

Code of practice 1

Consent



Code 1: Consent

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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. The HT Act specifies whose consent is needed in all the relevant circumstances but it does not generally give details of when and how consent should be sought, or of what information should be given. The code provides advice on these issues.

17. The code sets out guidance on the need for consent and addresses the closely related issues of communication and consultation with patients or other individuals, and where appropriate their families, which must support the consent process.

18. To the extent that consent underpins much of the remit of the HTA, this code's scope also encompasses guidance set out in other codes of practice issued by the HTA.

Scotland

19. The [Human Tissue \(Scotland\) Act 2006](#) (HT (Scotland) Act) has authorisation as its fundamental principle and specifies where authorisation is needed for the use of human [tissue](#) for certain purposes. While provisions of the HT (Scotland) Act are based on authorisation rather than consent, these are essentially both expressions of the same principle. Establishments in Scotland, storing and using [tissue](#) and cells for human application or undertaking organ donation and transplantation activities should read this code on consent for guidance on good practice, but must comply with the authorisation provisions of the HT (Scotland) Act. Where we refer to coroner in this code, in Scotland we mean Procurator Fiscal. Where we refer to Mental Capacity Act 2005 in this code, in Scotland the relevant legislation is the [Adults with Incapacity \(Scotland\) Act 2000](#). Where we refer to Trusts in this code, in Scotland the relevant terminology is NHS Board.

Structure and navigation

20. This code is divided into two main sections: Consent: the fundamental principle and Consent requirements.
21. The first section highlights the importance of consent as the central tenet of the HT Act and should be read by all those who need to understand the issues implicit in the consent principle.
22. The second section of the code provides guidance on the requirements for consent and is divided into three parts for easy navigation:
1. Part 1: General provisions
 2. Part 2: Tissue from the deceased
 3. Part 3: Tissue from the living.
23. All those involved in the removal, storage and use of human [tissue](#) from the deceased or the living should take into account the general provisions on consent set out in Part 1 of the code.
24. There are different consent requirements which apply when dealing with [tissue](#) from the deceased and [tissue](#) from the living; these are set out in Parts 2 and 3. Parts 2 and 3 are further divided into consent requirements for adults and for children.

Status of this code

25. Amendments were made to Code of Practice 1 – Consent 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 1 as approved by Parliament is [available on request from the HTA](#).

Consent: the fundamental principle

26. The guidance outlined in this section highlights the importance of consent, which underpins the HT Act. The following issues are central to the application of the consent provisions of the HT Act.

1. is consent required?
2. appropriate consent
3. valid consent
4. scope of consent
5. duration of consent
6. withdrawal of consent.

Is consent required?

27. Consent under the HT Act relates to the purposes for which material might be removed, stored or used. These purposes are set out in Schedule 1 of the HT Act (see paragraph 81) and are called scheduled purposes.

28. In broad terms, the HT Act and the HTA's codes of practice require that consent is required to:

1. store and use dead bodies
2. remove, store and use relevant material from a dead body
3. store and use relevant material from the living.

29. Anyone removing, storing or using material in circumstances for which the HT Act requires consent must be satisfied that consent is in place.

30. Consent to treatment and examination is covered by the common law and the [Mental Capacity Act \(MC Act\) 2005](#) where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set

out in the [Department of Health's guidance](#). Guidance for healthcare professionals in Wales is available in the [Welsh Assembly Government's Reference guide to consent for examination and treatment](#). The Department of Health, Social Services and Public Safety (DHSSPS) (Northern Ireland) has published its own [Reference guide to consent for examination, treatment or care](#).

31. There are certain exceptions to the provisions set out in the HT Act for coroners and criminal justice purposes; these are explored in further detail at paragraphs 117-121.

Appropriate consent

32. The HT Act is clear about what constitutes 'appropriate consent'. [Appropriate consent](#) is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative or (in the absence of either of these) the consent of a person in a 'qualifying relationship' with them immediately before they died (see paragraphs 81-85).

Valid consent

33. The giving of consent under the HT Act is a positive act. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.
34. This code sets out guidance for practitioners on how to make sure [appropriate consent](#) is valid. All consent must be valid in the context of the HT Act. It is important to respect the consent given, regardless of its scope or duration (see sections on scope of consent, paragraphs 39-40, and duration of consent, paragraphs 41-42).
35. For consent to be valid, the person should understand what the activity involves and, where appropriate, what the risks are. When seeking consent, healthcare professionals or other suitably experienced people should ensure that it is appropriate for the intended purpose.
36. To ensure that the removal, storage or use of any tissue is lawful, it is important to establish clearly that consent has been given. Consent may be expressed in various ways, and does not necessarily need to be in writing, unless the HT Act requires it to be (see section on format of consent, paragraphs 61-65). Obtaining [valid consent](#) presupposes that there is a process in which individuals, including their families where appropriate, may discuss the issue fully, ask questions and make an informed choice.

37. *Good practice example - When seeking consent to store umbilical cord blood for potential use for transplantation, establishments should provide balanced information to the mother about the options available, including the benefits and risks, to enable them to make a fully informed choice. This may include guidelines from the [Royal College of Obstetricians and Gynaecologists](#), which is a reliable source of independent information and supported by the Department of Health; and information on altruistic donation to a public cord blood bank.*

38. A person's agreement or refusal to consent to the removal, storage or use of tissue for purposes under the HT Act must not affect the investigation or treatment that they receive.

Scope of consent

39. Consent may differ in its scope as it may be generic or specific.

40. Generic consent typically only applies to research. If conducting [research](#) on samples of tissue, it is good practice to request generic consent because this avoids the need to obtain further consent in the future. It is still important however that the consent is valid (see the [code of practice on research](#) for further guidance).

Duration of consent

41. Consent may differ in its duration. It may be enduring or time-limited.

42. Enduring consent means that it remains in force unless consent is withdrawn. A person may, however, specify a time limit for how long they wish their consent to remain in force. In both cases, the decision should be clearly documented in the patient's records, the laboratory records or both (see section on format of consent, paragraphs 61-65 for further detail).

Withdrawal of consent

43. Consent may be withdrawn at any time whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear, for example, for potential recipients if the donated tissue is for clinical use. Withdrawal of consent cannot be effective where tissue has already been used.

44. If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled purpose (e.g. research), this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent has been withdrawn. In addition, if someone withdraws consent for samples to be used in any future projects, this does not mean that information and [research](#) data should be withdrawn from any existing projects.

Consent requirements

45. This section is divided into three main parts:

1. Part 1: General provisions
2. Part 2: [Tissue](#) from the deceased
3. Part 3: [Tissue](#) from the living.

46. All those involved in the removal, storage and use of human [tissue](#) from the deceased or the living should take into account the general provisions set out in Part 1. There are different consent requirements which apply when dealing with [tissue](#) from the deceased and [tissue](#) from the living; these are set out in Parts 2 and 3. Consent requirements for the living fall under the HT Act, except for the removal of [tissue](#) which is a common law matter.

