Code F

DONATION OF SOLID ORGANS AND TISSUE FOR TRANSPLANTATION
PART 2 – DECEASED ORGAN AND TISSUE DONATION

Public Health

Cabinet Office | Cronk Coar, Noble's Hospital, Strang, Douglas, IM4 4RJ

Human Tissue and Organ Donation Act 2021

Code F: Donation of solid organs and tissue for transplantation

Part 2 – Deceased organ and tissue donation

Contents

Introduction to Cabinet Office's Codes of Practice for the Human Tissue and Organ Donation Act 2021

1. Section 19 of the Human Tissue and Organ Donation Act 2021 (HTODA) extended Cabinet Office's (CO) regulatory functions. These functions include –

    a. maintaining a statement of the general principles that CO believes should be followed when carrying-on activities, and functions in relation to them, under the HTODA;

    b. providing general oversight and guidance in relation to activities under the HTODA as CO considers appropriate;

    c. superintending, in relation to activities under the HTODA, compliance with Parts 2 and 3 of the HTODA and these Codes of Practice;

    d. providing to the public, and to persons carrying on activities under the HTODA, such information and advice as it considers appropriate about the nature and purpose of such activities; and

    e. securing publicity on or around 15th March of each year on the desirability of making organs and tissue available for the purposes of transplantation.

1A. Section 20 of the HTODA requires any person undertaking certain activities under the Act to, following an inspection, obtain a licence from CO.

Public Health (PH), as part of CO, have the delegated authority to undertake inspections, issue licences and advise CO on the undertaking of its other functions under the HTODA.

1AA. The types of activities PH will regulate on behalf of CO through licensing and inspection are –

    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.

1B. CO and PH will also regulate the Department of Health and Social Care's (DHSC) activities under the HTODA, which may be delegated by DHSC to Manx Care, or supported by National Health Service Blood & Transplant (NHSBT) as appropriate.

1BB. A comprehensive list of DHSC's activities under the HTODA are set out in section 18 (DHSC's remit) of that Act, but in summary they include –

    a. for either a scheduled purpose or for the purposes of UK legislation referenced by the HTODA, the obtainment[1], processing, testing, storage, distribution, removal, use, import, export and disposal of human tissue;

    b. for either a scheduled purpose or for the purposes of UK legislation applied by the HTODA, the donation, testing, characterisation, obtainment, preservation, transport, import, export, storage, transplantation and disposal of human organs;

[1] Note definition in glossary.

c. the disposal of an organ or tissue which has been removed from a person's body for medical treatment;

d. the carrying out of anatomical examination, and the making of post-mortem examinations undertaking of post-mortem and examinations, and the associated disposal of organs and tissues as a consequence of these activities.

2. Further information about the legislative background and context of the HTODA and its Codes of Practice is set out at Annex A.

3. This document is part of a suite of seven Codes of Practice produced by CO.

- **Code A**: Guiding principles and the fundamental principle of consent;
- **Code B**: Post-mortem examination;
- **Code C**: Anatomical examination (including import/export);
- **Code D**: Public display (including import/export);
- **Code E**: Research (including import/export);
- **Code F – Part 1**: Living organ donation;
- **Code F – Part 2**: Deceased organ and tissue donation;
- **Code G**: Donation of allogeneic bone matter and peripheral blood stem cells (PBSCs) for transplantation.

4. The Codes of Practice give practical guidance to professionals carrying out activities which lie within DHSC's and Manx Care's remit; CO's general functions under the HTODA; any secondary legislation made under that Act; and any UK legislation that is read as applied to the Island further to that Act (subject to any modifications made by an order under section 71 of the HTODA).

5. While the Codes of Practice will be of interest to members of the public, the Codes will be relevant to professionals carrying out activities under:

a. the [IOM equivalent to UK's Human Tissue (Quality and Safety for Human Application) Regulations 20**[2]]; and

b. the *[IOM equivalent to the UK's Quality and Safety of Organs Intended for Transplantation Regulations 20**[3]]*.

6. The Codes of Practice provide guidance on activities within the scope of CO's general functions under the HTODA. Whilst PH, and CO more generally, may offer advice on matters outside of those general functions, neither CO nor PH have any requirement under the HTODA in relation to the provision of such advice. CO and PH will endeavour to provide signposts to other agencies where issues arise that are beyond the reach of CO and PH.

7. The Codes of Practice do not include information about the analysis of DNA. This is because CO has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in section 68 (non-consensual analysis of DNA) and

[2] SD 20**/****.
[3] SD 20**/****.

Schedule 3 (section 68: supplementary) of the HTODA. Separate guidance in the form of frequently asked questions is available on the website www.gov.im.[4]

8. Code A (Guiding principles and the fundamental principle of consent) contains information that is applicable to all establishments and professionals operating under the HTODA (including any UK legislation referenced by that Act, or secondary legislation made under that Act). It sets out the four guiding general principles on which the work of CO and PH under the HTODA is founded.

