

# Human Tissue Authority

Code of Practice – The removal, storage and disposal of human organs and tissue

Code 5 July 2006



# Introduction

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- 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.

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- 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

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- 10 This code provides a model of good practice for all those involved in removing, storing and disposing of human organs or tissue, whether donated by living patients or removed from the body after death.
- 11 It does not deal with the legal and ethical issues relating to the use of human organs and tissue for research, education or other purposes.
- 12 The Act's consent and licensing provisions do not apply if at least one hundred years have elapsed since the date of the person's death. (This is to prevent museum collections of historical human remains being caught by the legislation, and in recognition of the impracticalities of tracing relatives for consent purposes for deaths that occurred long ago.)
- 13 To determine the Act's impact on the removal, storage or disposal of organs or tissue, consider the following:
  - is the organ or tissue classified as 'relevant material' i.e. material, other than gametes, which consists of or includes human cells?<sup>1</sup>
  - which, if any, of the scheduled purposes listed in the Act<sup>2</sup> is the material being removed or stored for?
  - was the material removed from a person in their lifetime, or after death?
- 14 Under the Act, fetal tissue and products of conception are treated no differently from any other tissue taken from a living person. Clearly, however, there are particular sensitivities relating to the use and disposal of such tissue. See Appendix B for guidance on the disposal of fetal tissue.

<sup>1</sup> See Glossary

<sup>2</sup> See Glossary

# Removal

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## Consent: organs/tissue removed from the living

15 The consent requirements of the Act do not apply to the removal of relevant material from the living but only to the removal of relevant material taken from the dead. Consent for removal of relevant material from a living person continues to be dealt with by the common law. This is because the removal of material from living patients is likely to be:

- a part of the patient's treatment (for example, during surgery or taking a blood sample), or
- part of a deliberate donation of organs, tissue or cells (see the *Code of practice on donation of organs, tissue and cells for transplantation*), or
- where a healthy person (who may or may not be a patient) participates as part of a research project or a trial of a new treatment. The consent of such individuals is required before they participate in clinical trials under the Medicines for Human Use (Clinical Trials) Regulations 2004. The consent gained for participation in such research must also cover any planned removal, subsequent storage and uses of relevant material (as defined in the Act).

16 The Department of Health's *Reference guide to consent for examination and treatment*<sup>3</sup> provides detailed guidance

on obtaining consent for examination and treatment.

17 Relevant material taken from a person in their lifetime continues to be treated as such after their death. It is the point at which the material is removed that determines how it is affected by the Act.

## Consent: organs/tissue removed after death

18 It is an offence under the Act to remove relevant material from a dead body for any scheduled purposes without obtaining consent other than under the coroner's authority or under proper authority for criminal justice purposes (see paragraphs 20–25 below). For further information, see the *Code of practice on consent* (which deals with the general principles of consent under the Act), and the *Code of practice on post mortem examination* (which deals more specifically with obtaining consent for post mortems).

19 In the case of material taken after death solely for use in research, three scenarios exist:

- *a specific use in a defined project.* This should only occur with consent and where the project has been ethically approved<sup>4</sup> as applicable to the specific project.

<sup>3</sup> [www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/](http://www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/)  
The DHSSPS (Northern Ireland) has published its own reference guide to consent for examination and treatment:  
<http://www.dhsspsni.gov.uk/consent-referenceguide.pdf>

<sup>4</sup> Defined under Regulations 2006 (The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) to mean approval given by a research ethics authority.

- *undefined research, presuming potential usefulness in future projects.* This type of removal should only occur with consent and the procedure for gaining consent should acknowledge that the potential uses are unforeseen at the time, but are broadly related to research into human health or the functioning of the human body. Before materials collected in this way are used in any future project, that project must be approved by a REC. The REC must be told how the material has been or will be procured.
- *material removed after death for possible transplantation proves unsuitable for that purpose, but could be suitable for use in research.* Such material should only be used for research where prior consent for such use exists and where REC approval has been obtained.

## Consent: coroner's post mortems

- 20 Consent is needed for the storage or use of material taken during a coroner's post mortem for scheduled purposes, once the material is no longer required for the coroner's purposes. The Coroner's Rules specify that the coroner must tell the pathologist carrying out the post mortem what material to store under their authority, and for how long<sup>5</sup>. The Rules
- also require the coroner to tell relatives<sup>6</sup> about any material which may be stored.
- 21 Consent is not needed for:
- carrying out a post mortem investigation on the order of a coroner
  - keeping material after post mortem on the instructions of a coroner, for the period of time specified by the coroner, or
  - keeping material in connection with a criminal investigation or following a criminal conviction (under the Police and Criminal Evidence Act 1984 or Criminal Procedure and Investigations Act 1996)<sup>7</sup>.
- 22 It is an offence to store and/or use material without consent for scheduled purposes after it is no longer needed for the coroner's purposes. Consent for storage of tissue post mortem should always be obtained.
- 23 The *Code of practice on post mortem examination* describes the need for local protocols between coroners and health organisations to ensure proper communication with the deceased person's relatives. Discussions about consent to store organs should ideally take place before the post mortem is carried out, and certainly before the coroner's time limit on storage expires. This not only avoids a second approach to

<sup>5</sup> The reference here and in the following paragraphs (21, 23, 24 and 25) relating to a period of time specified by the coroner, do not apply in Northern Ireland.

