Donation of solid organs and tissue for transplantation

Draft Code of Practice (Part two – Deceased organ and tissue donation)
Note: This document is a draft Code of Practice and as such is liable to change before being presented to Parliament.

This document is not to be used operationally.

If you have any questions, please contact the Human Tissue Authority on code@hta.gov.uk.
Code F: Donation of solid organs and tissue for transplantation (Part two – Deceased organ and tissue donation)

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Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority’s (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:
   a) post-mortem examination;
   b) anatomical examination;
   c) public display of tissue from the deceased; and
   d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.

3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.

4. This document is part of a suite of Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA’s remit under the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.

5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA’s remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.

6. **HTA Code A: Guiding principles and the fundamental principle of consent** contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:
   a) consent;
   b) dignity;
   c) quality; and
   d) honesty and openness.
7. With regard to organ and tissue donation, this means donated organs and tissue must be used in accordance with the consent in place¹, that donors and their families² must be given the information they need to be able to make a decision that is right for them and that those discussing consent should do so with sensitivity and an appreciation of the particular circumstances in each case. It also means that the dignity of the donor must be respected at all times and that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.

8. Code F is published as two main sections:
   a) Code F (Part One) Living organ donation
   b) Code F (Part Two) Deceased organ and tissue donation

   Code F (Part Two) provides guidance to Specialist Nurses for Organ Donation (SNODs), Specialist Requesters (SR), Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. See also paragraphs 31-35.

9. In combination, Code A and this Code (Code F) aim to support organ and tissue donation and transplantation, where appropriate consent is in place, by providing anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

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¹ In England, it is lawful for consent for deceased organ donation to be ‘deemed’ in certain circumstances. See paragraphs 115-121.
² Throughout the Codes, the term ‘family’ should be taken to include a spouse or partner and, in cases where there is no family, close friends of the deceased person. Where applicable, decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act, details of which can be found at paragraphs 101-110.
Deceased organ and tissue donation

Scope of this Code of Practice

10. In deceased donation, the removal, storage and use of organs and tissue for transplantation is governed by the HT Act, including Vascularised Composite Allografts. Before organs and tissue can be removed, stored or used for transplantation, appropriate consent must be obtained. This Code advises practitioners on meeting the necessary consent provisions for this activity to be undertaken lawfully.

11. This Code applies to England and Northern Ireland. The sections relating to consent which is expressly given apply to both England and Northern Ireland; the sections relating to deemed consent apply to England only.

12. In England, the Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) modifies the appropriate consent provisions in the HT Act for organ donation and transplantation after death such that consent can be deemed in certain circumstances.

13. In Northern Ireland, the Deemed Consent Act does not apply, and practitioners should follow the guidance in paragraph 44 of this Code.


16. In addition to the consent requirements above, establishments may also be subject to the licensing requirements of both the HT Act and The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q & S (Organ) Regulations). This Code does not include detailed information on the Q & S (Organ) Regulations. Further information can be found in Annex A paragraphs 6-7 and the HTA publication ‘The Quality and Safety of Organs Intended for Transplantation – a documentary framework’. Further information on the licensing requirements under the HT Act can be found in paragraphs 184-190.
Offences under the HT Act

17. The HT Act sets out a number of offences, for which the maximum penalty is imprisonment and/or a fine. In relation to organ and tissue donation, the offences are as set out below.

18. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.

19. Section 8 of the HT Act makes it an offence to store or use donated material for anything other than a qualifying purpose.

20. Section 32 of the HT Act makes it an offence to engage in commercial dealings in human material for transplantation.

21. Section 34 creates an offence of failing to comply with the Regulations made under this section, and failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations. This offence is subject to a fine only.

Conditions on consent for organ transplantation

22. Consent may be limited in a variety of ways. The HT Act does not prevent an individual from placing limits on their consent via the imposition of conditions, for example, to particular research studies or to donate specific organs.

23. The HT Act recognises that individuals have the autonomous right to give or refuse consent to all or any of their organs or tissue being used for transplantation after their death.
24. No organ should be transplanted under a form of consent which seeks to impose restrictions on the class of recipient of the organ, including any restriction based on a recipient's gender, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2010). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010.

25. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK and, as a matter of policy, does not accept organs from deceased donors where any restriction is attached. However, requested allocation (directed donation) of a deceased donor organ can be considered if this is carried out in line with NHSBT policy.

26. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could or would not be fulfilled, as valid consent would not be in place. Only the person who has attached the condition to the consent can put the condition aside.

Further legal considerations

27. This Code should be read in conjunction with the National Institute for Health and Care Excellence (NICE) clinical guideline 135 on Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation. NICE recommends that organ donation should be considered as a usual part of end-of-life care planning.

28. The HTA’s remit is to provide guidance on what constitutes lawful consent to organ and tissue donation after death has been diagnosed either using neurological death criteria or circulatory death criteria. Diagnosis of death is a matter for clinicians providing end-of-life care.

29. For a patient with a life-threatening or life-limiting condition, the clinical team may, in discussion with the family, decide to withdraw life-sustaining treatment. This would usually be expected to result in circulatory death with the attendant possibility of Donation after Circulatory Death (DCD). Where the patient lacks capacity, any decisions about the timing of withdrawal of life-sustaining treatment or the institution of new therapies or treatments to enable organ donation to proceed must be taken in the patient’s best interests. The patient’s
known decision with regard to organ and tissue donation, whether recorded or as expressed to the family, is one factor to include in the assessment of the patient's best interests. Any discussion with the family should be approached and conducted sensitively.

30. NHSBT is currently working with the British Medical Association (BMA) to produce guidance on legal aspects of interventions before death in DCD cases.

**Structure and navigation**

31. This Code provides guidance to Specialist Nurses for Organ Donation (SNODs), Tissue Donor Coordinators, and others who discuss consent for deceased organ and tissue donation.

32. Where the word ‘evidence’ is used this refers to the HT Act, where ‘information’ is used, it refers to the Deemed Consent Act.

33. The first part of the Code provides an overview of deceased organ and tissue donation, including general advice in relation to the role of the family and faith and beliefs (paragraphs 49-66)

34. The Code has further sections on consent which is expressly given (paragraph 67-81) and deemed consent (in England) (paragraphs 115-121).

35. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA’s website.
Overview of deceased organs and tissue donation

36. In all cases of donation, the decision of the potential donor either to consent, or not to consent, to donation of organs or tissue for transplantation is paramount. If a person made a decision regarding organ donation to donate or not donate when they were alive, their consent cannot be deemed. The Organ Donor Register (ODR) operates throughout the UK to allow individuals to record their decision to either donate or not to donate organs or tissue after their death.