   For the purposes of this Code, and with regard to organ and tissue donation, the application of these principles means:

   a. Donated organs and tissue must be used in accordance with the consent in place.

   b. Donors and their families must be given the opportunity to access the information they need to be able to make a decision.

   c. 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.

   Code of Practice F is published in two parts:

   - Part One: Living organ donation; and
   - Part Two: Deceased organ and tissue donation.

   This Code, 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). Part 1 provides supplementary guidance to clinicians working in living organ donation.

9. In combination, the Codes of Practice are intended to provide anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation as well as CO and PH policy.

[4] Based upon: https://www.hta.gov.uk/guidance-professionals/regulated-sectors/research/analysis-dna-under-ht-act

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.

10A. It is a function of CO, and PH on behalf of CO, to provide to the public and persons carrying on activities under the HTODA, such information as is considered appropriate about the nature and purpose of organ donation. Notably, CO has a duty to promote, on or about 15th March each year, organ and tissue donation for transplantation.

11. PH, as part of CO, has a central role in ensuring public confidence in the safe and ethical use of human organs and tissue with proper consent on the Isle of Man. 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 their 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 CO'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. CO has a statutory role in superintending compliance with this Code of Practice, the other codes of practice and the requirements imposed by or under Parts 2 and 3 of the HTODA. PH, as part of CO, supports CO's undertaking of this role.

Scope of this Code of Practice

16. In deceased donation, the removal, storage and use of organs and tissue, (including Vascularised Composite Allografts transplants) for transplantation is governed by the HTODA. 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, including any regulations made for the purposes of section 14 of the HTODA to enable the High Court to issue an order for appropriate consent for certain activities involving deceased persons, for this activity to be undertaken lawfully.

16A. Furthermore, as per the requirements of section 8 (authorisation of activities for scheduled purposes: further provisions), organs or tissue may only be removed from deceased persons

by either a registered medical practitioner, a person authorised in accordance with regulations made by the Cabinet Office, or by a person authorised by a registered medical practitioner further to regulations made by the Cabinet Office.

17. *Omit.*

18. *Omit.*

19. 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. Due to the interaction of the Island's organ and tissue donation process with the UK organ and tissue donation process via similar legislation to the HTODA (i.e. Human Tissue Act 2004, of Parliament) deemed consent for deceased persons will only apply to certain organs and tissue, i.e. "permitted material". The definition of organs and tissues that fall within the definition of permitted material, and organs and tissues that do not fall outside of this definition, are set out in the *Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 (of Parliament)*.

20. *Omit.*

21. *Omit.*

22. *Omit.*

23. In addition to the consent requirements above, establishments licensed by PH (on behalf of CO) are also subject to the licensing requirements of the HTODA, as supplemented by and Human Tissue and Organ Donation (Licensing) Regulations 2025 ["the Licensing Regulations"]. This Code of Practice does not include detailed information on the Licensing Regulations. Further information can be found on the gov.im website.

    Additional information on the licensing requirements under the HTODA can be found in paragraphs 220-226.

Interpretation and general guidance

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

25. This Code provides guidance to Specialist Nurses involved in organ donation (SNOD), Specialist Nurses involved in tissue donation (SNTD), Specialist Requesters (SR), Anatomical Pathology Technicians, 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. CO, DHSC and Manx Care are 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. While respecting patient confidentiality, 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. Section 5 (persons in a qualifying relationship with another) of the HTODA defines how a person may have a ***qualifying relationship*** (see paragraph 136) with respect 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 (see paragraphs 79 - 92).

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 HTODA which requires that the information used for reaching this conclusion 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. What organs and tissues constitutes permitted material, and the organs and tissues which are not permitted material and thus excluded from deemed consent, are set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 (of Parliament). Tissues that are not permitted material 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 from deemed consent.

32. ***Ordinarily resident*** refers to people living in the Isle of Man on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration, but deemed consent will not apply unless someone has been ordinarily resident in the Isle of Man for at least 12 months immediately before their death.

33. Where ***capacity*** is referred to in the HTODA this is interpreted to mean capacity under the Mental Health Act 1998 (MH Act) and the Mental Health Act 1998 Code of Practice [March 2011] (MH Act Code of Practice).

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 public display and anatomical examination, is outside the scope of deemed consent. Consent for research thus cannot be deemed. Where research involves organ and tissue for public display or anatomical examination, consent **must** be provided in writing by the donor. In addition, as far as it is reasonably practicable to do so, a Medical Certificate of Cause of Death (MCCD) must be obtained before organs or tissue are removed. Subject to this requirement, specific HTA guidance for professionals[5] on consent requirements may be of further assistance, and is considered applicable in the Isle of Man.

36. Material removed when consent has been deemed for the purpose of transplantation, which cannot be used for that purpose, can be used for research if expressed consent for that purpose is obtained in accordance with the requirements of the HTODA.