Consent requirements - Part 1: General provisions

Part 1: General provisions

47. Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:

1. Does the activity require consent? For tissue from the deceased, consent is required for all scheduled purposes (paragraph 81). Consent is not required under the HT Act for storage and use of tissue from the living in some circumstances (paragraphs 127-129)
2. Who may give consent? (paragraphs 83-105; 135-157)
3. Has sufficient written or verbal information been provided for the person giving consent to make a properly considered decision? (paragraphs 61-65; 106-108)
4. How will the consent be given and recorded? (paragraphs 61-65)
5. When is written consent required? (paragraphs 122-126)
6. Is consent needed for more than one purpose? (paragraphs 114-116)

7. If a child is involved, are they competent to consent and have they expressed particular wishes or views? (paragraphs 98-105; 151-157)
8. If an adult lacks capacity to consent, how should the provisions of the MC Act be applied? (paragraphs 137-150)
9. What are the exceptions to the consent provisions of the HT Act? (paragraphs 117-121)
10. Is DNA analysis likely to be involved? (paragraphs 164-170)
11. What are the consent implications for fetal tissue? (paragraphs 171-175)

When to seek consent

48. Consent is often sought in a clinical setting for treatment, research, or following the death of a patient. But this is not always the case. The following paragraphs refer generally to clinical settings, but apply equally to other circumstances.
49. Where possible, it is good practice to seek the person's consent to the proposed procedure in advance. Sufficient time should be allowed for questions and discussion.
50. Equally, discussions with families may often take place in hospital before a person's death. They may know the person's wishes in respect of, for example, donating organs for transplantation. It should be made clear to them, however, that knowing and understanding the dying person's wishes is different from giving consent on their behalf following their death (see paragraphs 83-116 for further guidance).
51. The seeking and obtaining of consent from patients before death or from those close to them after their death requires sensitivity. This is especially true for donations for transplantation, post-mortem examinations and the retention of tissue and organs for research. Further guidance is set out in the codes of practice on [Post-mortem examination](#) and [Donation](#) of solid organs for transplantation.

Who may seek consent?

52. It is usually the responsibility of the healthcare professional to seek consent from the person concerned, the person with parental responsibility, or a partner, relative or close friend (see paragraph 92 for hierarchy of qualifying relationships).
53. It is important to have procedures in place which clearly set out the responsibilities of all those involved in the process of seeking valid consent.

Where these are already in place, establishments should review them to ensure they meet the requirements of this code.

54. *Good practice example: Eye banks have formal agreements in place with specialist nurses for organ donation who obtain consent from donor families on their behalf. The system clearly sets out the responsibilities of the parties involved and documents the procedure for recording consent. This ensures that valid consent is obtained by appropriately trained staff in accordance with the HT Act and codes of practice.*
55. Seeking and obtaining consent is a sensitive issue. Staff seeking consent should have a good understanding of the activities they are seeking consent for. They should also be in a position to answer questions that donors or their families may ask. Healthcare professionals should obtain the support and guidance of their managers to develop the necessary skills in the implications and essential requirements of seeking consent.
56. Even if consent is not sought in a clinical setting, the person seeking consent should still be appropriately trained to ensure that the consent is valid.
57. Seeking consent may be assigned to someone else, as long as they are suitably trained. In particular, they should know enough about the proposed procedure, the intended use of the tissue and the risks involved, for the subject to make an informed decision. For example, a Specialist Nurse for Organ Donation or an appropriately trained member of a bereavement services team (see paragraph 53) could be involved in the consent-seeking process.
58. In practice, the deceased person's clinician would usually raise the possibility of a post-mortem examination, knowing the medical problems and the unresolved aspects that merit investigation. There may be different options for choosing who actually discusses the post mortem and obtains consent, but most will involve a team approach.
59. Anyone seeking consent for a hospital [post-mortem examination](#) should be sufficiently experienced and well informed, with a thorough knowledge of the procedure. They should have been trained in dealing with bereavement, in explaining the purpose and procedures and they should have witnessed a post-mortem examination. Those seeking consent may include members of the clinical team involved in the care of the patient before death, and may also include someone closely involved with the pathology department, such as an Anatomical Pathology Technologist (APT) or a specialist nurse. For requirements relating to the retention of tissue for scheduled purposes following coroners' post mortems, see section on exceptions (paragraphs 117-121) and refer to the [code of practice on post-mortem examination](#).

60. Establishments should also take into consideration the [MC Act 2005](#) which applies to adults who are unable to make decisions, because of a temporary or permanent impairment or disturbance in the functioning of the mind or brain. Further guidance is available from the [Office of the Public Guardian website](#) and in the [MC Act code of practice](#). There is separate [guidance for Wales](#) and for [Northern Ireland](#). The [Adults with Incapacity \(Scotland\) Act 2000](#) governs adults who lack capacity in Scotland.

Format of consent

61. The HT Act does not specify the format in which consent should be given or recorded, except for anatomical examination or public display which must be in writing (see section on written consent, paragraphs 110-113). The information required and the manner in which consent is obtained and recorded may vary depending on the particular circumstances.

62. Written consent serves as evidence of consent, but a signature on a form will not of itself make the consent valid (see section on valid consent, paragraphs 33-38). Systems or protocols should be in place to ensure that the process is correct and that the decision has been properly recorded. Trusts seeking to update existing consent forms or develop new protocols should ensure that they comply with this code and other relevant HTA guidance.

63. *Good practice example: An establishment obtains verbal consent via the telephone from the deceased persons' relatives for the [donation](#) of tissue (bone, skin, eyes, and heart valves) for transplantation. The family is provided with information about the [donation](#) process and the subsequent uses of the tissues and given the opportunity to ask questions, to ensure that valid consent is given. The establishment documents the consent in the donor's records, audio records the consent conversation with the family if possible, and follows up with a letter of confirmation.*

64. When consent is obtained but it is not in writing, for example for future storage or use of samples, this should be clearly documented in the patient's records, the laboratory records or both. The record should detail when consent was obtained and the purposes for which the consent was given.

65. A decision recorded on the NHS Organ Donor Register (ODR) constitutes the consent, or refusal, of the person. It is advised the decision recorded on the ODR is shared with family and friends to establish whether the person had made a different decision subsequently.

Religion, belief and culture

66. Attitudes towards the use of tissue and especially towards post mortems may vary widely among cultures and religions. All healthcare professionals should be sensitive to this. However, each case and decision is an individual and personal one, and should be treated as such. Trusts and other 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

67. Consent is valid only if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person interviewed (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.

68. Under the [MC Act](#), efforts should be made to provide information that is appropriate in terms of culture and language when assessing capacity, see chapter 3 of [the MC Act code of practice](#) (for further information on adults who lack capacity to consent see paragraphs 127-150).

