HTA
Human Tissue Authority

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Code of Practice – Anatomical examination

Code 4 July 2006

An independent statutory regulator sponsored by DH Department of Health

Contents

Introduction

1 **The Human Tissue Act 2004** (The Act) which extends to England, Wales and Northern Ireland only, sets out a new legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual' tissue following clinical and diagnostic procedures.

2 The Act repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992. There is separate legislation for Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA will perform certain tasks on behalf of the Scottish Executive. For the purpose of these codes, the term 'NHS Trusts' includes Health and Social Services (HSS) Trusts in Northern Ireland.

3 The Act also establishes the **Human Tissue Authority** (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for scheduled purposes. This includes responsibility for living donor transplantation. This is one of the functions which the HTA will carry out on behalf of the Scottish Executive.

4 The HTA is also responsible for giving advice and guidance on the Act and for licensing establishments that carry out particular activities under the Act.

5 One of the HTA's statutory functions is to issue codes of practice. This is one of the first six codes, which should be regarded as complementary:

1 Consent
2 Donation of organs, tissue and cells for transplantation
3 Post mortem examination
4 Anatomical examination
5 Removal, storage and disposal of human organs and tissue
6 Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

6 These codes give practical guidance to those carrying out activities which lie within the HTA's remit and lay down the standards expected. These are not a definitive guide to the law and licence holders should refer to the Act and keep themselves informed about future legal developments.

7 The guidance given applies to anyone undertaking relevant activities. Failure to follow this guidance is not in itself a criminal offence under the Act, but the HTA may take any such breach into account when carrying out its responsibilities in respect of licensing.

8 The codes have been approved by the Secretary of State and laid before Parliament in accordance with Section 29 of the Act.

9 Any references to the terms 'tissue', 'organ', 'part organ', 'material,' 'body parts' or 'cells' in this code refers to 'relevant material'. For definitions of terms used, please refer to the glossary at the back of this code.

Scope of the code

10 The Human Tissue Act permits, with consent, the donation of whole bodies for anatomical examination. It also allows for the storage and anatomical examination of a body, provided that it is carried out by or under the direction of a Designated Individual, within licensed premises, with consent, and providing that the death has been properly certified and registered.

11 This code sets out the requirements which must be met in order to obtain a licence to carry out an anatomical examination or to store anatomical specimens. It is subject to and may be supplemented by, further conditions attached to any licence issued by the HTA.

Licensing

12 The Designated Individual, under a licence, should be an anatomist or head of the department where anatomical examinations are performed. They will be responsible for these examinations and the storage of anatomical specimens under the licence. The application for a licence can also include a request for named individuals working under the Designated Individual's authority to be added to the licence. These named individuals could, for example, be anatomy teachers.

13 The Designated Individual has a duty to ensure that all those to whom the licence applies are suitable to carry out the licensed activity, that suitable practises are used and that the conditions of the licence are complied with at all times. The Designated Individual should also ensure that guidance is provided to staff on the correct procedures to follow. It is an offence to carry out a licensable activity without a licence or under the authority of a licence. It is a defence that the person reasonably believes that they are either not carrying out an activity requiring a licence or that they are acting under the authority of a licence.

14 Although the licence is granted to a Designated Individual, or where different, the licence holder, it also specifies the premises where the licensable activity can take place. Subject to specified exceptions, a person commits an offence if they have possession of an anatomical specimen or a former anatomical specimen and the specimen is not on licensed anatomy premises[1] or in the case of a former anatomical specimen, the specimen is not on licensed storage premises. Anatomical specimens, or former anatomical specimens, can be held away from these premises, providing the person holding them:

- has written authority to do so from the Designated Individual who holds the licence for that particular specimen and
  - only holds the specimen for a purpose for which they are authorised; and
  - the specimen has come from a licensed storage premises,
- has possession only for the purpose of transporting the specimen to licensed premises, (in the case of anatomical specimens, this refers to licensed anatomy premises and in the case of former anatomical specimens, this refers to licensed storage premises);
- has possession only for the purpose of transporting the specimen to the premises where it is to be used for the purpose of education, training or research[2];
- has possession for or under the authority of a coroner,
- in the case of a specimen being the body of a deceased to be used for anatomical examination, has lawful possession immediately following the death of the deceased and retains

1 Licensed anatomy premises refers to premises with an anatomy licence, namely a licence to carry out anatomical examinations or store anatomical specimens.