Offences under the HTODA

37. The HTODA 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 12 (prohibition of activities without consent etc.) of the HTODA makes it an offence to remove organs, tissue sample, blood (or any material derived from blood) or other body fluid from the deceased and to store and use bodies, organs and tissue for a purpose set out in Schedule 1 of the HTODA (a scheduled purpose), including determining the cause of death, without appropriate consent[6]. 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 12 (prohibition of activities without consent etc.) of the HTODA also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that section 7 (authorisation of activities for scheduled purposes) of the HTODA 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 15 (restriction of activities in relation to donated material) of the HTODA makes it an offence to store or use donated material for anything other than a qualifying purpose.

40. Section 31 (prohibition of commercial dealing in human material for transplantation) of the HTODA makes it an offence to engage in commercial dealings in controlled[7] material for transplantation. Notably, the term "controlled material" does not apply to gametes, embryos or material which is the subject of intellectual property rights because of an application of human skill.

41. Section 33 (information about transplant operations) creates an offence failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations. This offence is subject to a fine only.

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[5] e.g. Brain and spinal cord donation guidance for hospital and mortuary staff, HTA. Site: https://www.hta.gov.uk/guidance-professionals/regulated-sectors/post-mortem/brain-and-spinal-cord-donation-hospital-and, checked 8th October 2024.

[6] Appropriate consent includes, noting section 43 (consent of Coroner to post-mortem examination) of the HTODA, the consent of the Coroner of Inquests to the undertaking of a post-mortem examination of a body.

[7] See section 31 of the HTODA, or the glossary, for the definition of controlled material.

Conditions on consent for organ and tissue transplantation

42. The HTODA 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 HTODA 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 under the Equality Act 2017 or based on language. This includes the recipient's age, disability, gender reassignment, 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. This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 2001, and arises from the equality duty placed on CO (including PH), DHSC and other public authorities by the Equality Act 2017.

45. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK. It has responsibility for organ allocation on the Island as a consequence of arrangements with DHSC and Manx Care. 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[8] regarding end of life care and organ and tissue donation.

48. Further to its arrangement with the DHSC, the HTA's function is to provide guidance on what constitutes lawful consent to organ and tissue donation after death has been diagnosed

[8] e.g. *Treatment and care towards the end of life: good practice in decision making*, General Medical Council. Site: https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/treatment-and-care-towards-the-end-of-life, checked 8th October 2024.

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 57-59). Where the patient lacks capacity any decisions about the timing of withdrawal of life-sustaining treatment or the institution of interventions or procedures 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 this Code provides an overview of deceased organ and tissue donation (see paragraphs 54-78).

52. This Code has further sections on consent generally, 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 79-102). The Code then provides advice on consent that is expressly given (see paragraph 103-119) and deemed consent (see paragraphs 152-198).

53. A glossary is available at the end of the document. All of the Codes of Practice can be viewed, downloaded and printed from the gov.im website.

Overview of deceased organs and tissue donation

Organ donation after death

54. There are two types of organ donation after death which are undertaken:

    a. donation that takes place after a death which is diagnosed and confirmed using neurological criteria, ('DBD'); or

    b. donation which takes place after a death which is diagnosed and confirmed using circulatory criteria (commonly known as 'Donation after Circulatory Death' or 'DCD').

55. Consent to both types of organ donation may, in the appropriate circumstances, be deemed under the HTODA.

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

Donations taking place after death is diagnosed and confirmed using neurological criteria

57. Organ donation may take place following tests for diagnosis and confirmation of death by neurological criteria. This is commonly known as 'Donation after Brainstem Death' or 'DBD'.

    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.

Donations taking place after death is diagnosed and confirmed using circulatory criteria

58. A death which is diagnosed and confirmed using circulatory criteria, commonly known as 'Donation after Circulatory Death' or 'DCD', 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 MH Act and the MH Act Code of Practice) 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. Noting that organ donations from the Isle of Man must be processed via the HTA and NHSBT and consequently also in accordance with the Human Tissue Act 2004 (of Parliament), deemed consent applies only to certain types and categories of organs and tissue, i.e. "permitted material". The definition of permitted material is set out in the *[insert name of UK legislation modified to define this term]* (note paragraph 19).

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 NHS 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 HTODA in relation to nominated representative/s.

67. The HTODA provides 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. *Omit*

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

71. An excepted adult is:

    a. An adult who had not been ordinarily resident in the Isle of Man for a period of at least 12 months immediately before dying;

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

72. Deemed consent only applies to certain organs or tissue, referred to as permitted material. Further information on this is given in paragraphs 199-202.

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. The donation can only proceed where –

    a. in the event the child is alive, consent has been expressly given either by the child, or by a person with parental responsibility in the absence of any decision by the child.

    b. for the purposes of public display or anatomical examination (excluding excepted material), and where the child has died, the witnessed consent in writing from the child [see section 9(4), (5) & (6) of the HTODA];

    c. for any other purpose, in the event the child has died, consent can only be given by –

        i. the child before death;

        ii. a person with parental responsibility; or

        iii. in the absence of a person with parental responsibility, a person in a qualifying relationship aged 18 or over.

    A child cannot appoint a nominated representative (see paragraphs 121 and 148-150).

75. Where consent is deemed, there are particular considerations about activities before death, which are outlined in the Preservation for Transplantation section in paragraphs 209-218.

