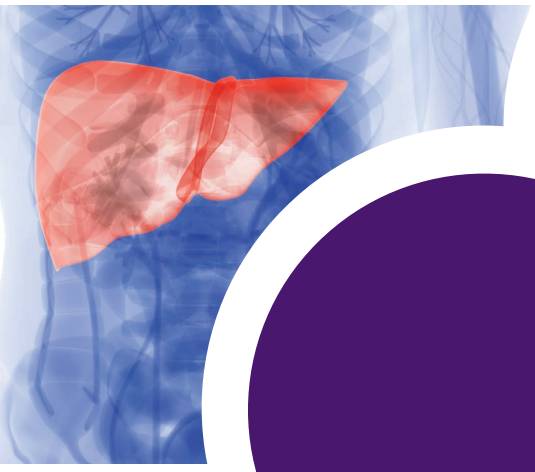
HTA
Human Tissue Authority

Code of practice 5
Disposal of human tissue



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Code 5: Disposal of human tissue

Contents

Introduction

The legislation and the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) covers England, Wales and Northern Ireland with the exception of the provisions relating to the use of DNA, which also apply to Scotland. The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006.

2. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) implement the European Union Tissue and Cells Directives (EUTCD). The HTA is the Competent Authority in the UK under the Q&S Regulations, which cover the whole of the UK, including Scotland.

3. The HTA is also the Competent Authority in the UK for the implementation of the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Directive). The requirements of the Directive are transposed into UK law via the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q & S Organs Regulations).

4. The HTA's remit in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 (Ref: NHS HDL (2006) 46) and the relevant codes of practice. Relevant guidance from Wales and Northern Ireland is referenced throughout the codes.

5. On 1 December 2015 an opt-out system for organ donation after death will become operational in Wales, the legislation on this is the Human Transplantation (Wales) Act 2013. The HTA has drafted a Code of Practice to provide advice and guidance on the Human Transplantation (Wales) Act. At the time of drafting this Code of Practice, the Code of Practice on the opt-out system in Wales had not yet gained Parliamentary or Welsh Assembly approval, however a copy of the draft document is available on the HTA website.

6. The Code of Practice on the Human Transplantation (Wales) Act 2013 should not be relied on until the law becomes operational on 1 December 2015. Up until that time the HTA's Code of Practice 2 is the relevant document.

About the codes of practice

7. The codes of practice give practical guidance to professionals carrying out activities which lie within the HTA's remit. They may also be of interest to members of the public. The first editions of the codes have been revised to reflect our experience of regulation and to update references to guidance from other organisations.

8. The codes are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA's website.

9. The HTA has now published nine codes of practice, which are listed below:

    1. Consent
    2. Donation of solid organs for transplantation
    3. Post-mortem examination
    4. Anatomical examination
    5. Disposal of human tissue
    6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
    7. Public display
    8. Import and export of human bodies, body parts and tissue
    9. Research

10. All nine codes of practice were originally brought into force by HTA Directions in September 2009.

Using the codes

11. In these codes, the word '**must**' refers to an overriding duty or principle, including all specific legal requirements derived from primary and secondary legislation – for example, the requirement to hold a licence to store human tissue for a scheduled purpose.

12. We use the word '**should**' when explaining how to meet the specific legal requirements. Establishments are expected to follow the guidance in the codes. Observance of the guidance in the codes is one of the ways in which the HTA assesses that establishments are complying with relevant legislation. Failure to follow a code of practice is not in itself a criminal offence under the HT Act but the HTA will carefully consider any breach of a code of practice and may take appropriate regulatory action.

13. The codes complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the

HTA's website. A glossary with terms specific to each code is available at the end of each document.

14. You can download and print copies of the codes from the HTA's website.

Other advice and guidance

15. A number of other organisations have also produced guidance on issues in the HTA's remit. Where this has been produced in collaboration with the HTA, it will appear on our website. The HTA's codes of practice and other guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Scope of this code

16. This code applies to the disposal of any human tissue which falls within the definition of 'relevant material' and is within the HTA's remit, as set out in the HT Act. The HTA has provided separate guidance in this area.

