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

Effective Date:	**October 2010**
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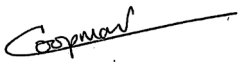
Date of next Review:	**October 2021**
Author (s)	**Mr Tony Goodall** **Ms Jacqueline Green** **Dr Donna Bentley**
Approved by	**Dr Karen Coopman**

Signed:  **Date: 15.12.2020**

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) and the Department of Chemistry, 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 Dept of Chemistry is primarily focussed on development of analytical techniques that help us interrogate human samples.

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 practise 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 (see HTA Code of Practice and Standards E: Research – Annex B and Annex C):

- 'Relevant material' held for a specific research project approved by a 'recognised' ethics authority[1]* for the duration of the project.

[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

- ‘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 HTA guidance on the definition of relevant material and accompanying supplementary list of materials). 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 offense, 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 E: Research and Code of Practice E: Research Standards and Guidance.
- General Medical Council guidance on the ethical considerations relating to seeking patients’ consent
- 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 Approvals (Human Participants) Sub-Committee (HPSC)

Trials) Regulations 2004. N.B. Loughborough University Ethics Approvals (Human Participants) Sub-Committee does not satisfy this criteria.

- Loughborough University HPSC Guidance notes 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)	Dr Karen Coopman, Reader in Biological Engineering
Persons Designated (PD) –	Dr Neil Martin, Lecturer (SSEHS)
	Professor Paul Thomas, Professor of Analytical Science (Department of Chemistry)
	Prof Rob Thomas, Professor of Manufacturing for Cell and Gene Therapies (CBE, School of Mechanical, Electrical and Manufacturing Engineering)
University Quality Manager (QM) –	Dr Jen Fensome, Director - Research and Enterprise
Departmental Quality Managers (dQM) –	Mr Tony Goodall, Technical Resources Manager Manager's (SSEHS)
	– Matthew Turner (Department of Chemistry)
	– Carolyn Kavanagh/Kulvindar Sikand (CBE, School of Mechanical, Electrical and Manufacturing Engineering)

The Regulatory - Compliance Officer (RCO)	Dr Donna Bentley (SSEHS)
Human Tissue Act License Committee – (HTASLC)	Membership includes: DI (Chair), QM, PDs, dQMs, Secretary (Research Office), The Regulatory Compliance Officer, 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 The Regulatory Compliance Officer

The Regulatory Compliance Officer (RCO) is responsible for supporting the dQMs and the DI, advising on HTA related matters. They report to the HTALSC. In addition, currently being based in SSEHS, the RCO is responsible for checking HTA compliance in SSEHS study applications and supporting researchers and their students in ensuring that they are working to best practise within the legislative guidelines.

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, ADs 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 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 Approvals (Human Participants) Sub-Committee (HPSC). HPSC meets twelve times each year. LUEC reports to The Council and The Senate annually. The DI interacts with the HPSC to ensure that ethics checklists and applications 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.

