

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

Code of Practice



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

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Introduction to the Human Tissue Authority Codes of Practice

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

8. This Code provides supplementary guidance to clinicians working in the field of allogeneic bone marrow and PBSC transplantation and HTA Accredited Assessors (AAs).
9. In combination, Code A and this Code aim to provide anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

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 PBSC transplantation and HTA Accredited Assessors (AAs).

Scope of this Code

11. The HT Act makes it an offence to remove bone marrow or PBSCs from a living person for the purpose of transplantation unless the HTA gives permission or where the Regulations provide an exemption to the definition of transplantable material for the purpose of the Act. The exemptions are donation of bone marrow and PBSCs by adults with capacity and children who are competent to give consent. These cases may proceed without HTA approval. For further information see paragraph 25.

12. The HTA therefore assesses applications for the donation of bone marrow and PBSCs from adults who lack capacity to consent and children who are not competent to consent to the removal of the transplantable material.

13. In addition to circumstances where HTA approval is required, establishments may also be subject to the licensing requirements of both the HT Act and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q & S Regulations). Establishments undertaking research should refer to the HTA Code of Practice on Research which gives further information on the licensing requirements under the HT Act. This Code does not include detailed information relating to the licensing requirements of the Q & S Regulations and further information can be found in Annex A paragraphs 6 - 7 and the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

Offences under the HT Act

14. The HT Act sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to bone marrow and PBSC donation, the offences are as set out below.

15. Section 8 of the HT Act makes it an offence to store or use donated material for anything other than qualifying purposes.

16. Section 32 of the HT Act makes it an offence to engage in commercial dealings in human material for transplantation (see paragraphs 57-61).

17. Section 33 prohibits removal and use of transplantable material from living donors unless the requirements set out in the Regulations are met.
18. Section 34 creates an offence of failing to comply with the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, and 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 PBSC donation, including advice on determining capacity in adults and competence in children. The second section provides supplementary guidance to clinicians working in this field. The final section provides advice to HTA Accredited Assessors (AAs).
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 [HTA's website](#).

Bone marrow and PBSC donation

Legal considerations

22. The HT Act governs consent for the storage and use of allogeneic bone marrow and PBSC taken from any living person for the purpose of transplantation.
23. Consent for the removal of bone marrow and PBSC from a living person, whether for transplantation or otherwise, is covered by the common law and the Mental Capacity Act 2005 (MC Act), where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health's Reference guide to consent for examination or treatment. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government's Reference guide to patient consent for examination and treatment. The MC Act does not apply in Northern Ireland; further information about the law on mental capacity in Northern Ireland is provided in paragraphs 32 to 35.
24. The restrictions on and requirements for living organ donation and transplantation are set out in sections 33 and 34 of the HT Act and sections 9-14 of the Regulations. They require that donations of bone marrow and PBSC from children (anyone under the age of 18) who are not competent to give consent, or from adults lacking capacity, must be approved by the HTA. The Regulations include the requirement that the HTA is satisfied that consent for removal of the material has been given, or the removal is otherwise lawful (for example sanctioned by the Court).
25. Donation of bone marrow and PBSC by adults with capacity and children who are competent to give consent is not classified as transplantable material for regulatory purposes and, subject to valid consent being obtained by the treating clinician, may proceed without HTA approval. For further information see paragraph 11.
26. The law and regulatory requirements relating to bone marrow and PBSC donation are relatively complex. If a practitioner is in any doubt about how to proceed with a case, they are advised to discuss it with the Living Donation Assessment Team (LDAT) at the HTA.

Determining capacity in adults

27. The HT Act does not specify the criteria for considering whether an adult has capacity to consent. Under the MC Act, a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

- a) understand the information given to them that is relevant to the decision;
- b) retain that information long enough to be able to make the decision;
- c) use or weigh up the information as part of the decision-making process;
- d) communicate their decision by any means.

