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**The Leeds Teaching Hospitals NHS Trust (LTHT) and the University of Leeds (UoL)**

**Joint Policy for the Storage and Use of Human Tissue**

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| **Executive Lead:** | Phil Wood, Chief Medical Officer.  Roger Gair, University of Leeds Secretary | | |
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| **Keywords:** | Human Tissue Act (HT Act); Human Tissue Authority (HTA); Designated Individual; Persons Designated | | |

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**1 Staff Summary & Introduction**

**Summary**

The **Human Tissue Act 2004** was an [act of the UK parliament](https://en.wikipedia.org/w/index.php?title=Act_of_the_UK_parliament&action=edit&redlink=1) applying to England, Northern Ireland and Wales. The Act consolidated previous legislation and created the [Human Tissue Authority](https://en.wikipedia.org/wiki/Human_Tissue_Authority) to regulate the removal, storage, use and disposal of human bodies, organs and tissue. Consent is the important principle that underpins the Human Tissue Act.

The Act was brought about as a consequence of, amongst things, the [Alder Hey organs inquiry](https://en.wikipedia.org/wiki/Alder_Hey_organs_scandal) in which organs of children had been retained by [Alder Hey Children's Hospital](https://en.wikipedia.org/wiki/Alder_Hey_Children%27s_Hospital) without consent, and the [Kennedy](https://en.wikipedia.org/wiki/Ian_Kennedy_(lawyer)) inquiry into heart surgery on children at the [Bristol Royal Infirmary](https://en.wikipedia.org/wiki/Bristol_Royal_Infirmary).

Leeds Teaching Hospitals Trust and the University of Leeds work together to ensure the requirements of the Human Tissue Act are followed. This applies to 5 areas when human tissue is used, each of which has its own license: anatomy, research, post mortem, human application (patient treatment) and Organ Donation and Transplant (ODT).

Further details on the scope of the Human Tissue Act can be found in appendix A and B (pages 16-19) in this policy.

**Background / Context**

The HT Act came into force on 1 September 2006. The Act makes consent the fundamental principle underpinning the lawful retention and use of ‘Relevant Material’ from the living or the deceased for ‘Scheduled Purposes’. (See key definitions section 3 and Appendices A and B).

The HT Act established a body called the Human Tissue Authority (HTA). The HTA is the governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for scheduled purposes; currently research, ODT, disposal, patient treatment, post-mortem examination, anatomical examination, teaching and public display.

A summary of the scope and requirements of the HT Act can be seen in Appendix A.

A summary of Scheduled Purposes and associated Consent requirements can be seen in Appendix B

LTHT and UoL between them hold five Human Tissue Act licences:

Post Mortem covering specific premises at LTHT

Research covering specific premises at LTHT & UoL

Human Application covering specific premises at LTHT

Anatomy covering specific premises at UoL

ODT covering organ procurement and transplant activities

Compliance with the Human Tissue Act and relevant Legislation is supported by joint governance arrangements to ensure both organisations are compliant with the Human Tissue Act. See Appendix C

To support implementation of the Act, HTA Codes of Practice have been published. These provide interpretation of the Act and Regulations and give practical guidance to support good practice in important areas of science and medicine. These can be found at the following web address:

<https://www.hta.gov.uk/guidance-professionals/codes-practice>

In addition to the HT Act:

**The Human Application licence** was regulated by the European Union Tissue and Cells Directives (EUTCD), which set out to establish a harmonised approach to the regulation of tissues and cells across Europe. The Directives required that systems be put in place to ensure that all tissues and cells used in human application were traceable from donor to recipient. The Directives were fully integrated into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and, post UK Transition in January 2021, by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) also known as the Q&S Regulations.

For further information refer to <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application>

**The ODT Licence** was originally regulated by the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012(EUODD) (Statutory Instrument (SI) 2012 No. 1501). This transposed into UK law the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation. The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) set the standards for the quality and safety of organs intended for donation and transplantation and to ensure traceability is maintained between donor and the recipient.

