Donation of solid organs and tissue for transplantation

HTA Human Tissue Authority

Part two: Deceased organ and tissue donation

Draft Code of Practice – Revised 2022

Draft to lie before Parliament for forty days, during which time either House may resolve that the code be not approved

Human Tissue Authority
Draft Code of Practice

Code F, Part two: Deceased organ and tissue donation
Revised 2022

Presented to Parliament pursuant to Section 29(1) of the Human Tissue Act 2004

Code F: Donation of solid organs and tissue for transplantation

Part two – Deceased organ and tissue donation

Contents

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 donation, bone marrow donation, 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 place. Donors and their families must be given the opportunity to access the information they need to be able to

make a decision. Those discussing consent should do so with sensitivity and an appreciation of the particular circumstances in each case. It also means that the donor must always be respected and that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.

8. Code of Practice F is published as two main sections:

    a) Code of Practice F (Part One) Living organ donation; and
    b) Code of Practice F (Part Two) Deceased organ and tissue donation

    Code of Practice F (Part Two) provides guidance to Specialist Nurses for Organ Donation (SNODs), Specialist Nurses for Tissue Donation (SNTD), Specialist Requesters (SR), and others who seek consent for deceased organ and tissue donation. See also paragraphs 25-26 for more information on the role of Specialist Nurses (SN).

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

Introduction to Code F – Part Two

10. Organ and tissue transplantation from deceased donors have the potential to greatly enhance or save the life of a person receiving a transplant. Donation has the scope to save thousands of lives.

11. While the HTA does not promote organ and tissue donation, it does play a central role in ensuring public confidence in the safe and ethical use of human organs and tissue with proper consent. Trust and confidence in the organ and tissue donation system as a whole requires widespread acceptance of its legitimacy. This means it is reliant not only on the lawful fulfilment of the donor's decision, but on the sensitive support of those close to the donor who are involved as part of end-of-life care. This in turn requires practitioners to be sympathetic to the needs of individuals in every case where donation after death is a possibility.

12. A core principle underpinning this Code is that, in reaching a decision about organ and tissue donation as part of end-of-life care, medical practitioners should make every effort to establish the decision of the potential donor during his or her lifetime and support the fulfilment of this decision.

13. Each set of circumstances surrounding a donation is unique and it is impossible to be prescriptive about precisely what should happen in every case. It is the role of the practitioner to balance the information available to them and reach a judgement about whether it is right for a donation to proceed. Sometimes clinical staff will reach the judgement that although there is a legal basis to proceed with the donation, the human considerations involved mean that it should not go ahead. While the presence of appropriate consent permits organ and tissue donation to take place, it does not mandate that it must.

14. The guidance in this Code of Practice reflects the HTA's position that where the risks to public confidence might outweigh the benefits of donation proceeding, donation should not proceed even though the law permits it.

15. The HTA has a statutory role in superintending compliance with this Code of Practice.

Scope of this Code of Practice

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

17. The sections relating to consent which is expressly given, and the examples, apply to both England and Northern Ireland unless otherwise stated. Any reference made to "deemed consent" throughout this Code of Practice applies to either the Organ Donation (Deemed Consent) Act 2019 in England or the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022, or both (as applicable).

18. England and Northern Ireland have separate deemed consent legislation. Both modify the appropriate consent provisions in the HT Act for organ and tissue donation and transplantation after death such that consent can be deemed in certain circumstances.

19. In England and Northern Ireland, all individuals over 18 are considered potential organ and tissue donors after death, unless they make a decision that they do not want to be a donor, they have nominated a representative to make a decision on their behalf after death or they are an excepted adult.

20. Deemed consent only applies to certain organs and tissue: the list of organs and tissue excluded from deemed consent in England is set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020. The list of organs and tissue excluded from deemed consent in Northern Ireland is set out in the [The Human Tissue (Permitted Material: Exceptions) (Northern Ireland) Regulations 2022 - Title be inserted once confirmed].

21. In Wales, the Human Transplantation (Wales) Act 2013 introduced deemed consent for deceased organ and tissue donation in 2015. Practitioners in Wales should continue to follow the Code of Practice on the Human Transplantation (Wales) Act 2013.

22. In Scotland, the Human Tissue (Authorisation) (Scotland) Act 2019 introduced deemed authorisation for deceased organ and tissue donation in 2021.

23. In addition to the consent requirements above, establishments licensed by the HTA 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 (as amended) (Statutory Instrument (SI) 2012 No. 1501) (the Q & S (Organs) Regulations). This Code of Practice does not include detailed information on the Q & S (Organs) Regulations. Further information can be found in Annex A and the HTA publication 'The Quality and Safety of Organs Intended for Transplantation – a documentary framework'. In addition, establishments may be subject to the licensing requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (Q & S Regulations). Licensed establishments are required to meet the standards which are detailed in

the HTA's 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment' Further information on the licensing requirements under the HT Act can be found in paragraphs 217-222.

Interpretation and general guidance

24. This section explains terms that appear throughout the Code of Practice in relation to organ donation.

25. This Code provides guidance to Specialist Nurses involved in organ donation (SNOD), Specialist Nurses involved in tissue donation (SNTD), Specialist Requesters (SR) or other clinical staff who seek consent for deceased organ and tissue donation. The acronym ***SN*** for ***Specialist Nurse*** is used in this document but refers to a SNOD/SNTD/SR or others seeking consent. The individual leading the family approach for organ donation must be suitably trained and qualified, with sufficient knowledge and skills to sensitively answer any questions and have the time to support the family. The HTA is of the opinion that the SN is the most suitable person to lead the family approach, working in collaboration with the treating medical team.

26. When a SN is required to make a difficult decision, or encounters an unusual situation, they should draw on the necessary decision-making support. SNs should discuss the situation with colleagues and, if necessary, contact a member of their senior management team to make the final decision. This ensures consistency of approach and high-quality decision making.

27. In England and Northern Ireland, there is a particular legal role for individuals who stood in a ***qualifying relationship*** (see paragraph 136) to a potential donor. This Code makes clear the role of those in a qualifying relationship.

28. In practice, there may be other people involved in the end-of-life care of an individual, beyond those who stood in qualifying relationship, who may be able to provide background knowledge about them and assist in establishing their decision with regard to organ and tissue donation. This Code uses the term ***family*** to denote this wider group. Family encompasses those in a qualifying relationship to the deceased person immediately before death and may also include other family members, close friends and those who may have been familiar with the faith and beliefs of the potential donor. This Code outlines the role of the family in the donation process and distinguishes this from the legal role of individuals standing in a qualifying relationship to the potential donor.

29. This Code makes reference to ***information that would lead a reasonable person to conclude that the potential donor would not have consented to***

organ and tissue donation. This reflects the language of the HT Act (as amended) which requires that information used for this purpose can only be provided by a person who stood in a qualifying relationship to the potential donor immediately prior to death. We consider that the term information should be interpreted widely to include any insight into the decision of an individual with regard to organ and tissue donation. This information may be in writing, but could equally be oral information, for example a report or recollection of a prior conversation held with the potential donor.

30. ***Permitted material*** refers to organs and tissue for which deemed consent could be used as a lawful basis for removal for transplantation provided the donor is not a child or an excepted adult. Material that is excluded from deemed consent is set out in The Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and the [The Human Tissue (Permitted Material: Exceptions) (Northern Ireland) Regulations 2022 - Title to be inserted once confirmed] in Northern Ireland. Material which is not permitted must have expressed consent for donation.

31. Where ***expressed consent*** is used, this refers to a decision to consent to organ and tissue donation that was expressed by an individual in life. This is not a legal definition but is used to distinguish this form of consent with deemed consent.

