

Code G

DONATION OF ALLOGENEIC BONE MARROW AND
PERIPHERAL BLOOD STEM CELLS FOR TRANSPLANTATION

Public Health

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Human Tissue and Organ Donation Act 2021

Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

Contents

Contents	2
Introduction to Cabinet Office’s Codes of Practice for the Human Tissue and Organ Donation Act 2021	3
Introduction to the Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation Code	6
Scope of this Code	6
Offences under the HTODA.....	6
Structure and navigation	6
Bone marrow and PBSCs donation	7
Legal considerations.....	7
Determining capacity in adults	7
Assessing capacity to consent	8
Requirements for court approval for adults lacking capacity.....	8
Determining competence in children.....	9
Children aged under 16	9
Children aged 16 and 17.....	9
Requirements for court approval for children without competence.....	9
Commercial dealings in human material for transplantation	10
Guidance for clinicians	11
Valid consent for child donors	11
Involving the donor.....	12
Annex A	13
To be inserted.	13
Glossary	14

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

¹ See glossary.

- c) the disposal of an organ or tissue which has been removed from a person's body for medical treatment;
 - d) the carrying out of anatomical examination, and the making of post-mortem examinations undertaking of post-mortem and examinations, and the associated disposal of organs and tissues as a consequence of these activities.
2. Further information about the legislative background and context of the HTODA and its Codes of Practice is set out at Annex A.
 3. This document is part of a suite of seven Codes of Practice produced by CO.
 - **Code A:** Guiding principles and the fundamental principle of consent;
 - **Code B:** Post-mortem examination;
 - **Code C:** Anatomical examination (including import/export);
 - **Code D:** Public display (including import/export);
 - **Code E:** Research (including import/export);
 - **Code F – Part 1:** Living organ donation;
 - **Code F – Part 2:** Deceased organ and tissue donation;
 - **Code G:** Donation of allogeneic bone matter and peripheral blood stem cells (PBSCs) for transplantation.
 4. The Codes of Practice give practical guidance to professionals carrying out activities which lie within DHSC's and Manx Care's remit; CO's general functions under the HTODA; any secondary legislation made under that Act; and any UK legislation that is read as applied to the Island further to that Act (subject to any modifications made by an order under section 71 of the HTODA).
 5. While the Codes of Practice will be of interest to members of the public, the Codes will be relevant to professionals carrying out activities under:
 - a) the *[IOM equivalent to UK's Human Tissue (Quality and Safety for Human Application) Regulations 20^{**2}]*; and
 - b) the *[IOM equivalent to the UK's Quality and Safety of Organs Intended for Transplantation Regulations 20^{**3}]*.
 6. The Codes of Practice provide guidance on activities within the scope of CO's general functions under the HTODA. Whilst PH, and CO more generally, may offer advice on matters outside of those general functions, neither CO nor PH have any requirement under the HTODA in relation to the provision of such advice. CO and PH will endeavour to provide signposts to other agencies where issues arise that are beyond the reach of CO and PH.
 7. The Codes of Practice do not include information about the analysis of DNA. This is because CO has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in section 68 (non-consensual analysis of DNA) and

² SD 20^{**}/****.

³ SD 20^{**}/****.

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

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

For the purposes of this Code, and with regard to regard to bone marrow and PBSCs donation, the application of these principles means the donors and those providing consent should be given the information they need at a level appropriate to their understanding to reach a decision that is right for them, including an understanding of all the material risks.

It also means that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.

This Code provides supplementary guidance to clinicians working in the field of allogeneic bone marrow and PBSCs transplantation.

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

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

Introduction to the Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation Code

10. This Code provides supplementary guidance to clinicians working in the field of allogeneic bone marrow and PBSCs transplantation.

Scope of this Code

11. The HTODA makes it an offence, by breach of section 15 (restriction of activities in relation to donated material) of the HTODA and the Human Tissue and Organ Donation (Ethical Approval, Qualifying Purposes and Transplantable Material) Regulations 2025, to remove bone marrow or PBSCs from a living person for the purpose of transplantation on the Island..
12. Manx Care may choose to support adult donors with capacity and children who are competent to consent in travelling to making such donations in the UK or elsewhere. The definition of competent and capacity are as provided by the Mental Health Act 1998 and the associated Mental Health Act Code of Practice 2011. CO may issue a direction to provide further guidance on "capacity" or "consent" as may be required.
13. Establishments undertaking research involving such material should refer to Code E (Research) which gives further information on the licensing requirements under the HTODA.

Offences under the HTODA

14. The HTODA sets out a number of offences, for which the maximum penalty is imprisonment or a fine or both. In relation to bone marrow and PBSCs donation, the offences are as set out below.
15. Section 15 (restriction of activities in relation to donated materials) of the HTODA makes it an offence to store or use donated material for anything other than qualifying purposes.
16. 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 57-61).
17. 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.
18. Section 33 (information about transplant operations) creates an offence of knowingly or recklessly supplying information which is false or misleading in a material respect about transplant operations. This offence is subject to a fine only.

