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# University HTA Licence Compliance Quality Manual
# University of Westminster, Licence Number 12015

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

**Version History**

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| Author(s): | Dr Nadège Presneau<br>Dr Tony Madgwick |
| Approved by: | Dr Nadège Presneau |

Signed: Date:

**Authorisation and Document Control**

The Quality Manual and Standard Operating Procedures (SOPs) will be reviewed on an annual basis by the Human Tissue Act Steering Group (HTASG) and any revisions to the documentation agreed and approved. The Designated Individual is Chair of the HTASG and has overarching authority for the Quality Management System. Any revisions to documentation will be communicated to staff members.

The Master Copy of this document is filed by the University and the latest version will be available via Sharepoint. If errors or omissions are identified at any time it is the responsibility of all staff to bring this to the attention of the HTASG or their supervisor (in the case of students) immediately.

**Security Statement**

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# 1 Purpose and Scope

The University of Westminster is a post-1992 university, formerly known as the Royal Polytechnic Institution or The Polytechnic of Central London. Along with delivering teaching excellence for undergraduate and postgraduate students, the University also conducts research across four London campuses – three in central London and all within walking distance of each other, and a fourth in Harrow, north-west London. The University is organised into three Colleges, each with four Schools.

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 and 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 the University of Westminster for the purposes of research in order to comply with the requirements of licensing in accordance with the Human Tissue Act (2004).

These procedures apply to all research activities involving relevant material within the University of Westminster. This work is currently confined to activities within the College of Liberal Arts and Sciences and is mostly undertaken within the School of Life Sciences, along with a limited range of activity in the field of psychophysiology in the School of Social Sciences. Scientific research in the College of Liberal Arts and Sciences is dedicated to advancing knowledge and expertise in the areas of basic science, health, sports and exercise performance, and psychophysiology. Human tissue is also used in learning and teaching activities.

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 in which it is engaged. 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.

The University of Westminster holds an HTA Research Licence, **licence number 12015**

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

the person's death.

Within the Human Tissue Act 'relevant material' is limited to material which consists of, or includes, human cells (see 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, as they are obtained from 'relevant material' they are subject to the consent requirements of the Human Tissue Act and the 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 of analysing its DNA without qualifying consent is an offence, unless a specific exemption has been granted by the HTA.

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

## 3 Policy

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

- HTA Codes of Practice and Standards with particular reference to Code of Practice A: Guiding principles and the Fundamental Principle of Consent and Code of Practice E: Research Standards and Guidance.
- University of Westminster Code of Good Practice for Researchers
- University of Westminster Framework for Research Governance
- Health Research Authority on the use of human tissue in research
- 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
- University Research Ethics Committee, University of Westminster
- College Research Ethics Committee (College of Liberal Arts and Sciences)

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 University of Westminster HTASG will:

- Operate a Quality Management System to integrate the organisations procedures, processes and resources for the control and management of HTA licensable activity.
- HTASG will report to the University Research Ethics Committee (UREC) 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 that 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) – | University of Westminster |
| | Contact: Mr David Burt, Authorised Representative |
| Designated Individual (DI) | Dr Nadège Presneau, Senior Lecturer |
| The Human Tissue Act Steering Group (HTASG) | |
| | Membership includes: DI (Chair), Secretary (Research Office), School Health and Safety Officer, School Research Ethics Coordinator, Lead Technician, Research Academic Representative. |
| Principal Investigator | Nominated for each study involving human participants or human tissue |
| 'Recognised' Research Ethics Committee | |
| | University of Westminster research Ethics Committee (UREC) |
| | College of Liberal Arts and Sciences Research Ethics Committee (LASCREC) |
| | Consideration by submission via the HRA and IRAS |

### 4.1.1 Corporate Licence Holder (University of Westminster)

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.

### 4.1.3 HTA Licensing Steering Group (HTASG)

The HTASG is responsible for the management of relevant material in research and within the School with regards to HTA compliance. It is the responsibility of the HTASG to liaise with or make

representation to the School and College Senior Management Teams if changes are needed, with support of the DI as necessary.

