

Human Tissue Legislation

Guidance from the BMA's Medical Ethics Department

England, Wales and Northern Ireland

Scotland

UK-wide

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1 INTRODUCTION

On 1 September 2006 the bulk of the Human Tissue Act 2004 (covering England, Wales and Northern Ireland) and the Human Tissue (Scotland) Act 2006 came into force. The scope of the two pieces of legislation differs with the 2004 Act being far more wide ranging than its Scottish equivalent. This guidance sets out the main provisions of each Act, and describes the principal ways in which they impact on clinical and research practice. There are a small number of areas, such as living organ donation, where the procedures are the same across the UK and these are covered at the end. This guidance is intended as a brief introduction to the new legislation with signposts to where to find more detailed information. Clearly, however, this type of document cannot cover every situation and individual advice may also be sought from the Medical Ethics Department.

The new legislation will directly affect:

- post-mortem services
- anatomy schools
- the transplant community
- establishments storing tissue, and
- sites displaying human material, such as museums or exhibitions.

Other sources of information

General guidance on the Human Tissue Act 2004 can be found on the Department of Health's website at: <http://www.dh.gov.uk/assetRoot/04/10/36/86/04103686.pdf>

Specific advice about licensing under the Human Tissue Act and copies of the codes of practice issued under the Act can be obtained from the Human Tissue Authority at: www.hta.gov.uk

General guidance on the Human Tissue (Scotland) Act can be found on the Scottish Executive's website at: http://www.show.scot.nhs.uk/sehd/mels/HDL2006_46.pdf

2 ENGLAND, WALES AND NORTHERN IRELAND – HUMAN TISSUE ACT 2004

This legislation regulates the storage and use of human organs and tissue from living individuals and the removal, storage and use of human organs and tissues from the deceased. It replaces, in England and Wales:

- Human Tissue Act 1961
- Anatomy Act 1984
- Human Organ Transplants Act 1989

In Northern Ireland, the legislation replaces:

- Human Tissue Act (Northern Ireland) 1962
- Human Organ Transplants (Northern Ireland) Order 1989
- Anatomy (Northern Ireland) Order 1992

The Act also established the Human Tissue Authority (HTA) to issue guidance about the Human Tissue Act, to ensure best practice and to regulate those areas of practice that are subject to licensing (see below).

The HTA is also one of the competent authorities under the EU Tissues and Cells Directive (EUTCD) for regulating establishments storing tissue for human application throughout the UK.

The HTA has taken over the roles of the Unrelated Live Transplants Regulatory Authority (ULTRA) and the post of HM Inspector of Anatomy for England, Wales and Northern Ireland, both of which have been abolished. The role of HM Inspector of Anatomy will continue in Scotland.

2.1 What is covered by the Act?

The Act covers the storage, use and, for deceased patients, removal of human tissue. Human tissue is referred to in the Act as "relevant material" and includes any material that has come from a human body that consists of, or includes human cells, with the exception of hair and nails from living people, and live gametes and embryos created outside the human body. It includes blood (except for treatment) and other bodily fluids. Stem cells used for human application are also included but cell lines, which are created outside the body, are not currently covered by the legislation. This will change in April 2007 when the EUTCD is fully implemented where the cell lines are stored for treatment purposes. Information on this can be obtained from the Human Tissue Authority. The Act has different provisions in relation to the analysis of DNA (see section 4.2)

The activities covered by the Act are referred to as "scheduled purposes". They are divided into two groups:

Part 1:

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to that person
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

Part 2:

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

The removal, storage and use of tissue from living individuals as part of their diagnosis or treatment does not fall within the scope of the Human Tissue Act and is covered by the usual ethical rules on consent to treatment.

2.2 Consent

Consent is the central focus of the legislation and carrying out any of the activities listed as scheduled purposes without the necessary consent (see below) is an offence punishable by imprisonment of up to 3 years or a fine or both. More information about consent can be found in the Human Tissue Authority's code of practice on consent.

When is consent required?

The general rule is that Part 1 activities always require consent. Part 2 activities require consent if the material is from a person who was dead at the time the material was removed but do not require consent if the material is tissue taken from living individuals.