For further information refer to <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/organ-donation-and-transplantation>

**2 Purpose and Effect**

**Purpose**

The Human Tissue Act (HT Act) regulates activities relating to the storage and use of human tissue. The purpose of this policy is to ensure that staff involved in any of the HT Act activities do so within the framework of the Leeds Teaching Hospital NHS Trust (LTHT) / University of Leeds (UoL) Human Tissue Authority (HTA) Licenses; that they understand and comply with relevant sections of the HT Act (2004), other relevant Legislation, HTA Licensing conditions, Codes of Practice and related LTHT / UoL Policies and Standard Operating Procedures.

**Effect**

All areas where relevant human organs or tissue are removed, stored, used, transplanted or disposed of will have processes in place to ensure compliance with the Human Tissue Act and associated Legislation. This is the responsibility of the Designated Individual (DI) for each of the licences held under the HT Act. These processes will be supported by the Persons Designated (PD) and by a suite of Standard Operating Procedures (SOP) determined by the relevant DI. The DI has primary legal responsibility as the individual under whose supervision the licensed activity is undertaken. PDs, under the direction of the DIs, are also responsible for developing and co-ordinating their own local Standard Operating Procedures (SOPs) using agreed standardised templates approved by the Leeds Teaching Hospitals Trust (LTHT) / University of Leeds (UoL) HTA Management Group (HTA MG) or the DI.

PDs, under the direction of the DIs will have local documented processes in place for complying with the licensing standards; these will include processes to ensure that

* Consent is obtained in accordance with the requirements of the HT Act and as set out in the [Codes of Practice](https://www.hta.gov.uk/guidance-professionals/codes-practice)
* Premises and equipment are fit for purpose, maintained and quality assured.
* The collection, transport and handling of all tissues in such a way as to ensure confidentiality, tissue integrity, and safety.
* Robust record management systems are in place for recording details of holding, usage and disposal of human tissues in ways which are accurate, secure and confidential.

PDs will co-ordinate and undertake annual risk assessments in their areas, using DI agreed standardised templates, to address licensable activities falling under the HT Act in their areas of responsibility. In addition, risk assessments will be undertaken whenever there is a change in circumstance, equipment, substance use, location or a serious adverse event / reaction.

Serious Incidents, Serious Adverse Events and / Reactions or HTA Reportable Incidents (as defined by the HTA) regarding HTA relevant activities will be reported promptly and in line with HTA, UoL and Trust reporting requirements. Reporting will be co-ordinated by the HTA Manager in conjunction with the relevant DI. This is in addition to the LTHT incident reporting requirements.

All HTA reportable incidents relating to the ODT licence will be reported to NHS Blood and Transplant (NHSBT) via their electronic portal. All transplant related incidents are reviewed and coordinated nationally by NHSBT’s Governance Improvement Group and then reported to the Human Tissue Authority as part NHSBT’s assisted function. This is in addition to the LTHT incident reporting requirements.

<https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/>

<https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>

Authorisation to add an activity and area to the Licence will be requested via the HTA Management group (HTA MG) using the agreed template and process and endorsed by the relevant DI.

**Training**

The HTA requires DIs to ensure that all staff working under the authority of an HTA license are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

Details of specific training requirements are set out in separate licence specific Standard Operating Procedures, which will be reviewed by the relevant Management Groups at least every two years. Full records will be maintained of all training undertaken by employees in relation to HTA Licences and will be logged locally by the PD.