<sup>6</sup> Throughout this code, the term 'relatives' should be taken to include close friends of the deceased person in cases where there are no relatives.

<sup>7</sup> In Northern Ireland the Police and Criminal Evidence (Northern Ireland) Order 1989 takes the place of the Criminal Evidence Act 1984.

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relatives at a difficult time, but also ensures that material is not stored other than under the coroner's authority or with consent.

- 24 If the deceased person's relatives indicate that they wish organs or tissue to be disposed of, this should be done as soon as possible and certainly within two weeks of the deadline on storage specified by the coroner.
- 25 Where they have not expressed a preference by the time the coroner's time limit expires, the organs or tissue may be stored for up to six weeks. The relatives should then be advised that unless they specify otherwise, the organs or tissue will be disposed of in a further four weeks' time.

### **Consent: storing tissue, including blocks and slides, for scheduled purposes**

- 26 The Act does not distinguish between blocks and slides and any other form of human tissue. Whilst it may be desirable for blocks and slides to be taken and kept for clinical audit, teaching or other purposes, it should not be assumed that consent to a post mortem implies consent to removing and keeping blocks and slides.
- 27 The implications of a post mortem, including the need to remove organs or tissue for further examination, must be explained to the deceased person's

relatives when obtaining consent. It should be made clear that consent to the removal, storage and/or use of organs or tissue for any scheduled purpose is a separate decision from consent to conducting a post mortem examination (whether partial or full).

### **Principles of acquisition**

- 28 The underlying principle of the Act is that giving or withholding consent to the taking of organs or tissue from the living or the dead for any scheduled purpose are decisions which deserve respect.
- 29 Procedures for conducting post mortems, and for the removal and storage of organs or tissue for examination, must always maintain the dignity of the deceased person. Every effort should be made to reconstruct the body as far as possible after the post mortem. Reconstruction should be of a high standard so that the body can be viewed by relatives.<sup>8</sup> Those wishing to see the body of their relative should be told if any procedures have caused disfigurement, so that they are prepared. Such information should be provided as sensitively as possible, taking care to try to judge how much information individuals would wish to have before going into details.
- 30 The evidence from those affected by the discovery that organs and tissue had been taken from their relatives and stored without their knowledge or consent suggests that a major cause of concern



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was that the material had never been used for research or any other purpose that might have benefited others.<sup>9</sup>

31 It is therefore important that when organs and tissue are taken and stored, their use can be explained to living donors or to the relatives of deceased donors. Evidence suggests that most people are willing to consent to the removal and use of organs and tissue to:

- explain why their relative died
- help other family members (for example, siblings where there may be genetic risk factors)
- contribute to education of clinical staff and quality control, or
- help others in the future through medical research.

32 The *Code of practice on post mortem examination* provides guidance on discussing the implications of donation for research with the deceased person's relatives, including the need to tell them that not all material donated will necessarily be used. However, those giving consent expect donated material to be used if possible. Similarly, living donors expect their material to be put to good use. The *Code of practice on consent* provides guidance on obtaining consent from a living donor and on discussing donation for research.

33 Material may need to be held for a long time, possibly decades, before being used – for example because of the need to build up materials from a sufficient number of donors. It is often impossible to anticipate the future use to which donated material may be put.

34 Therefore it is important to explain to those giving consent that it may not be possible to say exactly what the material will be used for, or when. Many donors or their relatives are willing to provide consent for future unforeseen uses and the *Code of practice on consent* explains the benefits of seeking broad or generic consent where possible. However, if consent has only been given for a specified use when broader consent was sought, the wishes of the donor should be respected and the uses restricted appropriately.

## Record-keeping

35 NHS Trusts and other establishments should ensure they have systems in place to maintain proper records and documentation for all tissue and organs they acquire and/or pass on to others.

36 The Designated Individual<sup>10</sup> named in licences issued by the HTA should ensure that such systems are in place. It is important to be able to track what happens to organs and tissue for health

<sup>9</sup> 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.

<sup>10</sup> See Glossary

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and safety reasons – for example, should an infection occur, resulting in the need to trace people who came into contact with the material. Keeping proper records of donated material also demonstrates respect for the donation.

37 The duty to create and maintain proper records starts with the establishment where the material is removed from the body, or where the material is identified as surplus to requirements for healthcare purposes and is set aside for a scheduled purpose. Such initial records should include:

- details of who gave consent
- exactly what the consent related to, and any restrictions on use stipulated during the consent process
- what processes are applied to the tissue
- if tissue is transferred, when and to whom and
- if relevant, when and how disposal is undertaken.

38 Tissue may be transferred from one place to another many times. So that an audit trail can be maintained, each establishment that handles human organs or tissue must have systems that can record:

- when the material was acquired, and from where
- what has been consented to
- the uses to which the material is put whilst in the establishment's care and any processes applied to it and

- when the material is transferred elsewhere, and to whom.