### 4.1.4 Principal Investigator

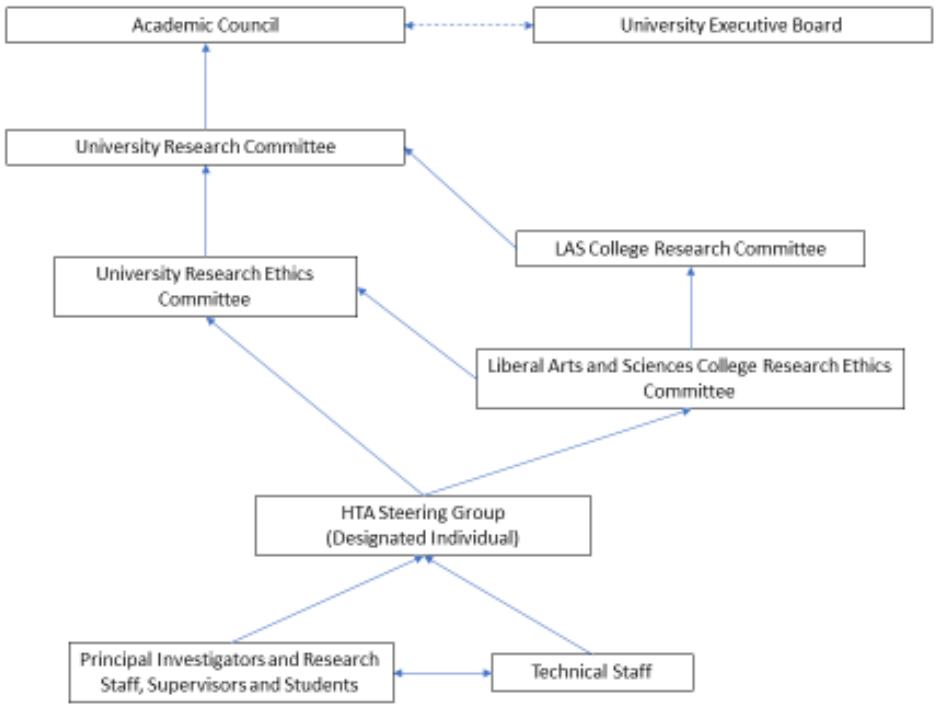
The Principal Investigator is the person responsible, individually or as the leader of a team, for the conduct of a study. They are responsible for ensuring the research is conducted in accordance with legal requirements and University Policies including the Quality Management System. The Principal Investigator 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 HTASG.

### 4.1.5 Hierarchy of Governance

The DI will communicate with the HTA regarding the licence on behalf of the License Holder (University of Westminster). The HTASG will meet biannually but may be convened by the Chair (DI) at any time should the need arise. The HTASG reports to the University and College Research Ethics Committee. The RECs meet regularly throughout the year. UREC considers all Class 3 and Class 4 research ethics applications. UREC delegates responsibility for all Class 2 (and Class 1) ethical applications to the cognate College Research Ethics Committee. The College RECs report to UREC annually.

Figure 1 below summarises the organisational relationships in the quality management of HTA compliance. It should be noted that every 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 HTA Quality Management**



# 5 Organisation and Design

### 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 the University of Westminster, 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 (UREC, LAS CREC or through the HRA)
- 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 (Research) or the Technical Team Leader (Teaching and Research Material) will act as custodians 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.
- 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 HTASG will carry out 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).

## 5.1 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 HTASG. All changes are reviewed and approved by the HTASG. All appropriate staff will be informed when documents are updated. Master copies will be retained and archived by the HTASG in order to document changes.

## 5.2 Consent Process

### 5.2.1 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.

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.

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).

### 5.2.2 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.

### 5.2.3 Consent Process and Forms

Consent procedures and forms are reviewed by the relevant research ethics committees. These offer templates for suitable Participant Information Sheets (PIS) and Consent Forms, and offer advice to applicants on request. As the procedures for acquisition and use vary by project, the PIS and Consent Forms are version-controlled and submitted to the RECs (and thus the DI) by the Principal Investigator or Supervisor.

### 5.2.4 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 belong to the child. 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. All applications of this nature should be submitted to the HRA for ethical consideration, not the University of Westminster research ethics committees.

### 5.2.5 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 upon new or updated consent from the participants.

### 5.2.6 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.

### 5.2.7 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 and the University of Westminster Personal Data Protection Policy must 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 the University being in receipt of material, consent forms or a sample consent form, shall be requested to provide evidence that informed consent has taken place. In addition, it is only permitted to utilise university approved modes of transport.

When acquiring samples directly, the University will not pay donors for their human tissue sample(s). Where costs are remunerated, details of how this will be done should be included in the application for research ethics consideration and included in any favourable opinion given.

