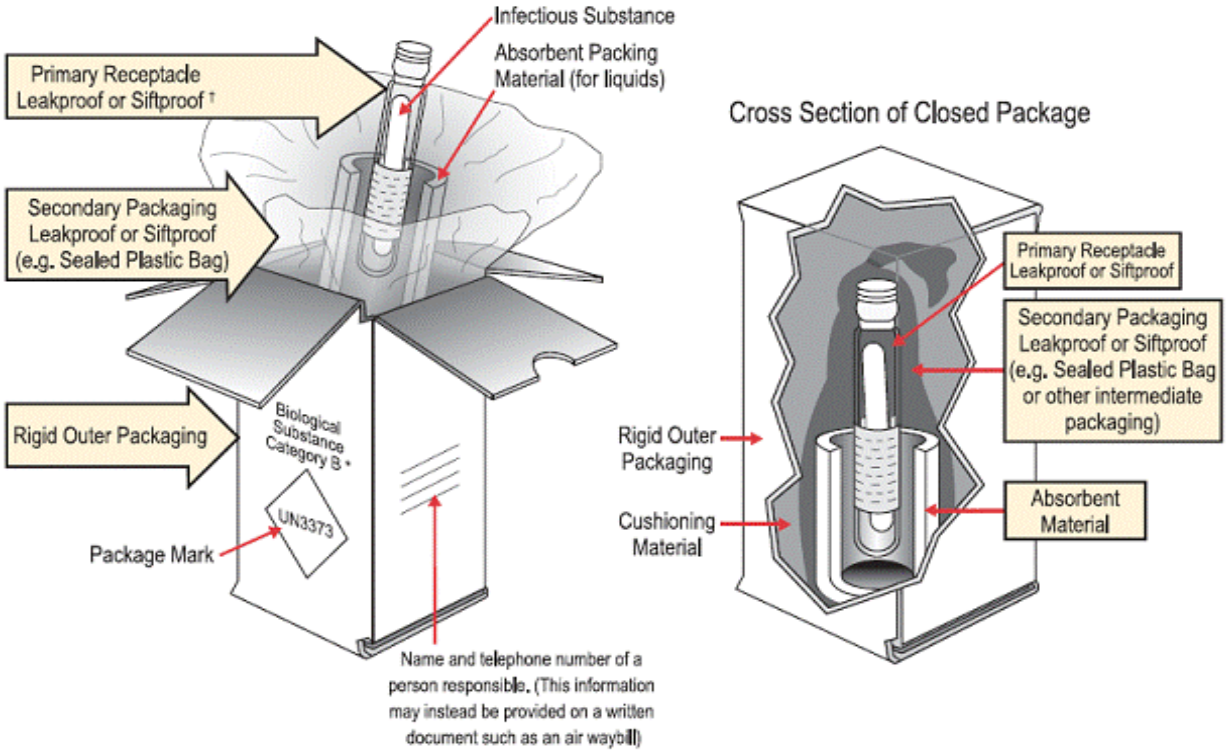


Figure 1 is a pictorial representation of how biological samples should be packaged to be compliant to the transport of dangerous goods act and UN3373 .

- Biological agents are allocated to UN division 6.2, infectious substances. This division includes biological products, cultures, GMO and medical/clinical waste.
- Infectious substances are further divided into category A or Category B. Our sample's will fall under Category B (samples where there is no reason to suspect the subject/donor is suffering from a sever infectious disease)

5.10 Continuity of ownership should be demonstrated with the signature and time and date of receipt of each person in the chain of custody.

5.11 Each sample must be tracked and recorded from collection to disposal according to the existing arrangements for storage of HTA licensable material.

5.12 Unless anonymised each sample must be individually labelled with a unique identifier/barcode.

5.13 If any details which could identify the sample donor are to be retained this information should be crossed referenced with a unique identifier database which should be kept separately and

University guidance in respect to security access and back up followed. Any supporting documents such as receipts, analysis results and consent forms should also be kept separately.

5.14 On completion of the transfer the Universities record of each sample must be maintained i.e. a field for 'Information regarding transfer to and from other locations' should be completed alongside a record of the sample's unique identifier/barcode and any planned return dates if relevant.

5.15 Records of HTA licensable holdings must be reviewed annually by the researcher and cross-checked with appropriate consent, research protocols and the location of storage. If the samples are held by an external organisation material transfer agreements should be cross-checked with notice of destruction from the external organisation and any anomalies investigated and records updated.

5.16 Any adverse incident should be reported to the department Quality Manager and any corrective action taken should be recorded.

5.17 You should also consult the local level School SOP for reporting an adverse incident.

6 Special Notes

6.1 No HTA licensable material may be transported from one establishment to another unless both establishments are subject to an appropriate HTA Licence or the sample(s) are part of a study with ethical approval from a 'recognised' ethics authority[1]*. Please see link: Find an establishment | Human Tissue Authority

6.2 If HTA licensable material is being transferred into or out of the University from an establishment outside of the UK, a Material Transfer pre-agreement form will still need to be completed and transfer proposed material subject to ethical approval. It is also important to note that consent assurances for the donated material should also be sought in line with expected good practice. Please see link for further guidance: Importing and exporting human tissues and cells if you are an establishment based in Great Britain | Human Tissue Authority

6.3 Local level documentation may align with this SOP but it must not conflict with this SOP or any other part of the Quality Management System for the control of HTA licensable material.

7 Documentation

7.1 Accident online reporting links Lboro: Services/health-safety

7.2 University Occupational Health Surveillance Form

7.3 Material Transfer pre-agreement template form: for HTA Licensable Material
https://www.lboro.ac.uk/research/support/collaboration/

7.4 University Form to report an adverse incident involving a HTA licensable activity

HTA_ADVERSE_EVENT_FORM

Disposal of HTA Licensable Material

HTALSC/SOP 004
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
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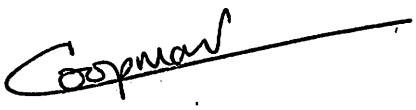
Author (s)	**Mr Tony Goodall**
	Dr Donna Bentley
	Dr Jackie Green-Smith
Approved by	**Dr Karen Coopman**



Signed: ___ _____Date: __September 2025_____

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has overarching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, QM or their Supervisor immediately.

Security Statement

1 Purpose

To describe the procedure for the disposal of HTA licensable material. Thus providing written instruction and record of procedures agreed and adopted as standard practice for the purposes of compliance with the University HTA Licence.

2 Scope

This procedure is applicable to the disposal of HTA licensable material and should be read in conjunction with the University HTA Licence Compliance Quality Manual.

3 Responsibilities

3.1 Any person using HTA licensable material is responsible for ensuring they are familiar with the procedure and appropriately trained.

3.2 The Principal Investigator of the study has a responsibility to ensure all those involved in the study are appropriately trained.

3.3 All those involved in the study must be familiar with the Human Tissue Act (2004) and HTA Codes of Practice and guidance, and have read the University HTA Licence Compliance Quality Manual.

3.4 The departmental Quality Manager for the University HTA Licence is responsible for the control of centrally held information stored within the School, including documentation or information held electronically (e.g. within a centrally held database).

3.5 The Designated Individual for the University HTA Licence is responsible for ensuring that the appropriate processes and resources are in place in order that the disposal of human tissue complies with the Human Tissue Act (2004) and current HTA Codes of Practice and guidelines. Persons Designated, may be enlisted to help meet these requirements however they cannot relieve the Designated Individual of their statutory responsibilities.

4 References

The Human Tissue Act (2004) and HTA codes of practice standards and legislation

The University HTA Licence Compliance Quality Manual, available via the following link; Human Tissue Act License Sub Committee

5 Procedure

5.1 HTA licensable material should normally be disposed of in accordance with the study protocol; Sample disposal takes place upon completion of the research, on occasion where consent has been withdrawn. Samples may also be destroyed due to lack of quality, stability or should they be found to be contaminated.

5.2 Where consent is obtained directly, donors will be informed of the disposal method during the consent process. Samples will not be returned to the participant, and this will also be made clear during the consent process.

5.3 The limitations on withdrawal of the consent to use the samples must also be made clear during the consent process. This must also be written on the participant information sheet. After the samples have been analysed it will no longer be possible to withdraw that sample for use in research. Participants need to be given a clear end date for the withdrawal of the consent for use of samples within research.