39 European Directive 2004/23/EC requires that adequate systems be set up to ensure the traceability of human tissue and cells intended for human applications. The Directive will be transposed into law by Regulations.

## Cultural/religious considerations

40 Attitudes to post mortem examination and other uses of organs and tissue differ greatly. Healthcare professionals should be aware of and sensitive to the values and beliefs of a wide range of cultures and religions, particularly those of their local community. They should also be aware that every decision is one for the individual concerned. Organisations should ensure that the necessary training and support is given, so that employees are equipped to identify and meet the widest possible range of needs and wishes.

41 The *Code of practice on post mortem examination* discusses the handling of cultural and religious views in more detail.

## Preservation for transplantation

42 Where any part or parts of a body lying in a hospital, nursing home or other establishment is, or may be, suitable for use for transplantation, it is lawful for the individual in charge to:

- 
- take steps to preserve the relevant body part or parts for use for transplantation and
  - store the body for that purpose.

43 However, this authority only extends to taking the minimum steps necessary for preservation and to the use of the least invasive procedure. The *Code of practice on donation of organs, tissue and cells for transplantation* deals with this in detail.

# Storage

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## Storage of whole bodies

44 There are special requirements for the lawful storage of a body for anatomical examination, carried over from the Anatomy Act 1984. This is dealt with in detail in the *Code of practice on anatomical examination*.

## Existing holdings

45 It is lawful to store and use for scheduled purposes, without consent, relevant material and the body of a deceased person that is already held in storage for a scheduled purpose on 1 September 2006. However, where the views of the deceased person or of their relatives or friends are known, those views must be respected. The existing holdings provisions do not apply to the storage and use of bodies or material, which are the subject of an authority under the Anatomy Act 1984 and where the anatomical examination has not been completed by 1 September 2006. This is dealt with in detail in the *Code of practice on anatomical examination*.

## Storage of relevant material taken from the living

46 The Act makes it lawful to store relevant material taken from a living person for scheduled purposes (Part 1<sup>11</sup>) provided consent from an appropriate person is obtained.

47 Material may be taken from the living in a variety of circumstances, for example:

- in the course of a diagnostic procedure (e.g., blood sample, biopsy)
- in the course of treatment procedures (e.g., the removal of organs or tumours during surgery)
- specifically for the purposes of research (e.g., a blood sample taken as part of a population screening programme) or
- for transplantation – see the *Code of practice on donation of organs, tissue and cells for transplantation*.

48 The Act allows material taken from the living for any reason to be stored (and used) without consent for the following scheduled purposes on the basis that these are bound up with the general provision of clinical and diagnostic services:

- clinical audit
- education or training relating to human health
- performance assessment
- public health monitoring and
- quality assurance.

49 Consent is required to store tissue from the living for:

- obtaining scientific or medical information about a person which may be relevant to any other person (now or in the future)
- public display

<sup>11</sup> Scheduled Purposes Part 1 refer to purposes requiring consent from both the living and the deceased; Scheduled Purposes Part 2 refer to purposes requiring consent from the deceased only.

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- research into disorders, or the functioning, of the human body and
  - transplantation.
- 50 Consent should where possible be obtained for the use of tissue removed from the living for research. Where this is not possible, it is lawful for material taken from a living person to be stored without consent for research purposes only if:
- the research is ethically approved
  - the material is anonymised, and the researcher takes all necessary steps not to identify the person from whose body the material has come.
- 51 This does not necessarily mean that samples must be permanently and irrevocably unlinked – linking can be made through a third party where necessary – or that the person holding the samples cannot themselves carry out the research.
- 52 There may be occasions when a clinician involved in research may also have access to a secure database which would permit identification of a sample used in research. Providing the research material is coded and the researcher does not seek to link the tissue with the patient, the sample will still be regarded as non identifiable and research in this context is permissible without consent, if approved by a research ethics authority.

- 53 In general, obtaining consent is preferable to developing complex systems for keeping samples unlinked. It represents best practice and has the added benefit of facilitating ethical approval by a research ethics authority.

### **Storage of relevant material taken after death**

- 54 It is an offence under the Act to store relevant material taken after death without consent for any scheduled purposes, apart from material stored for coroners' or criminal justice purposes.

### **Non-consensual analysis of DNA**

- 55 It is an offence to have human tissue, including hair, nail and gametes in this context, with the intention of analysing its DNA without 'qualifying consent', subject to exceptions. (This is normally the consent of the individual from whom the tissue came or of those close to them if they have died.) This provision applies UK-wide. Medical diagnosis and treatment and criminal investigations, etc., are excluded from the offence. (See the *Code of practice on consent* for details of the consent requirements relating to DNA analysis and the permitted exceptions.)