32. ***Ordinarily resident*** refers to people living in England or Northern Ireland on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration. For deemed consent to apply to a person who dies in either England or Northern Ireland, the potential donor must have been ordinarily resident in that jurisdiction for at least 12 calendar months immediately prior to their death. The definition of ordinarily resident is the same in England and Northern Ireland.

33. Where ***capacity*** is referred to in the Deemed Consent Act, this is interpreted to mean capacity under the Mental Capacity Act (MCA) 2005. Where capacity is referred to in The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022, this is understood to mean capacity under The Mental Capacity Act (NI) 2016.

34. ***Significant period*** refers to a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed due to the lack of capacity of the donor before death. As guidance, this period of time should be considered to be 12 months at the point of death.

Research

35. Use of organs and tissue for non-transplantation purposes, such as research, is outside the scope of deemed consent. Consent for research cannot be deemed.

36. 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 expressed consent for this purpose is obtained in accordance with the requirements of the HT Act.

Offences under the HT Act

37. The HT Act establishes 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.

38. 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.

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

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

41. 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 and tissue transplantation

42. 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.

43. 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 participate in particular research studies or to donate specific organs and tissue and not others.

44. However, 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 protected characteristic or based on language. This includes the recipient's age, disability, gender, marriage or civil partnership, pregnancy or maternity, race (which includes colour, nationality and ethnicity), religion or belief (which includes philosophical belief), sex or sexual orientation, or political opinion. 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 and in Northern Ireland section 75 of the Northern Ireland Act 1998.

45. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK. As a matter of policy, NHSBT does not accept organs from deceased donors where any restriction is attached. However, requested allocation of a deceased donor organ to a specific recipient can be considered if this is carried out in line with NHSBT policy, as set out in "Introduction to Patient Selection and Organ Allocation Policies Appendix 1" (Requested Allocation of a Deceased Donor Organ).

46. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could not 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.

Example

An individual decides to donate their organs after death, but only wants to do so on the condition that they are received by someone of the same ethnic origin. While there is nothing to prevent the individual expressing this as a condition, their organs could not be retrieved or transplanted while this condition remains in place.

End of Life Care

47. This Code should be read alongside the most recent applicable professional guidance regarding end-of-life care and organ and tissue donation.

48. 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 criteria or circulatory criteria. Diagnosis of death is a matter for clinicians providing end of life care.

49. For a patient undergoing end of life care, the medical team, in discussion with the family, may decide to withdraw life-sustaining treatment. This would usually be expected to result in death diagnosed using circulatory criteria with the possibility of Donation after Circulatory Death (DCD) (see paragraphs 58-60). Where the patient lacks capacity and has not made a prior advance decision to refuse treatment, 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.

50. It is appropriate that other national professional bodies and healthcare agencies, who have responsibility for, or are involved in organ and tissue donation, issue guidance consistent with the law, ethics and best clinical practice. These organisations should be aware of, and incorporate where appropriate, the recommendations in this Code.

Structure and navigation

51. The first section of the Code of Practice F provides an overview of deceased organ and tissue donation (see paragraphs 54-63).

52. The Code of Practice has further sections on consent, including the role of the family in the consent process and the need to take into account the donor's faith and beliefs (see paragraphs 80-103). The Code then provides advice on consent that is expressly given (see paragraphs 104-119) and deemed consent in England and Northern Ireland (see paragraphs 151-196).

53. A glossary with terms specific to this Code of Practice is available at the end of the document. All of the Codes of Practice can be viewed, downloaded and printed from the HTA's website.

Overview of deceased organ and tissue donation

Organ donation after death

54. There are two types of organ donation after death which are undertaken in the UK: donation that takes place after a death which is diagnosed and confirmed using neurological criteria, (commonly known as 'Donation after Brainstem Death') or donation which takes place after a death which is diagnosed and confirmed using circulatory criteria (commonly known as 'Donation after Circulatory Death').

55. Consent to both types of organ donation may, in the appropriate circumstances, be deemed in England and Northern Ireland.

56. Further guidance on the diagnosis and confirmation of death can be found in the Academy of Medical Royal Colleges (AoMRC) Code of Practice for the Diagnosis and Confirmation of Death 2008.

Donation after Brainstem Death (DBD)

57. Donation after Brainstem Death is donation that takes place following tests to diagnose and confirm death using neurological criteria. Increasingly this is referred to as diagnosis and confirmation of death by neurological criteria. The majority of patients will have suffered a spontaneous and devastating bleed in the brain. 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)

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

59. Controlled DCD describes organ retrieval which takes place after the planned withdrawal of life-sustaining treatment at the end of a critical illness. In those circumstances a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005 for England and the Mental Capacity Act (NI) 2016 for Northern Ireland) by the treating medical team in consultation with those close to the patient.

60. 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. Tissue donation after such an unexpected death could still be possible.

Tissue donation after death

61. Tissue donation is a possibility after death for both organ donors and those who are not suitable to donate organs.

62. Consent for tissue donation will be sought by a trained SN who is responsible for identifying the last known decision of the donor.

63. Deemed consent legislation applies only to certain tissues. Exceptions are set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and the [The Human Tissue (Permitted Material: Exceptions) (Northern Ireland) Regulations 2022 - Title to be inserted once confirmed] in Northern Ireland.

Consent

Overview

64. 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 to donate or not to donate organs and tissue when they were alive, their consent cannot be deemed.

65. The Organ Donor Register (ODR) operates throughout the UK to allow individuals to record their decision either to donate or not to donate organs and/or tissue after their death, or to nominate a representative to make a decision on their behalf.

66. Individuals may nominate one or more representatives to make a decision on their behalf about donation of their organs and tissue after they have died. There are specific requirements (see paragraphs 79-85 of Code of Practice A) under the HT Act in relation to nominated representative/s.

67. In England and Northern Ireland, the implementation of deemed consent legislation amended the HT Act so that where an adult has neither: a) made a decision to donate or not to donate organs or tissue before their death; nor b) appointed a nominated representative to make a decision on their behalf after

their death, consent for donation of permitted organs and tissue will be considered to be in place (“deemed consent”).

68. This will be the case unless the potential donor is a child, an excepted adult, or information is provided by a person in a qualifying relationship that would lead a reasonable person to conclude that the potential donor would not have consented. If such information is provided, then consent cannot be deemed and the donation must not proceed.

69. Under deemed consent in England and Northern Ireland:

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

71. An excepted adult is:

    a) An adult who died either in England or in Northern Ireland and had not been ordinarily resident in the country of their death 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.

72. Deemed consent only applies to certain organs or tissue, referred to as permitted material for the purposes of transplantation. Further information on this is given in paragraphs 197-200.

73. Where the potential donor is an excepted adult, consent cannot be deemed. Donation can only proceed where consent has been expressly given, either by the potential donor before their death, or by a nominated representative or a person in a qualifying relationship.

74. Where the potential donor is a child, consent cannot be deemed and donation can only proceed where consent has been expressly given either by the potential donor before their death, or by a person with parental responsibility. If there is nobody with parental responsibility, consent can be given by a person in a qualifying relationship. A child cannot appoint a nominated representative (see paragraph 147).

75. Where consent is deemed, there are particular considerations about activities before death, which are outlined in the Preservation for Transplantation section in paragraphs 205-214.

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

Recording a decision about organ and tissue donation

77. Neither the HT Act nor the deemed consent legislation in England or Northern Ireland mandate how a person must record their decision about organ and tissue donation.

78. This means that it is for the individual to decide how they wish to do this. Options include registering their decision to donate or not to donate on the ODR, telling a friend or family member, or recording it in writing. Further information is provided in paragraph 29 and 108-119.

