



Human Tissue Authority

Code of practice 2 Donation of solid organs for transplantation

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Introduction

The legislation and the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1] covers England, Wales and Northern Ireland. The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 [www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1].

2. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) [www.opsi.gov.uk/si/si2007/uksi_20071523_en_1] implement the European Union Tissue and Cells Directives (EUTCD). The HTA is a Competent Authority in the UK under the Q&S Regulations, which cover the whole of the UK, including Scotland.

3. The HTA's remit in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 (Ref: NHS HDL (2006) 46) [http://www.hta.gov.uk/db/documents/Information_about_HT_%28Scotland%29_Act.pdf] and the relevant codes of practice. Relevant guidance from Wales and Northern Ireland is referenced throughout the codes.

About the codes of practice

4. The codes of practice give practical guidance to professionals carrying out activities which lie within the HTA's remit. They may also be of interest to members of the public. The first editions of the codes have been revised to reflect our experience of regulation. We have made the codes more relevant to the sectors we regulate by including case studies and examples; and have restructured them in a way that makes them more user-friendly.

5. The codes are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA's website.

6. The HTA has now published nine codes of practice, which are listed below : [www.hta.gov.uk/guidance/codes_of_practice.cfm]

1. Consent
2. Donation of solid organs for transplantation
3. Post-mortem examination
4. Anatomical examination
5. Disposal of human tissue
6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
7. Public display
8. Import and export of human bodies, body parts and tissue
9. Research

7. All nine codes of practice have been brought into force by HTA Directions [www.hta.gov.uk/guidance/licensing_guidance/expected_standards.cfm].

Using the codes

8. In these codes, the word '**must**' refers to an overriding duty or principle, including all specific legal requirements derived from primary and secondary legislation – for example, the requirement to hold a licence to store human tissue for a scheduled purpose.

9. We use the word '**should**' when explaining how to meet the specific legal requirements. Establishments are expected to follow the guidance in the codes. Observance of the guidance in the codes is one of the ways in which the HTA assesses that establishments are complying with relevant legislation. Failure to follow a code of practice is not in itself a criminal offence under the HT Act but the HTA will carefully consider any breach of a code of practice and may take appropriate regulatory action.

10. The codes 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. A glossary with terms specific to each code is available at the end of each document, and a full list of glossary terms is on the HTA's website.

11. You can download and print copies of the codes from the HTA's website [www.hta.gov.uk/guidance/codes_of_practice.cfm].

Other advice and guidance

12. A number of other organisations have also produced guidance on issues in the HTA's remit. Where this has been produced in collaboration

with the HTA, it will appear on our website. The HTA's codes of practice and other 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.

Scope of this code

- 13.** This code sets out the HTA's requirements for living donation of organs for transplantation. It includes specific information on the requirements of the HT Act and about the HTA's role in approving donations.
- 14.** This code also includes guidance on deceased organ donation. It sets out the legislative requirements for seeking consent to donation and information about the roles of the HTA and NHS Blood and Transplant (NHSBT) in the deceased donation process.
- 15.** An overview of licensing requirements and exceptions in relation to organ transplantation is also provided within the code.
- 16.** Domino and autologous donations are outside the scope of the HT Act and guidance within this code does not therefore apply. Whilst not regulated by the HTA, good practice guidance on consent and domino donation (see paragraph 27) is provided within the HTA's Guidance for transplant teams and Independent Assessors [www.hta.gov.uk/transplantation/organ_donation/independent_assessors.cfm].
- 17.** Guidance on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation is provided in another HTA code of practice and practitioners in this area should familiarise themselves with the provisions of that code.

Scotland

- 18.** The HTA regulates living organ donation in Scotland on behalf of the Scottish Government, and the guidance on living organ donation within this code applies to Scotland (see paragraphs 54-57 for specific guidance on Scottish legislation).
- 19.** The guidance on deceased donation does not apply to Scotland, as deceased donation in Scotland is regulated under separate legislation; however paragraph 95 provides details of relevant guidance for Scottish practitioners.
- 20.** Guidance within the code on the licensing requirements of the HT Act ([see paragraphs 135-150](#)) is not applicable to Scotland, where separate requirements apply. However the requirements of the Q&S Regulations, referred to in [paragraph 140](#) , apply UK-wide.

Structure and navigation

- 21.** This code is divided into two main sections: living organ donation and deceased organ donation.
- 22.** The first section of this code describes different types of living organ donation, the requirements of the HT Act and the role of the HTA. It also provides guidance on the process that must be followed before organ donation can go ahead, including giving the necessary information to prospective living donors for them to be able to make an informed decision to consent.
- 23.** The second section of this code sets out the requirements of the HT Act, the roles of the HTA and NHSBT, the Organ Donor Register and the requirements relating to the preservation of organs for transplantation.
- 24.** At the end of this code there is a section on licensing requirements and exceptions related to organ transplantation. Those involved in organ transplantation should also refer to this section.

Status of this code

25. Transplantation falls within the HTA's statutory remit. This code on Donation of solid organs for transplantation replaces the previous code of practice. In accordance with Section 29 of the HT Act, it has been approved by the Secretary of State following consultation with the Welsh Assembly Government and the relevant Northern Ireland department, and it has received Parliamentary approval.

Living organ donation

Types of living organ donation

26. The HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1] and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) [www.opsi.gov.uk/si/si2006/20061659.htm] allow the following types of living organ donation:

1. Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired donation).
 - i. genetically related donation: where the potential donor is a blood relative of the potential recipient
 - ii. emotionally related donation: where the potential donor has a relationship with the potential recipient, for example, spouse, partner, or close friend
 - iii. paired donation: where a relative, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, and they are matched with another donor and recipient in a similar situation, so that both people in need of a transplant receive a compatible organ
 - iv. pooled donation: a form of paired donation whereby the pair are matched with other donors and recipients from a pool of pairs in similar situations, and more than two donors and two recipients are involved in the swap, so that more than two people in need of a transplant receive a compatible organ
2. Altruistic non-directed donation: A form of living donation whereby an organ (usually a kidney) or part organ (for example liver or lung lobe) is donated by a healthy person who does not have a relationship with the recipient and who is not informed whom the recipient will be.

27. Domino donation is a further form of living donation where an organ or part organ is removed for the primary purpose of a person's medical treatment. The organ/s removed may prove suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart / lung transplant). The HTA does not regulate domino donations. While consent for use of the organ for transplantation does fall under the consent requirements of the HT Act (see [paragraphs 71–75](#)), the donation would not be subject to the same regulatory requirements as other types of living donation (see [paragraphs 33–41](#)). This is because, although it is a living donation, the donation primarily arises from the removal of the organ as part of a patient's treatment. Consent to treatment and examination is covered by the common law, and the legal position is set out in Department of Health's guidance [www.dh.gov.uk/consent].