There are a small number of exceptions to these general rules. Consent is not required where:

- an investigation into the cause of death is carried out under the authority of a coroner
- material removed from a person after death is stored for coroners' or criminal justice purposes
- the material used is classed as "existing holdings" in that it was already in storage for a scheduled purpose when the Act came into force
- residual tissue from living individuals is used anonymously for research that has approval from a research ethics authority (see below) or approval is pending
- the tissue has been imported or comes from a body that has been imported
- the tissue comes from the body of a person who died before 1 September 1906.

Who gives consent?

Where the activity to be undertaken is anatomical examination or public display, the individual's own written and witnessed consent is required and nobody else has the authority to give consent.

For other activities covered by the Act appropriate consent means:

For competent living adults:	the individual's own consent
For living children who are able and willing to make a decision:	the individual's own consent
For children unable or unwilling to make a decision:	A person with parental responsibility ¹
For deceased people (who were competent before they died):	<ul style="list-style-type: none"> ▪ the individual's own consent given before death; or ▪ if an adult did not give consent, any person nominated by that person to make decisions after death; or ▪ in the case of children, or where an adult did not nominate anyone, someone who was in a "qualifying relationship" (see below) with the individual before death.

The "qualifying relatives" ranked in order of priority are:

- spouse or partner, including civil partner
- parent or child
- brother or sister
- grandparent or grandchild

- niece or nephew
- stepfather or stepmother
- half brother or half sister
- friend of long standing

Where there is more than one person at the same level of the hierarchy, such as a brother and a sister, the consent of only one of them will provide authority to proceed. The codes of practice, and guidance, issued under the Act make it clear that the known wishes of the deceased individual take precedence over the views of relatives and that nominated individuals or those in a qualifying relationship with the deceased do not have a legal right to veto the wishes of the person who has died.

When may consent be deemed to be in place?

For adults who are unable to give consent because of lack of capacity, Regulations set out the circumstances in which consent may be deemed to be in place so that the storage and use of tissue may proceed lawfully. The circumstances in which consent may be deemed to be in place are:

- where it is in the best interests of the adult who lacks capacity
- where clinical research is covered by the Clinical Trials Regulations 2004 and
- where the storage and research use of tissue is in line with provisions in the Mental Capacity Act (from April 2007).²

The BMA has also lobbied the Department of Health for additional Regulations to make it lawful to test an existing sample for serious communicable diseases for the benefit of a third party who has sustained a needle-stick injury. Up-to-date information about this can be obtained by contacting the Medical Ethics Department.

In addition, an application may be made to the Human Tissue Authority for consent to be deemed to be in place, for the use of residual tissue to obtain medical information for the benefit of another person (usually genetic testing) where:

- the donor is believed to be alive and to have capacity but cannot be traced or
- the donor is believed to be alive and to have capacity but has not responded to repeated attempts to obtain consent.

The consent procedures for DNA analysis differ from the rest of the activities covered by the Act (see section 4.2).

2.3 Regulation

What activities require a licence?

The Human Tissue Authority is established as the regulatory body to license a number of activities set out in the Act. The licensing requirement applies to all establishments whether operating within the NHS, a university or the private or commercial sector. It is unlawful to carry out the following activities without a licence from the HTA:

- Both hospital and coroner's post-mortem examinations
- The removal, use and storage of material, organs or tissue after death (except for whole and part organs for transplantation)
- Anatomical examinations

- Storage of human bodies, body parts or human tissue (but see exceptions below)
- Public display of human tissue.

There are some exceptions to the licensing requirement for the storage of tissue. A licence is required for the storage of tissues or organs removed from deceased patients, except:

- storage for use in a research project that has research ethics committee approval (or pending approval)
- storage of solid organs for transplantation.

A licence is not required for the storage of tissue from living individuals except:

- storage for more than 48 hours for human use (both allogeneic and autologous transplantation)
- storage for generic future research (both identifiable and anonymised).

Any establishment or individuals who are unsure of whether they require a licence should look at the information provided on the HTA website and, if necessary, contact the Human Tissue Authority directly for advice.

The licensing and inspection process

Establishments carrying out any licensable activities are required to have applied for a licence by 31 August 2006. Detailed information about the application, licensing and inspection procedures can be found on the HTA's website at: <http://www.hta.gov.uk/licensing.cfm>. Specific advice and guidance is provided to "Designated Individuals" who are responsible for supervising compliance with the licensing arrangements in the legislation.