**3 Key Definitions**

**Governance requirements for each licence:**

|  |  |
| --- | --- |
| **Licence Holder** (LH) | The Licence Holder is a person or corporate body responsible for applying for the Licence and any changes to the Licence:  Leeds Teaching Hospitals (LTHT) is the corporate body for the Post Mortem, Transplant, Research and Human Application Licences, with the LTHT Chief Medical Officer as the named representative.  The University of Leeds (UoL) is the corporate body for the Anatomy Licence, with the UoL Secretary as the named representative. |
| **Designated Individual** (DI) | Designated Individual is the individual under whose supervision the licensed activity is authorised to be carried out. This individual is responsible for ensuring that other persons to whom the licence applies are suitable persons; that suitable practices are carried out in the course of carrying-on the licensed activity and for compliance with the conditions of the licence. There is one DI per licence. |
| **Person(s) Designated** (PD) | A Person Designated is appointed by the DI and acts at a local level to support the DI. |
| **Licensable Activities** | Activities relating to tissues and cells from the living or deceased for patient treatment (human application) are licensed by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)  The activities licensed by the HTA under the Human Tissue Act are:   * Carrying out of an anatomical examination * Making of a post-mortem examination * Removal of relevant material from a deceased person; * Storage of relevant material for a number of “scheduled purposes” * Storage of anatomical specimens * Public display of a body or relevant material from a deceased person * The procurement of human organs for the purpose of transplantation * The assessment, retrieval and preservation of human organs for the purpose of transplantation |
| **Relevant Material** | Relevant material under the HT Act is any material, other than gametes and embryo’s, removed from the body that consists of or includes human cells.  Further guidance on whether specific materials fall within the definition of relevant material under the [HT Act](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004) or <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/material-covered-human-tissue-quality> are available from the HTA Website in the form of supplementary lists. |
| **Scheduled Purposes** | Scheduled purposes are the activities relating to the removal, storage and use of human tissue that require consent. They are divided into part 1 and part 2. Full details can be found at Appendix B. |

**4 Key staff and committees/ groups**

**The Leeds Teaching Hospitals NHS Trust and the University of Leeds**

It is the responsibility of both organisations to ensure relevant activities are covered by the appropriate licence and that staff[[1]](#footnote-1) comply with the law and this Policy.

**Accountable Officers / Licence Holders**

The Trust Chief Medical Officer is the Accountable Officer / Licence Holder for LTHT and is the named representative for the Post Mortem, Research, ODT and Human Application Licences.

The UoL Secretary is the Accountable Officer / Licence Holder for UoL and is the named representative for the Anatomy licence.

The Accountable Officers report respectively to LTHT’s Trust Board and UoL’s Vice-Chancellor’s Executive Group (or where necessary UoL’s Council) and are responsible for:

* providing assurance to their management and governing bodies that appropriate policies, procedures and structures are in place for HT Act compliance
* Ensuring that the relevant DIs and PDs are appointed and supported in their roles.
* Reporting any serious adverse incidents, including breaches of the licences, and actions taken to reduce the risk of a recurrence

**Designated Individual (DI)**

Under the HT Act (and the associated legislation for the Human Application and ODT Licences), the DI has primary legal responsibility as the individual under whose supervision the licensed activity is undertaken. The DI is responsible for putting in place, designing and developing practices, procedures and appropriate training for HT Act compliance. The DI has the authority and responsibility to stop any activity which contravenes regulatory requirements or policy requirements. Contraventions are to be immediately reported to the relevant Accountable Officer/s.

**Person(s) Designated (PD)**

These are appointed by and report to the relevant DI. Their role is within their defined area, to apply this policy and implement procedures and training.

**Human Tissue Act Manager (HTA Manager)**

The HTA Manager is jointly appointed by LTHT and UoL to support DIs and PDs in developing the systems and processes to implement the actions required to ensure the LTHT and UoL are compliant with the HTA and associated legislation.

The HTA Manager will work with all groups of staff at LTHT and UoL to facilitate compliance providing expert advice to staff in relation to the HT Act; liaising with the Human Tissue Authority in order to advise the Trust and UoL on changes in legislation and all other matters relating to the HT Act. The HTA Manager will provide the key link between the LTHT, UoL and Human Tissue Authority in preparing for licence inspection visits and will co-ordinate the action plans arising from these inspection visits.

The HTA Manager will work with DIs to develop the required assurance processes to demonstrate compliance with the HT Act, co-ordinating the action plans and policies required to support this.

The HTA Manager will support DIs and PDs in auditing SOPs and specific actions that are required to demonstrate compliance with the HT Act.

The HTA Manager will provide advice and support to LTHT CSUs and specialties where this is required to ensure compliance with HTA legislation through the CSU management structure.

**General Managers**

**LTHT CSU General Managers and UoL academic management**

General Managers for relevant CSUs and Academic management in the University will ensure that the necessary infrastructure and resources are in place for compliance with this Policy. They will support the respective DIs, PDs, Clinical Directors, Heads of Nursing, Lead Clinicians, Business Managers, Matrons and Heads of School/Service in meeting their obligations relating to the HT Act. Any changes to the Act or variation in the licences, storage facilities and designated storage areas will be communicated to the General Manager to ensure they are aware of these changes in their area of responsibility and directly involved in the decisions that are made.

