Guidance on deceased organ and tissue donation in Scotland: Authorisation requirements for donation and pre-death procedures

1st edition published March 2021 (1st Ed.)

March 2021

Scottish Government
Riaghaltas na h-Alba
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Contents

Chapter 1: Introduction

1. Deceased organ and tissue donation is a unique act of generosity which has the potential to greatly enhance or save the life of a person receiving a transplant. The donation system relies on public trust and confidence in order for it to function and provide the life-saving and life-enhancing transplants it has the potential to. Key to this is the lawful fulfilment of the donor's decision, but also sensitive support of the donor's family who are involved as part of end of life care.

2. A core principle in current good practice, enshrined in the new duty to inquire under the Human Tissue (Authorisation) (Scotland) Act 2019[1] ("the 2019 Act"), is that health workers should make every effort to establish the decision or views of the potential donor, and then to support their decision being fulfilled.

3. Each scenario 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 practitioners to balance the information available to them and reach a judgement about whether it is lawful and appropriate for donation to proceed. This guidance makes clear that the presence of authorisation permits organ and tissue donation to take place, but does not mandate that it must. Sometimes a clinician will reach the judgement that although the legal basis to proceed with donation is in place, the broader considerations involved mean that it should not go ahead.

4. Further, in limited circumstances, the risks to public confidence in the donation process may outweigh the benefits of proceeding with donation. In these limited circumstances, this guidance outlines that donation should not proceed even though the law permits it.

Purpose and scope of this guidance

5. In Scotland, deceased donation is governed by the Human Tissue (Scotland) Act 2006[2] ("the 2006 Act"). The 2006 Act was amended by the 2019 Act, the primary aim of which was to introduce a system of deemed authorisation for transplantation and to provide clarity on the approach to authorisation and carrying out of medical procedures to facilitate transplantation (known as 'pre-death procedures'). References in this guidance to the "HTS Act" are to the 2006 Act, as amended by the 2019 Act. This guidance applies from 26 March 2021 when the 2019 Act comes into effect.

6. Before organs and tissue can be removed and used for any of the purposes[3] set out in the HTS Act, and before a pre-death procedure may be carried out, authorisation for that activity must be in place. This guidance advises practitioners on how to ensure the necessary authorisation is in place for such activity to be undertaken in accordance with the HTS Act.

[1] http://www.legislation.gov.uk/asp/2019/11/contents
[2] http://www.legislation.gov.uk/asp/2006/4/contents
[3] Purposes as listed in s.3 of the HTS Act are: transplantation, research, education or training, audit, quality assurance.

7. This guidance is not intended to be prescriptive about what should happen in every scenario. It provides guidance about the HTS Act and aims to assist the reader in making an assessment of whether authorisation for donation activities is in place and whether other relevant legal requirements have been fulfilled.

8. This guidance relates to the removal and use of organs and tissue for deceased donation only and relates only to Scotland. This guidance should be read in conjunction with the HTS Act. It is not, and is not intended to be, a comprehensive description of the Act, nor a substitute for seeking legal advice in complex cases.

Who this guidance is for

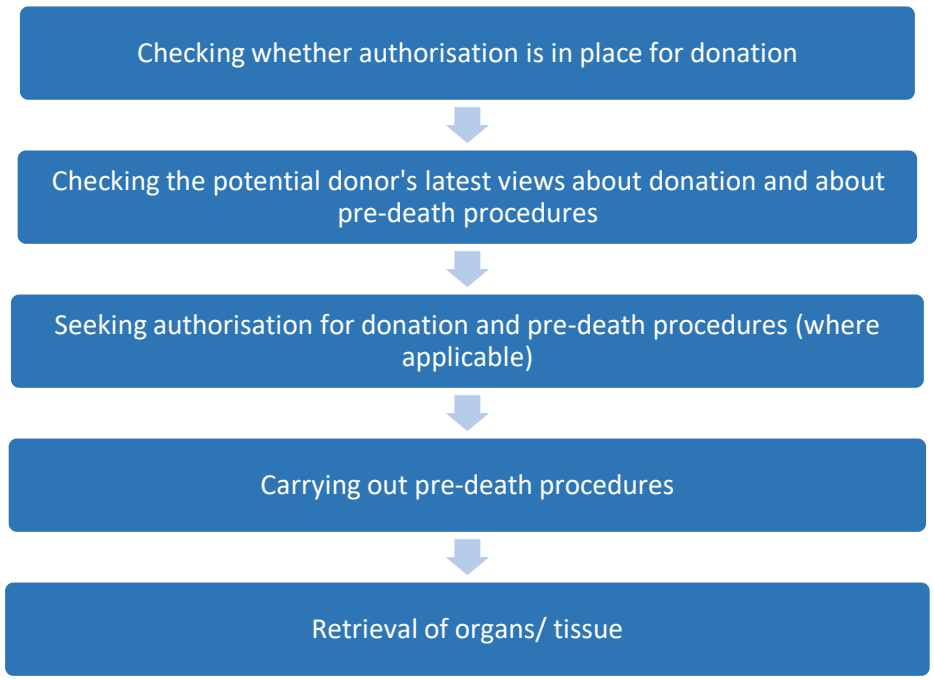
9. This guidance is for those involved in the donation process, particularly those involved in the authorisation process, who will be Specialist Nurses for Organ Donation (SNODs), Specialist Requestors (SRs) or Tissue Donor Coordinators (TDCs, also sometimes referred to by NHS Blood and Transplant (NHSBT) as "Specialist Nurses for Tissue Donation"). It is also relevant to those who are carrying out, or authorising others to carry out, pre-death procedures and those carrying out retrieval of organs and tissue. Guidance for those who refer potential donors is also included.

Interpretation and navigation

10. An interpretation section is included at Annex A, which details some of the terms used throughout this guidance.

11. The guidance includes the following chapters which cover the key stages in the donation process, as relevant to the HTS Act, shown in figure 1.

Figure 1: Outline of key stages in the donation process, as relevant to the HTS Act



- **Chapter 1** – Outlines broad principles and the purpose and scope of this guidance
- **Chapter 2** – Provides guidance on the new principles introduced by the 2019 Act.
- **Chapter 3** - Provides an overview on the role of the potential donor's family and the relevance of faith and beliefs in the context of the HTS Act, as well as details of different types of donation.
- **Chapter 4** – Referral is not part of the HTS Act, but for completeness, chapter 4 provides information on the process for those areas of the NHS which might refer potential donors.
- **Chapter 5** – Explains how donation can be expressly authorised and how opt-out declarations are made.
- **Chapter 6** – Provides guidance on establishing whether or not donation is authorised, including on establishing whether authorisation can be deemed under the HTS Act. It also provides guidance on establishing the views of the potential donor.
- **Chapter 7** – Provides guidance on the circumstances in which authorisation may be given on behalf of the potential donor.
- **Chapter 8** – Provides guidance on the legal requirements around the authorisation and carrying out of pre-death procedures.
- **Chapter 9** – Provides guidance on the requirements which must be fulfilled before retrieval can take place and the related offences.
- **Annex A** – Explains various terms in the HTS Act

Role of the Crown Office and Procurator Fiscal

12. There is an existing agreement[4] between the Crown Office and Procurator Fiscal Service and the Scottish Donation and Transplant Group in relation to Organ and Tissue Donation regarding the Procurator Fiscal's role in consenting to organ and/or tissue donation proceeding in cases where a patient's death needs to be reported to the Procurator Fiscal. This agreement reflects the 2019 Act and should be referred to for more details.

Principles

- Where there is reason to believe that a death should be reported to the Procurator Fiscal, no parts of a body may be removed without the Procurator Fiscal's prior consent[5]. Where consent has been given verbally, this should be confirmed in writing, for example by email, as soon as is reasonably practicable. The guidance entitled 'Reporting deaths to the Procurator Fiscal - Information and Guidance for Medical Practitioners' provides details of the categories of deaths which must be reported to the Procurator Fiscal[6].

[4] https://www.gov.scot/ISBN/978-1-80004-743-3
[5] See section 5 of the HTS Act
[6] See Guidance for Medical Practitioners at https://www.copfs.gov.uk/investigating-deaths/deaths

- The Procurator Fiscal will normally permit removal of organs and/or tissue, subject to the need to ensure that sufficient evidence is available for any criminal proceedings or Fatal Accident Inquiry.

- In any case of proposed organ (and tissue) donation after circulatory death (DCD), once a decision to withdraw life-sustaining treatment has been reached, the Procurator Fiscal should be consulted in advance of proposed treatment withdrawal if there is reason to believe that the death would need to be reported to the Procurator Fiscal.

- Similarly, if the death of a brain-stem dead organ donor or a tissue only donor needs to be reported to the Procurator Fiscal, the death must be reported before any donation can take place.

Points to consider

13. The SNOD/SR/TDC or hospital medical staff must inform the Procurator Fiscal of any potential organ and/or tissue donation in appropriate cases as soon as possible.

14. The Procurator Fiscal may wish to discuss the particular circumstances of the case with the doctor in charge, the SNOD/SR/TDC or the crown/fiscal pathologist.

15. If there is uncertainty as to whether, subsequent to death, the retrieval operation could affect evidence, the Procurator Fiscal may ask the SNOD/SR/TDC to put him or her in touch with the senior retrieval surgeon on the organ retrieval team and/or tissue retrieval staff to discuss the procedure/operation plans and ensure co-operation with any requirement for pathological investigation.

How to contact the Crown Office and Procurator Fiscal Service

16. The Scottish Fatalities Investigation Unit (SFIU) is a specialist unit within the Crown Office and Procurator Fiscal Service. SFIU has responsibility for receiving reports of deaths occurring in Scotland which are sudden, suspicious, accidental or unexplained.

17. There are three SFIU teams in Scotland. The SFIU North team has staff located in Dundee, Aberdeen and Inverness. The SFIU East team is based in the Procurator Fiscal's office in Edinburgh and the SFIU West team is based in the Procurator Fiscal's office in Glasgow. The death should be reported to the SFIU team in whose area the significant event leading to the death occurred:

North
Telephone: 0300 020 2387
Email: SFIUNorth@copfs.gov.uk

East
Telephone: 0300 020 3702
Email: SFIUEast@copfs.gov.uk

West
Telephone: 0300 020 1798
Email: SFIUWest@copfs.gov.uk

18. Where a death or expected death needs to be reported out of normal office hours, the homicide out of hours Fiscal should be contacted. SNODs/SRs can provide the relevant contact details. For more information on the Crown Office and Procurator Fiscal Service visit https://www.copfs.gov.uk.

Use of organs and tissue outside of Scotland

19. The use of organs and tissue for transplantation or other purposes in other parts of the UK or elsewhere is regulated by legislation in those respective jurisdictions. Organs and tissue retrieved lawfully in Scotland in accordance with the HTS Act - including those retrieved on the basis of deemed authorisation - may be transported to other parts of the UK or elsewhere and utilised there, provided that any relevant statutory and regulatory requirements are met in the relevant jurisdiction. Subject to those same conditions, organs and tissue lawfully retrieved in other parts of the UK or elsewhere are able to be used in Scotland for the purposes specified in the HTS Act.

Chapter 2 - New principles introduced by the 2019 Act

20. As well as making provision for the purpose of introducing a deemed authorisation system and providing clarity on pre-death procedures, the 2019 Act introduced several new concepts and principles:

- Requirements as to who can carry out certain functions: The HTS Act permits specific functions to be carried out only by those meeting the definition of a 'health worker'. (See paragraphs 21-28 for more information)

- The duty to inquire: The HTS Act places a duty on certain health workers, who in most cases will be SNODs/SRs/TDCs, to make inquiries about a potential donor and their views. (See paragraphs 29-37 for more information)

- The concept of the 'relevant time': This replaces the references to 'immediately before death' in the 2006 Act to take account of the fact that a potential donor might not yet be deceased at relevant points during the authorisation process. (See paragraphs 38-42 for more information)

- The Organ Donor Register: The HTS Act places the NHS Organ Donor Register (ODR) on a statutory basis in Scotland and sets out with whom information from the ODR may be shared (see paragraphs 43-48 for more information). It also requires that donation decisions recorded other than on the ODR must be in writing.

