HTA
Human Tissue Authority

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Guidance for transplant teams, Independent Assessors and Accredited Assessors in Scotland

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Contents

Introduction to the guidance

1. The Human Tissue Authority (HTA) is responsible for assessing applications for living organ donation and allogeneic donation of regenerative tissue on behalf of Scottish Ministers under arrangements entered into by the Scottish Ministers and the HTA. This guidance does not apply to autologous donation of regenerative tissue.

2. The law in Scotland is different from that of the rest of the UK. This publication has been produced to give practical guidance to professionals.

3. The legislation that governs donation and transplantation in Scotland is the Human Tissue (Scotland) Act 2006 (HT Scotland Act) and The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (the Regulations).

4. The HTA's remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland, which the Scottish Health Department issued on 20 July 2006[1].

5. This guidance contains information that is applicable to all establishments and professionals operating under the HT Scotland Act and the Regulations. It is consistent with the four guiding principles articulated in the HTA's Codes of Practice and should inform the actions of anyone involved in using materials originating from people. The four principles are:

   a) **Consent**, or authorisation in Scotland, and the wishes of the donor (where an adult has capacity), or where appropriate, their nominated representatives or relatives, have primacy when removing, storing and using human tissue;

   b) **Dignity** should be paramount in the treatment of human tissue and bodies;

   c) **Quality** should underpin the management of human tissue and bodies; and

   d) **Honesty and openness** should be the foundation of communications in matters pertaining to the use of human tissue and bodies.

6. This guidance aims to provide anyone undertaking activities with a reference source, which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

7. This guidance does not deal with solid organ donation from deceased donors.

[1] Ref: NHS HDL (2006) 46 - http://www.sehd.scot.nhs.uk/mels/HDL2006_46.pdf

Scope of this guidance

Solid organ donation

8. The law creates a prohibition on the removal and use of solid organs from living donors for transplantation. This prohibition can be lifted in certain circumstances where Scottish Ministers are satisfied a number of conditions are met. Scottish Ministers have entered into an arrangement with the HTA, which means that decision-making responsibilities for living organ donation applications are undertaken by the HTA. This guidance advises practitioners on the circumstances under which the prohibition on living donations can be lifted and HTA approval given. Further information about criminal offences is set out in paragraphs 19-22 below.

9. For living organ donation from adult donors who have capacity, the conditions include being satisfied that donor authorisation is in place and that this has been given free from duress, coercion, and reward.

10. Donations of solid organs from children and adults with incapacity cannot be considered in Scotland unless the donation is part of a domino donation (where the organ removal is part of that person's medical treatment).

11. The legal requirements in relation to organ donation from children and adults with incapacity are complex, and applications of this nature are infrequent. Any practitioner with an application involving a donor who is either a child or an adult with incapacity is advised to contact the HTA for specific advice at an early stage in the application process. Please see paragraphs 29-35 below for more information.

12. In addition to the requirements above, establishments may also be subject to the licensing requirements of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organ) Regulations) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (The Q&S Regulations). This guidance does not include detailed information on the Q&S (Organ) Regulations or the Q&S Regulations. Further information can be found in Annex A paragraph 5 and the HTA publications: The Quality and Safety of Organs Intended for Transplantation – a documentary framework and The Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment.

Donation of regenerative tissue

13. The HT Scotland Act does not place any prohibition on the donation and transplantation of regenerative tissue by adults with capacity, and such cases are not subject to HTA approval. Adults aged 16 and over who are able to make their own decisions about medical treatment have the legal right to decide whether to donate regenerative tissue without seeking authorisation from the HTA. Further information for clinicians about assessing a young person's capacity is available in the GMC 0-18 years guidance.

14. In cases of donation of regenerative tissue, such as bone marrow or peripheral blood stem cell (PBSC) donation from a child or an adult with incapacity, the HTA's role is to evaluate whether the necessary legal conditions set out in the Regulations have been met.

15. As the legal requirements in relation to the donation of regenerative tissue from adults with incapacity is complex, and applications of this nature are infrequent, this guidance covers only the requirements for children. Any practitioner with an application involving a donor who is an adult with incapacity is advised to contact the HTA for specific advice at an early stage in the application process.

Structure and navigation

16. This guidance document is divided into two main sections: living organ donation for transplantation and donation of regenerative tissue for transplantation.