**All LTHT / UoL staff who use or store relevant human tissue are required to:**

Comply with the directions given by the relevant DI, PD and other persons responsible for HTA compliance.

Comply with the HT Act and associated legislation

Comply with this Policy

**HT Act Management Group**

The HTA Management Group (HTA MG) is responsible for developing, changing and ratifying policy prior to approval by the Executive Team, monitoring compliance and approving licence activities across both LTHT and UoL. The group is made up of DIs and other representatives from both organisations. The Chair of this Group reports directly to the Accountable Officers.

**5 Equality and Diversity Impact**

This Policy has previously been assessed for its impact upon equality. The Leeds Teaching Hospitals NHS Trust and University of Leeds is committed to ensuring that the way that we provide services and the way we recruit and treat staff reflects individual needs, promotes equality and does not discriminate unfairly against any particular individual or group.

**6 Consultation and review process**

Version 7 of the Policy was subject of consultation with:

HTA Management Group

University Secretary

Selected UoL staff

The final version will be available on the LTHT Policy section of the intranet and on the LTHT HT Act Intranet site. This policy will also appear on the research pages of the UoL intranet under good practice in research.

Following approval, the policy will be circulated to targeted groups as follows:

* Through the HTA Management Group, DI’s and PD’s
* LTHT CSU Management Teams **-** communication directly by e-mail and through team briefings.
* The policy will be uploaded to the LTHT policy section of the intranet and also the Human Tissue Act Site of the LTHT intranet.
* The policy will be uploaded to the research pages of the UoL intranet under good practice in research.

This Policy will be reviewed every three years from the date of approval by the HTA Management Group, or sooner if either HTA guidelines change or LTHT / UoL circumstances change.

**7 Standards/ Key Performance Indicators**

The HTA has developed a number of standards against which establishments must comply. These standards are contained in codes of practice addressing consent; donation of organs; post mortem; anatomy; disposal; research; public display; import and export and donation of bone marrow. These standards are built into SOPs within LTHT and the UoL.

**8 Monitoring Compliance and Effectiveness**

| **Policy element to be monitored** | **Standards/ Performance indicators** | **Process for monitoring** | **Individual or group responsible for monitoring** | **Frequency of monitoring** | **Responsible individual or group for development of action plan** | **Responsible group for review of assurance reports and oversight of action plan** |
| --- | --- | --- | --- | --- | --- | --- |
| **Transplant Licence** | | | | | | |
| Transplant Licence:  Compliance with statutory conditions outlined in schedule 1 and the HTA’s directions.  Annual HTA Standard Audit | 100% compliance | Presentation of reportable incidence at following meeting   * CSU Governance forum Annual NORs contract review * Speciality governance   Human Tissue Act Management Group (HTA MG)  Annual Audit of HTA standards  (September) | DI for Transplant  Lead Nurse for Transplant  NORS Lead | Annual | PD / Lead Nurse for transplant overseen by DI  Commissioning team NHSBT | HTA MG to review and annual assurance report to be provided to Policy and procedure Group |
| **Traceability Systems - (Research, Post Mortem, Human Application and Anatomy Licences)** | | | | | | |
| Areas storing relevant human tissue have an accurate traceability system for all stored, used and disposed of Human Tissue | 100% compliance | Supporting documentation to be uploaded to relevant computer drive which is reviewed by HTA Manager and reported to HTA MG  By request for Research Licence | HTA Manager  DI for Research | Annual | PDs, supported by DIs, overseen by CSU Managers in LTHT & Academic Management in UoL  Results summarised in HTA Manager’s and relevant DI’s HTA MG assurance report | HTA MG Group to review and provide annual assurance report to Policy and procedure Group |
| **HTA Standards Compliance Reports- (Research, Post Mortem, Human Application and Anatomy Licences)** | | | | | | |
| Compliance reports re HTA standards relevant for each licence are produced by the HTA and submitted on a biennial basis  Assurance reports for each area (via audit results for Research Licence) and completed annually for each licenced area | 100% compliance | Compliance report for each area  Assurance reports and supporting documentation : - uploaded to LTHT Shared HTA G Drive folders for Human Application and Post Mortem Licences  - HTA compliance report used for Anatomy Licence assurance and available by request from the DI  - By request for Research Licence | HTA Manager  HTA Manager  DI for Anatomy  DI for Research | Biennial HTA inspection for Human Application  Biennial reports for Post Mortem, Research and Anatomy  Annual  Annual | DI and PDs supported by HTA Manager  DI supported by HTA Manager and PDs  PDs supported by DIs  DI for Anatomy Licence  DI for Research Licence | HTA Management Group to review results and summary actions. Assurance and progress to be provided to Policy and procedure Group annually. |
| **Audit of Compliance with SOPs/Regulatory Requirements - (Research, Post Mortem, Human Application and Anatomy Licences)** | | | | | | |
| Persons Designated(PDs)are required to undertake a rolling programme of local audits to assess compliance with SOPs/Regulatory Requirements  Independent audits are undertaken to ensure compliance with SOPs for Human Application licence | 100% compliance | Evidence of post mortem and human application audits are uploaded to G Drive for review by HTA Manager  Results of Anatomy Licence audits discussed at quarterly sub group meetings  Results of research licence audits discussed by request  Quarterly Consent audits for research licence discussed at sub group  Independent audits (Human Application Licence only) | PDs and HTA Manager  PDs and DI  PDs  HTA Manager  HTA Manager | Rolling programme  Rolling programme  Rolling programme  Quarterly  Rolling programme over two years | HTA Manager and PDs supported by DIs  DI supported by PDs and HTA Manager  PDs supported by DIs  HTA Manager, supported by PDs and DI  HTA Manager, supported by PDs and DI | HTA Management Group to review results and summary actions in quarterly assurance reports. Assurance and progress to be provided to Policy and procedure Group on annual basis. |