28. Although consent for domino donation is not regulated by the HTA in the same way as other types of living donation, good practice guidance is set out within the HTA's Guidance for transplant teams and Independent Assessors [www.hta.gov.uk/transplantation/organ_donation/independent_assessors.cfm].

Requirements of the legislation

29. The HT Act governs consent for the storage and use of organs or part organs taken from a living person for the purpose of transplantation.

30. Consent for the removal of organs from living donors, whether for transplantation or otherwise, is outside the scope of the HT Act. It is instead covered by the common law and the Mental Capacity Act (MC Act) 2005 [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1] 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 guidance [www.dh.gov.uk/consent]. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government's Reference guide to consent for examination and treatment [www.wales.nhs.uk/consent]. The Department of Health, Social Services and Public Safety (DHSSPS) (Northern Ireland) has published its own Reference guide to consent for examination, treatment or care [www.dhsspsni.gov.uk/consent-referenceguide.pdf].

31. The requirements for living donor transplantation are set out in sections 33 and 34 of the HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_4#pt2-pb6] and 9–14 of the Regulations [www.opsi.gov.uk/si/si2006/20061659.htm].

32. It is an offence to remove or use any organ or part organ from the body of a living person for transplantation unless the requirements of the HT Act and the Regulations are met.

33. The Regulations require that, with the exception of domino donations (see [paragraph 27](#)), all living organ donations for transplantation must be approved by the HTA before the donation can take place.

34. Before the HTA can approve such cases, the Regulations require that the Authority must be satisfied that:

- i. no reward has been, or is to be, given

- ii. consent to removal for the purpose of transplantation has been given (or removal for that purpose is otherwise lawful)
- iii. an Independent Assessor (IA) (see [paragraphs 60–64](#)) has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient (or the person acting on behalf of the recipient) and submitted a report of their assessment to the HTA

Additionally in cases of directed genetically or emotionally related donation, the HTA requires evidence of relationship to be provided, so that it can be satisfied the relationship between donor and recipient is as stated.

35. A person is qualified to conduct such an interview if:

- i. they meet the HTA's person specification for becoming an IA and have completed the approved HTA training
- ii. 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
- iii. in the case of an interview with the donor (or other person giving consent), the IA is not the same person who gave them information about the procedure and its risks.

36. The Regulations also specify the matters to be covered in the report submitted by the IA to the HTA, which are:

- i. the information given to the potential donor (or other person giving consent) as to the nature of the medical procedure and the risk involved
- ii. the full name of the person who gave that information to the potential donor (or other person giving consent), and their qualification to give it
- iii. the capacity of the potential donor (or other person giving consent) to understand the nature of the medical procedure and the risk involved and that consent may be withdrawn at any time before the removal of the organ or part organ
- iv. whether there is any evidence of duress or coercion affecting the decision to give consent
- v. whether there is any evidence of an offer of a reward
- vi. 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

37. There are two levels of decision-making for living organ donation: the first where the HTA transplant approvals team can make the final decision on a case; and the second where a case must be assessed by an HTA panel.

38. A decision on a transplant must be made by an HTA panel:

- i. if the donor is a child
- ii. if the donor is an adult who lacks capacity to consent to removal of an organ or part organ
- iii. in all cases of paired and pooled donation
- iv. in all cases of altruistic non-directed donation

39. All other cases can be approved by the HTA transplant approvals team, although they can also refer complex or novel cases to a panel where required.

40. 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 [www.opsi.gov.uk/si/si2006/20061659.htm] and requires a fresh decision to be made by the HTA.

41. Further guidance on the HTA approvals process and the roles of the IA and HTA panels can be found at [paragraphs 58–70](#) .

Payment, advertising and commercial dealings

42. The HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_4#pt2-pb6] 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.

43. All such payments should be made by a proper authority, for example a Trust or foundation hospital, or, in the case of a private patient, the hospital. Details on the levels of reimbursement are available in the Department of Health's guidance on Reimbursement of living donor

expenses by the NHS [[www .dh.gov.uk/en/Healthcare/NationalServiceFrameworks/Renal/RenalInformation/DH_4069293](http://www.dh.gov.uk/en/Healthcare/NationalServiceFrameworks/Renal/RenalInformation/DH_4069293)].

44. Donors should not be reimbursed directly by the recipient or by their family or friends. The HTA requires that checks are made to ensure that no other payment or reward is made and that the donor does not profit from the donation.

45. The HT Act also prohibits commercial dealings in human material, including organs or part organs, for the purposes of transplantation. Unless designated by the HTA to carry out such activity, a person is committing an offence if they:

- i. give, offer or receive any type of reward for the supply or offer of supply of any organ or part organ
- ii. look for a person willing to supply any organ or part organ for reward
- iii. offer to supply any organ or part organ for reward
- iv. 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
- v. 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
- vi. 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 indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising

46. This offence 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 as discussed above, or reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.

Children – special considerations

47. Children can be considered as living organ donors only in extremely rare circumstances. In accordance with common law and the Children Act 1989 [[www .opsi.gov.uk/acts/acts1989/ukpga_19890041_en_1](http://www.opsi.gov.uk/acts/acts1989/ukpga_19890041_en_1)], before the removal of a solid organ or part organ from a child for donation, court approval should be obtained. Further guidance on seeking court approval can be found in [Appendix A](#) .

48. Living donation by a child under the HT Act can only go ahead with the approval of an HTA panel (see [paragraphs 69–70](#)). The HT Act defines a child as being under 18 years old [[www .opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5#pt3-pb2-l1g54](http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5#pt3-pb2-l1g54)]. Such cases should only be referred to the HTA for decision after court approval to the removal has been obtained.

49. The position in Scotland regarding children is somewhat different and the Scottish Government has issued guidance on these cases [[www .hta.gov.uk/ db/ documents/Information_about_HT_\(Scotland\)_Act.pdf](http://www.hta.gov.uk/db/documents/Information_about_HT_(Scotland)_Act.pdf)]. Further information on the relevant requirements under the Scottish Act can also be found at [paragraphs 54–57](#) .

Adults – special considerations

50. Where an adult lacks the capacity to consent to the removal of an organ or part organ, 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 ([see paragraphs 69–70](#)).