5.4 The Principal Investigator must ensure that they themselves, and other members of their research team are familiar with the Human Tissue Act, the HTA guidance and Codes of Practice, have undertaken the appropriate training including the University HTA Licence Training course (this must be undertaken prior to commencement of activity involving HTA licensable material and every three years thereafter), and have a record of such training and competencies. Training can be requested by contacting the relevant School dQM or by e mailing ssehs.regulatory@mailbox.lboro.ac.uk if you are based in SSEHS. All University staff or students working with unscreened biological matrices for the first time should be referred to occupational health for assessment for fitness to work, in accordance with local and University Health, Safety and Environment Policy including the University Biological Safety Policy, Blood Borne Viruses Policy and Control of Substances Hazardous to Health Policy.

5.5 The practicalities of clinical waste disposal on the University premises are handled at School level and specific local SOPs should be followed. The following points apply to the disposal of all HTA licensable material within the University.

5.5.1 Always wear appropriate protective clothing and practice good hand washing technique in accordance with local policy and procedures.

5.5.2 Facilities, equipment, and procedures for the disposal of clinical waste must be appropriate and sufficient and all current legislation and University policies and procedures adhered to.

5.5.3 Waste facilities must be appropriately and consistently labelled across all the laboratories within the School/Centre.

5.5.4 Where practical separate HTA material separately from other clinical waste.

5.5.5 Where disposing of tissue samples or segments thereof, where practical, it is preferable for a new bag to be used in order that 'relevant material' is bagged separately from other waste.

5.5.6 Always use the most appropriate waste utensil. Never put an item which could cause a puncture directly into a plastic bag. Sharp objects must be disposed of in specific containers fit for purpose.

5.5.7 For example, if the bin has a lid ensure the lid is shut and that it is not overfull before you leave the room.

5.5.8 When disposing of clinical waste be sure to handle the waste with care. Do not engage in practise such as 'throwing' or 'dragging' the waste bags.

5.5.9 Appropriate precautions should be taken to reduce the likelihood of spillage during the transfer of clinical waste. Ensure the waste is double bagged and the sealed (especially sharps containers) prior to removal.

5.5.10 Care should be taken to avoid any spillage or splashes when handling relevant material that is in liquid form.

5.5.11 If there is any problem with the maintenance or collection of biological waste contact the technical team or the University Health and Safety Office as appropriate, with immediate effect.

5.6 Each sample must be logged and traceable from the point of collection through to disposal. This must be in accordance with the existing arrangements for storage of HTA licensable material. Currently samples are logged within the Pro-curo database. To request an account within Pro-curo, or associated system training, please contact your relevant School dQM.

5.6.1 Following the complete use or disposal of a sample, the relevant fields in the record associated with the storage of that sample (identified by its unique identifier/barcode) should be updated to reflect the date and reason for disposal.

5.6.2 If the sample was sent to Loughborough from another organisation, the investigators at Loughborough should inform the named correspondent at the sending organisation of the destruction of the sample. This should be done in accordance with the details within the material transfer agreement.

5.7 Records of HTA licensable material must be reviewed annually by the researcher. The Regulatory Team will also carry out regular sample audits. Samples held will be cross-checked with appropriate consent, research protocols and the location of storage. If any sample(s) have reached the date that they are due for destruction and no additional ethical approval has been obtained the sample(s) should be disposed of in an appropriate manner.

5.8 Any adverse incident should be reported to (any of the contacts listed are appropriate) the departmental Quality Manager; Regulatory Manager; Persons Designate; Health and Safety Officer, Technical Team Member. Incidents should be escalated in the appropriate manner. It

may be that an internally managed reporting and correction process is sufficient. Not all incidents may need to be directly reported to the HTA.

6 Special Notes

6.1 Samples will not normally be returned to the participant, and this will be made clear during the consent process.

6.2 Local level documentation may align with this SOP but it must not conflict with this SOP or any other part of the Quality Management System for the control of HTA licensable material.

7 Documentation

7.1 University Hepatitis B and Biological Agent Form Hepatitis B and Biological Agent Form

7.2 University Health and Safety Online Reporting Form; Health and Safety Online Reporting Form

7.3 University HTA Adverse Event Reporting Form

Obtaining Consent-Human Participants

HTALSC/SOP005
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
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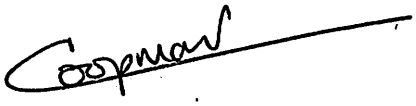
Author (s)	**Mr Tony Goodall**
	Dr Donna Bentley
	Dr Jackie Green-Smith
Approved by	**Dr Karen Coopman**



Signed: ___ _____Date: _September 2025_____

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has overarching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

The Master Copy of this document is filed by the University Quality Manager and the latest version will be available on the University network. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTALSC, QM or their Supervisor immediately.

Security Statement

1. PURPOSE

The purpose of this SOP is to set out procedures for obtaining consent for the acquisition of human tissue for research.

2. SCOPE

This procedure is applicable to ALL staff / students whose research studies require the recruitment of human participants with the intention of acquiring tissue samples.

Consent under the Human Tissue Act (2004) relates to the purposes for which material might be removed, stored or used. These purposes are listed in detail in schedule 1 (Paragraph 81) of the Human Tissue Act and are referred to as scheduled purposes. The scheduled purpose of "Storing and using relevant material from the living" takes place within laboratories within the SSEHS, as such ANYONE removing, storing or using material for which the Human Tissue Act requires consent, must ensure that consent is in place.

3. RESPONSIBILITES

ONLY STAFF AND RESEARCHERS WHO HAVE UNDERTAKEN MANDATORY HTA TRAINING CAN TAKE CONSENT FOR THE USE, STORAGE AND DISPOSAL OF HUMAN TISSUE

3.1 Principal investigators and Associated Staff and Postgraduate Research Students.

3.1.1 In all instances Loughborough University staff and students (research) are responsible for obtaining informed consent from research participants for the use of their tissue(s) for research.

3.1.2 The researchers also have a responsibility to follow the procedures defined by the SOP for obtaining consent and if applicable, the procedures defined by the 'Withdrawal of consent process'. Researchers must ensure that all associated documentation and amendments are completed.

3.2 Research Governance

Is responsible for overseeing the DI in providing oversight and guidance to all staff and principal investigators and postgraduate students carrying out or overseeing Human Tissue Authority (HTA) related appropriate training, such that they are aware of their responsibilities within the scope of the Human Tissue Act (2204).

3.3 The Regulatory Team

The Regulatory Team are responsible for carrying out consent competency audits. Consent competency audits must be carried out during the initial stages of the study such that any deficits in practise can be corrected as soon as possible.

3.3 The University Quality Manager

The University Quality manager, in conjunction with the Department Quality Managers, is responsible for the management of the Quality Management System documentation to ensure that any local documents comply with the quality management system.

3.4 The Departmental Quality Manager

The Departmental Quality Manager or their representatives are responsible for carrying out internal consent competency audits of activities carried out under the University HTA licence; including the consent process.

3.5 Investigators

Investigators are responsible for ensuring that they have the appropriate approvals in place for their study. Investigators are responsible for ensuring that they are appropriately trained. Investigators are also responsible for ensuring that they engage with the consent audit and consent competency assessment process.

4. REFERENCES

HTA Codes of Practice and Standards with particular reference to Code of Practice A; Guiding Principles and the Fundamental principle of Consent; Code of Practice and Standards E.

https://www.lboro.ac.uk/committees/human-tissue-authority-licence/

Relevant Local Level School SOP: Withdrawal of consent to use tissue donated for research (HTA).

5. PROCEDURE

5.1 Valid Consent

5.1.1 Valid consent constitutes consent which has been obtained voluntarily. Consent must be sought from an appropriately informed person who not only has the mental capacity to understand what the study involves and their involvement within it, but also the capacity to agree to participate in the study.

5.1.2 There are various ways in which consent can be expressed, although best practice advises that consent is sought in writing. This does NOT mean however that a signature on a form constitutes consent. Consent is a process, and is only valid if given by an appropriately informed person who has the capacity to understand the information given and freely make a decision regarding their intent to consent to donating their tissue for research. This includes ensuring that the potential donor has had time to discuss the issue fully, ask questions and make an informed choice.

5.1.3 For consent to be valid, the participant/ tissue donor should understand what the study/ activity involves, and what the associated risks (of participation) are.

5.1.4 When seeking consent, suitably experienced people should ensure that it is appropriate for the intended purpose. For example, for research where several areas of specialist knowledge are involved participants should be offered access to specialists if they require additional information to enable them to make a fully informed choice.

5.1.5 It is expected that a written Participant Information Sheet (PIS) will be used to support the process of gaining consent. This can be and is often sent out in advance of the consent session.