Use of documentation

69. Information leaflets and consent forms are useful and recommended for:

1. post-mortem examination
2. anatomical examination
3. organ and tissue donation.

70. Patient information sheets should be provided about [research](#) projects and these are also usually required by ethics committees approving [research](#) projects. [The Health Research Authority](#) (HRA) has issued guidance on developing model consent forms and information sheets for [research](#) establishments to use when obtaining consent.

71. Establishments should provide appropriate information on the activities for which they are seeking consent. The information might be in the form of leaflets or information sheets, or might be contained within the consent form. Many establishments, including Trusts, have policies on consent that include the use of standard documentation. Such documentation should make reference to the HT

Act and the role of the HTA and be reviewed to ensure that it is consistent with this code, as well as the requirements of the Clinical Negligence Scheme for Trusts, the relevant [Department of Health Consent guidance](#) and consent guidance from the [Welsh Assembly Government](#) and [DHSSPS](#) (Northern Ireland).

72. Where appropriate, information should be available in widely spoken languages and in a variety of formats, such as video or DVD, audiotape or Braille and in line with other legislation, such as the [Equality Act 2010](#). Wherever possible, professional translators trained in translating for the bereaved and in maintaining confidentiality should be used.

73. Good practice example - Some researchers have provided information about their [research](#) study via a computerised programme whereby the donor gives consent electronically. The computer programme allows information to be displayed in large font or listened to via audio play-back. The programme allows donors to submit questions by email or via a dedicated contact number. The patient information leaflet may be printed at the donor's request. The establishment also provides the information in hard copy to those who do not have computer access.

Existing holdings

74. The consent requirements of the HT Act are not retrospective. This means it is not necessary to obtain consent for material that was held when the [HT Act came](#) into force on 1 September 2006.

75. Although there are no statutory requirements to obtain consent for the storage or use of tissue that is an existing holding, this does not mean that all such human tissue can be used freely and without regard to issues of consent or other ethical considerations. If practical, the consent of the participant should be sought and the views of the deceased person or of their family (if known) should be respected, as long as the method of disposal is legal. See the [code of practice on disposal of human tissue](#) for further information on how to dispose of existing holdings.

76. Under the HT Act, consent is not required for carrying out [research](#) on [existing holdings](#) of human tissue and organs (see paragraph 77). Although it does not have an explicit role in the ethical approval of [research](#) on such material, the HTA endorses the guidance produced by the [Health Research Authority](#) (HRA).

77. Although [existing holdings](#) are exempt from the consent provisions in the HT Act, the HTA's licensing requirements may still apply where material is being stored or used for a scheduled purpose.

Consent and imported tissue

78. The consent provisions of the HT Act do not apply to material that has been imported. Nonetheless, the HTA considers it good practice for mechanisms to be in place which provide assurance that human tissue which is to be imported is obtained with valid consent. This also applies where the intention is to analyse DNA in the material. Guidance for those wishing to import human bodies, body parts and tissue from abroad into England, Wales and Northern Ireland, is provided in another HTA code of practice. Directions which bring into force the first edition of this code, as provided for under [Section 26 of the HT Act](#).

Use of images

79. The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the HT Act. However, the HTA requires Designated Individuals to put systems in place to ensure suitable practices are carried out, which may include systems to prevent the inappropriate use of images.

80. The HTA endorses the guidance on images provided by the [General Medical Council \(GMC\) in its publication Making and using visual and audio recordings of patients](#).

Consent requirements - Part 2: Tissue from the deceased

When is consent required?

Written consent

81. Under the HT Act, consent is needed for the removal, storage and use of material from the deceased for all [scheduled purposes](#) as listed below:

1. anatomical examination
2. determining the cause of death
3. establishing, after a person's death, the efficacy of any drug or other treatment administered to them

4. obtaining scientific or medical information, which may be relevant to any person including a future person
5. public display
6. research in connection with disorders, or the functioning, of the human body
7. transplantation
8. clinical audit
9. education or training relating to human health
10. performance assessment
11. public health monitoring and
12. quality assurance.

(see **appendix A**)

82. Although consent is not required for a coroner's post mortem, consent *is* required under the HT Act for the continued storage or use of tissue, for scheduled purposes, once the coroner's purposes are complete (see paragraphs 117-121). See the [code of practice on Post-mortem examination](#) for further guidance.

Who may give consent?

Adults

83. Where an adult has, whilst alive, given valid consent for any particular [donation](#) or the removal, storage or use of their body or tissue for [scheduled purposes](#) to take place following their death, then that consent is sufficient for the activity to be lawful.

84. If those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their nominated representative, see paragraphs 86-91) has explicitly consented, the healthcare professional should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes (see the [code of practice on donation of solid organs for transplantation](#)).

85. The emphasis in these difficult situations should be placed on having an open and sensitive discussion with those close to the deceased where the process is explained fully to them. Healthcare professionals should also consider the impact of going ahead with a procedure in light of strong opposition from the family, despite the legal basis for doing so. For example, healthcare professionals may consider that carrying out an [anatomical examination](#) would leave relatives or

family members traumatised (or lead to their objections), despite the deceased person having consented to this whilst alive.

Nominated representatives (applies only to England, Wales and Northern Ireland)

86. If a deceased adult had neither consented to, nor specifically refused, any particular [donation](#) or the removal, storage or use of their body or tissue for scheduled purposes, those close to them should be asked whether a [nominated representative](#) was appointed to take those decisions.
87. A [nominated representative](#) may be empowered to consent to the carrying out of a [post-mortem examination](#) and to the removal, storage or use of the body or tissue for any of the scheduled purposes, other than [anatomical examination](#) or public display.
88. The appointment of a [nominated representative](#) and its terms and conditions may be made orally or in writing. The HT Act sets out the requirements for a valid appointment. The appointment of a [nominated representative](#) may be revoked at any time.
89. If the deceased person appointed more than one nominated representative, only one of them needs to give consent, unless the terms of the appointment specify that they must act jointly.
90. The nominated representative's consent cannot be overridden by other individuals, including family members. It is advisable, nevertheless, to ensure that appropriate consultation and discussion takes place between all those involved.
91. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practical to communicate with the [nominated representative](#) within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraphs 92-97).

Qualifying relationships

92. If the deceased person has not indicated their consent (or refusal) to post-mortem removal, storage or use of their body or tissue for scheduled purposes, or appointed a nominated representative, then the appropriate consent may be given by someone who was in a 'qualifying relationship' with the deceased person immediately before their death. Those in a [qualifying relationship](#) are found in the [HT Act in the following order \(highest first\)](#). It should be noted that

the qualifying relatives for adults in Scotland is different and is set out in the HT (Scotland) Act.