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. The HTODA does not 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 nominated representative (e.g. a friend or family member) in accordance with section 11 of the HTODA, or recording it in writing. Further information is provided in paragraphs 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'*[9], which 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 SN in order to protect any recipients of organs or tissue. The SN 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 155). In such circumstances, the role of the family is the same as that in other circumstances where consent may be deemed (see paragraph 87), following the similar approach that is taken in England and Northern Ireland.

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, the HTODA 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 189-198).

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

[9] A copy this may be found at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/16266/the-journey-through-the-gift-of-organ-donation-2019-06-07.pdf

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 198.

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. Noting commitments made in Parliament during the passage of the Organ Donation (Deemed Consent) Act 2019 (of Parliament) to amend the HTA, that donation would not proceed in such circumstances and that the HTODA was drafted in part with regard to that Act, CO has concluded donations should not proceed in similar circumstances on the Island. In reaching this conclusion it was thought that the risk of losing public confidence, should a donation go ahead in these circumstances, would outweigh the benefits (see paragraphs 13 and 14).

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, individuals registering a decision to consent to organ and tissue donation on the ODR 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 94 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, whether made on the Island or elsewhere in the UK, 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 HTODA 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 HTODA 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.

107A. Certain organs and tissue are not considered to be permitted materials and are thus excluded from deemed consent. The donation of such organs and tissue will require expressed consent from someone in the hierarchy of qualifying relationships in order for donation to proceed (see paragraph 19).

The NHS Organ Donor Register (ODR) 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. Island residents have also been able to record their decision on the ODR since *[insert date here when ODR registration took effect on IoM]*. 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 an assessment of competence[10], for adults it is capacity (see paragraph 147).

[10] Note paragraph 31.11 on page 96 of the MH Code of Practice for children under 16. Paragraph 13.14 and 13.15 *[sic]* on pages 96 & 97 of the MH Code of Practice relate to children aged 16 or 17.

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 88-89 and 189-198).

> **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 as far as it is reasonably practicable to do so in the circumstances:

    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 the potential donor's 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 75, 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 49, 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(s) [i.e. 'nominated representative(s)] to make a decision regarding organ and tissue donation after their death, then a decision on consent must be given by that nominated representative(s) (see paragraphs 130-131).

120A. A person must be explicitly appointed to act as a nominated representative on behalf of a potential donor. A Power of Attorney may only allow a person to act as a nominated representative if the written appointment requirements, as set out in section 11 (nominated representatives) of the HTODA, are met.

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

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 HTODA.

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 paragraph 130).

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 69).

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, it is advised 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 is not applicable, appropriate consent may be given by someone who was in a qualifying relationship with the potential donor immediately before their death for the purposes of transplantation of organs or tissue. To enable transplantation, such consent

may apply to the storage of the body, the removal of organs or tissue from the body, and the storage of organs or tissue removed from the body.

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

136. The HTODA includes at section 5(1) (persons in a qualifying relationship with another) 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.

    This may be referred to, in this Code and elsewhere, as the 'hierarchy of qualifying relationships'.

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 ~~a~~ decision on consent should be obtained from the person whose relationship to the potential donor is accorded the highest ranking on the list of qualifying relationships (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 of persons in qualifying relationships 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. Deemed consent does not apply to:

    a. children under 18;

    b. excepted adults;

    c. material which is not permitted material or organs or tissue for research (see paragraphs 199-202).

144. If deemed consent does not apply, move on to section on 'The role of qualifying relationships in expressed consent' (see paragraph*s 134 – 141).*

145. If deemed consent does apply, move on to section on 'Deemed Consent' (see paragraphs 151 to 160).

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 HTODA 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 and the activity is not one that requires the child's consent in writing, 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 69 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. CO (noting the position of the HTA in the UK) 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 paragraphs 92 and 189-198).

Example

A potential donor has lived and died in the Isle of Man. The potential donor:

a. 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

b. 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.

Circumstances in which consent cannot be deemed

155. Consent cannot be deemed for children.

Consent cannot be deemed for an adult who has died if:

a. that person would be considered to meet the criteria of being an 'excepted adult' as;

i. they were not ordinarily resident in the Island for a period of at least 12 months immediately before their death (see paragraphs 161 – 175);

ii. they lacked capacity for a significant period[11] before their death (see paragraphs 176 – 182); or

[11] This means a sufficiently long period for a reasonable person to conclude that it would be inappropriate for consent to be deemed. This period of time is typically considered to be around 12 months.

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 organs or tissue that are not permitted material as specified in the [insert name of modified UK legislation here] (see paragraphs 199-202);

d. the transplantations activity is either public display or, unless it is excepted material, anatomical examination.

156. If a potential donor made a decision in regard to organ and tissue donation when they were alive, they have given appropriate 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 69) who haven't provided appropriate consent, consent cannot be deemed and consent should, in these circumstances, be sought from either a nominated representative or a person in a qualifying relationship (see paragraph 136).

