

# F Donation of solid organs and tissue for transplantation

## Part one: Living organ donation

### Code of Practice



# Code F: Donation of solid organs and tissue for transplantation

## Part one – Living organ donation

---

### Contents

Introduction to the Human Tissue Authority Codes of Practice .....	3
Introduction to the Donation of solid organs and tissue for transplantation Code.....	5
Scope of this Code .....	5
Offences under the HT Act.....	6
Legal considerations - Conditions on consent for organ transplantation.....	6
Structure and navigation .....	7
Living organ donation.....	8
Types of living organ donation .....	8
Legal considerations .....	8
Requirements for HTA approval to be given .....	9
Donation by children.....	12
Donation by adults lacking capacity to consent.....	12
Assessing capacity to consent in Northern Ireland.....	13
Requirements for court approval for adults lacking capacity in England and Wales.....	13
Guidance for Clinicians and Transplant Teams .....	14
Securing valid consent .....	15
Ensuring the donor gives informed consent.....	16
Additional information for potential non-directed altruistic and paired/pooled organ donors .....	17
Referring cases to the HTA.....	17
Guidance for Independent Assessors (IAs) .....	18
Accepting referrals .....	18
Statutory interviews .....	18
The donor interview.....	19
The recipient interview .....	20
General advice on interviewing child recipients.....	20
Completing and submitting an application.....	21

Requirements for Authority panel cases .....	21
HTA decision-making arrangements .....	22
Annex A .....	23
Legislative background and context .....	23
Scotland.....	24
Status and use of the Codes of Practice .....	24
Other advice and guidance .....	25
Glossary .....	26

## Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:
  - a) post-mortem examination;
  - b) anatomical examination;
  - c) public display of tissue from the deceased; and
  - d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.
2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.
3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.
4. This document is part of a suite of seven Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under the HT Act and the [Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006](#) (the Regulations). They will also be of interest to members of the public.
5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.
6. *HTA Code A: Guiding principles and the fundamental principle of consent* contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:
  - a) consent;
  - b) dignity;
  - c) quality; and
  - d) honesty and openness.

7. With regard to organ and tissue donation, this means donated organs and tissue must be used in accordance with the expressed wishes of donors, their nominated representatives, or their relatives<sup>1</sup>, that donors and their relatives must be given the information they need to be able to make a decision that is right for them and that those seeking consent should do so with sensitivity and an appreciation of the particular circumstances in each case. It also means that the dignity of the donor must be respected at all times and that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.
8. This Code is divided into two parts, part one: living organ donation and part two: deceased organ and tissue donation. Part one provides supplementary guidance to clinicians working in living organ donation and HTA Independent Assessors (IAs). Part two provides supplementary guidance to Specialist Nurses - Organ Donation (SN-ODs), Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. See also paragraphs 26-27.
9. In combination, Code A and this Code aim to support organ donation and transplantation where valid consent is in place by providing anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

---

<sup>1</sup> Throughout the Codes, the term 'relatives' should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act, details of which can be found at paragraphs 30-39 of Code A.

## Introduction to Code F – Part One

### Scope of this Code

10. Living organ donation requires donor consent and HTA approval to be in place before a donation can proceed. The law requires that appropriate consent is in place in order to remove, store and use organs and tissue from living donors for transplantation. Once this consent has been obtained it remains an offence under the HT Act to remove an organ from a living person for the purpose of transplantation unless the HTA gives permission. This Code advises practitioners on the circumstances under which the prohibition on living donation can be lifted and HTA approval given. The process of living tissue donation itself does not require HTA approval and is therefore not within the scope of this Code.
11. For the purposes of living donation, HTA approval is required for the removal of an organ, or part of an organ (if it is to be used for the same purpose as the entire organ in the human body), where the intention is that it will be transplanted into another person. HTA approval is also required before an organ, or part organ, that is removed in this way can be used.
12. In deceased donation, the removal, storage and use of organs and tissue for transplantation is governed by the HT Act, this includes Vascularised Composite Allografts. Before organs and tissue can be removed, stored or used for transplantation, appropriate consent must be obtained. This Code advises practitioners on meeting the necessary consent provisions for this activity to be undertaken lawfully.
13. In addition to the consent requirements above, establishments may also be subject to the licensing requirements of both the HT Act and the The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (Statutory Instrument (SI) 2012 No. 1501) (the Q & S (Organ) Regulations). This Code does not include detailed information on the Q & S (Organ) Regulations - further information can be found in Annex A paragraphs 6-7 and the HTA publication The Quality and Safety of Organs Intended for Transplantation – a documentary framework. Further information on the licensing requirements under the HT Act can be found in Code of Practice F, part two: Deceased organ and tissue donation.

## Offences under the HT Act

14. **The HT Act sets out a number of offences, for which the maximum penalty is imprisonment and/or a fine. In relation to organ and tissue donation, the offences are as set out below.**
15. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.
16. Section 8 of the HTA Act makes it an offence to store or use donated material for anything other than a qualifying purpose.
17. Section 32 of the HT Act makes it an offence to engage in commercial dealings in human material for transplantation (see paragraphs 40-43).
18. Transplants involving live donors are illegal under section 33 of the HT Act unless the requirements set out in the Regulations are met (see paragraphs 35-39).
19. Section 34 creates an offence of failing to comply with the Regulations made under this section, and failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations. This offence is subject to a fine only.