'Health Worker' functions

21. The HTS Act requires that certain functions within the donation process must only be carried out by a 'health worker'. These functions are:

- Carrying out the duty to inquire – this will generally be done by a SNOD, a SR or TDC, or on rare occasions, and particularly in relation to tissue-only donation, by a clinician or nurse if the SNOD/SR/TDC is not available.

- Receiving authorisation (and where appropriate, withdrawal of authorisation) for donation from a nearest relative of an adult or a person entitled to authorise donation on behalf of a child[7] – this will generally be done by a SNOD/SR/TDC or, on rare occasions, by a clinician or nurse if the SNOD/SR/TDC is not available.

- Carrying out or authorising a person to carry out pre-death procedures and ensuring that the requirements of the HTS Act are met before the procedure goes ahead (see chapter 8) – this will generally be done by a registered

[7] Authorisation for donation may be given on behalf of a child by a person with parental rights and responsibilities in relation to them, including a local authority. Where there is no person with parental rights and responsibilities or that person is incapable of providing authorisation, section 10A of the HTS Act sets out who is permitted to authorise donation on behalf of a child (see chapter 7 for more information).

medical practitioner, registered nurse or a range of other appropriately skilled and trained health professionals, for example a radiographer.

22. The HTS Act also recognises that the responsibility for making assessments and decisions about a potential donor's condition and care in the context of pre-death procedures is a matter for a 'health worker'. In practice, these decisions will be made by a registered medical practitioner, for example an ICU consultant (see paragraph 190).

Meaning of 'Health Worker' and how a person may be authorised to carry out the functions of a Health Worker

23. The Act provides a definition of 'health worker' which encompasses the different professionals who may be involved in the donation process. Section 16J of the HTS Act defines a 'health worker' as a registered medical practitioner or a registered nurse.

24. In addition, a person or person within a description[8] can be authorised to undertake some or all of the health worker functions. This will usually be done on a case by case basis by asking a person to carry out a certain task which is a health worker function. For example, an ICU consultant or SNOD/SR is able to authorise a radiographer to carry out an X–ray as a pre-death procedure, by requesting them to carry out this task.

25. The registered medical practitioner or registered nurse must consider that the person that they are authorising to undertake the task has the appropriate skills, qualifications or experience to perform the relevant function(s).

Role of health bodies in authorising a person to carry out health worker functions

26. Section 16J of the HTS Act also gives powers for authorisations to carry out health worker functions to be made by health bodies[9] should it be necessary. This power is intended to provide additional flexibility should the circumstances require it. However, based on the current roles and responsibilities involved in the donation process, it is not envisaged that this will be necessary as all required authorisations can be made by an individual registered medical practitioner/registered nurse authorising an individual to carry out a specific health worker function.

Revoking authorisation of a person to carry out health worker functions

27. The HTS Act also enables authorisation of a person to carry out health worker functions to be revoked if required, for example if a person authorised to carry out a function is no longer qualified to do so. In practice revocation is unlikely to be necessary, particularly as most authorisations will be given on a case by case basis by virtue of asking a person to carry out a specific task.

[8] Such as people carrying out a particular role - for example, all radiographers.
[9] Authorisations can be given by a Health Board, a Special Health Board, or the Common Services Agency for the Scottish Health Service (of which SNBTS forms part).

28. In most cases, any person (a registered medical practitioner or registered nurse) or health body permitted to authorise can revoke an authorisation. It is only if a health body gives the authorisation to a description of person (for example, all radiographers working in a particular hospital) that it needs to be revoked by that health body.

Duty to inquire

29. The duty to inquire reflects current good practice whereby a discussion takes place with the potential donor's family about donation, including about the potential donor's views about donation, to ensure that donation doesn't proceed where it would be against a person's wishes.

30. The HTS Act requires that certain checks are undertaken before the carrying out of any pre-death procedure or retrieval can take place to determine a potential donor's status, any decisions which they may have recorded, and their views about donation and pre-death procedures.

31. The duty to inquire may only be carried out by a health worker, which in most cases will be a SNOD/SR/TDC. If the duty to inquire is being carried out by a health worker who isn't a SNOD/SR/TDC then they should do so following discussion with the SNOD/SR/TDC.

Inquiries which must be made

32. The SNOD/SR/TDC must ensure that the requirements of the duty to inquire[10], detailed below, are fulfilled, before the carrying out of any pre-death procedure or retrieval.

33. Under the duty, the SNOD/SR/TDC must take reasonable steps to inquire:

- whether there is an express authorisation for donation in place and
- whether there is an opt-out declaration in place.

34. Further, if the potential donor is an adult, and there is no recorded decision in place, the SNOD/SR/TDC must inquire into:

- whether the adult is in a category of persons in respect of which deemed authorisation does not apply ('an excepted category') (see paragraph 115).

35. In inquiring as to whether a potential donor is an adult who is incapable of understanding the nature and consequences of deemed authorisation (see paragraphs 133-141 for more information), the SNOD/SR/TDC must consult - so far as reasonably practicable - any person who has indicated a wish to provide evidence of the adult's incapacity.

[10] Provided for in new sections 16H and 16I of the HTS Act, in relation to adults and children respectively.

36. In all cases, whether a donation decision is in place or not, the SNOD/SR/TDC must inquire about the potential donor's views about donation, both in general and in the specific circumstances, which may include views based on the way the death has manifested – either after circulatory death or brain-stem death – for example for religious reasons. The SNOD/SR/TDC must also inquire about the potential donor's views about the carrying out of pre-death procedures. This should be done by consulting the following people, as far as is reasonably practicable:

- the nearest relative[11] of the potential donor (in the case of an adult);
- a person entitled to authorise donation on behalf of a child[7];
- any person who wishes to provide evidence of the potential donor's views;
- any other person the SNOD/SR/TDC considers it appropriate to consult.

37. Additionally, in a case where it is determined that an adult is incapable of understanding the nature and consequences of deemed authorisation, and a nearest relative is considering whether to authorise donation, the SNOD/SR/TDC must inquire not only as to the adult's most recent views, but also as to the adult's past wishes and feelings, so far as reasonably ascertainable.

Relevant Time

38. The 2019 Act introduces the concept of 'relevant time'[12] which is used to define a point or period of time during the donation process. This replaces the 'immediately before death' terminology in the 2006 Act and reflects the growth in donation following circulatory death (DCD) since the introduction of the 2006 Act. 'Relevant time' applies to various aspects of the process and is defined differently depending on whether the potential donor is alive, (but expected to die, as in the case of DCD donation) or deceased (as in the case of donation after brain-stem death (DBD)).

39. Where the potential donor is **alive**, the 'relevant time' is when:

- in the view of the person primarily responsible for the potential donor's medical treatment, they are likely to die imminently, including as a result of the withdrawal of life-sustaining treatment if it is being administered;
- the decision has been taken by the person primarily responsible for the potential donor's medical treatment to withdraw life-sustaining treatment, if being administered; and
- the person primarily responsible for the potential donor's medical treatment is of the view that they are incapable by reason of ill health of making a donation decision (adults and children aged 12 and over).

40. Where the potential donor is **deceased**, the relevant time is:

- immediately before the potential donor's death.

[11] See section 50 of the 2006 Act for a definition of 'nearest relative' and paragraph 145.
[12] Defined in section new section 16K of the 2006 Act, as inserted by section 27 of the 2019 Act.

41. The concept of 'relevant time' applies for the purposes of the HTS Act in relation to various aspects of the donation process. In particular, it is relevant when establishing the status of the potential donor and their decision about donation and pre-death procedures. For example:

- whether the potential donor is an adult or a child and, if a child, whether the child is under or over 12 years of age;
- whether a donation decision is in place in respect of a potential donor;
- how long an adult potential donor has been resident in Scotland;
- how long the potential donor has been incapable of understanding the nature and consequences of deemed authorisation;
- whether the carrying out of pre-death procedures has been expressly authorised by the potential donor.

42. The 'relevant time' is also relevant to establishing the status of a person who may authorise donation on behalf of the potential donor. For example:

- who the nearest relative of an adult potential donor is;
- who has parental rights and responsibilities in relation to a potential donor who is a child;
- if there is no person who has parental rights and responsibilities in relation to a child, or if they are incapacitated, who may authorise donation for the child (see paragraph 160 for more information).

Disclosure of information from the NHS Organ Donor Register

43. The HTS Act permits NHSBT (as the register organisation[13]) to disclose information from the ODR to assist or enable certain persons to carry out functions under the Act which relate to the removal and use of a body part for the purpose of transplantation.

44. The information which can be disclosed from the register about an individual is:

- whether there is an express authorisation in place and its detail,
- whether there is an opt-out declaration in place and its detail, or
- that there is no information about a person held in the register.

45. Information can only be disclosed by NHSBT to the following persons:

- A registered medical practitioner,
- A person authorised under the Human Tissue (Removal of Body Parts by an Authorised Person)(Scotland) Regulations 2006[14] to remove body parts, for example tissue retrievers (see paragraphs 210 for more information),

[13] Section 2B(1) HTS Act enables Scottish Ministers to delegate the functions of establishing maintaining the register to a 'register organisation'. NHSBT has been designated as the register organisation.

[14] https://www.legislation.gov.uk/ssi/2006/327/contents/made

- A health worker carrying out the duty to inquire in respect of a potential donor who is an adult or a child, for example a SNOD/SR/TDC.

46. To facilitate the process of transplantation and as part of the duty to inquire, the information received from NHSBT may be shared amongst the persons listed above and disclosed onwards to:

- the nearest relative of the potential donor or, if the potential donor is a child, a person entitled to authorise donation on behalf of a child,
- any other person who has been consulted about the latest views of the potential donor.

47. In practice this means that the SNOD/SR/TDC or other health worker is able to inform the family of the potential donor whether there is a decision recorded on the ODR (as well as the details of that decision), as well as any other person who is asked about the potential donor's latest views.

48. As well as permitting information to be shared within Scotland, the HTS Act allows the register organisation to disclose information about a person from the register to a person operating outwith Scotland if it is done for the purpose of enabling or assisting that person to carry out functions that relate to the removal and use of a part of the body for transplantation.

Chapter 3: Practical context around donation

This chapter details the different types of donation, the principles of the role of the family and considerations around faith and beliefs.

Types of organ and tissue donation after death

49. There are two types of organ and tissue donation after death which are undertaken in the UK - donation after brain-stem death (DBD) (sometimes referred to as diagnosis of death using neurological criteria (DNC)) and donation after circulatory death (DCD).

50. The HTS Act does not make a distinction between the types of death, however the 'relevant time' concept means that it takes account of the fact that the authorisation process may take place either when the potential donor is alive (but expected to die), or is deceased. Authorisation for donation for transplantation can be deemed irrespective of the type of death.

Donation after Brain-Stem Death (DBD)

51. Donation after brain-stem death means donation which takes place following tests which diagnose and confirm death using neurological criteria. The patient's organ support, including mechanical ventilation, is supported while authorisation is established or sought and (where applicable) arrangements are put in place for organ and/or tissue donation.

Donation after Circulatory Death (DCD)

52. Donation after circulatory death describes organ and tissue retrieval which follows the planned withdrawal of life-sustaining treatment at the end of a critical illness when a decision is taken by the treating clinical team and with the agreement of those close to the patient (e.g. family and friends) that ongoing treatment will not benefit the patient.

Tissue only donation

53. Tissue-only donation can occur in a wider variety of settings than organ donation given the timing of the process is different. Tissue-only donation takes place after an acute catastrophic event that leads to acute cessation of circulation. In the case of tissue-only donation, donation is often (but not always) discussed with the potential donor's family only after death has been verified.

54. The HTS Act makes no distinction between organs and tissue for the purposes of authorisation for donation and applies equally to both.