Codes of practice

The Human Tissue Authority publishes a number of codes of practice setting out the standards that are expected to be followed and useful advice on how to comply with the legislation. These are available from the HTA's website at: <http://www.hta.gov.uk/guidance.cfm> and cover:

- Code 1 – consent
- Code 2 – donation of organs, tissue and cells for transplantation
- Code 3 – post-mortem examination
- Code 4 – anatomical examination
- Code 5 – removal, storage and disposal of human organs and tissue
- Code 6 – donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

2.4 The impact of the Act on particular activities

Those carrying out activities that fall within the Human Tissue Act should ensure that they are familiar with the material provided by the Human Tissue Authority. This section sets out the main requirements, regarding consent and licensing, for the principal areas covered by the Act.

Post-mortem services

The main requirements of the Act in relation to post-mortem services are:

- Consent is needed for post-mortem examinations other than those carried out under the authority of a coroner.

- Consent is needed for the subsequent storage of material removed after death (including material removed during both hospital and coroner's post-mortem examination); this includes the storage of blocks and slides as part of the medical record and for a schedule purpose.
- Consent is needed for any subsequent use of material removed after death (including material removed during both hospital and coroner post-mortem examinations) for any of the activities governed by the Act, including activities such as quality assurance, education or research.
- Both hospital and coroner's post-mortem examinations must only take place on premises licensed by the Human Tissue Authority.

Detailed information and guidance can be found in the HTA's codes of practice on consent and post-mortem examinations. Everyone involved with pathology services and carrying out post-mortem examinations should be familiar with the guidance in these codes.

In addition to the changes in the Human Tissue Act, amendments to the Coroner's Rules introduced in June 2005 require coroners to notify the appropriate relative about any material that has been retained as part of the post-mortem examination and to invite them to state what should happen to the tissue once the coroner's investigation is complete.

Anatomical examination

The role of HM Inspector of Anatomy is taken over by the HTA. The main requirements of the Act in relation to anatomical examinations are:

- Written, witnessed consent is required from the individual before death; nobody else may give consent for anatomical examination.
- Anatomical examinations may only take place on premises licensed by the Human Tissue Authority.
- Storage of anatomical specimens requires a licence from the HTA.

Detailed information and guidance, including information about existing anatomical specimens and the use of anatomical specimens away from licensed premises (eg for teaching), can be found in the HTA's code of practice on anatomical examinations. Everyone involved with anatomical examinations and the storage of anatomical specimens should be familiar with the guidance in this code.

Research

The main requirements of the Act in relation to research involving human organs or tissues are:

- Consent must be obtained for any storage and use of tissue removed after death for research purposes
- Consent is required for the storage and use of tissue from living individuals for research unless:
 - The material has been anonymised, such that the person carrying out the research does not know the identity of the donor (there may still be a link to the donor via a third party), and
 - The research project has been approved by a "research ethics authority" or approval is pending.

- A “research ethics authority” is a United Kingdom Ethics Committee Authority (UKECA) recognised ethics committee or a person or committee recognised for the purpose by the Secretary of State, the National Assembly of Wales or the Department of Health, Social Services and Public Safety in Northern Ireland.

In very exceptional circumstances, such as an extreme public health emergency, the Secretary of State may make Regulations to allow tissue from the living or the dead to be used for research without consent.

Storage of human material

The main requirements of the Act in relation to the storage of human material, organs or tissue are:

- Consent is required for the storage of material from a living individual for any Part 1 activity except where it is anonymised tissue stored for a research project that has research ethics authority approval or approval is pending
- Consent is required for the storage of material from a deceased person for both Part 1 and Part 2 activities
- Storage of material removed from living individuals only requires a licence if it is stored:
 - For future research that does not have ethical approval (tissue banks).
 - For more than 48 hours for the purpose of transplantation (except blood).
- The storage of tissue from a deceased individual requires a licence except where:
 - It is stored for use in a research project that has received approval from a research ethics authority (see above) or approval is pending.
 - It is sent to unlicensed premises for the purpose of analysis (other than research) and will be returned to licensed premises once the analysis is complete.

