

## **THE HUMAN TISSUE ACT 2004**

### **New legislation on human organs and tissue**

#### **What is the Human Tissue Act 2004?**

The Human Tissue Act received Royal Assent on 15 November 2004. It is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health-related purposes and public display. It extends to England, Wales and Northern Ireland. A new offence of DNA "theft" applies throughout the UK.

The Human Tissue Act 2004 repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.

#### **Why has the law been changed?**

The existing law on retention and use of organs and tissue was reviewed following public inquiries into events at Bristol Royal Infirmary<sup>1</sup> and the Royal Liverpool Children's Hospital (Alder Hey).<sup>2</sup> These inquiries, together with the Isaacs Report,<sup>3</sup> which focused on the retention of adult brains following coroners' post mortems, showed that storage and use of organs and tissue without proper consent after people had died were commonplace. The legal review showed that the law on tissue retention, both from the living and the deceased, was inadequate, and that the law on anatomical examination and transplants needed to be updated. The Human Genetics Commission also raised concerns about the scope for DNA "theft", in cases of disputed paternity, for example. Additionally, the Government wished to change the law to give museums the power to move human remains out of their collections.

Following a public consultation, the Government decided to update the law in this area to reflect advances in good practice. This was to make it clear that living patients must consent to retention and use of their organs and tissue for particular purposes beyond their diagnosis and treatment. It would also make it clear that there must be consent for removal, retention and use of tissue from people who have died, given either by those people in life, or in the event that they die without expressing a wish, given by someone nominated by, or close to them.

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<sup>1</sup> *Learning from Bristol: The Report into Children's Heart Surgery at Bristol Royal Infirmary* (July 2001)

<sup>2</sup> *The Royal Liverpool Children's Hospital Inquiry Report* (January 2001) HC12-II

<sup>3</sup> Dept of Health (May 2003) *The Investigation of Events that followed the death of Cyril Mark Isaacs*; Dept of Health (July 2003) *Isaacs Report Response*



## What does the Act do?

- The 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 Act regulates removal, storage and use of **human tissue**. This is referred to in the Act as "relevant material" and is defined as material which has come from a human body and consists of, or includes, human cells. (Cell lines are excluded, as are hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation & Embryology Act 1990.)
- The Act lists the purposes for which consent is required in Schedule 1 (see Table 1) and they are referred to in this document as '**scheduled purposes**'. The consent required under the Act is called '**appropriate consent**', which broadly means consent from the appropriate person, as identified in the Act. **Penalties** of up to three years imprisonment or a fine, or both, are provided in the Act as a deterrent to failing to obtain or to misusing consent.
- The Act establishes a **Human Tissue Authority** to advise on and oversee compliance with the Act. The Authority will issue good practice guidance in statutory **codes of practice**. It will also **license and inspect** post mortem activities for both hospitals and coroners, anatomical examinations, public display of human remains and storage of human tissue.
- The Act makes it an offence to have human tissue, which includes hair, nail and gametes in this context, with the intention of **its DNA being analysed** 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. Penalties for not obtaining consent are provided.
- The Act makes it lawful to take minimum steps to **preserve the organs** of a deceased person while consent is sought from next-of-kin to removing them for transplantation. This clarifies that procedures such as cold perfusion of organs post mortem are lawful.
- The 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 less than one thousand years before the date that the relevant provision of the Act comes into force. This will allow the museums, for example, to return human remains to aboriginal groups.

**Table 1 - Scheduled purposes**

**Part 1: purposes generally requiring consent where the tissue is from the living or the deceased**

1. Anatomical examination - *requires witnessed consent in writing before death*
2. Determining the cause of death - *exception where a post mortem is ordered by a Coroner*
3. Establishing after a person's death the efficacy of any drug or other treatment administered to him - *eg 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) - *eg 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 where the tissue is from deceased persons**

8. Clinical audit
9. Education or training relating to human health - *includes training in research techniques*
10. Performance assessment - *eg testing medical devices*
11. Public health monitoring
12. Quality assurance

**Is consent always required?**

The 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.

Existing holdings

- It will be lawful to retain and to use for scheduled purposes without consent, (including for **research** and **obtaining medical information**) human tissue which is already held in storage for a scheduled purpose on the date that the requirement for consent takes effect.<sup>4</sup> This is expected to be in April 2006. The material may be from the living or the deceased.
- Storage and use of existing holdings will be subject to good practice guidance given in statutory codes of practice to be issued by the Human Tissue Authority.

