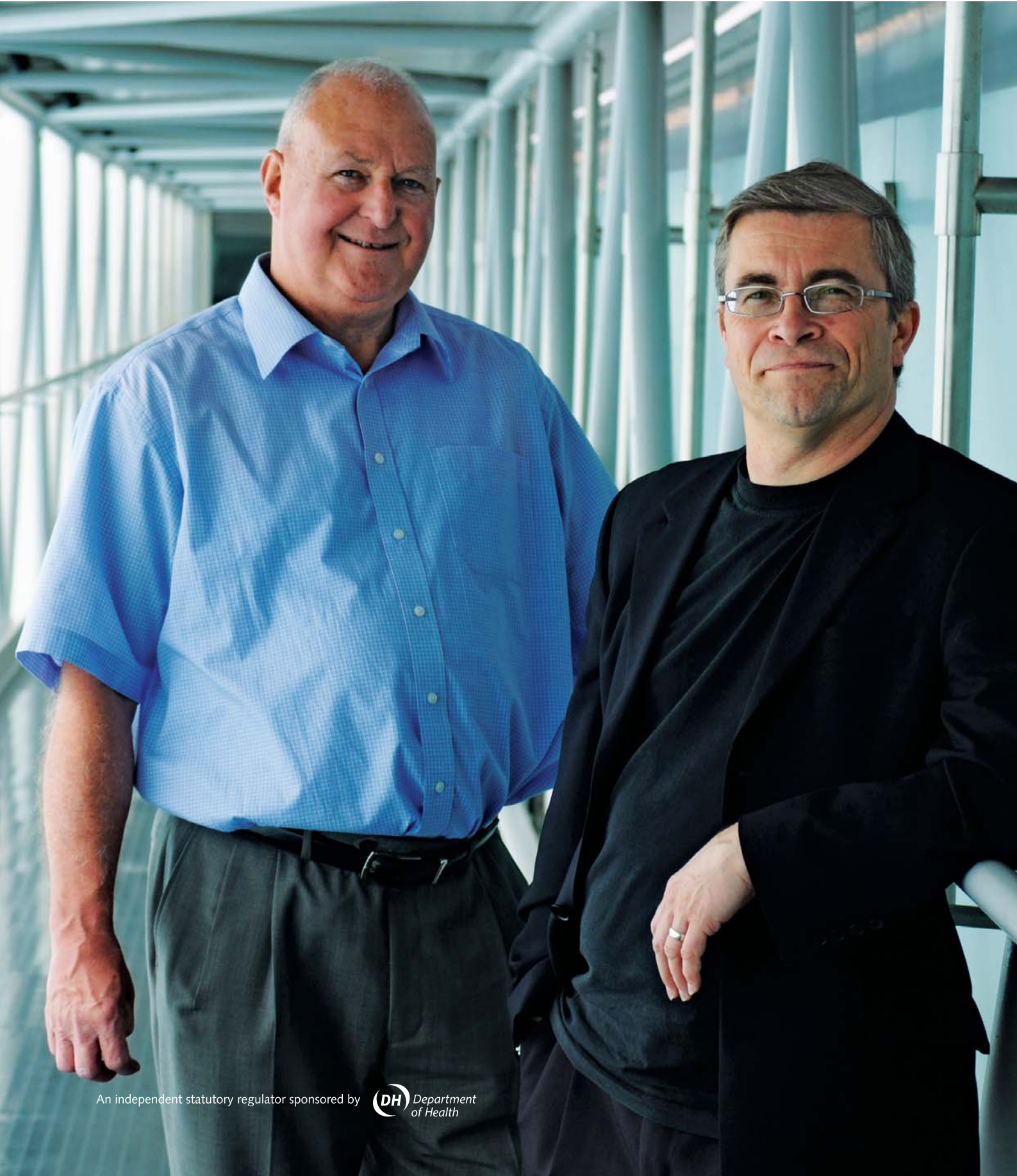


Guide to our key messages



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Cover image

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

1. Background to this guide

Why have we produced this guide?