Role of the Family

55. The HTS Act establishes the principle that the decision to authorise donation after death rests first and foremost with the donor themselves, where they are able to

do so, and there is no power in the Act for others to change or overrule the recorded decision of the potential donor.

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

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

58. Family and friends are also asked to provide medical and social background information about the potential donor. This is separate to the requirements around ensuring authorisation is in place but is a related and important part of clinical practice so that clinical decisions can be made about the suitability of donation in light of all of the relevant information.

Faith and beliefs

59. Consideration of a potential donor's cultural and religious/non-religious beliefs is an important part of person-centred care. Such beliefs should be considered sensitively and as a decisive factor in determining the views of the potential donor regarding authorisation for donation.

60. Under the duty to inquire, the SNOD/SR/TDC must explore not only views about donation in general but also what the potential donor's views would be in the specific circumstances, as the HTS Act requires health workers to explore the potential donor's views as they would relate to the specific circumstances of death. This takes into account that some people might want to change their decision, or be unwilling to donate if the circumstances of their death manifest in a particular way – either after circulatory death or brain-stem death – for example, for religious reasons. Where the evidence provided indicates particular views regarding the circumstances of death, donation may only proceed if and insofar as this is consistent with the potential donor's views.

61. Without making assumptions, discussions should establish whether the potential donor was of a particular faith, or held certain beliefs or cultural views that may influence how and whether donation could proceed. The views of the potential donor should be discussed sensitively and openly in order to establish whether donation is able to proceed.

62. When registering a decision to authorise donation on the ODR, individuals can record if their faith or beliefs are important to them in relation to 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".

63. Where an individual has selected that this statement is applicable to them, the SNOD/SR/TDC should explain this to the potential donor's family as part of a discussion about the potential donor's faith and beliefs with respect to organ and tissue donation. The SNOD/SR/TDC should answer any questions and seek further guidance and support from faith representatives if required.

64. Where an individual has authorised donation (either expressly or through the operation of deemed authorisation) but their family disagrees about whether donation is supported by the potential donor's faith or belief, the SNOD/SR/TDC should explore any issues raised by the family and work with them to address any questions. The SNOD/SR/TDCs should support consultation with faith representatives to provide counsel or clarification on how donation may proceed whilst ensuring that any religious obligations are observed. For example, the family may wish to ensure appropriate end of life rituals are followed, should donation take place.

65. Some faith and/or belief communities may also have specific arrangements in place to support families and SNOD/SR/TDCs 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 SNOD/SR/TDCs should ensure available services are utilised where this is indicated.

66. Hospitals also have Departments of Spiritual Care with faith trained co-ordinators and chaplaincy services which can help support conversations about donation with the family and SNOD/SR/TDCs.

Chapter 4: Referral of potential donors

This chapter signposts health professionals not directly involved in the donation process to discuss the potential for referral of patients for donation to NHSBT or SNBTS.

67. There is a significant shortage of donor organs and some tissue in the UK, which means that many people are having to wait a long time for a life-saving or life-enhancing transplant. And some people are still dying while waiting. Therefore it is important to ensure that everyone who could potentially be a deceased donor is considered. NHSBT provides best practice guidance[15] regarding referral and the key principles are set out below.

68. Where a patient in an Intensive Care Unit, Emergency Department or any other hospital area where patients may die could potentially donate, a referral should be considered and made if appropriate. The most important point to remember is that donation should start to be considered at an early stage where there is:

- an intention to use neurological criteria tests to confirm death;
- an intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death;
- admission of a patient with very severe brain injury (defined as a Glasgow Coma Score of 3-4 with at least one absent brain-stem reflex) that cannot be attributed to the effects of sedation.

69. For tissue-only donation, donation should also be considered early.

70. A Specialist Nurse for Organ Donation (SNOD), Specialist Requestor (SR) or Tissue Donor Coordinator (TDC) should be contacted to see if donation may be possible, even if it may seem unlikely. The SNOD/SR or TDC will be able to advise often quickly by telephone if the patient could be a potential donor and this early screening call will help to ensure that no potential donor is missed.

Contact Numbers

71. If there is a patient who could be a potential organ (and tissue) donor i.e. if it is expected that life sustaining treatment will be withdrawn soon or brain-stem death testing will be carried out on the patient, the donor referral line should be contacted on the number below to arrange for a SNOD/SR to respond.

- Donor referral line (24 hours a day, 7 days per week) - 03000 20 30 40

<u>Tissue only donation</u>

72. If the patient has already suffered circulatory death, (in particular for Emergency Departments or general wards) a TDC should be contacted on the

[15] https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donor-identification-and-referral/

number below as tissue donation may still be possible (tissue, such as heart valves and tendons can be retrieved up to 48 hours after death, and eyes up to 24 hours after death).

- TDC Tissue services pager (24 hours a day, 7 days per week) - 07623 513987

Next Steps

73. If a patient could potentially be a donor, the SNOD/SR or TDC will guide the next steps. If the patient is a potential organ (and/or tissue) donor, a SNOD/SR/TDC will check the NHS Organ Donor Register. In the setting of organ donation, a SNOD/SR will arrange to attend and approach the nearest relative (or person with parental rights and responsibilities in the case of a child) about donation alongside the clinicians who have been caring for the patient. The topic of donation should not be raised with family members until the SNOD/SR arrives. Sometimes the patient's family might raise the issue of donation themselves with clinical staff; if so, it is normally best to suggest that it is too early to discuss donation, but that clinical staff will discuss further if and when end of life care options require to be considered.

<u>Tissue only donation</u>

74. For patients who could potentially donate tissues, but not organs (those who have already died, those not on ventilation who are not expected to die in a controlled manner, or patients with a history of cancer), the TDC will give guidance on approaching the patient's family. Clinical staff will be asked to speak to the family to ask them whether they would be willing for a TDC to contact them, almost always by telephone, at an appropriate time that suits the nearest relative (or person entitled to give authorisation on behalf of a child). If they are willing to discuss donation, the TDC will contact them and, if donation is authorised, will arrange the next steps.

Chapter 5: Express authorisations and opt-out declarations for donation

This chapter explains how express authorisation for donation and opt-out declarations can be given and that if they are not recorded on the ODR, then they must be made in writing.

75. The HTS Act permits adults and children aged 12 years and over in Scotland to give an express authorisation or an opt-out declaration in respect of donation. A decision may be recorded in relation to any specific organ or tissue and in relation to any permitted purpose[3]. An authorisation applies to only those organs and/or tissue and only the purpose(s) that the potential donor has indicated.

76. The HTS Act does not permit children aged under 12 to make an express authorisation or opt-out declaration. In the case of a child aged under 12, authorisation may only be provided on behalf of the child. An "express authorisation" by a child under the age of 12, for example on the ODR, would not permit donation to proceed and authorisation should be sought on behalf of the child. The fact that the child has attempted to register on the ODR would though be evidence of the child's views which may be taken into account when a person is deciding whether to authorise on behalf of the child.

Recording a decision about donation

77. The most common way of recording a decision will be via the ODR, but the HTS Act does not limit decisions to being recorded there. The HTS Act requires that, if a decision about donation is recorded outwith the ODR, then it must be recorded in writing. This applies to express authorisations and opt-out declarations. Expressions of views about donation expressed orally would, however, be evidence about the potential donor's views about donation.

78. The HTS Act does not require written express authorisations or opt-out decisions to be witnessed. The HTS Act only requires a witness to be present where an express authorisation or opt-out decision is withdrawn in writing by a person who is blind or unable to write[16].

79. As long as the potential donor registered their decision voluntarily, had the information they needed to make the decision and had mental capacity or competence when they did so, then the decision recorded (on the ODR or elsewhere) constitutes a valid decision at the time of recording. Unless there is a suggestion that this is not the case, for example from the potential donor's family, then the assumption would be that the decision is valid. Any such suggestion should prompt further discussion and investigation.

[16] See section 10D of the HTS Act.

The NHS Organ Donor Register

80. The ODR operates throughout the UK to allow individuals to record their decision about organ and tissue donation. The HTS Act provides a statutory basis for the ODR in Scotland and makes clear that decisions recorded on the ODR are in relation to transplantation only. The ODR allows the following decisions to be recorded:

- I authorise the donation of all my organs/tissue after death;
- I authorise the donation of some (specified) organs/tissue after death;
- I do not authorise donation of my organs/tissue after death (an opt-out declaration).

Chapter 6: Establishing whether a donation decision is in place

This chapter is about establishing whether donation is authorised by checking the ODR and through discussions with the potential donor's family (as part of the duty to inquire) to ensure that the latest views of the potential donor are taken into account.

Evidence of the potential donor's views may be in any form (including oral) and guidance is included on assessing the weight of the evidence brought forward.

This chapter also provides guidance on determining whether a person may be deemed to have authorised donation and whether they fall within an excepted category.

Checking whether a decision has been recorded

81. The HTS Act respects the principle that the decision to authorise donation rests first and foremost with the donor themselves (in relation to adults and children aged 12 and over). As such, the potential donor's valid express authorisation where this is recorded, or the potential donor's views about donation, including where authorisation may be deemed, should form an integral part of end-of-life care planning.

82. In every case where donation is a possibility, the SNOD/SR/TDC should establish whether, at the relevant time, there is a decision in force by the potential donor, in line with the requirements of the duty to inquire (see paragraphs 29-37).

83. The SNOD/SR/TDC should check the ODR to establish whether a decision has been recorded on it and if so, what the latest decision recorded there is. If a decision is recorded on the ODR, the SNOD/SR/TDC should communicate this to the potential donor's family and other individuals where relevant (see paragraphs 43-48 for more information on who information from the ODR may be shared with).

84. If there is no decision recorded in the ODR, the SNOD/SR/TDC should explore with the potential donor's family whether a decision may have been recorded elsewhere and gain a copy of it, if possible. If a donation decision has been recorded somewhere other than on the ODR, then it must be in writing. The HTS Act does not require written express authorisations or opt-out decisions to be witnessed, dated or signed. The HTS Act only requires a witness to be present where an express authorisation or opt-out decision is withdrawn in writing by a person who is blind or unable to write[17].

Establishing whether a recorded decision permits donation to proceed

85. Where the potential donor has recorded their decision voluntarily, had the information they needed to make the decision, and had mental capacity or

[17] See section 10D of the HTS Act.

competence when they recorded it, then a donation decision recorded on the ODR or expressed in writing constitutes a valid decision at the time of recording. Unless there is a suggestion that this is not the case, then the assumption would be that the decision is valid. Any suggestion that the decision was not validly made should prompt further discussion and investigation. If a valid decision was made by a potential donor to authorise donation, this is sufficient to provide a lawful basis for donation to proceed, subject to the results of the inquiries about the potential donor's most recent views and the pre-death procedure requirements, as detailed in chapter 8.

86. The position for a child aged 12 or over, who was competent to record a decision before they died and who had authorised donation taking place after their death, is legally no different from that of an adult. The child's valid authorisation is sufficient to provide a lawful basis for donation to proceed, subject to the results of the inquiries about the child's most recent views and the pre-death procedure requirements, as detailed in chapter 8.

87. In circumstances where the potential donor has made an opt-out declaration, donation cannot proceed as authorisation is not in place. However, if when carrying out the duty to inquire, evidence that the potential donor would be willing to donate which meets the threshold is presented to a health worker, the potential donor is treated as though they have expressly authorised donation for the organ/tissue or purpose in question.

Establishing the potential donor's latest views

88. If a donation decision has been recorded, then the SNOD/SR/TDC must explore what the potential donor's latest views about donation were. As part of this, the SNOD/SR/TDC must explore not only views about donation in general but also what the potential donor's views would be in the specific circumstances. This may include views based on the way the death has manifested, for example for religious reasons (see paragraph 60 for more information).

89. The SNOD/SR/TDC should explore the potential donor's views with:

- the potential donor's nearest relative[11] (in the case of an adult);
- a person entitled to authorise donation on behalf of a child[7];
- any person who wishes to provide evidence of the potential donor's views;
- any other person the SNOD/SR/TDC considers it appropriate to consult.

