

Code F

DONATION OF SOLID ORGANS AND TISSUE FOR
TRANSPLANTATION
PART 1 – LIVING ORGAN DONATION

Public Health

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Human Tissue and Organ Donation Act 2021

Code F: Donation of solid organs and tissue for transplantation

Part 1 – Living organ donation

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

1. Section 19 of the Human Tissue and Organ Donation Act 2021 (HTODA) extended Cabinet Office’s (CO) regulatory functions. These functions include.
 - a) maintaining a statement of the general principles that CO believes should be followed when carrying-on activities, and functions in relation to them, under the HTODA;
 - b) providing general oversight and guidance in relation to activities under the HTODA as CO considers appropriate;
 - c) superintending, in relation to activities under the HTODA, compliance with Parts 2 and 3 of the HTODA and these Codes of Practice;
 - d) providing to the public, and to persons carrying on activities under the HTODA, such information and advice as it considers appropriate about the nature and purpose of such activities; and
 - e) securing publicity on or around 15th March of each year on the desirability of making organs and tissue available for the purposes of transplantation.
- 1A. Section 20 of the HTODA requires any person undertaking certain activities under the Act to, following an inspection, obtain a licence from CO.

Public Health (PH), as part of CO, have the delegated authority to undertake inspections, issue licences and advise CO on the undertaking of its other functions under the HTODA.
- 1AA. The types of activities PH will regulate on behalf of CO through licensing and inspection are –
 - a) post-mortem examination;
 - b) anatomical examination;
 - c) public display of tissue from the deceased; and
 - d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.
- 1B. CO and PH will also regulate the Department of Health and Social Care’s (DHSC) activities under the HTODA, which may be delegated by DHSC to Manx Care, or supported by National Health Service Blood & Transplant (NHSBT) as appropriate.
- 1BB. A comprehensive list of DHSC’s activities under the HTODA are set out in section 18 (DHSC’s remit) of that Act, but in summary they include –
 - a) for either a scheduled purpose or for the purposes of UK legislation referenced by the HTODA, the obtainment¹, processing, testing, storage, distribution, removal, use, import, export and disposal of human tissue;

¹ See glossary.

- b) for either a scheduled purpose or for the purposes of UK legislation applied by the HTODA, the donation, testing, characterisation, obtainment, preservation, transport, import, export, storage, transplantation and disposal of human organs;
 - c) the disposal of an organ or tissue which has been removed from a person's body for medical treatment;
 - d) the carrying out of anatomical examination, and the making of post-mortem examinations undertaking of post-mortem and examinations, and the associated disposal of organs and tissues as a consequence of these activities
2. Further information about the legislative background and context of the HTODA and its Codes of Practice is set out at Annex A.
 3. Further information about the legislative background and context of the HOTDA and its Codes of Practice is set out at Annex A.
 4. This document is part of a suite of seven Codes of Practice produced by CO:
 - **Code A:** Guiding Principles and the Fundamental Principle of Consent;
 - **Code B:** Post-mortem examination;
 - **Code C:** Anatomical examination (including import/export);
 - **Code D:** Public display (including import/export);
 - **Code E:** Research (including import/export);
 - **Code F – Part 1:** Living organ donation;
 - **Code F- Part 2:** Deceased organ and tissue donation;
 - **Code G:** Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation.
 4. The Codes give practical guidance to professionals carrying out activities which lie within the CO's remit under the HTODA the UK legislation applied to the Island further to that Act, and any secondary legislation made under that Act (subject to any modifications made by an order under section 71 of the HTODA).
 5. While the Codes of Practice will be of interest to members of the public, the Codes will be relevant to professionals carrying out activities under:
 6. The Codes of Practice provide guidance on activities within the scope of CO's general functions under the HTODA. Whilst PH, and CO more generally, may offer advice on matters outside of those general functions, neither CO nor PH have any requirement under the HTODA in relation to the provision of such advice. CO and PH will endeavour to provide signposts to other agencies where issues arise that are beyond the reach of CO and PH.
 7. The Codes of Practice do not include information about the analysis of DNA. This is because CO has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in section 68 (non-consensual analysis of DNA) and Schedule 3 (section 68: supplementary) of the HTODA. Separate guidance in the form of frequently asked questions is available on the website www.gov.im.

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

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

- a) donated organs and tissue must be used in accordance with the expressed wishes of donors, their nominated representatives, or their relatives;
- b) donors and their relatives must be given the information they need to be able to make a decision that is right for them; and
- c) 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.