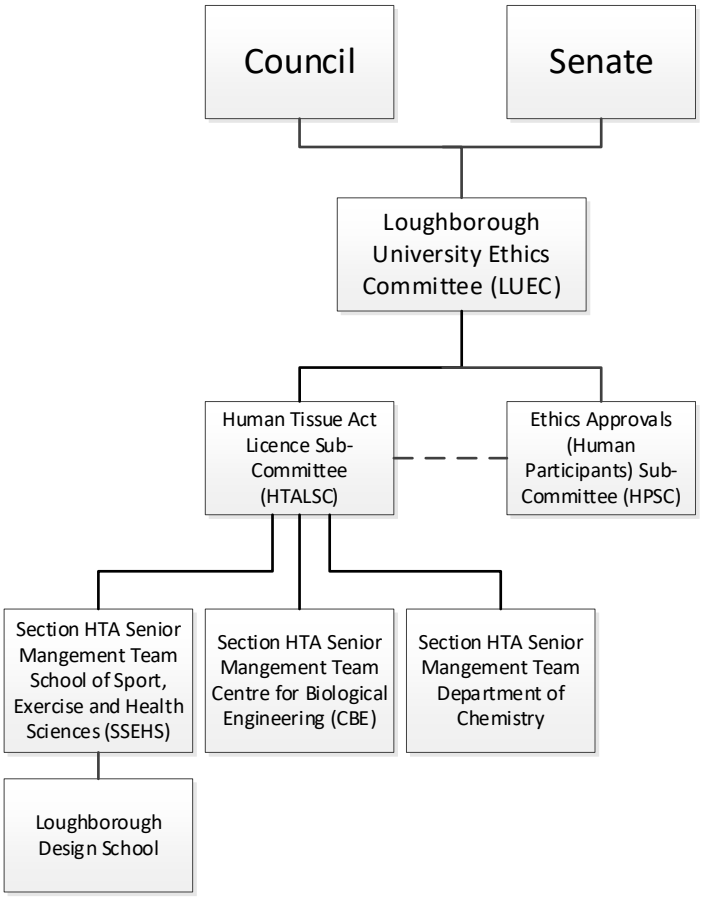


Figure 1: Governance Structure for Quality Management System

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.
- 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 in order 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 HPSC 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 (see Annex B, Code of Practice E: Research). 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 (see HTA guidance non-consensual use of DNA).

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. In order to make an informed choice the person should understand what the activity involves, and where appropriate, what the risks are; and 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 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 HPSC 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.

5.3.6 Other Relevant Legislation

It is important to be aware that in addition to the consent provisions of the Human Tissue Act 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 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 4 couriers on the University purchasing books, and the RCO holds information regarding approved transport 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 HPSC.

Details of the University's approach to Freedom of Information requests and Data Protection Policy can be found here https://www.lboro.ac.uk/admin/ar/policy/foi/index.htm and here https://www.lboro.ac.uk/services/policy/ respectively.

5.4 Acquisition and Use

Research involving the acquisition of HTA licensable material requires ethical approval. The University HPSC 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. (NB 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 Procuro including:

- Unique identifier (matching sample label)
- Research study
- Tissue type
- Date of collection/receipt from other establishment and where it came from
- Storage location

- Consent details (including where the consent is held)
- Dates of sample processing
- If relevant, information regarding transfer to and from other locations
- Date and details of disposal
- Reason for 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 Procuro Sample Inventory Database. It is also advised that samples held under NHS ethics are also logged on the Procuro 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 HPSC. 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 crosschecked 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 by the RCO during the annual 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 taken into account. 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). A HTA specific 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 will undertake Human Tissue Licence training course. This will be delivered by the DI, PDs and Regulatory Compliance Officer. dQMs may deliver additional training on local SOPs as necessary. All such training will be 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.

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), 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 and Procedure.

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 Regulatory Compliance and Departmental Quality managers to ensure all incident and compliance reporting is completed.

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 officer a minimum of 4 times per year. In addition, a minimum of 2 external audits will be carried out by the DI 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 evaluate 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

Standard Operating Procedures:

- Production and Control of SOPs for the Control of HTA Licensable Material
- Acquisition and Storage of HTA Licensable Material
- Transfer and Transportation of HTA Licensable Material
- Disposal of HTA Licensable Material

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

Anatomy Laboratory Code of Conduct

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

Standard Operating Procedure Template

Material Transfer Agreement Checklist for HTA Licensable Material

Log of Skeletal Material held by the University

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

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:	**October 2010**
Date of Last Modification:	**July 2016**
Date of next Review:	**October 2021**
Author (s):	**Mr Tony Goodall** **Ms Jackie Green**
Approved by:	**Dr Karen Coopman**

Signed: _____Date: _____

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 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.

2 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.

3 Responsibilities

3.1 Any person writing a relevant SOP must follow this procedure.

3.2 The University Quality Manager for the HTA Licence is responsible for the control of this document.

3.3 The Designated Individual for the University HTA Licence is responsible for ensuring that this SOP is reviewed and updated as necessary by the Human Tissue Act Licence Sub-Committee.