1. spouse or partner (including civil or same sex partner) The HT Act states that, for these purposes, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.
2. parent or child (in this context a child may be of any age and means a biological or adopted child)
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. friend of long standing.

93. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person high up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but others in the family wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs 84 and 85 should be observed in line with this principle. If there is no one available in a [qualifying relationship](#) to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person's body or tissue for scheduled purposes.

94. While the HT Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other family members - this may include people not on the list, for example, an aunt or uncle.

95. Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.

96. Where there is a conflict between those accorded equal ranking, then this needs to be discussed sensitively with all parties (see also paragraphs 84-85 which provide further guidance on handling difficult situations), whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead.

97. In applying the principles set out above, a person's relationship shall be left out of account if:

1. they do not wish to deal with the issue of consent
2. they are not able to deal with the issue
3. in relation to the activity for which consent is sought, it is not practical to communicate with that person within the time available if [consent in relation to the activity is to be acted on](#)
4. This means a person may be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, declines to deal with the matter or is unable to do so, for example, because they are a child or lack capacity to consent. In such cases, the next person in the hierarchy would become the appropriate person to give consent.

Children

98. [Under the HT Act](#), a child is defined as being under 18 years old. Under the HT (Scotland) Act, a child is defined as being under 16 years old. A child aged 12 and over, who is able to make their own decisions can give [authorisation for their organs or tissue to be donated](#).

99. The position of a child who, before they died, was competent to reach a decision and gave consent for one or more scheduled purposes to take place after their death, is no different from that of an adult. Their consent is sufficient to make lawful the removal, storage or use of tissue for that purpose. In the Gillick case, the court held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them fully to understand what was involved. The principle of 'Gillick competence' does not exist in Scottish law. Since there are extra sensitivities to take into consideration where the deceased donor is a child, the situation should be managed accordingly.

100. If a child consents to a procedure, then this consent carries over into adulthood unless they withdraw their consent.

101. In the case of [anatomical examination](#) or public display, written, [witnessed consent is required from the child](#). As with adults, the next of kin cannot agree to the use of a child's body after death for these purposes.

102. In some cases, it may be advisable to establish with the person who had parental responsibility for the deceased child, whether the child was competent to make the decision. A person who has parental responsibility will usually, but not

always, be the [child's parent](#). Clearly, in any case where a child has consented to the use of their body or tissue, it is essential to discuss this with the child's family.

103. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that the appropriate consent will be that of a [person with parental responsibility for the child](#). The consent of only one person with parental responsibility is necessary.
104. The issue should be discussed fully with relatives and careful thought should be given as to whether to proceed if a disagreement arises between parents or other family members. Any previously stated wishes of the deceased child should be considered, taking into account their age and understanding. Further guidance is included in the [code of practice on donation of solid organs for transplantation](#) and [code of practice on post-mortem examination](#).
105. If there is no person with parental responsibility (e.g. if the parents have also died, perhaps at the same time as the child), then consent should be sought from someone in a qualifying relationship, (see section on qualifying relationships, paragraphs 92-97). Under the HT Act, children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

Steps to take

Providing information about the process

106. Where no decision was made by the deceased, when seeking consent from a [nominated representative](#) or from a person in a qualifying relationship, full and clear information should be provided about the purpose for which consent is being sought. This should allow them to make a properly considered decision. This information should include the nature of the intended activities and the reasons for them.
107. Healthcare professionals need to tailor the information they provide to each specific situation, as some people may insist on in-depth detail, whereas others would prefer to consent having only had the basics of the procedure explained to them. Trust policy should set out a minimum amount of information for healthcare professionals to provide, see the [HTA's Directions 001/2006](#) which set out requirements for establishments licensed under the Q&S Regulations. Some people will want more detail than others about, for example, post mortem procedures and this information should be provided in accordance with their wishes (see the [code of practice on post-mortem examination](#)). Further

information may be found in the sections on the duration of consent, paragraphs 41-42 and use of documentation, paragraphs 69-73.

108. The way in which the options are discussed with the deceased person's family is extremely important. They should be approached with sensitivity and given:

1. honest, clear, objective information
2. the opportunity to talk to someone of whom they feel able to ask questions
3. reasonable time to reach decisions (about a hospital post mortem and about any [donation](#) of organs or tissue)
4. privacy for discussion between family members, if applicable
5. support if they need and want it, including the possibility of further advice or psychological support.

Disclosing information about the deceased

109. Care should be taken regarding the possible disclosure of information, such as genetic information (see section on consent and the use of DNA, paragraphs 164-170) or HIV status, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members. Healthcare professionals will have to make a decision based on the individual circumstances of each case about whether it is appropriate or not to disclose information about the deceased's medical history, as well as any other sensitive information that the Trust may hold (about the deceased), that the family may not necessarily be aware of. In making decisions, healthcare professionals will have to have regard to their duty of patient confidentiality and may have to consider the provisions of the [Data Protection Act 1998](#). In certain circumstances, it may be necessary to share sensitive information with the family if the results of the activity have the potential to affect them or other relatives. For further guidance see [GMC guidance on confidentiality](#) and the [Department of Health's guidance on confidentiality](#) which deals with disclosing information after a patient has died. See also the [Welsh Assembly Government's guidance on confidentiality](#).

Written consent

110. Written, witnessed consent is always needed for [anatomical examination](#) and for public display of dead bodies or body parts (see the [code of practice on anatomical examination](#) and [code of practice on public display](#) for detailed guidance).

111. Written consent should be obtained wherever possible for all other post mortem activities.

112. If verbal consent is obtained, this should be clearly documented in the patient's records (see paragraph 63).
113. [Model consent forms are available for post-mortem and anatomical examination on the HTA's](#) website. In Northern Ireland, HSC Trusts and other relevant organisations should use the standardised consent forms agreed with the [DHSSPS](#). HTA model consent forms provide a suggested format for Trusts obtaining consent for the above purposes. The forms are not prescriptive due to local variations in practice and may be adapted as necessary, providing they comply with the HT Act and the codes of practice. Consent forms are only one part of the consent process and should be completed after appropriate discussion and more detailed explanation where necessary.

Seeking consent for multiple activities

114. When someone has died, healthcare professionals may wish to seek consent for more than one scheduled purpose. For example, if a [post-mortem examination](#) is to be carried out, some tissue samples could also usefully be obtained for [research](#) purposes. In this case, it would be appropriate to seek the relevant consent to both activities. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking consent on repeated occasions. [Research](#) is one example (for further guidance about tissue to be used for [research](#) see paragraphs 160-161).
115. Where consent has been given for the use of tissue or organs after death for transplantation, separate consent is required for its storage and use for [research](#) purposes. In such cases, the necessary consents should ideally be sought in a single consent process and recorded in the same place.
116. In the case of post mortem tissue, and unless authorised by a coroner, all storage and use for scheduled purposes requires consent. But, if consent to the storage or use of post mortem samples by whoever originally consented to their storage or use is withdrawn, this must be respected for any samples that are still held. Healthcare professionals should discuss with the person concerned how the samples should be returned to them or disposed of, and tell them about any samples that may have already been used or disposed of (see the [code of practice on disposal of human tissue](#)).