The Human Tissue Authority (HTA) has a responsibility to give advice to the public about our work. In 2007 we carried out independent research with a company called Ipsos MORI, to find out what the general public knows about human tissue (HTA / Ipsos MORI General Public Quantitative and Qualitative Research, June 2007). The research showed that the general public is very aware of what human tissue is and how it can be used:

- skin, body parts, organs, blood and transplants were the words that people most often associated with tissue
- public understanding of the potential uses of tissue fell into two main categories – medical procedures and medical research. Education and training, post-mortem examination and anatomy were mentioned by a small number of people

The research also showed that the public wants to know more about how human tissue is regulated.

We believe that patients and families will have more confidence that their wishes will be respected and their tissue will be put to the best possible use if they know there is regulation of human tissue. We hope that by fostering an environment of trust, more people will be willing to donate their tissue for scientific and medical research, their organs for transplants, and their bodies for medical education and training. On that basis we can help healthcare to flourish.

Purpose of this guide

This guide explains in clear and accessible language what the HTA is and what we do. If you work with patients and the public, this guide will help you to explain our roles and responsibilities. It provides clear explanations about the different areas of our work, which you can use in your verbal and written communications. Please feel free to use any sections of this guide.

This guide is also aimed at HTA staff and Authority members, and we hope that it will enable them to communicate our work clearly and confidently to the outside world.

This guide does not provide specific advice or guidance for the professionals that we regulate. This is provided in our codes of practice and licensing guidance.

2. Who we are and what we do

In this section we give an overview of who we are and what we do. You will see that we have provided different lengths of text to explain our work. Please use whichever is most appropriate according to the detail that you need.

You can find out more about our responsibilities in particular areas later in this guide.

Around 50 words

The Human Tissue Authority (HTA) is a watchdog that protects public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We also give approval for organ and bone marrow donations from living people.

Around 100 words

The Human Tissue Authority (HTA) is an independent watchdog that protects public confidence by licensing and inspecting organisations that store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We also give approval for organ and bone marrow donations from living people through an independent assessment process.

We provide advice and guidance about two laws: the Human Tissue Act and the Quality and Safety Regulations. These laws ensure human tissue is used safely and ethically, with proper consent.

Our aim is to set standards that are clear and reasonable, and in which both the public and professionals can have confidence.

Around 250 words

The Human Tissue Authority (HTA) is an independent watchdog that protects public confidence by making sure human tissue is used safely and ethically, and with proper consent.

We license and inspect organisations that store and use human tissue for the purposes listed below:

- teaching about or studying the human body
- carrying out post-mortem examinations
- using human tissue to treat patients
- carrying out research on human tissue
- displaying human bodies or tissue in public (e.g. in a museum)

We also give approval for donations of organs and bone marrow from living people. A living person who wants to donate their organs or bone marrow has to go through an independent assessment process. This helps to make sure that the interests of donors are looked after.

We work under two laws: the Human Tissue Act and the Quality and Safety Regulations. Our aim is to make sure that these laws are followed by setting standards that are clear and reasonable, and in which the public and professionals can have confidence. We also help people to understand these requirements by providing codes of practice and other advice, guidance and support.

The HTA is accountable to the Secretary of State for Health. The professional members of our Board come from medical and scientific backgrounds linked to our work, and the lay members bring a wide range of business, commercial and public sector experience. You can find out more about the members of the Board on our website. Because the HTA is funded by the Department of Health and through licence fees, we make sure we provide good value for money.

3. What is human tissue and what is it used for?

There are many different types of human tissue including: skin, body parts, organs, stem cells and bone. This tissue has many different uses:

- human bodies are used to teach students about the structure of the body and how it works, and to train and develop the skills of surgeons and pathologists
- human tissue is used during a post-mortem examination to find out why someone has died
- human tissue, such as heart valves, skin and corneas (part of the eye), is used to treat patients who have particular medical conditions. Human tissue and cells, like umbilical cord blood, may also be stored for possible future use
- human tissue and cells are used to research the causes of, and treatments for, illnesses such as cancer or disorders of the brain or nervous system like Alzheimer's disease or multiple sclerosis.
- organs such as kidneys, liver and lungs are used in transplants to treat people whose organs have failed. Bone marrow transplants are also used to treat people with diseases of the blood such as leukaemia
- human bodies and body parts may also be displayed in public places such as museums

4. Information about the laws that the HTA works under

The HTA works under two laws: the Human Tissue Act 2004 (HT Act) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations).