28. Full guidance on how the MC Act defines capacity and how it should be assessed are given in chapter 4 of the MC Act Code of Practice.
29. The provisions of the MC Act should be considered together with general principles governing capacity to consent to medical procedures. Further information is available from the Office of the Public Guardian website and in the MC Act Code of Practice. The Welsh Government has published separate guidance for Wales.
30. The MC Act defines persons who lack capacity¹ and contains a set of key principles and a checklist to be used in ascertaining best interests². 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.
31. If a clinician intends to consider an adult lacking capacity as a bone marrow or PBSC donor they are advised to discuss the case with the HTA at the earliest opportunity.

Assessing capacity to consent in Northern Ireland

32. The Mental Capacity Act 2005 (MC Act) does not apply in Northern Ireland. The Mental Health Order 1986 covers the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment for treatment. Common law is used to assess the capacity of adults and children. The Mental Capacity Act (Northern Ireland) 2016 was passed in May 2016 (only certain provisions have been commenced to date, but research provisions within the NI Act (Part 8 of the Act) were commenced in October 2019).
33. The Department of Health (DoH) in Northern Ireland published its own reference guide to consent for examination, treatment or care in 2003. This guidance is based on mental health and capacity case law. Each of the five Health and Social Care Trusts has published its own policy on the assessment of mental capacity, based on the 2003 departmental guidance. These policies draw on the MC Act,

¹ See chapter 4 of the MC Act Code of Practice.

² See chapter 5 of the MC Act Code of Practice.

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. Advance decisions³ are made in Northern Ireland under common law and the 2003 departmental guidance, (but these decisions are not covered by statute). Enduring Powers of Attorney can be established under The Enduring Power of Attorney (Northern Ireland) Order 1987, but their decision-making powers are limited to financial matters and do not extend to welfare.

35. There is no Court of Protection in Northern Ireland, and therefore there are no Welfare Deputies; applications for decisions on welfare matters involving children and adults who have been found to lack capacity under common law and departmental guidance are made to the High Court.

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

36. The HT Act makes no provision for appropriate consent for the removal of material from a living adult who lacks capacity to consent for himself or herself. A lawful decision to give or refuse consent on behalf of an adult who lacks capacity can only be made through one of four routes:

- a) by an Advance Decision made by the donor to refuse consent for the proposed treatment which covers this type of donation and was made at the time when the donor had capacity. If such an Advance Decision is in place then no Court can override that decision and lawful consent will never be given;
- b) by the donor executing a valid Lasting Power of Attorney (LPA), giving another person power to make this type of decision. The LPA must have been made by the donor at a time when the donor had capacity (see section 9 of the MC Act);
- c) by a person who has been given the power to make such a decision when appointed as “welfare” deputy by the Court of Protection (see section 16(2)(b) of the MC Act). The HTA considers that a “welfare” deputy should not rely on a general welfare power to make these decisions but should only rely on his or her decision making power under the deputyship order if this is a matter where the power to give consent to a bone marrow or PBSC donation has been specifically given to him or her; or
- d) by a judge of the Court of Protection making a best interests decision on behalf of the adult lacking capacity (see section 16(2)(a) of the MC Act).

³ A decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future, including the refusal of organ, bone marrow or peripheral blood stem cell donation.

37. The Code of Practice for the MC Act states that, where an adult lacks the capacity to consent to the removal of bone marrow, the case must be referred to a court for a declaration that the removal would be lawful. The HTA believes that the same approach should be adopted for donation of PBSCs. 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.
38. As the court is authorising the removal, there is no-one else providing consent on the donor's behalf, and therefore only interviews with the donor and recipient can be undertaken.
39. Transplant units should take their own legal advice regarding how to seek appropriate court approval before referring to the HTA.
40. In situations where adult patients lack capacity, this should be documented by completing a consent form which is suitable for adults who are unable to consent to investigation or treatment. More information is available in the Department of Health's guidance document "Information to assist in amending consent forms".

Determining competence in children

Children aged under 16

41. For the purpose of the HT Act, a child is a person aged 18 and under. The HT Act does not set out its own definition of competence, and so for those aged under 16, the principle set out in common law of 'Gillick competence' applies.
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 a case is referred to the HTA.
44. Consent from a person with parental responsibility on behalf of a legally competent child will not be treated by the HTA as lawful consent. Parental involvement in the child's decision making should be encouraged, but the HTA considers that parents cannot make medical treatment decisions on behalf of a child who can make his or her own medical treatment decisions.