2 This does not mean that the premises need not have a licence under section 16(2)(e) to store relevant material for a scheduled purpose.

possession prior to its removal to a premises with an anatomy licence, or

- in the case of former anatomical specimens only, has possession only for the purpose of decent disposal.

15 An offence will have been committed if the conditions above are not complied with. It is a defence that the person reasonably believes that what they have possession of is not an anatomical specimen or former anatomical specimen, that the specimen is on premises where an anatomy (in the case of anatomical specimens) or storage (in the case of former anatomical specimens) licence is in force or that any of the above exceptions apply. A person guilty of an offence will be liable for a fine and / or imprisonment.

Treatment of existing anatomical specimens

16 This section applies to bodies donated for anatomical examination where the person concerned has died between 1 September 2003 and 31 August 2006.

17 If a person has died between 1 September 2003 and 31 August 2006, their body or separated parts of their body can be stored and /or used, with their prior consent, for anatomical examination, in accordance with the Anatomy Act 1984 where the anatomical examination has not been completed prior to commencement of the Act. Any existing authority granted under the Anatomy Act 1984 for the retention of the body or body parts after conclusion of the anatomical examination will be treated as appropriate consent for storing or using a body, or body parts, for anatomical examination, providing the relevant documentary evidence is available (see paragraphs 29–37 below). This authority is treated as appropriate consent for whichever is the shorter: three years beginning with the date of the person's death or the period from the date of death to the date the anatomical examination is concluded.

Where anatomical examination is concluded after 1 September 2006but before the end of the period of three years from the person's date of death, the authority under the Anatomy Act will be treated as appropriate consent for the storage and/or use of a part(s) or a specified part of the person's body where:

- storage and /or use is for a qualifying purpose namely research in connection with disorders or functioning of the human body or education or training relating to human health;
- the authority under the Anatomy Act relates to that particular part of the body; and
- the deceased cannot be recognised simply by examination of that particular part of the body.

18 Any conditions attaching to the authority given under the Anatomy Act to hold body parts after an anatomical examination will likewise apply to the appropriate consent under the Act. This includes any consent relating to:

- how long the body, or body parts, may be stored
- the use of body parts in relation to education and research.

19 All these requirements must be met to ensure compliance with the Act, this code and any licence issued.

Obtaining appropriate consent for anatomical examination

20 Under the Human Tissue Act, appropriate consent to an anatomical examination can only be given by those individuals who choose to donate their body. Transitional arrangements provide that documented consent for anatomical examination made prior to 1 September 2006 is therefore treated as appropriate consent under the Act.

21 For the consent to be valid, it must be in writing and:

- signed by the donor in the presence of at least one witness who attests their signature, or
- signed at the direction of the donor, in his/her presence and in the presence of at least one witness who attests their signature, or
- contained in the adult donor's will, providing the will is lawful.

22 In all cases (except if contained in a donor's will), a specific consent form must be completed by anyone who wishes to donate their body or part of his body for anatomical examination. This form must comply with any Authority directions or the conditions of a licence issued by the HTA and must be kept as part of the donation records.

23 Appropriate consent is not needed for removal, storage and use of material from a deceased body for anatomical examination where the body has been imported or it is a body of a person who died at least 100 years prior to the coming into force of the consent provisions of the Act.

24 Storing and / or using the body of a deceased person for anatomical examination is lawful provided that:

- there is appropriate consent;
- there is a signed death certificate under the Births and Deaths Registration Act 1953 or in the case of Northern Ireland the Births and Deaths Registration (NI) Order 1976; and
- the person's death has been registered in accordance with the legislation referred to above.

If these requirements are not met then an offence will have been committed unless the person reasonably believes that:

- there is appropriate consent;
- the death certificate has been signed;
- the death has been registered; or
- what s/he does is not an activity falling under section 1 of the Act.

In addition, an offence will have been committed if a person makes a false representation to another that appropriate consent exists or is not required where they either know the representation to be false or do not believe it to be true. A person found to have committed an offence shall be liable to a fine and /or term of imprisonment.