90. If it is a local authority which holds parental rights and responsibilities in relation to a child who has recorded a donation decision, the SNOD/SR/TDC should advise and guide the local authority through the requirements of the HTS Act. The local authority must, as far as is reasonably practicable, ascertain the child's most recent views by consulting:

- the child's parents, and
- such other persons as the local authority considers appropriate.

91. In practice, the relevant people are likely to be in attendance at the bedside and when this is the case, the local authority should discuss the child's most recent views with them, supported by the SNOD/SR/TDC.

If the potential donor's views have changed since recording their decision

92. The recorded decision by the potential donor may be treated as withdrawn if there is evidence of their views which is contrary to the recorded decision. This may be something that the potential donor has written or a recollection of a prior conversation held with the potential donor. In order for the recorded decision to be treated as withdrawn, evidence presented as part of the duty to inquire should meet the evidence threshold, that is it should be capable of leading a reasonable person to conclude that the potential donor's latest view was contrary to the recorded decision. For example, if an express authorisation has been recorded and evidence is given that the potential donor would be unwilling to donate which meets the evidence threshold, the express authorisation is treated as withdrawn and donation should not proceed. If an opt-out declaration has been recorded and evidence of the potential donor's willingness to donate, meeting this threshold, is produced, the opt out declaration is treated as withdrawn and the potential donor is treated as though they have expressly authorised donation for the organ/tissue or purpose in question.

93. Evidence may be presented which leads to the partial withdrawal of the potential donor's decision, either in relation to specific organs/tissue or specific purposes. Where this is the case, the decision is only withdrawn so far as it reflects those specific views and the remainder of the decision remains in force. For example, if a potential donor had authorised donation of their heart, lungs and liver for transplantation and subsequently changed their mind and no longer wanted to donate one of those organs for transplantation, then the authorisation for donation of that organ is treated as withdrawn. The remainder of the authorisation remains in force for the other organs for transplantation.

If there is express authorisation for donation and the family doesn't support donation proceeding

94. Where valid express authorisation has been given by the donor, but the family or others object to donation proceeding, then they should be sensitively supported to respect the potential donor's authorisation to ensure her or his decision is respected. A family's objection does not nullify valid authorisation for donation from the potential donor and only a potential donor themselves can revoke their legally valid authorisation or opt-out declaration.

95. The existence of valid authorisation by the potential donor permits donation to proceed, but does not mandate that it must. The final decision about whether to proceed with donation rests with the SNOD/SR/TDC, in conjunction with medical practitioners and through conversation with the potential donor's family.

If there is an express authorisation and there is no-one to consult about the potential donor's most recent views

96. There may be occasions where a potential donor has recorded an express authorisation for donation and, despite the best efforts of a SNOD/SR/TDC or other health worker, it does not prove possible to locate anyone who can be consulted about the potential donor's most recent views.

97. The HTS Act requires that inquiries must be made as to the potential donor's views about donation, as far as is reasonably practicable. The SNOD/SR/TDC should therefore seek out all available methods to establish whether there is a nearest relative or any other person who knew the potential donor recently to consult about the potential donor's views. After taking these steps, it may be apparent that there is no such person available or in existence.

98. In such a case, if the potential donor has recorded an express authorisation, lawful authorisation would be in place for the retrieval of the relevant organs/tissue to proceed. However, clinical consideration will be given as to whether there is sufficient information about the potential donor's medical and social history to inform an assessment of whether organ/tissue transplantation would pose risks for a potential recipient.

If no decision is in place - adults

99. If the SNOD/SR/TDC has established that there is no decision recorded on the ODR, or elsewhere in writing and the adult is not in an excepted category (see paragraph 115), then authorisation for donation may be deemed, subject to the results of the inquiries about the potential donor's views (see paragraphs 29-37).

100. Deemed authorisation does not apply where a person provides evidence to a health worker which would lead a reasonable person to conclude that the potential donor was unwilling to donate.

Deemed authorisation

101. In cases where a decision of a potential donor regarding authorisation for donation has not been recorded on the ODR or elsewhere in writing, then authorisation for donation for transplantation may be deemed, subject to certain exceptions. Deemed authorisation can only apply where the potential donor is an adult (aged 16 or over). Authorisation cannot be deemed if:

- the potential donor is an excepted adult (see paragraph 115) or a child;
- evidence (oral or written) is provided to a health worker that would lead a reasonable person to conclude that the potential donor would have been unwilling to donate, either in general or in the specific circumstances;
- it is in relation to body parts which are excluded from deemed authorisation, as specified by the Scottish Ministers in regulations (see paragraph 165-166 for more detail);
- it is in relation to purposes other than transplantation.

102. As outlined in paragraphs 82-84, steps must be taken to determine whether a decision of the potential donor has been recorded on the ODR or elsewhere. If a potential donor recorded a decision in regard to donation for transplantation purposes when they were alive, their authorisation cannot be deemed. As outlined in paragraphs 88-93, steps must also be taken to establish the potential donor's latest views about donation, as part of the duty to inquire.

103. Evidence may be presented to a health worker which may lead a reasonable person to conclude that the potential donor's most recent view was that they were unwilling to donate specific organs/tissue or that they would be unwilling to donate in the circumstances. Where this is the case, authorisation may only be deemed for those organs/tissue for which there is no evidence of unwillingness to donate. For example, if a potential donor is deemed to have authorised donation, but evidence is produced that would lead a reasonable person to conclude that they would have been unwilling to donate a particular organ, then authorisation could be deemed for organs/tissue other than that organ.

<u>If authorisation can be deemed and the potential donor's family doesn't support donation proceeding</u>

104. Where it has been established that authorisation may be deemed, but the potential donor's family or others object to organ or tissue donation proceeding, then they should be sensitively supported to respect the fact that in the absence of a recorded decision by the potential donor not to donate, and in the absence of evidence of unwillingness to donate, the law permits donation to proceed - a family's objection does not nullify deemed authorisation.

105. The existence of authorisation by the potential donor, including deemed authorisation, permits donation to proceed, but does not mandate that it must. The final decision about whether to proceed with the activity rests with the SNOD/SR/TDC, in conjunction with medical practitioners and through conversation with the family.

<u>If authorisation can be deemed and there is no-one to consult about the potential donor's most recent views</u>

106. There may be occasions where a potential donor has not recorded a decision and, despite the best efforts of the SNOD/SR/TDC or other health worker, it does not prove possible to locate anyone who can be consulted about the potential donor's most recent views.

107. The HTS Act requires that inquiries must be made as to the potential donor's views about donation, as far as is reasonably practicable. The SNOD/SR/TDC should therefore seek out all available methods to establish whether there is a nearest relative or any other person who knew the potential donor recently to consult about the potential donor's views. After taking these steps, it may be apparent that there is no such person available or in existence. In this case, the Scottish Government's policy position is that donation should not proceed as the risks to public confidence in the donation process may outweigh the benefits of proceeding with donation in these specific circumstances.

Evidence that would lead a reasonable person to reach a conclusion about the potential donor's views

108. In the case where a decision has been recorded or where authorisation is potentially deemed, the SNOD/SR/TDC should explore the potential donor's latest views about donation, as required by the duty to inquire. The SNOD/SR/TDC should consult, as far as is reasonably practicable, the persons required by the duty to inquire (see paragraph 36).

109. In some circumstances, those the SNOD/SR/TDC consults will confirm that the potential donor's latest view remained in line with their recorded decision to expressly authorise or opt-out of donation, or that the potential donor had no objection to authorisation being deemed.

110. However, in some circumstances, those consulted as part of the duty to inquire may note that they believe the potential donor's recorded view had changed or that in a case where authorisation could potentially be deemed, the potential donor would not be willing to donate. In these circumstances, the SNOD/SR/TDC must consider whether the evidence presented to them would lead a reasonable person to conclude that the potential donor was unwilling, or as the case may be, willing, to donate.

111. The reasonable person test enables the SNOD/SR/TDC to assess different, potentially conflicting evidence, decide how much weight to place on the evidence presented and make an objective assessment about its validity. This involves the SNOD/SR/TDC assessing whether a reasonable person would be led to a particular conclusion by weighing up the evidence, rather than deciding whether they themselves are led to that conclusion. Evidence from which the potential donor's views can be inferred, rather than being known absolutely should not be excluded from the assessment if it is produced.

Questions to guide the SNOD/SR/TDC in assessing evidence

112. In order to assess the weight of the evidence presented, the following questions may guide the SNOD/SR/TDC and assist them in assessing whether the evidence presented would be capable of leading a reasonable person to make conclusions:

- Is the evidence in writing? If this is the case, then this is likely to be a decision by the potential donor and it should be considered whether it reflects their most recent view – for example, does it post-date any previous decision made by the potential donor, as recorded in the ODR or elsewhere and do those consulted as part of the duty to inquire recognise this as reflecting the potential donor's most recent views?

- Is the evidence of the potential donor's views an account of views provided orally by the potential donor? If so, is it confirmed by more than one person? What level of detail is provided about the scenario in which the views were voiced? Where the evidence is an account of the potential donor's views

which were provided orally, this would constitute evidence of views rather than a decision;

- Is the evidence presented as reflecting the views of the potential donor, or the views of the person presenting it? The test requires that evidence presented must be of the potential donor's view. Therefore, weight should only be given to evidence which is presented as reflecting that potential donor's view; if the SNOD/SR/TDC is not satisfied that the evidence presented to them constitutes the views of the potential donor, it may be discounted;

- How well does the person providing the evidence know the potential donor? Somebody who knew the potential donor well may have more insight into their views, however, it is important to note that the quality of the evidence presented to the SNOD/SR/TDC is the over-riding consideration, rather than the relationship to the potential donor of the person presenting it;

- How recent is the evidence? The SNOD/SR/TDC should establish when the record was made, or the conversation took place.

113. If an opt-out declaration has been recorded, but there is evidence of willingness for donation to proceed which causes the opt-out declaration to be treated as withdrawn and the potential donor to be treated as though they have expressly authorised donation, the SNOD/SR/TDC should make a note of the evidence provided so there is a record in order to enable the retriever to be satisfied that the requirements of the HTS Act have been met.

114. It is important to note that the evidence produced to the SNOD/SR/TDC must relate to the potential donor's willingness or, as the case may be, unwillingness to donate. Information that the potential donor was not aware that deemed authorisation affected them is not sufficient, on its own, to lead a reasonable person to conclude that the potential donor would have been unwilling to donate. Similarly, the fact that the potential donor had not made or recorded a decision about donation, is not sufficient, on its own, to lead a reasonable person to conclude that the potential donor would have been unwilling to donate.

<u>Establishing whether the potential donor is an excepted adult</u>

115. For excepted adults, authorisation cannot be deemed and authorisation should, in these circumstances, be sought from the potential donor's nearest relative. An 'excepted adult' is:

- a person who was not ordinarily resident in Scotland for a period of at least 12 months ending immediately before the relevant time (a "non-resident adult")[18],

- an adult who, for a significant period ending immediately before the 'relevant time', was incapable of understanding the nature and consequences of deemed authorisation ("an adult who lacks capacity")[19].

[18] Section 6D(2)(a) of the HTS Act
[19] Section 6D(3) of the HTS Act

Adults ordinarily resident in Scotland for less than 12 months

116. Deemed authorisation does not apply to non-resident adults. A non-resident adult is a potential donor who has not been ordinarily resident in Scotland for at least 12 calendar months ending immediately before the relevant time, which in practice will be when end of life discussions are taking place. The duty to inquire requires that checks must be undertaken to establish whether a potential donor may be categorised in this way.

117. For the purposes of the HTS Act, "in Scotland" means within a Scottish local authority area. Local authority boundary maps can be viewed on the Local Government Boundary Commission website[20].

118. In most cases, a SNOD/SR/TDC will be able to establish where the potential donor lived, and whether they were resident at an address or several addresses in Scotland, either from medical records or through discussions with family and friends.

