

Human Tissue Authority  
Annual Review 2007/08



# Building confidence



This Annual Review covers the period 1 April 2007 to 31 March 2008.

The HTA's full Annual Report and Accounts are available at: [www.hta.gov.uk/about\\_hta/publications.cfm](http://www.hta.gov.uk/about_hta/publications.cfm)

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# Chair and Chief Executive's introduction

We are very pleased to introduce our third Annual Review, covering the HTA's activity in 2007/08. This was a busy year in which we approved almost 1000 living-donor transplants and licensed nearly 750 establishments. We also commissioned research and were delighted to find that professionals and the public have confidence in the regulation of human tissue. The continuing challenge for us will be to maintain and build on this confidence.

The pace, volume and complexity of the work has increased, largely because we are required to prepare for further regulation under the European Tissue and Cells Directive. Nonetheless, we are pleased to record that we have fully delivered on our widening remit. For such a small organisation this was an extraordinary feat that would have been impossible without the commitment, initiative and energy of staff and Authority members. We are very grateful for all they have done.

The HTA's stakeholders range from organisations that carry out research on human tissue and museums that display human bodies or body parts, to individuals who donate whole organs and bone marrow. This Annual Review describes the experiences of some of the people drawn from the sectors we regulate. We hope that this approach will give you a flavour not only of the diverse range of work that we are responsible for, but of the positive effect our regulatory activity has had.

In the autumn of last year, Ministers decided not to proceed with the creation of the Regulatory Authority for Tissue and Embryos (RATE). We are now looking to a future in which we continue to operate as a stand-alone arm's length body. We are determined that the principles and practices that have been a hallmark of the HTA should continue. This means that we will continue to deliver our statutory remit in a proportionate manner; provide comprehensive advice and guidance to the sectors we regulate; communicate with and engage our stakeholders; and deliver value for money.

By sticking to these principles and practices, we aim to continue to build on and retain the confidence of professionals and the public.



**Shirley Harrison,**  
Chair



**Adrian McNeil,**  
Chief Executive





# The HTA's remit and responsibilities

The HTA's remit is to regulate the removal, storage, use and disposal of human bodies, organs and tissue from the living and deceased. We have several key statutory functions. One is to inform the public and the Secretary of State for Health about issues within our remit. We meet this obligation by issuing codes of practice including:

- Consent
- Donation of solid organs and tissue and cells for transplantation
- Post mortem examination
- Anatomical examination
- Removal, storage and disposal of human organs and tissue
- Donation of allogeneic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation
- Public display
- Import and export of human bodies, body parts and tissue
- Storage of tissue for research

Another statutory function is to regulate through licensing the following sectors:

- anatomy
- post mortem services
- tissue for human application (patient treatment)
- research
- public display

And a third is to regulate, through a system of approvals, all live organ donations within the UK and the donation of bone marrow for transplantation.

Finally, the HTA is one of two UK Competent Authorities under the EU Tissue and Cells Directive for regulating establishments importing, procuring, testing, storing, and processing and distributing tissue for human application.

The HTA has 42 staff and a board of Authority members. The professional members come from the medical and scientific backgrounds relevant to the HTA's remit; and the lay members bring a wide range of business, commercial and public sector experience.

The HTA's strategic aim is to create a regulatory system for the removal, storage, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.



 HTA  
Healthcare Technology Authority  
Dr Hazel Uppington  
Regulation Manager  
HTA STAFF / AUTHORITY MEMBER

# Raising standards to provide the best basis for research

Professor Richard Reynolds runs the multiple sclerosis (MS) Tissue Bank at Imperial College London. This organisation is licensed by the HTA to store human tissue for research. Dave King's wife suffered from MS and she decided to donate her brain to research after her death.

## **Professor Richard Reynolds (right), MS Tissue Bank**

"I am Head of the Department of Cell and Molecular Neuroscience at Imperial College and one of the major aspects of my job is to run the UK MS Tissue Bank.

"It is rewarding for people to know they can make a lasting gift that may help future generations of MS sufferers. It is important that those who donate, and their families, know that tissue will be treated with respect and used only for good quality research.

"The study of human tissue affected by disease is absolutely vital in order to understand what is damaging the tissues. One of the biggest problems in our sector over the last 50 years has been variability of tissue quality which can affect the outcomes of research. With the HTA, we now have an organisation that can make sure the appropriate quality standards are consistently applied across the board."

## **Dave King (left), donated his wife's tissue for research**

"My wife, Doreen, had MS and she made the decision to donate her brain to the MS tissue bank after her death. Human tissue is central to studying disease. Studying diseases without human tissue would be a bit like a bricklayer working without bricks.