17. This code provides a model of good practice for all those involved in disposing of human tissue, whether from the living or the deceased. Disposing of human tissue from the deceased involves a different set of approaches and considerations from disposing of tissue from the living, as is explored in the code (see paragraphs 34–60).

18. This code does not cover disposal following pregnancy loss. The HTA will has issued separate guidance on the disposal of pregnancy remains, which reflects the very sensitive nature of these. Guidance is published on the HTA website.

Structure and navigation

19. All those involved in the disposal of human tissue from the deceased and / or the living should take into account the general provisions set out in the first section of the code.

20. In addition, there are different considerations involved in disposing of human tissue, depending on whether the tissue is from the deceased or the living; these are set out in later sections of the code.

21. Each section addresses the range of disposal options that are most appropriate. Any particular considerations that need to be taken into account are also included.

22. As the code is designed for different groups of users to consult, parts of its guidance are necessarily repeated, as users may in practice refer only to section/s which apply to their own particular circumstances.

Status of this code

23. Amendments were made to Code of Practice 5 – Disposal of human tissue in July 2014. These amendments were made to remove factual inaccuracies stemming from changes to the law, HTA policy decisions, and legal advice on the interpretation of the HTA's statutory remit. These amendments have not received Parliamentary approval, which will not be sought until the next full review of all HTA Codes of Practice. This is currently planned for 2015. The Department of Health, the Welsh Government and Department of Health, Social Services and Public Safety in Northern Ireland were consulted on these amendments. A copy of Code 5 as approved by Parliament is available on request from the HTA.

General guidance

Introduction

24. The HT Act and the HTA's codes of practice aim to ensure that human tissue is treated and used in accordance with the wishes of donors or their relatives. This code provides guidance to help establishments develop appropriate policies for disposal of human tissue which recognise the nature of the material being handled, the sensitivity of the feelings of the bereaved and the need for clarity when providing information.

25. Human tissue should be treated with respect, without placing a disproportionate burden on staff or resources. The guidance in this section applies to those involved in disposal of tissue from the deceased and the living, and covers existing holdings of tissue. It will also help a Designated Individual (DI) to supervise suitable practices as part of the HTA's licensing requirements.

Development of disposal policy

26. Processes should be in place to inform individuals, or their relatives, how tissue will be disposed of after use. Staff should be prepared to discuss the issue of disposal, explaining the options available and who will be responsible for any associated costs.

27. Staff should be familiar with the establishment's arrangements, including what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. They may wish to discuss it with relatives or community members before making their choice.

28. *Example – An establishment has worked with the local coroner to produce an information leaflet about relatives' options for disposal or retention of tissue following a post-mortem examination. This document reflects the establishment's disposal policy and associated restrictions, for example it notes that local crematoria will not accept blocks and slides, so this option is not available for this type of material. The leaflet provides information for relatives to help inform their choice, including that the cremation of organs will not produce any ashes and that returning the material to the body may delay funeral arrangements. The document also contains useful contacts at the establishment storing the material, the local crematoria and the burial grounds.*

Religion, belief and culture

29. Attitudes towards disposal may vary widely among cultures and religions. Staff should be sensitive to this, being aware that choices are for the individual or relative to make.

30. Establishments should ensure that their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes.

Communication

31. All establishments should give particular consideration to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person concerned (e.g. because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.

Maintaining proper documentation

32. Establishments should ensure that they have systems in place to maintain proper records and documentation for all tissue they acquire or pass on to others. Records should include:

1. when the material was acquired, and where from
2. what has been consented to
3. the uses to which the material is put whilst in the establishment's care and any processes applied to it
4. when the material is transferred elsewhere, and to whom
5. disposal details.

33. The HTA regulates the removal, storage and use of relevant material, but the management of related data and records remain the establishment's responsibility. The period of time for the retention of such documentation is a decision that should be made locally and in line with the establishment's policy and DH guidance. RCPath guidance on records and specimens retention is also a useful resource. Establishments storing tissue for human application must follow the requirements on retention of documentation under the Q&S Regulations and set out in HTA Directions.