**9 Plan for Communication and Dissemination of Policy**

The final version will be available on the LTHT Policy section of the intranet and on the LTHT HT Act Intranet site. This policy will also appear on the research pages of the UoL intranet under good practice in research.

Following approval, the policy will be circulated to targeted groups as follows:

- Through the HTA Management Group, DI’s and PD’s

- LTHT CSU Management Teams **-** communication directly by e-mail and

through team briefings.

- The policy will be uploaded to the LTHT policy section of the intranet and also

the Human Tissue Act Site of the LTHT intranet.

- The policy will be uploaded to the research pages of the UoL intranet under

good practice in research.

**10 References / Associated Documentation**

**Human Tissue Act 2004** <http://www.opsi.gov.uk/acts/acts2004/en/ukpgaen_20040030_en_1>

**HTA Codes of Practice** <https://www.hta.gov.uk/guidance-professionals/codes-practice>

* Code A: Guiding principles and the fundamental principle of consent
* Code B: Post Mortem Examination code of practice and standards
* Code C: Anatomical examination code of practice and standards
* Code D: Public Display code of practice and standards
* Code E: Research code of practice and standards
* [Code F: Donation of solid organs and tissue for transplantation code of](https://www.hta.gov.uk/sites/default/files/Code%20F%20-%20Organs%20for%20tx%20Final_0.pdf)  practice
* Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation code of practice

**Related Policies and Guidance**

* LTHT Policy for the consent to examination or treatment

<http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=1857>

* Policy on Post Mortem Consent  [http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=2001](%20http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=2001%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20)
* LTHT Waste Policy

<http://nww.lhp.leedsth.nhs.uk/policies/ref.asp?ref=PC033>

* UoL Human Tissue Act 2004: Core Policy – Anatomical Examination (held with Anatomy DI)
* University of Leeds Management of Healthcare waste Streams Policy

<http://wsh.leeds.ac.uk/info/232/healthcare_waste/267/healthcare_waste>

Staff can access local licence specific SOPs for further information and guidance as follows:

**Anatomy Licence** - All HTA relevant SOPs can be found locally with the DI for Anatomy Licence, with the Anatomy Administrator and on the Faculty of Medicine and Health shared network drive, which is available to PDs and other users authorised by the DI.