### Acquisition and Use

Research involving the acquisition of HTA licensable material requires ethical approval. The University Research Ethics Committee 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.

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 Manual.

The use and storage of HTA licensable material will:

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

## 5.5 Storage

### 5.5.1 Definition of Storage

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

- Where in storage pending transfer elsewhere, providing it is held for a matter of hours or days and certainly no longer than a week.
- Where human tissue is being held whilst it is processed with the intention to render the tissue acellular (e.g. extract DNA or RNA, or other subcellular components that are not 'relevant material'), providing the processing takes a matter of hours or days and certainly no longer than a week.
- Material that is created outside the human body and is for the purpose of research that

does not involve any application of tissues or cells into humans. N.B. Cell cultures are 'relevant material' if they contain cells that were created inside the human body, e.g. if the culture contains original cells from a biopsy or blood sample. It will be up to PIs to provide evidence of at what point their cell cultures no longer contain any primary cells. This can be in the form of a significant body of literature or experimental data.

### 5.5.2 Control of Storage

All HTA licensable material must be stored appropriately for the integrity of the sample and intended analysis, in line with health, safety and environmental guidelines, and recorded. SOPs must be followed and risk assessments of the storage provision made.

Access to the University of Westminster is controlled by security gates that ensure that only staff and students with a UoW card have free access. Guests are requested to sign a Visitor's book upon arrival and when they leave the University. 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.

The storage equipment is maintained and monitored by the technical staff.

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

- Acquisition Date
- Unique identifier (Sample Identifier Number)
- Name of researcher
- Study title
- Purpose of sample collection
- Evidence of ethical consideration
- Sample type and details
- Source
- Consent details
- Storage location
- Storage method
- Date of removal from storage
- Purpose of removal
- Date of return to storage
- Date of disposal and reason.

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.

### 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 relevant Research Ethics Committee. 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 three 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 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 an HTA licensable tissue bank or is part of a project with ethical approval from a 'recognised' ethics authority.

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 is 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). An 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

Before commencing any procedures involving relevant material, all staff and students involved in HTA licensable activity will complete necessary training. Currently this requires the completion of the MRC HTA e-learning: Research and Human Tissue Legislation Assessment – England, Wales & NI. At the end of the assessment, the completion certificate shall be sent to the DI in the form of a scanned electronic document before commencing any procedures involving relevant material. A lecture on the implications and practical requirements of the Human Tissue Act (2004) is delivered to all undergraduate and postgraduate students in SLS as part of their training in research methods.

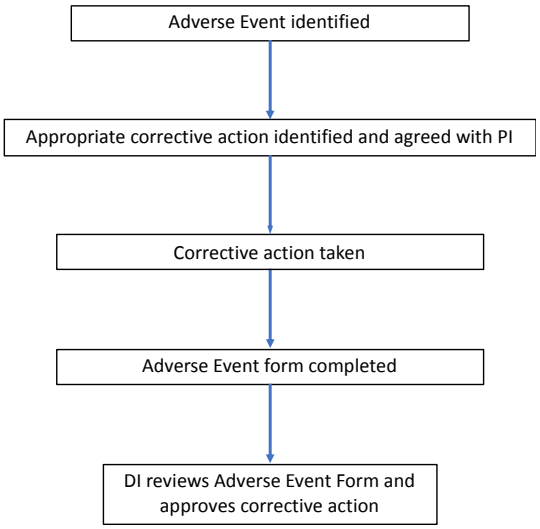
All such training will be compulsory and renewed every three years or as necessary. Line managers are responsible for identifying and making recommendations on the training needs of their staff and for ensuring that employees are suitably qualified and experienced to undertake their duties and responsibilities 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 involving relevant material, an Adverse Report form must be completed and the reporting process in Figure 2 followed.

**Figure 2. Process for Reporting Adverse Events**




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 its resolution in a reasonable timescale.

## 6 Audit and Management Review

### 6.1 Internal Audit

The HTASG will make an annual unannounced audit of up to three laboratories/research groups, ensuring that different labs and research groups are audited on rotation per year. The frequency of the audit may be increased at the discretion of the HTASG (e.g. following a rise in relevant adverse incidents). Non-compliance issues will be brought to the attention of the person responsible, documented and subject to timely corrective action.

The audit will reflect the HTA Licensable activity.

### 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 HTASG 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.