37. Individuals may appoint one or more persons (nominated representative/s) to make a decision about donation after they have died. There are specific requirements (see paragraphs 79-85 of Code A) under the HT Act in relation to nominated representative/s.

38. In England, the Deemed Consent Act amends the HT Act so that where an adult has neither a) made a decision to donate or not to donate organs or tissue, nor b) appointed a nominated representative to make a decision on their behalf, then consent for donation of organs and tissues will be considered to be in place (“deemed consent”).

39. This will be the case, unless the potential donor is a child, an excepted adult, or information is provided by their family that demonstrates that the potential donor would not have consented.

40. A child is a person under the age of 18.

41. An excepted adult is:

   a) An adult who had not been ordinarily resident in England for a period of at least 12 months immediately before dying;

   b) An adult who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

42. The Deemed Consent Act only applies to certain organs or tissue, referred to as permitted material. Further information on permitted material is given in paragraphs 158-161.

43. Where the donor is a child or an excepted adult, and consent cannot be deemed, donation can only proceed where consent has been expressly given by the potential donor before their death, or is given after their death by a nominated representative or a person in a qualifying relationship (see glossary).
44. In **Northern Ireland**, the Deemed Consent Act does not apply. Consent must always be given expressly by the potential donor before their death, or after their death by a nominated representative or a person in a qualifying relationship.

45. The existence of appropriate consent permits an activity to proceed, but does not mandate that it must.

**Recording a decision about organ donation**

46. Neither the HT Act nor the Deemed Consent Act require that a person records their decision about organ and tissue donation in a specific manner.

47. This means that it is for the individual to decide how they wish to do this. Options include registering their decision whether to donate or not to donate on the Organ Donor Register (ODR), telling a friend or family member, or recording it in writing. Further information on the ODR is provided in paragraphs 71-81.

48. The ODR is checked in every potential case of organ and tissue donation and the information stored is communicated by the Specialist Nurse for Organ Donation/Specialist Requester (SNOD/SR) to family and/or friends.

**Role of the family**

49. The family plays a key role in the donation process. The nature of the role with respect to consent will depend on a number of factors including whether consent has been expressly given by the potential donor, whether the circumstances are such that consent may be deemed, or whether the family will be asked to make the decision. Further information on the role of the family in different donation situations is given throughout this Code.

50. Regardless of the particular role, sensitive communication and engagement with the family play an essential part in supporting them throughout the donation process.

51. Family and friends are asked to provide medical and social background information about the potential donor. This is not part of the consent process,
but a necessary part of clinical practice so that clinical decisions can be made about the suitability of organ donation in light of all of the relevant information.

52. There are many factors that need to be considered in deciding whether donation can proceed, based on the circumstances of each case. Each stage of organ donation, from intensive care admission to organ retrieval, is comprehensively set out in NHSBT’s guide ‘The Journey Through Intensive Care and the Gift of Organ Donation’ which may provide useful information for families.

53. If those close to the potential donor object to the donation where appropriate consent is in place, the SNOD/SR should discuss the matter sensitively with them to understand their concerns. Although the family does not have the legal right to overrule appropriate consent, it is important that its views are considered (see paragraphs 75-81).

54. There may be situations where family members hold differing views. In these cases the SNOD should provide them with the time and information they need to come to an agreement. Further guidance on specific situations is given in paragraphs 79, 108-110 and 157.

55. Where no individual in a qualifying relationship can be traced and there is no record on the Organ Donor Register that the potential donor wanted to donate, it is NHSBT policy that donation should not proceed.

56. If there is a decision to donate recorded on the Organ Donor Register but it is not possible to trace an individual in a qualifying relationship, consent would be in place. However, it is still unlikely that donation would proceed. This is for the protection both of the patient and any recipients of organs, as the family plays a key part in providing clinicians with medical information.

**Faith and beliefs**

57. Attending to a potential donor’s cultural and religious/non-religious beliefs is an important part of person-centred care. Such beliefs should be considered sensitively and as a decisive factor in determining the views of the potential donor regarding consent for donation.

58. When registering a decision to consent to organ donation on the ODR, individuals can record if their faith or beliefs are important to them in relation to organ donation. The text on the ODR reads “I would like NHS staff to speak to
my family and anyone else appropriate about how Organ Donation can go ahead in line with my faith or beliefs”.

59. The question is not mandatory, and individuals have the option to select whether this statement is applicable to them, is not applicable to them or they would prefer not to say. The SNOD/SR should use the information to guide the approach to the family.

60. Where an individual has selected that this statement is applicable to them, the SNOD/SR should explain this to the potential donor’s family and discuss the potential donor’s faith, beliefs and values. The SNOD/SR should answer any questions and seek further guidance and support from faith representatives if required.

61. Where an individual has indicated that the statement is not applicable to them, the SNOD/SR should respect that the potential donor did not want faith or beliefs to be discussed prior to organ donation proceeding.

62. In the absence of a specific record on the ODR in relation to faith or belief, the SNOD/SR should explore whether these were important to the potential donor through conversations with family.

63. Without making assumptions, discussions should establish whether the potential donor held particular faith, belief or cultural views that may influence how and whether donation could proceed. The views of the potential donor and their family should be discussed sensitively and openly in order to reach the decision that is right for the person in question.

64. Where an individual has registered as a donor, but their family disagrees about whether donation is supported by the potential donor’s faith or belief, the SNOD/SR should explore any issues raised by the family and work with them to address any fears or concerns. Where indicated, SNOD/SRs should facilitate consultation with faith leaders to provide counsel or clarification on how donation may proceed whilst ensuring that any religious obligations are observed. For example, the family may wish to ensure appropriate end of life rituals are followed should donation take place.

65. SNOD/SRs should be given the necessary training and support to help them identify and meet the widest possible range of needs and wishes. Training should include an awareness and understanding of different cultural and religious imperatives, and how these may influence donation proceeding. It should also include the assistance that may be offered to, or requested by, the family in order that they feel informed and supported.
66. Hospitals may also have faith trained co-ordinators or a multi-faith chaplaincy service which can help facilitate conversations about organ donation between the family and SNOD/SRs.

Consent which is expressly given

Establishing whether a potential donor made a decision in life – adults

67. The HT Act establishes the principle that the decision to consent to the use of organs and tissue for transplantation after death rests first and foremost with the donor themselves. As such, the donor’s valid consent where this is recorded, or known decision as expressed to the family, should form an integral part of end-of-life care planning.

68. The HT Act makes clear that where an adult with capacity made a decision to consent to organ donation after their death, such consent is sufficient for donation to be lawful but does not mandate that it must proceed.

69. Where an adult with capacity made a decision not to consent to organ donation after their death, donation must not proceed as consent is not in place.

