



# Human Tissue Authority

Guidance to Bone Marrow and  
Peripheral Blood Stem Cell Transplant  
Teams and Accredited Assessors in  
England, Wales, and Northern Ireland

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1. The purpose of this document is to provide guidance and assistance to Accredited Assessors (AAs), clinicians and clinical teams about the regulatory and legal requirements under the Human Tissue Act (2004) (“the Act”) for the assessment of prospective donations of bone marrow and peripheral blood stem cells (PBSC) **from children who are not competent to consent and from adults who lack capacity to consent.**
2. The guidance explains what the Human Tissue Authority (HTA) expects of bone marrow referring units, donors, consent decision makers and recipients who are involved in the process.
3. The HTA’s code of practice on the Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation provides supplementary guidance to Clinicians and Accredited Assessors working in this field and can be found on our website.

## The legislative framework

### The Human Tissue Act 2004

4. The Human Tissue Act 2004 (the Act) sets out the legal framework for the removal, storage and use of human organs and tissue from living and deceased donors. The Act covers England, Wales, and Northern Ireland.
5. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 and associated Regulations and Orders. This demonstrates some marked differences between Scotland and the rest of the UK. Supplementary guidance for Scotland is available on our [website](#).
6. The Act makes **consent** the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased people. The Act requires consent for the storage and use of regenerative materials taken from a living or deceased person for the purpose of transplantation.
7. Under section 33 of the Act, unless the HTA gives permission or a statutory exemption applies, a person commits an offence if they remove bone marrow or PBSC from a living person for the purpose of transplantation. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the “Regulations”) is the secondary legislation that sets out the requirements that must be met in order for the legal restriction on living donation to be dis-applied.

8. Section 32 of the Act also creates offences associated with commercial dealing in human material. The penalty for these offences is a prison sentence of up to three years, a fine, or both.

### **The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006**

9. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) is the secondary legislation that sets out the legal requirements that must be met in order for the HTA to give approval for bone marrow and PBSC donations. The role of the HTA is to decide whether the conditions set out in this legislation are proved to exist before approval can be given.

10. The Regulations set out that HTA approval is only necessary in cases where the **donor** is:

- An adult who lacks the capacity to consent to the removal of the bone marrow or PBSC; or
- A child who is not competent to consent to the removal of the bone marrow or PBSC.

11. Adults and children who are able to make their own decisions about medical treatment have the legal right to decide whether to donate bone marrow or PBSCs without seeking consent from the HTA. Further information for Clinicians about assessing a young person's capacity is available in the [GMC 0-18 years guidance](#).

12. The Act does not provide a definition for "competent." Whether or not a child is competent must be established via the *Gillick* test. As above, a competent child does not need to be referred to the HTA for approval, however the Clinician responsible for the donor must be satisfied that the requirements of section 2 of the Act ("Appropriate consent" children) are satisfied.

13. To grant approval under the Regulations, the HTA must be satisfied:

- That no reward has been given or is to be given; and that
- When transplantable material is removed, consent for its removal for the purpose of transplantation has been given, or its removal for that purpose is otherwise lawful.

## **Other legislation**

14. The HTA must consider other legislation when carrying out its duties. The Mental Capacity Act (MCA) 2005, which applies in England and Wales only, Mental Capacity Act (Northern Ireland) 2016, and the Human Rights Act (HRA) 1998, in particular, have bearing on the way the HTA conducts its role. In addition, the HTA must act in accordance with public law principles. These oblige the HTA to act within its lawful powers, to act reasonably, and to follow fair procedures.

## **The Human Tissue Authority**

15. The Act established the HTA to regulate activities concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for the scheduled purposes set out in the Act, including for the purpose of transplantation.

16. By law, one of the HTA's functions is to issue codes of practice. These codes give practical guidance to professionals carrying out activities which lie within the HTA's remit; they also lay down the standards expected.

## **Overview of the regulatory framework for bone marrow and peripheral blood stem cells**

17. Regulation of bone marrow and PBSC donation by adults lacking capacity and children not competent to consent exists because Parliament wanted to introduce an independent element to the process in order to provide potentially vulnerable donors with a degree of protection.

18. The HTA's role is to dis-apply the legal restriction on living transplants where it is satisfied that the conditions set out in the Regulations have been met. That is to say, the criminal offence that exists for living donors is only lifted when the requirements outlined below are met.

19. Specifically, the Regulations require that:

- A registered medical practitioner with clinical responsibility for the donor must have arranged to refer the case to the HTA [Regulations 11(2)].
- The HTA is satisfied that no reward has been given or is to be given and that where transplantable material is removed, consent for its removal for the

purpose of transplantation has been given, or its removal for that purpose is otherwise lawful [Regulations 11(3)].

- The HTA must consider a report from a qualified person (the HTA uses the term “Accredited Assessor” to designate a qualified person in bone marrow and PBSC donation cases) [Regulations 11(4)]. The AA must have interviewed the donor, the person giving consent on their behalf, and the recipient [Regulations 11(6)]. The report must contain information set out in Regulations 11(8) and 11(9).
  - The HTA must give notice of its decision to the donor, the recipient and the referring medical clinician [Regulations 11(5)].
20. While the HTA must take into account the report from the AA in its decision making, the HTA is free to seek appropriate additional information from the donor and/or the person giving consent, the recipient or the referring clinician before reaching a decision.
21. This document sets out the circumstances under which additional information may be sought, and the forms that this might take. In all cases the HTA will discharge its duties in line with the principles of best regulatory practice (transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed) [the Act s38(2)].
22. In reaching a decision about whether the HTA is “satisfied” in relation to each of the statutory criteria, the HTA will consider whether it has sufficient evidence to be satisfied on the balance of probabilities that the criteria is established on the facts of the case. If the HTA is not satisfied on any of the elements in an individual case, the HTA does not have the power to approve the donation.
23. In situations where it is not satisfied, the HTA’s policy is that it should provide its reasoning as part of its notice of decision set out in regulation 11(5). However, there may be cases where the HTA decides that it would not be appropriate to provide reasons. For instance, if 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.

#### *Duress and coercion*

24. The HTA is required to investigate whether there is evidence of duress or coercion. AAs will consider this in every case based on the individual facts of a case. The HTA is required to make a judgement about whether the person giving consent has exercised his or her own free will in making the decision to

consent to donation, or whether external influences exist which are acting on them strongly enough to say that this is not the case. Duress may come from inappropriate pressure, threats or intimidation from a third party.