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<sup>4</sup> Special provision is also made for existing anatomical specimens, where an anatomical examination has not been completed by the time the Act comes into force

### Tissue from the living

- Consent is not needed for the use of surplus or "residual" tissue taken from living patients which is left over from diagnostic or surgical procedures for the purposes set out in **Part 2 of Schedule 1** (see Table 1).
- Consent is not needed for the use of "residual" tissue in **research**, provided that the research project has ethical approval, and that the researcher cannot identify the tissue donor and is not likely to be able to do so in the future. This allows for linking with medical records, provided patient-identifying information is not obtained.
- Application can be made to the Human Tissue Authority which may "deem consent" in two exceptional circumstances. These relate to when it is not possible to obtain appropriate consent to use "residual" tissue for the purpose of **obtaining medical information** which may be relevant to another person (usually genetic data to inform the healthcare of a relative):
  - i. where the donor cannot be traced and there is no reason to believe that he/she has died, has refused consent or lacks capacity;
  - ii where the donor has not responded to repeated attempts to obtain consent, and there is no reason to believe that he/she has died, has refused consent or lacks capacity.
- Since **adults lacking capacity** cannot give consent on their own behalf, the Act provides for Regulations to set out the circumstances in which consent may be deemed to be in place so that storage and use of their tissue may be lawful. These Regulations will be subject to consultation and to debate in both Houses of Parliament. The circumstances in which consent is deemed to be in place are expected to be:
  - i where it is in the best interests of the incapacitated person;
  - ii to allow for clinical research involving tissue from incapacitated persons in line with the Clinical Trials Regulations 2004; and
  - iii to allow for storage and research use of tissue from incapacitated persons consistent with provisions of the Mental Capacity Bill, which is at present going through Parliament.

### Tissue from the living and the deceased

- The Act contains a power for the Secretary of State to make regulations to allow tissue from the living or the deceased to be used for research without consent. These regulations, to be made at a later date, have been provided to allow such use only as a last resort in cases of extreme public health emergency.

- Consent is not required for tissue that has been imported or comes from a body that has been imported, nor for tissue that is or comes from the body of a person who died before the consent regime is brought into force, and at least 100 years have passed since the date of death.

### **Who can give consent?**

The Act identifies the person who can give "appropriate consent" which is required for lawful storage or use of human tissue for scheduled purposes.

**Table 2 - Appropriate consent**

Living competent adult, or competent child willing to make a decision	His/her consent
Living child (incompetent, or competent but unwilling to make a decision)	Consent of a person with parental responsibility
Deceased adult	i. His/her consent before death ii. if no prior consent, consent of a nominated representative, iii. if no representative, the consent of a qualifying relative

**Table 3 - Qualifying relatives**

Spouse or partner Parent or child Brother or sister Grandparent or grandchild Child of a brother or sister Stepfather or stepmother Half brother or half sister Friend of longstanding
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These "qualifying relatives" relationships are ranked in order when consent is being sought to use tissue or organs from deceased persons for scheduled purposes. Civil partners will be added to the first rank of the hierarchy alongside spouse and partner by an Order under the Civil Partnerships Act 2004.

Where there is more than one person in the same rank in the hierarchy, brother or sister for example, the consent of any one of them will make it lawful (not obligatory) to store or use tissue for a scheduled purpose. For the purpose of consent to analyse

the DNA in the tissue of a deceased person, the consent of any qualifying relative will be enough - the list of relatives is unranked.

### **The Human Tissue Authority**

The Human Tissue Authority (HTA) will have a general role in informing the public and the Secretary of State about issues within its **remit**. This includes:

- storage and use of human bodies and tissue, and removal of tissue from human bodies, for scheduled purposes,
- import and export of bodies and human tissue for scheduled purposes and
- disposal of human tissue, including imported tissue, following its use in medical treatment or for scheduled purposes.

Blood and its derivatives for transfusion purposes are excluded from the remit as they are regulated separately. Cell lines for therapeutic use will be added to the remit of the HTA by Regulations in order to implement the EC Tissues and Cells Directive from April 2006 (see below). Additionally, exclusions from both the HTA's remit and the licensing regime apply to activities relating to bodies, and to tissue from bodies, of people who died before the relevant provisions take effect and at least 100 years have passed since the date of death.

The Authority will issue **codes of practice** covering consent, communicating with relatives regarding post mortems, anatomical examination, import and export, existing holdings and disposal of tissue. It will issue draft codes of practice for consultation before they are finalised.

The HTA will also **license** a number of activities and **inspect** to ensure compliance with the Act and licence conditions:

- storage and use of human bodies for anatomical examination and related research (previously licensed by Her Majesty's Inspector of Anatomy under the Anatomy Act 1984);
- the carrying out of post mortem examinations, including removal and retention of human tissue;
- removal of human tissue from the body of a deceased person for other scheduled purposes, except transplantation ;
- storage and use of human bodies or parts for public display;
- storage of human tissue for other scheduled purposes, for example, human tissue banking for transplant purposes or research.