Disposal of tissue from the deceased

Communication

34. If a deceased person has been the subject of a post mortem examination, tissue may have been retained. This tissue should be handled in accordance with any reasonable wishes expressed by the deceased person or their relatives, as long as the method of disposal is legal.

35. The deceased person or their relatives may have expressed wishes for the tissue samples to be retained for future use or made their own arrangements for disposal. Such requests should be considered on a case-by-case basis by the holding establishment, assessing the risks involved. Sufficient information about the disposal options should be given to allow informed choices to be made. The establishment should make a decision based on its understanding of the risk associated with releasing the material in question.

36. Often the bereaved do not know what needs to be done following a death. The bereavement adviser or the coroner's officer should be in a position to offer information to relatives about the options available for cremation, burial and funeral arrangements, the legal requirements and any other relevant details. This information will probably be needed before relatives can make proper decisions about what happens to any tissue retained at post-mortem examination (see paragraphs 53–59).

37. Bereaved relatives may enquire about tissue that was taken during post-mortem examination some time later. It may be that tissue has 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. For more information about communicating with the bereaved in relation to coroners' post-mortem examinations see the Ministry of Justice (MoJ).

Handling of tissue

38. This code sets out the main disposal options; the chosen disposal method should reflect the type of tissue and the relatives' wishes where possible, in order to ensure respectful disposal. Those who are responsible for the packaging and disposal of the material should familiarise themselves with this code.

Disposal options

39. If someone has given consent to the storage of tissue, they should be offered the option of allowing the establishment to dispose of the material after its further examination or use.

40. Currently, basic disposal options are incineration, cremation or burial (see paragraphs 47–52 and Appendix A). The HTA's role is to empower establishments to make decisions locally about the most suitable methods of disposal in each case. The HTA encourages establishments to have a disposal policy that they might make available to the public (see paragraphs 26–28). Establishments should be open about their processes so relatives have the information required to make an informed choice.

41. Where an organ has been removed at post-mortem examination, the establishment may offer to store the body until the organ can be returned to it. This may not always be practical as there may be a long delay; in these cases, the consequences should be explained to relatives. Where a body is released without an organ, relatives should be made aware that this is the case.

42. Relatives may want a funeral director of their choice to collect tissue or an organ after the release of the body, and to make their own arrangements for cremation or burial. Second funerals and burials of this nature may have significant emotional (and financial) implications. These should be discussed sensitively with those involved.

43. If the deceased person has been buried or cremated, and relatives ask for the remaining tissue to be returned later, this should be released:

1. preferably to funeral directors acting for those who have legitimate responsibility for the disposal of the body
2. with authoritative confirmation of the identity of the tissue or organ
3. with confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

44. There is no legal rule preventing the release of stored material directly to relatives, but the proposed method of disposal must be lawful and safe. This may not always be easy to establish. The establishment must act in accordance with any relevant legislation to ensure the recipient, or burial or cremation authorities, are aware of any hazards associated with the tissue and its fixative and confirm they can 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.

45. Because of the potential health hazards, releasing tissue directly to relatives for its indefinite storage is generally not advisable. Establishments should make an assessment based on the risks involved and the possible consequences of releasing the material. Further guidance on disposal options is set out below.

Incineration

46. Tissue removed from the deceased for use for scheduled purposes may be incinerated after use; care should be taken to ensure that this method is appropriate to the nature of the tissue.

Burial

47. An establishment wishing to bury tissue from the deceased 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 as appropriate.

48. The HTA recognises that local circumstances vary and is mindful of the practicalities involved in securing separate incineration. Where practical, human tissue that is incinerated should be bagged separately from clinical waste. It is not necessary for each tissue sample to be disposed of individually.

49. Relatives may want to be reassured about the suitability of burial or other arrangements. They should be told what the establishment may provide, and that any additional requirements will be at their own expense.

Cremation

50. Although there is no legal barrier to cremating tissue blocks, crematoria have discretion about what they may accept. Crematoria have particular concerns about material on glass slides because of health and safety issues.