Exceptions for coroners and criminal justice purposes

117. The guidance in this section should be read in conjunction with the relevant sections relating to coroners in the [code of practice on donation of solid organs](#)

[for transplantation](#), [code of practice on post-mortem examination](#) and [code of practice on disposal of human tissue](#).

118. For tissue from the deceased, consent is not needed for:

1. carrying out an investigation into the cause of death under the authority of a coroner
2. retention of material after a post mortem under the authority of a coroner, for a period no longer than the time needed by the coroner to discharge their statutory functions, if certified in writing with an explanation by the pathologist that it bears on evidence concerning the cause of death. See Coroners Rules for further detail.

119. However, consent is required for [research](#) or other scheduled purposes where the coroner's authority to retain the material has ended and the deceased's family have not opted to dispose of the material. This applies to all tissue removed at post mortem, including small samples such as blocks and slides, and samples that might include relevant material such as toxicology and microbiology specimens. For detailed guidance, see the [code of practice on post-mortem examination](#), the [Coroners Rules \(see the Ministry of Justice \(MoJ\) website for information on coroners\)](#) and the [Coroners Practice and Procedure Rules \(Northern Ireland\)](#).

120. Once the coroner's authority has ended, if the material is not disposed of, the further storage and use of post mortem samples fall within the remit of the HT Act. The complexities surrounding disposal following a coroner's post mortem and subsequent communication with families are explored in further detail in the [code of practice on disposal of human tissue](#). Once the coroner's authority has ended, it is not lawful to use or store tissue for a scheduled purpose without consent. The code covers communication between coroners, pathologists and the family of the deceased.

121. Keeping material in connection with a criminal investigation or following a criminal conviction falls outside the remit of the HT Act.

Consent requirements - Part 3: Tissue from the living

When is consent required?

122. Under the HT Act, consent from the living *is* needed for storage and use of [tissue](#) for:

1. obtaining scientific or medical information which may be relevant to any person including a future person
2. public display
3. research in connection with disorders, or the functioning, of the human body (but see paragraphs 127-134, and
4. transplantation.

123. Under the HT Act, consent from the living is not needed for storage and use of [tissue](#) clinical audit

1. education or training relating to human health (including training for [research](#) into disorders, or the functioning, of the human body)
2. performance assessment
3. public health monitoring
4. quality assurance.

(See Appendix A)

124. Consent to treatment and examination is covered by the common law and the [MC Act](#) where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the [Department of Health's guidance](#). Guidance for healthcare professionals in Wales is available in the [Welsh Assembly Government's Reference guide to consent for examination and treatment](#). The [DHSSPS \(Northern Ireland\) has published its own Reference guide to consent for examination](#), treatment or care. See also the [GMC guidance on consent and decision making in Consent: patients and doctors making decisions together](#).

125. Tissue may be taken in a variety of circumstances, for example:

1. in the course of diagnostic procedures, e.g. taking a blood or urine sample, [tissue](#) biopsy, cervical screening, etc
2. in the course of treatment, e.g. removing [tissue](#) (organs, tumours, etc.) during surgery
3. when removed specifically for the purpose of research.

126. Although consent for treatment and examination is dealt with under the common law and consent for scheduled purposes is dealt with under the HT Act, the consent for each activity may be obtained at the same time. It is still important to explain clearly the activity for which consent is being obtained, including the risks and wider implications. Further guidance on this issue in respect of obtaining consent for [donation](#) may be found in the [code of practice on donation of solid organs for transplantation](#)

Consent exception for research in specific circumstance

See also the [code of practice on research](#)

127. Tissue from the living may be stored or used without consent, provided that:
1. the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come; and
 2. the material is used for a specific [research](#) project with ethical approval.
128. Data about the [tissue](#) does not have to be permanently or irrevocably unlinked, and may be pseudonymised where, for example, a system of coding is used.
129. There may be occasions when a clinician involved in [research](#) may also have access to a secure database that would permit identification of a sample used in [research](#) and the identity of the patient whose material is being used. Providing the [research](#) material is not identifiable to the researcher (e.g. coded by a laboratory accession number) and the researcher does not seek to link the sample to the patient, it will still be regarded as non-identifiable and the [research](#) will be permissible without consent if it is given ethical approval by a recognised [research](#) ethics committee.

Applying for ethical approval for research

130. The HTA's remit does not include ethical approval of [research](#) on human tissue, which must be applied for using the guidance provided by the [Health Research Authority](#) (HRA) and the [GMC](#). For the consent exception to apply ethical approval can only be given by a recognised [research](#) ethics committee which is either:
1. a [Research](#) Ethics Committee (REC) established under and operating to the standards set out in the [governance arrangements issued by the UK Health Departments](#); or
 2. an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the [Medicines for Human Use \(Clinical Trials\) Regulations 2004](#).
131. See the [code of practice on research](#) for further information on ethics committees.

132. It should be noted that consent is normally required to use identifiable patient data in research. In cases where researchers do not have consent to use identifiable patient data for research, they should refer to the [HRA](#).
133. Researchers intending to use patient data in [research](#) should be aware that such information is subject to the common law duty of confidentiality and the requirements of the [Data Protection Act 1998](#).
134. In general, obtaining consent is preferable to developing complex systems for keeping samples unlinked.

Who may give consent?

Adults who have capacity to consent

135. If an adult has the capacity to make the decision in question, then only they are permitted to give consent.
136. Surplus [tissue](#) is often an important source of material for [research](#) and consent procedures may include an agreement to its use. The HT Act makes it lawful to dispose of surplus tissue. See the [code of practice on disposal of human tissue](#) for further guidance.

Adults who lack capacity to consent

137. The HT Act does not specify the criteria for considering whether an adult has capacity to consent.
138. Under the [MC Act](#) a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:
1. understand the information given to them that is relevant to the decision
 2. retain that information long enough to be able to make the decision
 3. use or weigh up the information as part of the decision-making process
 4. communicate their decision by any means.
139. Full guidance on how the MC Act defines capacity and how it should be assessed is given in chapter 4 of the [MC Act code of practice](#).
140. The provisions of the [MC Act](#) should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the [Office of Public Guardian website](#) and in the [MC Act code of](#)

[practice](#). There is [separate guidance for Wales](#) and for [Northern Ireland](#). The [Adults with Incapacity \(Scotland\) Act 2000](#) governs adults who lack capacity in Scotland.