79. The ODR is checked in every potential case of organ and tissue donation and the information stored is communicated to the family.

Role of the family

80. The family play a crucial 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 expressed by the potential donor, whether the circumstances are such that consent may be deemed, or whether a person in a qualifying relationship will be asked to make the decision. The role of the family should be to help establish the decision of the individual with regard to donation.

81. Sensitive communication and engagement with the family by the SN and medical team play an essential part in supporting the family throughout the donation process.

82. 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' that may provide useful information for families.

83. If the potential donor has expressed consent, the SN should discuss this decision with the family. The family will be asked to provide additional and detailed medical and social history about the potential donor. This is not part of the consent process, but a necessary part of clinical practice so that decisions can be made about the suitability of organ and/or tissue donation in light of all of the relevant information. This information should not be sought from the family until consent to donation has been established.

84. If the potential donor has expressed consent, but no family is available to provide medical and social history, consent would still be in place and donation could still proceed. However, this requires a clinical judgement and risk assessment by the medical team in order to protect any recipients of organs or tissue. The medical team should also take account of any conditions placed on consent by the donor and assess whether these can be fulfilled before reaching the final decision about whether or not to proceed.

85. If there is an expressed decision on the ODR that the person did not want to be a donor, this should be communicated to the family by the SN or medical team. Donation must not proceed unless the family has information that the person had expressed consent to donation which superseded the individual's earlier decision.

86. If there is no expressed decision and the potential donor was an adult who nominated a representative, any decision on consent must be made by that nominated representative (see paragraphs 120-133). The role of the family in circumstances where the nominated representative gives consent is equivalent to that where the donor themselves had expressed consent.

87. If the nominated representative cannot be reached or is unable to make a decision, consent may be deemed (see paragraph 92 and 154). In such circumstances, the role of the family is the same as that in other circumstances where consent may be deemed (see paragraph 88).

88. If there is no expressed decision by the potential donor, they have not nominated a representative/s and they are not a child or an excepted adult, then consent may be deemed. The SN should explain this to the family and have a sensitive discussion to best support their needs and to facilitate donation. In these circumstances, deemed consent legislation allows for someone in a qualifying relationship to provide information that would lead a reasonable person to conclude that the person did not want to be a donor. If such information is provided, then donation must not proceed (see paragraphs 187-196).

89. If the family of the potential donor object to the donation where appropriate consent (whether expressed or deemed) is in place, the SN should discuss the matter sensitively with them to understand and, if appropriate, attempt to overcome their concerns.

90. Although the family cannot revoke legally valid consent, their views will always be taken into account throughout the donation process and will have a strong influence on whether or not donation proceeds. The presence of valid consent is sufficient for donation to be lawful but does not mandate that it must proceed.

91. Family members may have differing views about donation when appropriate consent is in place. The SN, in discussion with the medical team, should provide the family with the appropriate time and information they need to come to an agreement. Further guidance on specific situations is given in paragraphs 117 and 196.

92. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. During the passage of the legislation which led to the Organ Donation (Deemed Consent) Act 2019 in England, a commitment made in Parliament that donation would not proceed in these circumstances, led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14). Whilst this commitment was specifically made in relation to England, the HTA's view is that this should also apply in Northern Ireland.

Taking account of the potential donor's faith and/or beliefs

93. Discussions with the family should aim to establish the potential donor's decision with regard to organ and tissue donation. Taking account of the potential donor's faith and/or beliefs, be they cultural, spiritual, religious or non-religious 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. As such, these discussions should seek to involve individuals who are familiar with the faith and/or beliefs of the potential donor.

94. The maintenance of trust in the organ donation and transplantation system requires the sensitive consideration of matters of faith and/or belief. SNs should be given the necessary training and support to help them identify and meet the widest possible range of needs. Training should include an awareness and understanding of different cultural and religious and non-religious beliefs, and how these may influence donation decisions. Training should also include the identification of sources of assistance that may be offered to, or requested by, families in order that they are informed and supported.

95. Since December 2018, when registering a decision to consent to organ and tissue donation on the ODR, individuals have been able to record whether their faith and/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".

96. Where an individual has indicated that this statement applies to them, the SN must explain this to the potential donor's family and discuss the potential donor's faith and/or beliefs with respect to organ and tissue donation. The SN should answer any questions and seek further guidance and support from faith leaders if required.

97. Certain faiths may have specific faith and/or belief statements that form the basis on which potential donors have come to a decision about whether to donate their organs and tissue. SNs should be aware of these statements and ensure that families are aware of them as they will determine the basis on which donation can be made.

98. Some faith and/or belief communities may also have specific arrangements in place to support families and SNs with appropriate, real-time advice that will facilitate the donation process in line with an individual's decision including, in some cases, dedicated telephone helplines. Where an individual has made clear that they wish for donation to go ahead in accordance with their beliefs and practices, the family should be made aware that this support is available and SNs should ensure available services are utilised where this is indicated.

99. Where an individual has indicated that the statement in paragraph 95 does not apply to them, this should be explained to the family. SNs should still explore the potential donor's faith and/or beliefs and those of the family, while recognising that these are unlikely to have been a defining factor in the individual's donation decision.

100. For ODR registrations prior to December 2018, the SN should explore whether faith and/or beliefs were important to the potential donor through conversations with the family.

101. The views of the potential donor and their family should be discussed sensitively and openly. Without making assumptions, discussions should establish whether the potential donor held particular faith, belief or cultural views that could influence how and whether donation could proceed. The faith and/or beliefs of the donor, and how they respond to aspects of that faith and/or belief, may be different to that of the family and should be considered in order to reach the decision that is right for the donor.

102. Where an individual has registered as a potential donor, but their family disagrees that donation is consistent with the potential donor's faith and/or belief, the SN should explore any issues raised by the family and support them to address any concerns. Where indicated, SNs can facilitate consultation with

religious and non-religious leaders to provide counsel or clarification on donation. For example, the family may wish to ensure appropriate end of life rituals are followed or that any religious obligations are observed should donation take place.

103. Hospitals may also have faith-trained co-ordinators, a chaplaincy service representing different faiths, or accredited non-religious pastoral carers, which can help support families.

Example

A potential donor registered a decision to consent to donate all organs and tissue on the ODR. They have also recorded that their faith or beliefs are important to them in relation to organ and tissue donation on the ODR. The SN should explain this to the potential donor's family and discuss the potential donor's faith, beliefs and values. The SN should support the family and answer any questions they may have. The SN may also seek further guidance and support on behalf of the family from faith or belief representatives if required.

Consent which is expressly given

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

104. 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 potential donor. As such, the potential donor's valid consent where this is recorded, or last known decision as expressed to the family, should form an integral part of end-of-life care planning.

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

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

107. In every case where organ and tissue donation is a possibility, the SN should determine whether the potential donor has made a decision with regard to organ and tissue donation. The SN should seek to establish the most recent decision of

the potential donor in conversation with their family, i.e. the decision in force immediately before their death.

The NHS Organ Donor Register as a source of consent

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

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

a. I consent to donate all my organs and tissue after death;
b. I consent to donate some (specified) organs and tissue after death; or
c. I do not consent to donate my organs and tissue after death.

110. NHSBT provides the form 'Appointing a representative to make organ donation decisions on your behalf' to allow potential donors to appoint a nominated representative.

111. As long as a potential donor registered their decision voluntarily, had the information they needed to make the decision to register and had mental competence or capacity when they registered, then the decision recorded on the ODR constitutes valid and appropriate consent at the time of registration. For children this is a test of competence, for adults it is capacity (see paragraph 146.

112. A legally valid decision from the potential donor 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.

113. If the recorded decision was not to consent to organ and/or tissue 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 SN should obtain information from the family about the potential donor's more recent decision to consent to organ donation.

