

# The Human Tissue Act 2004: A guide for the public



# A guide for the public to the Human Tissue Act 2004

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This guide is intended to be read alongside [the Human Tissue Act 2004](#).

## The role of the HTA

The [Human Tissue Authority](#) (HTA) is a regulator set up in 2005 following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent.

We were created by Parliament as a non-departmental public body (otherwise known as an "arms'-length body") of the [Department of Health and Social Care](#), and are overseen by an [Authority of lay and professional members](#) appointed by the Government.

The HTA license and inspect organisations that remove, store and use human tissue for research, medical treatment, post mortem examination, education and training, and display in public. We also work to ensure organ and stem cell donations from living people for the purpose of transplantation do not involve any reward or coercion.

The HTA was established by [the Human Tissue Act 2004](#) (the Act). This guide gives an overview of our legislation and explains common terms found in the Act.

This guide should be read alongside our public guides to the sectors we regulate, which are:

- [Anatomy](#)  
We regulate the storage and use of human bodies and material for anatomical examination. Anatomical examination refers to the teaching of students or healthcare professionals about the structure and function of the human body.
- [Bone Marrow and Peripheral Blood and Stem Cell donation](#)  
We are responsible for ensuring bone marrow and PBSC donations are carried out in a way that is lawful and with informed consent.
- [Organ Donation](#)  
We regulate the donation of organs from both living and deceased people in the UK, and provide advice and guidance about the Act
- [Post mortem](#)  
A post mortem examination is an examination of a body after death. The HTA regulates all mortuaries where post mortem examinations take place.
- [Public Display](#)  
The HTA is responsible for regulating the public display of human material. This includes the display of deceased persons, as well as body parts and tissues taken from both the deceased and the living
- [Research](#)  
Our role in research is limited to licensing premises to store tissue from the living and the deceased.

The Act also lists certain activities for which an organisation must hold a licence.

For more information about licences and when they are required, please refer to the public guide to the relevant sector.

## Our legislation

The HTA was established to regulate the removal, storage, use, and disposal of human tissue. Our core functions are set out in four pieces of legislation. These are:

1. [The Human Tissue Act 2004 \(The Act\)](#)
2. [The Human Tissue \(Quality and Safety for Human Application\) Regulations 2007](#)
3. [The Quality and Safety of Organs Intended for Transplantation Regulations 2012](#)
4. [The Human Transplantation \(Wales\) Act 2013](#)

These laws ensure human tissue is used safely and ethically, with appropriate consent.

The Act covers England, Wales and Northern Ireland.

In Scotland, [the Human Tissue \(Scotland\) Act 2006 applies](#). However, some provisions in the Act related to the analysis of DNA also cover Scotland.

The Regulations listed above set out the legal requirements for England, Scotland, Wales and Northern Ireland for the sectors to which they apply (human application and organ donations and transplantation).

The Human Transplantation (Wales) Act 2013 sets out the framework for deceased organ donation in Wales.

## Commonly used terms

The following terms are used frequently throughout the public guides to our Codes of Practice. These terms are taken from the legislation listed above.

### Tissue and organs

#### Organs

Where we use the term organ, or organs, in this guidance, it refers specifically to a whole solid organ, or organs, including:

- Kidney
- Liver
- Heart
- Brain
- Eyes

The general definition of what constitutes an organ in this context is a body part which has a specific vital purpose.

#### Tissue

Where we use the term tissue, this refers to all other various human materials that are not whole solid organs.

## Tissue and Organs

When we refer to “tissue and organs”, this is to make it clear there is a combination of both.

## Consent

The HTA sees consent as essential to the lawful removal, storage, and use of body parts, organs and tissue. The requirements for consent vary between the different purposes for which tissue may be used.

The Act lists the activities or purposes for which consent is required - these are called scheduled purposes.

### Scheduled Purposes.

The Act requires that appropriate consent be in place. What is considered appropriate consent varies depending on the purpose. There are also different consent requirements for some purposes depending on whether with the tissue is from the deceased and the living.

For example, to donate your body for public display or anatomical examination, you must personally give consent while you are alive. No one else can give consent for you after your death. In contrast, for donating your tissue for research purposes a family member or close friend would be able to consent on your behalf after your death.

For more information on the consent requirements for a particular purpose, please refer to the guides to each sector listed above.