159. *Omit*

160. *Omit*

Residency

161. For deemed consent to apply, the potential donor must have been ordinarily resident in the Isle of Man for 12 calendar months immediately prior to their death. For the purposes of deemed consent, the time of death is taken to be the date on which death is confirmed by one of the processes laid out in the AoMRC 2025 Code of Practice for the diagnosis and confirmation of death

162. For the purposes of the HTODA, "in the Isle of Man" means within the Island and its territorial waters. See map on the gov.im website relating to the Island's territorial sea.

163. In most cases a SN will be able to establish where the potential donor lived, and whether they were ordinarily resident (see paragraphs 169-176) at an address or several addresses in the Isle of Man, 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 the Isle of Man. 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 the potential donor cannot safely be assumed to be ordinarily resident in the Island, then consent should not be deemed.

Example

An adult dies in hospital in the Isle of Man 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 the Isle of Man on 17 January of the previous year.

Deemed consent does not apply, as the potential donor had not lived in the Isle of Man for 12 calendar months prior to their death.

If consent has not been recorded on the ODR or elsewhere, consent may be given by a nominated representative or someone who was in a qualifying relationship with the deceased person immediately before their death.

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

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 to confirm the time since the potential donor started living in the Isle of Man, consent should not be deemed.

Ordinarily resident

167. A potential donor will be "ordinarily resident" in the Isle of Man 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 in the Isle of Man for at least 12 months immediately before dying. The criteria which must be established are:

a. *The residence is lawful.*

British and Irish citizens will always have a right to live in the Isle of Man so will always be in the Isle of Man lawfully. Some Commonwealth citizens also have an automatic right to live in the Isle of Man. For people who do not have an automatic right, they will need permission to be in the Isle of Man 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 the Isle of Man. A failed asylum seeker cannot be considered lawfully resident, and therefore cannot be ordinarily resident.

People who are unlawfully in the Isle of Man 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 the Isle of Man voluntarily. For example, the fact that the potential donor chose to come to the Isle of Man at the request of an employer, rather than seek another job, is unlikely to make their presence in the Isle of Man involuntary. Prisoners, and other persons subject to legal restrictions requiring them to live on the Isle of Man are considered at paragraph 173.

c. *The potential donor was resident for settled purposes.*

There must be an identifiable purpose for their residence here with a sufficient degree of continuity to properly be described as settled. Business, education, employment and family can all provide a settled purpose, but this list is not exhaustive. There may be one purpose or several, and it may be for a limited period. Students are considered at paragraphs 170-172.

d. *The potential donor's residency in the Isle of Man supported the regular order of their life for the time being.*

There is no requirement for any person to be living in the Isle of Man permanently or indefinitely. The potential donor may have had temporary absences from the Isle of Man 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 in the Isle of Man, then consent should not be deemed.

Example

A potential donor worked in Douglas and lived there four nights a week, spending the other three nights at their family home in London. The potential donor dies in the Isle of Man.

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 the Isle of Man.

If the SN establishes that the potential donor considered London to be their home and Douglas to be their place of work only, consent could not be deemed.

Example

Two friends who are ordinarily resident in Wales go on a holiday to the Isle of Man. During the holiday, one of the friends dies in hospital.

Deemed consent does not apply as the person was not ordinarily resident in the Isle of Man.

Consent may be given by a nominated representative or someone who was in a qualifying relationship with the person immediately before their death.

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 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 in the Isle of Man 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 in the Isle of Man 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 and persons subject to legal restrictions requiring them to live on the Island

173. A person who is in prison (including a person held on remand), or subject to legal restrictions requiring them to live on the Island (i.e. persons subject to electronic monitoring requirements[12] or bail conditions preventing their leaving the Island[13]) cannot be considered to be residing in the Isle of Man voluntarily, and cannot be considered ordinarily resident in the Isle of Man during their time in prison. This includes prisoners who normally live in the Isle of Man and who are in prison in Isle of Man. People in prison, or subject to legal restrictions requiring them to live on the Island, 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 in the Isle of Man. There are also those who live in the Isle of Man 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 working or stationed at a specific location 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 in in that specific location 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 185-188), 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 by the MH Act and MH Code of Practice, rather than the HTODA.

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.

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[12] Further to section 47 (electronic monitoring) of the Criminal Justice, Police and Courts Act 2007 and associated secondary legislation.
[13] Further to section 3A (conditions for bail) of the Bail Act 1952.

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 the Isle of Man, 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 if they lacked capacity to understand that consent could be deemed for a significant period prior to their death.

184. The HTODA 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 in this Code of Practice that covers deemed consent in the Isle of Man in order to provide regulatory certainty to SNs and other practitioners. It is consistent with how deemed consent works under the relevant legislation in England and Wales.

186. The lack of capacity to understand that consent can be deemed for a significant period only negates deemed consent. If a potential donor has 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. In the event that the potential donor –

    a. had not expressed a decision to consent, or not to consent; and

    b. for a significant period before their death did not have the capacity to understand that deemed consent would apply,

    then deemed consent cannot apply.