70. In every case where organ donation is a possibility, the SNOD/SR should determine whether the potential donor has made a decision with regard to organ donation. The SNOD/SR should seek to establish the most recent decision of the potential donor in conversation with their family and friends, i.e. the decision in force immediately before death.

The Organ Donor Register as a source of consent

71. The ODR operates throughout the UK to allow individuals to record their decision about organ and tissue donation. The ODR allows people to record whether they want to donate all, some, or no organs and tissue.

72. As long as a potential donor registered their decision voluntarily, had the information they needed to make the decision to register and had mental capacity or competence when they registered, then the decision recorded on the ODR constitutes valid and appropriate consent at the time of registration.

73. A legally valid decision from the donor themselves is sufficient to allow organs and tissue to be retrieved for transplantation where they have decided to donate. Similarly, in circumstances where they have decided not to donate,
donation cannot proceed. There is no legal right for anyone in a qualifying relationship to revoke a legally valid decision to give or withhold consent (see paragraph 79).

74. The ODR allows the following decisions to be recorded:

a) I consent to donate all my organs after death;

b) I consent to donate some (specified) organs after death;

c) I do not consent to donate my organs after death;

d) I wish to appoint a representative to make a decision on organ donation after death on my behalf.

75. If the recorded decision was not to consent to organ donation, then this can be communicated to the family. If the family believe that this was not the most recent decision of the potential donor, the family should provide the SNOD/SR with evidence that the potential donor had made a more recent decision to consent to organ donation, and that this decision supersedes the recorded decision not to consent to organ donation.

76. If it is clear to the SNOD/SR that the potential donor had changed their mind, having previously recorded a decision not to consent on the ODR, then donation could go ahead.

**Example**

The potential donor registered on the ODR her decision not to donate her heart. Unless information is provided that she had changed her mind since registering, this constitutes a legally valid decision not to consent, and heart donation could not proceed. The family cannot overturn a decision not to consent. However, if the family can provide evidence of a more recent decision, this needs to be carefully assessed.

77. If family or friends state that a potential donor who was registered on the ODR had revoked their decision to consent to organ donation, the SNOD/SR should explore this further with the family in order to support this assertion.
Example

A potential donor registered a decision to consent to donate all organs on the ODR. The potential donor’s mother says that her son subsequently changed his mind about donation prior to his death. The SNOD/SR will want to understand the context of the evidence that is presented by the mother including whether it was written or verbal, and, if verbal, whether such a conversation was witnessed. The SNOD/SR will have a sensitive discussion with the potential donor’s mother exploring the reasons why the deceased changed his mind.

78. In making a decision about whether there is valid consent to proceed with donation, the SNOD/SR must decide how much weight to attribute to the evidence. These questions may be:

   a) Is the evidence in writing, signed and dated by the potential donor and witnessed? If this is the case, then this is likely to be an express decision by the potential donor (it is important to note that revocation of a decision to consent, or a decision not to consent, does not need to be written, but that a written revocation will be of greater weight);

   b) Is the evidence given orally? If so, is it confirmed by more than one person?

   c) Is the evidence presented as reflecting the views of the potential donor, or the views of the family? If the latter is the case, then this is likely to constitute an objection rather than evidence that the potential donor had changed his or her mind.

79. Where valid consent has been given by the donor, but the family object to organ or tissue donation proceeding, then they should be sensitively supported to respect the potential donor’s consent to ensure his or her decision is fulfilled. A family’s objection does not nullify appropriate, valid consent from the potential donor.
Example

A potential donor has given valid consent to the donation of her organs for transplantation. Her son does not want the donation to proceed because he does not want organ retrieval to take place during a traumatic time for the wider family. The son should be sensitively supported to honour his mother’s decision, thereby fulfilling her end of life wishes. The SNOD/SR will support the family’s needs and attend to whatever is important for them, in respect of culture, faith or simply to provide time with the donor. The donor’s consent is still valid and retrieval could proceed (see more information below).

80. As stated in paragraph 45, the existence of appropriate consent permits an activity to proceed, but does not mandate that it must. The final decision about whether to proceed with the activity rests with the SNOD/SR, in conjunction with medical practitioners and in conversation with the family.

81. Those close to the patient will be involved in making best interests decisions for the patient who lacks capacity when Donation after Circulatory Death (DCD, see paragraph 168) is a possibility. As described in paragraph 29, ODR consent is one factor to take into account when assessing whether ante-mortem interventions to facilitate organ donation are in the potential donor’s best interests.

Nominated representative

82. If the potential donor’s decision is not known and they were an adult who had nominated a person to deal with the use of their body after death, then any decision on consent must be given by that nominated representative (see paragraphs 79 – 85 of Code A). The HT Act sets out the requirements for a valid appointment of a nominated representative.

83. The name and contact details of the nominated representative/s may have been recorded on the ODR. If there is a recorded nominated representative/s, the SNOD/SR should contact them and ask them to make a decision on behalf of the potential donor.

84. If the details of the nominated representative are on the ODR, the SNOD/SR does not need to carry out the checks at paragraphs 87-91.

85. If there is no record of a nominated representative on the ODR, the SNOD should make reasonable enquiries at the hospital and with those close to the potential donor to ask whether a nominated representative was appointed to take those decisions.
86. If the SNOD/SR has been informed verbally that there is a nominated representative/s, the checks at paragraphs 87-91 below should be undertaken to ensure they have authority under the HT Act.

87. If the nomination was made orally, the SNOD/SR should check that the appointment was witnessed by at least two people present at the same time. This can be confirmed either by the two witnesses or in a document produced with the two witnesses’ signatures confirming they witnessed the nomination.

88. If the nomination was made in writing, the SNOD/SR should be assured that one of the statements at a-c below is true:

   a) The document making the nomination was signed by the potential donor in the presence of a witness who confirmed the signature; or

   b) It was signed by another person at the direction of, and in the presence of, the potential donor, and in the presence of a witness who confirmed the signature; or

   c) It was contained in the will of the potential donor, and that will was made lawfully.

89. If more than one person has been nominated, only one of them needs to give consent unless the terms of the appointment specify that they must act jointly.

90. However, the appointment may provide that multiple representatives must act jointly. This means that all representatives must agree in order for consent to be given. In these circumstances, if one representative cannot be contacted then the other representative(s) cannot give consent.

91. It may be the case that a potential donor nominated a representative/s but did not record them on the ODR or tell their family/friends about them. It is recognised that it is not practical for the SNOD/SR to make extensive checks to establish whether a potential donor nominated a representative/s. It is therefore considered reasonable for a SNOD/SR to check the ODR and to ask family/friends. If the SNOD/SR is not made aware of a nominated representative/s at this stage, it is reasonable to proceed as if no representative had been appointed. It is important that a note is made of these checks and any discussions with family/friends.