Human Tissue Act (HT Act)

The HT Act applies to England, Wales and Northern Ireland. Scotland has its own law called the Human Tissue (Scotland) Act 2006, but the HTA was asked by the Scottish Government to approve transplants from living donors and license organisations that use human tissue to treat patients, on its behalf.

Consent is the most important principle of the HT Act. Consent must be given for bodies, body parts, organs and tissue to be stored and to be used for specific purposes.

The HT Act and the work of the HTA have introduced major changes which have had a positive impact on professionals, patients and families. Together they have given the public confidence that their wishes will be respected, and professionals the confidence that they are working within a clear framework and regulated by an organisation that understands their work.

The HTA does not regulate the diagnosis or treatment of illnesses in living people, as this is not covered by the HT Act.

Quality and Safety Regulations (Q&S Regulations)

The EU Tissue and Cells Directive (EUTCD) is a European law which covers the whole of the UK, including Scotland. It has been implemented in the UK via a law called the Q&S Regulations. The EUTCD aims to set a standard across Europe for activities using human tissues and cells to make sure that tissue is safe and of high quality. It also means that tissue and cells can be traced from the donors to the people who receive them, and moved more easily between European countries.

Under the Q&S Regulations the HTA is responsible for licensing organisations that: remove, store, test, process, use or distribute human tissue or cells that will be used to treat patients. Examples include: collecting umbilical cord blood in maternity units, storing corneas in eye banks, and processing cartilage for repairing knee injuries.

5. How does the HTA license organisations?

The HTA aims to implement the HT Act and Q&S Regulations in a supportive and well-considered way. Our work is based on the five key principles of Better Regulation – being transparent, accountable, proportionate, consistent and targeted. We also make sure that we provide value for money both for the taxpayer and the organisations that we license.

An HTA licence is granted to an organisation if it shows it will comply with certain essential standards set down by the HTA. When an organisation applies for a licence it assesses itself against our standards. We then evaluate the information they provide and where necessary ask for more information before we can issue a licence. We may issue a licence with conditions that have to be met within a certain timeframe. We also inspect organisations to check that they maintain good standards and follow appropriate procedures. Organisations we consider to be highest risk are among the first to be inspected.

Each licensed organisation has to nominate a person who will supervise the activities being carried out. This person is called the Designated Individual (DI). DIs are trained by the HTA to carry out this important role. We list DIs and the organisations that we license on our website: www.hta.gov.uk/licensing/licensed_establishments.cfm

6. What does consent mean?

In general terms when we refer to giving consent, we mean giving permission for human tissue to be used for reasons set out in the HT Act and Q&S Regulations. The key principle of the HT Act is that a person has the right to be asked for consent before any part of their body is used for particular purposes. This applies whether the tissue comes from a living or a dead person.

- the HT Act uses the term 'appropriate consent' and this refers to the person who may give their consent. This could be the person from whom tissue is being taken, or if they are dead, by someone close to them, like a family member
- giving consent is a positive act. For consent to be valid it must be given voluntarily and by a person who has the ability to make an informed decision. The person giving consent must also have the best information given to them so that they can make their decision
- consent can be given in different ways and depending on what it is being given for, it does not always need to be in writing. A person can also withdraw their consent at any time
- because giving consent is not always straightforward, we provide detailed advice on consent in a code of practice

7. Our role in anatomy

Human bodies are used to teach students about the structure of the body and how it works. This is called anatomical examination. Human bodies and parts of bodies are also used to train surgeons and other healthcare professionals. Organisations which carry out these activities are licensed by the HTA.

People can decide in advance to donate their body to medical science after their death. These donations are highly valued by staff and students at medical schools.

The HTA is not responsible for promoting body donation, but medical schools have been encouraged to do so and we provide them with support and information. People wanting to donate their body should contact their local medical school for more information. They will need to put their wishes in writing before they die by completing a consent form or by stating their wishes in a will. A list of local medical schools and more information for the public is available on the HTA website: www.hta.gov.uk/about_hta/donating_a_body_to_medical_science.cfm

8. Our role in post-mortem examinations

A post-mortem examination is a detailed study of a body after death. It is also known as an autopsy. Post-mortem examinations are carried out by pathologists – medical professionals who specialise in the diagnosis of disease after death and identifying the causes of death – at a location licensed by the HTA. Post-mortem examinations are carried out for two main reasons:

- if the cause of a death is unknown, or when a death happens unexpectedly or suddenly, it is referred to a coroner who orders a post-mortem examination. By law, coroners' post-mortem examinations can take place without the consent of the family
- at the request of the family of a deceased person in order to provide information about illness and cause of death. In these cases consent should be obtained from the deceased's family

All post-mortem examinations, whether or not authorised by a coroner, must take place on premises licensed by the HTA.