Providing information about whole-body donation

25 It is important that anyone wishing to donate their body or part of their body for anatomical examination is given all the information necessary to make an informed decision. This information should be made available in a variety of formats (electronic, leaflet, face-to-face, etc.) so that donors can choose which is most appropriate for them.

26 Donors should be provided with clear advice on the following:

- contact details of the university medical school or anatomy laboratory which holds the donor's witnessed consent to body donation
- consent procedures and the right to withdraw consent
- the limited circumstances in which organ donation, e.g., corneas, skin and bone grafts, may be possible
- what happens after death:
  - enquiries into the cause of death
  - contact with the last doctor in attendance
  - coroner's cases and post mortems
  - the documentation required
- what the body may or may not be used for
- how long the body and body parts may be kept. (The Human Tissue Act does not specify a time limit, but experience suggests that some relatives prefer a period of three to five years to provide closure. Because of new preservation techniques, body parts can be kept indefinitely.)
- consent for the retention of body parts
- public display (for which prior written and attested consent is required – see paragraphs 40–41 below) and images
- what happens to the body once it is no longer needed
- costs.

27 Clear guidance should also be provided to staff on the correct procedures to follow.

Putting procedures in place

28 The Designated Individual, and all other persons to whom the licence applies, should ensure the following:

- no body is accepted for donation for anatomical examination unless it is accompanied by a Disposal Certificate. (This is currently the 'green form' issued by the Registrar of Births and Deaths once the death and cause of death have been correctly registered.)
- where a Designated Individual has accepted a body for anatomical examination, they must ensure that on arrival the identity of the body is checked against the disposal certificate, any other documents accompanying the body and any wrist band or other identification attached to the body. Where there is no wrist band or other identification, a tag must be attached to the body as soon as the identity has been confirmed.
- at the time that the donation is made, the wishes of the donor regarding disposal of their body and /or ashes are confirmed and fully recorded.
- as soon as is practicable after a body is received at the place where preservation for anatomical examination is to take place, the body is subjected to a suitable process for its preservation.
- the body is held only as long as an adequate state of preservation can be maintained.
- all bodies and body parts are stored in an orderly and hygienic manner, and in suitably designed rooms equipped with adequate facilities.
- if an anatomical examination is carried out by someone other than the Designated Individual or individual(s) named on the licence, they must be authorised to do so and be acting under the direction of the Designated Individual or the individual(s) named on the licence Direct supervision will not be necessary if the person carrying out the examination is sufficiently qualified and trained.
- donated whole bodies, with the exception of parts for which consent has been given for indefinite retention, should be kept for no longer than is necessary to complete the designated procedures. However, if it is necessary to store the tissue for a longer period, then consent for this must have been obtained. Every effort should be made to make an accurate assessment of the length of time donated bodies or parts will be retained.
- after the relevant anatomical examinations have been completed, the body should be disposed of in accordance with the deceased person's wishes. Separated body parts, other than those which have consent for further retention, should be buried or cremated with the body from which they were removed. If the donor has not expressed a preference for disposal, the family should be asked how they wish the body to be disposed of.
- records on the disposal of whole bodies or body parts are kept in line with the HTA's requirements and guidance.

- there is a rigorous process in place for validating paperwork against body identity and a body is tagged immediately its identity is confirmed. All these procedures should comply with Authority directions or any conditions of a licence which the HTA issues.

Documentation and record keeping

Records relating to anatomical examinations and anatomical specimens

29 All places where anatomical procedures are carried out should keep records in a permanent form for each body or body part in their possession (or in the possession of another person permitted by the Designated Individual to hold the anatomical specimen). These records should be held on the premises where the donated body was first received and on any other premises to which the body, or parts of the body, may have been moved. The records must be available for inspection and review at all times.

30 Where a Designated Individual accepts a body and arranges for procedures for its preservation to be carried out in premises for which they are not personally responsible, that Designated Individual must authorise the person receiving the body on their behalf to undertake the checks to confirm the body's identity before preservation procedures begin. The person authorised to receive the body should maintain permanent records for each body they accept and provide this information to the Designated Individual who first accepted the body for anatomical examination.