51. The HT Act does not specify the criteria for considering whether an adult has capacity to consent.

52. In determining whether a person of 16 or over has capacity, the provisions of the MC Act [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1] should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website [www.publicguardian.gov.uk/mca/mca.htm] and in the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm]. There is separate guidance for Wales [<http://new.wales.gov.uk/topics/health/nhswales/healthservice/mentalhealthservices/mentalcapacityact/?lang=en>] and for Northern Ireland [www.dhsspsni.gov.uk/public_health_consent]. The Adults with Incapacity (Scotland) Act 2000 [www.opsi.gov.uk/legislation/scotland/acts2000/asp_20000004_en_1] governs adults who lack capacity in Scotland. See [paragraphs 78–83](#) for further information on determining capacity and the MC Act.

53. The position in Scotland regarding adults with incapacity and living organ donation is somewhat different and the Scottish Government has issued guidance on these cases [[www.hta.gov.uk/ db/ documents/Information_about_HT_\(Scotland\)_Act.pdf](http://www.hta.gov.uk/db/documents/Information_about_HT_(Scotland)_Act.pdf)]. Further information on the relevant requirements under the Scottish Act can also be found at [paragraphs 54–57](#) below.

Scottish legislation

54. The legal framework for living organ donation and transplantation is different in Scotland, and is set out in section 17 of the HT (Scotland) Act 2006 [www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_3#pt1-pb3]. These provisions are supplemented by the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (the Scottish Live Transplants Regulations) [www.oqps.gov.uk/legislation/ssi/ssi2006/ssi_20060390_en_1].

55. Under Scottish legislation (see [paragraph 52](#) , above), adults without capacity to make their own decisions and children (defined as persons who have not yet reached the age of 16) are only able to donate solid organs or part of an organ which has to be removed as part of a domino organ transplant operation (see [paragraph 27](#)). Unlike other forms of living organ donation this form of donation is not regulated by the HTA. Guidance within this code is not therefore applicable to adults with incapacity or children in Scotland.

56. Scottish law covering living organ donation by adults with capacity is broadly similar to that which applies in the rest of the UK (see [paragraphs 58–70](#)), although in Scotland a person becomes an adult when they reach the age of 16.

57. Scottish Ministers have asked the HTA to regulate donation approvals on their behalf.

HTA Process

Roles of the HTA

58. As required by the Regulations, the HTA must approve all cases of living organ donation (except domino donations) for transplantation. The HTA undertakes this role through an independent assessment process.

59. Before a transplant involving a living donor takes place, a donor and recipient must receive a full medical assessment to determine whether they are suitable to undergo the procedure. The decision about whether a person is medically fit and suitable as a living organ donor is a matter for the practitioners concerned. If the donor is deemed suitable, the clinician responsible for the donor must then make a written referral to an HTA IA.

Independent Assessors (IAs)

60. In order to become an IA, a person must have completed the training and have been accredited by the HTA to undertake the role. Further guidance on IA accreditation can be found in the Guidance for transplant teams and Independent Assessors [www.hta.gov.uk/transplantation/organ_donation/independent_assessors.cfm].

61. IAs are professionals who are usually, but not exclusively, based in hospitals with transplant units or referring nephrology units. IAs act as a representative of both the HTA and the donor in order to help the HTA ensure the requirements of the HT Act and Regulations have been met.

62. The IA's responsibility is to interview the donor and recipient to assess whether the requirements of the HT Act and Regulations (see [paragraph 34](#)) have been met. Separate interviews must be carried out with the donor and recipient, and IAs also interview the donor and recipient together.

63. The exceptions to this are:

- i. when the recipient is a child, the donor will be interviewed separately, but it is expected that the child and the person with parental responsibility for the child, would be seen together by the IA, even when the person with parental responsibility is also the potential donor
- ii. in non-directed altruistic donation, the IA would only see the donor

64. Following the interview the IA must prepare a report for the HTA which states whether they are satisfied that the relevant requirements of the HT Act and Regulations (see [paragraphs 34 and 36](#)) have been met. The report should also include a recommendation from the IA as to whether the HTA should approve the donation or not.

HTA approval process

65. Following submission of the IA's report, the HTA will make a final decision on approval of the donation.

66. All straightforward directed donations where the donor and recipient are genetically or emotionally related can be assessed by the HTA transplant approvals team. However, the transplants approval team is able to refer complex cases (including those relating to newer types of organ transplant) to a panel for decision.

67. Decisions on all other donations must be made by a panel of Authority members. These include altruistic non-directed donation, paired or pooled donation, donations by children, and donations from adults who lack capacity to consent. In the rare case of donation by a child or an adult who lacks capacity, an HTA panel will consider the case only after a court declaration has been made on whether the proposed intervention is lawful. See [Appendix A](#) for requirements for court approval.

68. Approval for donation by the HTA is valid for six months from the date of decision. If the transplant does not happen within that time for whatever reason, a repeat report is required to ensure circumstances have not changed, and a further decision of the HTA will be made.

HTA Panels

69. HTA panels consist of three Authority members. A panel may ask the advice of experts; however, these advisors are not involved in the final decision-making on a donation. Panels are supported by the HTA transplant approvals team.

70. Detailed information on the referral, assessment and approval process for each type of donation is available in the Guidance for transplant teams and Independent Assessors [www.hta.gov.uk/transplantation/organ_donation/independent_assessors.cfm].

Consent

71. The HT Act requires consent be obtained to use organs or part organs from a living person for transplantation.

72. The giving of consent is a positive act. 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.

73. Obtaining valid consent presupposes that there is a process in which individuals, including their partners, relatives or close friends where appropriate, may discuss the issue fully, ask questions and make an informed choice. Sufficient time should be allowed for questions and discussion. Surgeons should always check before surgery that the person still consents to the procedure, and be clear that consent has not been withdrawn before they proceed.

74. While the HT Act does not specify the format in which consent should be given or recorded, it is good practice to obtain written consent for significant procedures such as organ 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 the consent was given. It is also good practice to document details of discussions held regarding the risks of the procedure (see [paragraph 90](#)).

75. Further guidance on consent and the HT Act is available in the code of practice on Consent.

Consent – adults

76. 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.

77. As outlined in [paragraph 51](#), the HT Act does not specify the criteria for considering whether an adult has capacity to consent.

78. Under the MC Act [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_2#pt1-pb1-l1q1], a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

- i. understand the information given to them that is relevant to the decision
- ii. retain that information long enough to be able to make the decision
- iii. use or weigh up the information as part of the decision-making process
- iv. communicate their decision by any means

Full guidance on how the MC Act defines capacity and how it should be assessed is given in chapter 4 of the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm].

79. The provisions of the MC Act [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1] should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website [www.publicguardian.gov.uk/mca/mca.htm] and in the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm].