This Code is divided into two parts:

- a) Part 1: Living organ donation; and
- b) Part 2: Deceased organ and tissue donation.

This Code, Code of Practice F (Part 1) provides supplementary guidance to clinicians working in living organ donation. Part 2 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, the Codes of Practice are intended to provide anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation as well as CO and PH policy.

Introduction to Code F – Part One

Scope of this Code

10. Living organ donation does not take place on the Island. It may take place in the UK, or elsewhere, subject to the legal and regulatory controls in effect in those jurisdictions.
11. Manx Care may provide support to persons wishing to consent to, or undergo, living organ donation, i.e. 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.
12. In deceased donation, the removal, storage and use of organs and tissue for transplantation (including Vascularised Composite Allografts transplants) is governed by the requirements of the HTODA and Part 2 of this Code. Before organs and tissue can be removed, stored or used for transplantation from deceased person, appropriate consent must be obtained. Part 2 of this Code advises practitioners on meeting the necessary consent provisions for this activity to be undertaken lawfully in those circumstances.
13. In addition to the consent requirements above, establishments may also be subject to the licensing requirements under the HTODA.

Offences under the HTODA

14. The HTODA sets out a number of offences, for which the penalty may be imprisonment or a fine, or both. In relation to organ and tissue donation, the offences are as set out below.
15. Section 12 (prohibition of activities without consent etc.) of the HTODA makes it an offence to remove organs and tissue from the deceased and to store and use bodies, organs and tissue for a purpose set out in Schedule 1 of the HTODA (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 12 of the HTODA also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that section 7 (authorisation of activities for scheduled purposes) of the HTODA does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.
16. Section 15 (restriction of activities in relation to donated material) of the HTODA makes it an offence to store or use donated material for anything other than a qualifying purpose.
17. Section 31 (prohibition of commercial dealings in human material for transplantation) of the HTODA makes it an offence to engage in commercial dealings in human material for transplantation (see paragraphs 40-43).
18. Section 32 (restrictions on transplants involving a live donor) makes it an offence to remove and use transplantable material from living donors unless in compliance with regulations made under that section.
19. Section 33 (information about transplant operations) 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. Unlike the offences set out in paragraphs 15 to 18, 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 HTODA 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 (e.g. requesting an organ be allocated to a specific person or group of persons – a “requested allocation”).
21. Whilst living organ donation may not take place on the Island, the HTODA recognises that individuals have the autonomous right to give or refuse consent to all or any of their organs or tissue being used for transplantation after their death 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 2017). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 2001, and arises from the equality duty placed on CO, DHSC and other public authorities by the Equality Act 2017.
24. On behalf of the DHSC and Manx Care, NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation in the Island (and 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:
 - a) Part 1: Living organ donation; and
 - b) Part 2: Deceased organ and tissue donation.

Part 1 provides supplementary guidance to clinicians working in living organ donation. Part 2 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 set out in Annex B at the end of the document. You can view, download and print copies of all the Codes from the website www.gov.im.

Part One – Living organ donation

Types of living organ donation

28. There are a number of different concepts in living organ donation. These concepts, which are defined in the glossary set out in Annex B, 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. There is no provision under the HTODA to allow for living organ donation to take place on the Island. Before supporting donor in providing such materials in the UK, or elsewhere, Manx Care should take reasonable steps to ensure the donor is making an informed decision.
30. The HTODA governs the consent requirements for the storage and use of organs or part organs taken from a living person for the purpose of transplantation, which may also serve to meet the consent requirements for organ donation in the United Kingdom further to the requirements of the Human Tissue and Organ Donation Act 2004 (of Parliament).
31. Consent for the removal of organs from living donors, whether for transplantation or otherwise, is covered by common law, the Mental Health Act 1998 (MH Act) and the [Mental Health Act 1998 Code of Practice](#) [March 2011] (MH Act Code of Practice), where appropriate. Manx Care should have a local policy in place for obtaining consent to treatment having regard to the legal position set out in the UK DHSC's *Reference guide to consent for examination or treatment*.
32. The restrictions on and requirements for living organ donation and transplantation are set out in sections 32 (restriction on transplants involving a live donor) and 33 (information about transplant operations) of the HTODA and the associated regulations. The law and regulatory requirements relating to bone marrow and PBSCs donation are relatively complex. If a practitioner is in any doubt about how to proceed they are advised to discuss it with the NHSBT or PH.
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 HTODA, the donation would not be subject to the regulatory requirements which apply to other types of living donation (see paragraphs 35-39).
35. Omit.
36. Omit.