Post-mortem examinations of some tissue and organs may take several weeks. The family can decide either to delay the funeral so that the tissue or organs can be replaced in the body, or to hold the funeral, in which case the tissue and organs will be sensitively and respectfully disposed of.

Alternatively, a family may decide to consent to the tissue or organs being kept for research.

More information about post-mortem examinations is available on the NHS Direct website:

www.nhsdirect.nhs.uk/articles/article.aspx?articleID=488#

9. Our role in human tissue that is used to treat patients

The HTA licenses organisations that treat patients with human tissue and cells, including stem cells, skin and heart valves. We sometimes refer to these organisations as having an HTA licence for ‘human application’. This means that the human tissue will be used to treat patients. This type of licence can be issued to a wide variety of organisations, including:

- eye banks that store corneas to treat people who have sight problems
- maternity units where umbilical cord blood is collected. The cord blood is then stored and may be used in the future to treat the child or another person. The HTA licenses the collection and storage of the cord blood, but not any treatment using stem cells taken from it. More information is provided in the Royal College of Obstetricians and Gynaecologists’ leaflet on cord blood banking:
www.rcog.org.uk/index.asp?PageID=1673
- organisations that store skin and bone. These can be used in grafts, for example to treat burns or to repair bone injuries
- organisations that store heart valves which are used to treat people with heart disease or other conditions

10. Our role in research

The HTA licenses organisations that store human tissue for research. One of our key aims is to ensure that research continues to thrive in the UK. We believe that good regulation supports good science, which in turn leads to improved healthcare. We hope that by explaining how we regulate research, we will give people confidence that donated tissue will be put to the best possible use; and this in turn will increase the willingness of the public to donate.

By studying human tissue, scientists can improve their understanding of how diseases start and progress, and what keeps us healthy. They may find different ways of diagnosing disease, or develop new treatments. Examples of types of research involving human tissue include:

- developing screening tests for different types of cancer
- testing new treatments for conditions like heart disease and diabetes
- looking at how the immune system works to help understand how it combats diseases
- researching how stem cells could be used to treat conditions like Parkinson's disease and multiple sclerosis

If tissue is removed during the course of treatment or an investigation, there may be some remaining tissue after the procedure that can be used for research. Tissue for research can only be used with the person's consent. The HTA ensures that this tissue is removed and stored in an appropriate and well managed way.

If a person does not want their tissue to be used for any medical research, or they only want it to be used for specific types of research, it is important that they make this clear to the doctor or nurse who asks for their consent, and that they state their wishes in writing on the consent form.

A person may also give consent for their tissue to be used for research after their death. If there is no record of the deceased person's wishes, consent for research can be obtained from someone nominated by them to act on his or her behalf; or, if no one has been nominated, from a person in a 'qualifying relationship' – such as a partner, relative or friend.

11. Our role in organ transplants

Organ donations from living people

Most organs for transplants are donated from people who have died, but every year, more and more people receive organs from living donors.

The HTA is responsible for approving all transplants involving living people following an independent assessment process. All donors and recipients see a local Independent Assessor (IA) who acts on behalf of the HTA and as a representative of the donor.

The IA interviews the donor and recipient together and separately, and writes a report. They make sure that the donor and recipient have been thoroughly assessed and understand what is involved in giving and receiving an organ, and that the risks have been properly explained. The IA must be satisfied that the donor is not under any pressure to donate and can give their consent freely and voluntarily.

