

6. A Guide to the Human Tissue Act and the Use of the Tissue Bank

What is covered by the Human Tissue Act?

The Human Tissue Act (2004) covers the storage, use and removal of human tissue. It requires that consent must be given for body parts, organs and tissue from the living or deceased to be removed, stored or used for certain specified purposes.

Human tissue is referred to in the Act as “relevant material” (see definition below).

The activities covered by the Act are referred to as “scheduled purposes”. They are divided into two groups, the activities in **bold** are those understood to take place at Northumbria University and for which tissue will be stored in the licensed Tissue Bank.

Part 1:

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to that person
- 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
- Transplantation

Part 2:

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

When planning a project that requires the use of human tissue, consideration must be given to: consent; obtaining ethics approval; and the safe disposal of human tissue. You have a duty to abide by the legislation and ensure that all necessary measures have been taken.

The general rule is that Part 1 activities always require consent. Part 2 activities require consent if the material is from a person who was dead at the time the material was removed, but do not require consent if the material is tissue taken from living individuals.

Any activity not described by a Scheduled Purpose does not fall within the remit of the Act and does not need to be licensed by the Human Tissue Authority (HTA).

Definition of relevant material

The definition of relevant material in the Human Tissue Act is:

Section 53: Relevant material:

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.
2. In this Act, references to relevant material from a human body do not include:
 - (a) embryos outside the human body, or
 - (b) hair and nails from the body of a living person.

Categories of relevant material

The Human Tissue Authority divides potentially relevant material into three categories: Specifically identified relevant material; processed material and bodily waste products.

1. Specifically identified relevant material

This includes material like bodily organs and tissues, consisting largely or entirely of cells that are clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone; and specifically the following:

- stem cells created inside the human body
- embryonic stem cells
- non blood derived stem cells
- umbilical cord blood stem cells
- bone marrow
- primary human cell cultures

but not:

- cultured cells which have divided outside the human body
- artificially created embryonic stem cells
- cell lines
- extracted DNA
- plasma extracted DNA

2. Processed material

Where a processed material is generally agreed – as a result of the process – to leave it always either cellular or acellular, then the presumption should be that all examples should be regarded as such. The HTA would rely on the stakeholder's assurance that the process in question had been carried out. Under this category plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are to be regarded generically as relevant material; while plasma or serum, for example, will be regarded as not relevant. The two latter processed materials, widely produced from blood taken for treatment, are however examples of where 'normal expectations' may well need to be exercised.

3. Bodily waste products (including excretions and secretions)

Bodily waste is a less well characterised group of material. Nevertheless, the HTA considers it important to provide a framework of guidance. The HTA considers that bodily waste should normally be regarded as relevant material: The Act cannot be denied on this point. The Act's wording is clear and reflects the possibility that even a single cell can be subject to research. While acknowledging the views of stakeholders who have argued for greater individual discretion, it would be inappropriate to encourage people to grant themselves an exemption on the basis of their own interpretation of the Act. However, the HTA may be able to offer nuanced advice in specific instances. There will be cases where a stakeholder believes that material, intended for a scheduled purpose, is actually acellular. In such cases the stakeholder would need to consult the HTA, and we would then refer the case for advice to a members' panel if necessary.

Regulation

What activities require a licence?

The Human Tissue Authority is established as the regulatory body to license a number of activities set out in the Act. The licensing requirement applies to all establishments whether operating within the NHS, a University NHS or the private or commercial sector. It is unlawful to carry out the following activities without a licence from the HTA:

- Both hospital and coroner's post-mortem examinations

- The removal, use and storage of material, organs or tissue after death (except for whole and part organs for transplantation)
- Anatomical examinations
- Storage of human bodies, body parts or human tissue (but see exceptions below)
- Public display of human tissue.