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) of the Family Law Reform Act 1969 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 has an impairment of the mind or brain then the tests in the MC Act should be considered. However, parents retain parental rights to make medical treatment decisions for children under the age of 18 and so could provide valid consent in law for such a child.
47. If the HTA receives a referral where it appears that the donor may have competence the HTA may:
 - a) request that the clinician referring the case provides the HTA with details of the competence assessment that was undertaken for the child;

- b) following that, if the matter remains unclear, the HTA may make an application to the Court of Protection under the Children Act 1989 for the court to decide if the donor child is competent to make their own decisions about medical treatment. The court would then decide whether the child had competence to consent to the procedure for him or herself.

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 referral to the HTA.
- 49. Transplant Units should take their own legal advice regarding how to seek appropriate court approval.

Requirements for HTA approval to be given

- 50. Donations of bone marrow and PBSCs by adults with capacity and children who are competent to give consent may proceed without HTA approval.
- 51. Before the HTA approves a case, a registered medical practitioner with clinical responsibility for the donor must have arranged to refer the case to the HTA.
- 52. The Regulations require the HTA to be satisfied that:
 - a) no reward has been, or is to be, given;
 - b) consent to removal for the purpose of transplantation has been given (or removal for that purpose is otherwise lawful);
 - c) an AA (see paragraphs 91-118) has conducted separate interviews with the donor, the person giving consent, and the recipient and submitted a report of their interviews to the HTA.
- 53. A person is qualified to conduct such an interview if:
 - a) they meet the HTA's person specification for becoming an AA and have completed HTA training;
 - b) they do not have any connection to those being interviewed, or their families, of a kind which the HTA considers might raise doubts about impartiality;

- c) in the case of an interview with the donor and the person giving consent, the AA is not the same person who gave the information about the procedure and risks to the donor.

54. The Regulations also specify that the following matters must be covered in every interview report submitted by the AA to the HTA:

- a) whether there is any evidence of duress or coercion affecting the decision to give consent;
- b) whether there is any evidence of an offer of a reward;
- c) whether there were any difficulties in communicating with the person interviewed (such as language or hearing), and if so, an explanation of how these difficulties were overcome.

55. Each report of an interview with the donor and the person giving consent must also contain:

- a) the information given to the person interviewed as to the nature of the medical procedure and the risk involved in the removal of the transplantable material;
- b) the full name of the person who gave that information to the person interviewed, and their qualification to give it;
- c) the capacity of the person interviewed to understand the nature of the medical procedure, the risk involved and that consent may be withdrawn at any time before the removal of the transplantable material.

56. 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 section 13 of the Regulations and requires a fresh decision to be made by the HTA.

Commercial dealings in human material for transplantation

57. The HTA requires that checks are 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 HT Act allows donors to receive reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation.

58. Where reimbursement is not made by the NHS, nothing in law prevents a recipient (or the family of the recipient) from directly reimbursing the donor's expenses. In this circumstance, the donor and recipient should 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 32 of the HT Act 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) 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;
- 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. This offence carries the risk of a fine 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 and transplant teams are responsible for the overall care of donors and recipients, and for assessing the medical suitability of potential donors. The decision about whether a person is medically fit and clinically suitable as a bone marrow or PBSC donor is a matter for the practitioners concerned.

63. The HTA provides advice on how our regulatory requirements will apply to individual cases. Where the Regulations require the HTA to approve a donation, the clinical decision on whether to proceed with a case rests with the transplant unit.

64. All potential donors should understand the way in which bone marrow and PBSC donation is regulated and how this will affect them. Further information is available on the [HTA website](#).

Securing valid consent

65. 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 bone marrow or PBSC is in place prior to referral to the HTA.

66. Part of the HTA's role is to act as an independent check that legally valid consent is in place for bone marrow and PBSC donations from adults without capacity or children who are not competent.