There is separate guidance for Wales

[<http://new.wales.gov.uk/topics/health/nhswales/healthservice/mentalhealthservices/mentalcapacityact/?lang=en>] and for Northern Ireland

[www.dhsspsni.gov.uk/public_health_consent]. The Adults with Incapacity (Scotland) Act 2000

[www.opsi.gov.uk/legislation/scotland/acts2000/asp_20000004_en_1] governs adults who lack capacity in Scotland.

80. The MC Act governs decision - making on behalf of adults (aged 16 and over) who lack capacity to make a particular decision because the way their mind or brain works is affected. For the purposes of the MC Act, unlike the HT Act, an adult is a person aged 16 or over. The MC Act only applies to persons aged 16 or over.

81. There are detailed provisions contained in the MC Act [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1] concerning decisions made on behalf of adults lacking capacity. All decisions must be made in the person's best interests, as laid out in chapter 5 of the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm]. Also, certain categories of people have a legal duty to have regard to the MC Act code of practice, when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in chapter 6 [www.publicguardian.gov.uk/mca/code-of-practice.htm].

82. The MC Act [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1] defines persons who lack capacity, see chapter 4 of the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm], and contains a set of key principles and a checklist to be used in ascertaining best interests, see chapter 5 of the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm]. The first core principle of the MC Act is that an adult must be assumed to have capacity 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 [www.opsi.gov.uk/acts/acts2005/ukpga_20050009_e www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_2].

83. It should therefore always be assumed that an adult has the capacity to make a decision unless there is reason to believe otherwise.

Consent – children

84. Under the HT Act, a child is defined as being under 18 years old [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5#pt3-pb2-l1g54]. Under the HT (Scotland) Act, a child is defined as being under 16 years old [www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_8#pt7-l1g60] (see information relating to Scotland at [paragraphs 54–57](#)).

85. As outlined within [paragraph 47](#) , the removal of an organ or part organ from a child is governed by the common law and the Children’s Act 1989 [www.opsi.gov.uk/acts/acts1989/ukpga_19890041_en_1]. Before any such procedure the approval of a court should be sought. Appendix A to this code provides further guidance on requirements for court approval.

86. The HT Act requires consent be given for the storage and use of organs for transplantation. Where a child is deemed competent to consent to that decision, the necessary consent will be their own. A person who has parental responsibility for the child can consent to the storage and use of organs for transplantation on the child’s behalf if there is no decision by the child either to, or not to, consent, and:

1. the child is not competent to deal with the issue of consent to donation
2. even though the child is competent to do so, they have not made a decision about consent to donation

87. 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 [www.opsi.gov.uk/acts/acts1989/ukpga_19890041_en_2].

Informing the donor

88. Potential donors must be provided with sufficient information for them to reach an informed decision about whether they wish to give consent. This information should be provided by the transplant team before the donor is interviewed by an IA.

89. All potential donors should be provided with a copy of the HTA leaflet Information about living donor transplants [www.hta.gov.uk/about_hta/publications/leaflets.cfm].

90. The following information should be explained in full to the donor:

1. the surgical procedures and medical treatments involved for the donor and the risks involved in both the short-and long-term (this should be explained by a medical practitioner with appropriate qualifications to give this information)
2. the chances of the transplant being successful and any possible side-effects or complications for both donor and recipient
3. the right to withdraw consent at any time, and the implications of doing so
4. their right to be free of any kind of coercion or threat against them or anyone else (for example, family or friends) and that consent seen to be given under any such pressure will not be validated by the IA
5. the fact that it is an offence to seek or receive payment or any other reward for providing organs or part organs for transplantation, and that this offence is subject to significant penalties (see [paragraphs 45–46](#))
6. donors are able to seek reimbursement of expenses, such as travel costs and loss of earnings that are reasonably attributable to and directly result from donation (see [paragraphs 42–44](#))

91. Information should be provided to the donor about the risks and potential complications or side effects for the recipient, as information on factors which could impact the life of the graft, or the recipient themselves, may be material to the donor’s decision-making process, and ensures fully informed consent can be given. Relevant information will vary on a case-by-case basis, and transplant teams should share information with donors following prior agreement with the potential recipient. Additional information for potential altruistic non-directed and paired organ donors

92. In respect of potential altruistic non-directed and paired or pooled donors the following information should also be provided:

1. anonymity of the donor and recipient is required before the operations, and that confidentiality must be respected
2. how the altruistic donor, paired or pooled process works and how suitable recipient/s, or in the case of paired or pooled donation suitable matches, are identified

Deceased organ donation

Requirements of the legislation and consent

93. The removal, storage and use of organs or part organs from a deceased person for transplantation is governed by the HT Act. Before they can be removed, stored or used for transplantation, appropriate consent must be obtained (see [paragraphs 96–103](#) and [115–118](#)).

94. The code of practice on Consent sets out guiding principles on how the law should be applied to consent for removal, storage and / or use of tissue, including organs, from the body of a deceased person. It should be consulted and read in conjunction with this code of practice.

95. Requirements for gaining authorisation for the removal and use of organs from a deceased person for transplantation in Scotland are laid down by the HT (Scotland) Act 2006 [www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1] and regulated by Scottish Ministers. The guidance in this section of the code does not therefore apply to Scotland. Guidance on requirements under the HT (Scotland) Act 2006 is available in the Scottish Health Department letter, Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland [http://www.hta.gov.uk/db/documents/Information_about_HT_%28Scotland%29_Act.pdf].

Consent – adults

96. The HT Act makes clear that where an adult made a decision to, or not to, consent to organ donation taking place after their death, then that consent is sufficient for the activity to be lawful.

97. In cases of potential deceased donation, the transplant coordinator or delegated person should be approached at an early stage and asked to determine whether the deceased person had consented to donate their organs after death. This should be done before partners, relatives or close friends are approached.

98. Trained staff should determine whether the deceased person had given consent for organ donation by checking relevant sources, such as the Organ Donor Register. If consent is established, those close to the deceased should be told.

99. If no records are held, an approach should be made to the deceased person's partner, relatives or close friends by a transplant coordinator or a member of the team who cared for the person, or both together, to establish any known decision of the deceased person to consent (or not) to donation.

100. Once it is known that the deceased person consented to donation, the matter should be discussed sensitively with those close to the deceased. They should be encouraged to recognise the wishes of the deceased and it should be made clear, if necessary, that they do not have the legal right to veto or overrule their wishes. There may nevertheless be cases in which donation is considered inappropriate and each case should be assessed individually.

101. If the deceased person's wishes are unknown and donation is a possibility, trained healthcare professionals should raise the subject of donation with the appropriate partner, relative/s or close friend/s. This approach should be made as sensitively as possible and provide enough information to allow a decision to be reached. Once a decision has been made, it must be respected.