51. Cremation of human tissue is possible under the Cremation (England and Wales) Regulations 2008 providing that:

    1. the death of the person was duly registered;
    2. an application for the cremation of the tissue has been made by an appropriate person on the proper forms; and
    3. a certificate on release of body parts has been provided by the holder or, if not possible to provide such a certificate, other evidence that the body parts were removed in the course of a post-mortem examination.

52. The Cremation (England and Wales) Regulations 2008 do not apply to Scotland. It should also be noted that different cremation legislation applies in Northern Ireland and that responsibility for this legislation lies with the Department of the Environment (NI).

Disposal following coroners' post-mortem examinations

53. It is an offence under the HT Act to remove relevant material from a deceased person for any scheduled purpose without appropriate consent, unless it falls under the coroner's authority. For further information, see the code of practice on consent which deals with the general principles of consent under the HT Act, and the code of practice on post-mortem examination.

54. Once the coroner's authority has ended, it is not lawful to use or store tissue for a scheduled purpose without consent. Nor is it lawful to store tissue for a scheduled purpose without an HTA licence, subject to certain exemptions. The Coroners Rules place an obligation on the coroner to inform the family of the deceased person what their options are once the coroner's authority has ended (see the Ministry of Justice (MoJ) website for information on coroners). It is important that the family understand the options available to them to enable them to make a fully informed decision. The three options are:

    1. to ask that the tissue be disposed of; or
    2. to ask for the tissue to be returned to them; or
    3. to consent to the use of the tissue for medical research or other purposes in accordance with the HT Act.

55. When the coroner has communicated the family's decision to the pathologist or establishment holding the material, the pathologist should act on this information as soon as possible following the expiry of the coroner's authority. Problems arise when relatives do not, or cannot, communicate their decision about what they wish to happen to the tissue. This creates uncertainty about the lawfulness of retention beyond expiry of the coroner's authority. Therefore, coroners should, when advising families about the options for disposal, ask the family to make a decision by the time that appropriate forms are issued by the coroner enabling release of the body for burial or cremation.

56. *Example – A coroner's investigation has included a post-mortem examination. The coroner's officer has attempted to discuss the disposal of tissue removed during the post-mortem examination with the family, but they have said they are too upset by their bereavement to contemplate the question. Despite their bereavement they still also have to decide about their options for funeral arrangements. The coroner's officer respectfully and sensitively obtains a specific decision on the disposal / retention options when they discuss the various funeral options. The decision is then communicated immediately to the pathologist who takes the appropriate action as soon as possible following the expiry of the coroner's authority.*

57. Good communication between coroners and pathologists is essential in order to ensure that tissue is not stored indefinitely without consent. The HTA recommends that a nominated person is identified to handle the communications channels between the pathology department and the coroner's office and, where necessary, the family. The nominated person should ensure that decisions are passed to and within the pathology department, and that there is no uncertainty about tissue disposal or retention when the coroner's authority has expired. The HTA has published a model communication flowchart to support good communication between coroners and pathologists.

58. If the family do not, or cannot, communicate their decision about what they wish to happen to the tissue, the nominated person should advise that the tissue will be held for three months by the pathology department from the time the coroner's authority ends, pending notification of a decision by the family. It should be made clear that if no decision is communicated within that time, the tissue will be disposed of. In such situations, the nominated person should inform the pathology department that the family have not made a decision, and at the end of the three month period, the tissue should be disposed of respectfully (further guidance is provided throughout this code).

59. It is important that the family understands what may be involved if they consent to the continued retention and use of the tissue for medical research or other

purposes. Appropriate consent should be sought in line with the provisions set out in the code of practice on consent (see sections on nominated representatives and qualifying relationships). Where a family gives their consent for tissue to be retained, they should be made aware that this does not guarantee use of the tissue, which may be disposed of if no use can be found for it.