## Relevant material

The HTA considers ‘relevant material’ to be material that is made of, or includes, human cells other than gametes (eggs and sperm). Gametes come under the regulation of the [Human Fertilisation and Embryology Authority \(HFEA\)](#).

If a sample is known to contain a single cell from a human body, then the sample is relevant material. This includes the body of a deceased person, as well as any human tissue, organs or cells removed from a deceased person. It also includes:

- hair, nails and saliva from the body of a deceased person; and
- human material that has been modified in some way.

A more detailed list of relevant material is available on [our website](#).

## The Regulation of Activities Involving Human Tissue – *Scheduled Purposes*

In the Human Tissue Act, a licence is generally required if an activity is being undertaken for what the Act calls a [scheduled purpose](#). Consent is required to use human tissue for these purposes. There are two types of purpose:

1. those requiring consent for tissue or organs taken from both the living and the deceased; and

2. those requiring consent for tissue or organs taken from the deceased, but not if taken from the living.

### **Purposes requiring consent whether it's from a living or deceased person**

Consent for the following purposes is required whether the person is alive or dead at the time the material is collected or removed.

Appropriate consent must have been taken to carry out any of the purposes listed below.

#### **1. Anatomical examination**

- the use of a body, body part or tissue to teach students or healthcare professionals about the functioning of the human body

#### **2. Determining the cause of death**

- carrying out a post mortem examination of a body to find out how a person died
- this is except in the case of post mortem examinations that are ordered by the coroner – you cannot object to a coroner's post mortem, but if you have asked the coroner must tell you (and the person's GP) when and where the examination will take place
- you can read more on coroner's post mortems here - <https://www.gov.uk/after-a-death/when-a-death-is-reported-to-a-coroner>.

#### **3. Establishing after a person's death the efficacy of any drug or other treatment administered to them**

- carrying out tests on cells, tissues or organs or tissue from a deceased person to investigate whether specific treatments they had were effective.

#### **4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)**

- carrying out tests on cells, tissue or organs or tissue from a living or deceased person to find out whether they had any unknown medical or genetic disorders.

#### **5. Public display**

- showing a body, body part or tissue to members of the public.

#### **6. Research in connection with disorders, or the functioning, of the human body**

- the use of cells, tissues or tissue and organs to find out more about the body and/or disease work.

#### **7. Transplantation**

- the removal of an organ or tissue from one person for implanting into another person.

In the case of public display and anatomical examination, **removal cannot take place based on someone else's consent**; if consent was not obtained from the individual before they died, the tissue or organ(s) cannot be taken.

For all other cases listed above, consent can be obtained from someone else (see the “**qualifying relationships**” below).

### **Purposes requiring consent for tissue or organs taken from the deceased but not from the living**

In order to carry out any of the activities listed below with tissue collected or removed from the deceased, appropriate consent must have been given.

However, consent is not needed to carry out these activities using tissue taken from a living person.

If a person dies after the tissue is taken, it can still be used for the activities below without their consent having been taken.

#### **8. Clinical audit**

- the review of processes used to test tissue.
- to check whether the right tests have been carried out
- and whether they have been carried out correctly

#### **9. Education or training relating to human health**

- the use of human tissue to train students and healthcare or medical professionals.

#### **10. Performance assessment**

- using human tissue to evaluate and assess diagnostic kits or medical devices

#### **11. Public health monitoring**

- using human tissue to identify and observe health or disease trends in the general public or specific groups

#### **12. Quality assurance**

- the use of tissue to monitor and evaluate a particular research project or health service to make sure effective clinical procedures and diagnostic tests are being used

## Qualifying relationships

The Human Tissue Act 2004 includes a list of 'qualifying relationships'. Qualifying relationships are ranked.

When consent can be given by a family member or close friend after death, such as for organ donation for transplantation, the person nearest the top of the list should be asked first to give consent for removal, storage or use of relevant material. Their decision has priority over someone below them on the list.

The list is as follows:

1. spouse or partner (including civil or same sex partner)
2. parent or child
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. friend of long standing

For these purposes, a person is considered a partner if they live as partners in an enduring family relationship.

Whilst the Act is clear on the hierarchy of relationships, there may be situations where relatives disagree on giving consent. There are procedures and advice on dealing with these conflicts in [Code A: Guiding Principles and the fundamental principle of consent, paragraphs 30-39](#).

We recommend that any decision on consent is sensitively discussed with other relatives of the deceased person. This may include relatives not on this list, for example, an aunt or uncle.