5.1.6 It is expected that consent will be confirmed in writing via a consent form being signed and dated by the Participant and the person seeking consent.

To decrease the risk of the participant not fully taking in what they have been asked to do, the consent form has been updated in line with NHS good practice guidelines such that each point needs to be initialled.

5.1.7 Two copies of the consent form should be signed and dated by both the Participant and the investigator.

One copy of the consent form should be given to the participant and the other copy of the consent form should be placed in the participant's research record. The latter should be held in a secure location in the investigator's office or laboratory.

5.1.8 Consent for research may be generic or specific.

It is good practice to request generic consent, thereby avoiding the need to obtain further consent in the future. For example, on the Loughborough University consent forms there is an initialled requesting permission for participants samples to be used in further research.

5.1.9 Consent may be withdrawn at any time whether it is generic or specific.

Please note withdrawal of consent could comprise; cessation of active participation in the study, withdrawal of consent for use of any samples collected, or withdrawal of consent for use of any data collected. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent should be made clear, especially when relating to samples or data. Participants must be made aware that they can withdraw consent at ANY time during active study participation/ sample acquisition, or any procedures involving interventions (e.g., exercise testing) or investigations prior to sample acquisition. However, the limitations of consent withdrawal MUST be made clear. For example, if consent is withdrawn by the participant, but their samples have already been used in a research project, withdrawal of consent cannot be as effective once the data has been collated and figures published for example. Guidance on managing withdrawal of consent is outlined within the relevant local level School SOP: "Withdrawal of consent to use tissue donated for research"

5.1.10 It is unlikely that non-written consent will be taken at Loughborough University; however, if an instance arises whereby consent has to be taken verbally, or via a phone conversation, say for someone with a sight limitation, then please contact the research office for further advice.

5.1.11. Consent is only valid if appropriate and legitimate communication has taken place. In instances where the participant's first language is NOT English and their standard of English inhibits their ability to understand and question the information given to them, then provision for a translator must be made. Provision for translators can be organised via the University Research Office.

5.1.12. Consent for Vulnerable groups

If you intend to obtain consent from vulnerable groups, which include:

- Children under 18 years of age
- Adults without capacity to give consent
- Prisoners and Young Offenders
- A participant who is a dependant of the investigator

5.1.13 It is important that all relevant legislation and requirements be considered when developing the consent process and associated documentation.

5.1.14 Please consult the departmental quality manager/ technical resources manager/ officer for advice.

6.0 OVERVIEW OF THE STEPS INVOLVED IN THE PROCEDURE FOR OBTAINING INFORMED CONSENT

6.1 Prepare the Participant Information sheet (s) and Informed Consent Form (s). Templates are available to download via the help section in LEON (Loughborough Ethics Online: https://leon.lboro.ac.uk/Personalisation/DisplayPage/50). Please download a new consent form template to adapt for every new study. This is to ensure that the most up to date form is being used. Please do NOT save copies locally.

6.2 Fill out an ethics application within LEON

6.3 Follow any and all feedback given by the Regulatory/ Ethics Team. Once feedback is actioned and the form returned, ethics application will then go to the Research Office ready for consideration by the Ethics Review Sub-Committee.

6.4 Please note that consent training is MANDATORY. Please contact the dQM within your relevant school to undertaken the relevant MANDATORY consent training.

On receiving clearance/favourable opinion for your study, you can start recruiting participants. Explain the study to the potential participant; answer any questions that they have; give/ send them a participant information sheet; make it clear to them that they do NOT have to participate and do NOT have to give a reason why they do not wish to participate. The participant information sheet should be provided to the participant in advance of the consent session.

6.3 Allow the potential participant time to decide if they wish to participate in the study and ensure that yourself or another individual with specialist knowledge of the study is available to answer any further questions that the potential participant has. You must NEVER disseminate a participant information sheet and then proceed with the consent process within a 24-hour period of the participant receiving the participant information sheet.

6.4 If the potential participant is willing to give consent, confirm the consent by signing and dating two copies of the consent form. (Please note that investigator and participant signatures and dates are required). The investigator must NEVER pre-sign the consent form. Signatures must always be provided in real time.

6.5 Give one copy of the consent form to the participant and file one copy of the consent form in the participant's research record.

6.6 It is also required that if participants are providing biological samples to ensure that you have undertaken the MANDATORY HTA training. Please contact the dQM within your relevant school to undertaken the relevant MANDATORY HTA training and process for setting up a Pro-curo account such that samples can be logged in accordance with the Human Tissue Act.

6. SPECIAL NOTES

7. DOCUMENTATION

LEON templates (consent form): https://leon.lboro.ac.uk/Personalisation/DisplayPage/50

Withdrawal of consent to use tissue donated for research (HTA)

HTALSC/SOP006
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
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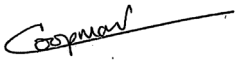
Author (s)	**Mr Tony Goodall** **Dr Donna Bentley** **Dr Jackie Green-Smith**
Approved by	**Dr Karen Coopman**

Signed:  **Date: September 2025**

Authorisation and Document Control

The Quality Manual and SOPs will be reviewed on a bi-annual basis by the Human Tissue Act Licence Sub-Committee (HTALSC) and any revisions to the documentation agreed and approved. The Designated Individual for the HTA Licence is Chair of the HTALSC and has overarching authority for the documentation. Any revisions to the documentation will be communicated to staff members by the departmental Quality Manager.

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Security Statement

1. PURPOSE

To outline the process that must be followed when a sample donor expresses a wish to withdraw consent for their donated tissue to be used in research. Note that withdrawal of consent MUST be discussed at the outset when consent is being sought. The practicalities of withdrawing consent, the withdrawal process, its limitations, and implications must be made clear from the beginning.

Consent can be removed for:

- Subject participation
- Collection and/ or use of tissues
- Use of data collected from the participants tissues.

2. SCOPE

This procedure is applicable to all researchers working for Loughborough University who are collecting samples from human participants.

3. RESPONSIBILITES

3.1 Principal Investigators and Associated Staff and Students

3.1.1. Have a responsibility to honour the withdrawal of consent. The participant does not have to give a reason or justify why consent has been removed, (however it is helpful to ask why, and see if they are willing to volunteer feedback, it may be that the feedback may aid future participant retention). If consent has been withdrawn for sample collection and use, ensure that all samples associated with the donor who has withdrawn consent are disposed of appropriately Ensure that the limitations of sample disposal are made clear as the sample cannot be withdrawn from the study once it has already been analysed. It is helpful to discuss the limitations of withdrawing consent at the outset when providing the potential participant with the information prior to the start of the study. The same also applies for the use of data.

3.1.2 The researchers also have a responsibility to follow the procedures defined by the 'withdrawal of

consent process' and ensure that all associated documentation and amendments are completed.

3.2 Persons Designate (PD)

3.2.1 To oversee the withdrawal of consent and ensure all processes relating to the withdrawal of consent for tissues to be used in HTA related activities are carried out in accordance with the Act as outlined in this SOP.

3.2.2 The PD is responsible for ensuring all staff and principal investigators and postgraduate students carrying out or overseeing HTA related activities have received the appropriate training and are aware of their responsibilities within the scope of the act.

3.3 University Quality Manager

3.3.1 The University Quality Manager, in conjunction with the Department Quality Managers, is responsible for the management of the Quality Management System documentation to ensure that any local documents comply with the Quality Management System,

3.4 Departmental Quality Manager (dQM)

3.4.1 dQM or their representative are responsible for carrying out internal audits of activities carried out under the University HTA licence, including auditing the consent process.

4. REFERENCES

See the Human Tissue Authority Website for more information,

http://www.hta.gov.uk/

Code of Practice A; Guiding Principles and the Fundamental principle of Consent.

5. PROCEDURE

This procedure shall be followed whenever a donor revokes consent for their donated tissue to be used in research. Means by which a donor may express their wish to revoke consent can comprise the following:

- verbal withdrawal of consent or in writing, by telephone, face-to-face, via e-mail, text or a formal letter.

5.1 Face-to-Face Withdrawal of Consent

5.1.1 It is ESSENTIAL that the participant does not feel that there are any barriers to withdrawal.

5.1.2 If a donor has decided that they wish to withdraw consent, NO attempt to change their mind must be made. Their wishes MUST be fully respected and actioned.

5.1.3 If possible, any participant who wishes to withdraw consent is referred to the individual that obtained consent.

5.1.4 If the person who obtained consent is unavailable, it is perfectly acceptable for any trained and competent individual to discuss withdrawal with a donor.