Criminal investigations

60. Material taken or retained under police authority is not subject to the provisions of the HT Act with regard to disposal. However, section 5.8.6 of Home Office guidance on Legal Issues in Forensic Pathology and Tissue Retention, requires the police, where practical, to dispose of the material in compliance with the HTA's requirements. See the code of practice on post-mortem examination for further guidance.

Disposal of existing holdings

Introduction

61. An existing holding is material (identifiable or unidentifiable) that was stored for use for a scheduled purpose when the HT Act came into force on 1 September 2006. This does not include material that was obtained and stored after that date and is being stored because relatives' wishes are still not clear.

62. This section advises establishments such as NHS Trusts, medical schools, museums, schools and colleges, and the police, which may have existing holdings of human tissue, on how to dispose of these holdings, once they have decided they are no longer needed.

63. If any NHS Trusts have collections of existing holdings that are considered by clinicians to be valuable for teaching, they should review the usefulness of the collection on a regular basis and, where items are found not to be of value, they should be disposed of sensitively and respectfully and the details documented.

64. Establishments may wish to consult the code of practice on consent when considering the use of existing holdings. It may also be helpful to consult joint guidance produced by the Royal College of Pathologists and Institute of Biomedical Science on The retention and storage of pathological records and specimens.

65. The guidance in this section advocates a flexible approach and does not attempt to address every possible scenario. This is because there are many

circumstances that necessitate disposal of human tissue separately from the rest of the body. Decisions should be taken on a case-by-case basis.

66. This section covers the disposal of existing holdings of:

    1. unidentifiable tissue taken at post-mortem examination
    2. identifiable (but unclaimed) tissue stored from post-mortem examination.

67. Where existing holdings include stored fetuses and fetal tissue, establishments should refer to the HTA's guidance on disposal of pregnancy remains.

Unidentifiable tissue

68. Unidentifiable tissue may include blocks and slides, organs, skeletons and bones. If samples are unidentifiable, it may be assumed they are from a post-mortem examination and are therefore covered by this guidance.

69. Decisions about the disposal of existing holdings should reflect whether they 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 post mortem material.

70. Tissue may be considered to be unidentifiable if:

    1. there is no label or identification mark of any description on the organ or tissue sample
    2. there is a label or identifying mark, but this cannot be linked to any existing register or record
    3. there is a label or identifying mark which may be linked to a register or record, but the identification requires links with other registers or records that no longer exist.

71. Since the Department of Health lifted its moratorium on the disposal of existing holdings of post mortem tissue in July 2007, it has been reasonable for establishments to consider whether to dispose of unidentifiable tissue. (The Welsh Assembly Government lifted its moratorium on the disposal of existing holding of post mortem tissue in August 2007.) Establishments should consider the most appropriate method of disposal for this material.

72. If the material is to be retained for use for scheduled purposes, it should be given a unique identification number and the establishment should ensure that traceability records are maintained.

73. Dignified treatment and separate disposal are the minimum considerations involved in disposing of stored tissue. This means disposal should be carried out separately from clinical waste, but not that each tissue sample necessarily needs to be disposed of individually see paragraph 48 for further detail). Arrangements for respectful and sensitive disposal should be made at local level. The establishment may wish to hold a simple but respectful ceremony.

74. Establishments 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. These arrangements should be negotiated with establishments locally where possible, or those further afield where it is not.

75. Where human tissue disposal is contracted to another establishment, the responsibility for compliance with the codes of practice and the HT Act lies with the department contracting such services. It may therefore be advisable to have formal agreements or Service Level Agreements (SLAs) in place as part of this process.

Disposal options

Incineration

76. Unidentifiable tissue stored following a post-mortem examination may be incinerated.

Burial

77. An establishment wishing to bury unidentifiable tissue should consult the local burial authorities to establish what level of service they may provide, as it is at the discretion of the Local Authority. 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 as appropriate.

Cremation

78. Where samples are unidentifiable, it will not be possible to cremate the material due to the necessary accompanying documentation stipulated under The Cremation (England and Wales) Regulations 2008.