3.4 The current version of this SOP must be approved by the Designated Individual for the University HTA Licence.

4 References

The Human Tissue Act (2004) and HTA guidance and Codes of Practice

The University HTA Licence Compliance Quality Manual

5 Procedure

5.1 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.

5.2 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.

5.3 SOPs must include the following:

The author's name

Version number
Effective Date
Review Date
Unique identification number

5.4 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.

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

5.6 Any revisions to the SOP must then be communicated to staff members by the departmental Quality Manager.

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

5.8 The Master Copy of the SOP must be filed and older versions retained and archived by the University Quality Manager.

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

SOP Template

Acquisition and Storage of HTA Licensable Material

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:	**October 2010**
Date of Last Modification:	**July 2016**
Date of next Review:	**October 2021**
Author (s)	**Mr Tony Goodall** **Ms Jackie Green**
Approved by	**Dr Karen Coopman**

Signed: _____Date: _____

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. Thus providing written instruction and record of procedures agreed and adopted as standard practice for the purposes of compliance with the HTA Licence.

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.

3.2 The principal investigator of the study, or departmental Quality Manager (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.

3.3 All those involved in the procedure 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 is 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

The Human Tissue Act (2004) and HTA guidance and Codes of Practice

The University HTA Licence Compliance Quality Manual

5 Procedure

5.1 Ethical approval must be obtained from the University Ethics Approvals (Human Participants) Sub-Committee (HPSC). The study protocol which is submitted to the HPSC must include the following.

5.1.1 Details about the procurement or direct acquisition process, including any planned checks to ensure external organisations/collaborators procedures comply with the Human Tissue Act and/or details of any University or local level SOPs to be followed.

5.1.2 Any risk assessments and control measures in place

5.1.3 Any Material Transfer Agreements and/or Participant Information Sheets

5.1.4 Consent Forms or details of the checks in place to ensure that the collection of procured samples complied with the Human Tissue Act.

5.1.5 Details regarding the planned location, duration and control of storage including any contingency plans in place in the event of facility or appliance failure.

5.1.6 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 every three years thereafter), the University Informed Consent Training course 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.

5.4 The Principal Investigator must liaise with the departmental Quality Manager regarding the planned acquisition, storage, use and disposal of HTA licensable material.

5.4.1 Agree any facilities to be used; arrange any maintenance, cleaning, and preparation of facilities necessary; the record/labelling system to be used for the samples collected; and the procedure for monitoring the storage of the sample(s).

5.4.2 Reciprocal arrangements for back up facilities should be made with other researchers as a contingency plan in the event of facility or appliance failure.

5.4.3 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 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[1*] 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.

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 the University HTA Licence Compliance Quality Manual for further clarification), and the planned duration of storage should be specified during the consent process. 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.

5.8 A code of conduct to ensure that samples are treated with appropriate dignity and respect must be displayed in all laboratories where HTA licensable activity occurs.

5.9 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.

5.10 Every sample must be individually labelled with a unique identifier/bar code 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

[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 Approvals (Human Participants) Sub-Committee does not satisfy this criteria.

Consent/Material transfer details (including where the documentation is held)
Dates of sample processing
Information regarding transfer to and from other locations (if relevant)
Date and details of disposal
Reason for disposal

5.11 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.

5.12 Any adverse incident should be reported to the dQM and any corrective action taken should be recorded. In addition if a person(s) was involved the incident should be reported in the usual way according to the University Policy on the reporting of Accidents, Dangerous Occurrences and Occupational Ill Health.

5.13 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.

5.14 Holdings must be reviewed annually by the researcher and crosschecked with appropriate consent and research protocols.