**Post Mortem Licence** - All SOPs are managed on EQMS (Electronic Quality Management System), which is available to all pathology staff that require access. Relevant HTA documents are held in shared G Drive folders, which are available to PDs and other users authorised by the DI.

**Research Licence** - All SOPs relevant to HTA activities can be found on the Research Support area of the UoL Website at: <https://ris.leeds.ac.uk/research-ethics-and-integrity/other-resources/research-involving-human-tissue> /

In addition to these, SOPs for specific areas are produced and held locally within that area.

**Human Application Licence** - All HTA relevant SOPs produced by the HTA Manager and DI can be found on the LTHTs HTA intranet site <http://lthweb.leedsth.nhs.uk/sites/human-tissue-act>

In addition to these, SOPs for the following specific areas are produced and held locally within that area:

* Orthopaedic Theatres, Chapel Allerton Hospital (CAH)
* Cardiac Theatres, Leeds General Infirmary (LGI)
* Liver Transplant Theatres, LGI and St James University Hospital (SJUH)
* Ophthalmic Theatres, SJUH
* Bone Marrow Transplant Unit, LGI and SJUH (also on EQMS)
* The Leeds Centre for Reproductive Medicine (Seacroft Hospital)
* Cardiovascular Unit, (LGI) Procurement and testing of peripheral blood stem cells (PBSCs) for a clinical trial.
* Bexley Wing for the Commissioned CAR-T service and approved CarT ATMPs

Relevant HTA documents are held in shared G Drive folders, which are available to PDs and other users authorised by the DI

**ODT Licence** –All SOP’s can be found on LTHT Sharepoint and are maintained by the Lead Nurse for Transplant.

**Appendix A**

**SUMMARY OF THE SCOPE AND REQUIREMENTS OF THE HUMAN TISSUE ACT**

**This appendix should be read along with Appendix B entitled ‘A summary of scheduled purposes and consent requirements’**

The HT Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display. It also covers the removal of such material from the deceased. (It does not cover removal of such material from the living - this will continue to be dealt with under common law.)

The HT Act regulates removal, storage and use of human tissue. This is referred to in the HT Act as **'relevant material'** and is defined as material that has come from a human body and consists of, or includes, human cells. Cell lines, after they have divided outside the human body, are excluded, as is hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation and Embryology Act 1990.)

The HT Act lists the purposes for which consent is required (see Appendix B) and they are referred to as **'scheduled purposes'**. The consent required under the HT Act is called 'appropriate consent', which broadly means consent from the appropriate person, as identified in the HT Act. The HT Act sets out penalties of up to three years' imprisonment or a fine, or both, as a deterrent to failing to obtain or to misusing consent.

The HT Act established a Human Tissue Authority (HTA) to advise on and oversee compliance with the HT Act. The HTA have issued good practice guidance in statutory codes of practice. It also licenses and inspects post mortem activities for hospitals and coroners, anatomical examinations, public display of human remains and storage of human tissue.

The HT Act makes it an offence to have human tissue, which includes hair, nail and gametes in this context, with the intention of analysing its DNA without the consent of the individual from whom the tissue came, or of those close to them if they have died. This provision applies UK-wide. There are penalties for not obtaining consent.

The HT Act gives specified museums in England discretionary power to move human remains out of their collections, if the remains are reasonably believed to be those of a person who died more than 100 years before the date of implementation of the relevant provision of the HT Act. This will allow museums, for example, to return human remains to aboriginal groups.

The HT Act provides a number of exceptions to the general rule that appropriate consent is required in order to store or use human tissue for scheduled purposes. These can be found on the HTA website, within the code of practice for consent.

From January 2021, the United Kingdom (UK) has left the [European Economic Area (EEA)](https://www.gov.uk/eu-eea) single market and customs union which has resulted in Human Tissue Authority (HTA) regulatory changes in the UK. These changes apply to the movement of human tissues and cells between Great Britain (GB), Northern Ireland (NI), and the EEA.

Establishments importing or exporting human tissues and cells intended for human application (patient treatment) may now require a HTA licence covering these activities.