Identifiable tissue

Introduction

79. Identifiable tissue may include blocks and slides, organs, skeletons and bones. Decisions about existing holdings that are identifiable should cover the following:

    1. for existing holdings that are identifiable and about which relatives are in contact: where an establishment is in contact with 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.
    2. for existing holdings which are identifiable but are unclaimed: where contact has not been made with relatives, it is reasonable for establishments to consider whether to dispose of identifiable but unclaimed tissue (see paragraph 71).

80. There may be cases where an establishment has been in contact with relatives but no decision was made by them about what to do with any existing holding/s, and contact is subsequently lost. In such cases, if despite an establishment's reasonable efforts to contact relatives again, there is still no further contact by relatives, any existing holding/s may be considered unclaimed. It would then be reasonable for establishments to consider whether to dispose of this identifiable unclaimed tissue. For information on maintaining proper documentation see paragraphs 32-33.

81. If the material is to be retained for use for scheduled purposes, the material should be given a unique identification number and the establishment should ensure that traceability records are maintained. If the existing holdings are not required the establishment should ensure that records detailing the method and reason for disposal are maintained.

Handling of tissue

82. Dignified treatment and separate disposal are the minimum considerations involved in disposing of stored tissue. This means disposal should be carried out separately from clinical waste, but not that each tissue sample necessarily needs to be disposed of individually (see paragraph 48 for further detail). Arrangements for respectful and sensitive disposal should be made at local level. The establishment may wish to hold a simple but respectful ceremony.

83. Establishments 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. These arrangements should be negotiated with establishments locally where possible, or those further afield where it is not.

84. Establishments that hold a large number of samples from members of a particular faith may wish to consider contacting or involving local religious leaders regarding their planned policies for disposal of existing holdings. It may be appropriate to approach local faith leaders to see if they would be willing to dispose of the tissue appropriately. Alternatively, they may advise on the proper disposal of these samples.

85. In keeping with medical confidentiality, the identity of the individual from whom the tissue was taken must not be disclosed.

86. Where existing holdings include identifiable tissue that has been retained at post-mortem examination on a coroner's behalf to establish cause of death, the coroner's office must be consulted before disposal may 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 (see paragraphs 53–59 for further guidance).

87. Where human tissue disposal is contracted to another establishment, the responsibility for compliance with the codes of practice and the HT Act lies with the department contracting such services. It may therefore be advisable to have third party agreements or SLAs in place as part of this process.

Disposal options

Incineration

88. Identifiable tissue stored following a post-mortem examination may be incinerated.

Burial

89. An establishment wishing to bury identifiable 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 as appropriate.

Cremation

90. Although there is no legal barrier to cremating tissue blocks, crematoria have discretion about what they may accept. Crematoria have particular concerns about material on glass slides because of health and safety issues.

91. Cremation of human tissue is possible under The Cremation (England and Wales) Regulations 2008 providing that:

    1. the death of the person was duly registered;
    2. an application for the cremation of the tissue has been made by an appropriate person on the proper form; and
    3. a certificate on release of body parts has been provided by the holder or, if not possible to provide such a certificate, other evidence that the body parts were removed in the course of a post-mortem examination.

92. The Cremation (England and Wales) Regulations 2008 do not apply to Scotland. It should also be noted that different cremation legislation applies in Northern Ireland and that responsibility for this legislation lies with the Department of the Environment (NI).

Disposal of tissue from the living

Disposal options

93. Most tissue from the living may be incinerated subject to the considerations outlined in paragraph 38. However, there are particular sensitivities relating to the disposal of pregnancy remains, and the HTA has issue separate guidance on pregnancy remains, which can be found here.

94. The HTA recognises that what is sensitive and what is feasible at local level needs to be taken into account. The HTA is mindful of the practicalities involved in securing separate incineration. Where practical, it is good practice for human tissue to be bagged separately from clinical waste. It is not necessary for each tissue sample to be disposed of individually

Disposal of surplus tissue

95. The HT Act permits disposal of surplus tissue as waste. This includes material which has come from a person's body in the course of:

1. receiving medical treatment
2. undergoing diagnostic testing
3. participating in research
4. any relevant material which has come from a human body and ceases to be used, or stored for use, for any scheduled purpose.