Structure and navigation

19. This Code is divided into three main sections: The first section provides more detailed guidance about the legal dimensions of bone marrow and PBSCs donation, including advice on determining capacity in adults and competence in children. The second section provides supplementary guidance to clinicians working in this field.
20. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the gov.im website.
21. Omit.

Bone marrow and PBSCs donation

Legal considerations

22. Further to the HTODA, and regulations made under the HOTDA, there is no provision for the storage and use of allogeneic bone marrow and PBSCs taken from any living person for the purpose of transplantation on the Isle of Man.
23. 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.
24. 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.
25. 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 and have regard to the legal position set out in the UK DHSC's *Reference guide to consent for examination or treatment*.
26. 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.

Determining capacity in adults

27. The HTODA does not specify the criteria for considering whether an adult has capacity to consent. Under the MH Act and the MH Act Code of Practice⁵, a person aged 16 or over is presumed to have capacity to make a decision unless that person is unable to –
 - a) take in and retain information material to the decision, especially as to the likely consequences of having or not having the treatment; or
 - b) believe the information; or
 - c) to weigh the information in balance as part of a process of arriving at a decision.
28. Full guidance on how the MH Act defines capacity and how it should be assessed are given in the MH Act Code of Practice (n.b. chapter 15, paragraphs 8 to 23 inclusive).
29. 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.
30. The MH Act Code of Practice defines how valid consent may be granted, defines persons who lack capacity to grant valid consent⁶, and contains a set of key principles in relation to determining valid consent and capacity⁷. The first core principle of the MH 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.

⁵ Note paragraph 15.10 of the MH Act Code of Practice.

⁶ See chapter 15 for adults and chapter 31 for children of the MH Act Code of Practice.

⁷ See chapter 5 of the MH Act Code of Practice.

31. If MANX Care intends to support an adult lacking capacity as a bone marrow or PBSCs donor they are advised to discuss the case with the NHSBT at the earliest opportunity.

Assessing capacity to consent

32. The MH Act and MH Act Code of Practice covers the assessment, treatment and rights of children and adults with temporary incapacity as well as a mental health condition who may need to be admitted to hospital for assessment for treatment. Common law is used to assess the capacity of adults and children. New primary legislation in this area is being developed, i.e. the Capacity Bill 2021, but at the time of publication this legislation had not yet been approved or implemented.
33. Consent for examination, treatment or care is detailed in the MH Act Code of Practice. This statutory guidance is based on mental health and capacity case law. Manx Care/DHSC has published its own policy on the assessment of mental capacity. These policies draw on the MH Act, the MH Act Code of Practice and common law with regards to its principles, the assessment of mental capacity and the best interests test. People are presumed to have capacity to make decisions unless it is established that they do not.
34. Powers of Attorney can be established under the Powers of Attorney Act 1983 and the Powers of Attorney Act 1987, but their decision-making powers are limited to financial matters and do not extend to welfare.
35. At present, there is no Court of Protection on the Island, and therefore there are no Welfare Deputies. Applications for decisions on welfare matters involving children and adults who have been found to lack capacity under common law, applicable legislation or guidance are to be made to the Courts.

Requirements for court approval for adults lacking capacity

36. There is no provision in regulations under section 13 (activities involving organs or tissue from adults who lack capacity to consent) of the HTODA makes no provision for appropriate consent for the removal of bone marrow or PBSCs, on the Island, 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.
37. 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 of 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 PBSCs outside of the Island in such circumstances.
38. Omit.
39. Manx Care should take their own legal advice regarding how to seek appropriate court approval as required.
40. Omit.

Determining competence in children

Children aged under 16

41. For the purpose of the HTODA, a child is a person aged under 18. The HTODA does not set out its own definition of competence, and so for those aged under 16, the principles set out in Chapter 31 of the MH Act Code of Practice and the common law of 'Gillick competence' apply.
42. Gillick competence means that a child is considered to be legally competent to make their own decisions on medical treatment matters when that child has sufficient understanding and intelligence to fully understand what is proposed. If a child has this level of understanding and intelligence for the proposed treatment, the child can give or refuse consent. Further information is available in guidance from the General Medical Council (GMC) *0-18 years: Assessing capacity to consent*.
43. It is the duty of the clinician responsible for the care of the donor to ensure a competence test is undertaken before Manx Care make arrangements for treatment outside of the Island.
44. Consent from a person with parental responsibility on behalf of a legally competent child *will not* be treated by as lawful consent, notwithstanding paragraph 31.11 of the MH Act Code of Practice. Parental involvement in the child's decision making should be encouraged, but CO agrees and aligns with the HTA's position under the Human Tissue Act 2004 (of Parliament), in that parents cannot make medical treatment decisions on behalf of a child who can make his or her own medical treatment decisions in this regard.