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

187. If a potential donor:

    a. is not a child or an excepted adult, and

    b. had neither:

        i. made a decision in life; nor

        ii. appointed a nominated representative/s who had then given consent under that appointment,

    then the potential donor's 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. As donations from the Island align with the UK's regulatory system, deemed consent only applies to permitted material: the list of organs and tissue included in the definition of permitted material is set out in Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 (of Parliament). .

198. The UK Government's Department of Health and Social Care consulted on the list of organs and tissue where expressed consent will still be required for the purpose of transplantation.

199. The list of those organs and tissue subject to expressed consent in the UK is published on the HTA website will be updated when changes are made to the list.

200. For such organs and tissue that do not fall within permitted materials, 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. The HTODA provides, as part of the remit of DHSC, for the import or export of a body of a deceased person, or an organ or tissue that has come from a human body, for use for a scheduled purpose.

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

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

Interventions prior to death

204. The HTODA does not address the matter of steps which may be taken prior to the death of a potential donor who may, after death is diagnosed and confirmed using circulatory criteria, become a donor.

205. Where the potential donor does not have capacity, interventions before death are governed by the MH Act and MH Act Code of Practice, rather than the HTODA.

206. 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

207. Section 66 (preservation for transplantation) of the HTODA 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.

208. 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 204 - 206.

209. 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 the Isle of Man.

210. 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.

211. 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.

212. 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.

213. 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).

214. 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.

215. 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).

216. These organ preservation techniques cannot be considered to be minimum steps and must be used only where appropriate consent to donation is in place (see paragraph 209).

Coroners

217. 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 the agreement (or a lack of objection) of the Coroner should be sought before any transplantation activities proceed, or steps taken to preserve the organs within the body of the person.

Licensing under the HTODA

HLA tissue typing

218. If tissue samples 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 Human Tissue and Organ Donation (Ethical Approval, Qualifying Purposes and Transplantable Material) Regulations 2025 if the material is stored for less than 48 hours. If those tissue samples 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 HTODA, they must be stored on PH-licensed premises, subject to any applicable licensing exemptions. Further guidance can be found in Code of Practice E on Research.

Licensing requirements - Research

219. A licence is required under the HTODA for the removal of organs or tissue 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.

220. The storage of organs or tissue 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 in the Isle of Man or the United Kingdom. For research undertaken on the Island, or involves an Isle of Man resident, appropriate approval should be sought from the Isle of Man Research Ethics Committee (IOMREC) before commencing such research.

221. If organs or tissue are removed for the purpose of transplantation and subsequently used for research, rather than transplantation, the storage of organs or tissue (or both) must be on premises specified in the licence unless the research has ethical approval as indicated above.

222. Organs or tissue 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).

223. 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.

224. 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

225. 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 PH). It also applies to the duty to abide by PH's licensing Standards. We use the word '**should**' when providing advice on how to meet these requirements.

226. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which PH assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HTODA. However, PH, on behalf of CO, will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

Other advice and guidance

227. 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 gov.im website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. CO 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 other public bodies and organisations will appear on the gov.im website.