102. If the deceased person's wishes are not known and they were an adult who had appointed a person to deal with the use of their body after death, then consent can be given by that nominated representative (see [paragraphs 104–108](#)).

103. If the deceased person's wishes are not known, and they had not appointed a nominated representative, consent can be given by a person who was in a qualifying relationship immediately before the death (see [paragraphs 109–114](#)).

Nominated representatives

104. Under the HT Act, adults may appoint one or more people to represent them after death and provide a decision on consent on their behalf. The trained healthcare professionals should make reasonable enquiries at the hospital, with the prospective donor's GP or with those close to the deceased person to ask whether a nominated representative was appointed to take those decisions.

105. The appointment of a nominated representative and its terms and conditions may be made orally or in writing. The HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_2#pt1-11q4] sets out the requirements for a valid appointment. The appointment of a nominated representative may be revoked at any time.

106. If the deceased person appointed more than one nominated representative, only one of them needs to give consent, unless the terms of the appointment specify that they must act jointly.

107. The nominated representative's consent cannot be overridden by other individuals, including family members. It is advisable, nevertheless, to ensure that appropriate consultation and discussion takes place between all those involved.

108. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practicable to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is

disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraphs 109–114).

Qualifying relationships

109. If the deceased person has not indicated their consent (or refusal) to the use of their organs for transplantation or, in the case of an adult, appointed a nominated representative, then the appropriate consent may be given by someone who was in a 'qualifying relationship' with the deceased person immediately before their death. Those in a qualifying relationship are found in the HT Act in the following order (highest first) http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_3#pt2-pb3-l1g27

- a. spouse or partner (including civil or same sex partner) The HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5#pt3-pb2-l1g54] states that for these purposes a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.
- b. parent or child (in this context a child can be any age and means a biological or adopted child)
- c. brother or sister
- d. grandparent or grandchild
- e. niece or nephew
- f. stepfather or stepmother
- g. half-brother or half-sister
- h. friend of long standing

110. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person high up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but others in the family wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs 111 and 113 should be observed in line with this principle. If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is unlawful to proceed with removal, storage or use of the deceased's persons organs or part organs for transplantation.

111. While the HT Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other family members – this may include people not on the list, for example, an aunt or uncle.

112. Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.

113. Where there is a conflict between those accorded equal ranking, then this needs to be discussed sensitively with all parties, whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead.

114. In applying the principles set out above, a person's relationship shall be left out of account if:

- i. they do not wish to deal with the issue of consent;
- ii. they are not able to deal with the issue; or
- iii. in relation to the activity for which consent is sought, it is not practical to communicate with that person within the time available if consent in relation to the activity is to be acted on [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_3#pt2-pb3-l1g27].

This means a person may be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, declines to deal with the matter or is unable to do so, for example, because they are a child or lack capacity to consent. In such cases, the next person in the hierarchy would become the appropriate person to give consent.

Consent – children

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

116. Clearly, in any case where a child has given consent to donation, especially if the child has self-registered on the Organ Donor Register [www.uktransplant.org.uk/ukt/how_to_become_a_donor/how_to_become_a_donor.jsp] it is essential to discuss this with the child's family,

and take their views and wishes into account before deciding how to proceed. In some cases it may also be advisable to establish with the person who had parental responsibility for the deceased child, whether the child was competent to make the decision. A person who has parental responsibility will usually, but not always, be the child's parent [www.opsi.gov.uk/acts/acts1989/ukpga_19890041_en_2#pt1-11g3].

117. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that in this instance the appropriate consent will be that of a person with parental responsibility for the child immediately before they died. The consent of only one person with parental responsibility is necessary.

118. If there is no person with parental responsibility (e.g., if the parents have also died, perhaps at the same time as the child), then consent for organ donation should be sought from someone in a qualifying relationship, as set out in [paragraphs 109–114](#). Under the HT Act, children cannot appoint nominated representatives and therefore provisions relating to seeking consent from nominated representatives do not apply.

Withdrawal of consent

119. Where a relative or close friend of a deceased person has been asked for consent to remove and use an organ (from the deceased person) for transplantation and consent has been given, that consent cannot be withdrawn once an incision has been made to remove the organ.

120. This must be made clear to the person giving consent at the time it is obtained, and their acceptance recorded.

Roles of the HTA and NHSBT

121. The HTA ensures that in all cases of deceased donation appropriate consent is in place, by overseeing the implementation of the HT Act requirements as outlined in [paragraphs 95–120](#).

122. NHSBT is responsible for the national allocation system which facilitates deceased donor transplantation. NHSBT also maintains the Organ Donor Register [www.uktransplant.org.uk/ukt/how_to_become_a_donor/how_to_become_a_donor.jsp].

Preservation of organs in cases of uncontrolled non-heart beating donation

123. As outlined earlier in this code (see [paragraphs 96–118](#)), where donation is a possibility, the deceased's wishes regarding organ donation should be established as soon as possible. Where the deceased's wishes are unknown, the views of the relatives on donation should be sought (see [paragraph 101](#)). There may be occasions when steps need to be taken to preserve the viability of an organ, while it is being established if a decision on consent has been, or will be, made.

124. Preservation of parts of a deceased person's body for potential use for transplantation is dealt with under Section 43 of the HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5]. The HT Act makes it lawful to take minimum steps to preserve part of a body for potential transplantation, including in those situations where it is still being established if a decision on consent has been, or will be, made.

125. In uncontrolled non-heart beating cases, the coroner's jurisdiction, common law powers and statutory obligations under the 1988 Coroners Act [www.opsi.gov.uk/acts/acts1988/ukpga_19880013_en_1.htm] also arise automatically and immediately (see [paragraphs 133–134](#)), and must also be taken into account when any decision regarding taking steps to preserve an organ is required. It should be borne in mind that the parallel powers of the coroner arise when the body is lying in that coroner's jurisdiction as well as within a hospital, nursing home or other institution.

126. In all cases, steps should therefore be taken as soon as possible to find out not only the deceased's wishes on donation, or where these are unknown, the views of the relatives of the deceased (see [paragraph 101](#)), but also whether the local coroner is obliged or otherwise intends to assume jurisdiction to investigate the cause of death (see [paragraphs 133–134](#)).

127. In cases where the wishes of the deceased regarding consent for organ donation cannot be established, consent should be sought, where possible, from their relatives before the preservation process begins.