141. The MC Act governs decision-making on behalf of adults (aged 16 and over) who lack capacity if unable to make a decision in relation to a matter at the relevant time because of an impairment of, or disturbance of, the mind or brain, whether permanent or temporary (see paragraph 60. For the purposes of the MC Act, unlike the HT Act, an adult is a person aged 16 or over. The MC Act only applies to persons aged 16 or over.
142. There are detailed provisions contained in the [MC Act](#) concerning decisions made on behalf of adults lacking capacity. All decisions must be made in the person's best interests, as laid out in [chapter 5 of the MC Act code of practice](#). Also, certain categories of people have a legal duty to have regard to the MC Act code of practice, when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in [chapter 6](#).
143. The [MC Act](#) defines persons who lack capacity, see [chapter 4 of the MC Act code of practice](#), and contains a set of key principles and a checklist to be used in ascertaining best interests, see chapter 5 of the [MC Act code of practice](#). The first core principle of the MC Act is that an adult must be assumed to have capacity to make a decision for themselves, unless it is [established that they lack capacity to make the particular decision at the time the decision needs to be made](#).
144. It should therefore always be assumed that an adult has the capacity to make a decision unless there is reason to believe otherwise.
145. Individuals may sometimes temporarily be unable to make a decision, for example people affected by trauma, illness or shock. It may therefore not be appropriate to seek consent at that time and in some cases it may be necessary to put off the decision until the person has the capacity to make it, as laid out in the [MC Act](#). See [chapter 4 of the MC Act code of practice for further guidance](#).
146. Some adults may have capacity to make decisions about some matters, but not others. The MC Act requires that care should be taken to ensure that patients are given every opportunity, and support where needed, to make their own decisions, see chapter 3 of the MC Act code of practice.
147. A person must not be treated as unable to make a decision unless all practicable steps to help them do so have been taken without success, nor must they be treated as being unable to make a decision merely because they make an unwise decision.

148. The ability of adults with learning difficulties, or with limited capacity to understand should not be underestimated. Where appropriate, someone who knows the individual well, such as a family member or carer, should be consulted, as they may be able to advise or assist with communication.
149. Since the MC Act came into force a person aged 18 or over may make a Lasting Power of Attorney (LPA). This allows for an attorney to make certain decisions in circumstances where the person no longer has capacity. One type is a personal welfare LPA, which provides for the appointment of a person to make certain healthcare decisions on their behalf. Where an LPA exists, it is good practice to check the detail to see if the attorney has the authority to make the decision in question. Detailed guidance on the role of the attorney is set out in [chapter 7 of the MC Act code of practice](#).
150. Storage or use of [tissue](#) from adults who lack capacity to consent is permitted in certain circumstances specified in the [Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006](#).

Children

151. Under the [HT Act](#), a child is defined as being under 18 years old. [Under the HT \(Scotland\) Act](#), a child is defined as being under 16 years old. A child aged 12 and over, who is able to make their own decisions can give authorisation for their organs or tissue to be donated.
152. Children may consent to a proposed medical procedure or the storage and use of their [tissue](#) if they are competent to do so. In the Gillick case, the court held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them fully to understand what was involved. The concept of Gillick competence does not exist in Scottish law. The legal position on obtaining consent to treatment is set out in the [Department of Health's guidance](#). Consent documents for [Wales can be found at on their website](#) and the DHSSPS (Northern Ireland) has published its own [Reference guide to Consent for examination, treatment or care](#).
153. If a child consents to a procedure, then this consent carries over into adulthood unless they explicitly withdraw it.
154. [Under the Children Act 1989, a person who has parental responsibility](#) for the child may consent on their behalf only if the child has not made a decision either way; and the child:
1. is not competent to do so; or

2. is competent to do so, but is unwilling to make that decision.

155. [A person who has parental responsibility will usually, but not always, be the child's parent](#). See also the [GMC guidance 0-18 years: guidance for all doctors](#).
156. Where there is any dispute between persons with parental responsibility or any doubt as to the child's best interests, the matter should be referred to court for approval. The need to refer cases to court does not apply to Scotland. For further guidance on court approval in cases of potential donation, see the [codes of practice on Donation](#) of solid organs for transplantation and [code of practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation](#).
157. Even if the child is competent to consent, it is good practice to consult the person who has parental responsibility for the child and to involve them in the process of the child making a decision. However, it should be emphasised that, if the child is competent, the decision to consent must be the child's. Information about a competent young person should only be disclosed to the person with parental responsibility for the child with the child's consent. It is also essential to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else.

Steps to take

158. To give consent, the individual (or the person with parental responsibility) should understand the nature and purpose of what is proposed and be able to make an informed decision. They should be told of any 'material' or 'significant' risks inherent in the way the sample will be obtained, how the [tissue](#) will be used and any possible risks or implications of its use, e.g. genetic tests. If the person concerned is not a patient, and is volunteering samples purely for research, the general principles of providing appropriate information still apply (see paragraphs 33-38 on valid consent).
159. Healthcare professionals should try to find out about the individual's needs and priorities when telling them about their options. Some people may not be interested in knowing the full details about the proposed use of the [tissue](#) and it is good practice to record this in the notes. People should nevertheless have all their options explained to them and be provided with an appropriate level of information. See [GMC guidance on Consent: patients and doctors making decisions together](#).
160. If identifiable [tissue](#) is to be used for research, donors should be informed about any implications this may have. For example, they may be contacted by

researchers, given feedback, or be asked for access to their medical records. Donors should be asked whether the consent they are giving is generic (for example, for use in any future [research](#) project, or specific). If it is the latter, detailed information about the [research](#) project should be provided, in line with good practice. Researchers will need to consider how they deal with [tissue](#) samples in the event of a later loss of capacity. There are certain safeguards which need to be in place where [research](#) involving adults who lack capacity is concerned (See the [code of practice on research](#) for further detail).

161. Donors should be told if their samples will or could be used for [research](#) involving the commercial sector. They should be given appropriate information on the range of activities and researchers which may be involved, and whether these include commercial establishments. The HTA also advises that it is good practice that donors are provided with adequate information upon giving consent, should their samples be exported for use abroad (see the [code of practice on import and export of human bodies, body parts and tissue](#) for further information).

Powers deeming consent to be in place

162. Section 7 of the HT Act allows the HTA to dispense with the need for consent in certain circumstances, as set out in paragraph 160.
163. The HTA has the power to deem consent to be in place for relevant material from someone who is untraceable, or who has not responded to requests for consent to use of their material, if that material could be used to provide information relevant to another person. This may be important where information could be obtained about the treatment and diagnosis of the applicant. The HTA has prepared guidance on the implementation of these provisions in relation to DNA analysis (see paragraphs 164-170 on Consent and the use of DNA).

Consent and the use of DNA

164. The guidance in this section also applies to RNA analysis where it is to be used to provide information about DNA. [Qualifying consent](#) is required to analyse DNA, subject to certain exceptions (see paragraph 167).
165. If consent under the HT Act has been given for material to be used for a scheduled purpose, it is not necessary to seek separate consent where that use involves use of the results of DNA analysis, but it should be made clear to the donor that their bodily material may be used in this way.