119. Where it is established that a person lived at an address in Scotland, it must then be considered whether they could be described as "ordinarily resident" there in the 12 calendar months leading up to the relevant time.

120. If, following investigation, it is not possible for the SNOD/SR/TDC to ascertain that the potential donor lived in Scotland, they cannot be assumed to be ordinarily resident in Scotland and authorisation should not be deemed. For example, if it is not possible to access information which would detail a potential donor's address (e.g. medical records) within a timeframe which would enable donation to proceed, and the potential donor cannot safely be assumed to be resident in Scotland, then authorisation should not be deemed.

Period of residence

121. The twelve month period test does not involve counting the number of days a potential donor had lived in Scotland. Rather, it is necessary to establish that a potential donor had been ordinarily resident in Scotland for at least twelve calendar months before the relevant time.

122. In some cases, it may not be possible to establish the exact date a potential donor became ordinarily resident in Scotland. For example, the potential donor's family/friends may not be able to remember exactly when the potential donor moved to Scotland, but they may know it was within the last ten to fourteen months.

123. When this is the case and there is no clear evidence available to confirm the time when the potential donor started living in Scotland, then authorisation should not be deemed.

124. A period of time during which a person was ordinarily resident in Scotland immediately before the age of 16 may be included in the calculation of the 12 calendar months to determine whether deemed authorisation could apply.

[20] http://www.lgbc-scotland.gov.uk/boundary-maps/maps

"Ordinarily Resident"

125. The HTS Act does not define what is meant by "ordinarily resident", however the term has been subject to extensive case law which gives it its meaning. Whether a person has been ordinarily resident in a place will be a question of degree in each case, but is not achieved by extraordinary, occasional or temporary residence.

126. A potential donor will be "ordinarily resident" in Scotland when that residence is lawful, adopted voluntarily, and for settled purposes as part of the regular order of their life for the time being. Residence can be of long or short duration, but deemed authorisation will not apply unless someone has been resident for at least 12 calendar months ending immediately before the relevant time. The SNOD/SR/TDC will need to ask questions to gather information to establish the quality of a person's residence. For the "ordinary residence" test to be met, it must be established that:

- **The potential donor's residence in Scotland is lawful**: British citizens will always have a right to live in Scotland, so will always be in Scotland lawfully. Some Commonwealth citizens also have an automatic right to live in Scotland. For people who do not have an automatic right, they will need permission to be in Scotland to be lawfully resident, for example, immigration permission. A person awaiting determination of their claim for asylum is likely to be considered lawfully resident in Scotland. A person whose claim for asylum has been refused cannot be considered to be lawfully resident in Scotland.

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

- **The potential donor was resident in Scotland for settled purposes**: There must be an identifiable purpose for their residence in Scotland 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.

- **The potential donor's residence in Scotland supported the regular order of their life for the time being**: There is no requirement for any person to be living in Scotland permanently or indefinitely. The potential donor may have had temporary absences from Scotland and still be considered resident. It is also possible to be resident in more than one place. In such cases, care should be taken to ensure that residence has been established.

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

128. When a SNOD/SR/TDC has reasonable cause to doubt that the potential donor was resident in Scotland, then authorisation should not be deemed and authorisation should be sought from the nearest relative.

Students

129. Education can have the quality of a settled purpose and a student may be regarded as resident in the place in which they are studying or the place they consider home. Students could be considered ordinarily resident in Scotland as soon as they begin studying there, but their authorisation could only be deemed after at least 12 calendar months of being so resident, ending immediately before the relevant time.

130. It will be for the SNOD/SR/TDC to discuss with the potential donor's family/friends to determine whether the student's residence in Scotland had the necessary qualities described above before deciding whether deemed authorisation could apply.

Prisoners

131. People who die in prison cannot have their authorisation for organ and tissue donation deemed.

Other groups

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

Adults without capacity to understand deemed authorisation

133. Almost all potential donors will lack capacity at the point at which discussions about donation are taking place as they will be critically ill. However, the protection in the HTS Act is in relation to adults who lack capacity to understand deemed authorisation over a significant period, rather than incapacity related to critical illness at the end of their life.

134. Deemed authorisation does not apply to a potential donor who, over a significant period ending immediately before the relevant time (which in practice will be when end of life discussions are taking place), lacked the capacity to understand the nature and consequences of deemed authorisation (referred to in this guidance as an 'adult who lacks capacity'). This means that the adult must have been incapable of understanding that they may be deemed to have authorised removal and use of part of their body for transplantation and that if authorisation were so deemed, part of their body could be used for transplantation purposes after death.

135. The HTS Act does not define what constitutes a “significant period”. This is to enable the specific circumstances in each case to be taken into account and to recognise that capacity may fluctuate over time. Whether or not the potential donor falls into the category of an adult who lacks capacity will be a matter for the SNOD/SR/TDC to assess based on the available information, including evidence presented as part of the duty to inquire.

136. The duty to inquire requires that, in all cases where authorisation for donation could potentially be deemed, checks must be undertaken to establish whether a potential donor may be categorised as an adult who lacks capacity.

137. An example of when a person may be an adult who lacks capacity is when there is evidence available to a SNOD/SR/TDC (including any evidence gathered as part of the duty to inquire) that would lead a reasonable person to conclude that the adult is so incapable. In this scenario, the adult must be categorised as such and authorisation for donation cannot be deemed.

138. In order to establish whether a potential donor is an adult who lacks capacity, the SNOD/SR/TDC should take the following steps:

- Where possible, 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 authorisation could be deemed and what that would mean. It is important to note that a record of an episode, or episodes, of such an illness would not necessarily mean that a potential donor would not have been able to understand this. However, it should prompt further investigation.

- Where there is evidence of an illness that may have affected the potential donor’s capacity to understand that authorisation could be deemed, in most cases it will be the family/friends who are able to provide the SNOD/SR/TDC with the most accurate information. The SNOD/SR/TDC should ask the family/friends whether they believe the potential donor had a level of capacity to understand deemed authorisation.

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

140. If there is any doubt about whether the potential donor lacked capacity to understand deemed authorisation over a significant period, then authorisation should not be deemed and authorisation should be sought from the nearest relative.

141. The fact that the potential donor was incapable of understanding the nature and consequences of deemed authorisation in terms of the HTS Act means that deemed authorisation cannot apply. However, if the potential donor had recorded an express authorisation or opt-out declaration while they had capacity to make that decision, then that decision remains valid regardless of a subsequent loss of capacity.

Chapter 7: Authorisation by a person other than the potential donor

This chapter sets out the circumstances in which authorisation for donation may be given by a person other than the potential donor. The person giving authorisation should take into account any evidence of the potential donor's views before doing so. Although evidence about a potential donor's views can come from any person, the HTS Act is prescriptive about who may give authorisation, as reflected below.

142. Deemed authorisation does not apply to:

- excepted adults
- children (under 16 years of age)
- excepted body parts
- purposes other than transplantation[3].

143. In relation to these categories, authorisation for donation may be given by a person permitted by the HTS Act to do so, in certain circumstances (see paragraphs 167-168 for more information).

Authorisation on behalf of an adult

144. In certain circumstances, authorisation for donation may be given in respect of:

- **Excepted adults**: Authorisation may be given on behalf of an excepted adult for donation of any organ/tissue for any purpose[3] set out in the HTS Act.
- **Excepted body parts**: Authorisation for donation of excepted body parts for transplantation may be given on behalf of an adult who is deemed to have authorised donation. The "excepted body parts" have been specified by the Scottish Ministers in regulations.
- **Purposes other than transplantation**: Authorisation may be given on behalf of an adult who has authorised donation for transplantation (either expressly or through deemed authorisation) for donation of any organ/tissue for purposes[3] other than transplantation.

145. Authorisation for donation on an adult's behalf may be given only by the potential donor's 'nearest relative'. For the purposes of the HTS Act, that person is the person who, at the relevant time, is highest in the following list (taking into account the factors set out at paragraph 146):

- the adult's spouse or civil partner (except in the case of permanent separation or continuing desertion);
- a person living with the adult as husband or wife or in a relationship which had the characteristics of the relationship between civil partners, if they had been so living for a period of not less than 6 months (or if the adult is in hospital at the relevant time, if they had been so living for such period when the adult was admitted to hospital);

- the adult's child (including step-child, ranked equally with child)[21];
- the adult's parent;
- the adult's brother or sister (including half siblings, ranked below full siblings)[22];
- the adult's grandparent;
- the adult's grandchild;
- the adult's uncle or aunt;
- the adult's cousin;
- the adult's niece or nephew;
- a friend of longstanding of the adult[23].

146. The SNOD/SR/TDC should establish who the nearest relative of the potential donor is and who is therefore permitted to provide authorisation. The SNOD/SR/TDC should leave a person's relationship with the potential donor out of account where:

- they are under 16 years of age;
- they do not wish or are unable to make a decision about authorisation; or
- it is not reasonably practicable to communicate with the person in the hierarchy in the time available.

147. Where any relationship requires to be taken out of account, the SNOD/SR/TDC should move down the list in order and identify who is the 'nearest relative' for the purposes of the HTS Act.

148. When there is a disagreement between people in different positions on the ranked list, it is recommended that the SNOD/SR/TDC seeks to provide those people with the time and information they need to come to an agreement.

149. If it is not possible to reach an agreement, the hierarchy of authorisation applies and a decision on authorisation should be obtained from the person whose relationship to the potential donor is listed highest. The SNOD/SR/TDC may wish to refer to senior managers.

150. Where there is more than one person in the highest ranking category, authorisation may be given by any person in that category. This does not mean that the authorisation of one person must be acted on, and if agreement cannot be reached between people of the same rank, the SNOD/SR/TDC will need to carefully consider the emotional impact of any decision on family and friends.

[21] In the adult hierarchy, the stepchild of an adult ranks equally to the child of an adult.
[22] In the adult hierarchy, relationships of the full-blood rank higher than relationships of the half-blood in relation to siblings. In all other relationships, relations of full and half-blood are ranked equally.
[23] A friend of long standing is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD/SR/TDC may ask questions and/or request information as necessary to establish what degree of friendship existed.

Authorisation on behalf of a child

151. If a child aged 12 or over did not make a valid decision about donation, or was not competent to make the decision they have recorded, in this instance authorisation may be provided by a person with parental rights and responsibilities[24] in relation to the child at the relevant time, including a local authority (see paragraphs 155-158 for more information). Authorisation may be given for donation of any organ/tissue for any purpose[3] set out in the HTS Act.

152. The framework of the HTS Act does not permit a child aged under 12 to make an express authorisation or opt-out declaration in respect of donation (see paragraph 76). In the case of a child aged under 12, authorisation for donation may be provided by a person with parental rights and responsibilities in relation to the child at the relevant time, including a local authority (see paragraphs 155-159 for more information).

153. The authorisation of only one person with parental rights and responsibilities is required. This does not mean that the authorisation of one person must be acted on, and if agreement cannot be reached between parents, the SNOD/SR/TDC will need to carefully consider the emotional impact of any decision on them and others.

154. When there is a disagreement between parents, it is recommended that the SNOD/SR/TDC seeks to provide them with the time and information they need to come to an agreement. If it is not possible to reach an agreement, the SNOD/SR/TDC may wish to refer to senior managers.

Where a Local Authority holds parental rights and responsibilities in relation to the child

155. The HTS Act enables a local authority to authorise donation where it holds parental rights and responsibilities in relation to the child.

156. There may be occasions where parental rights and responsibilities are shared between the local authority and others. If there is another person who holds parental rights and responsibilities, it may be more appropriate for them to consider authorisation. The SNOD/SR/TDC will need to carefully consider who in such circumstances would be most appropriate to consider authorisation and encourage parties to reach a consensus. If it is not possible to reach an agreement about who should consider authorisation, the SNOD/SR/TDC may wish to refer to senior managers.

157. Authorisation from only one person with parental rights and responsibilities is required. This does not mean that the authorisation must be acted on, and if agreement cannot be reached between different parties, the SNOD/SR/TDC will need to carefully consider the emotional impact of any decision on the different parties.