92. A child cannot act as a nominated representative under the HT Act.
93. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not reasonably practical to communicate with the nominated representative within the time available.

94. In England, if, despite all reasonable efforts, the nominated representative cannot be contacted in time to make a decision, or is unable to make a decision, then consent can be deemed if the potential donor is not in one of the excepted groups (see paragraph 115 on deemed consent). For all other circumstances then consent may be given by a person in a 'qualifying relationship'.

When there is no decision on the ODR or nominated representative(s)

95. Once the SNOD/SR has established that the potential donor had not recorded a decision on the ODR or nominated a representative/s, they should have further conversations with family/friends about whether they know of any decisions taken by the potential donor on organ donation after death.

96. If the SNOD/SR is informed that the potential donor had recorded their decision in writing, but not on the ODR, the SNOD/SR should seek to establish where that record is held and to gain a copy of it.

97. If the SNOD/SR is informed that the potential donor expressed their decision orally, the SNOD/SR should speak with the person who was informed of the decision and make a note of the details of this conversation.

98. The SNOD/SR must take a view as to whether the information they receive is reliable.

99. A written, signed, dated and witnessed record is very likely to satisfy the SNOD/SR that this was the decision of the potential donor. Other forms of information, including oral information such as a previous conversation, are also capable of satisfying the SNOD/SR that they represent the potential donor's most recent decision.

100. In England, if the SNOD/SR is not satisfied that the information presented to them constitutes the decision of the potential donor, or is informed that the potential donor had not made a decision, then consent can be deemed unless the potential donor is a child or an excepted adult. The final decision about whether to proceed rests with the SNOD/SR, in conjunction with medical practitioners and in conversation with the family.
The role of qualifying relationships in situations where deemed consent does not apply

101. Deemed consent does not apply to:

   a) excepted adults and children in England

   b) material which is not permitted material [subject to draft Regulations which DHSC is consulting on until 22 July; link will be provided in final text]

102. In such circumstances, then appropriate consent may be given by someone who was in a qualifying relationship with the potential donor immediately before their death.

103. Deemed consent also does not apply to donations taking place in Northern Ireland.

104. Further information on qualifying relationships can be found in paragraphs 32-39 of Code A.

105. The HT Act includes at section 27(4) a list of qualifying relationships that are ranked:

   a) Spouse, civil partner, or partner;
   b) Parent or child;
   c) Brother or sister;
   d) Grandparent or grandchild;
   e) Child of a brother or sister (niece or nephew);
   f) Stepfather or stepmother;
   g) Half-brother or half-sister; or
   h) Friend of long standing.

106. A person is another person’s partner if the two of them lived as partners in an enduring family relationship. Partner can be different sexes or be of the same sex.

107. A friend of long standing is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD/SR may ask questions and/or request information as necessary to establish what degree of friendship existed.
108. When there is disagreement between people in different positions on the ranked list, it is recommended that the SNOD/SR seeks to provide those people with the time and information they need to come to an agreement.

109. If it is not possible to reach an agreement, the hierarchy of consent applies and a decision on consent should be obtained from the person whose relationship to the potential donor is accorded the highest ranking on the list (see paragraph 105). The SNOD/SR may wish to refer to the Team Manager or Regional Manager on-call, who would consult with the Medical Director of NHSBT. The decision to proceed lies with the highest-ranking nurse/clinician consulted.

110. In a situation in which the list is ranked and agreement cannot be reached between people of the same rank, it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD/SR will need to carefully consider the emotional impact of any decision on family and friends.

Consent for organ donation – children

111. The position for a child, who was competent to reach a decision before they died and consented to organ and tissue donation taking place after their death, is legally no different from that of an adult. The child’s consent is sufficient to make the removal, storage or use of their organs for transplantation lawful.

112. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that in this instance the appropriate consent for organ and tissue donation will be that of a person with parental responsibility for the child immediately before they died. The consent of only one person with parental responsibility is necessary. Where no person had parental responsibility for the child immediately before they died, appropriate consent will be that of someone in a qualifying relationship to them.

113. Consent for organ and tissue donation from a child under 18 cannot be deemed.

114. Further information on consent by and on behalf of a child can be found in paragraphs 87-94 of Code A.
Deemed consent (England only)

Circumstances in which consent can be deemed

115. In cases where the decision of a potential donor regarding consent for organ and tissue donation cannot be established from the ODR or from family or friends, or where a nominated representative is unable to act, then consent can be deemed, subject to certain exceptions.

116. There may be occasions where a potential donor has not recorded a decision nor appointed a representative and, despite the efforts of the SNOD/SR, there are no friends or family in existence or available for the SNOD/SR to speak with. It is NHSBT policy in these cases that donation should not and does not proceed.

117. As outlined in paragraphs 67-99 steps must be taken to determine the decision of the potential donor using the ODR and information from family and friends, or as made by a nominated representative. If a potential donor made a decision in regard to organ donation when they were alive, their consent cannot be deemed.

118. If a person appointed a representative to make a decision, the decision of the nominated representative should be acted upon. If the nominated representative cannot be contacted in time to make a decision, or is unable to make a decision, then consent can be deemed subject to the exceptions set out below. The SNOD/SR should make every reasonable effort to contact the nominated representative and the family should be given the opportunity to provide further information (see paragraphs 148-157).

119. Deemed consent can only apply where the potential donor is an adult.

120. Consent cannot be deemed if:

   a) the donor is an excepted adult or a child

   b) a person in a qualifying relationship provides information that would lead a reasonable person to conclude that the potential donor would not have consented
c) the transplantation activity involves relevant material which is proposed to be excluded from deemed consent, as specified by the Secretary of State in draft Regulations\(^3\) (see paragraphs 158-161)

121. In circumstances where consent cannot be deemed, consent should be sought from a person in a qualifying relationship (see paragraphs 101-110).

**Establishing whether the potential donor is an excepted adult**

122. For excepted adults, consent cannot be deemed and consent should, in these circumstances, be sought from a person in a qualifying relationship (see paragraphs (101-110).

123. Excepted adults are:

a) An adult who had not been ordinarily resident in England for a period of at least 12 months immediately before dying; or

b) An adult who lacked the capacity to understand the notion of deemed consent for a significant period before their death. Further information on these circumstances is below.

**Residency**

124. For deemed consent to apply, the potential donor must have been ordinarily resident in England for twelve calendar months immediately prior to their death. For the purposes of deemed consent, the time of death is taken to be the date on which death is confirmed by one of the processes laid out in the Academy of Medical Royal Colleges (AoMRC) Code of Practice for the Diagnosis and Confirmation of Death.

125. For the purposes of the HT Act, “in England” means within an English local authority area. Information on the local authorities can be found on the [local government structure and elections](https://www.gov.uk/government) webpage.