114. If it is clear to the SN that the potential donor had changed their mind, having previously recorded a decision not to consent on the ODR, then donation could proceed.

Example

A potential donor has registered their decision not to consent to organ and tissue donation on the ODR. The SN or clinician will inform the family that a decision not to consent to organ and tissue donation exists and that it will be honoured. The family believe that there is a more recent decision to donate. The SN or clinician should obtain information from the family of the potential donor's more recent decision to consent to organ and tissue donation.

115. If the family believe that a potential donor who was registered on the ODR had revoked their decision to consent to organ and tissue donation, the SN should obtain information from the family about the potential donor's more recent decision to refuse consent to donation (see paragraphs 89-90 and 187-196).

Example

A potential donor registered a decision to consent to donate all organs and tissue on the ODR. The potential donor's mother says that her son subsequently changed his mind about donation prior to his death. The SN will have a sensitive discussion with the potential donor's mother to understand the context of the information that is presented, by exploring with her the son's decision to change his mind. The discussion will focus on what the potential donor decided, as his last known decision will have primacy.

116. In making a decision about whether there is valid consent to proceed with donation, the SN must make a judgement about the reliability of the information provided. It may be helpful to consider the following:

a) Is the information in writing, signed and dated by the potential donor and witnessed? If this is the case, then this is likely to be an expressed 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 in writing, but that a written revocation would be considered more reliable).
b) Is the information given orally? If so, can it be confirmed by more than one person?
c) Is the information 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 information about the potential donor's decision.

117. Where valid consent has been given by the potential donor, but the family object to organ and tissue donation proceeding, then they should be sensitively supported to respect the potential donor's consent in order to ensure his or her decision is fulfilled. The family's objection does not nullify valid consent from the potential donor.

Example

A potential donor registered a decision on the ODR to consent to their organs and tissue being donated for transplantation. However, the family do not want tissue donation to proceed. The SN will explore the family's concerns and answer any questions they may have. The discussion will focus on what the potential donor had decided. As the potential donor's consent is valid and their views have primacy, donation could be lawful but this does not mandate that it must proceed.

118. As set out in paragraph 76, the existence of appropriate consent permits donation to proceed, but does not mandate that it must. The final decision about whether to proceed rests with the SN and the medical practitioners caring for the patient, in conversation with the family.

119. Those close to the patient will be involved in making best interests' decisions for the patient who lacks capacity when DCD is a possibility. As described in paragraph 47, consent via the ODR is one factor to take into account when assessing whether interventions to facilitate organ and tissue donation are in the potential donor's best interests.

Nominated representative

120. If the potential donor's decision is not known and they were an adult who had nominated a person to make a decision regarding organ and tissue donation after their death, then a decision on consent must be given by that nominated representative (see paragraphs 130-131).

121. A child under the age of 18 cannot appoint or act as a nominated representative under the HT Act.

122. The name and contact details of the nominated representative/s may have been recorded via NHSBT's form Appointing a representative to make organ donation decisions on your behalf (see paragraph 110). If there is a recorded nominated representative/s, the SN should contact them and ask them to make a decision on behalf of the potential donor.

123. If the details of the nominated representative are readily available, the SN does not need to carry out the checks at paragraphs 126 -129.

124. It may be the case that a potential donor nominated a representative/s but did not use the form or tell their family about them. It is recognised that it is not practical for the SN to make extensive checks to establish whether a potential donor nominated a representative/s. If, having asked the family, the SN is not made aware of a nominated representative/s at this stage, it is reasonable to proceed as if no representative had been appointed.

125. If the SN has been informed orally that there is a nominated representative/s, the checks at paragraphs 126 -129 below should be undertaken to ensure the nominated representative/s have authority under the HT Act.

126. If the nomination was made orally, the SN should check that the appointment was witnessed by at least two people present at the same time. This can be confirmed either by asking the two witnesses, or by producing a document signed by the two witnesses confirming that they witnessed the nomination.

127. If the nomination was made in writing, the SN should be assured that one of the statements at a) to 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.

128. 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.

129. If the appointment requires 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 and consent may be deemed (see further at paragraph 131 below).

130. There will be no consent if a nominated representative is not available to give consent under the appointment. In such cases, the nomination may be disregarded. This includes situations where it is not reasonably practical to

communicate with the nominated representative within the time available or if they are not available.

131. 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 may be deemed if the potential donor is not an excepted adult (see paragraph 71).

132. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, the HTA advises that donation should not proceed (see paragraph 92).

133. In all other circumstances, consent may be given by a person in a 'qualifying relationship' (see paragraph 136).

The role of qualifying relationships in expressed consent situations

134. When deemed consent does not apply, appropriate consent may be given by someone who was in a qualifying relationship with the potential donor immediately before their death.

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

136. 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.

137. A person is another person's partner if the two of them lived as partners in an enduring family relationship. A partner can be of a different sex or be of the same sex.

138. A friend of long standing is not defined in the legislation. It does not necessarily require a specified time period attached to the friendship. Whether someone is a

friend of long standing will depend on all the facts and circumstances and should be considered on a case-by-case basis. The SN may ask questions and/or request information as necessary to establish what degree of friendship existed and whether the relationship could reasonably be considered to be a friendship of long standing.

139. Where there is disagreement between people in different positions on the ranked list, it is recommended that the SN seeks to provide those people with the time and information they need to come to an agreement.

140. 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 136). The decision whether or not to proceed lies with the SN, with the necessary decision-making support from senior management, in conversation with the family.

141. 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 SN will need to carefully consider the emotional impact of any decision on the wider family.

Establishing whether or not deemed consent applies

142. If the potential donor has neither made a decision in relation to organ and tissue donation nor appointed a nominated representative/s, then a decision must be made as to whether or not deemed consent may apply.

143. In England and Northern Ireland, deemed consent does not apply to:

    a. children under 18
    b. excepted adults
    c. material which is not permitted material (see paragraphs 197-200).

144. If deemed consent does not apply, move to section on ‘The role of qualifying relationships in expressed consent’.

145. If deemed consent does apply, move to section on ‘Deemed consent’.

Consent for organ and tissue donation – children

146. 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 and tissue for transplantation lawful.

147. 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. See also paragraph 141.

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

149. A child cannot nominate a representative to make a decision regarding organ and/or tissue donation.

150. Further information on consent by and on behalf of a child can be found in paragraphs 87-94 of Code of Practice A.

Deemed consent

Circumstances in which consent can be deemed

151. In cases where the decision of a potential donor regarding consent for organ and tissue donation cannot be established either from the ODR or from family, or where a nominated representative has not been appointed or is unable to act, then consent can be deemed, unless the potential donor is an excepted adult (see paragraph 71 on excepted adults).

152. There may be occasions where a potential donor has neither recorded a decision nor appointed a representative and, despite the efforts of the SN, there is no family in existence or available for the SN to speak with. The HTA advises that, in these circumstances, donation should not proceed (see paragraph 92).

153. When SNs are required to make a difficult decision, or encounter an unusual situation, there are decision-making processes in place to support them. SNs are always able to discuss the situation with colleagues and if necessary contact a member of the senior management team to make a final decision. This ensures consistency of approach and high-quality decision making.

154. If a person appointed a nominated 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 SN should make every reasonable effort to contact the nominated representative and the family should be given the opportunity to provide further information (see paragraph 92 and paragraphs 187-196).

Example

A potential donor has lived and died in England. The potential donor:
has not recorded a decision about organ and tissue donation on the ODR or expressed a decision in writing or verbally to family; is not an excepted adult, and there is no information that would lead a reasonable person to believe they did not want to be a donor.