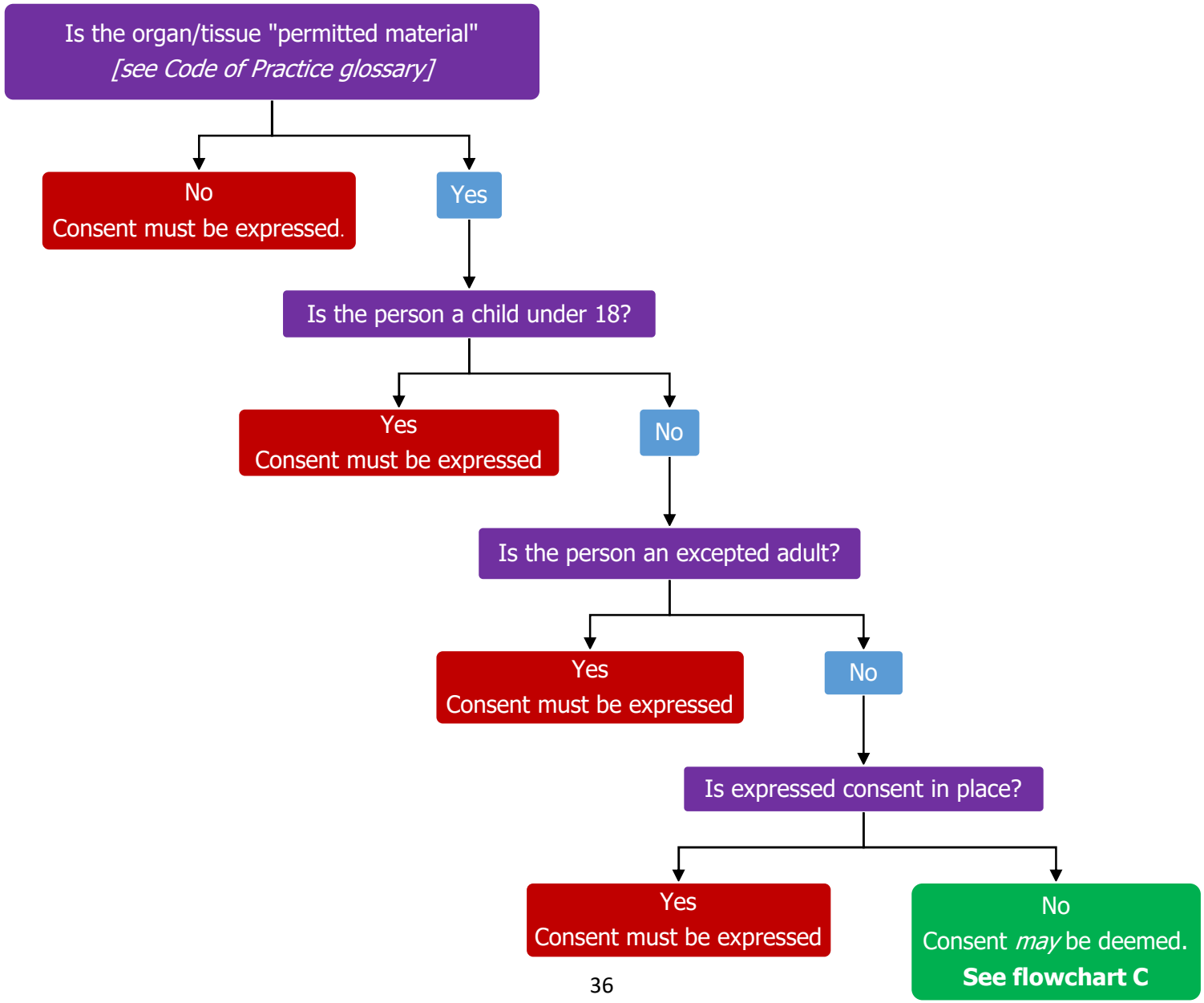
228. The Codes of Practice and other CO (and PH) guidance should, however, be used as the definitive source of information for issues within the remit of the HTODA. If you are in any doubt, please contact PH or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Annex A