126. In most cases a SNOD/SR will be able to establish where the potential donor lived, and whether they were ordinarily resident (see paragraphs 131-137) at an address or several addresses in England, either from medical records or through discussions with family and friends.

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\(^3\) [DHSC is consulting on what should be excluded from deemed consent until 22 July at https://www.gov.uk/government/consultations/opt-out-organ-donation-organs-and-tissues-excluded-from-the-new-system]
127. If there is reasonable cause for doubt, the SNOD/SR should check whether the potential donor’s address was in England. If this is not possible, for example the service to access a potential donor’s address (e.g. medical records) is unavailable for a period of time which would mean the opportunity for donation is missed, and the potential donor cannot safely be assumed to be ordinarily resident in England, then consent should not be deemed.

Example

An adult dies in a hospital on 15 February. It is established by speaking to their family/friends that they moved to England on 17 February of the previous year. Deemed consent does not apply to them, as they had not lived in England for twelve calendar months when they died.

Had the potential donor’s family/friends confirmed that they had moved to England on 15 February, and that the potential donor was ordinarily resident in England throughout that period, deemed consent would apply to them, as they had lived in England for twelve calendar months when they died.

128. The twelve-month period test does not involve counting the number of days a potential donor had lived in England. Rather, it is necessary to establish that a potential donor had been resident in England for at least twelve calendar months.

129. In some cases, it may not be possible to establish the exact date a potential donor started living in England. For example, their family/friends may not be able to remember exactly when they moved to England, but do know it was within the last ten to fourteen months.

130. When this is the case and there is no clear evidence available to confirm the time since the potential donor started living in England, then consent should not be deemed.

Ordinarily resident

131. A potential donor will be “ordinarily resident” in England when that residence is lawful, adopted voluntarily, and for settled purposes as part of the regular order of their life for the time being. Ordinary residence can be of long or short duration, but deemed consent will not apply unless someone has been ordinarily resident for at least 12 months immediately before dying. The
SNOD/SR will need to ask questions to gather evidence in such circumstances. More information on these qualities follows:

a) The residence is lawful.

British citizens will always have a right to live in England so will always be in England lawfully. Some commonwealth citizens also have an automatic right to live in England. For people who do not have an automatic right, they will need permission to be in England to be lawfully resident, for example, immigration permission.

Some people may be lawfully in England but will not be ordinarily resident. For example, an asylum seeker awaiting determination of their claim for asylum may be lawfully present in England but in most cases would not be ordinarily resident in England. Other people may lawfully live in England for an extended period (e.g. a person who has been granted asylum) but may not regard England as their home and are not settled here.

People who are unlawfully in England and who do not have permission to enter or remain cannot be ordinarily resident.

b) The residence was adopted voluntarily.

It will be rare for a person not to be in England voluntarily. For example, the fact that the potential donor chose to come to England at the request of an employer, rather than seek another job, is unlikely to make their presence in England involuntary.

c) The potential donor was resident for settled purposes.

There must be an identifiable purpose for their residence here with a sufficient degree of continuity to properly be described as settled. Business, education, employment and family can all provide a settled purpose, but this list is not exhaustive. There may be one purpose or several, and it may be for a limited period.

d) The potential donor’s residency in England supported the regular order of their life for the time being.

There is no requirement for any person to be living in England permanently or indefinitely. The potential donor may have had temporary absences from England and still be considered ordinarily resident. It is
also possible to be ordinarily resident in more than one place. In such cases, care should be taken to ensure that ordinary residence has been established.

132. These requirements must be assessed on a case-by-case basis weighing up the relevant information. Whether the requirements have been satisfied will primarily be a question of fact. In many cases the SNOD/SR will be able to establish easily whether the potential donor’s residence was characterised by the requirements above. When residence is initially unclear, it is recommended that there is a sensitive discussion with family/friends to gain more information about how the potential donor would have characterised their residence.

133. When a SNOD/SR has reasonable cause to doubt that the potential donor was ordinarily resident in England, then consent should not be deemed.

Example

A potential donor may work in London and live there four nights a week and spend the other three nights at their family home in Glasgow. The SNOD/SR should ask questions of the family/friends to establish how the potential donor would have identified their residency. The SNOD/SR may wish to ask where the potential donor would have referred to as home, amongst other considerations. It will then be for the SNOD/SR to weigh up the evidence to establish whether the potential donor was ordinarily resident in England.

Students

134. Education can have the quality of a settled purpose and a student may be regarded as ordinarily resident in the place in which they are studying or the place they consider home. Students could be considered ordinarily resident as soon as they begin studying, but their consent could only be deemed after at least 12 months of being ordinarily resident in England immediately before dying.

135. It will be for the SNOD/SR to discuss with the potential donor’s family/friends to determine whether the student’s residence in England had the necessary qualities described above before deciding whether deemed consent applies.

Prisoners
136. A person who is in prison cannot be stated to be residing in England through choice, and cannot be considered ordinarily resident in England during their time in prison. This includes prisoners who normally live in England and who are in prison in England. People in prison cannot have their consent to organ donation deemed.

*Other groups*

137. There are other groups of people, for example those detained under mental health legislation, who may or may not reside in England voluntarily. There are also those who live in England lawfully but not for a settled purpose and/or as part of the regular order of their lives. For example, diplomats, armed forces personnel or other posted workers who spend a portion of their time in England but who do not regard it as their home. It will be for the SNOD/SR to ask questions of family/friends to establish whether the person was ordinarily resident on a case-by-case basis.

*Mental capacity*

138. Deemed consent does not apply to people who, for a significant period before dying, lacked the capacity to understand that consent to transplantation activities can be deemed.

139. If a potential donor lacked capacity to understand that consent can be deemed for a significant period before their death, then consent should be sought from a person in a qualifying relationship (see paragraphs 101-110), as such an individual would be an excepted adult.

140. If at the point at which a potential donor lost capacity deemed consent did not apply to them, for example, they were a child or did not live in England, then their consent cannot be deemed.

141. In some cases, it will be evident that a potential donor lacked capacity for a significant period before dying as they may, for example, have been suffering from a persistent disorder of consciousness (coma, vegetative or minimally conscious state).