## Legal considerations - Conditions on consent for organ transplantation

20. Consent may be limited in a variety of ways. The HT Act does not prevent an individual from placing limits on their consent via the imposition of conditions, for example, to particular research studies or to donate specific organs.
21. The HT Act recognises that individuals have the autonomous right to give or refuse consent to all or any of their organs or tissue being used for transplantation after their death and for some organs, or tissue, to be used for transplantation while they are alive.

22. In law, individuals may also limit their consent by identifying a named recipient of an organ for transplantation, either as part of living donation, or for donation after their death. This is referred to as a directed donation.
23. No organ should be transplanted under a form of consent which seeks to impose restrictions on the class of recipient of the organ, including any restriction based on a recipient's gender, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2010). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010.
24. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK and, as a matter of policy, does not accept organs from deceased donors where any condition is attached. However, requested allocation of a deceased donor organ can be considered if this is carried out in line with NHSBT policy.
25. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could or would not be fulfilled, as valid consent would not be in place. **Only the person who has attached the condition to the consent can put the condition aside.**

### Structure and navigation

26. As noted above, this Code is divided into two parts, part one: living organ donation and part two: deceased organ and tissue donation. Part one provides supplementary guidance to clinicians working in living organ donation and HTA Independent Assessors (IAs). Part two provides supplementary guidance to SN-ODs, Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. See also paragraph 8.
27. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA's website.



## Part One – Living organ donation

### Types of living organ donation

28. The HT Act and the Regulations place an obligation on the HTA to assess all referrals for living organ donation that are submitted. The HTA distinguishes a number of different concepts in living organ donation. These concepts, which are defined in the glossary, are: directed donation; directed altruistic donation; non-directed altruistic donation; paired and pooled donation; non-directed altruistic donor chains, and domino donation.

### Legal considerations

29. The law requires that valid consent is required in order to remove, store and use organs from living donors for transplantation. Where consent has been obtained for the removal, storage and use of an organ, it is illegal to proceed with the living donor transplant unless the requirements of the HT Act and Regulations have been met. Therefore, in addition to securing valid consent, practitioners also require HTA approval before proceeding with the removal and use of organs for transplantation from the living.

#### Example

A clinician has obtained consent from a potential living donor for the removal, storage and use of his kidney for living donor transplantation to the donor's sister.

However, it is not legal to proceed without HTA approval and the clinician must refer the case to the HTA for decision via an Independent Assessor.

30. The HT Act governs the consent requirements for the storage and use of organs or part organs taken from a living person for the purpose of transplantation.
31. Consent for the removal of organs from living donors, whether for **transplantation** or otherwise, is covered by the common law and the Mental Capacity Act 2005 (MC Act), where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health's Reference guide to consent for examination

or treatment. Guidance for healthcare professionals in Wales is available in the Welsh Government's guidance on Patient Consent to Examination and Treatment. The MC Act does not apply in Northern Ireland; further information about the law on mental capacity in Northern Ireland is provided in paragraphs 51-54.

32. The requirements for living donor transplantation are set out in sections 33 and 34 of the HT Act **and** sections 9–14 of the Regulations. **They** require that donations of organs or part organs, **with the exception of domino donations** (see paragraph 34), must be approved by the HTA. The Regulations include the requirement that the HTA is satisfied that consent for removal of the organ has been given, or the removal is otherwise lawful (for example, it has been sanctioned by the Court).
33. The law allows a living donor to request that their donation be directed to any identified individual, regardless of whether or not he or she has a relationship (genetic or otherwise) with the intended recipient. It is not an offence to advertise, either via traditional or social media, to find a suitable donor. It is, however, an offence to offer a reward as part of any such advertisement (see paragraphs 40-43).
34. Domino donation is a form of living donation where an **organ** or part **organ** is removed for the primary purpose of a person's medical treatment, for example, where a heart is removed as part of a person's medical treatment and the patient consents to the organ being offered for transplantation (for example, a heart originally removed from the recipient of a heart and lung transplant). While consent for use of the organ for transplantation does fall under the consent requirements of the HT Act, the donation would not be subject to the regulatory requirements which apply to other types of living donation (see paragraphs 35-39) therefore HTA approval is not required.

