UNIVERSITY OF LIVERPOOL

Clinical Directorate Clinical Research Governance Team

Human Material Code of Practice

HTA003

Author	**Date of Approval**
Dr Hannah Davies	4th August 2022
Approved on behalf of ratifying committee	**Date of Approval**
Dr Neil French	11th August 2022

Document Control

Issue Date	17/08/2022
Effective Date	17th August 2022
Review Date	17th August 2024
This document is controlled using Q-Pulse and is made available on the University of Liverpool Clinical Directorate website. The web version of this document is the only version that is maintained. This document is uncontrolled when printed and as such, may not necessarily contain the latest updates and amendments.	

Document History can be viewed on Q-Pulse

Review Process Prior to Sign Off

Name of Committee	**Date**
Human Material Oversight Committee (Version 3)	20/6/22

Contents

1. General information

1.1 Background

The Human Tissue Act (HT Act) (2004) details the legal regulatory framework for the collection, use, storage and disposal of Human Tissue in England, Wales & Northern Ireland. The act applies to all "relevant material", defined as "material other than gametes, which consist of or includes human cells", excluding embryos outside the human body, or hair and nails from the living, but including "surplus" tissue following clinical and diagnostic procedures. The Human Tissue Authority (HTA) was established in 2005 as an independent regulatory body to oversee all activities concerning the removal, storage, use and disposal of relevant human material. The HTA achieves this task by defining standards, issuing licences for "Scheduled Purposes" and inspecting licenced premises or Institutions.

1.2 Purpose of Document

The Human Material Code of Practice (HM Code) has been developed by the Human Material Governance Team (HMGT) to provide a resource for staff and students using human material for research, education and training, in order to ensure that the regulatory framework defined by the HTA codes of practice (COP) is successfully incorporated into the University of Liverpool (University) guidance, practices, and policies. The HM Code provides an overview of the standards expected by the HTA and the University for any research activity involving human material (including nucleic acids, excretions and secretions). The HM Code is supplemented by a suite of supporting documents which further define compliance requirements of individual activities. Supporting documents are referenced as appropriate throughout the HM Code and should be referred and adhered to as required.

1.3 University Compliance

The corporate HTA licence holder is the University, whose representative is Professor Louise Kenny, Executive Pro-Vice-Chancellor.

The University holds two Human Tissue Act licences, a Research Licence (HTA Research Licence) and a separate Licence for Anatomy. The Designated Individual (DI) for Research at the University and its associated sites is: Dr Neil Simon French and the HTA Research Licence number is 12020.

The Anatomy Licence has a separate DI, Professor Nathan Jeffery, and operates quality systems that are distinct from those outlined in this document for general research governance.

It is recognised that related activities carried out by NHS employees within University research partner NHS Trusts are likely to be subject to HTA licences held by the Trusts. The University will aim to ensure, wherever possible, that there are no significant differences between its own procedures and protocols and those of partner Trusts.

