A decade of expertise
/Human Tissue Authority
The Human Tissue Authority (HTA) is the regulator for human tissue and organs. It was set up in 2005, following public inquiries into events at the Bristol Royal Infirmary and Alder Hey Children’s Hospital, which revealed how these hospitals had removed and stored tissue and organs without permission.

The inquiries led to the creation of the Human Tissue Act 2004, which enshrined consent for the use of tissue and organs in law.

April 2005: The HTA is established following the Human Tissue Act 2004

April 2006: The EU Tissue and Cells Directive is implemented and we begin licensing

July 2006: First HTA standards and Codes of Practice launched

September 2006: Human Tissue Act comes into force and we begin licensing other sectors

The HTA was set up to make sure organisations comply with this new law, which states that permission or consent must be sought and given if body parts, organs, or tissue, from the living or the deceased, are to be used for certain purposes.

Ten years on, and the HTA now oversees over 850 licensed premises that remove, store and use human tissue and organs for research, medical treatment, post-mortem examination, education and training, and public display.

We assess more than 1,200 organ and bone marrow donations from living people every year.

Our remit and responsibilities have grown over the years as we have built a reputation for being an effective and expert regulator that provides useful advice and guidance to those we regulate and to members of the public.

We build confidence by ensuring that human tissue and organs are used safely, ethically, and with proper consent.

The HTA regulates many activities, making sure that:

- consent is given by individuals or their families for the use of organs and tissue
- only tissue and cells that are safe and of high quality are used to treat patients
- the safety and quality of organ transplantation is safeguarded
- no reward or coercion takes place in living organ donation, and the donor is aware of any risks
- research into causes of, and treatments for illnesses such as cancer or diseases of the brain and nervous system, is enabled
- students can be taught about the human body and surgeons can be trained to develop their skills
- appropriate approval for the use of human bodies and body parts from the deceased, is obtained by museums and exhibitions
- mortuaries where post-mortem examinations are conducted operate to the highest standards

People can have confidence that if they donate, their wishes will be respected; that donated organs will be put to the best possible use; that tissue used in the treatments they receive will be safe; and that the deceased will be treated with dignity and respect.

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The difference we have made

The Human Tissue Act ensures that consent must be given before organs or tissue are removed, stored or used for certain purposes. Over the last ten years, as well as overseeing this change in law, we have led a shift in the culture around consent so that it is embedded in the work of those we regulate. Our role now is to maintain this, and identify any areas where we can raise standards further. Through this work we have facilitated many other important improvements in healthcare in the UK and beyond.

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<tr>
<th>Creating safer healthcare</th>
<th>Overseeing changes in organ retention</th>
<th>Reducing regulatory red tape</th>
<th>Improving education and training</th>
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<td>We have improved standards across the sectors we regulate, by helping hospitals, transplant centres, and research organisations to meet high working standards.</td>
<td>In May 2010, we conducted a national audit of tissue and organs kept on HTA-licensed premises. This led to a national audit of tissue and organs held for legal purposes.</td>
<td>We work hand-in-hand with those we license and other regulators to reduce regulatory burden and support growth, especially in the research sector. Our inspection process is risk based, which means we prioritise those organisations which pose greatest risk to patients and the public. We are increasingly conducting joint inspections with other regulators, helping to improve efficiencies and reduce burden. A reduction in our running costs has enabled us to reduce licence fees for organisations in recent years.</td>
<td>The Human Tissue Act 2004 created a regulatory framework in the UK which supports the use of donated bodies and body parts for surgical training. This has led to important improvements in training for surgeons; providing them with more opportunities, and more lifelike circumstances, in which to practise procedures without risk to patients.</td>
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<th>June 2009: Hampton Implementation Review praises HTA for using principles of Better Regulation</th>
<th>July 2007: First non-directed altruistic donation approved</th>
<th>December 2009: Number of people approved for living organ donation reaches 3,000</th>
<th>May 2010: HTA requires all mortuaries to report serious incidents that occur</th>
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<th>Ensuring dignity in death</th>
<th>Sharing learning to improve standards</th>
<th>Supporting confidence in living donation</th>
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<td>We have seen significant improvements in quality and standards in mortuaries across England, Wales, and Northern Ireland. We help to ensure that dignity and respect are maintained in death by supporting mortuaries, and helping them to ensure practices and premises are of a high standard. We investigate all serious incidents reported to us by mortuaries, and share experience, learning, and examples of best practice across this sector, so that future incidents can be avoided. Additionally, we work with museums and art galleries that display human specimens that are less than 100 years old. This ensures that any tissue displayed is treated with due respect and with regard to the specimens.</td>
<td>We have overseen a significant improvement in standards across all of the sectors we regulate. Where appropriate, we share experience and examples across sectors, to improve practice across the board. We regularly survey professionals working in and around the organisations we regulate. The results of these surveys show that confidence in our regulation has grown steadily over the last ten years.</td>
<td>We have created guidance and advice that supports living organ donation. As a direct result, in 2007, the first living person in the UK was able to give an organ altruistically to a stranger. We know from public surveys that more people are willing to donate, knowing that there is a regulator ensuring standards are set and met. Since 2006, we have assessed each and every case of living organ donation, making sure that valid consent has been given, that no reward has been sought or offered, and that risks have been explained and understood. There are currently 129 Independent Assessors, who act as our eyes and ears, carrying out interviews with the donor and recipient on our behalf.</td>
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<th>Using experience to inform policy</th>
<th>Offering transparent information that supports choice</th>
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<td>Our experience of regulation has been used to inform legislation and policy in the UK, and beyond. We led the implementation of a new European regulatory framework, which sets standards for hospitals that conduct organ transplants. We have worked with the Welsh Government on their changes to organ donation law, which creates a ‘soft’ opt out system in Wales. We have also worked with the Medical Research Council, Association of Chief Police Officers, Health and Safety Executive, NHS Blood and Transplant, and various charities and patient organisations such as Sands – the stillbirth and neonatal death charity, and Healthwatch, to support important areas of their work.</td>
<td>We offer clear information about each of the organisations that we license by publishing inspection reports on our website, allowing the public to find out how they meet our standards. Additionally, we have answered thousands of questions from the public about donation of organs, brains, bodies, and tissue such as cord blood.</td>
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Ready for the future

The HTA has come a long way in the last ten years, but there is more to do and we have a strong focus on the future. We have overseen significant improvements in the practices of hospitals, mortuaries, research organisations, and many others; our challenge now is to continue to drive up standards. Our goal is not only to promote best practice across the sectors we regulate, but also to be a model for excellence in regulation.

We work collaboratively as part of a scientific community which presents new and exciting challenges for regulation, such as the growing use of tissue and cells in innovative treatments. We need to be agile in our regulatory approach in order to adapt to these scientific and technological advances.

Looking to the future, we will closely monitor developments in life sciences, so that we can foresee potential challenges and articulate where we believe regulation can be improved. We will identify where the Human Tissue Act and EU legislation may need to be adapted to protect the public’s interests, and to facilitate innovative research. We will also support business growth and NHS efficiency by looking for opportunities to deregulate where risks are low.

We will continue to improve the quality and accessibility of information we provide to the public, as medical opportunities and patient choice continue to grow.

We will also continue to manage potential risks in a clear and authoritative way, and maintain public confidence.
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