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

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

Material Transfer Agreement Checklist for HTA Licensable Material

University Occupational Health Surveillance Form

Anatomy Laboratory Code of Conduct

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

University Forms to report an accident, near miss, a case of occupational ill-health or dangerous incident involving a person

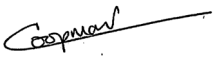
Transfer and Transport of HTA Licensable Material

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:	**October 2010**
Date of Last Modification:	**November 2019**
Date of next Review:	**October 2021**
Author (s)	**Mr Tony Goodall** **Ms Jackie Green**
Approved by	**Dr Karen Coopman**

Signed: _  **_____ Date: _26.11.2019_____**

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 transfer and transport of HTA licensable material for research. 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 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 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 procedure are appropriately trained.

3.3 All those involved in the procedure 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 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 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.

4 References

The Human Tissue Act (2004) and HTA guidance and Codes of Practice

The University HTA Licence Compliance Quality Manual

5 Procedure

5.1 Appropriate modes of transport, suitable routes and arrangements with people involved must be planned and arranged in advance.

5.2 A complete risk assessment of the transfer and any transportation must be undertaken and approved by the Designated Individual or Persons Designated prior to the planned transfer and transportation of HTA licensable material.

5.3 Ethical approval must be obtained from the University Ethics Approval (Human Participants) Sub-Committee (HPSC) and the relevant permission or approval for the activity secured from any external organisation HTA licensable material is being transferred from or to.

5.3.1 The study protocol submitted to the HPSC 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, including the status and any additional conditions of any HTA Licences or other relevant accreditation held.

5.4 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 two years thereafter), the University Informed Consent Training course and have a record of such training and competencies.

5.5 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.

5.6 There must be a Material Transfer Agreement for any planned 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 has been 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 and safeguards to ensure the destruction process complies with current legislation including the Human Tissue Act (2004).

5.7 Valid consent must be established or 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 the University HTA Licence Compliance Quality Manual for further clarification). 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[1*] may be stored without a HTA licence and do not necessarily require consent).

5.8 Samples must be packaged appropriately and suitable methods of transportation planned to maintain the integrity of the sample during transportation and according to current legislation and University policies including:

Data Protection legislation

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

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 samples unique identifier/barcode and any planned return dates if relevant.

[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 Ethical Approvals (Human Participants) Sub-Committee does not satisfy this criteria.

5.15 Records of HTA licensable holdings must be reviewed annually by the researcher and crosschecked with appropriate consent, research protocols and the location of storage. If the samples are held by an external organisation material transfer agreements should be crosschecked 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. In addition if a person(s) was involved the incident should be reported in the usual way according to the University Policy on the reporting of Accidents, Dangerous Occurrences and Occupational Ill Health.

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]*.

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

University Occupational Health Surveillance Form

Material Transfer Agreement Checklist for HTA Licensable Material

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

University Form to report an accident, near miss, a case of occupational ill-health or dangerous incident involving a person

Disposal of HTA Licensable Material

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:	**October 2010**
Date of Last Modification:	**July 2016**
Date of next Review:	**October 2021**
Author (s)	**Mr Tony Goodall** **Ms Jackie Green**
Approved by	**Dr Karen Coopman**

Signed: _____Date: _____

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 guidance and Codes of Practice

The University HTA Licence Compliance Quality Manual

5 Procedure

5.1 Prior to the destruction of any HTA licensable material, the sample(s) must have been identified and any conditions of donor consent, ethical approval or a material transfer agreement adhered to.

5.2 HTA licensable material should normally be disposed of in accordance with the study protocol on completion of the research, or occasionally where consent has been withdrawn. Samples may also be destroyed due to lack of quality or stability.

5.3 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.

5.4 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), the University Informed Consent Training course and have a record of such training and competencies.

5.5 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.

5.6 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.

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

5.6.2 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.

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

5.6.4 Waste collected in laboratories bins should be promptly removed and stored in the designated secure facility from which it is removed by the University Waste Removal Supplier. Bins should never be filled more than two thirds full.