#### Requirements for HTA approval to be given

35. Before the HTA can approve living donation cases, a registered medical practitioner with clinical responsibility for the donor must have arranged to refer the case to the HTA. The Regulations require that the HTA must be satisfied that:
  - a) no reward has been, or is to be, given (reasonable expenses can be reimbursed please see paragraphs 40-41);
  - b) consent to removal for the purpose of **transplantation** has been given (or removal for that purpose is otherwise lawful);

- c) an IA (see paragraphs 83-87) has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient, and submitted a report of their assessment to the HTA. A donor interview is still required in situations where he or she is not able to give consent.
36. **A person is qualified to conduct such an interview if:**
- a) they meet the HTA's person specification for becoming an IA and have completed the approved HTA training;
  - b) they do not have any connection to those being interviewed, or their families, of a kind which the HTA considers might raise doubts about impartiality;
  - c) in the case of an interview with the donor (and any interview with another person giving consent), the IA is not the same person who gave them information about the procedure and its risks.
37. **The Regulations also specify the matters to be covered in the report submitted by the IA to the HTA. For every interview the IA must report:**
- a) whether there is any evidence of duress or coercion affecting the decision to give consent;
  - b) whether there is any evidence of an offer of a reward;
  - c) whether there were any difficulties in communicating with the person interviewed (e.g. language, hearing), and if so, an explanation of how these difficulties were overcome.
38. In addition, for interviews with the donor (and any interview with another person giving consent), the following must be provided:
- a) the information given to the person interviewed as to the nature of the medical procedure and the risk involved;
  - b) the full name of the person who gave that information to the person interviewed, and their qualification to give it;
  - c) the capacity of the person interviewed to understand the nature of the medical procedure and the risk involved and to understand that consent may be withdrawn at any time before the removal of the transplantable material.
39. **A donor or recipient, a person acting on behalf of either, or the registered medical practitioner who caused the matter to be referred to the HTA, may ask for a review of any decision on a case made by the HTA. The process for doing this is laid out within the Regulations and requires a fresh decision to be made by the HTA.**

## Commercial dealings in human material for transplantation

40. The HTA requires that checks are made to ensure that no reward has been given, or is to be given, for the donation. However, **the HT Act** allows donors to receive reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation. Further information on reimbursement arrangements is available in NHS England's policy on Reimbursement of Expenses for Living Kidney Donors in England and the Welsh Government's Specialised Services Policy on Live Donor Expenses for living donors in Wales. Guidance in Northern Ireland was being developed at the time of drafting this Code.
41. Where reimbursement is not made by the NHS, nothing in law prevents a recipient (or the family of the recipient) from directly reimbursing the donor's expenses. In this circumstance, the donor and recipient should provide evidence to prove that the donor has not materially benefitted in any way, for example that only directly attributable costs were paid.
42. The HT Act also prohibits commercial dealings in human material, including organs or tissue, for the purposes of transplantation. A person is committing an offence if they:
  - a) give, offer or receive any reward (financial or other material advantage) for the supply or offer of supply of any organ or part organ;
  - b) look for a person willing to supply any organ or part organ for reward;
  - c) offer to supply any organ or part organ for reward;
  - d) initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any organ or part organ;
  - e) take part in the management or control of any type of group whose activities consist of or includes the initiation or negotiation of such arrangements;
  - f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any organ or part organ for reward, or indicating that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media. For further information please see the guidance on matching websites and social media on the HTA website and the NHSBT guidance on social media and living donation.
43. This offence, outlined in paragraph 42, carries the risk of a fine and up to three years imprisonment. No offence is committed, however, where payments relate to reimbursement of the donor's expenses, or where reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.

## Donation by children

44. Children can be considered as living organ donors only in extremely rare circumstances. The HT Act defines a child as being under 18 years old. If a clinician intends to consider a child as a living organ donor, they are advised to discuss the case with the HTA at the earliest opportunity.
45. In accordance with common law and the Children Act 1989 (which established the legal basis for who has parental responsibility), court approval should be obtained before the removal of a solid organ or part organ from a child for donation. Transplant Units should obtain their own legal advice regarding seeking court approval.
46. Living donation by a child under the HT Act can only go ahead with the approval of an HTA panel. Such cases must only be referred to the HTA for decision after court approval for the removal has been obtained.

## Donation by adults lacking capacity to consent

47. The HT Act does not specify the criteria for considering whether an adult has capacity to consent. Under the MC Act, a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:
  - a) understand the information given to them that is relevant to the decision;
  - b) retain that information long enough to be able to make the decision;
  - c) use or weigh up the information as part of the decision-making process;
  - d) communicate their decision by any means.
48. Full guidance on how the MC Act defines capacity and how it should be assessed are given in chapter 4 of the MC Act Code of Practice.
49. The provisions of the MC Act should be considered together with general principles governing capacity to consent to medical procedures. Further information is available from the Office of the Public Guardian website and in the MC Act Code of Practice. The Welsh Government has published separate guidance for Wales.
50. The MC Act defines persons who lack capacity<sup>2</sup> and contains a set of key principles and a checklist to be used in ascertaining best interests<sup>3</sup>. The first core principle of the MC Act is that an adult must be assumed to have capacity

---

<sup>2</sup> See chapter 4 of the MC Act Code of Practice.

<sup>3</sup> See chapter 5 of the MC Act Code of Practice.

to make a decision for themselves, unless it is established that they lack capacity to make the particular decision at the time the decision needs to be made.