5.1.5 Ensure that the withdrawal of consent is noted on in the study notes/ on the consent form.

5.2 Remote Withdrawal

5.2.1 If withdrawal is requested by telephone, e-mail, letter or fax then the “Acknowledgment of withdrawal of consent” letter in section 7 of this SOP must be sent to the donor to complete,

in addition to the withdrawal of consent form (in section 7 of this SOP). Both forms need to be signed by the donor and then returned to Loughborough University In the first instance the form for the withdrawal of consent should be sent to the principal investigator of the study (or his/her representative) to provide confirmation that the correct person is withdrawing consent and match these with the samples in Pro-curo. .

5.3 The Procedure for the Withdrawal of Consent

5.3.1 Within one day of notification of withdrawal of consent the principal investigator for the research group or their representative should locate all of the donor samples and any associated derivatives/ laboratory products from such.

5.3.2 Samples and derivatives shall be sought out and disposed of as per local level School SOPs.

5.3.3 Researchers who have received samples from the donor shall be contacted and notified that consent has been withdrawn.

5.3.4 Researchers will be asked to update any relevant sample records on Pro-curo.

5.3.5 The system audit trail must be preserved, so even though the donors' data is logged in the system, any and all sample identifiers, processing data and inventory details must be noted as deleted.

6. SPECIAL NOTES

7. DOCUMENTATION

7.1 Notification to researcher of donor withdrawal
7.2 Template withdrawal of consent form.
7.3 Template letter or e-mail to the donor requesting to withdraw consent.

8 Insert Title of Research Proposal]

CONSENT WITHDRAWAL FORM

Investigators Details:
Name Responsible Investigator, University postal address, email address, office telephone number
Names of Other Investigators, University postal address, email address, office telephone number

Withdrawal of consent	Please **initial one** of the following:
. **I confirm that I wish to withdraw from the study before data collection has been completed and that none of my data will be included in the study.**[Text Wrapping Break] .	
. **I confirm that I wish to withdraw all of my data from the study before data analysis has been completed and that none of my data will be included in the study.** .	
. **I confirm that although the results of the study have already been produced and cannot change, I wish that all of my personal data is deleted from verification records maintained by the university about the study.**[Text Wrapping Break]**I understand that this means that only those data identifying me will be deleted.** .	

Human tissue sample consent withdrawal

. **I confirm that I wish to withdraw permission to use my human tissue samples and that they are destroyed, and data deleted such that they are no longer available for use.** .	

Please note withdrawal of consent cannot be acted upon where tissue has already been used and analysed.

Your name is required to verify that you have withdrawn your data from the study as specified above.

In the case of (3), above, we will need to retain this form until Day/Month/Year.

This form will be stored securely until Day/Month/Year.

_____ _____ _____

Name of participant [printed] Signature Date

_____ _____ _____

Researcher [printed] Signature Date

Template-Letter or E-mail to the participant requesting to withdraw consent

Addressee's name
Street address
POST TOWN
County
Postcode

Date

Dear (Participant),

Thank you for notifying (insert individual) that you wish to withdraw consent for your samples and associated data held for research purposes at Loughborough University.

(Insert project details; title, reference number).

Before we destroy samples and data we normally ask the participant to sign a form to confirm their wishes in writing. This is to ensure that the person withdrawing consent is the same person who gave consent.

We would therefore be grateful if you could use the attached withdrawal of consent form and send it back to us at the following address, ……..

Your samples will be held in quarantine until the withdrawal of consent form is received. During this time, any samples that you donated to Loughborough University will not be used for research.

Upon receipt of the notice for the withdrawal of consent the samples donated by yourself will be removed from quarantine and destroyed. Your personal information will be removed from

the research database. If the signed “withdrawal of consent” letter is not received within one month of your initial communication to revoke consent, your samples will be destroyed.

Some of your samples may have already been used to generate experimental data. If this is the case it will not be possible to retrieve these samples, nor is it possible to withdraw the results of the research or prevent their publication.

Yours sincerely

Sender’s name
Title

Encs
cc

Consent Form Template

Use the latest template available within the ‘Templates’ section of LEON.

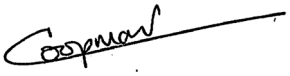
Protocol for production of acellular plasma samples (HTA)

HTALSC/SOP007
Standard Operating Procedure

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**September 2025**
Date of Last Modification:	**September 2025**
Date of next Review:	**September 2027**
Author (s)	**Mr Tony Goodall**
	Dr Matt Nickels
Approved by	**Dr Karen Coopman**

Signed:  **Date: September 2025**

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Security Statement

1. PURPOSE

To describe the procedure for the spinning down of whole blood to obtain acellular plasma samples.

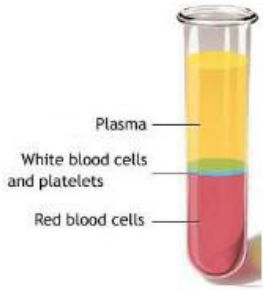

Figure 2. The different fractions of blood following centrifugation.

2. SCOPE

This procedure is applicable to persons performing or assisting in the spinning down of blood, using a centrifuge, to obtain acellular plasma samples.

NB, under the HTA, if the intention of spinning down blood samples is to render the sample acellular, the material is unlikely to fall under a HTA licence remit, but you may still need to log your samples on Pro-Curo. Check with your local Departmental Quality Manager.

3. RESPONSIBILITES

3.1 The investigator who performs the technique is responsible for the procedure and the appropriate experience of any persons assisting in the procedure.

3.2 All those involved in the technique must have read the appropriate RAs and SOPs.

3.3 It is the responsibility of all researchers/students generating samples, to ensure spin conditions are noted and that all records of consent are associated with the laboratory records whenever blood is being taken.

4. REFERENCES

Advancing Transfusion and cellular therapies worldwide (AABB) guidance.

http://www.aabb.org/Pages/default.aspx

You should refer to the following SOP titles within your relevant school (links only available to SSEHS):

- Disposal of clinical waste, including human tissue
- Good hand washing technique
- Storage of human tissue
- Disposal of sharps
- Reporting an adverse incident

5. EQUIPMENT AND MATERIALS

5.1 Equipment

5.1.1 Phlebotomy needle

5.1.2 Sharps and appropriate waste bin

5.2 Materials

5.2.1 Centrifuge

5.2.2 Disposable nitrile gloves

5.2.3 Blood collection tubes (lithium heparin or any other applicable tube)

5.2.4 Clinical tissue

6. PROCEDURE

6.1 Ensure consent has been obtained from the participant prior to any sample collection taking place.

6.2 Check the environment and equipment are appropriate, clean, and in good working order.

6.3 Wash hands according to your relevant school SOP: 'Good hand washing technique'.

6.4 After the blood has been collected (according to the appropriated SOP for blood collection; see

your relevant school SOP for either: Capillary blood sampling, Venepuncture, Cannulation) mix the blood gently by inversion six to eight times.

6.5 Switch on the centrifuge at the main power switch. This is often located to be at the back left of the instrument.

6.6 Open the centrifuge door by pressing 'OPEN DOOR' or the relevant symbol.

6.7 Place the tubes inside correctly sized tube holders and ensure the rotor is balanced. Inappropriate tube sizes, or an imbalanced set of tubes, may cause damage to the centrifuge or breakage of the tube inside the centrifuge. Place the lid on the holders. If the holders are not built into the centrifuge, attach the holders onto the centrifuge using the slide sides. Double check that they are fitted correctly before starting the centrifugation.

6.8 Close door/lid.

6.9 Set the desired centrifugal force, time, and temperature (if available).

6.10 Internal validation data states that to obtain cell and platelet free blood, samples should initially be centrifuged for a minimum of 10 minutes at 4000g. Note - see Section 8 for reference data.

6.11 Carefully transfer the plasma into an appropriate vessel ensuring that you do not touch the interface between the plasma and the red blood cell, so no cells are transferred to samples.

6.12 Store samples for future analysis according to your relevant school SOP: Storage of human tissue'.

6.13 Dispose of any clinical waste according to your relevant school SOP: Disposal of clinical waste, including human tissue or the disposal of sharps' where applicable.

6.14 Wash hands according to your relevant school SOP: 'Good hand washing technique'.

6.15. If the centrifuge you are using does not display the RCF, it can be calculated by measuring the radius (distance from the centre of the rotor to the bottom of the tube) as illustrated in Figure 2. The value should then be input together with the speed in revolutions per minute (RPM) into the equation provided at http://insilico.ehu.es/mini_tools/rcf_rpm.php or http://www.hettweb.com/mobile-app.