5.6.5 Where disposing of complete samples, where practical, it is preferable for a new bag to be used in order that ‘relevant material’ is bagged separately from other waste.

5.6.6 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.

5.6.7 Always use the waste utensil appropriately. For example if the bin has a lid ensure the lid is shut and that it is not overfull before you leave the room.

5.6.8 When disposing of clinical waste drop the item and never throw the item into the appropriate utensil.

5.6.9 Appropriate precautions should be taken to reduce the likelihood of spillage during the transfer of clinical waste, such as double bagging and the sealing of sharps containers prior to removal.

5.6.10 Care should be taken to avoid any spillage or splashes if any bodily fluids or fluids which may be contain 'relevant material' are disposed of in appropriate designated laboratory drains.

5.6.11 If there is any problem with the maintenance or collection of biological waste contact the University Health and Safety Office immediately.

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

5.7.1 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.

5.7.2 If the sample had been transferred from another organisation this organisation should normally be informed of the destruction of the sample according to the details of the material transfer agreement in place.

5.8 Records of holdings of HTA licensable material must be reviewed annually by the researcher and crosschecked 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.

5.9 Any adverse incident should be reported to the department Quality Manager and any corrective action taken should be recorded. In addition if a person(s) was involved the incident should be reported in the usual way according to the University Policy on the reporting of Accidents, Dangerous Occurrences and Occupational Ill Health.

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

University Occupational Health Surveillance Form

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

University Portal to report an accident, near miss, a case of occupational ill-health or dangerous incident involving a person

Consent Form Template

Use the latest template available at:

http://www.lboro.ac.uk/committees/ethics-approvals-human-participants/additionalinformation/applicationformsandtemplatesfordownload/

Please adapt this form to suit your project. Statements in yellow can be removed if not relevant.

Loughborough University

[Insert Title of Research Proposal]

INFORMED CONSENT FORM
(to be completed after Participant Information Sheet has been read)

Taking Part	**Please initial box**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the Loughborough University Ethics Approvals (Human Participants) Sub-Committee.	☐
I have read and understood the information sheet and this consent form. I understand that taking part in the project will include being photographed, interviewed and recorded (audio or video).	☐
I have had an opportunity to ask questions about my participation.	☐
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain my reasons for withdrawing.	☐
I agree to take part in this study.	☐
Use of Information	
I understand that all the personal information I provide will be treated in strict confidence and will be kept anonymous and confidential to the researchers unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities.	☐
I understand that anonymised data/quotes may be used in publications, reports, web pages, and other research outputs.	☐
I understand that the anonymised data I provide will be made publicly available for future research through a data repository or data archive at the end of the project.	☐
I agree to assign the copyright I hold in any materials related to this project to [name of researcher].	☐
Bodily Samples	
I agree that the bodily samples taken during this study can be stored until **[insert date]** for **future research** in the same research theme as this project.	☐
[Or] I agree that the bodily samples taken during this study can **only be used for this study** and will be disposed of within **XX years** [or]upon completion of the research **[insert date].**	☐

_____		_____	_____
Name of participant	[printed]	Signature	Date
_____		_____	_____
Researcher	[printed]	Signature	Date

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 possible violations are 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.

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_____

XXXXXXXXXX XX XXXXXXX

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

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

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

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

Material Transfer Agreement Checklist for HTA Licensable Material

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 in order 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.

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 anonoymised 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 recipients 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. Recipients obligation to confidentiality and freedom to publish
6. Providers access to reports and publication

7. Providers rights to recipients inventions and results
8. Intellectual Property Ownership and management
9. Warranty disclaimer and indemnification
10. Governing Law

Log of Skeletal Material held by the University

This list details the skeletal material held within the School of Sport, Exercise and Health Sciences for the purposes of teaching anatomy.