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## Methods of storage

- 56 Organs and tissue should be stored in line with current good practice on:
- security
  - traceability, including information about risk. Records should detail the location of the materials
  - health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to staff or others.
- 59 NHS Trusts and other organisations should therefore develop local policies for reviewing holdings<sup>12</sup>. These should lay down:
- the frequency of review and
  - the criteria for disposal/further storage.
- 60 These policies should take account of the duty to the donors to make use of their donations wherever possible and therefore the prospects of the material being put to good use (see paragraphs 30–31 above).

## Appropriate storage period

- 57 In the wake of the controversy surrounding organ storage at Alder Hey and Bristol, the Chief Medical Officer recommended considering a time limit on the storage of organs and tissue. In practice, a single time limit could lead to the premature loss of important and useful collections of material or, alternatively, to material being stored for longer than necessary, simply because it would be kept for a fixed period.
- 58 Long-term storage in tissue banks for future research may be acceptable to many donors or their relatives who have given their consent for such storage. But, it should not be forgotten that one of the most consistent complaints of relatives distressed by organ storage was that tissue and organs had, in fact, simply sat on a shelf for years with no prospect of ever being used.

<sup>12</sup> See also RCPATH guidance on “The retention and storage of pathological records and archives (3rd edition, 2005).

# Disposal

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## Policy on disposal

- 61 NHS Trusts and other establishments which store or use human organs and tissue should develop a clear and sensitive disposal policy. It is good practice to document this policy and make it available to the public.
- 62 If relatives donate organs, tissue or a whole body to an NHS Trust or other establishment for anatomical examination, teaching or research, they may wish to know how the material will be disposed of after use. Clinicians should be prepared to discuss this issue with them, explaining the options available and who will be responsible for any associated costs.

## Organs/tissue removed from the living

- 63 The Act makes it lawful to treat as 'waste' any relevant material which has come from a person who was:
- in the course of receiving medical treatment
  - undergoing diagnostic testing or
  - participating in research.
- 64 It also states that material no longer used, or stored for use, for any scheduled purpose can be dealt with as waste.

- 65 Material taken from the living should normally be disposed of by incineration in accordance with current guidelines.<sup>13</sup> See Appendix B of this code for specific advice on the disposal of fetal tissue.

## The patients' wishes

- 66 Some patients may wish to retain tissue samples or make their own arrangements for disposal. Such requests should be considered on a case-by-case basis, assessing the risk to the patient and others. Patients should be given sufficient information to allow them to make an informed decision.

## Organs/tissue removed after death

- 67 Tissue and organs should be handled in accordance with any reasonable wishes expressed by relatives or the deceased person, as long as the method of disposal is legal. The time, place and method of disposal should be recorded.
- 68 Often the bereaved do not know what needs to be done following a death. A hospital's bereavement adviser/officer or the coroner's officer should explain that the deceased person's executor (if there is one) is responsible for the disposal of the body. They should be in a position to offer relatives or friends information about the options available for cremation, burial and/or funeral arrangements, the legal

<sup>13</sup> See *Safe disposal of clinical waste*, second edition, HSE books, 1999.

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requirements and any other relevant details. This information will probably be needed before relatives can make proper decisions about what happens to any tissue or organs stored at post mortem.

- 69 Healthcare professionals should be familiar with hospital arrangements (including those for babies born dead before 24 weeks' gestation), what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of organs and tissue. Such information should be available in writing (and in an appropriate language) for people to take away with them. They may wish to discuss it with relatives or community members before making a decision.
- 70 Basic disposal options are cremation or burial. There is usually a funeral or other religious or non-religious ceremony, either arranged by relatives or friends, with the hospital's help if requested, or arranged by the hospital.<sup>14</sup>
- 71 Relatives may want to be reassured about the suitability of any burial or other arrangements the hospital makes. They should be told what the hospital can provide, and that any additional requirements will be at their own expense.
- 72 If someone has given consent to the storage of tissue or organs, they should be offered the option of allowing the hospital
- to dispose of the residual material after its further examination or use. If material is to be incinerated, care should be taken to ensure that the method is appropriate to the material in question.
- 73 Alternatively, the hospital may offer to store the body until the organ can be returned to it. This may not always be practical in the case of long delays.
- 74 Relatives may wish the hospital to arrange for collection of tissue or an organ, usually by a funeral director of their choice, at some specified time after the post mortem examination. They can then make their own arrangements for cremation or burial.
- 75 Second funerals and burials of this nature can have significant emotional (and financial) implications. These should be discussed sensitively with those involved.
- 76 If the deceased person has already been buried or cremated, and relatives ask for the remaining tissue or organs to be returned later, these should be released:
- preferably to funeral directors acting for those who have legitimate responsibility for the disposal of the body
  - with authoritative confirmation of the identity of the tissue or organ and
  - with confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

<sup>14</sup> Hospitals should consider making arrangements for the respectful burial or cremation of the bodies of babies following stillbirth or neo-natal death ensuring that women or couples are enabled to express their wishes: see the Department of Health guidance "When a patient dies – advice on Developing Bereavement services in the NHS" [www.dh.gov.uk/publications](http://www.dh.gov.uk/publications).