25. The HTA must also consider whether or not a decision maker is making a proper best interests decision and not, for example, acting out of guilt or worry about the effect on family if a donation does not proceed. As there is no directly relevant case law on this matter, and in line with the HTA's regulatory decision procedures, the HTA will seek independent legal advice on the adequacy of its evidence in every instance where it is minded to turn down an application because it believes the person providing consent on behalf of the donor may not be doing so freely. Please see paragraphs 55-60 for more information on best interests.

#### *Reward*

26. Section 32 of the Act creates various offences including that of offering or accepting reward for human material to be used for transplantation. A "reward" means "any financial or other material advantage". Thus a payment of money to the donor (or possibly someone else) will constitute an unlawful reward even if it is of a relatively trivial sum. An unlawful reward can also be created by providing any non-monetary benefit which is linked to the proposed donation (other than a reward of most trivial kind). Any reward which is linked to the donation may prevent the HTA approving the proposed donation.
27. A reward does not have to flow from a recipient to a donor, and may come instead from a third party. It is vital that this is addressed with the donor, the person consenting on the donor's behalf and recipient, and information on any third party involvement should be provided in the report to the HTA.
28. As the HTA must make a decision on whether or not reward is a factor in the decision to donate it is critical that the AA's interview and subsequent report cover the issue whether any reward exists, and the bearing this has had on the donor, or person consenting on their behalf, with regard to their decision to donate.
29. Further guidance on the interpretation of duress, coercion and reward are provided in the section of this document describing the AA interviews at paragraphs 100-123 below.

#### *Otherwise lawful*

30. In assessing whether removal for transplantation is "otherwise lawful", the HTA is bound by the common law principle that any voluntary action by an individual is assumed to be lawful unless the contrary is shown. This test will

be met unless the HTA is presented with evidence that the removal is unlawful.

## **The role and responsibilities of the Accredited Assessor**

31. The HTA's role in bone marrow and PBSC donation is to ensure that there has been no reward sought or offered for the donation and to provide an independent check to help protect the interests of donors: ensuring each individual donor and person providing consent has an opportunity to speak freely to someone not connected with the transplant unit in order to confirm that their wish to donate is free from any pressure to act against their will.
32. AAs help the HTA to do this by undertaking interviews to allow it to fulfil its role. AAs are responsible for acting as a checking point, to ensure a clinician has confirmed that the donor does not have capacity or competence and to ensure the person consenting on the donor's behalf has reached a decision to consent based on the best interests of the donor. AAs therefore play a key role in the system as a whole. For more information on best interests see paragraphs 55-60 below.
33. AAs must be independent of the bone marrow and PBSC donation process and of the donor and recipient. AAs will have different working relationships with the clinical teams; regardless of the relationship it is important that AAs bring an "independence of mind" to the AA interviews and that any information they might have heard prior to the interviews is put to one side.
34. All AAs receive initial training from the HTA, and this allows them to conduct interviews for all cases. Once trained and accredited by the HTA, AAs interview potential donors, the person consenting on the donor's behalf, and recipients, to explore whether the requirements of the Act and the Regulations have been met.
35. Regulation 11(6) sets out the requirement that the AA must conduct separate interviews with the donor, the person giving consent if different from the donor, and the recipient. As the donor and recipient will, in many cases, be very young children, the HTA accepts that it may be inevitable that all three parties will be present in the same room for interviews. The AA must attempt to fulfil the requirements of the statutory interviews with each separately and has the right to ask for separate interviews if any matters of concern arise which suggest that this may be appropriate.
36. The Regulations detail the content of the matters to be covered in the reports on the interviews to be submitted by AAs. As a matter of policy, the report

must also contain any relevant concerns the AA has which should contribute to the HTAs assessment of whether or not it is satisfied in relation to the legal tests described at paragraph 13.

37. The HTA will then make a decision about the case based on the information provided by the AA and any other relevant information gathered as part of its management of the case.
38. It is not the role of the AA to determine medical suitability of the donor or recipient. This is the responsibility of treating clinical teams.
39. The referral letter to the HTA, via the AA, from the Clinician responsible for the donor (or someone acting on their behalf) should contain all the necessary information for comprehensive interviews to be carried out with the donor, the person consenting on their behalf and the recipient. This must include confirmation that the donor does not have capacity or competence to consent for himself or herself and that the person consenting on the donor's behalf has parental responsibility (where the donor is a child). Please see further information at paragraphs 90-92.
40. The HTA does not believe it is necessary for AAs to have access to the donor or recipient's medical notes to fulfil the statutory requirements of the AA interviews.

### **Resources required for the role**

41. The resources required by AAs to carry out their roles should be provided by the hospital trust.
42. Ideally these resources should include:
  - time built into job plan/timetable;
  - a room in which to see the donor, person consenting on the donor's behalf, and the recipient;
  - access to networked IT equipment;
  - somewhere secure to temporarily store notes from interviews, for example a lockable filing cabinet.
43. The HTA is not funded to remunerate AAs and any queries should be dealt with by the hospital trust.
44. It is recommended that any travel expenses an AA incurs as part of this role should be paid by the hospital trust concerned.

## **Person specification**

45. Before contacting a Stem Cell Coordinator, individuals interested in becoming an AA should ensure they meet the person specification:

### **Skills**

- Professional expertise in working and speaking with children and their families;
- excellent oral and written communication skills;
- IT literate, with an ability to grasp new systems;
- excellent interpersonal skills;
- confidence in interviewing patients and exploring and addressing health issues and health risks;
- familiar with requirements to maintain patient confidentiality;
- the ability to work confidently in a hospital environment;
- experience of report writing to a high standard;
- familiar with equality and diversity legislation.

AAs come from varied backgrounds. Current AAs include:

- Clinical Psychologists;
- Play Specialists;
- Paediatric Nurse Practitioners
- Social Workers

46. If an individual is interested in applying to become an AA, but unsure whether they meet the requirements above, they should contact their local Stem Cell Coordinator in the first instance.

## **Training and Accreditation**

47. In order to be accredited, an individual must complete an application form, including details of a referee to support their application (usually their Head of Department or Manager), and submit it to the HTA LDAT. The HTA will only accept applications from people at transplant units where the Stem Cell Coordinator has indicated there is need for additional AAs to be trained.

48. The LDAT will check the application and request a reference. Once a satisfactory reference has been received, they will contact the individual with details of training.

49. Once AA training has been completed, an enhanced DBS check will be conducted by the HTA. This certificate is considered valid for a period of 3 years. After this, it is the responsibility of the Hospital Trust to keep DBS checks up-to-date and send a confirmation to HTA. AA training delegates that

have an existing DBS check dated within the last 6 months will be accepted by the HTA.