1.4 Roles and Responsibilities

1.4.1 Assigned Roles

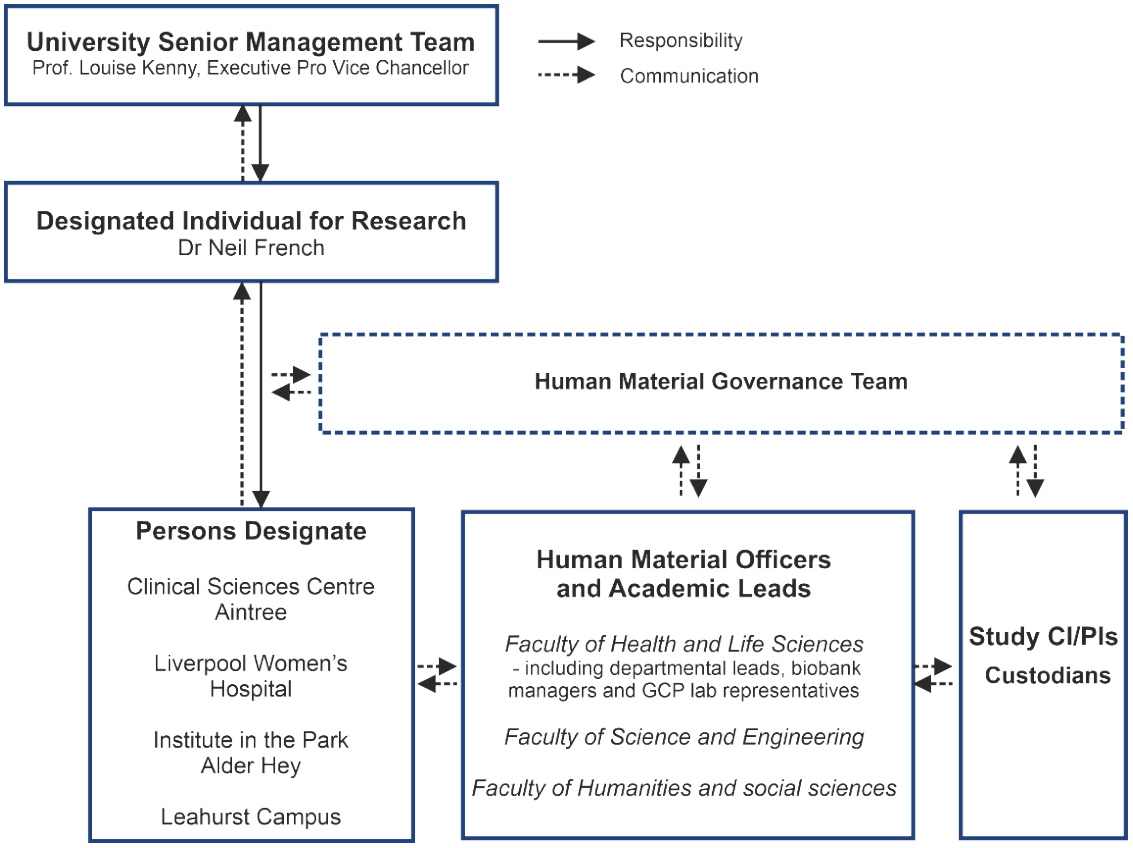
The DI is responsible for implementing the requirements of the HT Act and has the primary (legal) responsibility under Section 18 of the HT Act (2004) to ensure that suitable practices are used in undertaking the licensed activity, that other persons working under the licence are suitable and that the conditions of the licence are complied with.

Persons Designate (PD) work under the supervision of the DI and fulfil the same role as the DI in defined areas, for example, satellite sites. The University has five PDs who assist the DI by supervising the licensable activities within their defined area.

The University also has a network of Human Material Officers (HMOs) placed within each of the Research Institutes in the Faculty of Health and Life Science and at Faculty level in the two other Faculties at the University. The HMOs provide advice and support to research staff and support the DIs and PDs monitoring of storage and compliance of relevant human material (including nucleic acids, excretions and secretions).

A detailed description of the DI, PDs and HMOs roles and responsibilities are set out in the HT Act (2004) and are defined within the University of Liverpool Human Material Research Quality Manual (HMR Quality Manual) (HTA004).

The lines of communication and responsibility are shown in the following schematic:



1.4.2 Staff and Student Responsibility

The HM Code applies to all staff members and students engaged in research involving human material. References made throughout this document to the "Researcher" apply to all individuals working with human material including support and professional services staff and students.

It is fundamental to the integrity of the research conducted at the University, that all human samples are acquired lawfully, with appropriate consent and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all individuals working with human samples, from the living or deceased, strictly abide by procedures and standards set out in this HM Code and supporting document suite.

Staff and students are reminded that failure to observe the HT Act (2004), the University of Liverpool (UoL) Policy on the use and storage of Human Material for Research Purposes (HTA001) may mount to misconduct and could result in disciplinary action being taken. Failure to comply with the HT Act (2004) can lead to criminal penalties and fines for the individuals concerned, the DI and the University.

All researchers to whom the HM Code applies should report any known or suspected relevant misconduct. Members of staff and students are encouraged to raise concerns about suspected relevant misconduct either through their PD/HMO or in confidence under the Policy on Public Interest Disclosure. The University has a responsibility to investigate allegations of misconduct. It also has a responsibility to protect staff and students from malicious, mischievous or frivolous allegations.

1.5 The HTA Research Licence

1.5.1 The Licence

The University holds an HTA Research Licence (12020) granted under section 16 (2) (e) (ii) of the HT Act (2004).

The Research Licence authorises "the storage of relevant material which has come from a human body" for the following scheduled purposes at licenced premises:

- Determining the cause of death.
- Establishing after a person's death the efficacy of any drug or other treatment administered to them.
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
- Public display.
- Research in connection with disorders, or the functioning of the human body.
- Clinical audit.
- Education or training related to human health.
- Performance Assessment.
- Public Health monitoring.
- Quality Assurance.

A list of the University licenced premises is provided in the HMR Quality Manual (HTA004).

1.5.2 Human material covered by HTA Research Licence

The HT Act (2004), refers to human tissue as "relevant material", this is further defined as "material from a human body that consists of, or includes, human cells". Therefore, any sample known to contain even a single cell from a human body should be considered as "relevant material".

Examples include:

- Blood & Plasma*
- Urine.
- Faeces.
- Tissue Samples (including embedded Tissue blocks and Sections on slides).
- Saliva.
- Sputum.
- Skin.
- Bone.