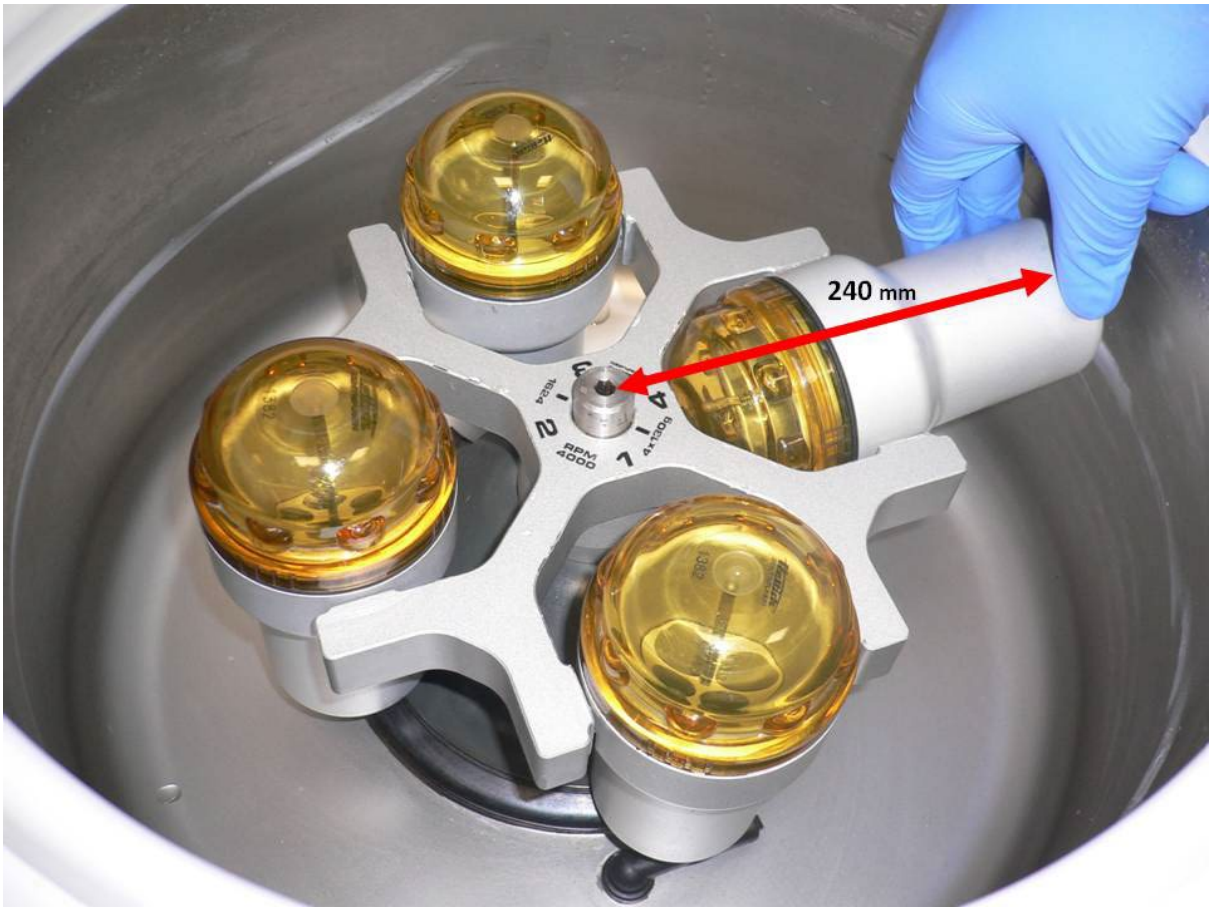

Figure 2. How to measure the radius of the centrifuge you are using: 1) Measure distance from centre to bottom of tube 2) Maximum radius of centrifuge in this example is 240 mm or 24 cm.

Note - alternatively, you can use the bench-top centrifuge nomogram (Figure 3).

Radius (cm)	RCF (g)	RPM

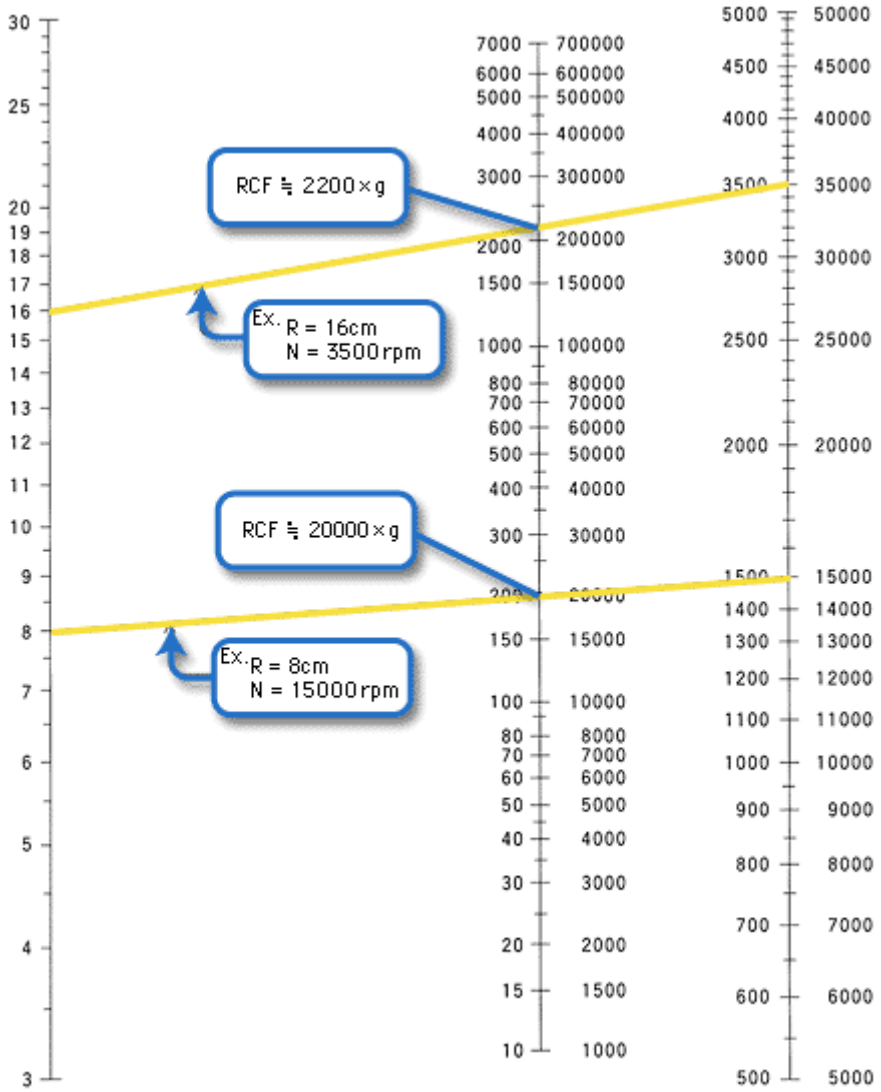

Figure 3. Nomogram for conversion of RPM to RCF for conventional bench top centrifuges

7. SPECIAL NOTES: HEALTH & SAFETY

7.1 Read appropriate risk assessment for this procedure.

7.2 Summary of risks for experimenter:

7.2.1 Sharps hazard

7.2.2 Biohazard

7.2.3 Non-compliance with HTA licence

7.3 Key safety issues (to minimise the above risks)

7.3.1 Sharps hazard: Handle all needles with care and dispose of appropriately and immediately after use. Ensure any persons working with sharps have read the relevant school SOP: 'Prevention of Sharps Injuries'.

7.3.2 Biohazard: Remove and replace any protective clothing which becomes contaminated

with blood or other bodily fluids as soon as possible. Clean spillages of blood or other body fluids with suitable disinfectant such as 1% Virkon solution (see your relevant school SOP: 'Disinfection Policies and Practices'). Dispose of clinical waste according to your relevant school SOP: 'Disposal of clinical waste, including human tissue' and clean any reusable equipment with warm soapy water. Wash laboratory clothing at high temperature (at least 60˚C).

7.3.3 Investigator must have been offered a current Hepatitis B inoculation, practice good hand washing technique, cover broken skin with plasters and wear appropriate protective clothing. Participants that have or have partners that have known blood borne viruses should be excluded from taking part in this procedure.

7.4 In the event that the skin of the investigator is cut or penetrated by a needle or other sharp object which may be contaminated with blood or body fluids, or blood or body fluids enter the investigator through mucocutaneous exposure such as blood splashing into their eye or mouth:

7.4.1 IMMEDIATELY

7.4.1.1 Where appropriate wash splashes off your skin with soap and running water.

7.4.1.2 Where appropriate wash out splashes in the eyes using tap water or an

eye wash bottle.