"It is my mission to get others to donate their tissue to research to help us find new treatments. Sometimes people are shocked that I am so keen to discuss this as it isn't something that people like to think about. But it is important because the doctors really don't know how MS acts on the body; and until they know, they can't make progress finding new treatments.

"I think Richard is doing a great job. The tissue bank supplies labs all over the world with tissue to study MS."





**In the last year the HTA has helped raise standards by:**

- delivering the five key principles of Better Regulation – being transparent, accountable, proportionate, consistent and targeted
- conducting 116 site-visit inspections prioritised on the basis of risk – 51 in the human application sector, 49 in the post mortem sector, 10 in the research sector, 4 in the anatomy sector and 2 in the public display sector
- holding 12 Regulatory Action Panels to consider significant regulatory action
- helping the UK to retain its world class reputation for excellence in biomedical research. We believe that good regulation supports good science, which in turn leads to improved healthcare
- drafting the first code of practice for the research sector to provide guidance and encourage good practice

# Enabling more people to benefit from a living-donor transplant

Barbara Ryder, a nurse from Cornwall, donated one of her kidneys to Andy Loudon – someone she had never met before. This type of altruistic donation has been made possible by the systems put in place by the HTA. Barbara and Andy were the UK's first altruistic donor and recipient to meet. The HTA arranged a press conference in December 2007 – three months after the operation – where they told their stories to the media.

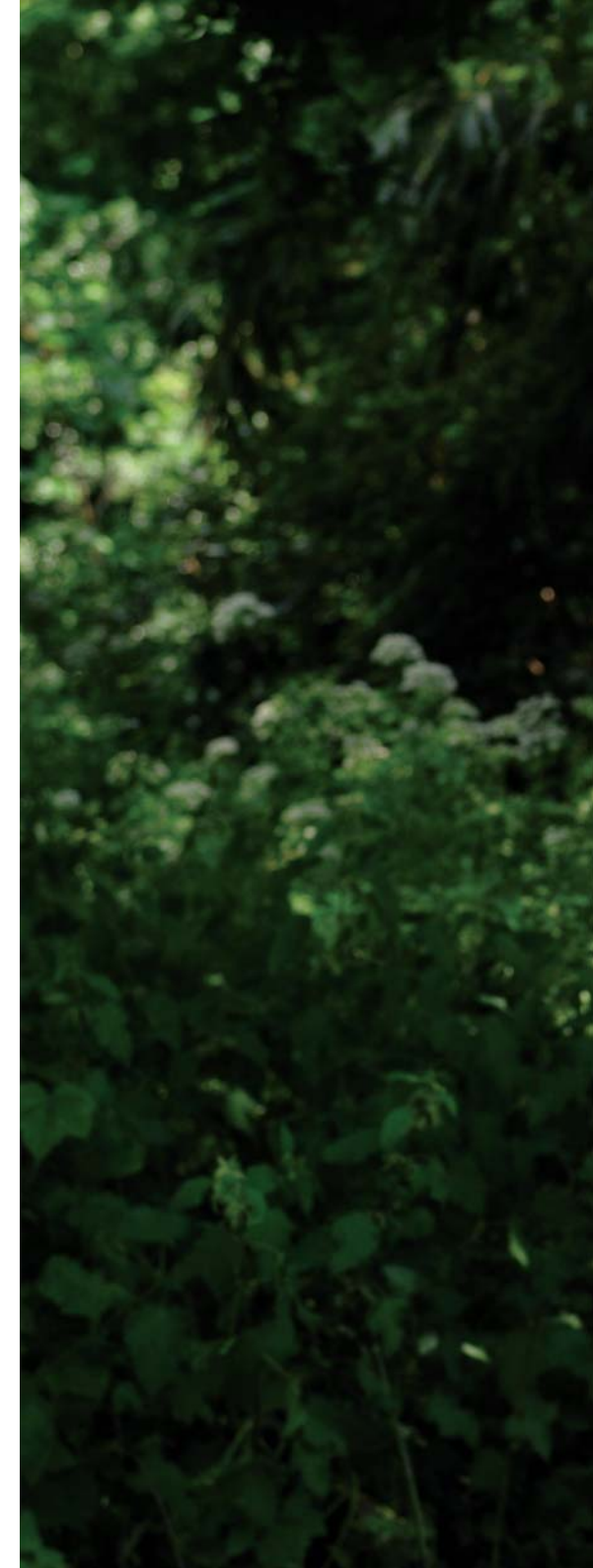
## Barbara Ryder, altruistic kidney donor

“It has been eight months since I became an altruistic donor, and I don't think about it very often now. I feel even better than I did before, I am feeling really well. If I had another kidney to spare, I would certainly donate again.