*unless assurance can be provided that all cells (i.e. platelets) have been completely removed.

Exceptions include:

- Gametes (regulated by the Human Fertilisation and Embryology Authority) (HFEA).
- Embryos outside the human body (regulated by HEFA).
- Hair and nail from the body of a living person.
- Cell lines (where all cells have divided in culture at least once).
- Processed/acellular material.
- DNA/RNA (covered by the HT Act (2004), but not relevant material).

Clarification of what constitutes "relevant material" can be found on the HTA website.

NB: Although the HTA research licence only covers the storage of "relevant material" for scheduled purposes, the University recognises that storage of all human material for current and future research should meet the same quality standards.

1.5.3 Licencing exceptions

There are a number of exemptions where an HTA Licence would not be required to store a "relevant material". These exemptions include:

- If the material is to be rendered acellular (cells removed or disrupted) within 7 days.
- If the material transported to another establishment within 7 days.
- If the material is to be stored for diagnostic purposes.
- If the material was collected prior to 1st September 2006.
- If the individual from whom the material was collected died more than 100 years ago.
- If the material has NHS Research Ethics Committee (REC) approval in place to use it.
    - If the material has come from an NHS Research Committee (REC) approved Research Tissue Bank (RTB)

NB Ethical approval from the University ethics committee or any other ethics committee other than an NHS REC does not confer exemption and therefore material collected and used under these approvals is actually stored under the University HTA Research licence.

2. Consent

2.1 Consent & the HT Act (2004)

One of the main underpinning principles of the HT Act (2004) is the requirement for informed consent. Consent is required to remove, store or use relevant material from the deceased and to store or use relevant material from the living for scheduled purposes, including research. The collection of relevant material from the living is covered under common law. Full details of the HTA regulations for consent and consent for research are defined in HTA COP A and COP E paragraphs 39-79.

In broad terms, under the act, consent is required to:

- Store and use dead bodies.
- Remove, store and use relevant material from a dead body.
- Store and use relevant material from the living (removal is covered by common law).
- Store human tissue, including hair, nail and gametes with the intention of analysing its DNA.
- Store human tissue, including hair, nail and gametes with the intention of analysing its RNA where it is used to provide information about DNA.

It is University policy that **appropriate and valid** consent be obtained to **remove, store and use any** human material (including nucleic acids, excretions and secretions) for research purposes *subject to exceptions described in section 2.1.1.

To meet this requirement, the consent must be given by an appropriately informed individual who has the capacity to agree to the activity in question. **Human material samples must only be used for research purposes for which specific consent has been obtained**. The intention to store human material for future, unspecified use must be specifically stated in the relevant patient information sheet and consent form.

In circumstances where the human material is from the deceased, then consent can be from either the individual prior to death or from their nominated representative. In the absence of prior consent and a nominated individual, consent can be obtained from a person forming a "qualifying relationship" (COP A paragraphs 30-39 & 79-94).

If making use of imported or transferred human material, Researchers must seek documented assurance from the supplier or collaborator that appropriate consent and ethical approval (in line with the country of collection) to export or transfer the material for research purposes was obtained.

Researchers are not required to seek separate consent specifically for DNA/genetic analysis, if consent has been given for the material to be used for a scheduled purpose. There is however, a **requirement to inform the donor** that their material may be used in this way.

If the research project is likely to reveal medically significant results e.g. a family genetic condition, living donors should be informed of the possibility and given a choice as to whether they wish such information

to be made known to them HTA COP A and E and MRC framework on the feedback of health-related findings in research.

2.1.1 Consent Exceptions

There are a number of instances where consent is not required for the storage and or use of human material for research, however **ethical approval from a recognised REC is required for its use**.

Exemptions include;

- Existing holdings (relevant material collected prior to 1st September 2006).
- Material collected from an individual who died more than 100 years ago.
- Surplus Material*.
- Anonymised material**
- Imported tissue or tissue from a body that has been imported.

* Surplus Material: material taken from the living for diagnostic purposes and subsequently stored for use in research.

Surplus tissue can be used with consent as part of a research project or without consent if it is to be released to the researcher in a non-identifiable form, as long as the project has approval from a recognised REC. Definition of what constitutes a Recognised REC detailed in HTA COP E paragraphs 65-69.

Anonymised material from the living can be stored and/or used without consent, **provided that the research is ethically approved by a NHS REC and the material is anonymised such that the researcher is not in possession, and is unlikely to come into possession, of information identifying the person from whom the material has come.

This does not mean that Material must be permanently and irrevocably unlinked. Linking is permissible through a third party where necessary and has been ethically approved. However, it is always preferential to seek consent whenever it is possible to do so.