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. The HT Act requires that consent be obtained to store and use tissue, such as bone marrow or PBSC, for transplantation. Consent for removal is governed under common law, but the HTA has the regulatory role of ensuring that valid consent for removal is in place. The necessary consents should ideally be sought in a single process.

69. Consent for the first and each repeat donation must be obtained before removing bone marrow or PBSC from a donor for transplantation. HTA approval must also be sought on each occasion for bone marrow and PBSC donations from adults without capacity or children who are not competent.

70. In cases where donors are unable to give consent themselves, the decision about consent will be made by a person acting on their behalf, which would usually be the court for adults lacking capacity and someone with parental responsibility for children without competence.

71. While it is not a legal requirement, it is good practice to seek and obtain written consent for significant procedures such as bone marrow or PBSC 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.

72. It is important that the person consenting on the donor's behalf is advised that they will need to provide consent to both the surgical procedure under common law, and the use of the bone marrow or PBSC for the purpose of transplantation under the HT Act.

Valid consent for child donors

73. A person who has parental responsibility can consent to the storage and use of bone marrow or PBSC 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, a person with parental responsibility can consent to removal, storage and use of bone marrow or PBSC for transplantation on behalf of the child, 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 Act 1989, the Adoption and Children Act 2002 and the Human Fertilisation and Embryology Act 2008.

76. For further guidance, practitioners should consult the following documents as appropriate:

- a) the Department of Health's Reference guide to consent for examination or treatment (second edition);
- b) the Welsh Assembly Government's guidance on Patient consent to examination or treatment;
- c) the DoH (NI) Reference guide to consent for examination, treatment or care;
- d) the GMC's Guidance 0-18 years: guidance for all doctors.

77. Where there is any dispute between people with parental responsibility or any doubt as to whether the decision to donate is in the child's best interests, the matter should be referred to the Court of Protection for approval. In such instances, the HTA would then only consider the case for approval if the court was of the view that donation was in the best interests of the donor child.

Information for the person giving consent

78. The person giving consent on the donor's behalf should be given information about all aspects of the donation process, including:

- a) the nature of the medical procedure and medical treatments involved for the donor and any material short and long term risks to the donor (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;
- b) that a further collection of bone marrow or PBSC might be needed;
- c) the chances of the transplant being successful and the possibility of the transplant failing in the recipient;
- d) the right to withdraw consent at any time and the implications for both donor and recipient of the withdrawal of consent;
- e) the fact that donation is an entirely voluntary act and that the donor (and, where applicable, the person consenting on their behalf) must be free of any kind of coercion;
- f) the fact that it is an offence to seek or receive payment or reward for providing tissue including bone marrow or PBSC for transplantation;
- g) where appropriate, that 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.

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. 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.

Referring cases to the HTA

83. The Regulations require that a medical practitioner with clinical responsibility for the donor must have caused the matter to be referred to the HTA. The referral should state that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and has:
- a) provided the donor (and the person acting on the donor's behalf) with the information the donor requires to understand the consequences of donation;
 - b) endeavoured to obtain information from the donor that is relevant to transplantation.
84. The referral must be made by a registered medical practitioner. The HTA has created a model referral letter template for transplant units to use to ensure that all the legislative and policy requirements are addressed in the referral letter to the HTA.
85. As a matter of HTA policy, the referral letter should state that the medical practitioner is satisfied that the donor lacks competence or capacity to consent to the donation. The referral letter should also provide information on the recipient's capacity to participate in an AA interview.
86. Arrangements for the statutory interviews can be made at the point at which the referral letter is received by an appropriately trained AA.
87. Transplant teams should ensure they factor in sufficient time for both the AA interviews and HTA process to be completed when scheduling provisional surgery or procedure dates.

Guidance for Accredited Assessors (AAs)

Accepting referrals

88. Before accepting a referral for a case, AAs should make sure that they will be able to:
- a) undertake the interview within one month of referral;
 - b) submit their report to the HTA within 10 working days of the interview;
 - c) be available in the five working days following the submission of their report, in case the LDAT needs to contact them for further information or clarification.