50. Following successful completion of the training, a DBS check will be carried out by the HTA. Once a copy of DBS check is received, a certificate of accreditation will be issued and a letter of confirmation sent to the individual. A letter will also be sent to the Chief Executive of the Trust and the Clinical Director at the unit, in addition to the Stem Cell Coordinator. This letter will confirm the AA's accreditation.

51. In addition, the HTA provides refresher training (online or in person) to keep the AAs informed of any relevant case studies and policy changes for assessing cases.

52. It is recommended that once accredited, AAs observe an AA interview with an experienced AA.

#### **Liability of Accredited Assessors**

53. All liabilities in regard to AAs and accredited assessment interviews fall to the HTA. The HTA has a duty of care to act in a reasonable manner towards AAs when they are acting on behalf of the HTA.

### **The assessment process and responsibilities of the Human Tissue Authority**

54. The HTA has a legal obligation to assess all cases of bone marrow and peripheral blood stem cell donation where the donor is either an adult that lacks capacity or a child that lacks competence to consent.

55. All cases are decided by a member of the HTA LDAT except cases where, having made an initial assessment of the AA report, rejecting the case is a possibility. In those circumstances the case will be referred to a panel of three HTA Authority Members.

## **Best interests**

56. The HTA must be assured in each case that the person providing consent on the donor's behalf has made a decision which has taken account of all relevant matters and is focused solely on the best interests of the donor. The decision maker must show that they have not taken a decision based upon the best interests of the recipient, or sought to balance the best interests of the donor and the recipient.
57. Where a parent or other decision maker makes a medical treatment decision on behalf of a child, the decision maker must weigh up all the risks and benefits of the proposed medical procedure and reach the decision that going ahead with the procedure is in the best interests of the donor child. The same approach applies in cases where there is a best interest decision maker for an adult who lacks capacity.
58. Where a decision is made on behalf of a child or an adult who lacks capacity, the Regulations require the AA to interview the donor to establish their views about the procedure. Where a child or adult expresses a wish not to go ahead with the procedure, the HTA must be assured that the person consenting on behalf of the donor has properly taken these views into account before reaching their decision.

### **Has the decision been made in the best interests of the donor?**

59. Making a 'best interests' assessment on behalf of a donor is not the role of the HTA. In cases where the donor is a child without competence to consent, it is the decision of the person with parental responsibility and the HTA must be assured that that person providing consent has asked himself/herself the right questions and has focussed on balancing the interests of the donor alone.
60. Clinicians with responsibility for the care of a donor must assure themselves that the donation is in the best interests of the donor before making a referral to an AA. The referral letter must contain confirmation of this.
61. AAs must check with the person consenting on the donor's behalf that the decision has been made in the best interests of the donor. We would advise that AAs do so by introducing the topic into the meeting, for example:
- Can you tell me about how you came to the decision that the donation is in the best interests of the donor?
  - Can you tell me about what factors you considered when reaching that decision?

## Responsibilities of Clinicians and Clinical Teams

62. The HTA recognises that particular cases will raise clinical, and sometimes ethical, issues. Clinicians are responsible for the overall care of donors and recipients, and for assessing the medical suitability of potential donors.
63. Consent underpins the lawfulness of treatment and all Clinicians have a duty of proper professional conduct in accordance with the [GMC Guide to Good Medical Practice](#) as expanded in its [Consent Guidance](#), to ensure that they have properly considered the ability of the donor to consent and are satisfied on whether or not they have competence or capacity to do so. There is a duty for doctors to take account of all relevant circumstances, including the treatment involved and the possible effect of this on the donor.
64. Adults and children who can make their own decisions about medical treatment are able to donate bone marrow or PBSCs without HTA involvement. Children and young people under 16 may have competency to consent, depending on their maturity and ability to understand what is involved in the donation of bone marrow or PBSCs. Further comprehensive information is available in the [GMC 0-18 guidance: Assessing capacity to consent](#).
65. If the HTA receives an application where the donor is a child, the first question for the HTA will be whether the child appears to be competent. The HTA only has power to make a decision if the child is not competent and so competence must be explored by the clinical team in advance of referral to the HTA via an AA.
66. If the HTA receives a case where it is felt the donor may have competence the HTA may:
- Request that the Clinician referring the case provides the HTA with details of the competence assessment that was undertaken for the child;
  - Following that, if the matter remains unclear, the HTA may make an application to the court 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 decide whether the child has competence to consent to the procedure for himself or herself.
67. The HTA can only make decisions for adults where satisfied that the adult lacks capacity to make their own medical treatment decisions. If the HTA receives an application in respect of a proposed adult donor, the HTA must consider whether the donor has capacity to consent to the medical treatment

decision for himself or herself. If there is any doubt, the HTA will require an application to be made to the Court of Protection for a decision about whether the proposed donor is able to make the medical treatment decision for himself or herself.

68. All families 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. Copies of this leaflet can be requested from the LDAT on [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) and is available to download in a range of languages from the [HTA website](#).
69. As a matter of either legislation or policy, certain activities need to be completed prior to the case being referred to the HTA. It is important to note that a case is considered to have been referred to the HTA at the point at which the AA receives the referral letter. The following sections will note the legal requirements and policy matters.
70. In cases where a repeat donation may be required, the HTA must make a decision based on a new AA report. The Clinician responsible for the donor must therefore write a new referral to an AA to enable a fresh set of statutory interviews to be undertaken.

## **Children without competence acting as donors**

71. For the purpose of the Act, a "child" is a person aged 18 and under. The Act does not set out its own definition of competence and so follows the common law rules established in a series of legal cases sometimes called the "Gillick rules."
72. 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. If a child has this level of understanding and intelligence for the proposed treatment, the child can give or refuse consent for treatment on behalf of himself or herself. Further information is available in the [GMC 0-18 years guidance](#).
73. 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.
74. The HTA recognises that if a child is competent, the right to give or refuse consent for medical treatment moves from the parents to the child. It follows that 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 decisions.

75. The person consenting on a donor's behalf must be provided with sufficient information to reach an informed decision about whether to provide consent for the donor to donate bone marrow or PBSC. This information should be provided by the clinical team before the AA interviews.

**Scenario – Question about whether the person providing consent on the donor's behalf fully understands the process and procedures**

The AA receives a referral to interview a sibling pair and their father, George, who is to provide consent on behalf of the potential donor.

During the interviews, the AA questions George about his understanding of the nature of the procedure and risks to the potential donor. George appears to lack understanding and has not been able to retain the information provided to him by the clinical team. The AA continues but remains concerned about whether he has capacity to give consent on behalf of the potential donor.