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77 There is no legal bar to releasing stored material directly to relatives, but the proposed method of disposal must be lawful and safe and it may be difficult to ascertain this. The pathologist should notify the recipient, or the burial or cremation authorities, of any hazards associated with the tissue and its fixative and obtain confirmation that they are able to handle them appropriately. For example, formalin, commonly used as a fixative, can cause an allergic disease of the lungs and is a low-grade carcinogen.

78 Because of the potential health hazards, releasing organs and tissue directly to relatives for their indefinite storage is not generally advisable.

## Surplus material from tissue samples

79 The Act permits disposal as waste of material that has come from a body in the course of:

- receiving medical treatment
- undergoing diagnostic research or
- participating in research.

and material that:

- has come from a human body and
- ceases to be used, or stored for use, for scheduled purposes.

80 It is normal practice to dispose of such material by incineration. This includes:

- tissue fragments trimmed from the tissue sample before it is processed for histology
- the tissue in the sections trimmed from a wax-embedded block before the usable sections are cut and
- the unrecoverable bodily material that is washed out of the tissue during its processing into a wax block.

81 Relatives will expect remains to be disposed of with respect. As a minimum, stored human body parts, organs and tissue should be disposed of separately from other clinical waste.

## Existing holdings of unidentifiable, and identifiable but unclaimed, organs and tissue

82 There are particular sensitivities around disposing of organs and tissue that may have been acquired before current practices on obtaining consent. See Appendix A of this code for guidance.

## Fetal tissue

83 Guidance on the disposal of fetal tissue is provided at Appendix B.

# Appendix A

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## The disposal of existing holdings of unidentifiable, and identifiable but unclaimed, human tissue and organs

### Introduction

- A1** The guidance in this appendix takes account of advice from the Retained Organs Commission (ROC) to the Department of Health and the Welsh Assembly,<sup>15</sup> based on two rounds of consultation carried out by ROC in 2002 and 2003.
- A2** It advises establishments such as NHS Trusts, medical schools, museums, schools and colleges and the police, which may have existing holdings of human tissue and organs, on how to dispose of these holdings, once they have made the decision that they are no longer needed.
- A3** NHS Trusts should offer to help any local school or college wishing to dispose of existing holdings and help to arrange disposal on their behalf in accordance with this code.
- A4** This guidance only sets out how existing holdings can be disposed of once the decision has been made that they are no longer needed. It does not offer advice on deciding whether or how the material can be used, or whether or not it should be disposed of. The HTA's *code of practice on consent* includes guidance on the use of existing holdings. Guidance provided by the Royal College of Pathologists on

storage and storage periods may also be helpful in this regard.<sup>16</sup>

- A5** Where existing holdings include identifiable organs and tissue that have been retained at post mortem on a coroner's behalf to establish cause of death, the coroner's office must be consulted before disposal can take place. This is necessary to confirm that the coroner has satisfactorily completed their investigation into the case and is content for the material to be disposed of.
- A6** It is acceptable to continue to store some material for future use. This guidance is not intended to imply that it is either compulsory or always appropriate to dispose of existing holdings.

### Scope of the appendix

- A7** This appendix covers the disposal of:
- existing holdings of unidentifiable organs and tissue taken at post mortem examination and
  - existing holdings of identifiable, but unclaimed, organs and tissue stored from post mortem examination.

<sup>15</sup> June 2003: Final outcome report on consultation on the use and disposal of unclaimed and unidentifiable human organs and tissue (Retained Organs Commission). [www.nhs.uk/retainedorgans/publications.htm](http://www.nhs.uk/retainedorgans/publications.htm)

<sup>16</sup> The retention and storage of pathological records and archives. Royal College of Pathologists. Third Edition 2005 [www.rcpath.org.uk](http://www.rcpath.org.uk)

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A8 It does not advise on the use of unidentifiable and unclaimed post mortem organs and tissue for research.

A9 It is intended for use by those involved in formulating local policy and in making decisions on the disposal of existing holdings of human organs and tissue (including stored fetal tissue and the bodies of stillborn babies).

A10 It is not intended to be used to provide information to patients or bereaved families.

A11 This document advocates a flexible approach and does not attempt to address every possible scenario. This is because there are many circumstances that may lead to the need to dispose of human organs and tissue separately from the rest of the body. Decisions should be taken on a case-by-case basis.

A12 It includes guidance on:

- the disposal of material taken at post mortem or as part of an anatomical examination and
- stored fetal tissue and the bodies of stillborn babies

If samples are unidentifiable, it can be assumed they are from a post mortem examination and therefore fall under the remit of this guidance.

A13 It excludes:

- the disposal of organs and tissue taken from the living (except in the case of stored fetal tissue and the bodies of stillborn babies)

If the existing holdings contain identifiable stored samples known to have been taken from the living, even if those individuals are now known to be dead, these can be incinerated in the same way as any other sample of tissue taken from a living person.

- embryos outside the human body (see advice given in the *Human Fertilisation and Embryology Authority Code of Practice*<sup>17</sup>) and
- hair and nail from the body of a living person.

A14 This guidance does not distinguish between different types of tissue, i.e. it covers whole organs, tissue and blocks and slides.