7.4.1.3 Where appropriate wash nose or mouth with plenty of tap water. DO NOT swallow the water.

7.4.2 If the skin is broken, encourage the wound to bleed and rinse thoroughly under running water. DO NOT suck the wound.

7.4.3 Record the source of the contamination.

7.4.4 Seek medical advice.

7.4.5 Report as an adverse incident according to SOP AI-008 ‘Reporting an adverse incident’.

7.5 Risk of non-compliance with HTA licence

7.5.1 Even though the production of platelet and cell free plasma renders the storage of these samples exempt from the HTA licence, the process and requirement for consent MUST still take place in accordance with the guidelines of the human tissue authority. To reduce any risk of non-compliance, all individuals working on the procedures above MUST have been adequately trained in; their responsibilities under the HTA, the laboratory techniques. In any suspected instance of non-compliance follow the procedures in your relevant school SOP: Reporting a serious adverse reaction under HTA licensable activity’.

8. DOCUMENTATION

8.1 Documentation to support this SOP

- Internal validation of centrifugation conditions to produce cell and platelet free plasma.

Process parameters	Whole blood				Plasma			
	RBC (10^{12}/L)	WBC (10^9/L)	Platelets (10^9/L)	MPV (fL)	RBC (10^{12}/L)	WBC (10^9/L)	Platelets (10^9/L)	MPV (fL)
1. 2500g for 20 mins	4.36	6.39	259	8.3	0.01	0.04	36	6.4
2. 4000g for 10 mins	4.39	6.34	265	8.6	0.01	0.05	23	6.6
3. 4000g for 20 mins	4.51	6.00	263	8.4	0.01	0.04	8	7.4

Table 1 - Internal validation data of plasma centrifugation conditions. Whole blood was passed through a cell counter and analysed for; red blood cell content (RBC), white blood cell content (WBC) and platelets. The whole blood was then centrifuged for the RCF and time noted in the table above. The resultant plasma samples were then passed through the cell counter and analysed for the same parameters.

Table 1 indicates that 10 mins at 4000g effectively removes RBCs, WBCs and platelets. In each instance, some particles were still detected but these were deemed to be within the margins of error of the detection method. For example, running de-ionised water through the cell counter regularly gives a reading of 0.03 x10^9 WBCs/L and the mean platelet volume of the spun plasma was lower than initially measured suggesting these are vesicles or debris, not cells. These results are in line with an equivalent SOP from Manchester Metropolitan University (V1.0 November 2022; MMU-HTA 016).

Table 2 further demonstrates that brake settings have no influence on outcomes.

Table 2 – Influence of brake settings on platelet number.

Condition number	Run 1			Run 2		
	RBC (10^{12}/L)	**WBC (10^9/L)**	**Platelets (10^9/L)**	**RBC (10^{12}/L)**	**WBC (10^9/L)**	**Platelets (10^9/L)**
1 – whole blood	3.84	8.26	261	3.82	8.22	263
2 – 4000g for 20 minutes (brake off)	0.00	0.04	18	0.00	0.03	12
3 – 4000g for 20 minutes (brake on)	0.00	0.03	17	0.00	0.03	18

Appendices 3

Anatomy Laboratory Code of Conduct

All users (staff or students) of laboratories where Human Tissue Authority (HTA) licensable activity occurs must adhere to this code of conduct.

The quality of work and the atmosphere in which work involving human tissue (including bone), is done is expected to be consistent with the reputation of Loughborough University as a leading educational and research institution. The personal, professional and ethical conduct of all staff and students should reflect the principles of dignity, integrity and respect for the law, rights, health and safety of all.

Staff and students should pay particular attention to respect the sensitivities, rights, and wishes of participants and any human tissue donated for research or teaching. High professional and ethical standards of handling such material must be upheld at all times.

Misconduct in the Anatomy Laboratory is unacceptable and will not be tolerated. Examples of misconduct include:

- Accessing the Anatomy Laboratory without permission or authorisation.
- Bringing in unauthorised visitors.
- Inappropriate and/or careless handling of human specimens.
- Photographing or video recording human specimens.
- Making disrespectful remarks, gestures or jokes relating to human specimens.
- Damage of human specimens and property.
- Unauthorised removal of any items from the Anatomy laboratory

This is not intended to be an exhaustive list and no code of conduct can set forth every applicable rule and cover every situation, however, staff and students should use common sense, adhere to all relevant University policies including the University HTA Licence Compliance Quality Manual, adhere to all applicable legislation including the Human Tissue Act (2004) and comply with up to date sources for guidelines of ethical conduct and best practice.

If you are unsure of whether a contemplated action is ethical and/or permitted by law or University policy, advice may be sought before taking action from the Designated Individual or Persons Designated for the purposes of the University HTA Licence.

Everyone is responsible within his or her scope of work for preventing unethical standards including violations of law and for speaking up if there is a possibility that violations have been observed. Reporting individuals can be assured that there will be no reprisals or retaliation of any kind for reporting any type of suspected problem or possible violation if the report is made in good faith. Failure to adhere to the standards in this code may result in disciplinary action, including but not limited to exclusion from the laboratory

Appendices 4

Report of an adverse incident involving a HTA licensable activity

This form can be used by anyone to report an adverse incident involving a HTA licensable activity. This includes any non-compliance with the University HTA licence.

Once completed the form should normally be filed with the departmental Quality Manager, unless the incident involves the departmental Quality Manager, in which case it should be filed with the University Quality Manager. See the University HTA Licence Compliance Quality Manual for further clarification of these roles.

1. Time and date of incident _____

2. Department/School/Centre_____

3. Name and details of person completing this form:

Title_____Surname_____Forename(s)_____

Position_____Email_____Tel_____

Description of incident:

Any subsequent action taken to reduce the impact/prevent future re-occurrence:

Any injury caused:

☐ Tick this box, if a University form to report an accident, near miss, a case of occupational ill-health or dangerous incident involving a person was completed.

Classification of significance (select the most appropriate classification and tick the box)*:

☐ Minor ☐ Major ☐ Critical

*A '**Minor**' incident is one that is classified as

- minor infringement of normal practice

A '**Major**' incident finding is a non-critical finding that:

- Reveals a significant and unjustified departure from the UK regulations, or
- Consists of a number of minor departures from the UK regulations or other relevant University guidance suggesting a systematic quality assurance failure, and/or
- Reveals a failure to comply with relevant legislative requirements of the HTA.

A '**Critical**' finding is defined as one where:

- Evidence exists that the confidentiality of study subjects has been (or has significant potential to be) jeopardised, and/or
- Serious doubt exists relating to the accuracy or credibility of sample data, or
- An incident likely to cause the HTA to revoke the Universities Research Licence.

Signature_____Date_____

Signature of department/University Quality Manager_____Date_____

Appendices 5: SOP Template

XXXXXXXXXX XX XXXXXXXX

Standard Operating Procedure (Template)

This Standard Operating Procedure (SOP) forms part of the University Quality Management System for the control of HTA licensable material within Loughborough University. This system is compliant with the Human Tissue Act 2004 and the Human Tissue Authority (HTA) standards and guidance.

Version History

Effective Date:	**xx xxx xxxx**
Date of Modification:	**xx xxx xxxx**
Date of next Review:	**xx xxx xxxx**
Author (s):	**xx xxx xxxx**
Approved by:	**xx xxx xxxx**

Signed: _____ Date: _____

Authorisation and Document Control

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Security Statement

1 Purpose

Description of the activity

2 Scope

To whom the SOP is applicable

3 Responsibilities

Individual responsibilities

4 References

Documents used to write the SOP

5 Procedure

Details of the procedure.

6 Special Notes

Any special notes relating to the activity or this document

7 Documentation

Accompanying documentation

Appendices 6: Material Transfer pre -agreement form

A Material Transfer Agreement (MTA) is a contract that governs the transfer/exchange of material. MTA's are designed to protect proprietary rights in the material and as such they should be initiated by the supplying organisation. These agreements can be used to restrict the use of the material to exert a measure of control over the transferred material to ensure that the tissue is used within the terms of consent, and that an audit trail is maintained. This level of control is a legal requirement for the transfer of Human Tissue Authority (HTA) licensable material. See the University HTA Licence Compliance Quality Manual for further clarification.