Tissue	Quantity	Required for teaching
Full complete skeleton	3	Yes
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
Vertebrae	87	Yes
Ribs	45	Yes
Sternum	6	Yes
Humerus	6	Yes
Radius	7	Yes
Ulna	5	Yes
Radius and Ulna (attached)	3	Yes
Hand	2	Yes
Femur	4	Yes
Tibia	7	Yes
Fibula	9	Yes
Tibia and Fibula (attached)	1	Yes
Foot	4	Yes
Scapula	4	Yes
Ilium	6	Yes
Sacrum	5	Yes
Clavical	8	Yes
Upper Turso	1	Yes
Teeth	28	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)
28/11/18	Donna Bentley 	Neil Martin/ Karen Coopman.	SSEHS (School of sport exercise and health sciences) -All suitable locations	001	28/11/20

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	Breech of HTA licence An individual not trained in consent taking consent.	LU The participant	The LU ethics committee have been asked by the HTA 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. Consent training sessions are run at least twice a year. For anybody that cannot make the sessions, small group sessions and 'one to ones' are offered by the regulatory team. HTA style consent audits are being carried out as of August 2018. 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. Consent competency assessments are also carried out across the SSHES.	3	4	12	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
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 around the SSEHS 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	4	12	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 Procuro. All investigators are encouraged to use Procuro. If any breaches are found, this needs to be escalated to the regulatory team, who will investigate and then inform the designated individual.	3	4	12	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
	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. Consent training is given to all people who declare that they will be working with HTA material in their ethics applications (within the SSEHS). All ethics applications from the SSEHS go via the regulatory team. Staff declaring that they intend to work with HTA material will have this logged, and checks will be made. HTA style consent audits take place.	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 Procuro projects and sample labels. HTA style sample traceability audits are carried out (in addition to the 6 audits per year 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.	Traceability is important. It demonstrates control over our sample collections and makes it easy to track a sample down should a participant withdraw consent or should ethics expire. Traceability is checked during the HTA visit and the outcomes are openly published in the HTA inspection report. Example of good practise are shared, as are areas for improvement. Potential collaborators, funding bodies and other parties can look at this information. If this does not reflect LU positively then this may affect a partnership organisation or funding bodies likelihood of working with us.	4	5	20	A	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 none trained individuals work with HTA material.

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.	2	5	10	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

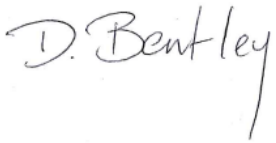
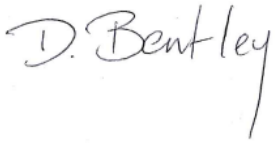
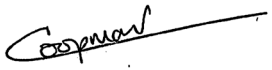
Task/ premises: **HTA Risk Assessment -Inappropriate consent and loss of traceability.**

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

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).	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 at www.hta.gov.uk/establishments	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- 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 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 must be packaged appropriately and suitable methods of transportation planned to maintain the integrity of the sample during transportation and according to the current legislation and University policies (including those for the correct labelling and identification of samples). 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 3 couriers on the University supplier list, all of which have been approved and will provide documents demonstrating continuity of ownership. Staff in the SSHES are made aware of which couriers to use at the HTA training. The 3 approved couriers all price differently. This is to allow researchers to choose more affordable options to prevent non declared transport of samples due to lack of funds. This mitigates the risk of the relevant samples being damaged, and loss of relevant material. The company chosen must be able to guarantee and demonstrate continuity of ownership. Samples for transportation must be collectively labelled to include:- The study The principle investigator 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.	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- 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 HTA training and are aware of the need to demonstrate continuity of ownership. If samples are suspected as lost all efforts must be made to retrieve the samples and this must be reported to the designated individual and the Regulatory Compliance Officer.	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	Storage failure	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. SOPs are available within each Departments internal document storage space. Designated back up freezer space is allocated for sample transfer if necessary. This can include space in other Depts if necessary and NCSEM has back up 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.	1	5	5	A	Risk adequately controlled.

Risk Assessment

SSEHS/RA-003

Task/ premises: Transport of material under a HTA licence

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**