The HTA has allowed more flexibility in who can donate to whom, so that more people can benefit from a living-donor transplant. The new options for living-donor transplants are as follows:

- a donor and recipient whose blood groups or tissue types are incompatible can be paired with another donor and recipient in the same situation. This is called 'paired donation'. Sometimes, more than two donors and two recipients will be involved in the swap (called 'pooled donation'); and, if all goes to plan, each recipient will benefit from a transplant that they would otherwise not have had
- a living person who has never met the possible recipient may be considered to become a donor. This is called 'non-directed altruistic donation'

The HTA leaflet 'Information about living donor-transplants' gives more information about the role of the HTA in approving organ donations from living people. The leaflet is available from the HTA website at: www.hta.gov.uk/about_hta/publications/leaflets.cfm

Organ donations from deceased people

The wishes of a deceased person must be established before their organs can be removed and used for a transplant. A person can indicate their agreement to donating their organs by joining the NHS Organ Donor Register. The Organ Donor Register is run by NHS Blood and Transplant (NHSBT): www.nhsbt.nhs.uk

If there is no record of the deceased person's wishes, the HT Act allows consent to be obtained from someone nominated by the deceased person to act on his or her behalf; or, if no one has been nominated, from a person in a 'qualifying relationship' – such as a partner, relative or friend.

A living person who is donating an organ can decide who receives the organ. Organ donations from deceased people are allocated to the person on NHSBT's national list who is most in need and who is the best match with the donor.

12. Our role in bone marrow transplants

People with serious illnesses such as cancer or leukaemia usually receive chemotherapy or radiotherapy as part of their treatment. As well as destroying the cancer cells, this treatment may damage their bone-marrow stem cells. Transplants of normal stem cells from bone marrow or blood allow doctors to give much bigger doses of drugs and radiation to these people.

The HTA is responsible for approving all donations of bone marrow or peripheral blood stem cells (these are cells found in the bloodstream which are able to develop into all of the different cell types in blood) from children and adults unable to make an informed decision.

A person acting on the donor's behalf, must be interviewed by a local Accredited Assessor (AA) who can recommend whether or not the HTA should give approval for the donation to go ahead. The AA interviews them to make sure they understand what is involved. The AA then reports to the HTA. The HTA must be satisfied that the donor is not under any pressure to donate and that they have given their consent freely.

The HTA leaflet 'Information about donating bone marrow or PBSC' gives more information about the role of the HTA in the approval process. The leaflet is available on the HTA website at: www.hta.gov.uk/about_hta/publications/leaflets.cfm



Ann Margaret Little is the Designated Individual 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. In early 2008, the Trust found a match for his bone marrow.

13. Our role in human tissue that is displayed in public

Human bodies and body parts may be displayed in public places, for example in exhibitions or in museums. The HTA licenses organisations that display any bodies of deceased people, or any tissue that has been taken from their bodies.

Under the HT Act, consent must be given by a person in writing whilst they are alive, for their body to be displayed in public after their death.

We do not license the display of human remains from people if they died more than 100 years ago. We also do not license the display of photographic or electronic images, for example on TV or in a textbook.

14. More information

You can find out more about the issues raised in this guide at the following sources:

- HTA website: www.hta.gov.uk
- HTA codes of practice:
www.hta.gov.uk/guidance/codes_of_practice.cfm
- Information about living-donor transplants leaflet:
www.hta.gov.uk/about_hta/publications/leaflets.cfm
- Information about donating bone marrow and peripheral blood stem cells: www.hta.gov.uk/about_hta/publications/leaflets.cfm
- Information about how to donate your body to medical science:
www.hta.gov.uk/about_hta/donating_a_body_to_medical_science.cfm
- List of organisations licensed by the HTA:
www.hta.gov.uk/licensing/licensed_establishments.cfm
- Information about HTA Authority members:
www.hta.gov.uk/about_hta/how_we_work/authority_members.cfm
- HTA / Ipsos MORI General Public Quantitative and Qualitative Research, June 2007: www.hta.gov.uk, type 'MORI' into the search box
- Information about how to join the Organ Donor Register:
www.nhsbt.nhs.uk
- Royal College of Obstetricians and Gynaecologists leaflet on cord blood banking: www.rcog.org.uk/index.asp?PageID=1673

15. Feedback on this guide

Please let us know if you have any comments or suggestions for improving future editions of this guide. We are also very interested to see any examples of work where the information in this guide has been used. Please contact the communications team at the HTA: enquiries@hta.gov.uk or 020 7211 3416.

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