89. Where the AA is made aware of a shorter deadline for the assessment of a case, for example, where there is an urgent clinical need, they should consider the implications of this before accepting the referral.
90. It is important that annual leave arrangements are taken into account when scheduling interviews, as delays may result in scheduled surgery or procedures not being able to proceed. If an AA considers they may not be able to undertake interviews, or submit reports within the above timescales, or they are on leave in the five days following submission to the HTA, it would be advisable to ask the transplant team to find an alternative AA for that case.

Statutory interviews

91. This section should be read in conjunction with the HTA Guidance to Bone Marrow and Peripheral Blood Stem Cell Transplant Teams and Accredited Assessors which provides detailed information on all aspects of the AA role, including good practice guidance on undertaking interviews.
92. The Regulations require that an AA must have conducted separate interviews with the donor, the person giving consent on the donor's behalf and the recipient in order to gather the material that must be reported to the HTA. Please see paragraphs 94 and 106 for further information on steps to take where the donor and recipient may be too young to be interviewed.
93. The statutory interviews should enable the HTA to ascertain whether the legal requirements have been met. The HTA system places the report of the AA interviews at the centre of our assessment process. We consider this to be the starting point for our assessment of a case, and if we cannot be satisfied on the basis of this, further investigations will be made. However, most cases are decided on the basis of the report of the interviews.
94. In addition to the statutory requirements, the report of the interviews should also contain an account of any relevant concerns the AA has which should contribute to the HTA's assessment of whether or not it is satisfied in relation to the legal tests described at paragraph 54.

The donor interview

95. The interview with the donor must, by law, cover the matters described in paragraphs 54-55.
96. The purpose of the interview is to ensure that the donor has an age-appropriate understanding of the procedure, to ascertain that there is no evidence of duress

or coercion having been placed on the donor and to ensure there is no evidence of the donor having sought, or been offered, a reward.

97. In all cases the AA must undertake, or attempt to undertake, an interview with the donor. The only exception is where the donor unarguably lacks capacity, for example attempting an interview with a baby or a pre-verbal child. In these cases the AA must clearly report to the HTA the reasons for not seeing the child. In all other cases the AA should at least see the donor and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible.
98. Where an AA considers that a potential donor may have competence or capacity to consent for themselves, AAs should report this conclusion and their evidence for it as part of the AA report.
99. On occasion, a donor may express a wish not to go ahead with the procedure a parent or best interest's decision maker can override the donor's wish not to proceed with the proposed donation. However, in order to make a lawful consent decision, the decision maker must clearly demonstrate that he or she has weighed up all the factors and reached the conclusion that the donation is in the donor's overall best interests. The HTA must be satisfied that the person consenting on the donor's behalf has properly taken these views into account before reaching their decision.
100. AAs must ensure that any conversations where the donor indicates a wish not to proceed are fully documented in their report to the HTA.

Interview with the person consenting on the donor's behalf

101. The interview with the person consenting on the donor's behalf must, by law, cover the matters described in paragraph 54-55.
102. The primary role of the HTA is to check that valid consent to the removal is in place. The interview must provide the HTA with sufficient information to be satisfied that:
 - a) the person giving consent has the legal right to do so;
 - b) the person giving consent has understood they have to be solely focused on the best interests of the donor child; and
 - c) the person giving consent has made a proper decision that the donation is in the donor's best interests.
103. The AA report will need to address whether the person consenting on the donor's behalf has been placed under any duress or coercion to consent to the procedure. The HTA interprets this to mean any evidence of (a) whether external pressure has been placed on the person making the consent decision which may have affected their decision to do so; and (b) whether any pressure has been placed on the donor to go ahead with the procedure. This may involve pressure being placed on a third party which is influencing the decision of the donor or the person making the consent decision. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.
104. The AA report will need to address whether there is any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to (a) the donor; (b) the person providing consent; or (c) any third party.
105. There may be occasions when the person consenting on the donor's behalf may have a conflict of interest in making their decision, for instance where they are also, or are closely related to, the intended recipient.
106. Provided the HTA is satisfied that the parent or other decision maker has made a decision which is focused on the right questions and has acted properly in a way that focuses on the best interests of the child making the donation, a conflict of interest will not prevent the parent's consent being given on behalf of the donor child and being legally valid consent. However, where there is doubt as to whether the decision has been made in the child's best interests, the HTA is likely to consider requiring an application to the Court of Protection for a decision on the child's best interests.