The potential donor's consent could be deemed and donation could lawfully proceed.

The same would apply if the donor had lived and died in Northern Ireland.

Circumstances in which consent cannot be deemed

155. 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 excluded from deemed consent, see paragraph 30.

156. If a potential donor made a decision in regard to organ and tissue donation when they were alive, they have given expressed consent and their consent cannot be deemed.

157. In circumstances where consent cannot be deemed, consent should be sought from a person in a qualifying relationship (see paragraph 136).

158. For excepted adults (see paragraph 71), consent cannot be deemed and consent should, in these circumstances, be sought from a person in a qualifying relationship (see paragraph 136).

159. Independent Mental Capacity Advocates (IMCA) act as safeguards for people who lack capacity, where it is not possible for them to be represented by family or friends, and can sometimes be involved in decision making on their behalf. An IMCA may be involved in decisions up to the point of death, but not beyond it. IMCAs can only act for individuals aged 16 and over. IMCAs are not lawfully entitled to give or refuse consent for organ and tissue donation on behalf of a potential donor, as they are not in the list of qualifying relationships.

160. If the potential donor had an IMCA appointed and in place prior to death this is likely to indicate that they were an excepted person who lacked the capacity to understand the notion of deemed consent for a significant period before their death. This will be a relevant consideration for the SN when determining whether consent can be deemed.

Residency

161. For deemed consent to apply in England, the potential donor must have been ordinarily resident in England for at least 12 calendar months immediately prior to their death. For deemed consent to apply in Northern Ireland, the potential donor must have been ordinarily resident in Northern Ireland for at least 12 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 AoMRC Code of Practice for the Diagnosis and Confirmation of Death 2008.

162. For the purposes of the HT Act: (i) “in England” means within an English local authority area. Information on the local authorities can be found on the local government structure and elections webpage; and (ii) “in Northern Ireland” means within one of Northern Ireland's local council areas. Information on local councils in Northern Ireland can be found on the NI direct government services webpage.

163. In most cases a SN will be able to establish where the potential donor lived, and whether they were ordinarily resident (see paragraphs 167-174.) at an address or several addresses, either from medical records or through discussions with family.

164. If there is reasonable cause for doubt, the SN should check whether the potential donor’s address was in England or Northern Ireland (as applicable). If it is not possible to access the relevant records for a period of time, which could mean

the opportunity for donation is missed, and it cannot safely be assumed where the potential donor was ordinarily resident, then consent should not be deemed.

Example – England

An adult dies in hospital in England on 15 January. Their death is diagnosed and confirmed using neurological criteria. The SN establishes by speaking to the family that the potential donor moved to England on 17 January of the previous year. Deemed consent does not apply, as the potential donor had not lived in England for at least 12 calendar months prior to their death. Consent may be given by a nominated representative or someone who was in a qualifying relationship with the deceased person immediately before their death.

Example – Northern Ireland

An adult dies in hospital in Northern Ireland on 20 August. Their death is diagnosed and confirmed using neurological criteria. The SN establishes by speaking to the family that the potential donor moved to Northern Ireland on 1 August of the previous year. Deemed consent does apply, as the potential donor had lived in Northern Ireland for at least 12 calendar months prior to their death.

165. The 12-month period test does not involve counting the number of days. Rather, it is necessary to establish that a potential donor had been ordinarily resident for at least twelve calendar months. See paragraph 161.

166. In some cases, it may not be possible to establish the exact date. When this is the case and there is no clear information available, consent should not be deemed.

Ordinarily resident

167. A potential donor will be “ordinarily resident” 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 criteria which must be established are:

    a) The residence is lawful.

British and Irish citizens have a right to live in England and Northern Ireland so will always be in either country lawfully. Some Commonwealth citizens also have an automatic right to live in England and Northern Ireland. For people who do not have an automatic right, they will need permission to be in England or Northern Ireland (as the case may be) to be lawfully resident, for example, immigration permission.

Subject to guidance on duration above, an asylum seeker awaiting determination of their claim for asylum is likely to be considered lawfully resident in England and Northern Ireland. A failed asylum seeker cannot be considered lawfully resident, and therefore cannot be ordinarily resident.

People who are unlawfully in England or Northern Ireland, 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 or Northern Ireland voluntarily. For example, the fact that the potential donor chose to come to England or Northern Ireland at the request of an employer, rather than seek another job, is unlikely to make their presence in England or Northern Ireland involuntary. Prisoners are considered at paragraph 173.

c) The potential donor was resident for settled purposes.

There must be an identifiable purpose for their residence within England or Northern Ireland 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. Students are considered at paragraphs 170-172.

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

There is no requirement for any person to be living in England or Northern Ireland permanently or indefinitely. The potential donor may have had temporary absences from England or Northern Ireland and still be considered ordinarily resident. It is also possible to be ordinarily resident in more than one country.

168. These qualities 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 SN will be able to establish easily whether the potential donor's residence was characterised by the requirements above. When ordinary residence is initially unclear, it is recommended that there is a sensitive discussion with family to gain more information about where the potential donor would have considered themselves ordinarily resident.

169. When a SN has reasonable cause to doubt that the potential donor was ordinarily resident, then consent should not be deemed.

Example - England
A potential donor worked in London and lived there four nights a week, spending the other three nights at their family home in Paris. The potential donor dies in England. The SN should ask questions of the family to establish where the potential donor would have considered themselves ordinarily resident. It will then be for the SN to weigh up the information to establish whether the potential donor was ordinarily resident in England. If the SN establishes that the potential donor considered Paris to be their home and London to be their place of work only, consent could not be deemed.

Example – ordinarily resident in England and Northern Ireland
The SN establishes by speaking to the family of a potential donor that they split their time equally between Manchester and Omagh and would have considered themselves ordinarily resident in both cities. Deemed consent can apply as the donor considered themselves ordinarily resident in both England and Northern Ireland.

Example – Northern Ireland
Two friends who are ordinarily resident in Wales go on a holiday to Northern Ireland. During the holiday, one of the friends dies in hospital. Deemed consent does not apply as the person was not ordinarily resident in Northern Ireland. Consent may be given by a nominated representative or someone who was in a qualifying relationship with the person immediately before their death.
The same would apply if the two friends had gone on holiday to England and one of the friends had died in England.

Example – living and working across borders
A potential donor lived in Dublin. They worked in Belfast at the weekends, commuting every Friday morning from Dublin and staying in Belfast until Sunday evening. The potential donor dies whilst at work in Belfast. The SN

should establish with the family where the potential donor would have considered themselves ordinarily resident. If the SN establishes that the potential donor considered Dublin to be their home, consent could not be deemed.

Students

170. 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 their home.

171. Students could be considered ordinarily resident in England or Northern Ireland (as the case may be) as soon as they begin studying, but their consent could only be deemed if they are 18 years old and after at least 12 months of being ordinarily resident immediately before dying.

172. It will be for the SN to discuss this with the potential donor's family to determine whether the student's residence had the necessary qualities described above before deciding whether deemed consent applies. The SN will want to gain an understanding of where the student would have considered themselves ordinarily resident.

Prisoners

173. A person who is in prison cannot be considered to be residing voluntarily, and cannot be considered ordinarily resident during their time in prison. This includes prisoners who normally live in England or Northern Ireland and who are in prison in either of these countries. People in prison cannot have their consent to organ and tissue donation deemed.

Other groups

174. There are other groups of people, for example those detained under mental health legislation, where it may be more difficult to establish whether they reside voluntarily. There are also those who live in England or Northern Ireland 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 or Northern Ireland, but who do not regard it as their home. It will be for the SN to ask questions of family to establish whether the person was ordinarily resident on a case-by-case basis.