166. When discussing consent, the donor should be made aware if the intended DNA analysis may reveal significant results e.g. a family genetic condition. Where this applies, their decision on whether they wish such information to be made known to them should be respected.. For more information about issues of consent and confidentiality in clinical practice in the genetics service, see the [report of the Joint Committee on Medical Genetics, Consent and confidentiality in genetic practice: Guidance on genetic testing and sharing genetic information](#). Guidance published by the [Medical Research Council](#) may also be helpful: [Research and the Human Tissue](#).
167. [Act - DNA Analysis](#). In most circumstances, it is an offence to hold material with the intention of analysing DNA and using the results without qualifying consent, unless the use is for an 'excepted purpose'. Unlike the other parts of the HT Act, which do not apply to Scotland, this offence applies to the whole of the UK. The following are excepted purposes:
1. medical diagnosis or treatment of the person whose body made the DNA
 2. the purposes of the coroner (England, Wales and Northern Ireland) / Procurator Fiscal (Scotland)
 3. prevention/detection of crime
 4. the conduct of a prosecution
 5. national security
 6. court / tribunal order or direction
 7. where the bodily material is from the body of a living person - use for clinical audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance
 8. where the bodily material is an [existing holding](#) - use for clinical audit, determining the cause of death, education or training relating to human health, establishing after death the efficacy of any drug or treatment administered, obtaining scientific or medical information about a living or deceased person which may be relevant to another person (including a future person), performance assessment, public health monitoring, quality assurance, [research](#) in connection with disorders or functioning of the human body and transplantation
 9. obtaining scientific or medical information about the person from whose body the DNA has come where the bodily material is the subject of either a direction by the HTA or a court order under paragraph 9 Schedule 4 of the HT Act and the information may be relevant to the person for whose benefit the direction or order is made
 10. research in connection with disorders or functioning of the human body, provided the bodily material comes from a living person, the person carrying out the analysis is not in, and not likely to come into, possession of identifying information and the [research](#) is ethically approved. The Secretary of State may also specify the circumstances in which the High

Court, or in the case of Scotland, the Court of Session may order that use of the results of DNA analysis for [research](#) purposes is an 'excepted' purpose

11. where the DNA has come from an adult lacking capacity under the law of England, Wales and Northern Ireland or is an adult with incapacity under the law of Scotland and neither a decision of that person to consent or not to consent to DNA analysis is in force, use for purposes specified in Regulations made by the Secretary of State.
168. Where someone has died, a person in a qualifying relationship to them who was close to them at the point of death (such as a relative or friend) may give consent for a DNA test. In much of the HT Act (as set out in subsection 27(4)), there is a hierarchy of qualifying relationships which are ranked, but in cases relating to DNA analysis, this ranking does not apply. The person giving consent should, however, be encouraged to discuss the decision with other family members. At the time of discussing consent, it should be raised with the family whether they wish to know of any results that may have potential significance, such as a genetic condition.
169. In exceptional circumstances where it is in the interests of another person to do so, the HTA or the Court of Session may direct that DNA analysis may be used for obtaining scientific or medical information about a living person, even if their consent has not been obtained. The [HTA has established a process to permit the analysis of DNA without consent, provided that it is satisfied that certain conditions have been met.](#)
170. As well as defining the excepted purposes for which consent for analysis of DNA is not required, some material is itself excepted under the HT Act. Consent is not required for the DNA analysis of bodily material if it has come from the body of a person who died over hundred years ago or it is an existing holding and the person's identity is unknown, and unlikely to become known, to the person holding it.

Fetal tissue

171. The law does not distinguish between fetal tissue and other tissue from the living; fetal tissue is regarded as the mother's tissue. Consequently, fetal tissue is subject to the same consent requirements under the HT Act as all other tissue from the living (see section on tissue from the living, paragraphs 122-160). However, because of the sensitivity surrounding pregnancy loss, it is good practice to always obtain consent for the examination of fetal tissue and for its storage or use for all scheduled purposes.

172. It is also good practice to obtain consent for [research](#) on non-fetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is non-identifiable.
173. It should be noted that the reference to fetal tissue within this code does not include stillbirths (babies born dead after 24 weeks gestation), or neonatal deaths (babies or fetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Obtaining consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for gaining consent for use of the tissue of the deceased (see paragraphs 81-121). It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.
174. It is recognised that, in the absence of specific legal requirements, guidance on the use of fetuses and fetal tissue for [research](#) has been derived from the 1989 Review of the Guidance on the Research Use of Fetuses and Fetal Material, also known as the Polkinghorne Guidelines. A number of aspects of the Polkinghorne Guidelines are outside the remit of the HTA and of this code of practice. However, it should be noted that guidance within the Polkinghorne guidelines which recommended that in the context of giving consent, women should not know the purpose for which the fetus would be used, or whether it would be used at all, is now superseded by guidance within this code on valid consent, which must be based on the person's understanding of what the activity involves (see section on valid consent paragraphs 33-38).
175. Pregnancy remains of less than 24 weeks gestation are considered to be the mother's tissue. The HTA will shortly issue separate guidance on the disposal of pregnancy remains, which reflect the very sensitive nature of these. [Interim guidance can be found here](#).

Appendix A

Table setting out consent requirements under the HT Act for scheduled purposes.

Scheduled purpose	Consent required for human tissue from the living			Consent required for human tissue from the deceased		
	Removal	Storage	Use	Removal	Storage	Use
Anatomical examination	N/A	N/A	N/A	✓	✓	✓
Determining the cause of death**	N/A	N/A	N/A	✓	✓	✓
Establishing after a person's death the efficacy of any drug or other treatment administered to them	N/A	N/A	N/A	✓	✓	✓
Obtainingscientific or medical information about a living or deceased person which may be relevant to any person (including a future person)	N/A	N/A	N/A	✓	✓	✓
Public display	X*	✓	✓	✓	✓	✓
Research in connection with disorders, or the functioning of the human body	X*	✓	✓	✓	✓	✓
Transplantation	X*	✓	✓	✓	✓	✓
Clinical audit	X*	X	X	✓	✓	✓
Education or training	X*	X	X	✓	✓	✓
Performance assessment	X*	X	X	✓	✓	✓
Public health monitoring	X*	X	X	✓	✓	✓
Quality assurance	X*	X	X	✓	✓	✓

✓ Consent is required under the HT Act

X Consent is not required under the HT Act

* Consent is required under the common law of removal of tissue from the living

** Consent is not needed for investigating cause of death under the authority of the coroner

Appendix B

Table setting out when consent is required for different activities and when it is recommended as good practice.