[24] A person who has parental rights and responsibilities will usually, but not always, be the child's parent. The Children (Scotland) Act 1995 governs who has such rights and responsibilities in Scotland.

158. Where a local authority is considering providing authorisation, the SNOD/SR/TDC should advise and guide the local authority through the requirements of the HTS Act. The local authority must, as far as is reasonably practicable, ascertain and have regard to the views of:

- the child,
- the child's parents, and
- any other person whose views the local authority considers to be relevant.

159. In practice, the relevant people are likely to be at the bedside and the local authority should discuss with them, supported by the SNOD/SR/TDC.

Where no person holds parental rights and responsibilities in relation to the child, or such a person is incapacitated

160. In very exceptional circumstances, there may be no person with parental rights and responsibilities in relation to the child or it may be impossible for them to give authorisation as they have become incapacitated. Those with parental rights and responsibilities would be considered to be so incapacitated if they are also critically ill and are expected to die, as a result of a common calamity, for example a road traffic accident involving parents and children. In these extremely limited circumstances, authorisation may be given by another adult with a close relationship with the child. Authorisation may be given by a person who, at the relevant time, ranks highest on the following hierarchy, (taking into account the factors set out at paragraph 161):

- a person who has (or has recently had) a significant involvement in the upbringing of the child;
- the child's brother or sister (including half siblings, ranked equally to full siblings)[25];
- the child's grandparent;
- the child's uncle or aunt;
- the child's cousin;
- the child's niece or nephew;
- a friend of longstanding of the child[23].

161. The SNOD/SR/TDC should establish who is the highest ranking person and therefore permitted to provide authorisation. The SNOD/SR/TDC should leave a person's relationship with the potential donor out of account where:

- the person is under 16 years of age;
- the person does not wish or is unable to make a decision about authorisation; or
- it is not reasonably practicable to communicate with the person in the time available.

[25] In the child hierarchy, a relationship of the whole-blood is to be treated equally to a relationship of the half-blood.

162. When there is a disagreement between people in different positions on the ranked list, it is recommended that the SNOD/SR/TDC seeks to provide those people with the time and information they need to come to an agreement.

163. If it is not possible to reach an agreement, the hierarchy of authorisation applies and a decision on authorisation should be obtained from the person whose relationship to the potential donor is accorded the highest ranking on the list. The SNOD/SR/TDC may wish to refer to senior managers.

164. Where there is more than one person in the highest ranking category, authorisation may be given by any person in that category. This does not mean that the authorisation of one person must be acted on, and if agreement cannot be reached between people of the same rank, the SNOD/SR/TDC will need to carefully consider the emotional impact of any decision on family and friends.

Authorisation of transplantation of excepted body parts

165. The Human Tissue (Excepted Body Parts) (Scotland) Regulations 2020[26] specify the parts of the body that deemed authorisation for transplantation **does not** apply to. Where the potential donor's authorisation for commonly transplanted organs/tissue is deemed, parts of the body listed in columns 1 or 2 of the table in figure 2 may only be removed and used for transplantation if authorisation is given by the nearest relative. Tissue or material listed in column 3 may be removed from a body part in column 2 with deemed authorisation. The regulations don't affect which organs/tissue may be donated under express authorisation.

166. This means that deemed authorisation for transplantation will apply to the following commonly transplanted organs and tissue: kidneys, liver (including for hepatocyte cell transplantation), pancreas (including for islet transplantation), heart, heart tissue (including valves, conduits and patches), lungs, intestinal organs and corneas. It will also apply to blood vessels, bone, muscle, nervous tissue, skin, and tendons unless they are part of a body part listed in column 1.

[26] https://www.legislation.gov.uk/sdsi/2020/9780111046562/contents

Figure 2: Parts of the body which are excluded from deemed authorisation.

Column 1 - **The whole or any part** of the following is excluded from deemed authorisation	Column 2 - The **whole** of the listed body part is excluded from deemed authorisation	Column 3 - Tissue that can be removed from a part listed in column 2 with deemed authorisation
• brain • cervix • clitoris • face[27] • fallopian tube • labia (labia minora) • ovary • penis • perineum • placenta • prostate • spinal cord • testicle • trachea[28] • umbilical cord • uterus • vagina • vulva (labia majora)	• finger • foot • forearm • hand • lower leg • thigh • toe • upper arm	• blood vessel[29] • bone • muscle • nervous tissue • skin • tendon

Circumstances in which authorisation may be given

167. Authorisation for donation may only be given on a potential donor's behalf where they have not made a valid, express authorisation or opt-out declaration (on the ODR or in writing). Additionally, it is not permitted for authorisation to be given for purposes other than transplantation where the potential donor has made an opt-out declaration for transplantation.

168. Authorisation may only be given where the person permitted to give it has no knowledge that the potential donor would have been unwilling to donate, either in general or in the specific circumstances (see paragraph 60). The person who is

[27] Meaning the front part of the head, extending widthways to and including the ears, and extending lengthways from and including the forehead to the top of the laryngeal prominence, containing the chin, nose and mouth but excluding the eyes.
[28] The trachea is not an excepted body part if it is attached to a lung.
[29] Meaning arteries, arterioles, capillaries, venules and veins.

considering whether to give authorisation should have regard to any evidence of the potential donor's views brought forward under the duty to inquire and if donation is to proceed, they must be satisfied that the potential donor would not have been unwilling to donate.

169. In a case where a nearest relative is considering whether to authorise donation on behalf of an adult who lacks capacity, they should have regard to the adult's past wishes and feelings as far as these are reasonably ascertainable.

170. The HTS Act makes clear that the mere absence of an explicit authorisation by the potential donor should not be considered as unwillingness to donate.

How authorisation can be given and withdrawn

171. Authorisation for donation by a person other than the potential donor must be either in writing and signed, or, if it is given orally, it must be given to a health worker, who will, in this case, normally be the SNOD/SR/TDC. If the authorisation is in relation to donation for a purpose[3] other than transplantation, it may be withdrawn by the person who provided it, by the methods given above. If it is in relation to transplantation, it may not be withdrawn.

Chapter 8: Guidance on the authorisation and undertaking of pre-death procedures

This chapter explains the steps which must be taken before any pre-death procedures (otherwise known as 'ante-mortem interventions') can be carried out in relation to potential organ and tissue donors who are still alive, but expected to die imminently, including as a result of the withdrawal of life-sustaining treatment. These patients will almost always be incapable of providing informed consent for any tests or procedures which may be necessary to enable donation to proceed.

This guidance outlines the legal position under the HTS Act in relation to such procedures being carried out on patients who are alive, including in donation following circulatory death (DCD) cases and in DBD cases before brain stem death has been confirmed. It is important to ensure processes are in place to help to facilitate donation where it is authorised (either expressly or through the operation of deemed authorisation), but also to ensure that a clear framework exists for safeguards to protect patients from any procedures (such as tests, interventions or administration of medication) where they are likely to cause harm or more than minimal discomfort to the patient.

The carrying out of pre-death procedures to facilitate transplantation is required for tissue-only donation far less frequently than in relation to organ donation. However, for completeness, the framework in the HTS Act covers both organ and tissue donation for transplantation as it may affect organ donors who are also expected to donate tissue, following circulatory death.

Background and clinical context

172. Any decision about whether or not treatment should be withdrawn must be made purely in the interests of the patient and independently of any consideration of possible donation. It is important to give the patient's family time to come to terms with the probable death of a loved one, and to be able to consider fully all end of life options, including donation.

173. Donation following circulatory death takes place when death has been established following irreversible cessation of the heart (i.e. following cardio-respiratory arrest). The Academy of Medical Royal Colleges issued guidance on the diagnosis and confirmation of death in 2008[30].

174. There are a number of steps that can be taken before a person has died, which can optimise the chances of a successful donation and subsequent transplant(s). These steps fall into the broad categories of actions to check the

[30] http://www.aomrc.org.uk/wp-content/uploads/2016/04/Code_Practice_Confirmation_Diagnosis_Death_1008-4.pdf

person's suitability to be a donor (such as blood tests), maintaining treatment and planning the timing of its withdrawal to coordinate with organ retrieval and introducing treatment or procedures that improve the chances of a successful transplant.

175. This guidance replaces the CMO guidance of 3 May 2010 (SGHD/CMO(2010)11) to reflect the provisions on pre-death procedures within the HTS Act[31]. The new legislative provisions provide a statutory basis for pre-death procedures, which aims to provide greater clarity for health professionals and safeguards for potential donors, particularly in light of the introduction of deemed authorisation in Scotland.

The law

176. The HTS Act provides a new statutory framework[32] for pre-death procedures, which is tailored to the practical and ethical issues relating to donation. A 'pre-death procedure' is defined as a medical procedure which is carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of their body after their death and which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person.

177. It is essential to be clear that up until the point at which the patient is confirmed to have died, the requirements of the HTS Act (as discussed below) must be followed in relation to any pre-death procedure. Once death has been confirmed, these requirements no longer apply and so this guidance does not need to be considered in relation to patients who have already been declared dead following brain-stem death testing.

178. The HTS Act is based on the concept of authorisation. 'Authorisation' is the expression of the principle that a person has the right to specify, during their lifetime, their decision about what should happen to their body after their death, in the expectation that this decision will be respected.

179. The HTS Act makes provision for two different types of pre-death procedures - Type A and Type B procedures - to be undertaken to facilitate donation, as long as certain requirements are met. **Type A procedures** are those which are generally considered as routine procedures which would be needed to enable deceased donation to progress. **Type B procedures** are less routine and are generally more invasive. These are discussed further below.

Authorisation of pre-death procedures

180. Subject to the outcome of the duty to inquire, **Type A procedures** will be considered to be authorised by the donor when they have either expressly authorised deceased donation for transplantation (such as where they had opted in on the ODR) or where their authorisation for donation is deemed under the HTS Act. The HTS Act also enables a person to expressly authorise pre-death procedures.

[31] This guidance applies from 26 March 2021 when the 2019 Act comes into effect.
[32] Section 16A to 16G of the HTS Act

181. Where authorisation for donation for transplantation is given by the patient's nearest relative (or a person entitled to authorise donation on behalf of a child[7]), then that person must also authorise the carrying out of a Type A pre-death procedure before it can proceed. The person authorising would normally be expected to authorise these as a group during the authorisation process, rather than needing to consider and authorise each test or procedure separately. Such authorisation may be given in writing or it may also be given orally, if so it must be given to a health worker, who in most cases will be a SNOD/SR/TDC.

182. Authorisation may not be given if the person permitted to give it has knowledge that the potential donor would have been unwilling to undergo the procedure. The person who is considering whether to give authorisation should have regard to any evidence of the potential donor's views brought forward under the duty to inquire and be satisfied that if the potential donor were capable of making a decision about the procedure they would not be unwilling to undergo it.

183. **Type B procedures**, whilst common in other settings, are likely to be more rare or novel in a donation for transplantation setting, and are generally of a more invasive nature. They therefore require additional authorisation and further criteria to be fulfilled before they could be undertaken (see paragraph 197-202 for more details).

End of life decisions

184. Potential DCD donors will usually (but not always) be in critical care, with relatives close by. A clinician will make treatment decisions based on considering whether any treatment is for the patient's benefit and is expected to safeguard or promote the physical or mental health of the adult, which means considering all aspects of their condition and consulting their family. At some stage, clinicians may reach the view that there is no prospect of recovery and further active treatment would therefore not be for the patient's benefit, in which case a decision may be made to withdraw treatment.

185. Guidance on end of life decisions and withdrawing treatment is available in the GMC's *Treatment and care towards the end of life: Good practice in decision making*[33].

Checks required before undertaking any pre-death procedures

186. Pre-death procedures can only be carried out where the patient is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment where a decision to withdraw treatment has been taken) and it is confirmed that authorisation is in place for deceased donation for the potential donor. This can either be express authorisation by the donor themselves (such as where they had opted in via the NHS Organ Donor Register (ODR)), via deemed authorisation or where appropriate, authorisation by a person entitled to authorise donation on behalf of an adult or a child. Such authorisation on behalf of a donor can be given orally

[33] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/treatment-and-care-towards-the-end-of-life

and if so it must be given to a health worker, who in most cases will be a SNOD/SR/TDC. If it is in writing it must be signed (see paragraph 171).