Transplantation from deceased donors

The main requirements of the Act in relation to transplantation after death are:

- Consent must be obtained for the donation of any organs or tissue from a deceased person.
- Donors can give consent in their lifetime and the wishes of the deceased take precedence over those of the relatives; the family do not have a legal right of veto over donation.
- Where it is believed that an examination by the coroner may be required, no body parts may be removed without the consent of the coroner.
- It is lawful to carry out procedures after death in order to preserve organs for transplantation whilst the appropriate consent to donation is being sought. Where the death falls under the coroner’s authority, it will be necessary to discuss this with the coroner before cold perfusing as this may impede tests order by the coroner to determine the cause of death.
- It is an offence to give, receive, initiate or negotiate any payment or reward in return for body parts for transplantation.

Transplantation from deceased individuals is not a licensable activity but those storing tissue (other than blood) for human use will need a storage licence (see

above). Those involved with transplantation are expected to follow the good practice guidance provided by the Human Tissue Authority in its code of practice on transplantation.

Public display

The main requirements of the Act in relation to public display are:

- Written consent is required from the adult or child in their lifetime; nobody else may give consent for public display.
- A licence is required from the HTA for the public display of the bodies of people who have died or material taken from the bodies of those who have died.

3. HUMAN TISSUE (SCOTLAND) ACT 2006 SCOTLAND

This Act replaces the provisions of the Human Tissue Act 1961 and amends the provisions of the Anatomy Act 1984 as they apply to Scotland. Unlike its English equivalent, the Human Tissue (Scotland) Act does not cover the storage and use of tissue removed from living individuals (except for transplantation) but focuses on the use of material removed from bodies after death. The Scottish legislation did not set up a statutory body to regulate this area. Under Regulations made under the Act, however, two tasks are delegated to the Human Tissue Authority (see above) – the regulation of the storage of tissue for human use (in order to comply with the European Human Tissue and Cells Directive) and living organ donation.

3.1 What is covered by the Act?

The Act will impact upon three separate uses of tissue and organs removed following death:

- Donation for transplantation, research, education or training and audit.
- Removal, retention and use following a post-mortem examination.
- Anatomical examination and public display.

Those who are storing tissue (other than blood) for human use (from both living and deceased donors) will also be affected by the legislation.

3.2 Authorisation

The Act introduces the concept of “authorisation” instead of consent. This applies both where an individual gives authorisation him or herself before death and where relatives give authorisation on behalf of a person who has died. The Act sets out the requirements for authorisation to be valid, including when authorisation needs to be in writing and whether witnesses are required and, if so, how many. The requirements vary depending upon the activity and whether the deceased was an adult or a child. Those responsible for ensuring that authorisation has been obtained must ensure they are familiar with these requirements, although they are incorporated in standard authorisation forms.

It is an offence to carry out any of the activities covered by the Act without the necessary authorisation, punishable by imprisonment for up to 3 years, or a fine, or both.

What is authorisation required for?

Authorisation is required for all removal, retention and use of material from the body of a deceased person except:

- A post-mortem examination or any other activity carried out under the authority of the procurator fiscal
- Tissue blocks and slides (not organs) that have been removed during post-mortem examination (both hospital and procurator fiscal) become part of the medical record and may be used for diagnostic and audit purposes without authorisation. In the case of tissue derived from a post-mortem examination instructed by the Fiscal, this happens once the Fiscal has given notice that the material is no longer required for the Fiscal's purposes.
- Organs or tissues acquired from a post-mortem examination carried out before 1 September 2006 may continue to be used, without the need to seek authorisation under the Act, for diagnosis, audit, education and training and for existing research that has research ethics committee approval.
- Material that is part of an existing archive or collection held before 1 September 2006 may be used for audit, education, training or research (but those holding such collections should assure themselves of the continuing value of the samples and, where there is no further value to retention, should dispose of the material). New research on organs in existing holdings derived from a Fiscal post-mortem examination requires Research Ethics Committee approval.
- Material that was removed from the body of a person who died before 1 September 1906.

Who can give authorisation?

Where the activity to be undertaken is anatomical examination or public display, the individual's own written authorisation is required and nobody else has the authority to give authorisation. For other activities covered by the Act authorisation may be provided by:

Adult (over the age of 16):	<ul style="list-style-type: none"> ▪ the adult's own authorisation given before death ▪ for hospital post-mortem examinations (and subsequent retention and use of organs), an individual may nominate one or more persons to give authorisation after the individual has died ▪ if the individual has not given authorisation before death, or nominated an individual to authorise a post-mortem examination, the adult's nearest relative (see below) may give authorisation provided he or she has no knowledge that the individual was unwilling for any part of the body to be used for the purpose proposed
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"Nearest relative" in order of priority is defined as an adult who is the deceased person's:

- spouse or civil partner
- partner living with the adult in a relationship resembling a spouse or civil partner for at least 6 months
- child
- parent

- brother or sister
- grandparent
- grandchild
- uncle or aunt
- cousin
- niece or nephew
- friend of long standing.