The recipient interview

107. The interview with the recipient must, by law, cover the matters described in paragraph 54.
108. In all cases the AA should undertake, or attempt to undertake, an interview with the recipient. The only exception is where the recipient unarguably lacks capacity, for example if they are a baby or a pre-verbal child and an interview would not be possible or the child is very unwell then attempting an interview would be disproportionate.
109. In all cases the AA should at least see the recipient (see paragraph 114 for more detail) and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible.
110. The AA report on the interview with the recipient must cover any evidence of duress or coercion affecting the decision to give consent. The HTA interprets this to mean any evidence of (a) any external pressure that has been placed on the person giving consent that would affect their decision to do so; and (b) whether any pressure has been placed on the donor to go ahead with the procedure. Such pressure may have been applied by the recipient or by another party. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.
111. The recipient interview must also cover any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to either (a) the donor; or (b) the person providing consent. Any reward may have been offered by the recipient, or by another party. Where it is not suitable to directly address financial reward with a child, a discussion on how the offer of donation arose could be considered.

General advice on interviewing child donors and recipients

112. The AA interviews the potential donor and recipient to assess whether the HTA requirements have been met. Interviews should take place both with the donor and recipient at a level appropriate to their age and understanding.
113. There is no statutory provision for someone to be interviewed on the recipient's behalf, so a recipient interview must be attempted. In cases where the recipient is a young child, AAs should adopt an extremely light touch approach to assessing the issues of duress, coercion and reward, by exploring what the

recipient knows about the procedure and their knowledge of how the donor came to be chosen to donate to them.

114. AAs should only be interviewing donors who have been judged by the clinical team to lack capacity or competence to consent to removal of the transplantable material. The AAs should interview younger child donors along with the person providing the consent on their behalf. The AA report should confirm that the registered medical practitioner has explained to the donor, to an age appropriate level, the nature of the medical procedure, the risks involved and any other wider implications, and to report on the donor's age appropriate understanding of these issues.

Completing and submitting an application

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

HTA decision making arrangements

119. The HTA aims to make decisions within deadlines published each year in the HTA business plan.
120. Once a decision has been made by the HTA, an automated notification will be issued to the AA, stem cell coordinator and the clinician detailed in the report.

The stem cell coordinator must inform the person consenting on behalf of the donor, the donor and the recipient of the decision on the HTA's behalf.

121. In cases where the requirements have not been met and the HTA turns a case down, the person consenting on the donor's behalf, the donor, recipient, and medical practitioner with responsibility for the donor will be notified in writing. The letter will also outline the procedure for reconsideration of the decision. See paragraph 53 for additional information.
122. However there may be cases where the HTA decides that it would not be appropriate to provide full reasons or that doing so would breach another person's rights under the Human Rights Act 1998 or would breach a duty of confidentiality owed to any person.
123. Detailed information on the way in which the HTA makes decisions can be found in the HTA Decision-Making Framework, the HTA Policy for the assessment of bone marrow and PBSC donation cases and HTA Standard Operating Procedures which are available on request from the HTA.

Annex A

Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.
2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes⁴ in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.
3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:
 - a) the person died before the HT Act came into force on 1 September 2006; and
 - b) at least 100 years have elapsed since the date of the person's death.
4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.
5. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations), as amended, implemented into UK law the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The Q&S Regulations set out the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for human application. In their amended form following UK's exit from the European Union, the Q&S Regulations modify the requirements of the EUTCD as applied to Great Britain to reflect the departure from the EU, but the same standards continue to apply. Those modifications do not apply to Northern Ireland where the HTA remains the Competent Authority for the purposes of the EUTCD.
6. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment and the requirements set out in Codes A and G.

⁴ Defined by the HT Act and explained in further detail in the glossary.