Imported material which has ethical committee approval for use granted by a committee other than an NHS REC will require UoL Research Ethics committee acknowledgement of such approval. Please refer to HM Code section 2.3. Ethical approval and the material reference therein for guidance on ethics applications.

Guidance on obtaining appropriate, valid consent and when consent is or is not required for research is detailed in the UoL Human Material Supporting Document-Consenting for Research (SDS001).

2.2 Sponsorship

The sponsor is the institution or organisation which takes ultimate responsibility for the quality and conduct of a research project (i.e. University or Commercial funder). Sponsorship **must** be obtained for projects which;

- Involve the use of NHS patient or users' data, tissue or other bodily material.
- Involves relatives or carers of NHS patients.

- Involves the use of NHS premises or resources.
- Involves international healthcare-based research
- Constitutes a Clinical Trial of an Investigational Medical Product (CTIMP).
- Recruitment of participants who lack capacity to consent;
- Research involving participant exposure to radiation.

The University also required studies accessing material stored in approved Research Tissue Banks (RTB) ("biobanks") to seek sponsorship.

The University will consider undertaking the role of sponsor for the following:

- University Student research projects (where the academic supervisor is a University employee)
- Research being undertaken by employees of the University;
- Submissions from Investigators external to University will be considered on a case by case basis.

Sponsorship should never be assumed and there is a formal application process in place, which must be adhered to.

Information and/or assistance with sponsorship, sponsorship applications and study setup can be found on the UoL clinical research governance web pages or by sending enquiries to sponsor@liverpool.ac.uk.

2.3 Ethical Approval

Researchers are responsible for ensuring research is conducted ethically. All research carried out must adhere to the legal requirements and guidelines produced by HTA and other relevant bodies, including but not limited to, this HM Code, the HT Act (2004), the Data Protection Act 2018, UK GDPR and any relevant research committees.

The University requires that research involving human participants, human material or personal data be reviewed by the appropriate UoL Research Ethics Committee (REC) unless;

- The research is being reviewed by a mandatory external ethics committee i.e. NHS Research Ethics Committee (NHS REC).
- The material is from an NHS Research Ethics Committee (REC) approved Research Tissue Bank (RTB) where ethics for the proposed research project can be conferred by the RTB.
- The research uses only information that is publicly and lawfully available e.g. census data, population statistics published by government departments and personal letters / diaries in public libraries.
- Or if the individual from whom the material was collected died more than 100 years ago.

All ethics committees are dependent on the information supplied by the Researcher to inform their decision-making. It is therefore the responsibility of the Researcher to ensure that the information provided to committees is complete and accurate.

Further information on NHS and other recognised research committees are detailed on the NHS Health Research Authority (HRA) web pages.

Information on the UoL Research Ethics Committee Structure and application procedure are also detailed on the UoL Research Support Office research ethics web pages or by sending enquiries to ethics@liverpool.ac.uk.

2.4 Collection and Use

2.4.1 Obtaining Tissue

The University HTA Research Licence does not cover the physical collection of human material or the use of this material for research purposes.

Researchers are therefore required to ensure ethical approval has been granted from either a recognised Research Ethics Committee (REC) where required or the UoL Ethics Committee for any study involving relevant human material (including nucleic acids, excretions and secretions) before work begins.

Researchers should complete FORMHTA003 and send to humanmat@liverpool.ac.uk in order to add new projects to the University registry of human material.

There are a number of options available to obtain human material collections for research:

- By accessing pre-existing collections from an approved Research Tissue Bank (RTB).
- By setting up a new human material collection.
- By transferring or importing human material from a collaborator or other Institution.
- By purchasing human material from a commercial supplier.

The University houses a number of RTBs ("biobanks"), many of which operate under NHS Research Tissue Bank (RTB) ethics. These RTBs can, in some circumstances, confer ethical approval to projects accessing their collections. However, it remains the responsibility of the Researcher to ensure that conferred ethical approval is in place before the start of the project. If ethical approval cannot be conferred by the source of the relevant material, then study specific approval must be obtained.

Requests to access RTB collections are generally made via biobank managers a list of current University of Liverpool Biobanks can be obtained on request from humanmat@liverpool.ac.uk .

NB Ethical approval must always be in place prior to: beginning any new human material collection (both NHS patients and/or heathy volunteers); using pre-existing relevant human material collections (including nucleic acids, excretions and secretions) for new or modified research projects; and prior to import of human material from outside the University. Please refer to HM Code section 2.3. Ethical approval and the material reference therein for guidance on ethics applications.