The AA completes the interviews and reports in detail their findings to the HTA highlighting the concerns about George's capacity.

In all scenarios where the AA would like further advice it is recommended they call the HTA.

76. To ensure that valid consent is given by the person consenting on the donor's behalf, for both common law and the Act, the clinical team should make sure the following areas are fully discussed:

- The nature of the surgical/medical procedure and medical treatments involved for the donor, and the short and long term risks (this should be explained by a medical practitioner with appropriate qualifications to give this information). This information should include the risks to the donor.
- The chances of the transplant being successful and any possible side-effects or complications for both donor and recipient.
- The right to withdraw consent at any time before the removal of the transplantable material.
- The decision to donate must be free of duress or coercion.
- That it is an offence to give or receive a reward for the supply of, or for an offer to supply, any transplantable material. It is also an offence to seek to find a

person willing to supply transplantable material for reward. As such, any offer of a reward in exchange for transplantable material is an offence in the UK. If found guilty of this offence a person may face up to three years in prison, a fine, or both.

77. The person consenting on behalf of the donor should have a clear understanding of the benefits and disadvantages of transplantation in their particular case, as well as the general risks and benefits.
78. In addition to the information above, there may be further information specific to that donor and/or recipient which the clinical team consider the donor and person consenting on their behalf must be told about in order to make an informed decision.
79. The donor, person consenting on their behalf and recipient should be made aware of the nature of the interviews with the AA, and that a report will be submitted for decision by the HTA. Information should be provided to the donor, person consenting on the donor's behalf, and recipient on the areas which will be covered in the interview and the type of questions which will be asked.

#### **Scenario – AA considers the potential donor to be competent**

The AA receives a referral to interview a 13 year old potential donor, Hossam. The referral letter states that Hossam lacks competence to consent for himself.

During the interviews, the AA questions Hossam on his understanding of the nature of the procedure and the risks involved and how he has come to be a donor for his sister. The AA finds Hossam to have a thorough understanding and appears to be able to weigh up the risks and benefits of the procedure, having known about his sister's illness for five years. The AA considers that Hossam may be Gillick competent.

The AA documents these findings in their report to the HTA, and uploads the referral letter. The HTA will investigate further and may request that the clinician responsible for Hossam provides the HTA with the details of the competence assessment undertaken for him.

## Adults lacking capacity acting as donors

80. 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.
81. Where a decision is made on behalf of an adult who lacks capacity, the Regulations require the AA to interview the donor to establish their views about the procedure. Where an incapacitous adult expresses a wish not to go ahead with the procedure, the HTA must be assured that the person consenting on behalf of the donor has properly taken these views into account before reaching their decision.
82. 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).
83. Unless paragraph 82 (b) or (c) apply in any case, where a donation is proposed from an adult who lacks capacity, the HTA requires the Unit making the application to show that an order has been made by a Judge of the Court

of Protection providing that it would be lawful to carry out the donation procedure.

84. This order should be obtained prior to referring the case to the HTA for a decision. In these circumstances, while the decision of the Court will provide for consent on the donor's behalf, the HTA will still need to be satisfied that no reward has been given or sought. For further details on capacity to consent please refer to our code of practice Code G: Donation of allogeneic bone marrow and peripheral blood stem cells from transplantation.

85.

### **Scenario – Adult who lacks capacity to consent to donation**

Seamus is a 38 year old potential donor who has been diagnosed with autism. His sister requires a bone marrow transplant, they have no other siblings, and no other matches have been found through the Bone Marrow Registries.

The AA receives the referral letter from the clinician with responsibility for Seamus which sets out that an application was made to the Court of Protection, and that an order has been made providing that it would be lawful to carry out the donation procedure. The referral letter states that Seamus has a level of understanding of the donation process similar to that of a 7 year old.

The AA will meet with Seamus and his sister together, and separately, to discuss whether any reward has been given or sought. Seamus is seen by the AA with a nurse present. In the interview the AA directs the questions to Seamus to seek his understanding of the donation process. The AA also asks Seamus if he was promised anything for helping his sister.

In the interview with the recipient the AA questions the recipient about her understanding of reward and whether anything has been promised to Seamus, by her or anyone else.

The AA then writes and submits the report to the HTA with the referral letter providing full details of the interviews.

## Translators

86. When a translator has been required in discussions between the clinical team and the donor, person consenting on the donor's behalf and recipient, this should be referenced in the referral letter so the AA is aware a translator will be required for their interview. It is acceptable for telephone translators to be used. Form HTA IT (DC) should also be completed and accompany the referral letter (see useful links and resources on page 32-33). Please note that the HTA IT (DC) form does not need to be sent to the HTA.
87. In situations where a local independent translator is not available, a facility such as 'Language Line' can be used, provided a signed declaration form is obtained. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing.
88. AAs should include in their report any problems experienced with the quality of the translation service provided, for example where there has been a complaint that responses are being mistranslated.
89. The translator used should have no personal connection with either the donor or the recipient; should have some understanding of medical matters, and should speak the donor's and recipient's language fluently.
90. AAs can also act as translators provided that they are fluent in the specified language.

## Referral letter

91. The Regulations require that a medical practitioner with clinical responsibility for the donor must have caused the matter to be referred to the HTA. It is important to note that a case is considered to have been referred to the HTA at the point at which the AA receives the referral letter.
92. The letter must include confirmation that the medical practitioner is satisfied:
  - that the donor's health and medical history are suitable for the purposes of transplantation
  - that the donor lacks the capacity or competence to consentand for child donors:
  - that the person providing consent has parental responsibility for the child and has capacity to provide consent; and

- has disclosed any evidence of any dispute between those with parental responsibility as to whether the consent should be provided

93. The referral letter should also provide information on the recipient's capacity to participate in an AA interview. An example template referral letter can be found on the [HTA website](#).

### **Scenario – Parental disagreement**

The AA receives a referral letter describing a disagreement between the parents of the 3 year old potential donor, Rachel. Rachel's father believes it is in her best interests to donate to her 1 year old half-sister, his child with a new partner. Rachel's mother disagrees and does not believe it is in Rachel's best interests.

The referral letter outlines that an order has been made by a Judge of the Court of Protection providing that it would be lawful to carry out the donation procedure as it is considered, by the Judge, to be in Rachel's best interests.

When the AA meets both Rachel and the recipient with their father present, the AA is unable to interview the recipient as she is preverbal and the potential donor has a limited understanding of the process as she presents as quite a shy child. The AA engages with the children as far as is possible but is unable to interview either child more formally.