31 The HTA must be notified of each new body accepted and must be provided with the following details:

The deceased person:

- full name
- date of birth
- sex
- date of death
- registered cause of death
- place of death
- date of signature of the consent
- name and address of witness to the consent
- was retention of parts authorised?
- any restrictions in relation to storage and /or usage

Licensed premises at which the body was received:

- name/address of Designated Individual
- date body was received
- time body was received

32 The records maintained by the Designated Individual should include:

- the full name of the donor whose body is to be used for anatomical examination, their sex, date of birth, date of death, age at the time of death and registered cause of death.
- the date and time at which the body was received at the premises where the anatomical examination is to be carried out.
- the relevant authority or consent for the anatomical examination under the Anatomy Act 1984 or the Human Tissue Act 2004.

- the names and addresses of anyone given permission by the Designated Individual to have possession of the body or any part of the body.
- details of any wishes expressed by the deceased person, the deceased's surviving spouse or any surviving relative regarding the disposal, storage and/or use of the body once the anatomical examination is complete.
- the date and method of disposal of the body.

33 All records should be kept for a period of five years from the date of disposal of the last remaining body part.

Records relating to body parts retained after anatomical examinations have been concluded

34 The records should be held on the premises in which the examination of the original anatomical specimen took place and on any other premises to which the parts may have been moved. The records should be available for inspection and review at all times.

35 The records should include:

- the unique number allocated to each body part
- a description of the body parts which are held on the licensed premises, identifying the bodies from which they were taken
- the consent or authority granted under the Human Tissue Act 2004 or the Anatomy Act 1984, and the name and address of the person who gave authority for the body part or parts to be stored
- the name and address of anyone who holds one or more of the body parts.

36 Records for parts of a body should be kept for five years from the date of disposal of the last remaining body part.

37 Body parts lent by an initial recipient department should also have accompanying records covering:

- the unique number allocated to each body part
- the source and body number from which the part was taken
- an adequate description of the part (and whether right or left side, if relevant)
- the date the part arrived at the recipient anatomy department
- the date the part was due to be returned to the lending department for disposal
- the actual date when the part was returned to the lending department
- by whom received at the lending department.

Care of the body and body parts

38 During dissection and any subsequent anatomical procedures, all parts of the body must be treated with due respect and consideration. All separated body parts must be catalogued, tagged and recorded so that the whole body and its parts can be tracked if necessary.

39 From the start of any donation process, it should be explained to the donor, where possible, how any tissue removed during dissection and subsequent procedures is to be disposed of. It is good practice to retain such tissue wherever possible for disposal along with the body. Any tissue removed from retained body parts can be disposed of as clinical waste.

Public display of bodies and the taking and use of images

40 The taking and displaying of images (including photographs, film and slides) is outside the scope of the Human Tissue Act. However, the HTA endorses the guidance on this issue provided by the General Medical Council: *Making and Using Visual and Audio Recordings of Patients*.[3] This states that images can be used for medical education, research and clinical audit without consent providing the donors cannot be identified.

41 The HTA views this advice as good practice and strongly recommends that when seeking informed consent for body donation, it should be explained that images could be taken and used for a variety of purposes (see paragraph 26 above).

3 www.gmc-uk.org/guidance/library/making_audiovisual.asp

Transfer/loan of bodies or body parts

42 Bodies or body parts can only be transferred or loaned for purposes for which consent was originally given.

43 Bodies or body parts must be kept at all times on licensed premises, unless the Designated Individual or an individual authorised by the HTA has given written permission to a suitable nominated person to move them to unlicensed premises and to store and use them for authorised purposes (see paragraphs 12-15 above).

44 Failure to comply with these requirements can lead to a fine, a prison sentence of up to three years, or both.

45 Records should be kept of any transfers, including relevant details of:

- the person authorised to hold the part
- for what purpose
- where the part will be held
- the period for which they are so authorised.

Premises

46 All premises where bodies and body parts are held must be completely secure at all times and conform to any directions or licence conditions made by the HTA.

Charging

47 A charge may be applied to cover the costs of embalming bodies and of preparing retained parts for use of others. These charges should in general reflect the cost involved in the preparation of the bodies.

Consent and the use of DNA

48 While consent makes it lawful to store and use tissue for Scheduled Purposes (including for anatomical examination), it is an offence under section 45 of the Act to have any bodily material (i.e. material which has come from a human body and which consists of or includes human cells) with intent to analyse the DNA in it without qualifying consent, subject to certain exceptions. Unlike the other parts of the Act, which do not apply to Scotland, this offence applies to the whole of the UK. See the HTA's *code of practice on Consent* for details of this offence and its exceptions.