If the individual's spouse is permanently separated from the deceased, they are disregarded from the hierarchy. Where there is more than one person at the same level of the hierarchy, for example a brother and a sister, the authorisation of one of them is sufficient to proceed.

Child, 12 years of age or over:	<ul style="list-style-type: none"> ▪ the child's own authorisation given before death ▪ for hospital post-mortem examinations (and subsequent retention and use of organs), a child may nominate one or more persons to give authorisation after the child has died ▪ if the child has not given authorisation before death or nominated an individual to authorise a post-mortem examination, a person with parental rights or responsibilities (but not a local authority) may give authorisation provided he or she has no knowledge that the child was unwilling for any part of the body to be used for the purpose proposed ▪ if the child had not given authorisation before death or nominated an individual and there is nobody with parental rights and responsibilities at the time of the child's death the organs and tissue may not be removed, stored or used because nobody has the power to give authorisation.
Child under 12 years of age:	<ul style="list-style-type: none"> ▪ a person with parental rights and responsibilities (but not a local authority) ▪ if there is nobody with parental rights and responsibilities at the time of the child's death the organs and tissue may not be removed, stored or used because nobody has the power to give authorisation.

Under the legislation, the authorisation of the deceased takes precedence over the views of relatives; relatives do not have a legal right of veto over the deceased patient's wishes. The exception to this is relatives' authorisation of transplantation, which takes precedence over an individual's own authorisation for post-mortem examination or anatomical examination.

With the exception of transplantation, any authorisation given under the Act can be subject to conditions and these conditions must be complied with so far as is reasonably practicable.

Objections

Guidance from the Scottish Executive³ advises that people who object to donation of material after death for transplantation or to a post-mortem examination should notify their general practitioners. GPs should ensure that such objections are included on the emergency care summary which they provide for out-of-hours use. The information can then be conveyed to the relevant person in the event of contact being made with the GP after the patient has died.

3.3 The impact on particular areas of practice

Donation for transplantation, research, education or training and audit

The main points in the Act relating to donation of organs or tissue after death are:

- Where it is believed that an examination by the procurator fiscal may be required, no body parts may be removed without the consent of the procurator fiscal.
- Authorisation must be obtained before organs or tissues are removed and used.
- The prior wishes of the deceased take precedence over the views of relatives; relatives do not have a right of veto over donation.
- Authorisation for transplantation whether provided by the individual, the nearest relative or a person with parental rights and responsibilities, will take precedence over any authorisation for post-mortem examination or anatomical examination.
- An adult may withdraw authorisation for donation of their organs or tissue after death but must do so in writing.
- Where authorisation for transplantation is given by the nearest relative or someone with parental rights and responsibilities, this cannot be withdrawn.
- It is lawful to carry out procedures after death in order to preserve organs for transplantation but such procedures must be discontinued if it becomes clear that there is no authorisation for donation of the organs or that such authorisation will not be forthcoming. If it is not clear that there is authorisation, the body cannot be moved to other premises for the purpose of preservation.
- It is an offence to give, receive, initiate or negotiate any payment or reward in return for body parts for transplantation.

Hospital post-mortem examinations

Unlike the 2004 Act in England, this legislation makes a distinction between tissue samples and organs reflecting the different emotional significance they can have. Tissue samples, blocks and slides (including samples taken from organs) automatically become part of the deceased person's medical record and may be used for diagnostic and audit purposes without the need for specific authorisation (retention and use for other purposes, such as research, requires authorisation). Any retention or use of organs after the conclusion of the post-mortem examination requires explicit authorisation.

The main points in the Act relating to hospital post-mortem examinations are:

- Where it is believed that an examination by the procurator fiscal may be required, no post-mortem.

may take place without the consent of the procurator fiscal.