Instead, the AA writes their report to the HTA highlighting the communication difficulties encountered, that an order from the court has been provided and their discussions with the father.

### **The referral process**

94. The referral should be made by a registered medical practitioner, or a person acting under their supervision. The HTA considers a Stem Cell Coordinator or Nurse Specialist to be a suitable person to make the referral.

### **Accepting referrals**

95. Before accepting a referral for a case, AAs should make sure that they will be able to:

- undertake the interviews within one month of referral;
- submit their report to the HTA within 10 working days of the interviews;
- 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.

96. It is important that annual leave arrangements are taken into account when scheduling interviews, as delays may result in scheduled 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 for the AA to ask the clinical team to find an alternative AA for that case.

## **The Accredited Assessor interview process – general guide to interviewing**

97. There are statutory requirements that must be met in each case before the HTA is able to give approval for the donation (please see paragraph 13).

98. The interview style and approach that an AA takes will depend on the circumstances and the ages of the people being interviewed. The HTA expects a light touch style where very young children are being interviewed.

99. AAs can structure the interview approach flexibly to ensure the statutory requirements are addressed. The interviews should enable the HTA to ascertain whether the legal requirements have been met. Please see paragraph 55-60 for further information about addressing the issue of best interests.

100. The HTA system places the report of the AA interviews at the centre of the 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

### **Interview with the donor**

101. The interview with the donor must, by law, cover the following matters:

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

102. 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.

103. AAs should undertake interviews sensitively and in an age appropriate manner. Some children may be unable to address or recall information required in these interviews and indeed many of the concepts which an AA is required to cover may be difficult for very young children to understand. Where this happens, reference must be made to this as a communication difficulty in the AA report. The report should also set out what steps the AA took to seek to overcome these difficulties, where possible.

*Steps to take where the donor cannot be interviewed due to being a baby/preverbal child*

104. In all cases, the AA should undertake, or attempt to undertake, an interview with the donor. The only exception is where the donor unarguably lacks capacity, for example if they are a baby or a preverbal child then attempting an interview would be disproportionate and result in unnecessary use of resources.

105. In all cases the AA should at least aim to see the donor and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible.

*Steps to take where AAs consider that the donor may have capacity or competency to consent*

106. Where an AA considers that a potential donor may have competence or capacity to consent for themselves, AAs should document this clearly within their report alongside the evidence on which they reached this conclusion.

*Steps to take where a donor indicates that they do not wish to proceed*

107. On very rare occasions, a donor may express a wish not to go ahead with the procedure. In this circumstance, 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.

108. A parent or best interests 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.

109. AAs must ensure that any conversations where the donor indicates a wish not to proceed are fully documented in their report to the HTA.

#### **Scenario – Potential donor who cannot be interviewed**

The AA receives a referral letter which states that the potential donor, Bhavna, is 1 year old and therefore unable to be interviewed.

The AA will still need to see Bhavna; this can be at the same time as interviewing the recipient and person consenting on behalf of the potential donor.

The AA will detail the communication difficulties with Bhavna in the report to the HTA, explaining why the interview was not attempted and reporting fully on the interviews with the recipient and the person consenting on Bhavna's behalf.

#### **Interview with the person consenting on the donor's behalf**

110. In cases where the donor is a non-competent child, the person consenting on their behalf must have parental responsibility for the child.

111. The primary role of the HTA is to ensure that consent is in place. The HTA must be satisfied in each case that:

- The person giving consent has the legal right to do so;
- The person giving consent has understood they have to be solely focused on the best interests of the donor child; and
- The person giving consent has made a proper decision that the donation is in the donor's best interests.

112. The Regulations require that the AA report covers "any evidence of duress, coercion or offer of reward" affecting the decision to give consent.

113. 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 whether (a) any external pressure has been placed on the person making the consent decision which may have affected their decision to do so and (b) any pressure which has been placed on the donor to go ahead with the procedure. This may involve pressure being placed on a third party who is influencing the decision of the donor or the person making the consent decision.

114. 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.
115. The AA report must confirm that the person consenting on the donor's behalf understands the nature of the medical procedure and the risks involved, and that consent may be withdrawn at any time.
116. The AA report must confirm that the person providing consent has considered the best interests of the donor. Please see paragraphs 55-60 for comprehensive information on best interests.
117. The AA must be satisfied that the person providing consent on behalf of a non-competent child has the necessary capacity to consent to the procedure.

### **Interview with the recipient**

118. In all circumstances, an interview should be attempted with the recipient. Where the recipient is a child, the AA should act in a proportionate manner when undertaking the interview. In line with legal provisions, the HTA considers it important that children are involved in discussions about their treatment.
119. The AA report on the interview with the recipient must cover any evidence of duress and coercion affecting the decision to give consent. The HTA interprets this to mean any evidence of whether (a) any external pressure has been placed on the person giving consent that would affect their decision to do so, or (b) 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.
120. The recipient interview should 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.
121. The AA should provide a report of the recipient interview, commenting on capacity problems under the provision of the Regulations relating to communication difficulties and how, where possible, these were overcome.

122. This section of the report may, under certain circumstances, simply report that it was not possible to interview the recipient and the reasons for this. This is likely to be in the following circumstances, although this list is not exhaustive:

- Where the recipient is a preverbal child or very young baby
- Where the recipient is extremely unwell and lacks capacity to be interviewed
- Where the recipient is in isolation

123. If the interview is undertaken and, as a result of the recipient's lack of capacity, elicits no information relevant to the HTA's requirements, then this should also be reported.

124. Where the recipient lacks capacity, there is no requirement for someone to be interviewed on their behalf.

#### **Scenario – Recipient who cannot be interviewed**

The AA receives a referral letter which states the recipient, Connor, who is 12 years old, cannot be interviewed as he is currently an inpatient and very unwell.

The AA confirms this with the clinical team at the time of interviews, and it remains the case that the recipient is too unwell.

The AA proceeds with the interviews with both the potential donor and the person consenting on behalf of the potential donor and the AA reports on these interviews to the HTA. The AA reports in detail to the HTA the reason for being unable to interview Connor. There is no requirement for anyone to be interviewed on Connor's behalf.

#### **Other requirements for the AA report**

125. As a matter of policy, the report must also contain any relevant concerns that the AA has which may need to be taken into account by the HTA, in making the decision on whether the HTA is satisfied, in relation to the statutory tests described above at paragraph 13.

126. As above, Regulation 11(6) sets out the requirement that the AA must conduct separate interviews with the donor, the person giving consent if different from the donor, and the recipient. As the donor and recipient will, in many cases, be very young children, the HTA accepts that it may be inevitable that all three parties will be present in the same room for interviews.