### **Assessing capacity to consent in Northern Ireland**

51. The MC Act does not apply in Northern Ireland. The Mental Health Order 1986 covers the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment in treatment. Common law is used to assess the capacity of adults and children. A new Act, The Mental Capacity Act (Northern Ireland) 2016 was passed in May 2016 but at the time of publication has not yet been implemented.
52. The Department of Health Northern Ireland published its own reference guide to consent for examination, treatment or care in 2003. This guidance is based on mental health and capacity case law. Each of the five Health and Social Care Trusts has published its own policy on the assessment of mental capacity, based on the 2003 departmental guidance. These policies draw on the MC Act, with regards to its principles, the assessment of mental capacity and the best interests test. People are presumed to have capacity to make decisions unless it is established that they do not.
53. Advance decisions<sup>4</sup> are made in Northern Ireland under common law and the 2003 departmental guidance, but these decisions are not legally binding under any statute. Enduring Powers of Attorney can be established under The Enduring Power of Attorney (Northern Ireland) Order 1987, but their decision-making powers are limited to financial matters and do not extend to welfare.
54. There is no Court of Protection in Northern Ireland, and therefore there are no Welfare Deputies; applications for decisions on welfare matters involving children and adults who have been found to lack capacity under common law and departmental guidance are made to the High Court.

### **Requirements for court approval for adults lacking capacity in England and Wales**

55. The HT Act makes no provision for appropriate consent for the removal of material from a living adult who lacks capacity to consent for himself or herself.

---

<sup>4</sup> A decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future, including the refusal of organ, bone marrow or peripheral blood stem cell donation.

A lawful decision to give or refuse consent on behalf of an adult who lacks capacity can only be made through one of four routes:

- a) by an Advance Decision made by the donor to refuse consent for the proposed treatment which covers this type of donation and was made at the time when the donor had capacity. If such an Advance Decision is in place then no Court can override that decision and lawful consent will never be given;
  - b) by the donor executing a valid Lasting Power of Attorney (LPA), giving another person power to make this type of decision. The LPA must have been made by the donor at a time when the donor had capacity (see section 9 of the MC Act);
  - c) By a person who has been given the power to make such a decision when appointed as welfare deputy by the Court of Protection (see section 16(2)(b) of the MC Act). The HTA considers that a welfare deputy should not rely on a general welfare power to make these decisions but should only rely on his or her decision making power under the deputyship order if this is a matter where the power to give consent to organ donation has been specifically given to him or her; or
  - d) By a judge of the Court of Protection making a best interests decision on behalf of the adult lacking capacity (see section 16(2)(a) of the MC Act).
56. The Code of Practice for the MC Act states that, where an adult lacks the capacity to consent to the removal of an organ for transplantation, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and, following court approval, the case is referred to, and approved by, an HTA panel.
57. As the court is authorising the removal, there is no-one else providing consent on the donor's behalf, and therefore only interviews with the donor and recipient can be undertaken.
58. Transplant Units should take their own legal advice regarding how to seek appropriate court approval.
59. If a clinician intends to consider an **adult lacking capacity** as a living organ donor, they are advised to discuss the case with the HTA at the earliest opportunity.

## Guidance for Clinicians and Transplant Teams

60. Clinicians and transplant teams are responsible for the overall care of donors and recipients, and for assessing the medical suitability of potential donors. The decision about whether a person is medically fit and clinically suitable as a living organ donor is a matter for the practitioners concerned. The **British Transplantation Society (BTS)** has published guidance for clinicians entitled *United Kingdom guidelines for living donor kidney transplantation* and the *United Kingdom guidelines for living donor liver transplantation*.
61. While the HTA provides advice on how our regulatory requirements will apply to individual cases, the decision on whether to work up a case rests with the transplant unit.
62. All potential donors should be provided with a copy of the HTA leaflet ***Our role in living organ donation*** and the HTA ***Guidance for living organ donors on the Human Tissue Authority's independent assessment process*** at an early stage in the work-up process to ensure that they understand the way in which living donation is regulated and how this will affect them. They should also be provided with a copy of the donor declaration form relating to reward for organ donation which is to be signed by the donor either before or at the IA interview. This form is available in multiple languages on the HTA website.

### Securing valid consent

63. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Clinicians have the responsibility of ensuring that valid consent to the removal, storage and use of organs or part organs is in place prior to referral to the HTA. Part of the HTA's role is to act as an independent check that legally valid consent is in place.
64. The HT Act requires that consent be obtained to store and use organs for transplantation. Consent for removal is governed under common law, but the HTA has the regulatory role of ensuring that valid consent for removal is in place. The necessary consents should ideally be sought in a single process.
65. While it is not a legal requirement, it is best practice to obtain written consent for significant procedures such as organ and tissue donation. When consent is obtained but is not in writing, this should be clearly documented in the patient's records. The record should detail when consent was obtained and the purposes for which it was given.
66. In situations where adult patients lack capacity, a consent form for adults who are unable to consent to investigation or treatment should be completed. More



information is available in the Department of Health's guidance *Information to assist in amending consent forms*.