Glossary

These terms have been defined with reference to the Human Tissue Act and the HTA's Codes of Practice and should be read in that context.

Allogeneic use: Cells, tissue or organs[4] removed from one person and applied/transplanted into another.

Altruistic non-directed donation A form of non-directed living donation, where an organ or part organ is donated by a healthy person who does not have a relationship with the recipient and who is not informed of whom the recipient will be.

Anatomical examination: Macroscopic examination of the body of a deceased person, or separate parts of such a body, by dissection for anatomical purposes (teaching or studying, or researching into, the gross structure of the human body).

Anatomical specimen: The body of a deceased person, including separated parts of such a body, to be used or in the course of being used for the purpose of anatomical examination. A former anatomical specimen is a deceased body, organ or body part donated for anatomical examination which is held once the examination of the rest of the body has been completed.

Anatomist: An expert in anatomy.

Anatomy: The science of the structure and organisation of the body and its parts.

Anonymisation: is a procedure to ensure that if relevant material is removed from a human body, all necessary steps are taken to prevent identifying the person from whose body the material has come.

Appropriate consent: is defined in the Act by reference to the person who may give consent.

Autologous use: Cells, tissue or organs removed from and applied/transplanted into the same person.

Autopsy: A post-mortem examination.

Biopsy: A procedure where tissue is removed from a living body for examination under a microscope.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue.

Clinical audit: A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Stored tissue previously needed for diagnosis, for example, may need to be reviewed as part of this process.

Clinical diagnosis: A process where a disease is identified from medical history-taking, diagnostic tests and physical examination.

4 Wherever the term 'organ' is referenced, this also includes 'part organs'.

Designated Individual: means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons, that suitable practices are carried out in the course of carrying-on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

Diagnosis: A process where a disease is identified by signs and symptoms, a history and laboratory tests.

Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part of an organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired / pooled donation).

DNA (deoxyribonucleic acid): the genetic material of humans which is located in the cell nucleus and controls heredity.

Domino donation: When an organ is removed as part of a person's treatment, it may be suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart and lung transplant).

Donation: The act of donating human tissue, cells or organs for a scheduled purpose.

Donor: Every human source, whether living or deceased, of human tissue, cells or organs.

Embryo: means a live human embryo where fertilisation is complete and includes an egg in the process of fertilisation.

Ethical Approval: Defined under Regulations[5] made under Section 1(9) of the Act to mean approval given by a research ethics authority.

Existing holdings: Body of a deceased person or relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for use for a scheduled purpose.

'Gillick'[6] competent (now also referred to as Fraser competent): A test of competence and method of determining the ability of a young person under the age of 16 to make decisions regarding their own healthcare.

Haemopoietic: Relating to the production of blood cells.

Heart-beating donors: This refers to the circumstances where organs and tissue for transplantation are removed from donors fulfilling the nationally agreed and legally defined criteria of brainstem death.

5 The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

6 Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

Human application: The use of tissue or cells on or in a human recipient.

Independent Assessor: A person who acts as a trained and accredited representative of the HTA, to conduct an interview and prepare a report in circumstances envisaged under the Regulations[7], for some living organ donations for transplantation.

JACIE: Joint Accreditation Committee – International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation.

Licensing: A number of activities can only be carried out where the establishment is licensed under the Act by the HTA for that purpose. The activities are:

- the carrying out of an anatomical examination;
- the making of a post-mortem examination;
- the removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplant;
- the storage of an anatomical specimen;
- the storage (other than of an anatomical specimen) of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose;
- the use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.

Licence Holder: The person who applies for and is granted a licence who can be, but is not necessarily the Designated Individual. The Licence Holder is responsible for the payment of any fees charged by the HTA including fees charged in respect of superintending compliance with licences and any other fees as specified by the HTA from time to time. The Licence Holder can be a corporate body. Where the applicant is not the proposed Designated Individual, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

Licensed premises: Where the licensed activity (e.g. storage, or public display) takes place. If the licensed activity will take place at more than one place, a separate licence will need to be issued. Premises in different streets or with different postal codes will be considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

Living donors: The person donating tissue, cells or organs for transplantation. The most common forms are live kidney donation (where one kidney is removed), or live bone marrow donation.