127. When the donor and/or recipient is a child, then it is appropriate for an adult to accompany them, although the donor and/or recipient interview itself should be with the child and not the adult. If this is not possible, then the AA should contact the HTA prior to the interview to discuss the options available.

128. All AAs must have a valid DBS check in order to interview a child where there is another adult in the room. Hospital trusts may have different policy requirements and we would advise Stem Cell Coordinators to seek further information on these from their trust's legal team.

### **Completing and submitting the Accredited Assessor report**

129. The HTA has a [secure online portal](#) accessed via the HTA website, for the submission of AA reports. The system allows AAs to write reports electronically and save them as frequently as they wish before submitting to the HTA. A copy of the referral letter required by the HTA should be uploaded alongside the report.

130. Separate guidance for AAs using the portal, is available on the [HTA website](#).

131. 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 team.

The table below provides a summary of what is required under each section of the online report to be completed by an AA.

<b>Report section</b>	<b>Mandatory information</b>
Section A – Type of transplant	<p>In this section, AAs are asked to confirm that they have read, understood and applied the guidance issued by the HTA.</p> <p>AAs are asked to confirm if the transplant will be taking place in Scotland. If yes, AAs should indicate this in the report to ensure they see the relevant report sections for Scotland.</p>
Section B – Details of donor, recipient and transplant unit	<p>Details on the donor, recipient and transplant units must be entered here.</p>
Section C – Details of person consenting on behalf of the donor	<p>Details of the person consenting on behalf of the donor, and their relationship with the donor are to be entered here.</p> <p>In this section, AAs are asked to provide details of a court approval if it has been required.</p>

<p>Section D – Communication</p>	<p>This section should be used to highlight any communication difficulties with those interviewed, and how any communication difficulties were overcome.</p>
<p>Section E – Understanding the risks and procedure</p>	<p>The AA must provide information on the donor’s understanding, to an age appropriate level, and their acceptance of the nature of the procedure and the risks involved in the donation.</p> <p>The AA must also provide information on the person consenting on behalf of the donor’s understanding and acceptance of the nature of the procedure and the risks involved in the donation.</p> <p>The AA must confirm that the donor and person consenting on behalf of the donor understand that they are able to withdraw consent and do not wish to do so at present.</p>
<p>Section F – Duress, coercion and reward</p>	<p>AAs must provide information on the details of the discussions had during the interviews with the donor, the person consenting on behalf of the donor and the recipient, in order to determine (as far as possible) that:</p> <ul style="list-style-type: none"> <li>• There was no evidence of duress or coercion affecting donor’s decision or the person consenting on behalf of the donor’s decision to give consent;</li> <li>• There was no evidence of an offer of reward that would affect the donor’s or the person consenting on behalf of the donor’s ability to give consent.</li> </ul> <p>The report must contain any evidence of duress, coercion or reward affecting the decision to give consent. There must be sufficient evidence for the HTA to exercise an independent judgement. It must include not only that the AA reached a conclusion, but also the rationale as to why the AA reached that conclusion.</p> <p>The HTA must be able to exercise an independent judgment in considering whether it can be satisfied that that no reward has been, or is to be given, and that there is no duress or coercion.</p>

<p>Section G – Best interest assessment</p>	<p>In this section, AAs are asked to provide details of the best interest’s discussion with the person consenting on behalf of the donor.</p> <p>AAs are also given an opportunity to draw to the HTA’s attention, any other issues which may be relevant to the case decision and are not covered elsewhere in the report.</p>
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132. A copy of the referral letter should be submitted at the time of the report submission, ideally by scanning and uploading the document alongside the AA report. For those without document scanning facilities, please forward a copy of the referral letter **immediately** after the interviews in a prepaid envelope provided by the HTA. These envelopes are available on request via [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk).
133. Once the online report is submitted, the AA will receive an email notification that the report has been received by the HTA.
134. Once a decision has been made by the HTA, an automated notification will be issued to the AA, the Stem Cell Coordinator(s) and the Clinicians detailed in the report. The decision can be accessed by logging into the portal.
135. The HTA recommends that more than one Stem Cell Coordinator/Nurse Specialist is detailed in each report (where the unit has two or more), to enable access to the decision when one person is on leave or unexpectedly absent.

## **Case review by the HTA**

136. Once the HTA receives a case from an AA, this will be assigned to a member of the LDAT. A general check of the report will be carried out to ensure that all required sections have been completed. The case will then be considered for decision.
137. If information is unclear or is missing from the report, the AA will be contacted for further clarification. When the HTA ask for more information, we are not questioning the judgement of the AA; we are simply gathering minimum evidence to make a lawful decision.

## **Case Review Meetings**

138. A Case Review Meeting will be convened if any of the contents of an application give rise to concerns that:
- i. there are indications that the donor or person providing consent is being coerced or is under duress;
  - ii. there is any indication that reward has been offered, given, sought or received;
  - iii. AA comments indicate any unease with the application.
139. Where, having made an initial assessment of the AA report, rejecting the case is a possibility, the case will become a panel case requiring a decision by three Authority Members. The LDAT will identify a panel and convene a Case Review Meeting. A Case Review Meeting exists to decide what further action needs to be taken in order to allow the case to proceed, or whether a Regulatory Decision Meeting is needed.
140. A Case Review Meeting will be attended by the Director of Strategy and Quality, the LDAT, and members of the panel. One aim of the meeting will be to identify any further evidence that the HTA should seek in order to enter the Regulatory Decision Meeting. This evidence could include, but is not limited to:
- further discussions with the Stem Cell Coordinator or the AA;
  - a further directed AA interview with the donor, person consenting on the donor's behalf, or the recipient;
  - further supporting documentation.

## **Regulatory Decision Meeting**

141. A regulatory decision meeting will be convened once the actions agreed at the Case Review Meeting have been completed.
142. Attendees at the Regulatory Decision Meeting will be the same as those at the Case Review Meeting, plus an external legal adviser. The aim of the meeting is to make the decision whether to approve or reject the application. A panel will always make the decision in cases that require a Regulatory Decision Meeting.

## **Other considerations**

### *Cases where approval cannot be given*

143. In situations where the HTA is not satisfied on the legal tests, the HTA's policy is that it should provide its reasoning as part of its notice of decision set out in regulation 11(5). However, there may be cases where the HTA decides that it would not be appropriate to provide reasons. For instance, by 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.