### Ensuring the donor gives informed consent

67. Potential donors must be provided with sufficient information to reach an informed decision about whether they wish to donate an organ. This information must be provided by the transplant team before the IA interview.
68. If a donor lacks the capacity to consent, it is recommended that contact is made with the HTA early on during the workup in order that specific advice can be provided. See further information at paragraphs 47-50.
69. It is important that the donor is advised that they will need to provide consent to both the surgical procedure under common law, and the use of the organ for the purpose of transplantation under the HT Act.
70. To ensure that the informed consent of the donor is secured, the transplant team must make sure the following areas are discussed with the donor:
  - a) the nature of the surgical/medical procedure and medical treatments involved for the donor, and any material short and long term risks (this should be explained by a medical practitioner with appropriate qualifications to give this information). A material risk is where, in the circumstances, a reasonable person in the donor's position would be likely to attach significance to the risk, or the transplant team is or should be reasonably aware that the donor would be likely to attach significance to it. This information should include the risk of death to the donor (see paragraph 96 of Code A for further information on the relevant case law);
  - b) the chances of the transplant being successful, and any significant side effects or complications for the recipient, and in particular the donor should be made aware of the possibility of graft failure in the recipient;
  - c) the right to withdraw consent at any time before the removal of the transplantable material;
  - d) that the decision to donate must be free of duress or coercion;
  - e) that it is an offence to give or receive a reward for the supply of, or for an offer to supply, any organ. It is also an offence to seek to find a person willing to supply any organ for reward. If found guilty of this offence a person may face up to three years in prison, a fine, or both.
71. The donor must have a clear understanding of the benefits and disadvantages of living donor transplantation in their particular case, as well as the general risks and benefits. Further information on this can be found in the BTS

document *UK Guidelines for living donor kidney transplantation* and the BTS *UK Guidelines for living donor liver transplantation*.

### Additional information for potential non-directed altruistic and paired/pooled organ donors

72. For potential non-directed altruistic and paired/pooled donors, the donor must also be informed of how the altruistic, paired/pooled process works, and how a suitable recipient, or in the case of paired/pooled donation, suitable matches, are identified.
73. The donor must also be informed that anonymity of the donor and recipient is required before the operations, and that confidentiality must be respected.
74. Further information on these types of transplantation is available on the NHS Blood and Transplant (NHSBT) website.

### Referring cases to the HTA

75. The Regulations require that a medical practitioner with clinical responsibility for the donor must have caused the matter to be referred to the Authority. Certain specified information is required from the referring clinician as part of this referral where it concerns an organ. Specifically, the referral must state that the medical practitioner, or person acting under their supervision is satisfied that the donor's health and medical history are suitable for the purposes of donation, and has:
  - a) provided the donor with the information the donor requires to understand the consequences of donation;
  - b) endeavoured to obtain information from the donor that is relevant to transplantation.
76. As a matter of HTA policy, the HTA requests that referring donor clinicians also state that the medical practitioner is satisfied that the donor has capacity to consent to the donation. It is also requested that detail is provided on the recipient's capacity to participate in an interview to allow the IA to make any necessary adjustments. The HTA has created a **model referral letter template** for units to use to ensure that all the legislative requirements are addressed in the referral letter to the HTA. The HTA cannot make an assessment until it has received the referral letter.
77. Arrangements for the statutory interview can be made at the point at which the referral letter is received by an appropriately trained IA. A list of these IAs is available from the HTA.

78. Transplant teams should ensure that they factor in sufficient time for both the IA interview and HTA process to be completed, when scheduling provisional surgery dates.
79. Where the donor is also the only suitable adult to accompany a child recipient to the IA interview, the transplant team is advised to contact the HTA's Living Donation Assessment Team (LDAT) for further advice.

## Guidance for Independent Assessors (IAs)

### Accepting referrals

80. Before accepting a referral for a case, IAs should make sure that they will be able to:
  - a) undertake the interview within one month of referral;
  - b) submit their report to the HTA within 10 working days of the interview;
  - c) be available in the five working days following the submission of their report, in case the LDAT needs to contact them for further information or clarification.
81. Where the IA is made aware of a shorter deadline for the assessment of a case, for example, where there is an urgent clinical need, they should consider the implications of this before accepting the referral.
82. It is important that annual leave arrangements are taken into account when scheduling interviews as delays may result in scheduled surgery not being able to proceed. If an IA considers they may not be able to undertake interviews, or submit reports within the above timescales, or they are on leave in the five days following submission to the HTA, it would be advisable to ask the transplant team to find an alternative IA for that case.

### Statutory interviews

83. This section should be read in conjunction with the HTA Guidance to Transplant Teams and Independent Assessors, which provides detailed information on all aspects of the IA role, including who can become an IA and good practice guidance on undertaking interviews.
84. The Regulations require that an IA must have conducted separate interviews with the donor (and the person giving consent if this is not the donor) and the recipient. In addition, it is HTA policy that, in the case of directed donation, an interview must be undertaken with donor and recipient together. The purpose of

this is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor's decision to donate, and to explore the issue of reward jointly with the donor and recipient.