142. In other cases, to establish whether a potential donor lacked capacity for a significant period before their death, the SNOD/SR should take the following steps:
a) Check the medical records of the potential donor to establish whether there was any history of conditions or illness which may have affected the potential donor’s capacity to understand that consent could be deemed. It is important to note that a record of an episode, or episodes, of such an illness would not necessarily mean that a potential donor would not have been able to understand that consent could be deemed. However, it should prompt further investigation by the SNOD/SR.

b) If there is no indication in the medical records of a condition or illness which may have impacted the potential donor’s capacity to understand that consent could be deemed, or any assessment of the potential donor’s capacity to understand this, the SNOD/SR should make a note of this.

c) If there is an indication in the medical records of a condition or illness that may have affected the potential donor’s capacity to understand that consent could be deemed, the SNOD/SR should undertake further investigations of the condition or illness. The issue of mental capacity should be raised by the SNOD/SR when speaking to the friends/family. This could take the form of a simple question, for example, “Do you think that your relative/friend could have understood that consent to organ donation could be deemed?”

d) Where there is evidence of an illness that may have affected the potential donor’s capacity to understand that consent could be deemed, in most cases it will be the family/friends who are able to provide the SNOD/SR with the most accurate information as to whether the potential donor understood that consent to organ donation could be deemed. The SNOD/SR should ask the family/friends whether they believe the potential donor had a level of capacity to understand deemed consent. This may be a detailed discussion, and if at the end of this the SNOD/SR is not satisfied that it is more likely than not that the potential donor could have understood that consent could be deemed, then consent should not be deemed.

143. If the potential donor had been in hospital for some time it may be appropriate to speak to a member of the team caring for them to establish their level of understanding of medical and consent issues generally.

**Significant period**

144. The potential donor will be an excepted adult only if they lacked capacity for a significant period before dying in order to understand that consent could be deemed.
145. The HT Act says that a significant period means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed. The significant period test is, therefore, an objective test that must be based on the circumstances of each case and the facts presented.

146. The significant period only negates deemed consent. If the potential donor had made a decision to consent, or not to consent, while they had capacity to make that decision then that decision remains valid regardless of a subsequent loss of capacity.

147. In practice, a significant period should mean that the potential donor did not have capacity to understand that consent could be deemed for a period of twelve months immediately before their death. The twelve month period is provided in this first Code of Practice that covers deemed consent in England in order to provide regulatory certainty to SNOD/SRs and other practitioners, and is consistent with how deemed consent works in Wales. In future this Code of Practice will be reviewed and consideration given as to whether 12 months is still the most appropriate period.

Information that would lead a reasonable person to conclude that the potential donor would not have consented

148. If a potential donor is not a child or an excepted adult, and they had not made a decision in life nor appointed a nominated representative/s who had given consent under that appointment, then their consent to organ donation may be deemed.

149. When this is the case the SNOD/SR should have that discussion with the family and friends and give them the opportunity to provide information that would lead a reasonable person to conclude that the potential donor would not have consented.

150. SNOD/SRs must take all reasonable steps in the circumstances of the individual case, to discover whether persons in a qualifying relationship are available to provide such information.

151. Any person in a qualifying relationship can provide information to show that the potential donor would not have consented. The hierarchy of qualifying relationships does not apply for the purposes of providing such information. This means that, in practice, it is the quality of the information that should be considered by the SNOD/SR, and not the relationship to the potential donor of the person presenting it.
152. When there is written information from the potential donor, and this is signed by
a witness, this would form the express decision of the potential donor and so
consent must not be deemed.

153. When there is written information from the potential donor that has not been
witnessed, it will be for the SNOD/SR to decide whether this is information that
would satisfy a reasonable person.

154. Where there is other oral information, it will be for the SNOD/SR to decide
whether this is information that would satisfy a reasonable person.

155. The reasonable person test is an objective one, and involves the person
making the assessment (in this case the SNOD/SR), deciding how much weight
to place on the information presented.

156. In order to assess the weight of the information presented, the following
questions may help the SNOD/SR:

   a) Is the information presented as reflecting the views of the potential
donor, or the views of the family/friends presenting it? The test requires
that information presented must be the potential donor’s view. Therefore,
more weight should be given to information which is presented as
reflecting that potential donor’s view.

   b) Is the information oral? If so, is it confirmed by more than one person?

   c) How recent is the information? The SNOD/SR should establish when the
record was made, or the conversation took place, and note this in the
potential donor’s medical record or other appropriate document.

   d) How well does the person providing the information know the potential
donor? It is not always the case that a person knows someone well
simply because they are related. Conversely, a person may have had a
carer who is not related to them but spent every day with them.

157. Information that the potential donor was not aware that deemed consent
affected them is not sufficient, on its own, to lead a reasonable person to
conclude that the potential donor would not have consented to organ donation.

Other considerations

Novel transplants

158. The HT Act (as amended) makes provision at section 3(9) for the Secretary of
State to make Regulations setting out which organs and tissues will not be
included in deemed consent.
159. DHSC is currently consulting on draft regulations proposing a list of organs and tissues where express consent will still be required.

160. The final list of such organs and tissues will be published on the HTA website, and this will be updated when changes are made to the list.

161. If an organ or tissue is on this list, then consent must be expressly given for the removal, storage or use for the purpose of transplantation to be lawful.

**Use of organs and tissue across UK borders**

162. Legislative provision has been made to allow the storage and use of organs and tissue in Northern Ireland which are removed in England. No such provision is needed in Wales or Scotland as this is covered by current legislation.

163. This will mean that organs and tissue removed when consent in England has been deemed can be lawfully transplanted into patients in Wales, Northern Ireland and Scotland (providing all other statutory and regulatory requirements have been met).

164. This also means that organs and tissue removed in England for the purpose of transplantation when consent has been deemed can be stored, used, processed and distributed lawfully across the whole of the UK.

165. Material removed when consent has been deemed for the purpose of transplantation, which cannot be used for this purpose, can be used for research if consent to this is obtained in accordance with the requirements of the HT Act. Consent to research cannot be deemed.
Types of organ donation after death

166. There are two types of organ donation after death which are undertaken in the UK. In England, consent to donation after death is diagnosed and confirmed using neurological criteria, (commonly known as Donation after Brainstem Death) or Donation after Circulatory Death can both be deemed under The HT Act.

Donation after Brainstem Death (DBD)

167. Donation after Brainstem Death means donation which takes place following tests which diagnose and confirm death using neurological criteria, in accordance with the Academy of Medical Royal Colleges' Code of Practice for the Diagnosis and Confirmation of Death (AoMRC 2008). The majority of patients will have suffered a spontaneous and devastating bleed in the brain, but others may have suffered head trauma, for example in a car accident, or a hypoxic (lack of oxygen) event, for example following cardiac arrest. The patient's organ support, including mechanical ventilation, is maintained while consent is established or sought and (where applicable) arrangements are put in place for organ donation.

Donation after Circulatory Death (DCD)

168. Donation after Circulatory Death may be either controlled or uncontrolled.

169. Controlled DCD describes organ retrieval which follows the planned withdrawal of life-sustaining treatment at the end of a critical illness when a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005) by the treating clinical team and with the agreement of those close to the patient (e.g. family and friends).