128. However, as outlined above it will not always be possible to obtain a decision on consent quickly enough to prevent the relevant organs deteriorating. In these circumstances, while continuing to establish a position on consent, it is lawful for the establishment to:

- i. take the minimum steps necessary (subject to the coroner's consent where required) to preserve the part for use in transplantation using the least invasive procedure, such as cold perfusion and intraperitoneal cooling
- ii. retain the body of a deceased person for that purpose

129. Whether a procedure constitutes the 'minimum steps' should be considered in terms of both what is least invasive to the donor, and also in terms of what may be perceived as appropriate by the family.

130. Permission to carry out preservation of this type ceases when it has been established that consent has not been given for organ removal. All procedures to preserve the body must then be stopped immediately.

131. The taking and storage of blood samples is a necessary action to ensure the preserved organ can be used for transplantation in cases where consent for donation is later given. Blood samples can also therefore be taken before perfusion in order to preserve the option for

donation until a decision on consent has been established.

132. Guidance on the process for preservation is provided in the British Transplantation Society's Guidelines relating to solid organ transplants from non-heart beating donors [<http://bts.demo.eibs.co.uk/transplantation/standards-and-guidelines/?locale=en>].

Working with the coroner in cases requiring steps to be taken for organ preservation

133. In order to ensure that conflicts do not arise between the provisions of section 43 of the HT Act [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5] for the preservation of organs and the lawful powers or authority of the coroner when a body is lying in the coroners jurisdiction, a generic memorandum of understanding should be pre-emptively agreed with the local coroner where possible. Specific notification of the coroner should also occur on a case-by-case basis where appropriate.

134. Appendix B provides good practice guidelines on the detailed steps to be taken in the process of organ preservation and working with the coroner. There will need to be local agreement to, and ownership of, the guidelines by the coroner and the organ retrieval teams.

Licensing requirements and organ transplantation

Licence exceptions

135. The storage of an organ or part organ (from the body of a living or deceased person) for the purpose of transplantation, which is to be used for the same purpose as the entire organ in the human body, is excepted from licensing requirements under the HT Act.

136. The storage of other tissue and cells for the purpose of transplantation is also excepted from licensing if the material is stored for less than 48 hours.

137. Blood and its derivatives used for the purpose of transplantation (including transfusion) are not considered relevant material [www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm], for the purposes of section 16 of the HT Act and are therefore excepted from the HTA licensing requirements under that section. Additionally, under the Q&S Regulations [www.opsi.gov.uk/si/si2007/uksi_20071523_en_1] the procurement, processing, preservation, testing, storage, distribution, import or export of blood and blood components for human application are not licensable. However, the procurement, processing, preservation, testing, storage, distribution, import or export of lymphocytes intended for haematopoietic stem cell transplantation are licensable under those Regulations.

138. A licence is not required under the HT Act for relevant material (from the living or deceased) removed, stored or used with the intention of transplantation and subsequently retained as part of a diagnostic archive.

Licence requirements – HLA tissue typing

139. If samples of relevant material from a deceased donor, such as blood, lymph nodes or spleen, are being stored for tissue typing to determine the suitability of an organ for a recipient, this is storage for the purpose of transplantation and subject to the licensing exceptions outlined above. If those samples of relevant material are subsequently stored as part of the diagnostic archive of the recipient, a licence is not required, however if such samples are subsequently stored for research, a licence may be required under the HT Act (paragraphs 142–145).

Licence requirements – procurement of vessels at the time of organ retrieval

140. A procurement licence will not be required for vessels that are removed at the same time as the donor organ and are used in a single procedure for one recipient.

141. A procurement licence (or third party agreement with a tissue establishment) is needed if vessels removed at the same time as a donor organ are intended to be stored for more than 48 hours and not used for immediate organ transplant. Vessels should be procured according to the standards set out in the Q&S Regulations [www.opsi.gov.uk/si/si2007/uksi_20071523_en_1] and HTA Directions 001/2006 and 002/2007 [www.hta.gov.uk/guidance/licensing_guidance/expected_standards.cfm] and a licence will be required for storage where storage exceeds 48 hours.

Licence requirements – Research

142. A licence is required under the HT Act for the removal of relevant material from a deceased person for the purpose of research. The removal must take place on licensed premises.

143. The compliance report licence application form for post mortem and related activities allows the option of requesting a licence for removal of relevant material from the body of a deceased person for use for a scheduled purpose other than transplantation. That means that most establishments that have a post mortem licence will also have a licence covering removal for research.

144. The storage of relevant material for the purpose of research also requires a licence, unless it is for a specific research project which is approved by a recognised research ethics committee (or where such approval is pending).

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

146. Relevant material removed for the purpose of transplantation can be used for research with the valid consent of the donor or a person in a qualifying relationship to the donor (see paragraphs 109–114).

147. In cases where it is unknown whether donated tissue or organs will be used for transplantation or research, valid consent should be obtained at the outset for both transplantation and research. For further guidance on valid consent, refer to the code of practice on Consent .

148. Further guidance on both consent and licensing requirements for research can be found in the code of practice on Research. The above guidance is applicable to cases involving research using tissue and organs from a deceased donor; the code of practice on Research also provides guidance on research using tissue from the living.

Further guidance on licensing

149. Further guidance on the licensing requirements of the HT Act is available from the HTA's website [www.hta.gov.uk/guidance/licensing_guidance.cfm].

150. For further detailed guidance on tissue for human application refer to Directions issued by the HTA summarising the requirements of the EUTCD and the Q&S Regulations [www.hta.gov.uk/about_hta/eutcd_information.cfm].

Appendix A - Guidance on requirements for court approval

A1. The guidance in this Annex does not apply to Scotland.

Adults without capacity

A2. Some decisions relating to medical treatment or intervention involving adults lacking capacity are so serious that case law determines that an application should be made to the Court of Protection [www.publicguardian.gov.uk/about/court-of-protection.htm] for a declaration that the proposed treatment or intervention is lawful, and under the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm] cases involving organ donation by an adult who lacks capacity to consent fall within this category. This is because the donation does not, on the face of it, directly or physically benefit the prospective donor. However the court may decide that it is in the overall best interests of the prospective donor.

A3. In all such cases relating to adults without capacity, a court declaration should be in place before the case is referred to the HTA for a decision on approval for the donation to proceed. It is expected that such cases would be rare.

A4. Cases where there is a dispute over whether a prospective donor has capacity should also be referred to the Court of Protection [www.publicguardian.gov.uk/about/court-of-protection.htm].

A5. In the case of a prospective donor, the Trust hospital where the transplant is to take place will normally be the person applying to court. The Trust's legal advisers should be consulted and any standard Trust procedures for referrals to court should be followed. The applicant could also be a relative or carer.