175. Spouses or family members of armed forces personnel are generally considered ordinarily resident if they choose to join them.

Mental capacity

176. Deemed consent does not apply to people who, for a significant period before their death (see paragraphs 183-186), lacked the capacity to understand that consent to donation can be deemed.

177. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.

178. If a potential donor lacked capacity to understand that consent can be deemed for a significant period before their death, then the person is an excepted adult, and their consent cannot be deemed. Therefore, consent should be sought from a nominated representative or a person in a qualifying relationship (see paragraph 136).

179. 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 or Northern Ireland, then their consent cannot be deemed.

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

181. In other cases, to establish whether a potential donor lacked capacity for a significant period before their death, the SN 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 lacked capacity to understand that consent could be deemed. However, it should prompt further investigation by the SN.

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 SN should document this on the consent form and/or medical records.

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 SN should undertake further investigations of the condition or illness. The issue of mental capacity should be raised by the SN when speaking to the family to ascertain if the potential donor had the capacity to understand that consent to organ and tissue donation could be deemed.

d) Where there is information about a condition that may have affected the potential donor's capacity to understand that consent could be deemed, in most cases it will be the family who are able to provide the SN with the most accurate information as to whether the potential donor had the capacity to understand that consent to organ and tissue donation could be deemed. The SN should ask the family whether they believe the potential donor had the capacity to understand that their consent could be deemed. This may be a detailed discussion, and if at the end of this the SN is not satisfied that the potential donor had the capacity to understand that consent could be deemed, then consent should not be deemed.

182. 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 about their capacity.

Significant period

183. The potential donor will be an excepted adult only if they lacked capacity to understand that consent could be deemed for a significant period prior to their death.

184. 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, based on what a reasonable person would consider to be a sufficiently long period, given the circumstances of each case and the facts presented.

185. In practice, as guidance 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 as guidance for England and Northern Ireland in order to provide regulatory certainty to SNs and other practitioners and is consistent with how deemed consent works in Wales.

186. The lack of capacity to understand that consent can be deemed for a significant period only negates deemed consent. If the potential donor had made an

expressed 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.

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

187. If a potential donor is not a child or an excepted adult, and they had neither made a decision in life nor appointed a nominated representative/s who had given consent under that appointment, then their consent to organ and tissue donation may be deemed.

188. When this is the case, the SN should have a discussion with the family and give them the opportunity to provide information that would lead a reasonable person to conclude that the potential donor would not have consented. This information can only be provided by a person in a qualifying relationship.

189. SNs must take all reasonable steps in the circumstances of the individual case to discover whether any person in a qualifying relationship is available to provide such information. When there is no family found or available, donation should not proceed (see paragraph 92).

190. 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 SN, and not the relationship to the potential donor of the person presenting it.

191. When there is written information from the potential donor, and this is signed by a witness, this would form the expressed decision of the potential donor and so consent cannot be deemed.

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

193. Where there is other oral information, it will be for the SN to decide whether this is information that would satisfy a reasonable person.

194. The reasonable person test involves the person making the assessment (in this case the SN and medical team), deciding how much reliance to place on the information presented.

195. In order to assess the reliability of the information presented, the following questions may help the SN:

    a) Is the information presented as reflecting the views of the potential donor, or the views of the family? The test requires that information presented must be the 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 SN should establish when the record was made, or when 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.

196. 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 and tissue donation.

Other considerations

Novel transplants

197. Deemed consent only applies to certain organs and tissue: the list of organs and tissue excluded from deemed consent in England is set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 which are subject to Parliamentary approval. The list of organs and tissue excluded from deemed consent in Northern Ireland is set out in the [The Human Tissue (Permitted Material: Exceptions) (Northern Ireland) Regulations 2022 - Title to be inserted once confirmed].

198. The Department of Health and Social Care in England and the Department of Health in Northern Ireland respectively consulted on the list of organs and tissue where expressed consent will still be required for the purpose of transplantation in each country.

199. The list of those organs and tissue is published on the HTA's website, and this will be updated when changes are made to the list.

200. For the organs and tissue on this list, expressed consent must be given for the removal, storage or use for the purpose of transplantation to be lawful.

Use of organs and tissue across borders

201. Organs and tissue removed when consent has been deemed can be lawfully stored, used, processed, distributed and transplanted into patients across the UK providing all other statutory and regulatory requirements have been met. Organs and tissues can, on occasion, be offered to a recipient in another country where there is no suitable recipient in the UK.

Interventions prior to death

202. The HT 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 death is diagnosed and confirmed using circulatory criteria.

203. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.

204. The taking and storage of blood samples from a potential donor is necessary to ensure that the organ and tissue can be used for transplantation. Blood samples should only be taken in cases where expressed consent for donation has been given (by the potential donor, their nominated representative or someone in a qualifying relationship) or consent has been deemed (which could only occur following discussion with the family).

Preservation for transplantation after death

205. 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.

206. 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 203-204.

207. 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.

208. 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.

209. 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.

210. In all cases, steps should therefore be taken as soon as possible to establish the decision on donation, or where this is unknown, whether consent can be deemed. Where possible, appropriate consent for donation should be established before the preservation process begins, or alternatively consent for the preservation process prior to donation.

211. The taking and storage of blood samples from a deceased person is necessary to ensure the preserved organ and tissue can be used for transplantation. Blood samples should only be taken in cases where expressed consent for donation has been given (by the deceased, their nominated representative or someone in a qualifying relationship) or consent has been deemed (which could only occur following discussion with the family).

212. If it is established, either (a) that consent has not been expressly given, and that consent cannot be deemed, or (b) a decision has been made not to donate, then the steps taken to preserve organs for the purpose of transplantation should cease or be withdrawn promptly.

213. An area of development in retrieval surgery is organ recovery. During the dying process organ injury can occur. Organ recovery seeks to maintain and improve viability leading to high quality 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 specialist machines (ex situ).

214. 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 (see paragraph 205).

Coroners

215. Where the person's death is violent or unnatural, or is sudden and the cause is unknown, the matter of organ and tissue donation must be referred to the coroner. In such cases agreement (or a lack of objection) of the coroner should be sought before any transplantation activities can be undertaken, or steps can be taken to preserve the organs within the body of the person.

Licensing under the HT Act

HLA tissue typing

216. 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 E on Research.

Licensing requirements - Research

217. 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.

218. 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.

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

220. Relevant material removed for the purpose of transplantation can be used for research with the valid consent of the donor, a nominated representative or a

person in a qualifying relationship to the donor (see paragraphs 30-39 of Code of Practice A).

221. 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 of Practice A.

222. Further guidance on both consent and licensing requirements for research can be found in Code of Practice E on Research. This guidance is applicable to cases involving research using tissue and organs from a deceased donor; Code of Practice E provides guidance on research using tissue from the living.

Status and use of the Codes of Practice

223. 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.

224. 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

225. 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.

226. 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

227. The Human Tissue Authority (HTA) is the regulator for human organs, tissue 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.

228. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes[1] in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

229. 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.

230. 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.

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

232. With the exception of Code of Practice A: Guiding principles and the fundamental principle of consent, and Code of Practice 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.

233. The HTA is the UK regulator for the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (the Q&S (Organs)

[1] Defined by the HT Act and explained in further detail in the glossary.

Regulations). With the exception of Code of Practice A: Guiding principles and the fundamental principle of consent, and Code of Practice F, the Codes of Practice do not 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.

234. A deemed consent system for organ and tissue donation after death is operational in England, Northern Ireland and Wales. This 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.

235. The deemed consent legislation in England and Northern Ireland respectively relate 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 Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and [The Human Tissue (Permitted Material: Exceptions) (Northern Ireland) Regulations 2022 - Title to be inserted once confirmed].