## Criteria to confirm genuinely unidentifiable organs and tissue

A15 Organs and tissue may be considered to be unidentifiable if:

- there is no label or identification mark of any description on the organ or tissue sample
- there is a label or identifying mark, but this cannot be linked to any existing register or record, or

- 
- there is a label or identifying mark which can be linked to a register or record, but the identification requires links with other registers or records that no longer exist.

## Making a decision about disposal

**A16** There is no time limit on the storage of human organs and tissue donated under the Human Tissue Act 2004. Existing anatomical specimens that have been donated under the Anatomy Act 1984 should be disposed of within three years of the date of the donor's death, unless consent has been given for further storage beyond this time.

**A17** Establishments that have existing holdings of human organs, tissue and blocks and slides need to decide whether particular samples can and should be disposed of.

**A18** Decisions about the disposal of existing holdings should reflect the following three categories:

- existing holdings that are unidentifiable according to the criteria in this code. If such holdings are no longer to be stored, they should be disposed of in the same way as other material post mortem is now treated. (Guidance on disposal is provided in paragraphs A33–A40 below.)

- existing holdings that are identifiable, and about which contact has been made by relatives.

Unless a commitment has been made to relatives to do otherwise, no holdings in this category should be disposed of. They should be stored until relatives feel able to make their wishes clear. There is no need to make further contact with relatives. Nor is it necessary for them to contact the Trust again to ensure storage is continued unless and until they wish to do so.

- existing holdings which are identifiable but about which no contact has been made by relatives.

It is reasonable for NHS Trusts and other establishments to consider whether to dispose of identifiable but unclaimed organs and tissue. Trusts should allow a period of 12 months from the date on which the Department of Health lifts its moratorium on disposal of existing holdings before taking any action<sup>18</sup>. During this period relatives may make contact with Trusts if they so wish, although Trusts should not initiate contacts. Trusts planning to dispose of such holdings will need to consider what level of local publicity is appropriate in the light of the size of the Trust holdings and any action taken so far; as well as any announcement made by the Department of Health.

<sup>18</sup> This twelve month period will not apply in Northern Ireland, where an extensive publicity campaign has already taken place.

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## Fetal tissue and the bodies of stillborn babies

- A19** Where existing holdings include stored fetuses and fetal tissue, establishments holding these samples will need to ask the same questions relating to their disposal as have been set out elsewhere in this guidance.
- A20** Where the holding is a whole body of what is believed to be a stillborn child, an individual burial or cremation is desirable. Disposal by incineration is not appropriate. This is consistent with existing best practice for hospitals to arrange and pay for the burial and cremation of stillbirths in hospital and the community.<sup>19</sup>

## Documentation and record-keeping

- A21** Once a decision has been made to dispose of any identifiable but unclaimed samples from existing holdings, it is essential that the reasons for disposal and the method used are carefully documented. Bereaved relatives may continue to enquire about organs and tissue that may have been taken during post mortem examinations of their family member. It may be that organs and tissue were stored and have been subsequently disposed of in accordance with this guidance – if this is the case, the bereaved relatives should be given full information in a sensitive manner.

- A22** Being able to respond effectively to these enquiries depends on reliable tracking and good record-keeping. The importance of appropriate and accurate record-keeping cannot be emphasised enough.
- A23** NHS Trusts and other establishments that have existing holdings of human organs and tissue should develop a clear and sensitive disposal policy which can be discussed with the bereaved. This policy should be documented and made available to the public.
- A24** If relatives are involved in the donation of organs and tissue or a whole body for use by an NHS Trust or other establishment for anatomical examination, teaching or research, they may wish to know how the material will be disposed of after use. Clinicians should be prepared to discuss this with them, explaining the options available and who will be responsible for any associated costs.
- A25** The various disposal options for different types of tissue are set out below.

## Deciding on the appropriate disposal method

- A26** Organs and tissue should be treated with respect, without placing a disproportionate burden on staff or resources. The disposal method as well as the degree and nature of any

<sup>19</sup> Health Service guidelines (91)19 – The welfare of children and young people in hospital, Department of Health, 22 July 1991 <http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tissue/TissueGeneralInformation/fs/en>. Northern Ireland has also produced guidance on this topic: 'Careplan for Women who experience a miscarriage, stillbirth or neonatal death'.

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accompanying ceremony will be influenced by the nature of the tissue involved.

**A27** Dignified treatment and separate disposal are the minimum requirements for disposing of stored organs and tissue.

This means disposal should be carried out separately from clinical waste, not that each tissue sample should necessarily be disposed of individually. A simple non-religious but respectful ceremony may be appropriate.

**A28** However, NHS Trusts and other establishments, working with interested local groups, may wish to vary the degree of ceremony involved in the disposal, depending on the nature of the tissue concerned.

**A29** An example of such collaborative local policy-making is the burial of a large number of unidentifiable fetuses in Liverpool. This project was led by the NHS Trust, but involved consultation with a large number of local organisations to agree a disposal method that was locally and legally acceptable.