In time for April 2006, Regulations will make the HTA the competent authority under the **EC Tissues and Cells Directive (2004/23/EC)** for regulating human tissue banking for transplant purposes. The main focus of licensing and inspection of banks holding tissue for this purpose will therefore be compliance with the safety and quality protocols that will form part of the Directive.

The exact scope of storage licensing for other scheduled purposes, like research, will be determined by Regulations, which can exempt from licensing storage in particular circumstances. These Regulations will be subject to consultation with interested parties.

When the Act takes effect it will be unlawful to carry on licensable activities without a licence. The HTA will be able to set out the conditions for types of licences and for individual licences. The Authority is required to ensure that licensing and inspection are proportionate and not unduly burdensome.

## **Offences and Penalties**

There are already offences under the Anatomy Act 1984 (including carrying out an anatomical examination without a licence under section 3 of the 1984 Act or on premises not licensed under section 4), and under the Human Organ Transplants Act 1989 (including making payments for the supply of organs for transplantation or advertising a request for, or offer of, such organs for payment). These offences have been carried forward into the HT Act 2004, with increased maximum penalties to bring them into line with the new legislation.

The Act also contains several new offences to underpin the principles of the legislation. These are:

- removing, storing or using human tissue for scheduled purposes, without appropriate consent;
- storing or using human tissue donated for a scheduled purpose for another purpose;
- trafficking in human tissue for transplantation purposes. (This extends the existing offence beyond just organs for transplantation);
- carrying out licensable activities without holding a licence from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the Authority in carrying out its powers or responsibilities); and
- having human tissue with the intention of its DNA being analysed without the consent of the person from whom the tissue came (medical diagnosis and treatment, criminal investigations etc are excluded from the offence).

These main new offences are triable in a magistrate's court or a Crown court and penalties range from a fine, to imprisonment for up to three years, or both.

"Reasonable belief" defences are provided in relation to these offences. The Act provides that the first two offences set out above, relating to consent, will not take effect until three months after publication of the HTA's code of practice on consent, so that professionals in the field can familiarise themselves with the standards expected.

## **Transplantation**

The Act contains a power to make Regulations similar to those made under the Human Organ Transplants Act 1989. These will set out the circumstances in which

live donations of "transplantable material", (from both related and unrelated donors) will be allowed by the Human Tissue Authority. Transplantable material will be defined in the Regulations. The HTA's role in this area will supersede and extend the role of the Unrelated Live Transplants Regulatory Authority (ULTRA). Regulations will also set out the information about transplants that must be supplied to UK Transplant or its proposed successor body, NHS Blood and Transplant. These Regulations will be circulated in draft for consultation in Summer 2005 and should be made by April 2006.

### **Expected Implementation Timetable**

Spring 2005	Human Tissue Authority will be set up. The lay Chairman of the HTA, the Rt Hon Baroness Helene Hayman, is appointed following an open competition. Up to sixteen members will similarly be appointed to the HTA, of whom the majority will be lay persons. <sup>5</sup> The National Assembly for Wales and the Northern Ireland Department will each appoint one member to the Authority. The HTA will take forward preparing and consulting upon the statutory codes of practice to be issued on commencement in April 2006.
Summer 2005	Implementation of s.47 of the Human Tissue Act 2004, which allows human remains to be moved out of the collections of nine named museums, is likely to take place in Summer 2005. This will be a matter for the Department of Culture, Media and Sport.
Summer 2005	Consultation with interested parties on draft Regulations is expected to take place from Summer 2005. These will include Regulations implementing the EC Directive on Tissues and Cells. The secondary legislation should then be in place by January 2006, in time for commencement of most of the Act by April 2006.  Consultation by the Human Tissue Authority on draft codes of practice is also likely to take place.
April 2006	The remainder of the Act, save for two consent offences, is expected to commence in April 2006. The HTA is expected to issue codes of practice.
July 2006	The two offences relating to failing to obtain consent and misusing consent (s.5 and s.8 of the HT Act 2004) will take effect, three months after the codes of practice are issued. The Act will be fully implemented.

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<sup>5</sup> For the purposes of the Human Tissue Act 2004, a lay person is someone who does not have, and has not had, a professional interest in any of the kinds of activity within the remit of the Authority.

Other sources of information:

For information about regulation of human tissue in relation to fertility treatment or research contact the Human Fertilisation & Embryology Authority.

Department of Health  
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## FREQUENTLY ASKED QUESTIONS

**Q Is the new Human Tissue Act in force now?**

**A No.** The legislation was enacted in November 2004 but most of its provisions will not be brought into force until **April 2006**.