Licensing exemptions – deceased

- Material more than 100 years' old
- Storage of material which has come from the body of a deceased person is exempted if the licensed activity relates to the body of a person who died before the day on which the Section came into force, or to material which has come from the body of such a person and at least 100 years have elapsed since the date of the person's death.
- Storage of relevant material which has come from the body of a deceased person is exempted from licensing if the person storing it is intending to use it for the purpose of "qualifying research" or for a specific research project for which such ethics approval is pending. "Qualifying research" refers to research which has been ethically approved by an NHS research ethics committee.
- Storage of relevant material which has come from the body of a deceased person, is exempted from licensing if the relevant material:
 - (i) has come from premises in respect of which a licence under Section 16 (2) is in force
 - (ii) is stored by a person intending to use it for the sole purpose of analysis for a Scheduled Purpose under the Human Tissue Act other than research
 - (iii) will be returned to premises in respect of which a licence under Section 16 (2) is in force when the analysis is completed.

Licensing exemptions – living or deceased

The licensing requirements for storage do not include storage which is incidental to transportation. This means that the storage of material while it is being conveyed from one place to another does not need to be licensed. This would normally be a matter of hours or days, rather than a week or longer.

Storage of relevant material is exempt from licensing where the person storing it is intending to use the material for transplantation:

- and the material is an organ or part of an organ (if it is to be used for the same purpose as the entire organ in the human body) or
- the storage is for a period of less than 48 hours

Licensing exemptions – living

Storage of relevant material which has come from the body of a living person is excepted where the person storing it is intending to use it for:

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or treatment administered to him
- Obtaining information which may be relevant to another person
- Public display
- Clinical audit
- Education or training related to human health
- Performance assessment
- Public health monitoring
- Quality assurance
- Qualifying research, i.e. research which has been ethically approved by an NHS research ethics committee.

The Impact of the Act on Particular Activities

Those carrying out activities that fall within the Human Tissue Act should ensure that they are familiar with the material provided by the Human Tissue Authority. This section sets out the main requirements, regarding consent and licensing, for the principal activities taking place at Northumbria University covered by the Act.

Research

The main requirements of the Act in relation to research involving human organs or tissues are:

- Consent must be obtained for any storage and use of tissue removed after death for research purposes
- Consent is required for the storage and use of tissue from living individuals for research unless the material has been anonymised, such that the person carrying out the research does not know the identity of the donor (there may still be a link to the donor via a third party), and the research project has been approved by an NHS research ethics committee or approval is pending.

In very exceptional circumstances, such as an extreme public health emergency, the Secretary of State may make Regulations to allow tissue from the living or the dead to be used for research, without consent.

Storage of human material

The main requirements of the Act in relation to the storage of human material, organs or tissue are:

- Consent is required for the storage of material from a living individual for any Part 1 activity, except where it is anonymised tissue stored for a research project that has research ethics authority approval or approval is pending
- Consent is required for the storage of material from a deceased person for both Part 1 and Part 2 activities
- Storage of material removed from living individuals requires a licence only if it is stored:
 - for future research that does not have ethics approval (tissue banks).
 - for more than 48 hours for the purpose of transplantation (except blood).
- The storage of tissue from a deceased individual requires a licence except where:
 - it is stored for use in a research project that has received approval from a research ethics authority (see above) or approval is pending.
 - it is sent to unlicensed premises for the purpose of analysis (other than research) and will be returned to licensed premises once the analysis is complete.

Analysis of DNA

It is an offence, throughout the UK, to have human tissue or cells, including hair, nails and gametes, with the intention of analysing its DNA without qualifying consent, subject to the following exceptions:

- where the material is from a living person and is used for Part 2 activities
- where the material is an existing holding and is used for the activities covered by the Act
- in the course of research where the material comes from a living person, the material is anonymised and the research project has been approved by an NHS research ethics committee.

The offence does not apply to exempt material which is:

- material from the body of a person who died at least 100 years before the Act came into force
- an anonymous existing holding

Consent

Organs/tissue removed from the living

The consent requirements of the Act do not apply to the removal of relevant material from the living but only to the removal of relevant material taken from the dead. Consent for removal of relevant material from a living person continues to be dealt with by the common law. This is because the removal of material from living patients is likely to be:

- a part of the patient's treatment (for example, during surgery or taking a blood sample)
- part of a deliberate donation of organs, tissue or cells
- where a healthy person (who may or may not be a patient) participates as part of a research project. The consent gained for participation in such research must also cover any planned removal, subsequent storage and uses of relevant material (as defined in the Act).