**A30** Trusts may wish to consider contacting or involving local religious leaders regarding their planned policies for disposal of existing holdings, especially if it is known that a large number of samples are from members of a particular faith.

**A31** If samples are identifiable, but unclaimed and known to be from a person of a particular faith, it may be appropriate

to approach local faith leaders to see if they would be willing to dispose of the organs and tissue appropriately. Alternatively, they may advise on the proper disposal of these samples.

**A32** In keeping with medical confidentiality, the identity of the individual from whom the organs and tissue were taken must never be disclosed.

## Disposal options for different types of tissue

### Incineration

**A33** Unidentifiable, or identifiable but unclaimed, organs and tissue stored following a post mortem examination may be incinerated.

### Burial

**A34** An establishment wishing to bury unidentifiable, or identifiable but unclaimed, organs and tissue should consult the local burial authorities to establish what level of service they can provide. If the establishment wishes to bury this material, and a service is not available locally, they may wish to contact other service providers further afield.

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## Cremation

A35 Cremation of body parts, organs and tissue is possible under the Cremation (Amendment) Regulations 2006<sup>20</sup> providing that:

- the death of the person was duly registered and
- an application for the cremation of the organs and tissue has been made by an appropriate person on the proper forms.

A36 If the crematorium's medical referee is not satisfied, then the Secretary of State may still permit the cremation in exceptional circumstances.

## Tissue blocks and slides

A37 As above, for the incineration and burial of organs and tissue.

A38 Although there is no legal barrier to cremating tissue blocks and slides, crematoria have discretion about what they may accept.

## Skeletons and bones

A39 As above, for the incineration and burial of organs and tissue.

A40 Skeletons and bones are likely to be unidentifiable, so disposal should follow the guidance for unidentifiable tissue.

<sup>20</sup> Different cremation legislation applies in Northern Ireland. Responsibility for this legislation lies with the Department of the Environment (NI).

# Appendix B

## Disposal following pregnancy loss before 24 weeks' gestation

### Scope of the appendix

- B1** This appendix is intended to help healthcare professionals to develop or modify their hospital's policy on disposal following pregnancy loss before 24 weeks' gestation. It refers to advice previously given in HSG(91)19<sup>21</sup> and replaces the advice given in EL(91)144,<sup>22</sup> which is hereby revoked. The issues covered in this advice were consulted on by the Department of Health in the 2002 consultation *Human Bodies, Human Choices*<sup>23</sup>.
- B2** The advice is suitable for developing policies on the disposal of fetal tissue resulting from a number of different pregnancy losses, including ectopic pregnancies, miscarriages, early intrauterine fetal deaths and termination for abnormality or for social reasons. It should not be used to give information to patients.
- B3** The term 'fetal tissue' is used throughout for consistency, although it is recognised that 'pregnancy loss before 24 weeks' covers a large developmental range and many different kinds of loss.
- B4** Although this advice does not mention the need for consent, hospitals should be aware that consent from a person with parental responsibility may be needed for some forms of disposal in their locality. A person who has parental responsibility will usually, but not always, be the child's parent.<sup>24</sup>
- B5** Pregnancy loss is a very difficult area of policy development and this appendix is not comprehensive. It aims to cover the main issues and suggests sources of further information.
- B6** Pregnancy loss should always be handled sensitively. The needs of the woman or couple should be paramount and disposal policies should reflect this.
- B7** This appendix does not apply to the following:
- Stillbirths and neonatal deaths  
Any baby, irrespective of gestational age, that is born alive and then dies immediately afterwards is a live birth and neonatal death and should be treated as such in terms of registration and disposal.
  - Unidentifiable stillbirths that have been stored for teaching or research  
See Appendix A of this code for advice on the disposal of existing holdings of fetal tissue and the bodies of stillborn babies.
  - Embryos created in vitro which have not been transferred into a woman

<sup>21</sup> Health Service guidelines (91)19 – *The welfare of children and young people in hospital*, Department of Health, 22 July 1991  
<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tissue/TissueGeneralInformation/fs/en>

<sup>22</sup> Executive letter – *Sensitive disposal of the dead fetus and fetal tissue*, 12 December 1991

<sup>23</sup> See guidance produced by Northern Ireland: '*Careplan for Women who experience a miscarriage, stillbirth or neonatal death*'.

<sup>24</sup> The category of persons with parental responsibility is as set out in the Children Act 1989 as amended. Further guidance is available in the Department of Health's *Reference guide to consent for examination and treatment*.



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These are covered by the Human Fertilisation and Embryology Act 1990 and disposal should be in accordance with the Human Fertilisation and Embryology Authority's Code of Practice.<sup>25</sup>

## Storage of fetal tissue before disposal

**B8** All fetal tissue should be stored in accordance with previous Department of Health guidance prior to disposal.<sup>26</sup>

## Disposal options

- B9** A woman or couple should be told that information on disposal options is available if they wish to see it. When providing information, account should be taken of the language spoken and any reading difficulties.
- B10** It should be clearly documented in the woman's medical notes whether or not information has been requested and whether it has been given.
- B11** The information provided should explain who to contact to request a particular disposal option and the timescale for this. Any personal, religious or cultural needs relating to the disposal of the fetal tissue should be met wherever possible and should be documented in the woman's medical notes.