Exceptions are the provisions establishing the Human Tissue Authority, which are likely to come into effect in Spring 2005, and the section about moving human remains out of museum collections, which is likely to take effect in Summer 2005.

Offences relating to the consent provisions of the Act will come into force three months after related codes of practice have been issued by the Human Tissue Authority, probably in Summer 2006.

**Q Has current legislation ceased to be in effect now that the Act has passed?**

**No.** Current legislation will remain in place until the sections of the Act that will replace it are brought into force. This is expected to be in April 2006.

**Q What should people who will be affected by the Act be doing now?**

**A** They should be maintaining good practice. The regime set up under the Human Tissue Act 2004 will be little different from current good practice. Current DH good practice guidance (on DH website) will remain in effect until the Human Tissue Authority issues guidance to supersede it. Information and draft guidance will be issued by the Human Tissue Authority for consultation during the course of the year so that people affected by the Act can be familiar with its requirements by the time it is fully implemented in 2006.

**Q When the Act is in force does it mean that pathologists will no longer be able to take and retain tissue from post mortems?**

A No. It means that if they wish to do so, they will need consent from the appropriate person. Appropriate consent means the consent of the deceased person, given by him before he died, or failing that, the consent of his nominated representative. If the deceased has not appointed a nominated representative, then the consent of the people close to him will be appropriate (see Table 3). For example, in the case of a post mortem ordered by a Coroner, once the cause of death has been established for the Coroner, a pathologist or researcher wishing to keep or use any tissue from the deceased for a longer period for other purposes will need consent from the appropriate person.

**Q. When will licensing be brought in?**

A. The Human Tissue Authority (HTA) will develop a licensing system when it is established in April 2005. It will not be necessary to hold a licence before 1 April 2006.

**Q. How much will a licence cost?**

A. The HTA will have the right to determine what, if any, fees are necessary for a licence to be issued. The level of any such fees will be a matter for the HTA to decide.

**Q. Does the Act cover existing stocks?**

A. The Act makes it clear that it will be lawful to continue to retain or use existing holdings of human tissue without consent, but subject to good practice guidance issued by the HTA. As a matter of priority, the HTA will also be issuing detailed guidance on disposal of existing holdings, including material which may have been retained in accordance with advice from the Retained Organs Commission.

**Q. When will the Codes of Practice be brought in?**

A. The HTA will publish draft Codes of Practice for consultation, probably in Summer 2005. A number of them must be approved by Parliament and they will be issued as final documents when the HTA has taken up its powers in April 2006.

**Q. Will they be legally binding?**

A. The Codes of Practice will be statutory (ie the Human Tissue Act 2004 requires the HTA to prepare them) and many will be subject to Parliamentary approval. There will be no legal penalty for not complying with a code, but the HTA may take account of adherence to codes when it makes licensing decisions.

**Q. Will you be able to appeal against any decisions the HTA makes?**

A. As with other regulatory authorities, the HTA will be obliged to have legally recognised appeals procedures in place that lay down when and how appeals can be made.

**Q. We already gain consent for the taking and using of human tissue for transplantation, how will this change?**

A. One of the changes relating to consent will be that the wishes of the deceased will take precedence. This may have particular importance when organs of the deceased are being considered for donation for transplantation. It will be lawful to take organs for transplantation where the deceased consented before his death. However, this does not mean it will be obligatory, and practitioners may decide against it for a variety of reasons. Such decisions will need to be made on a case by case basis and good practice will ensure that relatives are consulted.

**Q. Will museums be licensed and inspected by the HTA?**

A. Under the Act, consent (except for existing holdings) and licensing are only required for the storage and use of human tissue taken from people who are still alive, or who have been dead for less than 100 years. Museums and archaeological units will require consent, and need to be licensed, to the extent that they hold human tissue which falls within these categories. As the vast majority of museum and archaeological holdings are historical specimens that are older than 100 years in age, very few of these will fall within the consent and licensing regime.

**Q. Will there be a code of practice regarding human remains in museums ?**

A. Ministers agreed in Parliament to ensure that the museums listed in s.47 of the Human Tissue Act 2004 would have guidance on the exercise of the powers given by that section before it is brought into force. We are aware also of widespread support within the museum community for a Code of Practice available to the entire sector, dealing more generally with human remains in museums. The Department of Culture, Media and Sport has recently set up a drafting group to draw up such a Code; it is intended that this Code should be in place by Summer 2005. This will not be a statutory Code, and will be separate from any Codes of Practice issued by the HTA; museums with holdings within the remit of the HTA would, of course, also have to comply with any relevant HTA Code.