Relevant material taken from a person in their lifetime continues to be treated as removed from the living after their death. It is the point at which the material is removed that determines how it is affected by the Act.

Storing tissue, including blocks and slides, for scheduled purposes

The Act does not distinguish between blocks and slides and any other form of human tissue. Whilst it may be desirable for blocks and slides to be taken and kept for clinical audit, teaching or other purposes, it should not be assumed that consent to a post mortem implies consent to removing and keeping blocks and slides.

The implications of a post mortem, including the need to remove organs or tissue for further examination, must be explained to the deceased person's relatives when obtaining consent. It should be made clear that consent to the removal, storage and/or use of organs or tissue for any scheduled purpose is a separate decision from consent to conducting a post mortem examination (whether partial or full).

Record-keeping

NHS Trusts and other establishments should ensure that they have systems in place to maintain proper records and documentation for all tissue and organs they acquire and/or pass on to others.

The Designated Individual named in licences issued by the HTA should ensure that such systems are in place. It is important to be able to track what happens to organs and tissue for health and safety reasons – for example, should an infection occur, resulting in the need to trace people who came into contact with the material. Keeping proper records demonstrates respect for the donation.

The duty to create and maintain proper records lies with the institution where the material is removed from the body, or where the material is identified as surplus to requirements for healthcare purposes and is set aside for a scheduled purpose. Such initial records should include:

- details of who gave consent
- details of what the consent related to, and of any restrictions on use stipulated during the consent process
- the processes to be applied to the tissue
- when and to whom tissue is transferred (if applicable)
- when and how disposal is undertaken (if applicable).

Tissue may be transferred from one place to another many times. So that an audit trail can be maintained, each institution that handles human organs or tissue must have systems that can record:

- when the material was acquired, and from where
- what has been consented to
- the uses to which the material is put whilst in the institution's care and any processes applied to it
- when the material is transferred elsewhere, and to whom.

Removal of human tissue and its subsequent use and storage

Detail needs to be commensurate with the study. Freely given informed consent should be obtained from every subject prior to clinical trial participation. This is defined as:

'A subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.' (see below)

Consent can be obtained by the Principal Investigator or designated person.

Information about the study should be presented to the participants and should include:

- the study title and an invitation to participate
- the purpose of the study and whether the trial involves research
- why the participant has been chosen

- the voluntary nature of participation, including the right to withdraw from the trial at any time without penalty
- the trial procedures to be followed, including all invasive procedures
- those aspects of the trial that are experimental
- the approximate number of participants involved in the trial
- the participants' responsibilities in the study, including the expected duration of their participation in the trial
- the reasonably foreseeable risks or inconveniences to the subject
- the procedure for advising participants in the event of an abnormal test result. It is Northumbria University policy to provide participants with their own individual test results and the relevant normal ranges.
- details of anticipated prorated payments and expenses, if any, for participating in the trial and any other arrangements for payment, including an explanation of how payment may be influenced by duration of participation or completion of diaries etc.
- assurance that record regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential
- identifying the subject will remain confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential • the complaints procedure;
- relevant contact details.

Storage of Human Tissue

Storage of relevant material taken from the living

The Human Tissue Act makes it lawful to store relevant material taken from a living person for scheduled purposes, provided consent from an appropriate person is obtained.

Material may be taken from the living in a variety of circumstances, for example:

- in the course of a diagnostic procedure (e.g., blood sample, biopsy)
- in the course of treatment procedures (e.g., the removal of organs or tumours during surgery)
- specifically, for the purposes of research (e.g., a blood sample taken as part of a population screening programme) or
- for transplantation

The Act allows material taken from the living for any reason to be stored (and used) without consent for the following scheduled purposes, on the basis that these are concerned with the general provision of clinical and diagnostic services:

- clinical audit
- education or training relating to human health
- performance assessment • public health monitoring
- quality assurance.

Consent is required to store tissue from the living for:

- obtaining scientific or medical information about a person which may be relevant to any other person (now or in the future)
- public display.