85. There may be rare circumstances where the donor and recipient do not wish to be interviewed together. In these cases the HTA must be contacted to make an application for the requirement for the joint interview to be withdrawn.
86. A recipient interview cannot be undertaken in cases of non-directed altruistic donation because there is no identified recipient at the time of the interview.
87. The Regulations detail the matters to be covered in the reports on the interviews to be submitted by IAs (described in paragraph 37). As a matter of policy the report should also contain an account of any relevant concerns the IA has which should contribute to the Authority's assessment of whether or not it is satisfied in relation to the legal tests described at paragraph 35.

### The donor interview

88. The interview with the donor must, by law, cover the matters described in paragraphs 37-38.
89. The primary role of the HTA is to ensure that valid consent to the removal is in place. The IA report will need to address whether the donor has been placed under any duress or coercion to consent to the procedure. For the purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor, either by the recipient or a third party, to go ahead with the donation. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.
90. The IA report will need to address whether there is any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to either the donor or any third party, for example, to anyone acting as an intermediary to bring the donor and recipient together.

## **The recipient interview**

91. The interview with the recipient must, by law, cover the matters described in paragraph 37.
92. In all cases the IA must undertake, or attempt to undertake, an interview with the recipient. The only exception is where the recipient unarguably lacks capacity, for example if they are a baby or a pre-verbal child then attempting an interview would be impossible. In such cases the IA should, as a minimum, see the recipient and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible in the appropriate section of the report.
93. The IA report on the interview with the recipient must cover any evidence of duress and coercion affecting the decision to give consent. For the purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor by the recipient to go ahead with the donation. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.
94. The recipient interview must also cover any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to the donor or a third party. Any reward might have been offered by the recipient, or by another party. Where it is not suitable to directly address financial reward with a child, a discussion on how the offer of donation arose could be considered.

## **General advice on interviewing child recipients**

95. The IA interviews the potential donor and recipient to assess whether the HTA requirements have been met. Interviews should take place with the recipient at a level appropriate to their age and understanding.
96. There is no statutory provision for someone to be interviewed on the recipient's behalf, so a recipient interview must be attempted. In cases where the recipient is at a stage of development where language or comprehension are limited, IAs should adopt an extremely light touch approach to assessing the issues of duress, coercion and reward, by exploring what the recipient knows about the procedure and their knowledge of how the donor came to be chosen to donate to them. It is good practice to involve the parent(s) in these discussions but there is no legal role for the parents to respond on behalf of the child.

97. Please see paragraph 92 for further guidance on interviewing very young children.

### Completing and submitting an application

98. The legal framework requires that the HTA, not the IA, make the decision on whether a case can proceed. In every case of living organ donation the HTA decision maker must have sufficient evidence to exercise an independent judgement on whether the legal tests relating to living donation are met. The primary source of evidence to exercise this judgement is the IA report. This means that the IA must provide a comprehensive account of their interviews including the rationale for any conclusions they draw and not only the conclusions themselves.
99. Following an interview, IAs should submit a report of their interview to the HTA within 10 working days. If for any reason the report cannot be submitted within 10 working days, the IA should inform both the transplant team and the HTA.
100. The IA report is a confidential document between an IA and the HTA. It is not appropriate to share any details of the report, or the report itself, with the clinical team.
101. A copy of the referral letter and donor declaration should also be submitted at the time of the report submission.

### Requirements for Authority panel cases

102. The Authority has a legal obligation to assess all cases that are referred to it. Some cases can be delegated to a member of the HTA LDAT for a decision; other cases are assessed by a panel of three Authority Members (panel cases). The Authority currently distinguishes two types of panel case:
- a) Authority panel cases mandated by law, as described in the Regulations;
  - b) Authority panel cases, where the Authority has decided as a matter of policy (rather than legal obligation) to retain decision making responsibility and not delegate to the LDAT.
103. Authority panel cases by law comprise situations where:
- a) the donor is a child;
  - b) the donor is an adult lacking capacity to consent;
  - c) paired donations;
  - d) pooled donations;

e) non-directed altruistic donations.

104. Authority panel cases are decided by the level of regulatory risk associated with the circumstances of the case and are subject to change. The HTA Decision-Making Framework sets out which cases are retained and which are delegated.
105. Some panel cases require increased scrutiny and for independent assessments to be completed by an IA who has completed enhanced training. Cases which require an assessment by such an IA are included in the HTA's policy on IA assessments and Guidance to Transplant Teams and Independent Assessors. IAs must ensure that they are only allocated cases which they have the necessary training to assess.

### HTA decision-making arrangements

106. The HTA aims to make decisions within timeframes published each year in the HTA business plan.
107. Once a decision has been made by the HTA, an automated notification will be issued to the IA, Living Donor Coordinator(s) and the clinicians detailed in the report. Living Donor Coordinators must inform the donor and recipient of the decision on the HTA's behalf.
108. In cases where the requirements have not been met and the HTA turns a case down, the donor (or someone acting on their behalf), recipient, and medical practitioner with responsibility for the donor will be notified in writing. The letter will also outline the procedure for reconsideration of the decision.
109. However there may be cases where the HTA decides that it would not be appropriate to provide full reasons or that doing so would breach another person's rights under the Human Rights Act 1998 or would breach a duty of confidentiality owed to any person.
110. Detailed information on the way in which the HTA makes decisions can be found in the HTA Decision-Making Framework, its policy for the assessment of living organ donation cases and HTA Standard Operating Procedures, which are available on request from the HTA.