17. The first section provides supplementary guidance to individuals working in the field of living organ donation such as clinicians, surgeons, living donor coordinators (LDCs) and HTA Independent Assessors (IAs).

18. The second section provides supplementary guidance to individuals working in the field of regenerative tissue donation and transplantation such as clinicians, stem cell coordinators (SCCs) bone marrow transplant (BMT) specialist nurses and HTA Accredited Assessors (AAs).

Offences under the HT Scotland Act relevant to this guidance

19. The HT Scotland Act sets out a number of offences relevant to activities covered by this guidance, for which the maximum penalty is imprisonment and/or a fine. The offences relevant to this guidance are as set out below.

20. Section 20 (2) of the HT Scotland Act makes it an offence to engage in commercial dealings in parts of a human body for transplantation (see section one, paragraphs 54-60).

21. The removal of organs, parts of organs or tissue from the body of a living person for use in transplantation constitutes an offence under section 17 of the HT Scotland Act unless the requirements set out in the Regulations are met (see section one, paragraphs 25-27).

22. Section 19 (4) creates an offence of failing to comply with the Regulations, and failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations.

Section one: Living organ donation

Types of living organ donation

23. The HT Scotland Act and the Regulations place an obligation on Scottish Ministers to assess all applications for living organ donations from adults with capacity that are referred by their medical practitioner.

24. The HTA has been given responsibility to assess these applications through arrangements with Scottish Ministers. The HTA distinguishes a number of different concepts in living organ donation. These concepts are:

a) **directed donation** (adults with capacity only): A form of donation where a living person donates an organ or part organ to a specific, identified recipient with whom they have a genetic or pre-existing emotional relationship.

b) **directed altruistic donation** (adults with capacity only): The HTA defines these as cases which fulfil two conditions (a) the donation is being directed to a specified individual and (b) there is no evidence of a qualifying genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party - either a person or other mechanism such as a social networking site – bringing the donor and recipient together for the purpose of transplantation.

c) **non-directed altruistic donation** (adults with capacity only): A form of donation where a healthy living person donates an organ or part organ to an unknown recipient, that is, someone they have never met and is not genetically related or known to them.

d) **paired and pooled donation** (adults with capacity only): A form of donation where a healthy living person is unable to (or chooses not to) donate because they are either incompatible with their intended recipient, or prefer a better match. They may be matched with another donor and recipient in the same situation in the National Living Donor Kidney Sharing Schemes. The donor organs are then swapped. When two pairs are involved, it is a paired donation and where more than two pairs are involved, it is a pooled donation.

e) **non-directed altruistic donor chains** (adults with capacity only): A form of donation where a non-directed altruistic donor donates their organ into the paired/pooled scheme. By matching two or more recipients, a chain of operations can be carried out. The remaining organ at the end of the chain is then donated to the best-matched recipient on the national waiting list.

f) **domino donation** (HTA approval only required where the donor is an adult with incapacity or a child): A form of living donation in which an organ is removed for the primary purpose of the person's medical treatment. The organ removed may prove suitable for transplant into another person.

Legal considerations

25. The law requires that statutory conditions are met in order to remove and use organs from living donors for transplantation. Where donor authorisation has been obtained (applicable to donors with capacity) for the removal and use of the organ, it remains illegal to proceed with the living donor transplant unless the requirements of the HT Scotland Act and Regulations have been met. Therefore, in addition to securing donor authorisation, practitioners also require HTA approval before proceeding with the removal and use of organs for transplantation from the living.

> **Example**
>
> A clinician has obtained authorisation from the potential living donor for the removal and use of his kidney for living donor transplantation to the donor's sister. However, it is not legal to proceed without HTA approval and the clinician must refer the case to the HTA for decision via an Independent Assessor.

26. The requirements for living organ donor transplantation are set out in sections 17-21 of the HT Scotland Act and parts 2, 3 and 5 of the Regulations. They require that donations of organs or part organs must be approved by the HTA.

27. The law allows a living donor to request that their donation be directed to any identified individual, regardless of whether or not he or she has a relationship (genetic or otherwise) with the intended recipient. It is not an offence to advertise, either via traditional media or via social media, to find a suitable donor. It is, however, an offence to offer a reward as part of any such advertisement.

Donation by adults with capacity – solid organs

28. While it is not a legal requirement, authorisation should be provided by the donor in writing for the removal and use of the organ or part organ for transplantation.