Standard operating procedures for sample drop-off at Northumbria University's Human Tissue Bank

The following procedures must be followed if you wish to store human tissue at the University's Human Tissue Bank:

1. Send an email to the Human Tissue Bank at least 24 hours in advance to arrange a mutually convenient time for sample drop off

2. Provide a sealable storage box with the study number written on the box and on the lid with permanent pen. If more than one box is required, each box should be labelled with the study number and a number that indicates the total number of boxes being stored, e.g. '1 of 2', '2 of 2' etc.
3. Ensure all samples in the box are labelled with the study storage number and a series number

Existing holdings

It is lawful to store and use for scheduled purposes, without consent, relevant material and the body of a deceased person that was already held in storage for a scheduled purpose on 1 September 2006. However, where the views of the deceased person or of their relatives or friends are known, those views must be respected.

The existing holdings provisions do not apply to the storage and use of bodies or material, which are the subject of an authority under the Anatomy Act 1984 and where the anatomical examination has not been completed by 1 September 2006.

Disposal of Human Tissue

Obtained from the Living

The Act makes it lawful to treat as 'waste' any relevant material which has come from a person who was:

- in the course of receiving medical treatment
- undergoing diagnostic testing or
- participating in research.

It also states that material no longer used, or stored for use, for any scheduled purpose can be dealt with as waste.

Material taken from the living should normally be disposed of by incineration in accordance with current guidelines.

Surplus material from tissue samples

The Act permits disposal as 'waste', material that has come from a body in the course of:

- receiving medical treatment
- undergoing diagnostic research or
- participating in research

and material that:

- has come from a human body and ceases to be used, or stored for use.

It is normal practice to dispose of such material by incineration. This includes:

- tissue fragments trimmed from the tissue sample before it is processed for histology
- the tissue in the sections trimmed from a wax-embedded block before the usable sections are cut
- the unrecoverable bodily material that is washed out of the tissue during its processing into a wax block.

Relatives will expect remains to be disposed of with respect. As a minimum, stored human body parts, organs and tissue should be disposed of separately from other clinical waste.

Organs/tissue removed after death

Tissue and organs should be handled in accordance with any reasonable wishes expressed by relatives or the deceased person, as long as the method of disposal is legal. The time, place and method of disposal should be recorded.

Basic disposal options are cremation or burial. There is usually a funeral or other religious or nonreligious ceremony, either arranged by relatives or friends, with the institution's help if requested, or arranged by the institution.

Relatives may want to be reassured about the suitability of any burial or other arrangements the institution makes.

Disposal at Northumbria University

Human Tissue that can be classed as waste (see above) must be disposed of in line with the Clinical Waste guide below and should go through Northumbria University's Clinical Waste Skip located in Ellison Yard. Material in this skip will be incinerated.

The University has contracted out disposal of the following Clinical Waste Groups:

Group A

- Identifiable human tissue, blood, animal carcasses and tissue from veterinary centres, hospitals or laboratories
- Soiled surgical dressings, swabs and other similar soiled waste
- Materials from infectious disease cases.

Group B – in sharps boxes

- Discarded syringe needles, cartridges, broken glass and any other contaminated disposable sharp instruments or items.

Group C – in bags

- Microbiological cultures and potentially infected waste from pathology departments and other clinical or research laboratories

Use of the yellow Clinical Waste Skip in Ellison Yard

All material going out to this clinical waste skip should be autoclaved.

Clinical waste should not be mixed with special or hazardous wastes (significantly, chemically contaminated waste should go to the special waste disposal route).

Material going in the clinical waste skip should be in appropriately labelled yellow clinical waste bags or appropriately labelled sharps boxes.

Bags for the clinical waste skip should be:

- Handled wearing gloves
- Double bagged, where appropriate, and tied shut
- No more than 9kg in weight
- Labelled with ○ University post code ○ University name ○ Faculty name ○ Lab number (Labels are available from University Waste Management)
- Free of any items likely to cause a puncture of the bag. Items such as metal blades, glass slides or pipettes, hard plastic pipette tips, wooden sticks should all go into sharps boxes and then be placed in the clinical waste skip (the contractor will refuse to take any skip with loose material in it).