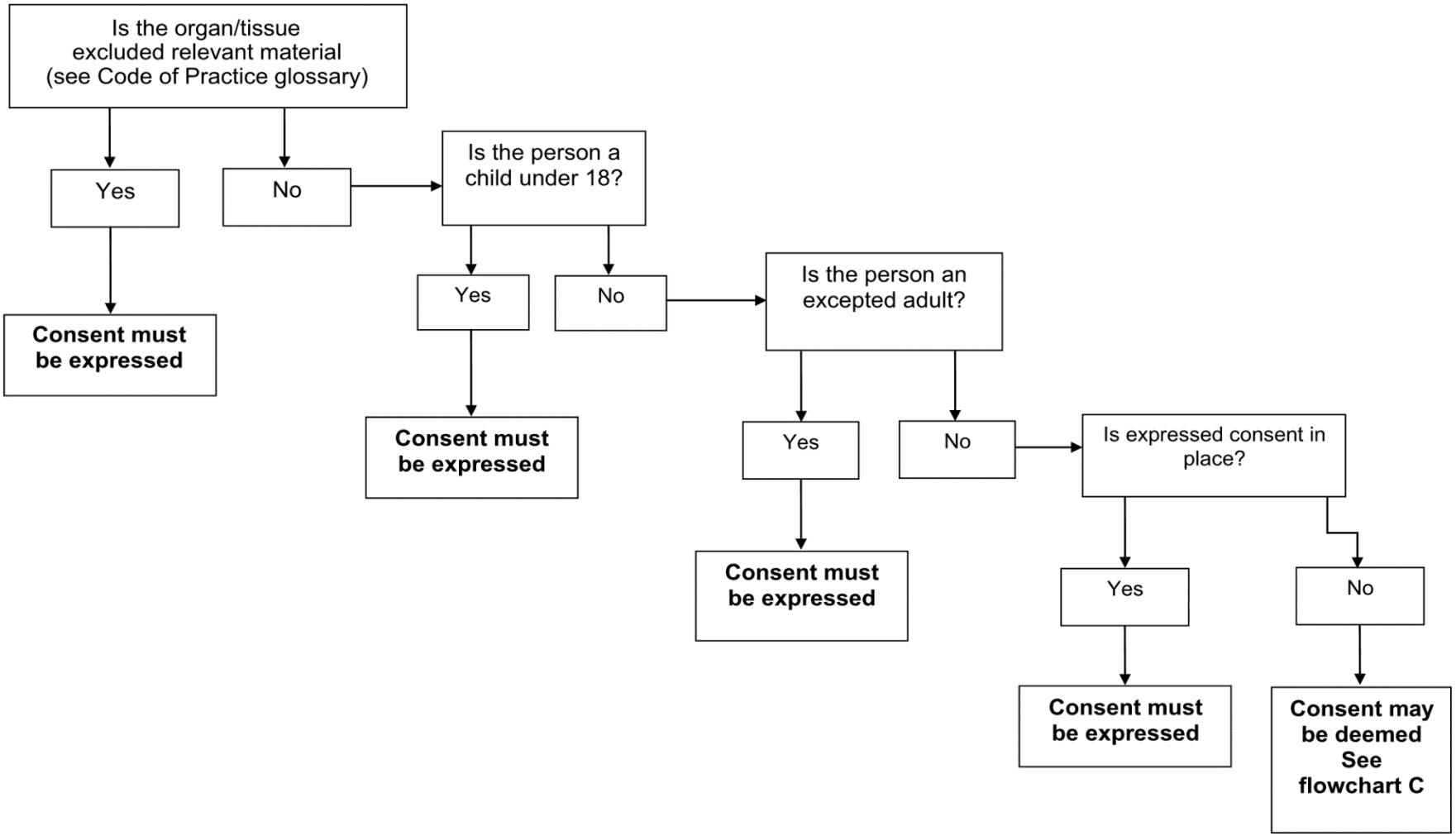
Scotland

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

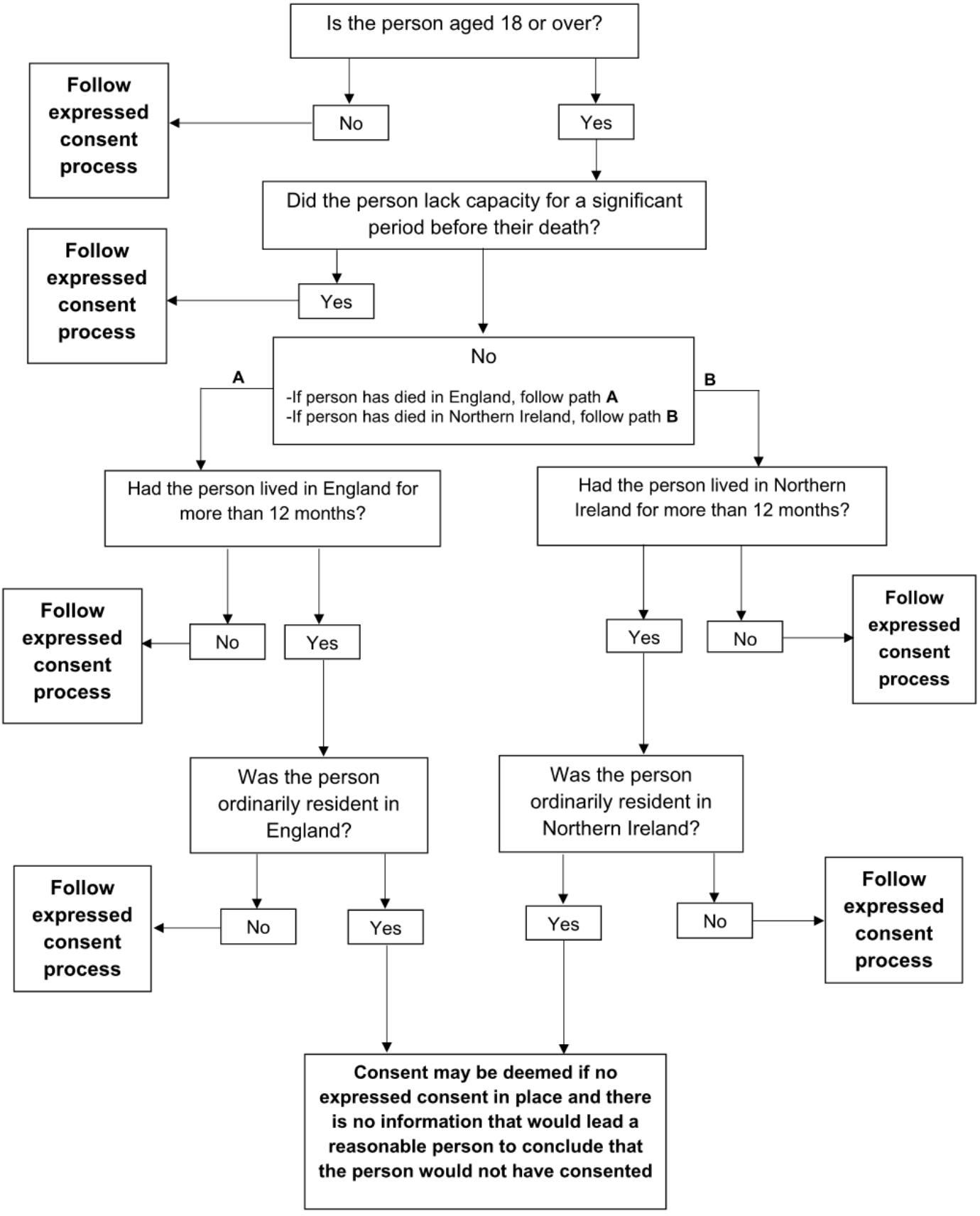
237. The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act) and The Human Tissue (Authorisation) (Scotland) Act 2019 apply in Scotland.