“The process set up by the HTA to become an altruistic donor is extremely stringent, but is absolutely necessary to check that you know what is involved.

“As a nurse I knew from a medical perspective what would happen, but I didn't truly realise what the donation process would involve. Because it takes a long time, it really gives you a chance to think about it. There is no pressure to continue, and you always know that you can drop out if you change your mind.

“I am still in touch with Andy and his wife; we speak about once a month. In fact, they are coming to visit soon and we are planning to go out for dinner. He is very well and it is good to know how he is doing.”





**In the last year the HTA has enabled more people to benefit from a living-donor transplant by:**

- launching an e-learning course to train Independent Assessors (IAs) who make recommendations about organ donations
- approving 997 living-donor organ transplants – including nine altruistic donations and 13 complex cases referred to a panel of HTA members – considerably more than in previous years
- approving all straightforward organ donations in an average of two working days
- holding two media briefing events to raise awareness about the new options for living-donor organ transplants allowed by the HTA – paired donation and altruistic donation
- approving 71 reports from Accredited Assessors (AAs), who make recommendations about bone marrow donations
- supporting IAs and AAs through feedback, regular bulletins, and an annual conference





# Ensuring that the wishes of individuals are respected

Iain Johnstone is the Mortuary Manager at the James Paget University Hospital in Norfolk. This is one of 270 organisations licensed by the HTA in which post mortem examinations can take place.

## Iain Johnstone, Mortuary Manager

“Mortuary Managers have many roles, from working with the families of deceased people, to working with pathologists to help determine the cause of death. My team acts as the voice of the patient and that of their family, ensuring that their wishes are respected.

“My organisation has pioneered a different approach for speaking to families about tissue retrieval. There is never a right time to ask a grieving family to donate tissue, but despite the terrible circumstances, families often readily agree to donate when they realise that their family member can help up to 40 or 50 people who are in need of skin, bone, cartilage, tendons and corneas. This year we won the Martyn Jon Walton award, from the British Association of Tissue Banks, for our work in this area.

“The HTA is important, not just from a legal point of view, but also to translate the law into practice. I am certain that HTA regulation has driven up standards in my field. One of the most important services the HTA offers is guidance and I know there is always someone at the end of the phone or by email to answer technical questions.”





**In the last year the HTA has ensured that the wishes of individuals are respected by:**

- initiating a review of our codes of practice, including the code on consent. The codes provide practical advice to the professionals that we regulate and set out the expected standards. We plan to run a full public consultation on the revised codes in 2008
- evaluating the professional sectors licensed by the HTA to find out their views on how the Human Tissue Act has been implemented. The results showed that, overall, stakeholders are very positive about the HTA. They believe we have had a significant impact and are fulfilling our role successfully. Nearly 70% of Designated Individuals (DIs) polled think that legislation and the HTA are driving up standards in their sector
- working with the Home Office to develop a process and system for the licensing of emergency mortuaries

# Giving confidence to professionals and the public

Tony Hill is the DI at the Museum of Science and Industry in Manchester, which is licensed by the HTA for public display. The HTA is responsible for licensing organisations that display bodies or tissue from deceased people.

## Tony Hill, Manchester Museum of Science and Industry

"I am the Acting Director of the Museum of Science and Industry in Manchester so it is predominantly down to me to choose our exhibitions. Working with human tissue is not something we do every day, so applying for an HTA licence seemed a bit daunting. But the staff at the HTA helped and advised us every step of the way.

"The Body Worlds exhibition is a particularly sensitive one and the process of applying for a licence reassured me, and more importantly our board of trustees, that we had approached the necessary standards with rigour.

"We have had a phenomenal response from the public, with around 130,000 people through the door so far. It is definitely an educational tool and we have tied the exhibition into events on stop smoking day, kidney disease and issues around obesity. We were also giving out cards for the organ donor register and they were so popular we ran out."





In the last year the HTA has given confidence to professionals and the public by:

- working with Ipsos MORI to research what the general public understands about human tissue and its uses, so that we can improve our future communications materials. Our poll showed that 52% of the general public had at least a fair amount of confidence in human tissue regulation, which compares well with other polls
- responding to 98% of enquiries within 20 working days
- producing six issues of our e-newsletter which is distributed to 4000 subscribers and provides up-to-date advice and guidance. Our website is visited around 25,000 times a month
- holding two Authority meetings in public and an annual report-back event
- continuing to look for the most efficient and cost effective ways of delivering our remit in order to reduce costs to the licence fee payer and government

# Playing a leading role in human tissue regulation in Europe

Ann-Margaret Little is the DI at the Anthony Nolan Trust, which maintains a register of people who have volunteered to donate their bone marrow to help people with diseases like leukaemia. Their bone marrow bank has an HTA licence to ensure the quality and safety of the samples. Justin Adams had been on the Anthony Nolan Trust register for 11 years. Earlier this year, the Trust found a match for his bone marrow.