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

Scotland

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

Status and use of the Codes of Practice

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

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

Other advice and guidance

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

Glossary

Term	HTA definition
Accredited Assessor (AA)	The designation given by the HTA to the 'qualified person' for the purpose of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Accredited Assessors (AAs) are trained by the HTA. They undertake the statutory interviews with the donor (and the person consenting on the donor's behalf) and the recipient in each application for bone marrow or peripheral blood stem cell (PBSC) donation where the donor is an adult who lacks capacity, or a child without competence, to consent.
Advance Decision	An advance decision is a decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future. To be legally binding in England and Wales, an advance decision must comply with a number of criteria which are described in the Mental Capacity Act 2005. With regard to organ and tissue donation, an advance decision could be used to exclude the possibility of donation from a living adult who lacks capacity at the time of the proposed donation.
Allogeneic transplantation	Allogeneic stem cell transplantation involves transferring stem cells from a healthy person (the donor) to a recipient.
Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.
Appropriate consent	Defined in the Human Tissue Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died. Deemed consent modifies the appropriate consent provisions in England and Wales and Northern Ireland for organs and tissue donation for donation after death.
Best interests	A test of a person's best interests takes into account not only the medical aspects, but also the wider emotional, psychological and social aspects of the potential medical procedure, as well as the risks.
Bone marrow	A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.

Term	HTA definition
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Coercion or duress	The HTA examines whether the recipient and donor have been put under any coercion or duress when assessing Independent Assessor reports. Both coercion and duress are referred to in The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but they are not distinguishable in law. The HTA interprets coercion to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.
Court of Protection	Makes decisions on financial or welfare matters for people in England and Wales who are unable to make decisions at the time they need to be made because they lack mental capacity to do so.
Deemed consent	Deemed consent means that all individuals over 18 in England, Wales or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue (i.e., they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent). Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.
DNA	<p>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics.</p> <p>Find out more information about the HTA's role with regards to DNA on the HTA's website.</p>
Donated material	For the purposes of the HT Act, the term 'donated material' refers to the body of a deceased person, or relevant material which has come from a human body, which is being stored or used for scheduled purposes with appropriate consent.

Term	HTA definition
Donation	The act of giving 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.
Duress (Coercion)	Both words are referred to in The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but are not distinguishable in law. The HTA interprets duress to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.
Gillick competence	A term used to help assess whether a child has the maturity to make their own healthcare treatment decisions without the permission of their parents and to understand the implications of those decisions. A child will become legally competent to make their own decisions on medical treatment matters when the child has sufficient understanding and intelligence to fully understand what is proposed.
Health and Social Care (HSC) Trust	Health and Social Care (HSC) Trusts provide integrated health and social care services across Northern Ireland.
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Lasting Power of Attorney (LPA)	A Lasting Power of Attorney (LPA) is a power of attorney under which the donor (a person aged 18 or over) confers authority to another person or people (a third party) to make certain decisions on their behalf, should they lose capacity in the future. An LPA is a legal document and decisions that the third party makes are as valid as any made by the donor. An attorney is bound by the principles set out in the Mental Capacity Act; for example, any decisions they make must be made in the best interests of the person lacking capacity. Further information about LPAs is set out at chapter 9 of Part One of the Mental Capacity Act. An LPA is only applicable in England and Wales.

Term	HTA definition
Licensing	A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.
Organ	Defined by The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.
Parental responsibility	A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.
Payment or reward (in IA and AA cases)	<p>The HTA examines whether payment or reward has been given, offered or received when assessing Accredited Assessor cases. Under the Human Tissue Act, a person is committing an offence if they:</p> <ul style="list-style-type: none"> 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 controlled material; e) take part in the management or control of any type of group whose activities consist of or include the initiation or negotiation of such arrangements; 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.

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

Term	HTA definition
Scheduled purpose	<p>Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also relate to activities for scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</p> <ul style="list-style-type: none"> • 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, and quality assurance.
Standard Operating Procedure (SOP)	A document that sets out the established process to be followed to complete a task.
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.
Transplant Unit	A department within a hospital that provides range of transplant services to patients.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.

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