170. Uncontrolled DCD occurs following a sudden, irreversible cardiac arrest. Currently there are no uncontrolled DCD programmes in the UK, although it is practised internationally, particularly in France and Spain.

Preservation for transplantation

171. Section 43 of the HT Act allows for minimum steps to be taken to preserve parts of a potential donor's body when it is, or may be, suitable for transplantation, but consent or the absence of consent has not yet been established.
172. These provisions relate only to the preservation of a potential donor’s body after their death. Information on interventions prior to death is provided in paragraphs 181-183.

173. In order for preservation to be lawful, the body of the potential donor must be lying in a hospital, nursing home or other institution in England or Northern Ireland.

174. The steps which can be taken to preserve the organs within the body for transplantation must be minimal and it is a requirement that the least invasive procedure is used.

175. Whether a procedure meets this test will depend on the facts of the case, including how invasive it is, when consent might be obtained, and how the family would perceive it.

176. In all cases, steps should therefore be taken as soon as possible to find out the deceased’s decision on donation, or where this is unknown, the views of their family. Where possible, appropriate consent for donation should be established before the preservation process begins, or alternatively consent for the preservation process prior to donation.

177. The taking and storage of blood samples is a necessary action to ensure the preserved organ can be used for transplantation, but may be considered to be somewhat invasive. As such, blood samples should only be taken in cases where express consent for donation has been given (by either the deceased, their nominated representative or someone in a qualifying relationship) or can be deemed.

178. If it is established that consent has not been expressly given or a decision has been made not to donate, and that consent cannot be deemed for the potential donor, then the steps taken to preserve organs for the purpose of transplantation should cease or be withdrawn promptly, as applicable.

179. An area of development in retrieval surgery is organ recovery. During the dying process organ injury can occur. Organ recovery seeks to maintain viability leading to longer-lasting organ transplants, as well as using organs that previously would not have been considered transplantable. Organ recovery procedures use machine perfusion of the organs, which takes place either in the donor after death (in situ) or on the organ following retrieval from the donor in special machines (ex situ).
180. These organ preservation techniques cannot be considered to be minimum steps and must only be used only where appropriate consent to donation is in place, and after death has been diagnosed.

**Interventions prior to death**

181. The Human Tissue Act 2004 does not address the matter of steps which may be taken prior to the death of a potential donor who may become a donor after circulatory death.

182. The steps which may be taken prior to death of a potential donor to facilitate DCD are detailed in the Department of Health document ‘Legal issues relevant to non-beating organ donation’ published in November 2009 and is currently being reviewed at the time of writing.

183. Where the potential donor does not have capacity, interventions before death are governed by the Mental Capacity Act 2005, rather than the Human Tissue Act 2004.
Licensing under the HT Act

HLA tissue typing

184. If samples of relevant material from a deceased donor, such as blood, lymph nodes or spleen, are being stored for tissue typing to determine the suitability of an organ for a recipient, this is storage for the purpose of transplantation and excepted from licensing under the Human Tissue (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 if the material is stored for less than 48 hours. If those samples of relevant material are subsequently stored as part of the diagnostic archive of the recipient, a licence is not required. However, if such samples are subsequently stored for research within the scope of the HT Act, they must be stored on HTA-licensed premises, subject to any applicable licensing exemptions. Further guidance can be found in the HTA’s Code of Practice for Research.

Licensing requirements - Research

185. A licence is required under the HT Act for the removal of relevant material from a deceased person for the scheduled purpose of research 'in connection with disorders, or the functioning, of the human body'. The removal must take place on premises specified in the licence.

186. The storage of relevant material for the purpose of research also requires a licence, unless it is for a specific research project which is approved by a recognised research ethics committee.

187. If relevant material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the storage of this material must be premises specified in the licence unless the research has ethical approval as indicated above.

188. Relevant material removed for the purpose of transplantation can be used for research with the valid consent of the donor or a person in a qualifying relationship to the donor (see paragraphs 30-39 of Code A).

189. In cases where it is unknown whether donated tissue or organs will be used for transplantation or research, valid consent should be obtained at the outset for both transplantation and research. For further guidance on valid consent, refer to Code A.
190. Further guidance on both consent and licensing requirements for research can be found in the Code of Practice on Research. This guidance is applicable to cases involving research using tissue and organs from a deceased donor; the Code of Practice on Research also provides guidance on research using tissue from the living.

**Status and use of the Codes of Practice**

191. Throughout the Codes, the word ‘**must**’ applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA’s licensing Standards. We use the word ‘**should**’ when providing advice on how to meet these requirements.

192. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

**Other advice and guidance**

193. The Codes of Practice 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. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others’ guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.

194. The HTA’s Codes of Practice and other HTA 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.
Annex A

Legislative background and context

195. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.

196. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes\(^4\) in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

197. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:

a) the person died before the HT Act came into force on 1 September 2006; and
b) at least 100 years have elapsed since the date of the person’s death.

198. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.

199. The HTA is the UK regulator for tissues and cells (other than reproductive cells). Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q & S Regulations), the HTA licenses and inspects establishments that undertake the procurement, testing, processing, storage, distribution, import and export of tissues and cells for human application.

200. With the exception of Code A: Guiding principles and the fundamental principle of consent, and Code F, the Codes of Practice do not provide guidance on complying with the requirements of the Q & S Regulations. Establishments licensed under the Q&S Regulations should refer to the HTA’s Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

201. The HTA is the UK regulator for the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (the Q&S (Organs) Regulations). With the exception of Code A: Guiding principles and the fundamental principle of consent, and Code F, the Codes of Practice do not

\(^4\) Defined by the HT Act and explained in further detail in the glossary.
provide guidance on complying with the requirements of the Q & S (Organs) Regulations. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA’s The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

202. On 1 December 2015 a deemed consent system for organ and tissue donation after death became operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA’s regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent for deceased organ donation system.

203. On DAY MONTH 2020 a deemed consent system for organ and tissue donation after death became operational in England, as a result of the implementation of Organ Donation (Deemed Consent) Act 2019. This legislation relates to donation of those organs and tissue which constitute “permitted material” from the deceased, and as such does not have an impact on the HTA’s regulation of living organ donation. Exceptions to the definition of “permitted material” are set out in the draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 20XX.

Scotland

204. The HTA’s remit does not extend to Scotland, and therefore the HTA’s Codes of Practice do not apply to establishments in Scotland.

205. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA’s remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NH Scotland, which the Scottish Health Department letter issued on 20 July 2006.5

206. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this code does not apply in Scotland.

# Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>HTA definition</th>
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</thead>
<tbody>
<tr>
<td>Anatomical examination</td>
<td>Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.</td>
</tr>
<tr>
<td>Ante-mortem</td>
<td>Clinical investigations or interventions that take place preceding death.</td>
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<tr>
<td>Appropriate consent</td>
<td>Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative, deemed consent or (in the absence of any of these) that of a person in a qualifying relationship to them immediately before they died.</td>
</tr>
<tr>
<td>Best interests</td>
<td>A test of a person's best interests takes into account not only the risks and benefits, but also the wider emotional, psychological and social aspects of the potential medical procedure.</td>
</tr>
<tr>
<td>Cells</td>
<td>Individual human cells or a collection of human cells that are not bound by any form of connective tissue.</td>
</tr>
<tr>
<td>Deemed consent</td>
<td>The deemed consent arrangements mean that from Spring 2020 all adults over 18 in England will be considered to have agreed to become an organ and tissue donor after their death, unless they make a decision that they do not want to be a donor or are in an excluded group. The excluded groups are: people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in England for at least 12 months immediately before their death.</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>The identification of the nature of an illness or other problem.</td>
</tr>
<tr>
<td>Directed donation</td>
<td>A form of donation where a person, usually a living person, donates an organ or part organ to a specific, identified recipient with whom they have a genetic or pre-existing emotional relationship.</td>
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</tbody>
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6 In England, the Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) modifies the appropriate consent provisions in the HT Act for organ donation and transplantation after death such that consent can be deemed in certain circumstances.
<table>
<thead>
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<tr>
<td>DNA</td>
<td>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics. Find out more information about the HTA's role with regards to DNA on the HTA's website.</td>
</tr>
<tr>
<td>Donated material</td>
<td>For the purposes of the HT Act, the term ‘donated material’ refers to the body of a deceased person, or relevant material which has come from a human body, which is being stored or used for scheduled purposes with appropriate consent.</td>
</tr>
<tr>
<td>Donation</td>
<td>The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.</td>
</tr>
<tr>
<td>Donation after Brainstem Death (DBD)</td>
<td>A form of organ donation in circumstances where a patient, whose death has been diagnosed using neurological criteria, continues to be ventilated. This keeps the heart beating and blood circulating after death, until after donation takes place.</td>
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<tr>
<td>Donation after circulatory death (DCD)</td>
<td>A form of organ donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs after death is diagnosed and confirmed using cardio-respiratory criteria.</td>
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<td></td>
<td>This is described as controlled when treatment has been actively withdrawn within a hospital setting or uncontrolled where a patient has experienced an unexpected cardiac arrest from which they cannot be resuscitated.</td>
</tr>
<tr>
<td>Donor</td>
<td>Every human source, whether living or deceased, of tissue, cells, organs or part organs.</td>
</tr>
<tr>
<td>Express consent</td>
<td>Express consent is consent to donation given by the potential donor, their nominated representative, or their family or close friends.</td>
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<tr>
<td>Family</td>
<td>Throughout the Code, the term ‘family’ should be taken to include a spouse or partner and, in cases where there are no family, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act.</td>
</tr>
<tr>
<td>Term</td>
<td>HTA definition</td>
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<tr>
<td>Human application</td>
<td>In relation to tissue or cells, human application 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.</td>
</tr>
<tr>
<td>Licensed premises</td>
<td>Where the licensed activity takes place.</td>
</tr>
<tr>
<td>Licensing</td>
<td>A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.</td>
</tr>
<tr>
<td>Minimum steps</td>
<td>The HT Act allows for the minimum steps necessary to be taken to preserve organs in a state which allows successful donation, using the least invasive procedure such as cold perfusion and intraperitoneal cooling.</td>
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<tr>
<td>Nominated representative</td>
<td>A person appointed by a person to represent them after their death for the purposes of activities under the HT Act for which consent is required. A nominated representative may be entitled to consent to, or refuse 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.</td>
</tr>
<tr>
<td>Novel and rare transplants</td>
<td>Transplants that are new and are usually at a research or practical evaluation stage, or have gone through research and service evaluation stages, but are still rare and unusual. An example of a novel transplant would be face transplantation. An example of a rare transplant would be limb transplantation. These forms of transplant are unusual, and people might not expect them to be included in opt-out for organ and tissue donation.</td>
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<td><strong>Organ</strong></td>
<td>Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.</td>
</tr>
<tr>
<td><strong>Organ Donor Register (ODR)</strong></td>
<td>A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs after their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.</td>
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<tr>
<td><strong>Parental responsibility</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Perfusion</strong></td>
<td>A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death.</td>
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<tr>
<td><strong>Post-mortem examination</strong></td>
<td>Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.</td>
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<td><strong>Practitioner</strong></td>
<td>A person working with relevant material in an establishment licensed by the HTA.</td>
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<tr>
<td><strong>Procurement</strong></td>
<td>The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.</td>
</tr>
<tr>
<td><strong>Qualifying relationship</strong></td>
<td>The relationship to the deceased of a person/s who can give consent for the removal, storage and use of tissue from the deceased person’s body for scheduled purposes, if the deceased person did not indicate their decision in life or appoint a nominated representative.</td>
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<td>Relevant material</td>
<td>Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue 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.</td>
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<tr>
<td>Research</td>
<td>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 or new knowledge.</td>
</tr>
<tr>
<td>Scheduled purpose</td>
<td>Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also relate to activities for scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</td>
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<td>• 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.</td>
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<td>• Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, and quality assurance.</td>
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<tr>
<td>Specialist Nurse for Organ Donation (SNOD)</td>
<td>A senior nurse who is the focal point of contact for organ donation within the Hospital / Trust. The role encompasses different aspects which all come together in the identification and referral of potential organ and tissue donors. It is recognised as best practice to have a SNOD or specialist requester involved in the donation conversation. The SNOD or SR is the expert in both donation conversation and the legislation.</td>
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<tr>
<td>Specialist Requester</td>
<td>An individual who is responsible for providing support to the potential donor family and whose area of expertise is in obtaining consent to donation of organs for transplantation</td>
</tr>
<tr>
<td>Tissue</td>
<td>Any and all constituent part/s of the human body formed by cells.</td>
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<tr>
<td>Tissue Donor Co-ordinators</td>
<td>An individual who is responsible for the coordination of tissue donation after death, and provides support and assistance to the newly bereaved families of tissue donors.</td>
</tr>
<tr>
<td>Transplantation</td>
<td>An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.</td>
</tr>
<tr>
<td>Valid consent</td>
<td>Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.</td>
</tr>
<tr>
<td>Vascularised Composite Allograft transplant</td>
<td>The transplantation of parts of the human body that contains multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue, that is recovered from the human donor as an anatomical or structural unit and requires its own blood supply and without altering its relevant characteristics. This may include novel transplants such as face, hand and limb and uterus</td>
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