A6. The Court of Protection Rules 2007 [www.opsi.gov.uk/si/si2007/uksi_20071744_en_1], and the accompanying Practice Directions [[www.publicguardian.gov.uk/docs/09E - Serious Medical Treatment PD.pdf](http://www.publicguardian.gov.uk/docs/09E_-_Serious_Medical_Treatment_PD.pdf)] and [[www.publicguardian.gov.uk/docs/10B - Urgent and interim applications PD.pdf](http://www.publicguardian.gov.uk/docs/10B_-_Urgent_and_interim_applications_PD.pdf)], set out the procedure for bringing an application to the court. However, before a decision is made about an application, a family and medical litigation lawyer at the Official Solicitor's office should be contacted. More information can be obtained from the Official Solicitor's website [<http://www.officialsolicitor.gov.uk/>].

A7. In most cases, the applicant must first obtain court permission to proceed for a court declaration, and this will involve the filing of relevant forms and submission of evidence for court consideration. In certain emergency cases, an application can be made out of court hours by telephone to a judge, without issuing a written application and without notice to the other parties to the application. Further details can be obtained from the Official Solicitor's website [<http://www.officialsolicitor.gov.uk/>].

Children

A8. In the rare case where a child (a person under 18) is being considered as a potential organ donor, case law suggests that the case should be referred to court for a ruling on whether the proposed intervention is lawful. (In cases involving 16–17 year olds who may lack capacity under the terms of the MC Act [that is lacking capacity due to an impairment of, or disturbance of, the mind or brain, whether permanent or temporary] the requirements of the MC Act code of practice [www.publicguardian.gov.uk/mca/code-of-practice.htm] apply.)

A9. As with cases involving adults lacking capacity, this is because the procedure is not, on the face of it, therapeutic and obviously in the best interests of the prospective donor child. The court will have to determine, based on the evidence, whether it is in fact in the best interests of the prospective donor child. This test is not limited to medical interests, and should take account of potential emotional, psychological and social benefits and risks.

A10. In such cases, a court ruling on best interest should be in place before the case is referred to the Authority for a decision on approval for the donation to proceed.

A11. If the court is asked to consider the matter, the welfare of the prospective donor child will be the court's paramount consideration and not the welfare of the recipient. The 'welfare checklist' which is set out in the Children Act 1989 [www.opsi.gov.uk/acts/acts1989/ukpga_1989004:www.opsi.gov.uk/acts/acts1989/ukpga_19890041_en_1] will be considered by the court in determining the application.

A12. Any application to court would usually be made by the Trust wishing to carry out the procedure, or in some cases a parent (or other person with parental responsibility for the child) if the donation is for a sick sibling or other relative.

A13. The Family Proceedings Rules 1991 (SI 1247) [www.opsi.gov.uk/si/si1991/Uksi_19911247_en_1.htm] set out the procedure for such applications. The equivalent Northern Ireland legislation is The Family Proceedings Rules (Northern Ireland) 1996 (SR 322) [http://www.opsi.gov.uk/Sr/sr1996/Nisr_19960322_en_1.htm]. Any Trust or person considering making an application should consult their own solicitors and a family lawyer at the Children and Family Court Advisory and Support Service (CAFCASS) [<http://www.cafcass.gov.uk/>] or, in Wales, CAFCASS Cymru [www.new.wales.gov.uk/cafcasscymru/home/?lang=en] before embarking on such an application. CAFCASS is an independent body set up by the government to safeguard the welfare of children and make provision for them to be represented.

Appendix B

Guidelines for transplant teams and coroners in cases of potential uncontrolled non-heart beating donation requiring steps to be taken for organ preservation

B1. The following steps in the process are recommended:

- i. The potential donor should be identified by emergency department staff. The coroner must be informed and advised whether a medical practitioner will issue a Medical Certificate of The Cause of Death (MCCD) or that the death is sudden and of unknown cause or unnatural, traumatic or violent.
- ii. The donor coordinator should be contacted to attend, in order to determine likely suitability based on history and duration of warm ischaemia, and liaise with the coroner's officer or court staff.
- iii. Any requirements of the coroner should be met to enable determination of the cause of death. This may mean that the coroner requires a post-mortem examination and that perfusion and organ retrieval cannot proceed. If the coroner exercises discretion in favour of permitting perfusion subject to further investigations, then the local memorandum of understanding agreed with the coroner should be adopted, in order to obtain blood samples for potential toxicology as well as samples required for potential organ retrieval and donation.
- iv. Certain criteria may mean that this could proceed without immediate coroner notification in some situations. It is possible that when death is verified in the emergency department and then certified by a registered medical practitioner who is able to issue a MCCD for a natural cause of death, then the death does not need to be reported to the coroner. If in doubt then the case should be reported.
- v. The Organ Donor Register (ODR) should be searched in order to ascertain wishes of the patient.
- vi. If the patient is registered on the ODR, this should be communicated to the nominated representative or person in a qualifying relationship if they are available, and subject to coroner approval, perfusion should commence. In the case of a child the person with parental responsibility must be consulted in the first instance.
- vii. If the patient is not registered on the ODR and their wishes relating to donation are not known, consent should be sought from the nominated representative or person/s in a qualifying relationship, and subject to the coroner's approval, perfusion should commence.
- viii. If the wishes of the deceased are unknown and no nominated representative or person/s in a qualifying relationship can be contacted, perfusion may be instigated, subject to the coroner's approval, while attempts to contact the nominated representative or person in a qualifying relationship continue.
- ix. Subject to the coroner's approval as discussed above, and where they are contactable, the consent of the nominated representative or person in a qualifying relationship, the femoral vessels should be cannulated. Blood specimens for both the coroner and organ donation purposes must be taken before perfusion is started.
- x. Where the deceased wishes are unknown and the nominated representative or a person/s in a qualifying relationship is not available before perfusion being instigated, consent or refusal to consent to organ donation should be confirmed/ obtained when they arrive. In any event, it should be advised that the death may still remain the subject to the jurisdiction of and investigation by the coroner.
- xi. If consent for organ donation has been established or obtained, the patient may be transferred to theatre for removal of organs.
- xii. All conversations and discussions including operative findings, should be documented in the patient's notes for reference by other healthcare professionals and the coroner.

References

References are listed in the order in which they appear in the code. Supplementary references are included at the end.

[Human Tissue Act 2004](#)

[Human Tissue \(Scotland\) Act 2006](#)

[The Human Tissue \(Quality and Safety for Human Application\) Regulations 2007](#)

[Human Tissue \(Scotland\) Act 2006: A guide to its implications for NHS Scotland issued on 20 July 2006 \(Ref: NHS HDL \(2006\) 46\)](#)

[HTA codes of practice](#)

[HTA Directions](#)

[HTA Guidance for transplant teams and Independent Assessors](#) sets out in detail, by way of a step-by-step guide, the process that should be followed when assessing and approving cases of living organ donation. This code focuses on the HT Act requirements. Both documents should therefore be read in conjunction.

[Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006](#)

[Department of Health Consent guidance](#)

[Mental Capacity Act \(MC Act\) 2005](#)

[Welsh Assembly Government Reference guide to consent for examination or treatment](#)

[Department of Health, Social Services and Public Safety \(DHSSPS\) \(Northern Ireland\) Reference guide to consent for examination, treatment or care](#)

[Department of Health guidance Reimbursement of living donor expenses by the NHS](#)

[Children Act 1989](#)

[Office of Public Guardian](#)

[Mental Capacity Act 2005 code of practice](#)

[Welsh Assembly Government guidance on the Mental Capacity Act 2005](#)

[Department of Health, Social Services and Public Safety \(DHSSPS\) \(Northern Ireland\) Consent documents](#)

[The Adults with Incapacity \(Scotland\) Act 2000](#)

[Human Organ and Tissue Live Transplants \(Scotland\) Regulations 2006 \(the Scottish Live Transplants\)](#)

[HTA leaflet on Information about living donor transplants](#)

[Organ Donation Register](#)

[Coroners Act 1988](#)

[British Transplantation Society standards and guidelines](#)

[HTA definition of relevant material](#)

[HTA licensing guidance](#)

Guidance on tissue for human application is not covered in this code. Information on this can be found in [Directions issued by the HTA summarising the requirements of the Q&S Regulations and the EUTCD](#). These Regulations transpose into UK law the requirements of the EUTCD, which creates a common framework that ensures high standards in the procurement, testing, processing, storage, distribution and import / export of tissues and cells across the European Economic Area (EEA) community.

[Court of Protection](#)

[Court of Protection Rules 2007](#)

[Practice Directions to supplement part 9 of the Court of Protection Rules 2007](#)

[Practice Directions to supplement part 10 of the Court of Protection Rules 2007](#)

[Official Solicitor's website](#)

[Family Proceedings Rules 1991](#)

[Children and Family Court Advisory and Support Service \(CAFCASS\)](#)

[CAFCASS Cymru](#)

Supplementary references

[Welsh Assembly Government consent documents](#)

[Welsh Language Act](#)

[E-learning course for IAs](#)

[HTA guide to our key messages](#) – which explains the HTA's roles and responsibilities

[HTA e-newsletter](#) – which provides regular news and updates about the HTA's work

Glossary

Altruistic non-directed donation: A form of living donation whereby an organ (usually a kidney) or part organ (for example liver or lung lobe) is donated by a healthy person who does not have a relationship to the recipient.

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.

Autologous: Cells, tissue or organs removed from and applied or transplanted into the same person.

Best interests: A test of a person's best interests takes into account not only the medical but also the wider emotional, psychological and social aspects of the potential procedure, as well as the risks.

Bone marrow: The soft, spongy tissue found in the centre of most large bones that produces the cellular components of blood: white cells, red cells and platelets.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue. For establishments licensed for human application this includes cell lines grown outside the human body but not gametes, embryos outside the human body, or blood and blood components.

Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part of an organ (e.g. liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired / pooled donation).

Domino donation: A form of living donation where an organ or part organ is removed for the primary purpose of a person's medical treatment. The organ(s) removed may prove suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart or lung transplant).

Donation: The act of donating human tissue, cells, organs or part organs for a scheduled purpose either during life or after death.

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

Emotionally related donation: Where the potential donor has a relationship with the potential recipient, for example, spouse, partner or close friend.

Genetically related donation: Where the potential donor is genetically related to the potential recipient.

Heartbeating donors: Patients diagnosed with brain stem death that continue to be ventilated. This keeps the heart beating and blood circulating after death, until donation takes place.

Human application: In relation to tissue or cells, 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: A person trained and accredited by the HTA to act as a representative of both the donor and the HTA to ensure the relevant requirements of the HT Act and HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 are met, for certain types of living organ transplantations.

Intraperitoneal cooling: A method of surface cooling of organs by infusing cold fluid into the abdominal cavity to aid preservation after death of the donor for the purposes of transplantation.

Licensing: A number of activities can only be carried out where the establishment is licensed under the HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under an HTA licence. All establishments working under an HTA licence must work to specified standards set by the HTA.

Licensed premises: Where the licensed activity takes place. If the licensed activity will take place at more than one place, a separate licence will be issued for each place. Premises in different streets or with different postal codes are considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

Living donor: The person donating tissue, cells or organs for transplantation. The most common forms are live kidney donation (where one kidney is removed), or live bone marrow donation.

Lymphocytes: White blood cells that fight infection and disease.

Nominated representative: A person appointed to represent someone after their death who is empowered 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-heartbeating donation: A form of donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs once death is certified following cardiorespiratory arrest (i.e. the donor's heart has stopped beating). 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.

Organ: Defined by the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

Organ Donor Register: A confidential, computerised 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. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.

Paired donation: Where a relative, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, and they are matched with another donor and recipient in a similar situation, so that both people in need of a transplant receive a compatible organ.

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.

Part organ: For the purposes of the HT Act and the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, material is part of an organ if it is to be used for the same purpose as the entire organ in the human body.

Perfusion: A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death, and in the living donor after the organ has been removed.

Pooled donation: A form of paired donation whereby the donor and recipient are incompatible and so are matched with other donors and recipients from a pool of pairs in similar situations. More than two donors and two recipients are involved in the exchange, so that more than two people in need of a transplant receive a compatible organ.

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. A hospital post-mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post-mortem examinations are carried out under the authority of the coroner and without consent to assist coroners in carrying out their functions.

Processing: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human application.

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: Person/s who can give consent for the deceased person if the deceased person has not indicated their consent nor appointed a nominated representative.

Relevant material: Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT 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 [www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm].

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 of new knowledge.

Recognised Research Ethics Committee:

- a Research Ethics Committee (REC) established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727]; or
- an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004 [www.opsi.gov.uk/si/si2004/20041031.htm].

Scheduled purposes: Under the provision of the HT Act consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The purposes are divided into 2 parts:

Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation.

Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance

assessment, public health monitoring, quality assurance.

Stem cell: A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.

Tissue: Any and all constituent part/s of the human body formed by cells.

Transplantation: An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.

Transplant coordinator: A person who helps a potential transplant recipient to understand the transplant process and also coordinates the transplant evaluation between the dialysis unit, transplant surgeon, and tissue typing laboratory. After a transplant operation, the transplant coordinator provides a communication link between the recipient and the transplant doctors for post-transplant care.

Valid consent: Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.