238. 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.

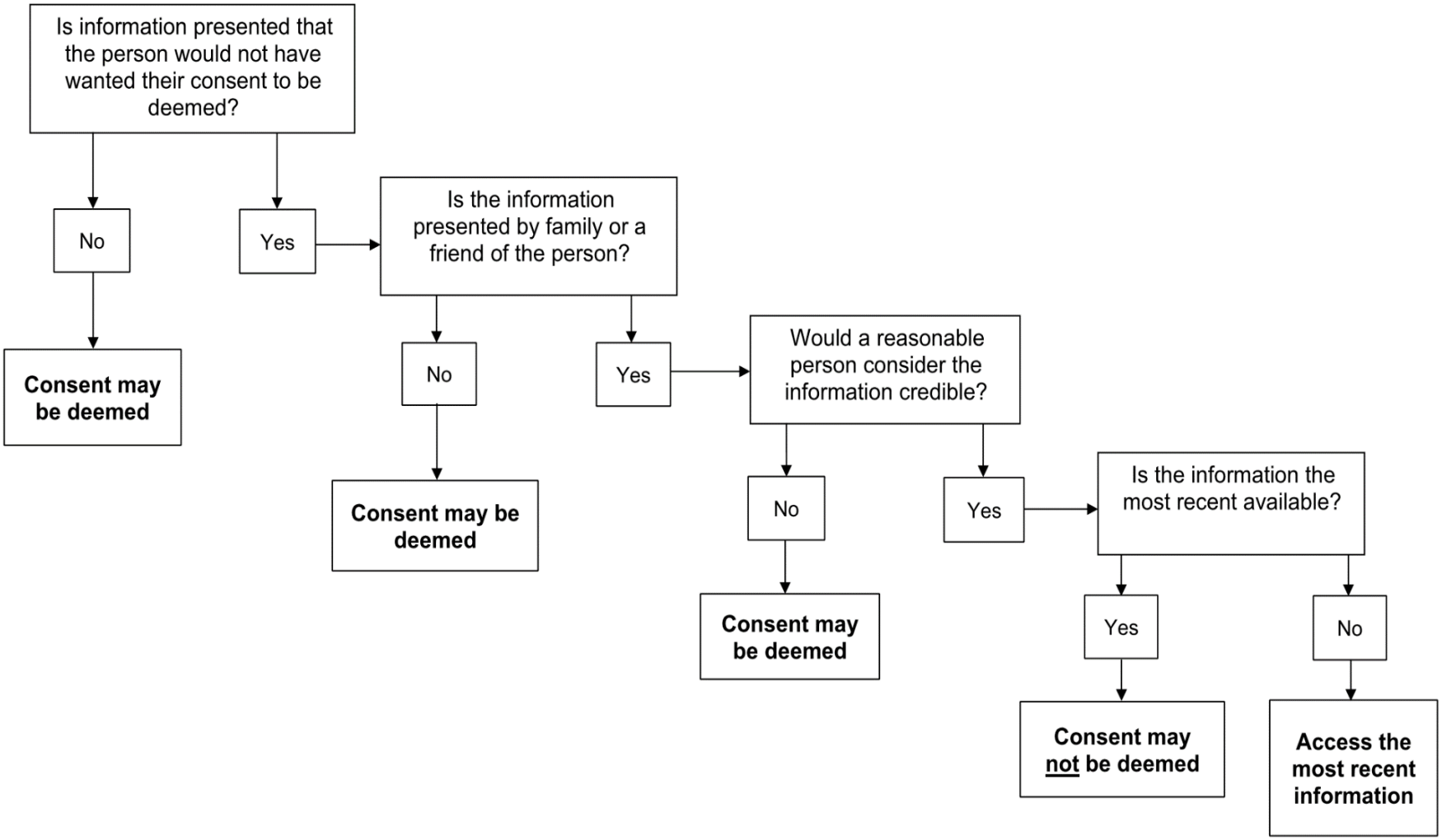
Flowchart A – Overview of deemed and expressed consent



Flowchart B – Can deemed consent apply to the person?



Flowchart C – Is there information that would lead a reasonable person to conclude that the person would not have consented?



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 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.

Best interests: An assessment of a person's best interests takes into account not only the risks and benefits of a proposed intervention, but also its wider emotional, psychological and social aspects.

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

Deemed consent: Deemed consent means that all individuals over 18 in England or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue, i.e. they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent. Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.

Diagnosis: The identification of the nature of an illness or other problem.

Directed donation: 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.

DNA: 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.

Donated material: 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.

Donation (organ and tissue): The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.

Donation after Brainstem Death (DBD): A form of organ donation in circumstances where a patient, whose death has been diagnosed and confirmed using neurological criteria, continues to be ventilated. This keeps the heart beating and blood circulating after death, until after donation takes place.

Donation after circulatory death (DCD): 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.

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.

Excepted adult: An adult who (i) died either in England or in Northern Ireland and had not been ordinarily resident in that jurisdiction for a period of at least 12 calendar months immediately before dying; or (ii) who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

Expressed consent: Expressed consent is consent to donation given by the potential donor, their nominated representative, or their family.

Family: Throughout the Code, the term family should be taken to mean people involved in the end-of-life care of an individual, who may be able to provide information about them and their decision with regard to organ and tissue donation. Family encompasses those in a qualifying relationship to the deceased person immediately before death and may also include other family members, close friends and those who may have been familiar with the faith and beliefs of the potential donor.

Human application: 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.

Licensed premises: Where the licensed activity takes place.

Licensing: 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.

Minimum steps: 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.

Nominated representative: A person appointed by an individual 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.

Novel transplants: 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.

Organ: 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.

NHS Organ Donor Register (ODR): A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ and tissue donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs or tissues 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 and tissues.

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 set out in the Children Act 1989.

Perfusion: A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death.

Post-mortem examination: Also called an autopsy, a post mortem is an examination of the body after death. Post mortems are performed if the cause of death is not known or if there are any unusual circumstances. Information obtained from a post mortem often helps bereaved families understand what happened to their loved one as well as helping doctors learn about how diseases can affect the body.

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

Practitioner: A person working with relevant material in an establishment licensed by the HTA.

Procurement: The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.

Qualifying relationship: The relationship to the deceased of a person/s who can give consent for the removal, storage and use of organs and tissue from the deceased person's body for scheduled purposes in certain circumstances, or provide information that would lead a reasonable person to conclude that a potential donor would not have consented in circumstances where consent could be deemed. Those that are in a qualifying relationship are: a spouse or partner; a parent or child; a brother or sister; a grandparent or grandchild; a niece or nephew; a stepfather or stepmother; a half-brother or half-sister; a friend of longstanding.

Reasonable person: A reasonable person is one who exercises an ordinary degree of care, skill, and judgement in particular circumstances.

Relevant material: 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.

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 or new knowledge.

Scheduled purpose: 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.

• 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, and quality assurance.

Specialist Nurse (Specialist Nurse for Organ Donation (SNOD)/Specialist Requester (SR)/Specialist Nurse in Tissue Donation (SNTD)): A senior nurse who is the focal point of contact for organ and tissue 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/SR/SNTD involved in the donation conversation. The SNOD/SR/SNTD is the expert in both donation conversation and the legislation and are represented as 'SN' throughout this document.

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. Valid consent is explained in detail in Code of Practice A: Guiding principles and the fundamental principle of consent.

Vascularised Composite Allograft transplant: 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.