Commercially* sourced relevant human material and nucleic acid does require UoL ethical approval before use. It is expected that the Researcher seek documented assurance from the supplier that appropriate consent and ethical approval exists for the use of the material (within the governance framework of the country from which the samples originated) for the intended research purpose and that consent to export or transfer the material was obtained.

*Commercial sourced is used to describe purchased material in this context, but excludes REC approved RTBs.

2.5 Human Sample Movement

2.5.1 Movement - (Import/Export)

The HTA has developed guidelines, relating to the import and export of relevant material for use for "scheduled purposes" (COP E paragraphs 98-114).

In brief: Relevant human material should be "procured, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came". It is the responsibility of the individual importing human material into (England, Wales or Northern Ireland) or exporting human material out of (England, Wales or Northern Ireland) to ensure that the guidance defined by HTA codes of practice and requirements of counties receiving the material are followed.

When relevant material is transferred between establishments, a formal transfer arrangement, in the form of a Material Transfer Agreement (MTA) must be in place. Preventative action should also be taken to minimise the risk of theft, damage or loss of the material during transit. This includes any commercially sourced relevant human material.

2.5.2 Movement - (within England, Wales or Northern Ireland)

The University requires that relevant human material (including nucleic acids, excretions and secretions) transferred within the University organisation (internally) or between the University and external organisations (externally) has a sufficient documented trail to ensure traceability.

2.5.2.1 Internal transfer

Internal transfers should be governed by a sample transfer Standard Operating Procedure (SOP) and signed transfer log.

Internal movement of human material from a UoL laboratory to another UoL laboratory on the same site requires a signed record of movement and the new storage location must be recorded.

2.5.2.2 External transfer

The external movement of human material includes movement to/from external organisations i.e. to/from UoL and the NHS or another University within England, Wales or Northern Island. **This includes movement from NHS sites to UoL even if the premises are in the same location.**

External transfers should be governed in most circumstances by a Material Transfer Agreement (MTA). An MTA may not be required for external movement of human material if the study has current NHS project specific ethics and details of the sample movement and oversight are included in the study documentation. If this is the case please seek confirmation from the clinical research governance team.

2.5.2.3 Material transfer agreements

MTAs provide the organisation and researcher with assurance that the consent obtained is suitable for the proposed research. **Where the purpose of the transfer includes storage beyond the original purpose/study for future use this should be detailed in the MTA.**

MTAs are generally supplied by the human material provider. The University has an incoming MTA pro forma which should be used by the CI/PI alongside incoming human material MTAs. The University can provide template MTA documents which can be used when transferring material to external individuals or organisations.

Advice on MTAs can be sought through your Institute Head of Operations or a member of the University Legal & Governance Research Contracts Team. Further Information on shipping/movement of human material can be sought from the HMGT.

NB Transferred samples must be anonymised or pseudo-anonymised (coded/linked-anonymised) unless specific consent for transferring identifiable information was obtained. Ethical approval is also required for transfer of identifiable human material.

Your Institute Head of Operations should be consulted for local policy advice if you are leaving the University entirely and wish to take your sample collections with you.

2.6 Sample storage – (including record keeping)

2.6.1 Sample Storage

The storage of "relevant material" for research is licensed by the HTA subject to exceptions (described in section 1.5.2).

The HT Act (2004) does not define the term storage. Neither does it give any minimum or maximum term for storage of relevant human material for research. Therefore, the HTA considers storage as relevant material kept for any period of time for the purpose of research.

The HT Act (2004) does not stipulate exact requirements for storage however, good practice as defined by the HTA is as follows;

- Premises must be "fit for purpose".
- Samples and sample records must be securely stored.
- Facilities are required to be maintained and storage conditions suitably monitored.
- Sample records must be in sufficient order to provide full traceability*.
- Health and safety must be considered and risk assessments documented.
- Adverse events should be recorded.

* Compliance with the HT Act requires clear, robust, auditable documentation for relevant human material collection, processing, storage, use, distribution and final use or disposal. **This applies to all aliquots or portions of relevant human material.**

2.6.2 Records of Stored Material

The University requires that **all human material** be associated with appropriate records to account for consent where applicable, collection, storage, use, distribution and disposal.

The University policy on the Use and Storage of Human Material for Research Purposes (HTA001) details these responsibilities and can be found on the Human Material Governance web pages.

The documents considered to meet the appropriate record requirement for human material storage include, but are not limited to, records of;

- The origin of the human material and date acquired.
- The governance which the material is stored under i.e. the HTA licence or Research Ethics.
- Evidence of consent, evidence of ethical approval for stored material including favourable opinion reference, Principal/Chief Investigator and end date.
- Sample identification numbers, description and storage location.
- Date and details of use, transfer (including copy of material transfer agreement) and disposal.
- Contingency plans.
- Adverse event recording.