187. In addition, where the potential donor is still alive at the point where authorisation for deceased donation is being ascertained and pre-death procedures are expected to be required, the SNOD/SR has a duty to inquire about whether the patient had expressed any views about pre-death procedures. Where the patient's family or friends provide evidence regarding the views of the patient in relation to pre-death procedures, this must be taken into account. For example, if a family member explains that the patient had previously said they did not want to undergo a particular form of procedure or provides any other evidence that indicates that the patient would have been unwilling to consent to that procedure, then those views must be respected.

188. In the case of patients for whom either express authorisation or deemed authorisation for donation for transplantation is in place, if, following inquiries by a SNOD/SR, there are no known objections by the patient to a pre-death procedure, then it can be considered to be authorised as long as all of the following apply:

- it is a type of procedure listed in regulations by the Scottish Ministers, which have been approved by the Scottish Parliament and brought into force (for a Type A procedure, the relevant regulations are the Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations 2020[34]. (See paragraph 197 in relation to Type B procedures);
- the health worker who is to carry out or who has authorised another person to carry out the procedure has no actual knowledge that the patient was unwilling for the procedure to be carried out;
- the health worker who is to carry out or who has authorised another person to carry out the procedure has had regard to the person's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence brought forward under the duty to inquire); and
- the health worker who is to carry out or who has authorised another person to carry out the procedure is satisfied that if the person were capable of making a decision about the authorisation of the procedure, they would not be unwilling for it to be carried out.

189. In practice, if no evidence of objections by the patient has been brought forward under the duty to inquire, then it will be rare for these conditions not to be met. However, if there is any cause to doubt the position, this should be investigated before the procedure is carried out.

190. In addition to the authorisation requirements set out above in paragraphs 180-181 needing to be fulfilled, the clinician primarily responsible for the patient's medical treatment must be of the view that the patient is likely to die imminently, including as a result of the withdrawal of life-sustaining treatment where the decision to withdraw treatment has been taken. ('Imminently' is not defined in the legislation, but in this

[34] https://www.legislation.gov.uk/sdsi/2020/9780111043981/contents

context can be taken as including any patient who is expected to die within a couple of days).

191. Finally, either the person carrying out the procedure or the person who has authorised another person to carry out the procedure (who could be, for example, a SNOD, the clinician responsible for the patient's care or another member of staff within the Critical Care Unit) needs to be satisfied that:

- the procedure(s) is/are included in the list of procedures specified in regulations by the Scottish Ministers, which have been approved by the Scottish Parliament and brought into force (see paragraph 195 in relation to Type A procedures). Where the procedure is a Type B procedure, there are additional authorisation requirements, as set out in paragraph 197.

- the procedure is necessary for the purpose of ascertaining whether a part of the person's body is suitable for transplantation, or for the purpose of increasing the likelihood of successful transplantation of a part of the person's body.

- that carrying out of the procedure is not likely to cause more than minimal discomfort to the patient, nor is it likely to harm them.

192. In practice, this means that certain routine tests, (those listed at paragraph 196), can be carried out when the requirements of paragraphs 188 to 191 have been met, as donation could not normally be expected to be able to proceed without them. While all of the permitted Type A procedures (see list at paragraph 196) are routine, the person carrying out or authorising someone to carry out the procedure(s) must still be satisfied that the requirements of paragraph 191 are met in respect of every proposed procedure. In particular, they should consider that the procedure is necessary – to determine whether an organ/ organs or tissue are safe or suitable for transplantation or to improve the likelihood of a successful transplant(s), for example by improving the condition of the organ(s).

<u>Assessing the risk associated with individual procedures</u>

193. While all Type A procedures should not cause more than minimal discomfort to a patient or be likely to harm them, whoever is performing or authorising another person to perform the procedure needs to consider if any pre-existing medical conditions or other particular circumstances (such as allergies) might increase the risk of harm or discomfort to the patient from a particular procedure. If, in the view of the person performing, or authorising another person to perform the procedure, it is considered likely to cause more than minimal discomfort or to cause harm to the patient, then it may not be carried out.

<u>Discussing pre-death procedures with family</u>

194. As is the case with other aspects of end of life care, it is good practice to discuss planned pre-death procedures with the potential donor's family in advance of them being carried out. This is in addition to the requirements to consult the family about the potential donor's views about pre-death procedures as part of the duty to inquire.

Type A Procedures

195. The Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations 2020[34] specify those procedures which are classified as Type A. The regulations list the specific procedures which may be carried out as type A procedures. For example the regulations list as a procedure the 'taking of a blood sample' but do not specify by which method that blood sample should be taken. This is in order to enable the most appropriate method to be undertaken, based on clinical assessment as well as taking into account the requirements in the Act, including consideration of the likely discomfort or harm associated with carrying out the procedure. If there is no method specified, the regulations do not place any restriction on the method by which the procedure may be carried out, and would permit the insertion or reinsertion of any peripheral or central lines if required. However, where more than one method is available the method which involves the more minimal interference with the potential donor should be pursued wherever possible and appropriate.

196. The current permitted 'Type A' procedures are shown in figure 3. In figure 3:

- "arterial line" means a cannula inserted into an artery;
- "blood component" means any of the following constituents of human blood
    - red cells,
    - white cells,
    - platelets, and
    - plasma;
- "blood product means any therapeutic product derived from human blood or plasma;
- "intravenous fluids" means any electrolyte solution intended for intravenous administration;
- "pre-established airway and ventilatory support" means any method of airway or ventilatory support administered to the person for the primary purpose of the person's medical treatment prior to any decision to withdraw life sustaining treatment;
- "pre-established suprapubic catheter" means a suprapubic catheter inserted into the person for the primary purpose of the person's medical treatment prior to any decision to withdraw life sustaining treatment.

Figure 3: Type A pre-death procedures

Class of procedure	Type of procedure
Collection of bodily fluids and microbiological samples	Taking of a blood sample Taking of a urine sample including by way of a pre-established suprapubic catheter Taking of a chest secretion sample (excluding bronchoscopy) Swabbing or scraping of the body including inside of the mouth, nostril or ear canal but excluding the swabbing or scraping of any part of any other body orifice
Radiological imaging	Carrying out of an X-Ray without transferring the patient from their existing location Carrying out of ultrasound imaging without transferring the patient from their existing location Carrying out of transthoracic echocardiography without transferring the patient from their existing location
Cardiovascular Monitoring	Carrying out of electrocardiogram (ECG) Cardiac output monitoring by way of an arterial line Carrying out of central venous pressure monitoring Arterial blood pressure monitoring including by way of an arterial line
Respiratory Monitoring and Support	Measuring of oxygen saturation Sustaining the appropriate operation of any pre-established airway and ventilatory support
Administration of medication or other product	Administration of antimicrobials Administration of intravenous fluids Administration of medication to manage blood pressure Administration of blood, blood components and blood products

Type B Procedures

197. The Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations 2021[35] specify those procedures which are classified as Type B. The Regulations also set out how those procedures may be authorised and the conditions which must be met before they can be carried out, in addition to those required by the HTS Act as set out above in paragraphs 188 to 191.

198. The current permitted 'Type B' procedures are shown in figure 4.

Figure 4: Type B pre-death procedures

Class of procedure	Type of procedure
Collection of bodily fluids and microbiological samples	Swabbing or scraping of a bodily orifice other than the mouth, nostril or ear canal
Radiological imaging	Carrying out of Magnetic Resonance Imaging (MRI) scan Carrying out of Computerised Tomography (CT) scan Carrying out of an X-Ray where the patient is transferred from their existing location Carrying out of ultrasound imaging where the patient is transferred from their existing location Carrying out of a transthoracic echocardiography where the patient is transferred from their existing location
Tissue sampling	Taking of a skin biopsy
Endoscopic procedure	Carrying out of a bronchoscopy

[35] https://www.legislation.gov.uk/sdsi/2021/9780111048580/contents

199. In addition to meeting the requirements set out above in paragraphs 188 to 191, the following conditions must be met before a Type B procedure may be carried out:

- two Registered Medical Practitioners (RMPs) must be of the view that the conditions set out in section 16E(2)(c) to (e) of the 2019 Act are met, namely:
    - the carrying out of the procedure is necessary;
    - the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and;
    - the carrying out of the procedure is not likely to harm the person; and
- the two RMPs must also be of the view that it is not possible to obtain the required information by carrying out a Type A procedure.

200. One of the RMPs must be the health worker primarily responsible for the person's medical treatment, which in most cases will be an ICU consultant. Neither of the RMPs can be part of the team involved in the retrieval or transplant process. A record of the agreement between the two RMPs must be made in writing.

Authorisation of Type B procedures

201. Authorisation for the Type B procedure in question must be in place before it can be carried out. Authorisation may be given expressly by the donor themselves or by their nearest relative (or person entitled to give authorisation on behalf of a child). It is likely that in the vast majority of cases there will not be an express authorisation by the potential donor, however if such an authorisation is given then it must be in writing. An authorisation given by the nearest relative (or person entitled to give authorisation on behalf of a child) must be either in writing, or, if it is given orally, it must be given to a health worker, who will, in this case, normally be the SNOD/SR.

202. Authorisation may not be given if the person permitted to give it has knowledge that the potential donor would have been unwilling to undergo the procedure. The person who is considering whether to give authorisation should have regard to any evidence of the potential donor's views brought forward under the duty to inquire and be satisfied that if the potential donor were capable of making a decision about the procedure they would not be unwilling to undergo it.

Additional considerations

203. It is important to emphasise that pre-death procedures for the purpose of facilitating donation cannot be carried out if they are not included in the list of either Type A or Type B procedures. Even where they are listed as a Type A or Type B procedure, they can only be carried out where the requirements of paragraphs 186 to 191 are met.

204. Note, however, that where a procedure or test would be undertaken anyway for the purposes of caring for or treating the patient even if donation was not being considered, it is not necessary to consider the requirements of the HTS Act, but

instead whether the procedure is for the patient's benefit. For example, if a test has been undertaken as part of the patient's care, the results can then be used for considering the viability of donation without needing to consider the requirements above.

205. In addition, as noted in paragraph 191, pre-death procedures are only permissible for transplantation purposes and so cannot be carried out only to support the other purposes for which organs or tissue can be donated after death (research, education and training, audit or quality assurance). Therefore, a procedure may be permitted if it is carried out to facilitate transplantation, but the results may also subsequently be used for other purposes (e.g. a blood sample sent for testing being used later for audit purposes), but the procedure cannot be permitted under this pre-death procedures framework prior to the patient's death where it is only going to be used for a purpose not related to facilitating transplantation.

Timing and location of withdrawal of treatment

206. Decisions about the timing and location of withdrawal of treatment are not considered as 'pre-death procedures' within the HTS Act, so are not subject to the requirements set out above. It is generally understood and accepted that there are a number of reasons for flexibility in the timing of withdrawal of treatment, for example to allow family members to be present or to make sure the relevant healthcare professionals are available to oversee the process. In practice, the timing is a matter of discussion and agreement between a patient's family and clinicians. An important aspect of timing may be the need to allow time for absent family members and friends to be present when withdrawal happens. This recognises that a person has an interest in the manner in which they die and in how they are remembered.

207. There will almost invariably be a lapse of time between reaching agreement on the withdrawal of treatment and the actual moment at which treatment is withdrawn, for the reasons given in the previous paragraph. During that period, keeping the patient stable would be reasonable, so as not to cause distress to the relatives. Their ongoing care is not covered by the pre-death procedure requirements as it would be likely to happen anyway even if the patient was not a potential donor; donation may well affect the timing of withdrawal of treatment, but is only one factor in this.