From 2007, the activity of procurement and storage of tissue for human application has been added as a licensable activity for the Human Application licence. The HTA, as one of the Competent Authorities in the UK under the European Union Tissue and Cells Directive (EUTCD) and its implementation in UK via the Human Tissue (Quality and Safety for Human Application) Regulations 2007, has responsibility for regulating tissues and cells (other than gametes and embryos) for human application (therapeutic use). The changes resulting from the end of the UK Transition relate to the import and export of human tissue and cells for Human Application (HA) and regulated under the [Human Tissue (Quality and Safety for Human Application) Regulations, 2007 (as amended)](https://www.hta.gov.uk/policies/licensing-under-human-tissue-quality-and-safety-human-application-regulations-2007-amended).The Human Fertilisation and Embryology Authority (HFEA) is the other Competent Authority in the UK and is responsible for the regulation of gametes and embryos for human application.

From 2012, the HTA’s regulatory requirements for the procurement and transplantation of organs are licenced according to the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012. This was transposed into UK law by the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Organ Donation Directive). The licensing requirements of the Quality and Safety of Organs Intended for Transplantation Regulations 2012 are not affected by the UK Transition.

The HTA’s regulatory requirements are designed to promote the safe use of human

organs and ensure traceability is maintained between donor and recipient.

The HTA audits establishments it licences against eight groups of assessment criteria:

* Donor characterisation and organ characterisation
* Retrieval of organs for transplantation
* Organ preservation
* Making arrangements to transport an organ
* Implantation
* Traceability
* Serious adverse events and serious adverse reaction

The licensing requirements of the Human Tissue Act 2004 are not affected by the UK Transition.

**Appendix B**

**A SUMMARY OF SCHEDULED PURPOSES AND CONSENT REQUIREMENTS**

**This appendix should be read along with Appendix A entitled ‘Summary of the Scope and Requirements of the Human Tissue Act ‘**

**Scheduled Purposes** are the activities relating to the removal, storage and use of human tissue that require consent. They are divided into part 1 and part 2.

**Part 1:** Purposes requiring consent: General (tissue from the living or the deceased)

1. Anatomical examination – requires witnessed consent in writing before death.
2. Determining the cause of death – except where a post-mortem is ordered by a coroner.
3. Establishing after a persons’ death the efficacy of any drug or other treatment administered to him – e.g. hospital post-mortem.
4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person) – e.g. genetic information.
5. Public display – requires witnessed consent in writing before death.
6. Research in connection with disorders or the functioning of the human body.
7. Transplantation - includes all bodily material such as blood, bone marrow, skin, tissue and organs.

**Part 2:** Purposes requiring consent: Deceased persons

1. Clinical audit
2. Education or training relating to human health – including training in research techniques
3. Performance assessment – e.g. testing medical devices.
4. Public health monitoring
5. Quality assurance

**Consent:** The fundamental principle which underpins the HT Act. The following are amongst the issues integral to the consideration of the consent provision of the HT Act. Further information can be found in the HTA code of practice for consent:

- Is consent required?

- Is it appropriate consent?

- Is it valid consent?

- What is the Scope of the consent?

- What is the duration of the consent?

- Are processes in place for the possible withdrawal of consent?

**General provisions:**

Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:

- Does the activity require consent?

- Who has authority to give consent (appropriate consent)?

- Has sufficient verbal or written information been provided for the person giving consent, to understand the issues (valid consent)?

- How will the consent be given and recorded?

- When is written consent required?

- Is consent needed for more than one purpose?

- If a child is involved, are they competent to consent and have they expressed particular views or wishes?

- If an adult lacks capacity to consent, how should the provisions of the Mental Capacity Act be applied?

- Are there exemptions to the provisions to the HT Act?

- Is DNA analysis likely to be involved?

- What are the consent implications for foetal tissue?

The answers to the above questions and considerations can be found in the HTA’s Code A: ‘Guiding Principles and the Fundamental principle of Consent’ Code of Practice:

<https://www.hta.gov.uk/guidance-professionals/codes-practice>

This link also includes reference to any exceptions and existing holdings relevant to the HT Act.