Records can be in electronic or paper format. Individuals using human material are required to keep records pertaining to collections up to date, accurate and secure.

Guidance on best practice for storage and use including labelling, identifying approved locations, appropriate document guidelines, document control procedures and SOP templates can be sought from the HMGT via humanmat@liverpool.ac.uk.

2.6.3 Storing Imported Material

Whilst the consent provisions of the HT Act (2004) do not apply to imported relevant material, the provisions for storage do apply. Imported relevant material for research (including fixed tissue and tissue on slides) should be treated in the same way as tissue originating from participants in England, Wales or Northern Ireland. This also means that the same exceptions to licensing apply.

The University requires that **all imported human material** is stored with the same considerations that apply to **relevant human material** (including nucleic acids, excretions and secretions) originating from participants in England, Wales or Northern Ireland.

2.6.4 End of Study

As described in 1.5.3, a HTA licence is not required to store relevant human material when the associated NHS ethical approval is still valid. If there is a requirement to continue storage of the material following the end of an approval period, then a University of Liverpool end of study form FORMHTA001 must be completed stating the Researchers intention to;

- Apply to extend the current NHS ethics.
- Apply for new ethics to use the material in a new project.
- Store the material under the University HTA Research Licence.
- Transfer the material to a new custodian or NHS REC approved RTB.
- Dispose of the material in accordance with HTA guidelines & the University HM Code (HTA003)

If there is a requirement to continue to store material under the University HTA Research Licence, the Principal/Chief Investigator or collection custodian must satisfy the DI that appropriate permissions (i.e. consent for future research) and audit trail documentation exists for the material.

Ethical approval must be in place before pre-existing relevant human material (including nucleic acids, excretions and secretions) can be used in any future research project.

A copy of FORMHTA001 can be obtained via the Human Material Governance web pages or by contacting humanmat@liverpool.ac.uk.

2.7 Data Storage

2.7.1 Data storage – (HT & Data Protection Acts)

The HT Act (2004) Storage requirements also apply to the storage of data. Data relating to donated samples may be either:

- Identifiable data – Data which clearly link to a particularly individual e.g. name, address, date of birth or NHS number.
- Coded/link-anonymised data – Data which cannot directly identify an individual, but can be reconnected back to the donor, if required, by the use of a controlled code.
- Anonymised data – data which cannot be linked back to the original donor, as all links have been removed.

It is important that individuals involved in research involving human material are aware that, in addition to the consent provisions of the HT Act (2004), they are required to adhere to the legal requirements of the Data Protection Act (DPA (2018)), UK GDPR and the common-law duty of confidentiality.

It is therefore necessary that only essential information for the purpose of the research project is collected and managed. The key principles are that data is;

- Obtained and processed fairly, lawfully and in a transparent manner.
- Processed for limited (legitimate) purposes.
- Adequate, relevant and not excessive.
- Accurate and up to date.
- Not kept longer than is necessary.
- Processed in accordance with the rights of the data subject.
- Secure.
- Not transferred without adequate protection measures.

Responsibility for the management of research data produced during research activities lies with the Principal/Chief Investigator. Where research is conducted with other institutions and independent researchers, the UoL Principal/Chief Investigator remains responsible for the data held by UoL.

2.7.2 Retention Periods

Retention periods vary depending on the type of data, study type and funder, regulations and guidance examples include:

The University requirements can be found within the UoL Data Retention Schedule which, f**or research data is 10 years.** Records relating to human material samples including evidence of consent, should be

held for the lifespan of the sample which may go beyond the statutory requirements. Enquires into retention periods for other study types or funders can be directed to data@liverpool.ac.uk

Researchers should ensure that all records are archived appropriately upon the conclusion of the research. Researchers are directed to Sponsor SOP020 and the University Records Management department for further information on the archiving process.

2.8 Disposal

2.8.1 Respectful disposal

The HT Act (2004) and the HTA codes of practice were created to ensure that human tissue is treated and used in accordance with the wishes of donors or their relatives. The University recognises the value and sensitive nature of the material being gifted for research and has established appropriate policies for disposal of human material which reflect this, without placing a disproportionate burden on staff or resources.

In general disposal should be avoided unless necessary. Human material samples collected with consent for unspecified future use can be retained for use in future studies, collaborations or RTBs, subject to **relevant ethical approval,** thus preventing the need for unnecessary disposal.

This policy applies to circumstances where it is necessary to dispose of human material collected for research purposes when:

- The patient has withdrawn consent for use
- The consent or ethical approval for a study/project indicates that samples must be destroyed one the study/project ends
- The sample integrity has been compromised

Where sample destruction is required, researchers must be aware of and comply with the requirements under HTA COP A paragraphs 13, 25, 143, 151 and COP E paragraphs 127-130 and refer to HTA 001 policy on the storage use and disposal of human material.