**B12** All healthcare professionals should be aware of and sensitive to the values and beliefs of a wide range of cultures and religions, particularly those of their local community. They should also be aware that every decision is one for the individual concerned. Organisations should ensure that the necessary training and support is given, so that employees are equipped to identify and meet the widest possible range of needs and wishes.

**B13** Some women or couples may not wish to know about, or take part in, the disposal of the fetal tissue. Providing they have been told that the information is available, their wishes should be respected.

**B14** A woman or couple may decide to arrange disposal themselves and they are free to do so.

## Burial

**B15** Fetal tissue can be buried providing there has been consultation with the woman or couple, where appropriate. Hospitals/clinics wishing to bury fetal tissue should consult the local burial authorities to establish what level of service is available. If they wish to offer burial, and this service is not available locally, they might consider contacting other service providers further afield. Communal burial is permitted for fetal tissue.

<sup>25</sup> Human Fertilisation and Embryology Authority, Code of Practice, Sixth Edition, 2003

<sup>26</sup> Health Service guidelines (91)19 – Disposal of Fetal Tissue, 12 November 1991. In Northern Ireland, storage should be in line with the Standards for the management of post mortem examinations.

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**B16** A woman or a couple can bury fetal tissue at home, if they wish, providing certain criteria have been fulfilled. The tissue should be supplied in a suitable opaque container. It may be necessary to contact local authorities to discuss this option.

### **Cremation**

**B17** Although not covered by the Cremation Regulations, fetal tissue can be cremated, providing there has been consultation with the woman or couple where appropriate. Some crematoria are willing to provide a service to dispose of fetal tissue, but this is at their discretion. Hospitals/clinics wishing to cremate fetal tissue will need to negotiate with the local crematoria to establish what level of service can be provided. If this service is not available locally, they might consider negotiating with other service providers further afield. Communal cremation for fetal tissue may be permitted by some crematoria.

**B18** Women or couples should be told that the cremation of fetal tissue does not produce any ashes for them to scatter.

### **Incineration**

**B19** Fetal tissue from a pregnancy lost before 24 weeks may be incinerated, although how appropriate this is depends on the individual circumstances. A woman or couple should be told that information on disposal options is available and they should be given the opportunity to express any personal wishes.

**B20** Incineration should be carried out in accordance with previous Department of Health guidance.<sup>27</sup> The maceration and sluicing method of disposal is not permitted for fetal tissue.

### **Development of NHS Trust policies**

**B21** In drafting their policies, NHS Trusts may wish to take into account gestational age and the nature of the fetal tissue.

**B22** Women or couples may seek information about the Trust's policy on the disposal of fetal tissue. All appropriate staff should therefore be aware of policy and practice and be prepared to discuss these issues sensitively.

### **Fetal tissue resulting from abortions carried out by private clinics on behalf of the NHS**

**B23** Healthcare professionals may wish to discuss issues relating to the disposal of fetal tissue with the independent sector clinic carrying out abortions on the hospital's behalf.

### **Reference material available on this subject**

**B24** NHS Trusts may wish to refer to two documents that address this issue in some detail:

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*Pregnancy loss and the death of a baby: Guidelines for professionals*, Nancy Kohner – published by the Stillbirth and Neonatal Death Society, 1995;<sup>28</sup>

- Royal College of Pathologists
- Stillbirth and Neonatal Death Society
- Welsh Assembly Government

*Sensitive disposal of all fetal remains* published by the Royal College of Nursing, 2001.<sup>29</sup>

In Northern Ireland, the relevant guidance is the *Careplan for Women who experience a miscarriage, stillbirth or neonatal death*.

**B25** Healthcare professionals are encouraged to build professional networks to help support the development and modification of their NHS Trust policy.

**B26** This advice was developed by the Department of Health in association with representatives from:

- Antenatal Results and Choices
- British Pregnancy Advisory Service
- Child Bereavement Trust
- Confidential Enquiry into Maternal and Child Health
- Department of Health, Social Services and Public Safety (Northern Ireland)
- Marie Stopes International
- Miscarriage Association
- Nursing and Midwifery Council
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists

<sup>28</sup> [www.uk-sands.org](http://www.uk-sands.org)

<sup>29</sup> [www.rcn.org.uk/members/downloads/disposal\\_fetal\\_remains.pdf](http://www.rcn.org.uk/members/downloads/disposal_fetal_remains.pdf)

# Glossary

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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<sup>30</sup> 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.

<sup>30</sup> Wherever the term 'organ' is referenced, this also includes 'part organs'.

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**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<sup>31</sup> 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'<sup>32</sup> 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.

<sup>31</sup> The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

<sup>32</sup> Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

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**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<sup>33</sup>, 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.

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**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.<sup>34</sup>

**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.

<sup>34</sup> 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.

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**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,



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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<sup>22</sup> 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.

# Background reading

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*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 2003