NHS Organ Donor Register: A confidential, computerised database managed by UK Transplant, which holds details of people who have signed up to become organ donors in the event of their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.

7 Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

Non-directed donation: A form of donation where a person donates tissue, cells or organs an unknown recipient. Most commonly, this is deceased donation where the organ is allocated to the most suitable person on the transplant waiting list.

Non-heartbeating donation: A form of donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs once death is certified following cardiorespiratory arrest (i.e. the donor's heart has stopped beating).

Organ: A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

Paired donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to another couple in a similar situation, so that both people in need of a transplant receive a compatible organ.

Peripheral blood stem cells: Cells found in the bloodstream which are able to differentiate into all the cell types found in the blood.

Pooled donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to other couples in a similar situation, so that all people in need of a transplant receive a compatible organ.

Post mortem: Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes. A hospital post mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post mortem examinations are carried out under the authority of the Coroner and without consent to assist Coroners in carrying out their functions.[8]

Preservation: The use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues.

Processing: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.

Procurement: A process by which tissues or cells are made available.

Public display: includes organised displays and exhibitions held in museums, galleries, exhibition venues and educational establishments, but not for the purpose of education or training. This definition is subject to change pending further consideration by the HTA.

8 Coroners' post mortems are carried out in accordance with the provisions of the Coroner's Act 1988 and the Coroner's Rules 1984 (amended 2005) and the Coroners Act (Northern Ireland) 1959 and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963.

Public health monitoring: Using population-based or epidemiological techniques to ascertain the prevalence, spread and pattern of an established disease or condition in the community and relating its occurrence to public health programmes and activities.

Quality assurance: A programme for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Relevant material: is defined by the Act as material other than gametes, which consists of or includes human cells. In the Act, references to relevant material from a human body do not include:
(a) embryos outside the human body, or
(b) hair and nail from the body of a living person.

Research: is concerned with creating new knowledge by addressing clearly defined questions with systematic and rigorous methods. It is about testing innovations or discovering the right thing to do e.g. finding out whether new treatments work and whether certain treatments or models of service delivery work better than others. Research forms the basis of nationally agreed clinical guidelines and standards and is designed to establish best practice.

Research ethics authority: an ethics committee established or person appointed to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body.

Residual tissue: is material left over from a diagnostic or therapeutic intervention.

Scheduled purposes: Scheduled Purposes are the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the Act that require consent. The Purposes are divided into 2 parts:

Part 1: Purposes Requiring Consent: General
- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- 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: Purposes Requiring Consent: Deceased persons
- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

Serious adverse event: Any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissue and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients,

or which might result in, or prolong, hospitalisation or morbidity.

Serious adverse reaction: An unintended response, including a communicable disease, in the donor or in the recipient, associated with the procurement or human application of tissue and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Stem cell: A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.

Storage: Maintaining the tissue under appropriate controlled conditions.

Surplus tissue: Relevant material which has come from a person's body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research.

Tissue: Any and all constituent part(s) of the human body formed by cells.

Tissue establishment: A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissue and cells are undertaken. It may also be responsible for procurement or testing of tissue and cells.

Transplant: An implant of an organ, tissue or cells either from and into the same body or from one person to another.

Transplant coordinator: A person who helps a potential transplant recipient to understand the transplant process and also coordinates the transplant evaluation between the dialysis unit, transplant surgeon, and tissue typing laboratory. After a transplant, the nurse provides a communication link between the recipient and the transplant doctors for post-transplant care.

Transplantable material: Defined under Regulations[9] made under Section 34 of the Act to mean the whole or part of any of the following organs if it is their function to be used for the same purpose as the entire organ in the human body: kidney, heart, lung or a lung lobe, pancreas, liver, bowel, larynx, face, or limb. Defined in the same Regulations under Section 33 of the Act to mean organs or part of an organ if it is to be used for the same purpose as the entire organ in the human body, bone marrow and peripheral blood stem cells.

9 The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

Background reading

Learning from Bristol: the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995, Bristol Royal Infirmary, July 2001

Report of the Royal Liverpool Children's Inquiry, January 2001

Department of Health (May 2003) *The investigation of events that followed the death of Cyril Mark Isaacs*; Department of Health Isaacs Report Response, July 20