Additionally please see the Loughborough Research Support page for the pre-approval MTA agreement form and guidance on processes and completion:
https://www.lboro.ac.uk/research/support/collaboration/

An MTA for HTA licensable material should address the following:

1. Identification of the parties in the agreement (i.e. supplier and recipient)
2. Definition of the material to include:
    a. Statement that the sample(s) is 'relevant material' as defined by the HTA according to the Human Tissue Act (2004),
    b. Statement that the sample(s) is HTA licensable material (i.e. it is not from a HTA licensed tissue bank, part of a study approved by a HTA recognised ethics committee or from a deceased person where more than 100 years have elapsed since the person's death).
    c. Whether the sample(s) was obtained prior to 1st September 2006.
    d. Description of tissue type e.g. full blood/stem cell/bone.
    e. Whether the sample(s) was obtained from a living or deceased person.
    f. Whether the sample(s) is anonymised and if so the details of the process.
    g. Whether the recipient of the material will be provided with any additional information about the donor(s).
3. Any restrictions on the recipient's use of the material to include:
    a. The parameters and any restrictions of consent
4. Compliance with the Human Tissue Act (2004) to include:
    a. Details of HTA Licences held by the supplier and recipient.
    b. Details of the permitted use.
    c. Details for the planned disposal of any surplus material at the end of the permitted use (in compliance with any requirements of the consent provided).

    d. Requirement to maintain an audit trail documenting the transfer, use and disposal of the sample(s).

5. Recipient’s obligation to confidentiality and freedom to publish
6. Providers access to reports and publication
7. Providers rights to recipient’s inventions and results
8. Intellectual Property Ownership and management
9. Warranty disclaimer and indemnification
10. Governing Law

Appendices 7: Log of Skeletal Material held by the University

This list details the skeletal material held within the School of Sport, Exercise and Health Sciences. Only the skull, ribs, clavicle bones, humerus bones and vertebrae bones are used for the purposes of teaching anatomy.

Tissue	Quantity	Required for teaching
Full complete skeleton	5	Yes
Skeleton (2) – incomplete	2	
Fibia, Tibia, Patella and Foot from incomplete skeleton (designated as skeleton 2)	1	
Skull and facial bones	0	
Skull (complete)	2	Yes
Skull (partial)	2	Yes
Skull - Parietal	5	Yes
Skull - Frontal	3.5	Yes
Skull – Temporal	4	Yes
Skull – Occipital	4	Yes
Skull – Spenoid	2	Yes
Skull - Mandible (complete)	2	Yes
Skull - Mandible (partial)	5	Yes
Skull and its associated fragments (Sealed bag)	1	No
Vertebrae	88	Yes
Ribs	45	Yes
Sternum	6	Yes
Humerus	6	Yes
Radius	7	Yes
Ulna	5	Yes
Radius and Ulna (attached)	3	Yes
Hand	3	Yes
Incomplete Hand (bones)	3	
Whole arm and shoulder Girdle	1	
Femur	4	Yes
Tibia	7	Yes
Fibula	9	Yes
Tibia and Fibula (attached)	1	Yes
Foot	4	Yes

Incomplete midfoot	2	Please advise
Individual bones of the foot	3	Please advise
Patella	6	Please advise
Scapula	4	Yes
Ilium	6	Yes
Sacrum	5	Yes
Clavical	8	Yes
Upper Turso	1	Yes
Teeth	29	Yes

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Date	Assessed by (name and signature required)	Checked / Validated (delete as appropriate) by (name and signature required)	Location	Version no.	Review date (typically 2 years from date of first assessment)
28/11/22	Donna Bentley 	Karen Coopman.		003	28/11/24
19/09/2025	Jennifer Tranter	Karen Coopman	Reviewed and updated to ensure applicable to all schools that undertake research with the use of human tissue	004	September 2027

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Taking consent from participants to source HTA relevant material	Breech of HTA licence An individual not trained in consent taking consent.	LU The participant	The LU ethics committee have been asked by the HTALSC to issue a list of all studies involving HTA material to the DI and the regulatory team (for those studies that take place away from the SSEHS) to enable them to cross check that the persons involved had completed consent training/ HTA training etc. All individuals undertaking research with human tissue are provided with guidelines on how to access mandatory HTA training MRC HTA training 1) MRC Human Tissue Training : MRC training link is: http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1 University online HTA training modules via the LEARN platform. HTA style consent audits are being carried rut. As well as matching the consent to the sample, the consent audits also check that the consent form has been appropriately filled in such that the consent sign off is for either project specific or enduring consent, and not both.	3	5	15	A	

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
			Consent competency observations are typically booked in as soon as possible after the study starts. This is so any deficits in practise regarding the consent process or the form can be corrected. A consent competency online module is available for students to access on the LEARN platform before undertaking consent with their first recruited participant.					

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
Taking consent from participants to source HTA relevant material	Inappropriate consent sought.	The participant LU may experience a loss of public confidence if malpractice or complaints ensue. This could be the case if an incident arose that made it to the press.	Consent training takes place. Consent competency assessments take place to observe how researchers are delivering and managing the consent process. It is intended that any non-compliance or bad practise will be picked up on and actions formally noted. The LU consent form template has been updated such that the consent fields for project specific or enduring consent are clear that this field is an either, or option on the consent form.	3	5	5	A	
Taking consent from participants to source HTA relevant material	Work continues after a tissue donor withdraws consent, or beyond the ethics expiry.	The participant, The investigator LU; this is a breach of regulatory/ licensing standards.	Sample expiry dates are added as a mandatory field on Pro-curo. All investigators are encouraged to use Pro-curo. If any breaches are found, this needs to be escalated to the regulatory team, who will investigate and then inform the designated individual.	3	5	15	A	

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
Work with HTA material	Failure to evidence consent for a sample.	The participant, The investigator LU; this is a breach of regulatory/ licensing standards. LU may suffer a loss of public confidence. HTA inspection reports are published online so collaborators and other organisations/ funding bodies can view this. They may take a decision not to work with LU.	If any breaches are found, this needs to be escalated to the regulatory team, who will investigate and then inform the designated individual. Mandatory consent training is provided via the University online HTA consent module on the LEARN platform and via HTA MRC learning Staff declaring that they intend to work with HTA material will have this logged, and checks will be made to ensure training is completed HTA style consent form audits take place as part of routine sample traceability audits.	3	5	15	A	

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
Working with HTA material – loss of traceability.	Loss of traceability	The participant, The investigator, Loughborough University-breech of licensing standards.	Support is given to assist with the set-up of Pro-curo projects and sample labels. HTA style sample traceability audits are carried out to aid with the maintenance of standards.	3	5	15	A	
Working with HTA material – loss of traceability.	Loss of traceability leading to loss of public confidence	LU as a organisation and any researchers aspiring to take part in collaborative research.	Regular sample audits to check records are as they should be. This is going to be done internally to the department and also externally to the department. Ensure no one trained individuals work with HTA material.	4	5	20	A	

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
	Breech of security leading to loss of samples	The participant, The investigator, Loughborough University- breech of licensing standards.	Key card access is required to access the laboratory areas where samples are kept. Samples are only handled within laboratory areas, except if they have been packaged up and are leaving the lab to go via courier to a partnership organisation (with an appropriate MTA set up). If any breech should occur, the regulatory team and DI should be noted and adequate investigations and incident reporting take place.	3	5	15	A	

Risk Assessment

Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Key: T= trivial risk; **A** = adequately controlled, no further action necessary; **N** = not adequately controlled, actions required; **U** = unable to decide (further information required)

***Likelihood**

5 Very likely – risk will occur repeatedly. To be routinely expected once every 20 – 100 operations, possibly weekly or more frequently if done regularly.

4 Likely – will occur several times a year so does not surprise when it happens.

3 Possible – may occur sometimes. Likely to occur once a year.

2 Unlikely – but may occur perhaps once in every 10 to 100 years.

1 Very unlikely to occur. Likelihood approaching zero.

****Severity**

5 Critical – Loss of Licence, loss of HTA relevant material, severe reputational damage,

4 Major shortfall– severe loss of traceability, some reputational damage

3 Medium shortfall – some reputational damage, potential to lead to loss of traceability or HTA relevant material.

2 Minor shortfall – some loss of traceability, minor compliance issues that are indicative of lack of control.

1 No loss of traceability or HTA relevant samples but is not best practice and not in line with the HTA quality control manual.