96. It is normal practice to dispose of surplus tissue by incineration (see Appendix A) in accordance with current guidance (see the Department of Health's guidelines on Safe management of healthcare waste and Welsh guidance on safe management of healthcare. This includes tissue fragments trimmed from the tissue sample before it is processed for histology, and tissue in sections trimmed from wax-embedded blocks before the usable sections are cut.

Existing holdings

97. Identifiable and unidentifiable tissue taken from the living may be incinerated, subject to the considerations outlined in paragraph 38.

Disposal of pregnancy remains

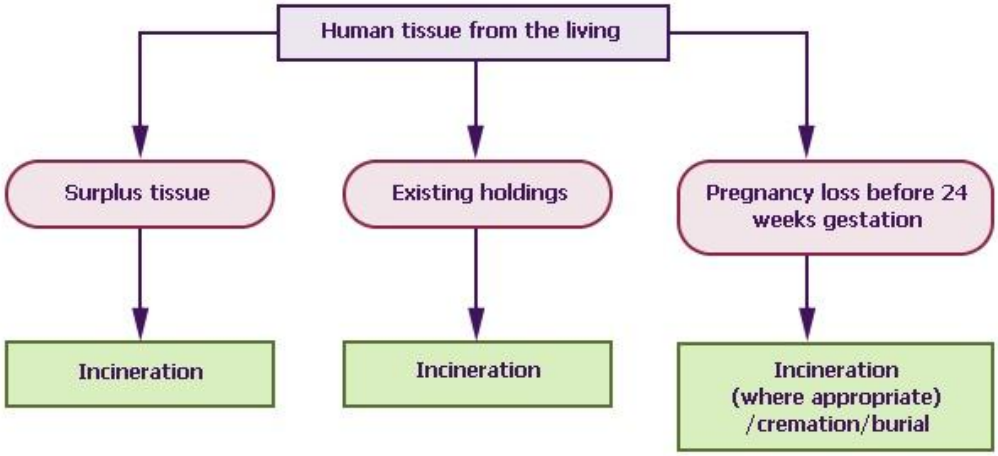
98. Pregnancy remains of less than 24 weeks gestation are considered to be the mother's tissue. The HTA will has issued separate guidance on the disposal of pregnancy remains, which reflect the very sensitive nature of these. Guidance can be found here.