- 37. Omit.
- 38. Omit.
- 39. Omit.

Commercial dealings in human material for transplantation

- 40. Checks must be made to ensure that no reward has been given, or is to be given, for the donation. However, the HTODA 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 Donors in England.
- 41. Where reimbursement is not made by DHSC or Manx Care, 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. Section 31 (prohibition of commercial dealings in human tissue for transplantation) of the HTODA 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 controlled material;
 - b) seeks to find a person willing to supply any controlled material for reward;
 - c) offer to supply any controlled material 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 controlled material;
 - e) omit;
 - f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any controlled material 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. It is not an offence to advertise, via either traditional or social media, to find a suitable donor. It is however an offence to offer a reward as part of any such advertisement.

Donation by children

44. Children can be considered as living organ donors only in extremely rare circumstances. The HTODA 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 PH at the earliest opportunity. Regard should also be given to chapters 15 and 31 of the MH Act Code of Practice with respect to the capacity of children to grant consent.
45. In accordance with common law and the [Children and Young Persons Act 2001](#) (which established the legal basis for who has parental responsibility), court approval should be obtained before a child is transported off-Island for the removal of a solid organ or part organ from a child for donation. Manx Care should obtain their own legal advice regarding seeking court approval.
46. Omit.

Donation by adults lacking capacity to consent

47. The HTODA does not specify the criteria for considering whether an adult has capacity to consent. Under the MH Act Code of Practice, a person aged 16² and over is unable to make a particular decision if they cannot do one or more of the following things:
 - a) take in and retain the information given to them that is material to the decision, especially as to the likely consequences of having or not having that treatment;
 - b) believe the information;
 - c) weigh up the information in the balance as part of the decision-making process;
48. Full guidance on how the MH Act defines capacity and how it should be assessed are given in chapters 15 and 16 of the MH Act Code of Practice.
49. The provisions of the MH Act and the MH Act Code of Practice should be considered together with general principles governing capacity to consent to medical procedures.
50. The MH Act and the MH Act Code of Practice defines persons who lack capacity and how consent may be provided for medical treatments³. Paragraph 15.10 of the MH Act Code of Practice provides that, as a basic principle, an adult must be presumed 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.
51. Omitted.
52. Omitted.
53. Omitted.
54. Omitted.

² Paragraph 13.14 provides that a child aged 16 or 17 to consent to any surgery, medical or dental treatment as if he or she were of full age, and if that consent is given the consent of a parent (or other person with parental responsibility) is unnecessary further to section 8 of the [Family Law Reform \(Isle of Man\) Act 1971](#).

³ See chapters 15 and 16 as well as, with respect to matters involving children, chapter 31 of the MH Act Code of Practice.

Requirements for court approval for adults lacking capacity

55. There is no provision in regulations under section 13 (activities involving organs or tissue from adults who lack capacity to consent) of the HTODA for appropriate consent for the removal of material from a living adult who lacks capacity to consent for himself or herself. If such a treatment is to be provided it must be undertaken outside of the Island.
56. The MH Act Code of Practice states that, where an adult lacks the capacity to consent then, in accordance with the common law doctrine of necessity, the treatment must be necessary to save life or prevent a deterioration or ensure an improve in the patient's physical or mental health. Chapter 15 of the MH Act Code of Practice sets out the procedures that are to be followed in applying this common law doctrine. CO believes that the same approach should be adopted where Manx Care are supporting the donation of organs and tissue outside of the Island in such circumstances.
57. Omitted.
58. Manx Care should take their own legal advice if they are considering following the above route.
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 NHSBT and PH at the earliest opportunity.

Guidance for Clinicians and Transplant Teams

60. Clinicians are responsible for the overall care of donors.
61. Omit.
62. Any person travelling to the UK with the support of Manx Care to make a donation 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 in that jurisdiction and how this will affect them.
- 62A All decisions made on behalf of the donor must be made in the donor's overall best interests.

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.
64. The HTODA requires that consent be obtained to store and use organs for transplantation. Consent for removal is governed under common law. 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 and guidance may be provided via the gov.im website.

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.
68. If a donor lacks the capacity to consent, it is recommended that contact is made with the NHSBT early on during the work-up process 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 HTODA.
70. To ensure that the informed consent of the donor is secured, the following areas must be 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.

Paragraphs 75 to 110 are omitted.

Annex A

To be inserted.

Annex B: Glossary

To be inserted