- Authorisation must be obtained before a hospital post-mortem examination may take place.
- Any subsequent retention or use of material removed at post-mortem examination (except the use of tissue samples from the medical record for diagnostic and audit purposes) requires authorisation. This also applies to retention and use of material following a post-mortem examination carried out under the authority of the Procurator fiscal once the fiscal has given formal notification that the material is no longer required for the fiscal's purposes.
- Where authorisation is given by a nominated person, nearest relative or person with parental rights and responsibilities, the standard authorisation form should be used.

Anatomical examinations and public display

The main points in the Act relating to anatomical examinations are:

- The role of HM Inspector of Anatomy, in licensing establishments undertaking anatomical examinations, continues.
- Authorisation must be provided by the individual before death and must be in writing and countersigned by a witness (for children aged 12 and over, two witnesses are required). Nobody else may give authorisation for anatomical examination on behalf of another person.
- It is intended that a standard authorisation form will be developed for use throughout Scotland.
- The definition of anatomical examination has been broadened to allow bodies donated for this purpose to be used for surgical training and the development of new surgical techniques.

The main points in the Act relating to public display of bodies and body parts are:

- Specific authorisation by the deceased individual must be provided for the use of bodies or body parts for public display.
- A licence is required from Scottish Ministers for the public display of the bodies of people who have died or material taken from the bodies of those who have died.
- Regulations exempt certain museums from the requirement for licensing.

The Act states that the Scottish Ministers may prepare a code of practice to give practical guidance to, and setting out standards to be followed by, those licensed to carry out anatomical examinations, to have possession of bodies or body parts and to publicly display a body or parts of a body. At the time of writing this code of practice had not been prepared but further advice can be obtained by contacting the Scottish Executive Health Department.

Storage of tissue for human use

Any individual storing material (other than blood) for more than 48 hours for human use (both allogeneic and autologous transplantation) from living and deceased patients, must have a licence from the Human Tissue Authority (HTA). This is in order to comply with the European Human Tissue and Cells Directive. Information

about licensing and inspection can be found on the HTA's website at: <http://www.hta.gov.uk/licensing.cfm>.

4. UK-WIDE

4.1 Living Donation

The same procedures for the donation of organs and tissues from living donors apply throughout the UK. These are described in detail in the Human Tissue Authority's codes of practice on:

- donation of organs, tissue and cells for transplantation
- donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

The approval procedures described in the codes, and summarised below, do not apply to "domino" donations, where the organ is removed for the benefit of the donor him or herself. For example, where the donor requires a heart and lung transplant but the heart is suitable for donation to someone else.

The only difference between the jurisdictions is that under the Scottish legislation, adults with incapacity and children may only be living donors of regenerative tissue (including bone marrow and peripheral blood stem cells), not organs or parts of organs (other than as part of a domino-transplant operation). In England, Wales and Northern Ireland cases involving donation of organs by these groups are given additional scrutiny but are permitted. There is a Scottish annex to the Human Tissue Authority's Code of Practice on transplantation which sets out the main features of the Scottish legislation in relation to children and adults with incapacity.

Donation of organs or parts of organs

- Consent (authorisation in Scotland) must be provided for the donation of organs or parts of organs, from living donors.
- For donation of organs, or parts of organs from a living donor an application for approval must be submitted to the Human Tissue Authority.
- the donor and recipient must be interviewed by an Independent Assessor who is accredited by the HTA
- The Independent Assessor must be satisfied that the person giving consent (authorisation in Scotland) to the donation has been given and understood the necessary information, that there is no evidence of reward or coercion or evidence that they have been subjected to pressure to consent.
- A report is submitted to the HTA from the Independent Assessor and a decision is made by the HTA as to whether the donation may proceed.
- The same procedures apply whether the donor and recipient are related or unrelated but emotionally close.
- There are some cases where additional safeguards are in place, and each case must be considered by a panel of at least three members of the Human Tissue Authority before approval is given. These cases are:
 - in England, Wales and Northern Ireland where the donor is an adult who lacks capacity or a child who lacks capacity to consent (in some of these case prior court authorisation may be required for the removal of the organs)

- "paired" and "pooled" donations. These allow a donor and recipient who are not compatible with each other to pair up with one or more other incompatible donor and recipient pairs in an organ exchange (eg donor A's organ goes to recipient B, donor B's organ goes to recipient C and donor C's organ goes to recipient A).
- donation to a stranger (non-directed altruistic donation).