## Annex A

### Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.
2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes<sup>5</sup> in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.
3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:
  - a) the person died before the HT Act came into force on 1 September 2006; and
  - b) at least 100 years have elapsed since the date of the person's death.
4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.
5. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations), as amended, implemented into UK law the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The Q&S Regulations set out the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for human application. In their amended form following UK's exit from the European Union, the Q&S Regulations modify the requirements of the EUTCD as applied to Great Britain to reflect the departure from the EU, but the same standards continue to apply. Those modifications do not apply to Northern Ireland where the HTA remains the Competent Authority for the purposes of the EUTCD.
6. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment and the requirements set out in Codes A and G.

---

<sup>5</sup> Defined by the HT Act and explained in further detail in the glossary.



7. The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) implemented into UK law the European Union Organ Donation Directive 2010/53/EU (EUODD). The Q&S (Organs) Regulations set quality and safety standards for organ donation and transplantation. In their amended form following UK's exit from the European Union, the Q&S (Organs) Regulations modify the requirements of the EUODD as they apply to Great Britain, but the same standards continue to apply. Those modifications do not apply to Northern Ireland where the HTA remains the Competent Authority for the purposes of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's Quality and Safety of Organs Intended for Transplantation: a documentary framework and the requirements set out in Codes A and F (parts one and two).
8. A deemed consent system for organ and tissue donation after death is operational in England, Wales and Northern Ireland . This does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a [Code of Practice on the Human Transplantation \(Wales\) Act 2013](#) for establishments in Wales.

### **Scotland**

9. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.
10. The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act) and the Human Tissue (Authorisation) (Scotland) Act 2019 apply in Scotland.
11. The HTA assesses applications for living organ donation and donation of regenerative tissue on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this Code does not apply in Scotland.

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

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

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

### Other advice and guidance

14. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.
15. The HTA's Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

## Glossary

Term	HTA definition
Advance Decision	An advance decision is a decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future. To be legally binding in England and Wales, an advance decision must comply with a number of criteria which are described in the Mental Capacity Act 2005. With regard to organ and tissue donation, an advance decision could be used to exclude the possibility of donation from a living adult who lacks capacity at the time of the proposed donation.
Anatomical examination	Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.
Ante-mortem	Clinical investigations or interventions that take place preceding death.
Appropriate consent	Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died. Deemed consent modifies the appropriate consent provisions in England and Wales and Northern Ireland for organs and tissue donation for donation after death.
Best interests	A test of a person's best interests takes into account not only the medical aspects, but also the wider emotional, psychological and social aspects of the potential medical procedure, as well as the risks.
Bone marrow	A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.

Term	HTA definition
Coercion/ Duress	The HTA examines whether the recipient and donor have been put under any coercion or duress when assessing Independent Assessor reports. Both coercion and duress are referred to in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but they are not distinguishable in law. The HTA interprets coercion or duress to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.
Coroner	Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.
Court of Protection	Makes decisions on financial or welfare matters for people in England and Wales who are unable to make decisions at the time they need to be made because they lack mental capacity to do so.
Deemed Consent	Deemed consent means that all individuals over 18 in England, Wales or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue (i.e., they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent). Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.
Diagnosis	The identification of the nature of an illness or other problem.
Directed donation	A form of donation where a person, usually a living person, donates an organ or part organ to a specific, identified recipient with whom they have a genetic or pre-existing emotional relationship.

Term	HTA definition
Directed altruistic donation	The HTA defines these as cases which fulfil two conditions (a) the donation is being directed to a specified individual and (b) there is no evidence of a qualifying genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party - either a person or other mechanism such as a social networking site - bringing the donor and recipient together for the purpose of transplantation.
DNA	<p>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics.</p> <p>Find out more information about the HTA's role with regards to DNA on the HTA's website.</p>
Domino donation	A form of living donation in which an organ is removed for the primary purpose of the person's medical treatment. The organ removed may prove suitable for transplant into another person. The HTA does not regulate domino donations.
Donated material	For the purposes of the HT Act, the term 'donated material' refers to the body of a deceased person, or relevant material which has come from a human body, which is being stored or used for scheduled purposes with appropriate consent.
Donation	The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.
Donation after Brainstem Death (DBD)	A form of organ donation in circumstances where a patient, whose death has been diagnosed using neurological criteria, continues to be ventilated. This keeps the heart beating and blood circulating after death, until after donation takes place.
Donation after circulatory death (DCD)	<p>A form of organ donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs after death is diagnosed and confirmed using cardio-respiratory criteria.</p> <p>This is described as controlled when treatment has been actively withdrawn within a hospital setting or uncontrolled where a patient has experienced an unexpected cardiac arrest from which they cannot be resuscitated.</p>