208. Since it is necessary to begin organ retrieval very soon after death has been declared in relation to DCD donors, this means in practice that the surgical retrieval team must be ready in an operating theatre before cardio-respiratory support is withdrawn. Because it commonly takes some hours for arrangements for retrieval to be completed, this requires withdrawal of cardio-respiratory support to be delayed if DCD is to be possible. For similar reasons, local circumstances may necessitate moving the patient to a different location within the hospital, close to or within the operating theatre complex, ahead of withdrawal of treatment.

Figure 5: Steps to be taken before Type A and Type B pre-death procedures may be carried out – see paragraphs 199-200 for more detail in relation to Type B procedures requirements

Is the PDP listed in regulations?	• The procedure must be listed in regulations in order to be carried out
Are the following conditions met?	• Patient is likely to die imminently (including as a result of withdrawal of life sustaining treatment) • Where the patient is receiving life sustaining treatment, a decision to withdraw that treatment has been taken • The PDP is necessary (to assess suitability for transplantation or to increase the likelihood of successful transplantation)* • The PDP is not likely to cause more than minimal discomfort* • The PDP is not likely to harm the patient* *For Type B, two RMPs must agree that these conditions have been met, and agree that a Type A procedure couldn't be used instead
Is authorisation for donation in place?	• Express authorisation for donation (for example on the ODR) • Deemed authorisation for donation • Authorisation from the Nearest Relative or person entitled to authorise on behalf of a child
Is authorisation for PDPs in place?	• **Type A pre-death procedures are authorised when:** Donation is expressly authorised (for example on the ODR) / Authorisation for donation is deemed / Authorisation is given by Nearest Relative/person entitled to authorise on behalf of a child (where they are permitted to authorise donation) / Authorisation is given expressly for the PDP by the patient • **Type B pre-death procedures are authorised when:** Authorisation is given expressly for the PDP by the patient / Authorisation is given by Nearest Relative/person entitled to authorise on behalf of a child
Has the duty to inquire been carried out?	• Following the carrying out of the duty to inquire there is no suggestion that the patient would have objected to donation or the carrying out of PDPs
Is the Health Worker requesting /carrying out the PDP satisfied of the following?	• They have no actual knowledge the patient was unwilling for PDPs to be carried out • They have had regard to the patient's past wishes and feelings regarding PDPs • If the patient was capable of making a decision about PDPs they would not be unwilling for them to be carried out

Chapter 9 - Retrieval

Conditions which must be satisfied before retrieval of organs and tissue can proceed

209. Section 11(1) and (4)(a) of the HTS Act set out the conditions which must be met before the removal of a body part can take place.

210. First, the removal of the body part must be carried out by a registered medical practitioner or a person (or category of person) authorised to do so in accordance with regulations made by the Scottish Ministers. The existing regulations are the Human Tissue (Removal of Body Parts by an Authorised Person)(Scotland) Regulations 2006[14]. These outline that a registered medical practitioner can authorise someone who is not such a practitioner to undertake the removal of a body part, provided that they are sufficiently qualified and trained to perform the procedure competently. In practice, authorised persons are persons who are specially trained to retrieve tissue, for example tendons or eyes.

211. Second, a number of criteria need to be met before the retrieval is undertaken. Those are that:

- the life of the potential donor is extinct;
- if the consent of the procurator fiscal to the carrying out of the removal is required by section 5(1) of the HTS Act, the consent has been given; and
- the removal and use for the purpose in question is authorised in accordance with the relevant section of the HTS Act:

    - Section 6 - Express authorisation: adult
    - Section 6D - Deemed authorisation for transplantation: adult
    - Section 6E - Non-resident adult: authorisation for transplantation by nearest relative
    - Section 6F - Adult incapable of understanding deemed authorisation: authorisation for transplantation by nearest relative
    - Section 6G - Excepted body parts: authorisation for transplantation by nearest relative
    - Section 6H - Authorisation for purpose other than transplantation by nearest relative
    - Section 8 - Authorisation: child 12 years of age or over
    - Section 8D - Authorisation by person with parental rights and responsibilities: child 12 years of age or over
    - Section 10 - Authorisation by person with parental rights and responsibilities: child under 12 years of age
    - Section 10A - Authorisation by other persons: children

212. The person proposing to carry out the retrieval must satisfy themselves that the latter two criteria have been met. In terms of verifying that the life of the potential donor is extinct, where a registered medical practitioner is undertaking the retrieval, it is sufficient for that person to examine the donor's body to confirm the donor is deceased.

213. However, where the person undertaking the retrieval has been lawfully authorised to do so and is not a registered medical practitioner, then they must satisfy themselves that a registered medical practitioner has examined the donor's body to confirm the donor is deceased. In practice, this will usually be done by checking that there is a record of such an examination having taken place. It is not a requirement that a registered medical practitioner has to be present at the retrieval when it is being undertaken by an authorised person.

Checking authorisation is in place

214. To be satisfied that the removal and use of a body part is authorised in accordance with the HTS Act, the person undertaking the retrieval must consider that there is an appropriate record of authorisation in place. The record should reflect the inquiries undertaken by the SNOD/SR/TDC and should include confirmation that:

- there is an authorisation in place in relation to the potential donor under the relevant section of the HTS Act, which was given in accordance with the relevant section and which pertains to the removal and use of the relevant body part for the relevant purpose. Where authorisation is in place for a particular purpose, organs/tissue may only be used for that purpose. For example, an organ or tissue removed under authorisation for transplantation purposes cannot be used for research unless there is an authorisation in place for research.
- there is no opt-out declaration as respects removal and the use of the relevant part for the purpose in question.
- in the case where an adult who is deemed to have authorised donation, the deceased adult does not fall into one of the categories of individual that deemed authorisation does not apply to (i.e. a non-resident adult or an adult who lacks capacity).

215. As well as ensuring that there is an appropriate record of authorisation of donation, the person proposing to carry out the removal of a body part must also have no reason to believe that:

- authorisation for the removal and use of the potential donor's body part for the relevant purpose is not, in fact, in place or has not been properly given;
- the deceased person would be unwilling in the circumstances for the part to be removed and used for the purpose in question.

216. In practice, it will be rare for the person proposing to carry out the removal to have any reason to believe that authorisation is not in place or that the deceased person would be unwilling for the removal to be carried out. However, if there is any cause for them to doubt the position (for example, where it is suspected that there may be an error in the documents recording authorisation), this should be investigated before retrieval proceeds.

Cases involving the Procurator Fiscal

217. Where the circumstances of death require to be reported to the Procurator Fiscal, a person cannot remove a body part until the Procurator Fiscal has consented to the removal. Where consent has been given verbally, this should be confirmed in writing, for example by email, as soon as is reasonably practicable. See paragraphs 12-15 for more information.

Offences

218. Section 16(1)(a) of the HTS Act sets out that it is an offence for a person to remove or use a part of a person's body for a specific purpose if there is not an authorisation in place for removal or use for that purpose. The offence is committed if authorisation is not in place under the relevant section of the HTS Act. If a person is charged with this offence, it is a defence for them to show that at the time of carrying out the activity, the person reasonably believed that the removal and use for the purpose had been authorised in accordance with the HTS Act.

219. It is also an offence under section 16(1)(b) of the HTS Act to remove a body part or use a body part in Scotland which has been retrieved in Scotland if any of the requirements in section 11(1) or (4)(a) of the Act (as outlined above in paragraphs 210-215) are not satisfied. Again, it is a defence for a person charged with this offence to show that they reasonably believed that the requisite requirements were satisfied.

Annex A – Interpretation

220. **Express authorisation for donation** – refers to a decision by the potential donor to authorise donation, made during life. If this is not recorded on the ODR, then it must have been given in writing, for example in a will or other written declaration.

221. **Opt-out declaration** – refers to a decision by the potential donor not to authorise donation, made during life. If this is not recorded on the ODR, then it must have been made in writing, for example in a will or other written declaration.

222. **Deemed authorisation** – the HTS Act enables authorisation to be deemed for most adults where there is no express authorisation (opt-in) or opt out declaration (opt-out) recorded and no evidence of unwillingness to donate. Deemed authorisation applies only to transplantation and doesn't apply to excepted body parts or excepted adults.

223. **Nearest relative** – the HTS Act recognises the position of the 'nearest relative' and enables them to give authorisation on behalf of an adult potential donor in certain circumstances. It also requires that inquiries about the potential donor's views are made of the nearest relative, amongst others. The nearest relative hierarchy is listed in paragraph 145.

224. **Family** – in practice, there will often be a broad group of people involved in the end of life care of a potential donor - for example family, friends or others. This guidance often uses the term 'family', which could encompass any individuals. The guidance also makes clear that in addition to requiring that inquiries about the potential donor's views must be made of the nearest relative, the HTS Act requires such inquiries to be made of any person who wishes to provide evidence of views and any other person the SNOD/SR/TDC considers appropriate. In many cases, these will be people who are involved in the end of life care.

225. **Evidence** – the HTS Act enables evidence of the potential donor's latest views to establish whether or not donation is authorised. The Act does not require the evidence to be in any particular form – it may be written information (for example, the potential donor's views as expressed on social media) or oral information (for example, a recollection of a prior conversation held with the potential donor). Evidence from which the potential donor's views can be inferred, rather than being known absolutely should not be excluded if it is produced, for example if the potential donor expressed views that they didn't like the idea of donation. The HTS Act isn't prescriptive about who can provide such evidence, meaning that it can come from anyone.

226. **Evidence threshold** – the HTS Act requires evidence of a potential donor's views to be capable of leading a reasonable person to conclude either that the potential donor was unwilling to donate (where they have opted in or are potentially deemed to have authorised donation) or that they were willing to donate (where they have made an opt-out declaration).

227. **Not unwilling** – the HTS Act requires that, if donation is to proceed, the potential donor must not be unwilling to donate. This means that they must not have expressed an objection to donating.

228. **Excepted adult** – an adult to whom deemed authorisation does not apply (either an adult who lacks capacity or non-resident adult).

229. **Adult who lacks capacity**– an adult who, over a significant period ending immediately before the relevant time, lacked the capacity to understand the nature and consequences of deemed authorisation. This means that the adult must have been incapable of understanding that they may be deemed to have authorised removal and use of part of their body for transplantation and that if authorisation were so deemed, part of their body could be used for transplantation purposes after death.

230. **Significant period** - the HTS Act is not prescriptive as to what constitutes a "significant period", as it is likely to vary from case to case, but it should be long enough so as to mean that the potential donor cannot have been reasonably considered to have had an understanding of the opt-out system.

231. **Non-resident adult** - an adult who has not been ordinarily resident in Scotland for at least 12 calendar months ending immediately before the relevant time.

232. **Ordinarily resident** – refers to people living in Scotland on a lawful, voluntary and settled basis. Ordinary residence can be of long or short duration but deemed authorisation will not apply unless the potential donor has been ordinarily resident for at least 12 months before the relevant time.

233. **Pre-death procedures** – These are medical procedures which are carried out on a potential donor for the purpose of increasing the likelihood of successful transplantation, rather than as part of their ongoing care to promote their physical or mental health. The HTS Act includes a framework for the authorisation and carrying out of these procedures. (See chapter 8).

234. **Health worker** – for the purposes of the HTS Act, a health worker is a registered medical practitioner, a registered nurse or a person authorised to carry out health worker functions (see paragraphs 21-25 for more detail).

235. **Registered Medical Practitioner** – this term refers to a fully registered person within the meaning of the Medical Act 1983 who holds a licence to practise under that Act.

236. **Relevant time** – this term replaces the language regarding steps being taken 'immediately before death' used in the 2006 Act, to reflect the growth in DCD donation. In practice the relevant time will be when end of life care discussions are taking place (see paragraphs 38-42 for more detail).

237. **Duty to inquire** - the requirement in the HTS Act that inquiries are made about whether a donation decision is in force, whether a potential donor is in an excepted category and about the potential donor's views about donation and pre-death procedures (see paragraphs 29-37 for more detail).

This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at

The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-80004-780-8

Published by The Scottish Government, March 2021

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS839546 (03/21)