2.8.2 General disposal considerations

The method of disposal varies depending on the nature of the material, when and from whom it was collected. In general, the disposal of any human material should be handled in accordance with any reasonable wishes expressed by the donor or their relatives, as long as the method of disposal is legal.

Whichever method of sample disposal is utilised, appropriate documentation of the disposal route must be maintained.

It is generally acceptable to dispose of human material by incineration unless there are donor-specific wishes for disposal. There is no need to bag individual samples separately however, donated material should be bagged separately from other clinical and laboratory waste before entering a common waste stream.

2.8.3 Identifiable anatomical waste

Anatomical waste (body parts or other recognisable anatomical items) must be disposed of in line with the UK government Health Technical Memoranda management and disposal of healthcare waste (HTM 07-01). This may require slight variation to your normal local disposal route.

Please check your local disposal arrangements, **ahead of disposing** of any donated human material.

2.8.4 Foetal Tissue

If there is a requirement to use foetal tissue as part of a research project, then further guidance on how to respectfully and lawfully dispose of this material can be found within the HTA web pages.

2.8.5 Disposal of Imported material

Unless stipulated otherwise, imported material would follow the same disposal arrangements as material sourced from England, Wales and Northern Ireland. Specific requests made regarding disposal during the consenting process must be carried out. This may include, for example, the return of material to the country of origin.

2.8.6 Disposal Records

Disposal records must include details of; Collection date, Unique sample number, Sample custodian i.e. CI/PI/RTB, Institute, contact information, Study/Project/RTB name, Date of disposal, Method of disposal, Bag and Tag ID, Type and Amount of material disposed, Reason for disposal, Person responsible for disposal, any disposal request details and Information on the risk level of the sample.

The Human Material Disposal form (FORMHTA002) is available from the University Human Material Governance web pages.

2.9 Training

2.9.1 Training Considerations

It is important that all individuals utilising human material as part of their research projects have a good understanding of the HT Act (2004) and the HTA codes of Practice relevant to their role.

In addition to the information and references within this HM code, The University also conducts regular HTA training courses for Staff and Students utilising human material to ensure compliance. The full course content of which, is available on the University Human Material Governance web pages to view all year round.

New members of staff and postgraduate students who intend to collect, store, use and/or dispose of human material on University premises shall read and sign the University's human material policy HTA001, this HM code of practice HTA003 and attend local training as soon as reasonably possible before undertaking such activities.

If attendance at the local training is not possible prior to onset of activities then completion of the MRC Research and human tissue legislation E-Learning package entitled 'Research and human tissue legislation' must be completed.

In line with Good Clinical Practice (GCP) retraining requirements, human material training shall be repeated every 3 years. Copies of training certificates must be available for auditing purposes.

2.9.2 Training Logs

Principal/Chief Investigators are required to ensure training logs are maintained and that all research personnel utilising human material are aware of the regulations to which they must comply.

Researchers should receive training on all pertinent human material SOPs relating to their role, prior to beginning work with human material (details of which, to be included within a training log).

A document HTA005 - Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT ACT (2004) and a suite of template human material SOP's are available via the HMGT to provide guidance on the types of SOPs that research projects using human material may require.

2.10 Adverse events

An adverse event is any occurrence which threatens, or has the potential to threaten, the integrity of samples, and/or associated data, the safety of staff, or undermines good practice.

Adverse events must be reported during the annual review of human holdings, Adverse Event Report (AER) must be completed and suitable corrective and preventative actions (CAPAs) put in place. All CAPAs must be managed in a timely manner to maintain the integrity of samples, protect patient data and ensure staff safety.

If a Researcher is unsure whether something should be classed as an adverse event, they should contact their local HMO/PD or the Designated Individual for advice. Alternatively, queries can be directed to humanmat@liverpool.ac.uk

2.11 Monitoring and Audit

The University requires all individuals utilising human material to maintain secure and accurate records available for auditing purposes. An audit schedule will be devised annually for RTBs and project specific studies holding relevant human material under the University HTA research licence. Full details of audit schedule, review and implementation can be found within HTA007 - Internal audit of Relevant Human Material.

An annual return of all **relevant human material** (including nucleic acids, excretions and secretions) stored on University premises will be led by the Designated Individual in order to gain an overall view of the material being stored on University premises and the purpose of the storage of the material.

Persons Designate and Human Material Officers will also be responsible for monitoring the storage and use of human material in the departments within their Institute, Faculty or site.

The University requests researchers to routinely perform periodic self-audits to assess compliance and identify areas for improvement. Template self-audit forms are available from the HMGT.