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Storage and/or use of tissue from the <u>living</u> for the scheduled purposes of: I. obtaining scientific or medical information which may be relevant to any other person, now or in the future II. public display III. research IV. transplantation	✓		Paragraph 113	
Storage and/or use of tissue from the <u>living</u> for research, where the research is ethically approved and the tissue is non-identifiable	X	✓	Paragraph 117 - 123	
Storage and/or use of tissue from the <u>living</u> for the scheduled purposes of: I. clinical audit II. Education or training relating to human health III. performance assessment IV. Public health monitoring V. quality assurance	X		Paragraph 114	
Diagnosis and treatment	X	Consent is required under the common law for removal of tissue from the living	Paragraph 115 - 116	<ul style="list-style-type: none"> · Department of Health guidance · Northern Ireland Reference guide to consent for examination, treatment or care · Welsh Assembly Government guide to consent for examination or treatment

Table setting out when consent is required for different activities and when it is recommended as good practice

Activity (Consent may be sought for more than one activity at the same time)	Consent required	Consent recommended as good practice	Guidance	
			Code reference	Further guidance
Removal, storage and/or use of material from the <u>deceased</u> for any scheduled purpose	✓		Paragraph 72	
Coroner's post-mortem	X		Paragraph 108 - 112	<ul style="list-style-type: none"> · The Cremation (England and Wales) Regulations 2008 · HTA code of practice on post-mortem examination
Criminal justice	X		Paragraph 112	<ul style="list-style-type: none"> · Section 39 of the HT Act (Criminal justice purposes)
Storage and/or use of imported material	X	✓	Paragraph 69	<ul style="list-style-type: none"> · HTA code of practice on import and export of human bodies, body parts and tissue
DNA analysis (other than for an excepted purpose)	✓		Paragraph 152 - 156	
DNA analysis (for an excepted purpose)	X		Paragraph 154 - 156	
Making and displaying of images	X	✓	Paragraph 70 - 71	<ul style="list-style-type: none"> · General Medical Council making and using visual and audio recordings of patients
Storage and/or use of existing holdings	X		Paragraph 65 - 68	

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](#)

[Mental Capacity Act \(MC Act\) 2005](#)

[Department of Health Consent guidance](#)

[Welsh Assembly Government Reference guide to Consent for examination or treatment](#)

[Department of Health, Social Services and Public Safety \(DHSSPS\) \(Northern Ireland\) Reference guide to Consent for examination, treatment or care](#)

[Royal College of Obstetricians and Gynaecologists guidelines Cord blood banking: information for parents](#)

[Office of the Public Guardian](#)

[Mental Capacity Act 2005 code of practice](#)

[Welsh Assembly Government guidance on the Mental Capacity Act 2005](#)

[Department of Health, Social Services and Public Safety \(DHSSPS\) \(Northern Ireland\) Consent documents](#)

[The Adults with Incapacity \(Scotland\) Act 2000](#)

[The Health Research Authority \(HRA\) guidance on model consent forms / information sheets](#)

[Welsh Assembly Government Consent documents](#)

[Equality Act 2010](#)

[Health Research Authority \(HRA\) guidance](#)

[General Medical Council \(GMC\) publication Making and using visual and audio recordings of patients](#)

[Children Act 1989](#)

[Data Protection Act 1988](#)

[General Medical Council \(GMC\) guidance](#)

[Department of Health guidance Confidentiality: NHS code of practice](#)

[Welsh Assembly Government guidance Confidentiality: Code of practice for health and social care in Wales](#)

[Model consent forms](#)

[Department of Health, Social Services and Public Safety \(DHSSPS\) \(Northern Ireland\) guidance Post mortem examinations: careplan and consent forms](#)

[Ministry of Justice \(MOJ\) information on coroners](#)

[Coroners Practice and Procedure Rules \(Northern Ireland\)](#)

[General Medical Council \(GMC\) guidance Consent: patients and doctors making decisions together](#)

[Department of Health Governance arrangements for NHS Research Ethics Committees](#)

[The Medicines for Human Use \(Clinical Trials\) Regulations 2004](#)

[Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006](#)

[General Medical Council \(GMC\) guidance 0-18 years: guidance for all doctors](#)

[Report of the Joint Committee on Medical Genetics Consent and confidentiality in genetic practice: guidance on genetic testing and sharing genetic information \(September 2011\)](#)

Medical Research Council: [Research and the Human Tissue Act - DNA Analysis \(October 2007\)](#)

[HTA guidance on Non-consensual DNA analysis](#)

Supplementary references

[HTA guide to licensing for DIs and LHs](#)

[Welsh Language Act](#)

[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

Anatomical examination: Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.

Appropriate consent: Defined in the [Human Tissue Act](#) by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.

Best interests: A test of a person's best interests takes into account not only the medical but also the wider emotional, psychological and social aspects of the potential procedure, as well as the risks.

Bodily material: Defined by the HT Act as material which has come from a human body and consists of or includes human cells. Unlike relevant material this includes gametes, embryos outside the human body and hair and nail from the body of a living person.

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.

Clinical audit: A process to review explicit criteria and the implementation of change to continuously improve patient care and outcomes.

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.

DNA (deoxyribonucleic acid): A polymer made up of a series of repeating units. DNA encodes the instructions required to assemble cells and regulate processes in living cells. The instructions are contained within sections of DNA which are known as genes.

Donation: The act of donating human tissue, cells, organs or part organs for a scheduled purpose either during life or after death.

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.

Gillick competent (or Fraser competent): In the case of *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] 1 AC 112 the court found that a child below 16 years of age will be competent to consent to medical treatment if they have sufficient intelligence and understanding to make decisions regarding their own healthcare.

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.

Nominated representative: A person appointed to represent someone after their death who is empowered to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.

Non-identifiable: Ensuring that if human tissue is removed from a human body, all necessary steps are taken to prevent the person from whose body the material has come from being identified.

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.

Parental responsibility: A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.

Part organ: For the purposes of the HT Act and the HT Act [Human Tissue 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.

Performance assessment: This term is intended to encompass use of material in the evaluation and assessment of in vitro diagnostic kits. This is to make it quite clear, for example, that surplus diagnostic tissue can continue to be used to calibrate and assess the comparative performance of medical devices without specific consent.

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.

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.

Qualifying relationship: Person/s who can give consent for the deceased person if the deceased person has not indicated their consent nor appointed a nominated representative.

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: 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.

Recognised Research Ethics Committee:

- a Research Ethics Committee (REC) established under and operating to the standards set out in the governance arrangements issued by the [UK Health Departments](#) or
- an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the [Medicines for Human Use \(Clinical Trials\) Regulations 2004](#).

RNA (ribonucleic acid): A type of nucleic acid present in the nucleus, and occasionally in the cytoplasm. Cellular forms include ribosomal RNA, messenger RNA and transfer RNA. Messenger RNA can be used to obtain genetic information.

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 his 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.

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

Valid consent: Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.