Existing holdings

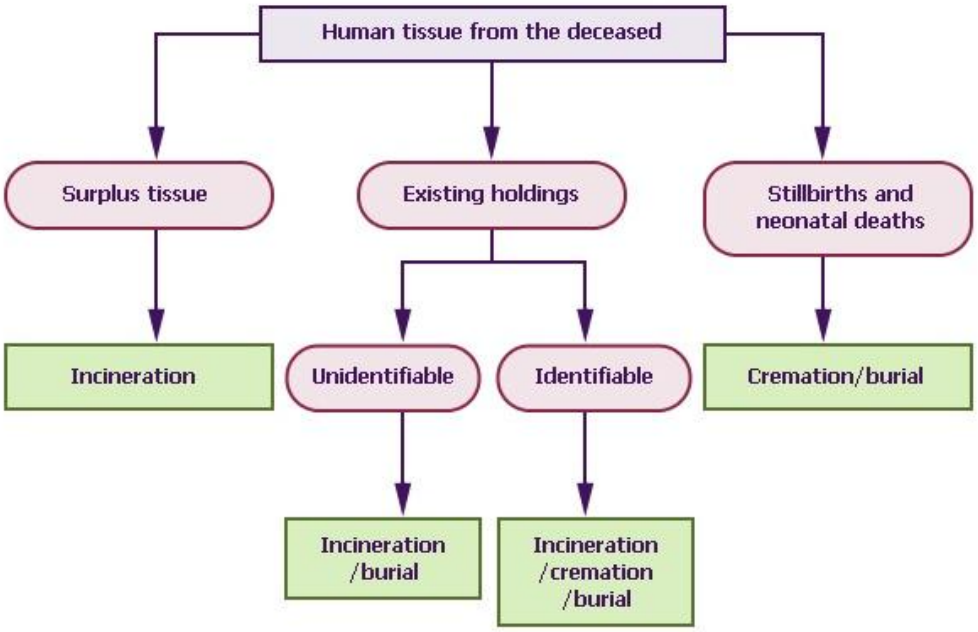
Appendix A

Flowcharts setting out disposal options for specific categories of human tissue

Disposal options for human tissue from the living



Disposal options for human tissue from the deceased



NB These flowcharts are for reference purposes only to set out the disposal options for human tissue in this code; they should not be used as a substitute for a disposal policy.

References

References are listed in the order in which they appear in the code. Supplementary references are included at the end.

Human Tissue Act 2004

Human Tissue (Scotland) Act 2006

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland issued on 20 July 2006 (Ref: NHS HDL (2006) 46))

HTA codes of practice

HTA Directions

HTA definition of relevant material

Ministry of Justice (MoJ) Guide to coroner services and coroner investigations

Cremation (England and Wales) Regulations 2008

Home Office guidance Police and coroners approach to pathology

Royal College of Pathologists and Institute of Biomedical Science joint guidance The retention and storage of pathological records and specimens (4th edition, 2009)

Department of Health guidance Safe management of healthcare waste

Welsh Health Estates guidance Safe Management of healthcare waste

Human Fertilisation and Embryology Act 2008

Stillbirth and Neonatal Death Society (Sands) Pregnancy loss and the death of a baby: guidelines for professionals, Judith Schott, Alix Henley and Nancy Kohner (Third edition, 2007)

NHS guidance: When a person dies: guidance for professionals on developing bereavement services

The Royal College of Obstetricians and Gynaecologists' Good practice guidance No. 5

Department of Health, Social Services and Public Safety (DHSSPS) (Northern Ireland) Careplan for women who experience a miscarriage, stillbirth or neonatal death

The Royal College of Nursing guidance Sensitive disposal of all fetal remains

Supplementary references

Welsh Assembly Government consent documents

Welsh Language Act

HTA guide to licensing for DIs and LHs

HTA summary inspection reports

HTA guide to our key messages - which explains the HTA's roles and responsibilities

HTA e-newsletter – which provides regular news and updates about the HTA's work

Glossary

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue. For establishments licensed for human application this includes cell lines grown outside the human body but not gametes, embryos outside the human body, or blood and blood components.

Designated Individual (DI): The individual designated on the licence to supervise the licensable activities being carried out. DIs are trained by the HTA to carry out this important role and they have statutory responsibilities they must fulfil.

Diagnosis: A process where a disease is identified.

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

Existing holdings: The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to 1 September 2006.

Human application: In relation to tissue or cells, means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.

Licensing: A number of activities can only be carried out where the establishment is licensed under the HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under an HTA licence. All establishments working under an HTA licence must work to specified standards set by the HTA.

Moratorium on disposal of tissue: The moratorium relates to trusts which were holding post mortem human organs and tissue in accordance with restrictions on disposal imposed by the Secretary of State in February 2000. The moratorium has now been lifted.

Neonatal death: A neonatal death is a fetus of any gestational age which is born alive and dies before the age of 28 days.

Organ: Defined by the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. 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.

Part organ: For the purposes of the HT Act and the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, material is part of an organ if it is to be used for the same purpose as the entire organ in the human body.

Post-mortem examination: 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.

Relevant material: Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT 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. See policy guidance on how to apply this definition on the HTA's website.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Scheduled purposes: Under the provision of the HT Act consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. 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.

Stillbirth: A stillbirth is defined under section 41 of the Registration of Births and Deaths Act 1953 as "where a child issues forth from its mother after the 24 week of pregnancy, and which did not at any time after being completely expelled from its mother, breathe or show any signs of life."

Surplus tissue: Includes material which has come from a person's body in the course of receiving medical treatment, undergoing diagnostic testing, or participating in research; or material that is relevant material that has come from a human body and ceases to be used, or stored for use, for scheduled purposes.

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