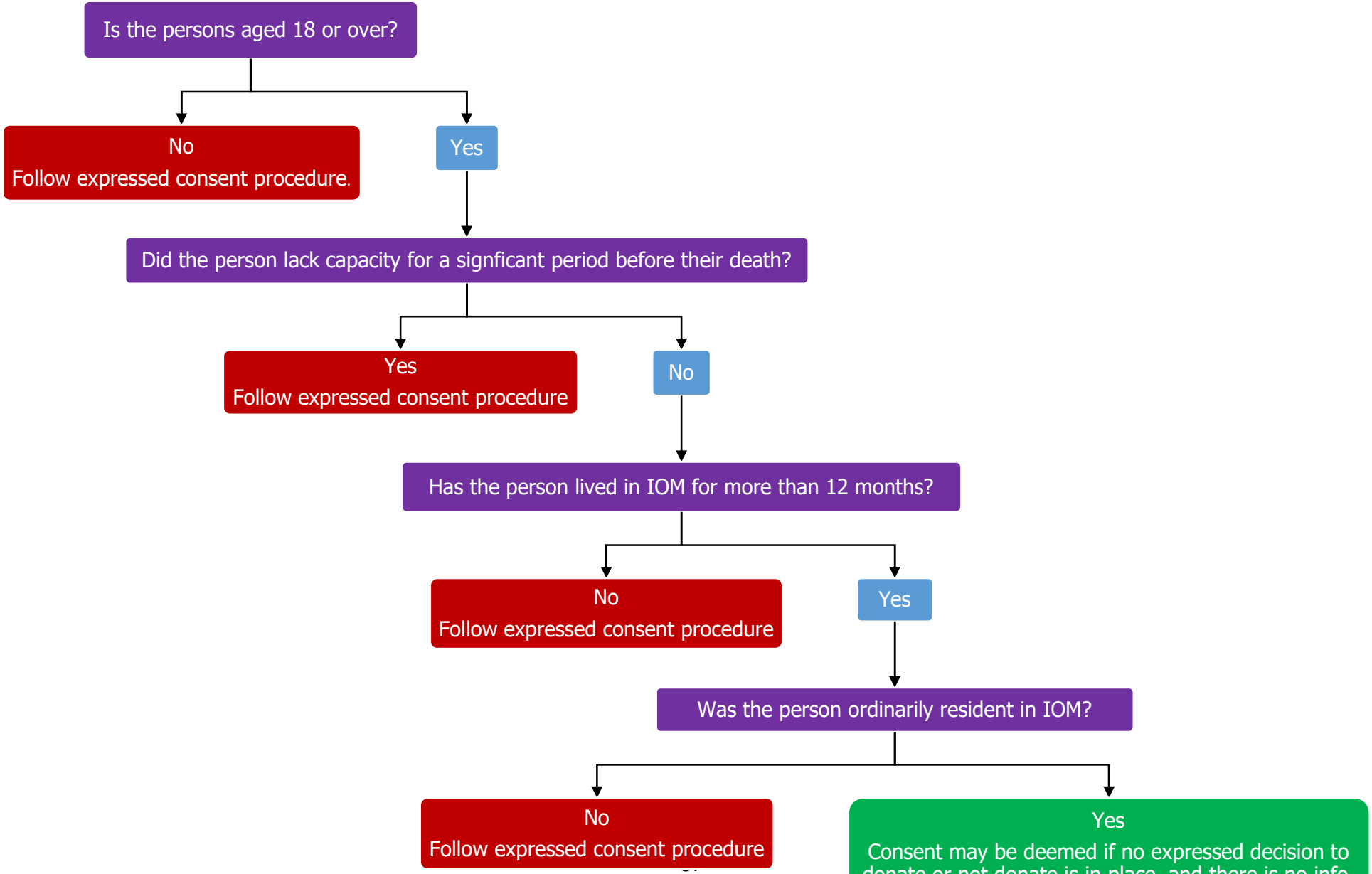
Legislative background and context

[Annex A from Code A to be inserted once finalised.]

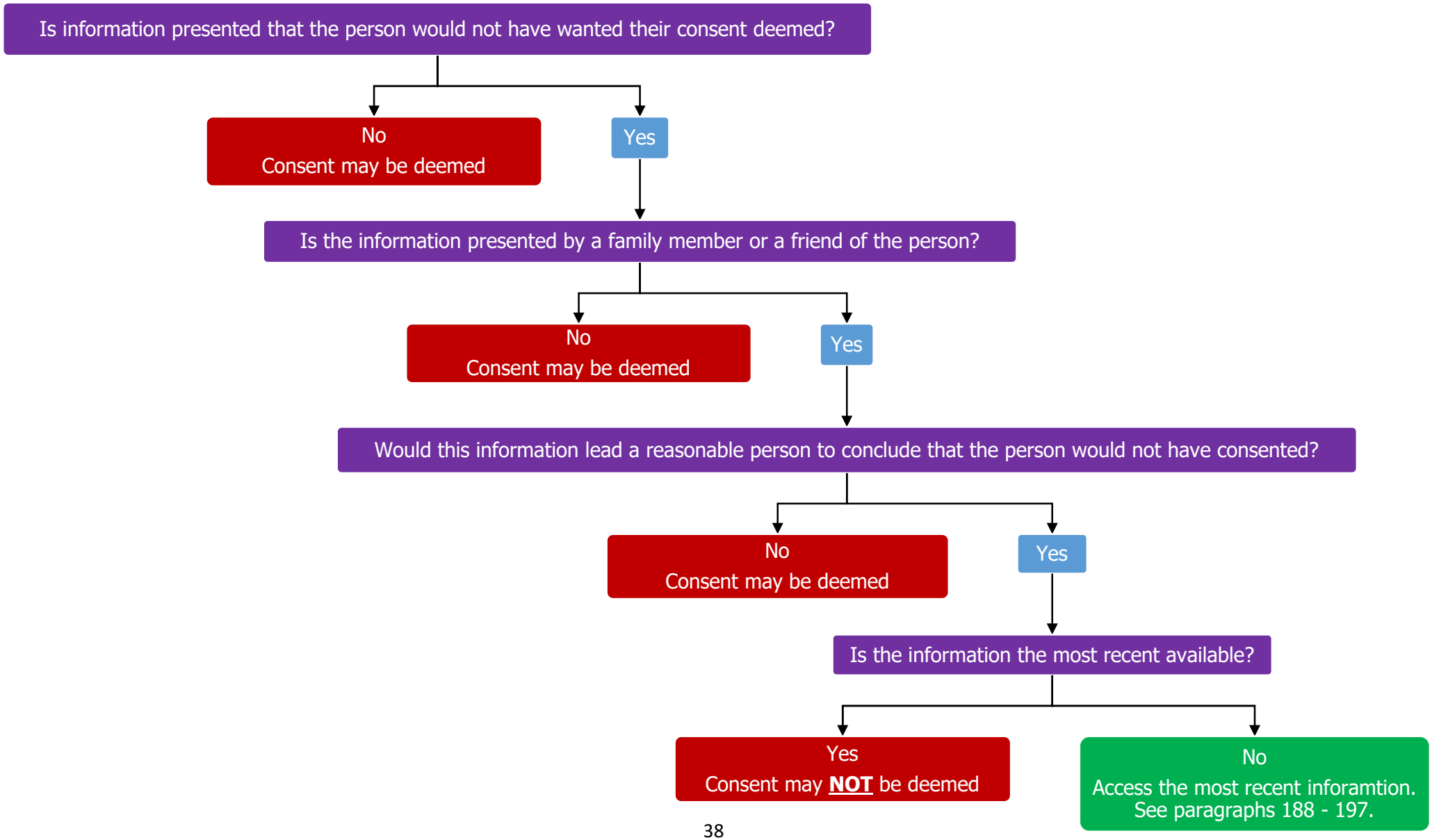
Flowchart A - Overview of deemed and expressed consent



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

To be added