## **Reconsiderations (appeals)**

144. Once the HTA has given approval, it will have done so on the basis of being satisfied that the legal tests have been met, as well as being satisfied that there is no other legal reason that would make the surgery unlawful. If the HTA receives evidence between giving approval and the procedure taking place that could affect the test of being satisfied, then it has power under the Regulations (13) to reconsider the case and make a fresh decision.
145. In deciding whether to reconsider a decision, the HTA must be satisfied that any information given for the purpose of the decision was, in any material respect, false or misleading, or that there has been a material change of circumstances since the decision was made [Regulations 13(1)]. The Regulations (14) require that reconsideration is made as a fresh decision at a meeting of the Authority, and that any members involved in the original decision are disqualified from participation in the fresh decision. Depending on the facts of the case, further information may be required from the donor, person consenting on behalf of the donor, and/or the recipient, in order to reach a decision.
146. The Regulations also allow specified persons, listed below, to request a reconsideration of a decision of the HTA. For reconsiderations initiated by

specified persons [Regulations 13 (2) and (3)] the reconsideration will be managed in line with the appropriate Standard Operating Procedure.

147. Specified persons who can request a reconsideration of a HTA case decision are:

- The donor, or any person acting on his/her behalf;
- The recipient, or any person acting on his/her behalf;
- The registered medical practitioner who caused the matter to be referred to the HTA.

## **Service Standards**

148. The HTA aims to assess all non-panel cases within five working days. The timeline starts from the point at which the HTA has all the information it needs to assess the case.

149. The HTA is committed to ensuring we deal with enquiries swiftly and accurately. We commit to responding to all enquiries within ten working days, and urgent requests are dealt with as soon as possible.

## **Contingency report system**

150. Should the portal be unavailable for any reason, the process for submitting AA reports is as follows:

- if the system cannot be accessed online, AAs should retry after a few hours and if still unavailable contact the HTA;
- if the HTA confirms that the portal is unavailable AAs should complete a contingency version of the report using the word template which can be downloaded from the AA page of the [HTA website](#).

151. The report should then be submitted by email to [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) with 'AA report' in the subject line.

152. If a report cannot be received or submitted by email, a copy should be sent to fax number 020 7269 1999. It is key that the HTA is contacted before the fax is sent to confirm that it can be securely received.

## Useful links and resources

### Human Tissue Authority resources

Leaflets	<p><i>Our role in bone marrow and peripheral blood stem cell donation (multiple languages)</i>  <a href="https://www.hta.gov.uk/guidance-public/bone-marrow-and-pbsc-donation">https://www.hta.gov.uk/guidance-public/bone-marrow-and-pbsc-donation</a></p>
Guidance	<p><i>Guidance for using the portal</i>  <a href="https://www.hta.gov.uk/policies/information-about-hta-portal-including-login">https://www.hta.gov.uk/policies/information-about-hta-portal-including-login</a></p>
Forms	<p><i>Accredited Assessor application form</i>  <a href="https://www.hta.gov.uk/policies/become-accredited-assessor">https://www.hta.gov.uk/policies/become-accredited-assessor</a></p> <p><i>Form HTA IT (IA)</i>  <a href="https://www.hta.gov.uk/sites/default/files/Form_HTA_IT_(IA).pdf">https://www.hta.gov.uk/sites/default/files/Form_HTA_IT_(IA).pdf</a></p> <p><i>Form HTA IT (DC)</i>  <a href="https://www.hta.gov.uk/sites/default/files/From_HTA_IT_(DC).pdf">https://www.hta.gov.uk/sites/default/files/From_HTA_IT_(DC).pdf</a></p>

### External resources

Leaflets	<p><i>Children's cancer and leukaemia group: Jess' bone marrow donation</i>  <a href="http://www.cclg.org.uk/our-publications/all-publications/jess-s-bone-marrow-donation">http://www.cclg.org.uk/our-publications/all-publications/jess-s-bone-marrow-donation</a></p>
Guidance	<p><i>General Medical Council:</i></p> <p><i>Good Medical Practice</i>  <a href="http://www.gmc-uk.org/guidance/index.asp">http://www.gmc-uk.org/guidance/index.asp</a></p> <p><i>Consent:</i>  <a href="http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp">http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp</a></p> <p><i>0-18 years</i>  <a href="http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp">http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp</a></p>
Legislation	<p><i>Human Tissue Act 2004</i>  <a href="http://www.legislation.gov.uk/ukpga/2004/30/contents">http://www.legislation.gov.uk/ukpga/2004/30/contents</a></p> <p><i>Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006</i>  <a href="http://www.legislation.gov.uk/uksi/2006/1659/contents/made">http://www.legislation.gov.uk/uksi/2006/1659/contents/made</a></p>

*Mental Capacity Act 2005 (applies to England and Wales only)*  
<http://www.legislation.gov.uk/ukpga/2005/9/contents>