Term	HTA definition
Donor	Every human source, whether living or deceased, of tissue, cells, organs or part organs.
Duress (Coercion)	Both words are referred to in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but are not distinguishable in law. The HTA interprets duress to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.
Health and Social Care (HSC) Trust	Health and Social Care (HSC) Trusts provide integrated health and social care services across Northern Ireland.  For further information see the Department of Health's website.
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Independent Assessor	The designation given by the HTA to the "qualified person" for the purpose of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Independent Assessors are trained by the HTA and undertake the statutory interviews with the donor and the recipient in each application for living organ donation.
Intraperitoneal cooling	A method of surface-cooling organs by infusing cold fluid into the abdominal cavity to aid preservation of the donor after death for the purpose of transplantation.
Lasting Power of Attorney (LPA)	A Lasting Power of Attorney (LPA) is a power of attorney under which the donor (a person aged 18 or over) confers authority to another person or people (a third party) to make certain decisions on their behalf, should they lose capacity in the future. An LPA is a legal document and decisions that the third party makes are as valid as any made by the donor. An attorney is bound by the principles set out in the Mental Capacity Act; for example, any decisions they make must be made in the best interests of the person lacking capacity. Further information about LPAs is set out at chapter 9 of Part One of the Mental Capacity Act. An LPA is only applicable in England and Wales.

<b>Term</b>	<b>HTA definition</b>
Licensed premises	Where the licensed activity takes place.
Licensing	A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.
Minimum steps	The HT Act allows for the minimum steps necessary to be taken to preserve organs in a state which allows successful donation, using the least invasive procedure such as cold perfusion and intraperitoneal cooling.
Nominated representative	A person appointed by a person to represent them after their death for the purposes of activities under the HT Act for which consent is required. A nominated representative may be entitled to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.
Non-directed altruistic donation	A form of donation where a healthy living person donates an organ or part organ to an unknown recipient, that is, someone they have never met and is not genetically related or known to them.
Non-directed altruistic donor chains	A form of donation where a non-directed altruistic donor donates their organ into the paired/pooled scheme. By matching two or more recipients, a chain of operations can be carried out. The remaining organ at the end of the chain is then donated to the best matched recipient on the national waiting list.
Organ	Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.

Term	HTA definition
Organ Donor Register (ODR)	A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs after their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.
Paired and pooled donation	A form of donation where a healthy living person is unable to (or chooses not to) donate because they are either incompatible with their intended recipient, or prefer a better match. They may be matched with another donor and recipient in the same situation in the National Living Donor Kidney Sharing Schemes. The donor organs are then swapped. When two pairs are involved it is a paired donation and where more than two pairs are involved it is a pooled donation.
Parental responsibility	A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.
Payment or reward (in IA and AA cases)	<p>The HTA examines whether payment or reward has been given, offered or received when assessing Independent Assessor cases. Under the Human Tissue Act, a person is committing an offence if they:</p> <ul style="list-style-type: none"> <li>a) give, offer or receive any type of reward for the supply or offer of supply of any transplantable material;</li> <li>b) look for a person willing to supply any transplantable material for reward;</li> <li>c) offer to supply any transplantable material for reward;</li> <li>d) initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any transplantable material;</li> <li>e) take part in the management or control of any type of group whose activities consist of or include the initiation or negotiation of such arrangements;</li> <li>f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any transplantable material for reward, or indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media.</li> </ul>



<b>Term</b>	<b>HTA definition</b>
Perfusion	A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death.
Peripheral blood stem cells (PBSCs)	Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the blood stream by giving a drug, and collected with an apheresis machine.
Post-mortem examination	Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.
Practitioner	A person working with relevant material in an establishment licensed by the HTA.
Procurement	The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.
Qualifying relationship	The relationship to the deceased of a person/s who can give consent for the removal, storage and use of tissue from the deceased person's body for scheduled purposes, if the deceased person did not indicate their wishes in life or appoint a nominated representative.
Relatives	Throughout the Codes, the term 'relatives' should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website.
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.

Term	HTA definition
Scheduled purpose	<p>Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also relate to activities for scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</p> <ul style="list-style-type: none"> <li>• Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person’s death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation.</li> <li>• Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, and quality assurance.</li> </ul>
Specialist Nurse for Organ Donation (SN-OD)	A senior nurse who is the focal point of contact for organ donation within the Hospital / Trust. The role encompasses different aspects which all come together in the identification and referral of potential organ and tissue donors.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplant Unit	A department within a hospital that provides range of transplant services to patients.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.
Vascularised Composite Allograft transplant	The transplantation of parts of the human body that contains multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue, that is recovered from the human donor as an anatomical or structural unit and requires its own blood supply and without altering its relevant characteristics. This may include novel transplants such as face, hand and limb and uterus

Term	HTA definition
Welfare deputy	A person who has been appointed and given the power to make certain decisions by the Court of Protection (see section 16(2)(b) of the Mental Capacity Act). Welfare deputies are only appointed in England and Wales.
Work-up process (in organ, bone marrow and PBSC donation cases)	A full medical assessment process involving a series of medical tests and investigations to determine whether a person is suitable as a living donor.