Donation of bone marrow and peripheral blood stem cells

- Consent must be obtained for the donation of bone marrow or peripheral blood stem cells from living donors.
- Where the donor is an adult or young person with capacity, the usual procedures for obtaining consent to a clinical procedure apply.
- Where the donor is an adult who lacks capacity or a child who is unable to give consent (in Scotland, an adult with incapacity or a child), additional scrutiny is given and donation may only proceed if it is considered to be in the best interests of the donor him or herself (in some cases it will be necessary to seek a court declaration about best interests). In these cases
 - an application for approval must be submitted to the Human Tissue Authority
 - the donor and his or her family (or where the donor is a child, someone with parental responsibility) should be interviewed by an accredited Independent Assessor
 - the Independent Assessor must be satisfied that, amongst other criteria: the person giving consent to the donation has been given and understood the necessary information, that there is no evidence of reward or coercion or evidence that they have been subjected to pressure to consent, there is no other suitable donor available who is able to give consent, the best interests of the donor have been properly considered and the donor's family understand the nature of the procedure and any risks and side-effects
 - a report is submitted to the HTA from the Independent Assessor and a decision is made by the HTA as to whether the donation may proceed.

4.2 Analysis of DNA without consent

It is an offence, throughout the UK, to have human tissue or cells, including hair, nails and gametes, with the intention of analysing its DNA without qualifying consent, subject to the following exceptions:

- medical diagnosis or treatment of that person
- coroner/procurator fiscal purposes
- prevention or detection of a crime or for the prosecution of a crime
- national security
- court/tribunal order or direction
- where the material is from a living person and is used for part 2 activities
- where the material is an "existing holding" and is used for the activities covered by the Act
- where the DNA comes from an adult who lacks capacity and the use is consistent with Regulations made under the Act

- where the HTA has ruled that consent may be deemed to be in place, where
 - the donor is believed to be alive and to have capacity but cannot be traced; or
 - the donor is believed to be alive and to have capacity but has not responded to repeated attempts to obtain consent
- In the course of research where the material comes from a living person, the material is anonymised and the research project has been approved by a research ethics authority.

The offence does not apply to excepted material which is:

- material from the body of a person who died at least 100 years before the Act came into force
- an anonymous existing holding
- an embryo created outside the human body.

In relation to the analysis of DNA, qualifying consent means:

For competent living adults:	the individual's own consent
For living children who are able and willing to make a decision:	the individual's own consent
For children unable or unwilling to make a decision:	a person with parental responsibility ¹
For deceased people (who were competent before they died):	<ul style="list-style-type: none"> ▪ the individual's own consent given before death; or ▪ if a child did not give consent, a person with parental responsibility; or ▪ if the individual did not consent and, for a child there is nobody with parental responsibility, someone who was in a "qualifying relationship" with the individual before death (see section 2.2). For DNA analysis the hierarchy does not apply and consent may be given by anyone in a qualifying relationship.

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ADDITIONAL INFORMATION

Additional information is available by contacting:

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

Scottish Executive Health Department

St Andrew's House, Edinburgh EH1 3DG

Transplantation: Will Scott – Tel: 0131 244 2420 |


Fax: 0131 224 2989 | Email: will.scott@scotland.gsi.gov.uk

Post-mortem examinations & Anatomy Act:

Fiona Warner – Tel: 0131 244 5184 | Fax: 0131 244 2989 |

Email: Fiona.warner@scotland.gsi.gov.uk

For further information about these guidelines, BMA members may contact:

askBMA on 0870 60 60 828 or 

British Medical Association

Department of Medical Ethics, BMA House

Tavistock Square, London WC1H 9JP

Tel: 020 7383 6286 | Fax: 020 7383 6233

Email: ethics@bma.org.uk

Non-members may contact:

British Medical Association, Public Affairs Department,

BMA House, Tavistock Square, London WC1H 9JP

Tel: 020 7383 6603 | Fax: 020 7383 6403

Email: info.public@bma.org.uk

References

¹ The BMA has separate guidance on parental responsibility – www.bma.org.uk/ethics

² The BMA will produce guidance covering the provisions of the Mental Capacity Act – www.bma.org.uk/ethics

³ Scottish Executive Health Department. *Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland. NHS HDL (2006) 46.* Edinburgh: Scottish Executive.