Children aged 16 and 17

45. Children aged 16 or 17 are presumed to have capacity unless there is evidence to suggest otherwise. Where a child is over 16 section 8(1) (Consent by persons over 16 to surgical, medical and dental treatment) of the Family Law Reform (Isle of Man) Act 1971 states that the decision of a child shall be as effective as that of an adult.
46. If a child is over the age of 16 and incapable of giving consent then the provisions in Chapter 31, paragraph 13.15⁸ of the MH Act Code of Practice and Part 2 of the MH Act should be considered. The application of such provisions, given parents retain parental rights to make medical treatment decisions for children under the age of 18, allow for parents to provide valid consent in law for such a child.
47. Omit.:

Requirements for court approval for children without competence

48. In cases where the potential donor is a child without the competence to consent, court approval is not required as a matter of course. In cases where a child is not competent to consent to donation themselves, and there is a dispute between those with parental responsibility, or between them and the clinicians looking after the child, or there is a doubt as to best interests of the child, the court should be asked to rule in advance. Again, the court ruling should be in place before Manx Care take any action to enable that child to travel to the UK or elsewhere for the purpose of making a donation.

⁸ Note this is a numbering error in the Code, otherwise the paragraph would be numbered 31.15.

49. Transplant Units should take their own legal advice regarding how to seek appropriate court approval.
50. Omit.
51. Omit
52. Omit.
53. Omit.
54. Omit.
55. Omit.
56. Omit.

Commercial dealings in human material for transplantation

57. Checks must be made to ensure that no reward has been or is to be given for the donation (please see glossary definition of reward on page 31). 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.
58. 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 be able to provide evidence to prove that the donor has not materially benefitted in any way, for example that only directly attributable travel costs were paid.
59. Section 31 (prohibition of commercial dealings in human material for transplantation) of the HTODA prohibits commercial dealings in human material for the purposes of transplantation. A person is committing an offence if they:
 - a) give or receive any type of reward for the supply or offer of supply of any controlled material;
 - b) look for 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 transplantable 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 indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media.
60. These offences carry the risk of a fine up to level 5 on the standard scale (i.e. £10,000) and / or up to three years imprisonment. No offence is committed, however, where payments relate to reimbursement of the donor's expenses (see paragraphs 57-58), or where reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.
61. 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.

Guidance for clinicians

62. Clinicians are responsible for the overall care of potential donors.
63. Omit.
64. 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 bone marrow and peripheral blood stem cell donation*' at an early stage in the work-up process to ensure that they understand the way in which bone marrow and PBSCs donation is regulated in that jurisdiction and how this will affect them.
65. Omit.
66. Omit.
67. All decisions made on behalf of a donor must be made in the donor's overall best interests. See paragraphs 74-77 for further information.
68. Omit.
69. Omit.
70. Omit.
71. Omit.
72. Omit.

Valid consent for child donors

73. A person who has parental responsibility may make arrangements for the storage and use of bone marrow or PBSCs for transplantation on the child's behalf if a decision is not already in force and:
 - a) the child is not competent to deal with the issue of consent to donation for transplantation (i.e. they are not "Gillick competent"); or
 - b) even though the child is competent to do so (i.e. they are "Gillick competent"), they have not made a decision about consent to donation for transplantation.
74. In these cases, Manx Care may support a person with parental responsibility in making arrangements to support removal, storage and use of bone marrow or PBSCs for transplantation on behalf of the child, at a location outside of the Island, if the donation is assessed as being in the child's overall best interests. This decision must take into account not only the medical but also emotional, psychological and social aspects of the donation, as well as the risks. The consent of only one person with parental responsibility is necessary.
75. It is good practice for the practitioners involved to assess the donor child's best interests by talking to the child and the person who has parental responsibility for them. A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is set out in the Children and Young Persons Act 2001.
76. For further guidance, practitioners should consult the following documents as appropriate:
 - a) the UK Department of Health and Social Care's *Reference guide to consent for examination or treatment* (second edition);
 - b) omit;

- c) omit;
 - d) the GMC's *Guidance 0-18 years: guidance for all doctors*.
77. Where there is any dispute between people with parental responsibility, or doubt as to whether any decision to donate is in the child's best interests, the matter should be referred to the Courts. In such instances, PH would only consider the matter for approval if the Court was of the view that the donation was in the best interests of the donor child.
78. Omit.
79. Practitioners should also be aware of other specific requirements, under the HTA's *Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment on the application of the Q&S Regulations*, regarding the information that should be given to potential donors.

Involving the donor

80. Where Manx Care are supporting the donation process, the child donor should be provided with information about the procedure and its risks to an age-appropriate level. The level of communication required for child donors depends on the child's ability to understand the donation procedure.
81. Where children have some potential to understand the donation procedure, the information outlined at paragraph 7 should be explained in terms that they find easy to understand – with help from appropriately qualified staff, as required.
82. Even small children can be helped to understand some aspects of the procedure and its associated risks. This understanding can be assisted by involving a play therapist, psychologist or specialist nurse in the communication process so that the child can gain a better understanding of what the donation would involve.

Paragraphs 83 to 122 are omitted.

Annex A

To be inserted.

Glossary

To be inserted.