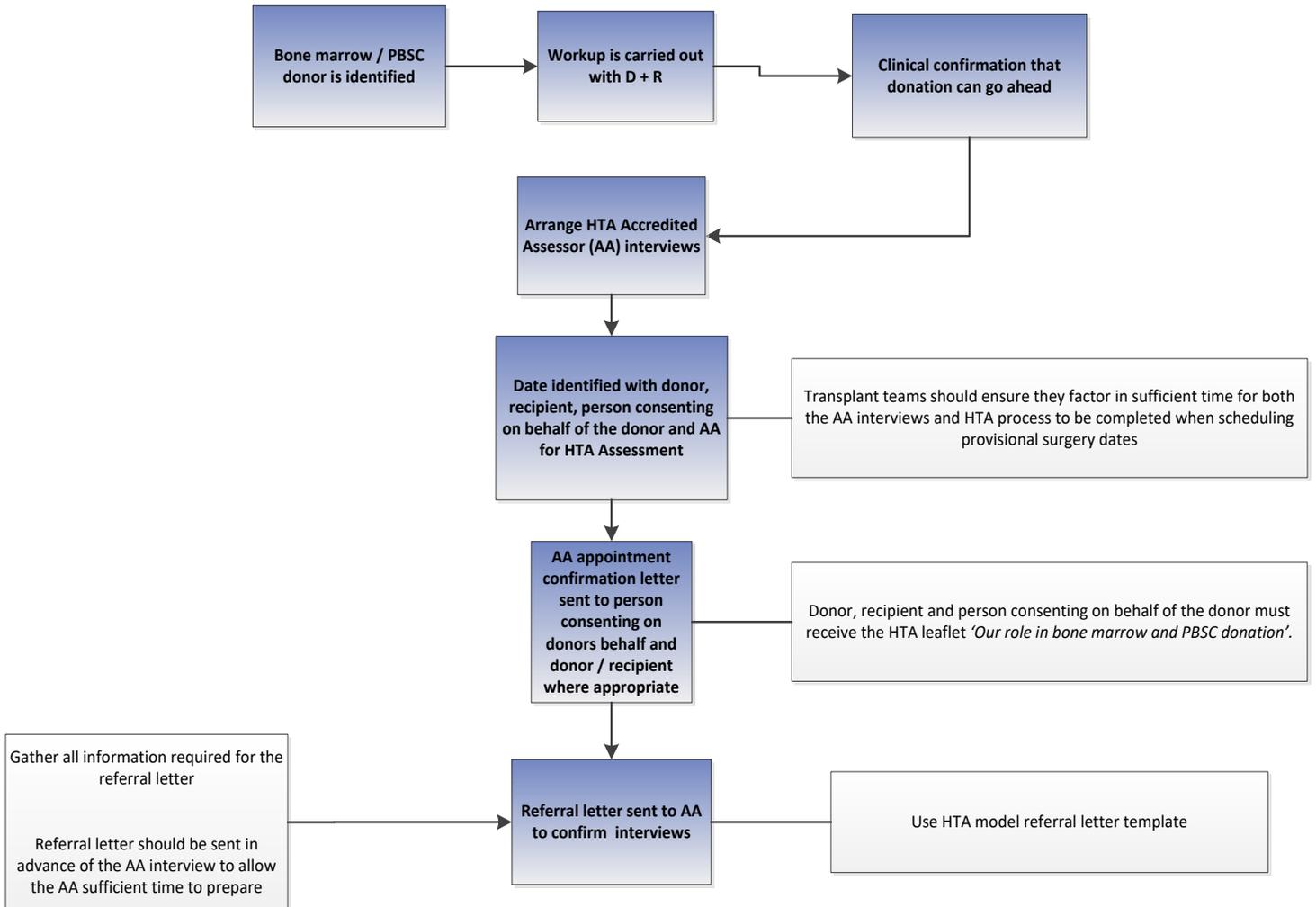
*Mental Capacity Act code of practice 2005 (applies to England and Wales only)*  
<http://www.imperial.ac.uk/pls/portallive/docs/1/51771696.PDF>

*Mental Capacity Act (Northern Ireland) 2016*  
<http://www.legislation.gov.uk/nia/2016/18/contents>

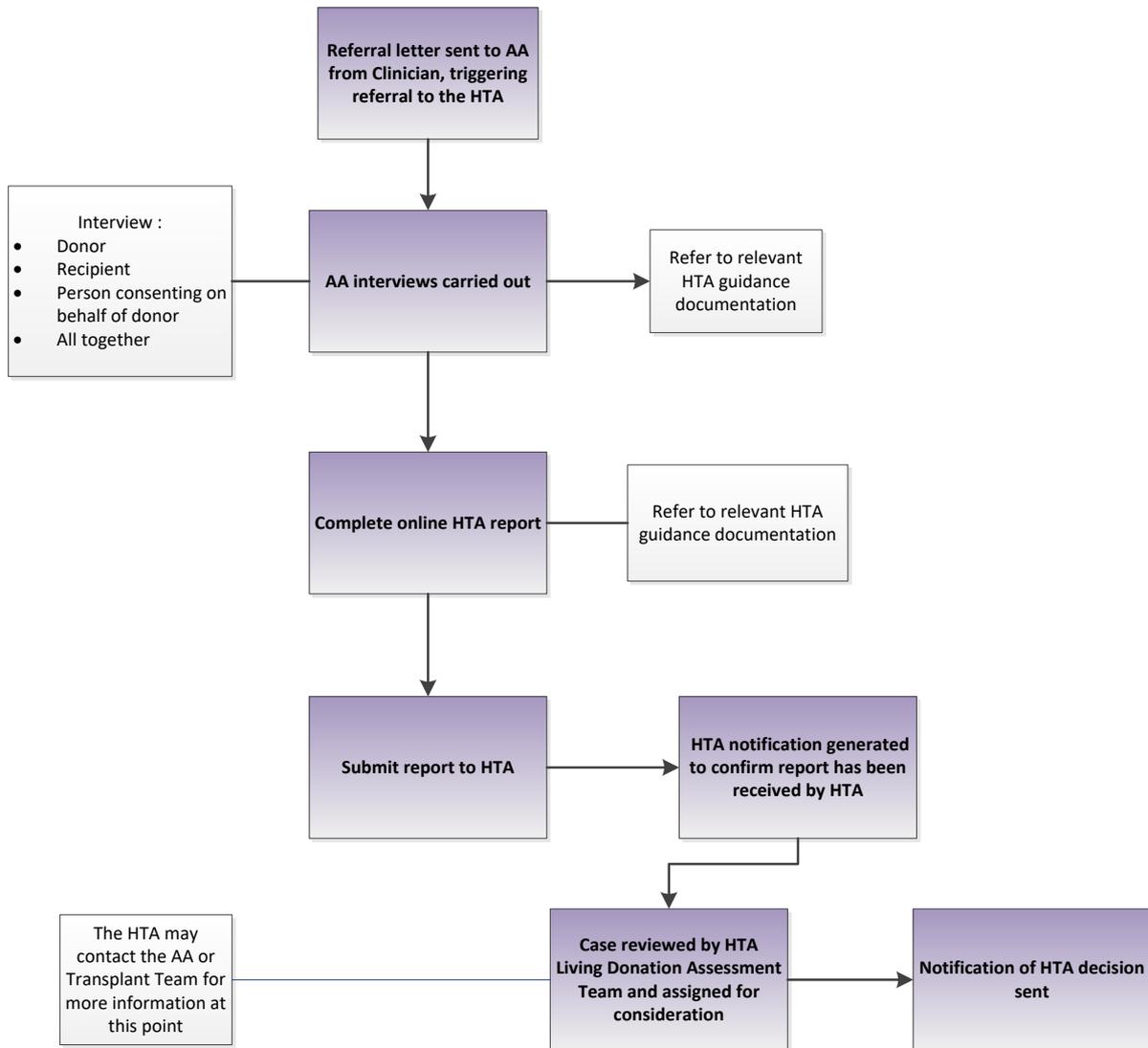
*Human Rights Act 1998*  
<http://www.legislation.gov.uk/ukpga/1998/42/contents>

# Annex A: Process flowcharts

## Stem Cell Coordinator quick reference process flowchart



## Accredited Assessor quick reference process flowchart





**For more information contact:**

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**Human Tissue Authority**  
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