2.12 Research, Human Application and Clinical Trials

The boundaries between research and human application are continually shifting and the potential for cross-over between the sectors is significant. This cross-over can alter the type of licence and permissions required. To clarify;

Human tissue for research in vitro (i.e. will not be transplanted into humans) must be stored under a HTA Licence, subject to the exceptions as described in section 1.5 of this HM Code.

Tissue or cells, including cell lines, which may be transplanted into humans, even where it is for research, must be licensed by the HTA under the Human Tissue Quality and Safety for Human Application Regulations (2007) (Q&S Regulations). Detailed information about the licensing requirements of the Q&S Regulations can be found on the HTA web pages.

The storage of human tissue as part of a clinical trial (where the material itself will not be used in human application) must take place on HTA-licensed premises, subject to the exceptions as described in section 1.5 of this HM Code.

Establishments using tissues or cells for human application as part of a clinical trial must be licensed under the Q&S Regulations. It is important to note that licensing under the Q&S Regulations still applies where tissue or cells are used for human application as part of a clinical trial approved by a recognised ethics committee. **The University does not hold a human application licence.** Please contact the HMGT to discuss human application studies.

3. Health and safety

3.1 General Health and Safety

The University is committed to providing a safe environment for its students, employees, contractors and visitors, by conducting its business in a way that protects the health, safety and welfare of each individual. The University therefore recognises its responsibility to prevent staff, students, visitors and contractors being exposed to hazardous biological hazards.

In order to ensure a safe working environment, the University has a number of Health and Safety Policies and Codes of Practices (Safety P&COP) and has adopted Health and Safety training into its obligatory induction training schedule.

It is beyond the scope of this document to summarise the content of each of these codes however, Researchers working with human material are required to adhere to the UoL Safety Policy & COP on Biological Safety.

3.1.1 Screened human material samples

Obtained through the Blood Transfusion Service or from a tissue bank that undertakes screening of their samples for harmful pathogens.

If these samples are proved to be negative for harmful pathogens, the material can be handled at Containment Level 1.

If samples are screened and are shown to contain a pathogen, they should be handled at the appropriate Containment Level for that pathogen.

3.1.2 Unscreened human material samples

Human materials that do not come from a screened source. These must be regarded as potentially infectious (e.g. harbour Blood Borne Viruses (BBV's) such as HIV and Hepatitis B).

They must therefore be handled at Containment Level 2 with the additional precautions highlighted in the tables below:

If the materials come from a high-risk population (e.g. intravenous drug users, or from Sub-Saharan Africa) where the potential for pathogens is higher, the Containment Level should be increased accordingly.

If a sample is shown or discovered to be infected at a later date, then the risk assessment should be revisited and the Containment Level altered accordingly (or the sample correctly disposed of).

Information on what control measures are required and containment level advice should be sought through the Institute or Faculty Biological Safety Officer.

4. Consequences

Failure to conform to the HM Code could result in significant implications for Researchers:

- Research conducted using the material may be invalidated.
- The reputation of the University could be placed at risk.
- Public confidence may be lost, limiting the provision of future samples.
- Subject to implications relating to research misconduct.
- The University licence could be removed, preventing the storage of relevant human material for use in research.

It is therefore of fundamental importance that all Researchers work together with the DI, PDs, HMOs and the research governance team to ensure high quality, ethical research across the University. Staff and students are reminded that failure to comply with the HM Code may mount to misconduct and could result in disciplinary action being taken.

5. Abbreviations

BBV's	Blood Born Viruses
CAPA/CAPAs	Corrective and Preventative Action/Actions
CI/PI	Chief/University Principal Investigator
COP	Code of Practice
CTU	Clinical Trials Unit
DI	Designated Individual

DPA	Data Protection Act 2018
GCP	Good Clinical Practice
HM Code	University of Liverpool Human Material Code of Practice
HMO/HMOs	Human Material Officer/Officers
HMGT	Human material governance team
HRA	Human Research Authority
HT Act (2004)	Human Tissue Act (2004)
HTA	Human Tissue Authority
HTA Research Licence	Human Tissue Authority Research Licence
HTM	Health Technical Memoranda
MTA	Material Transfer Agreement
NHS	National Health Service
NHS REC	National Health Service Research Ethics Committee
PD	Persons Designate
Q&S Regulations	Human Tissue Quality & Safety for Human Application Regulations 2007
RTB	Research Tissue Bank
Safety P&COP	University of Liverpool Health and Safety Policies and Codes of Practices
SOP	Standard Operating Procedure
UK GDPR	United Kingdom General Data Protection Regulations.
University	University of Liverpool
UoL	University of Liverpool