**Any specific questions relating to post mortem consent should be directed to the LTHT Post Mortem Consent Nurse Specialist.**

**LTHT and UoL Governance Arrangements for Human Tissue Act Appendix C**

**QMG**

**UoL Accountable**

**Officer**

**UoL Secretary**

**HTA Management Group (HTA MG)**

Designated Individuals for each licence (5)

Director of Quality (Chair)

HTA Manager (secretary),

Head of Research Integrity and Governance, UoL

**Persons Designated**

**Trust Board**

**UoL Council**

**Chair of HTA MG**

**LTHT Accountable Officer**

**Chief Medical Officer**

**Chief Executive**

**Performance Management**

**Individual staff members**

**Designated Individuals**

**UEG**

**Appendix D**

**Local Governance details for all five Licences**

An Organisational Chart and table, listing the contact details for the Designated Individual, Licence Holder, HTA Manager and all current Person’s Designated, for all five licences, can be found on LTHT intranet site under H for Human Tissue Act <http://lthweb/sites/human-tissue-act> and locally with each PD.

The Organisational Charts and Tables which are UoL relevant can be found on the research and innovation (R+I) pages of the UoL internet site <https://ris.leeds.ac.uk/research-ethics-and-integrity/other-resources/research-involving-human-tissue/> and the Faculty of Medicine and Health Research Office website.

They are also available for each specific licence in the following areas:

**Human Application Licence:** LTHT intranet site and locally with each PD

**Anatomy Licence:** DIs documentation and with the Anatomy

Administrator

**Post Mortem Licence:** EQMS, LTHT intranet site and locally with each PD

**Research Licence:** LTHT intranet site, locally with each PD and on the

R+I site at UoL

**ODT Licence:** LTHT intranet site and locally with Lead Nurse for Transplantation

**Checklist for the Review and Approval of Policy**

**LEEDS TEACHING HOSPITALS NHS TRUST**

**Approving Body Checklist for the Review and Approval of Trust Policy or Procedure**

To be completed and attached to the policy when submitted to the appropriate committee for consideration and approval.

|  | **Title of document being reviewed:** | **Yes/No/ Unsure** | **Comments** |
| --- | --- | --- | --- |
| **1.** | **Format and Content** |  |  |
|  | Is it in the correct format? | Yes |  |
|  | Is the staff summary clear and adequate? | Yes |  |
|  | Are the intended outcomes clearly described? (the Policy/Procedure Effect) | Yes |  |
|  | Is there a Definitions section giving an explanation of key terms used. | Yes |  |
|  | Has the policy’s impact on Equality and Diversity been fully considered? | Yes | The previous version was discussed with the Equality and Diversity Manager. This reviewed version has minimal updates. |
| **2.** | **Consultation and Review** |  |  |
|  | Has there been appropriate consultation with stakeholders and users? | Yes |  |
|  | Has an appropriate governance group reviewed and supported the document prior to submission for formal approval? | Yes |  |
|  | For HR Policies only, has the TCNC approved the document? | NA |  |
|  | If it is a clinical policy/procedure has it been reviewed by the Clinical Guidelines Group? | NA |  |
|  | Has it been reviewed by the counter fraud team? | No |  |
| **3.** | **Dissemination and Implementation** |  |  |
|  | Is there a communications plan to identify how it will be communicated and implemented? The Communications Team can help you with advice. | Yes |  |
| **4.** | **Process to Monitor Compliance and Effectiveness** |  |  |
|  | Is there a monitoring table setting out measurable standards or KPIs together with clear monitoring and reporting mechanisms (to ensure there is assurance of implementation) | Yes |  |
| **5.** | **Review Date** |  |  |
|  | Is the review date in 2 years? If not is there a justified reason? | No | This policy has a 3 year review date, as previously approved. |

**If the document needs urgent approval before all of the above are satisfactorily addressed, please bring this to the attention of the appropriate committee so conditional approval can be given.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Endorsement from appropriate group(s)**  **(This will vary depending on content and nature of policy)**  For example, a policy relating to radiation should be considered by the radiation safety committee.  A staff policy should be reviewed by TCNC. | | | |
| If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation’s database of approved documents. | | | |
| Group |  | Date |  |
| Group |  | Date |  |

1. Staff, for the purposes of this Policy, to include the organisation’s employees, students, agents and other representatives. [↑](#footnote-ref-1)