## Ann-Margaret Little, Anthony Nolan Trust

"The Anthony Nolan Trust saves lives thanks to over 390,000 UK residents who have volunteered to donate their bone marrow to any patient in need. We maintain a register of prospective donors, which can be searched to try to find a match for someone who needs a stem cell transplant. We are particularly targeting young adults and those from minority ethnicities to get them to join the register.

"The register has given the chance of life to over 5000 patients since 1974 and we have always strived for high standards. Now that we are regulated by the HTA this reassures the medical community that we are a professional body, which fulfils criteria set at a national level.

"Regulation has confirmed that we are working in the best way we can. The work of the HTA means that the UK is ahead of many other European countries when it comes to implementing this regulation."

## Justin Adams, bone marrow donor

"I have been on the Anthony Nolan Trust register for 11 years. In October I got a letter and was surprised to find that the Trust had found a match for me.

"I had to go for more tests and I was very aware that someone out there needed my bone marrow and I just wanted to get on with it. But everyone was very nice and helpful; they were keen to make sure I really understood what would happen. It is good to know that this area is regulated; it's important that someone is checking that there is no bad practice.

"My bone marrow went to help a young boy, but I don't know anything else about him. I want everyone to know that the process is not very painful.

"I would gladly do it again and I would recommend it to anyone. It's such a simple way to give someone the chance to live. I can think of no good enough reason to justify not becoming a donor."





**In the last year the HTA has played a leading role in human tissue regulation in Europe by:**

- establishing a framework for our extended remit to regulate organisations that procure, process, test, distribute, and import or export human tissue for use in patient treatment under the EU Tissue and Cells Directive. The Directive has set a benchmark for the quality and safety of human tissue and cells across Europe
- developing an online system for establishments in the human application sector to report adverse events
- publishing a code of practice on the import and export of human tissues and cells
- holding an international conference for professionals working in the human application sector to share their experiences
- holding two workshops for procurement organisations to help us develop our regulatory policy arising from the legislation

# Improving training for the health professionals of the future

David Yu is an Anatomy Demonstrator at Brighton and Sussex Medical School. Human bodies are used to teach medical students about the structure of the body and how it works, and to train surgeons on different surgical procedures. Organisations like Brighton and Sussex Medical School, which carry out these activities, are licensed by the HTA.

## David Yu, Anatomy Demonstrator

"I am an Anatomy Demonstrator at Brighton and Sussex Medical School. We use whole body dissection to help teach our students – it is an important part of their medical training alongside lectures and experience of a healthcare environment. With whole body dissection, students get a much better understanding of how each organ relates to the others.

"It is essential that people realise what a central role dissection plays in teaching the doctors of the future. It isn't just medical students who benefit – we now have surgeons coming in to develop new techniques on real bodies. This is a good thing, as it is important for surgeons to develop their techniques in the dissection room before going into the operating theatre.

"The surgeons that work here have different specialities; we have those who work on bones and joints, as well as heart surgeons who teach emergency doctors how to get safely into the chest. Recently we also had mechanical engineers come in to take measurements to help develop new types of prosthetic joints.

"Regulation by the HTA is important as this reassures the public that bodies that are being used for educational purposes are treated with respect."





**In the last year the HTA has improved training for health professionals by:**

- launching an e-learning course to provide continuing support and training for the people in licensed establishments, including DIs. Around 330 people have used the course
- holding eight training workshops for DIs
- providing advice to people who want to donate their body to medical science and a list of local medical schools on our website to help ensure a supply of bodies for education and training

# The year ahead

During the year ahead we plan to continue to build the confidence of professionals and the public by:

- completing the review of our codes of practice, including developing a new code on research, and undertaking a full public consultation
- holding a series of workshops and events to develop further our regulatory methods
- delivering a programme of consistent, targeted advice and guidance across the sectors
- undertaking a risk-based programme of site visit inspections across the five licensed sectors
- continuing to implement the requirements of EU legislation, including licensing organisations that carry out procurement
- managing the live organ and bone marrow transplant approval programme
- working with other organisations to streamline regulation
- developing a proportionate fee structure for the future
- answering all enquiries in a timely, appropriate and accurate manner
- launching a guide to our key messages to help others communicate with the public about our work
- implementing the organisational review to help meet our expanding remit





**Human Tissue Authority**

Finlaison House

15–17 Furnival Street

London EC4A 1AB

**Tel** 020 7211 3400

**Fax** 020 7211 3430

**Email** [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)

**Web** [www.hta.gov.uk](http://www.hta.gov.uk)

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