***** Risk rating = Likelihood x Severity**

Likelihood x Severity = Risk assessment score

(LOW RISK 1-8 / MEDIUM RISK 9-15 / HIGH RISK 16-25)

1 - 5	**Very low risk** - often require doing nothing!
6 - 10	**Low risk** - improve if possible (typically within 1 - 2 years)
11 - 15	**Medium Risk** - Introduce further controls to reduce risk further (typically 1 - 3 months)
16 - 20	**High Risk** - Possibly stop operation? or immediately introduce control measures within a day or two.
21 - 25	**Totally unacceptable risk** - stop operation and rectify immediately.

Risk Assessment

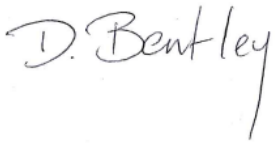
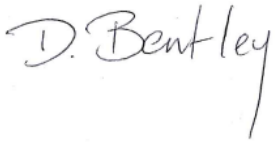
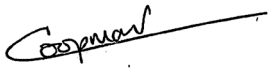
Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

Action plan				
Version no.	**Further action required**	**Action by whom**	**Action by when**	**Done**

Risk Assessment

SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Date	Assessed by (name and signature required)	Checked / Validated (delete as appropriate) by (name and signature required)	Location	Version no.	Review date
01/02/2017	Donna Bentley 	Neil Martin 	All suitable locations within the SSEHS	003	01/02/2019
22/6/2018	Donna Bentley 	K Coopman 	Reviewed to formally encompass all areas of the University	004	22/6/2020
11/06/2020	Donna Bentley 	K Coopman	Reviewed to ensure information is up to date. Hyperlinks checked and updated if necessary. Severity scales updated	005	11/06/2022
11/06/2022	Donna Bentley 	K Coopman		006	11/06/2024
19/09/2025	Jennifer Tranter	K Coopman	Reviewed and updated to ensure applicable to all schools that undertake research with human tissue	007	September 2027

Risk Assessment SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
Work under HTA licensable activity- transport of relevant material.	Loss of relevant material	The researcher conducting the study (via loss of sample). LU as a whole may experiences consequences in terms of former grant applications etc. due to delays in research.	Each sample must be tracked and recorded from collection to disposal according to the existing arrangements for storage of HTA licensable material. Backups of sample records MUST exist. Records of samples MUST be kept up to date. Disposal of samples must be logged. If samples are being transferred between sites or different locations on the same site; On completion of the transfer the universities record of each sample must be maintained, i.e. a field of information regarding transfer to and from other locations should be completed alongside a record of the samples unique identifier/ barcode and any planned return dates if relevant. There must be a material transfer agreement in place for any planned transfer of relevant material. No material can be transported without a planned transfer. An SOP is provided for the transfer and transportation of HTA licensable material (see AI-028 if based in the SSEHS or HTAL/SC/SOP 003 for the central SOP record.	1	5	5	A	Risk adequately controlled.

Risk Assessment SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
Work under HTA licensable activity-	Infringement of HTA license/ loss of relevant material.	The researcher conducting the study (via loss of sample). LU as a whole may experiences consequences in terms of former grant applications etc. due to delays in research/ revoked HTA license.	NO HTA licensable material may be transported from 1 establishment to the other unless both establishments are subject to an appropriate HTA license or the samples are part of a study with ethical approval from a recognised ethics authority. The named establishments are checked for a HTA licence prior to the transfer taking place. This is done by looking at the HTA website https://www.hta.gov.uk/professional/establishments	1	5	5	A	Risk adequately controlled.

Risk Assessment SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Work under HTA licensable activity- transport of relevant material.	Damage of relevant material / samples rendered unusable due to inappropriate packaging/ storage conditions/ prolonged delays during transport.	The researcher conducting the study (via loss of sample). LU as an organisation may experience consequences. The consequences may take the form of regulatory action. If relevant material is lost, work may be stopped in lieu of a formal investigation. Associated bad press may ensue, which impacts upon the reputation of the University. There may be refusal of formal grant applications etc. due to delays in research due to sample loss, or associated regulatory incident.	Technical support is available to ensure that samples are packaged appropriately and in accordance to The Transport of Dangerous Goods Act)-UN3373. Packaging samples appropriately mitigates against the risk of sample loss / damage or leakage of biological sample should an adverse event occur during transit. If and when transport of relevant material occurs between sites/ establishments; specialist courier companies, conversant in the transport of HTA licensable material and biological storage conditions are employed. There are several couriers on the University supplier list, all of which have been approved for the transport of HTA material. Documents demonstrating continuity of ownership will be provided. Staff are made aware which University approved couriers to use at the HTA training, and of the importance of keeping up to date records of sample transport. The university approved couriers are all price differently. This is to allow researchers to choose more affordable options to prevent alternative methods of sample	1	5	5	A	Risk adequately controlled.

Task/ premises: Transport of material under a HTA licence

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
			transport taking place due to lack of funds. This mitigates the risk of the relevant samples being damaged, and loss of relevant material. PI's are trained such that they are aware that samples for transportation must be collectively labelled to include:- The study The investigator The sample ID and type Period during which samples were collected Details of appropriate storage conditions. Collection and delivery locations. Planned time and date of delivery. The carrier responsible for consignment. The planned date of disposal The signatures and times and date of receipt of each person in the chain of custody.					

Risk Assessment SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk
HTA licensed activity - transport of relevant material.	Loss of relevant material.	The researcher conducting the study (via loss of sample). LU as a whole may experiences consequences in terms of former grant applications etc. due to delays in research/ revoked HTA license/ enforced cessation of work. LU may also suffer loss of reputation/ integrity.	Samples of "Relevant material" are NOT to be released to anybody unless continuity of ownership can be demonstrated, and the relevant records kept. Samples of "relevant material are not to be released to unauthorised individuals. All staff undergo mandatory HTA training which includes sample management and are aware of the need to demonstrate continuity of ownership. A material transfer agreement is required for the transport of all material out of or into the University. Templates and guidance on completing the MTA is available from Collaboration | Research Support | Loughborough University If samples are suspected as lost all efforts must be made to retrieve the samples and this must be reported to the Designated Individual	1	5	5	A	Risk adequately controlled.

Risk Assessment

SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

HTA licensed activity	Storage failure at sample start point or during transit.	The researcher conducting the study (via loss of sample). LU as a whole may experience consequences in terms of former grant applications etc. due to delays in research/ revoked HTA license/ enforced cessation of work. LU may also suffer loss of reputation/ integrity.	Freezer alarm systems and an out of hours call out procedure is in place, such that if storage failure does occur, staff can be alerted to deal with the issue straight away. Courier services have vehicles with temperature monitoring facilities available, such that if the sample temperature deviates, it can be dealt with in time. Designated back up freezer space is allocated for sample transfer if necessary. This can include space in other Depts if necessary and the freezer room in the NCSEM has access to a backup generator in case of power failure. Human samples are stored and logged in specific designated locations such that if an adverse incident (involving storage failure) did occur they could be located and moved quickly. Keeping adequate records can also aid in the identification of any damaged samples, such that not all samples are lost, should and incident occur. A business continuity plan is in place to ensure continuation of service and maintenance of sample integrity in the event of a power failure.	1	5	5	A	Risk adequately controlled.

Risk Assessment

SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

Activity	Hazard	Who might be harmed and how	Existing measures to control risk	Likelihood*	Severity**	Risk rating***	Result (T,A,N,U)	Additional controls required to adequately control the risk

Key: T= trivial risk; **A** = adequately controlled, no further action necessary; **N** = not adequately controlled, actions required; **U** = unable to decide (further information required)

***Likelihood**

5 Very likely – risk will occur repeatedly. To be routinely expected once every 20 – 100 operations, possibly weekly or more frequently if done regularly.

4 Likely – will occur several times a year so does not surprise when it happens.

3 Possible – may occur sometimes. Likely to occur once a year.

2 Unlikely – but may occur perhaps once in every 10 to 100 years.

1 Very unlikely to occur. Likelihood approaching zero.

****Severity**

5 Fatality – death of an employee or multiple fatalities.

4 Major injury – permanent disability, serious amputation e.g. Loss of hand.

3 Medium injury e.g. Bad scald, or burn, fracture, minor amputation, temporary injury, loss of consciousness. Reportable to the HSE as a three day lost time (employee unavailable for normal work for over 3 days) or serious injury.

2 Minor injury – More severe cut, sprain, strain, burn, etc. where return to work is not possible after treatment. It may be lost time less than 3 days.

1 No injury or very low injury – scratch, bruise, knock, minor cut, needle stick etc. where the injury allows return to work after first aid treatment – no lost time.

***** Risk rating = Likelihood x Severity**

Action plan				
Version no.	**Further action required**	**Action by whom**	**Action by when**	**Done**