Donation by adults with incapacity – solid organs

29. Adults with incapacity cannot be considered as living organ donors in Scotland unless the removal of the organ is for the patient's own medical treatment – known as a domino donation. Further information on domino donation is available in section one, paragraph 10, 42 and 51.

30. The Adults with Incapacity (Scotland) Act 2000 explains what is meant by 'incapacity' and sets out the principles to be followed by everyone who is authorised to act on behalf of someone with incapacity. The law in Scotland generally presumes that adults are capable of making personal decisions for themselves and of managing their own affairs.

31. Under the Adults with Incapacity (Scotland) Act, an adult is a person that has attained the age of 16 years. Incapable means incapable of:

    a) acting; or

    b) making decisions; or

    c) communicating decisions; or

    d) understanding decisions; or

    e) retaining the memory of decisions.

32. The provisions of the Adults with Incapacity (Scotland) Act should be considered together with general principles governing capacity to authorise medical procedures. Further information is available from the Adults with Incapacity (Scotland) Act 2000: A short guide to the Act document.

33. Before the HTA can make an assessment of an application for a domino donation from an adult with incapacity, the HTA must be satisfied that the donor is an adult with incapacity and that the transplant is a domino donation. It is the responsibility of the Scottish Ministers to certify that an adult has incapacity.

Donation by children – solid organs

34. For the purpose of the HT Scotland Act, children are defined as those aged under 16 years of age.

35. Children cannot be considered as living organ donors in Scotland unless the removal of the organ is for the patient's own medical treatment – known as a

domino donation. Further information on domino donation please see section one, paragraph 10, 42 and 51.

The role of the HTA and requirements for HTA approval to be given

36. The role of the HTA is to lift the prohibition on living organ donation that exists unless all the conditions described in the Regulations have been met. The Regulations are included as Annex A and the necessary conditions differ from case to case as follows:

    a) for organ donation from adults with capacity please refer to Part 2 (Regulations 2-10)

    b) for domino donation from adults with incapacity please refer to Part 3 (Regulations 3–13)

    c) for domino donation from children please refer to Part 4 (Regulations 5-16)

37. Before the HTA can approve living donation cases, a registered medical practitioner with clinical responsibility for the donor must have arranged to refer the case to the HTA. This should only be done once the registered medical practitioner is satisfied that the donor's health and medical history make them a suitable candidate.

38. At this stage the registered medical practitioner can refer the case to an Independent Assessor (IA) who will submit their report of the interviews with the donor and recipient to the HTA.

39. Once submitted to the HTA, the Regulations require that the HTA must be satisfied that:

    a) no reward has been, or is to be, given (reasonable expenses can be reimbursed please see section one, paragraphs 54-56);

    b) the registered medical practitioner who has caused the matter to be referred has clinical responsibility for the donor;

    c) the donor has authorised the removal and use of the organ or part of an organ in question for transplantation purposes;

    d) there is no evidence of duress or coercion affecting the decision of the donor to authorise the removal and use of the organ or, (in cases of directed

donation) of the recipient to be a recipient of the organ or part organ in question;

e) the donor has the capacity to understand the nature of the medical procedure and risk involved and that the donor understands that they may withdraw their authorisation at any time before the removal of the organ;

f) the donor has been given sufficient information about the nature of the medical procedure and risk involved by a person who is qualified to give that information;

g) in any case of directed donation, the relationship (if any) between the donor and recipient is as stated by each of them; and

h) any relevant wider implications arising from the intended donation have been considered by the donor. The HTA interprets this to include that the effect on any children or dependent relatives of the donor have been taken into account.

Referral to the HTA

40. 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 requirements of the Q&S (Organs) Regulations make it mandatory that certain specified information is required from the referring clinician as part of this referral. Specifically, the referral must state that the medical practitioner, or person acting under their supervision:

a) is satisfied that the donor's health and medical history are suitable for the purposes of donation;

b) has provided the donor with the information the donor requires to understand the consequences of donation; and

c) endeavoured to obtain information from the donor that is relevant to transplantation.

41. As a matter of HTA policy, the HTA requests that referring donor clinicians also state that the medical practitioner is satisfied that the donor has capacity to authorise the donation. It is also requested that detail is provided on the recipient's capacity to participate in an interview to allow the IA to make any necessary adjustments. The HTA has created a model referral letter template for units to ensure that all the legislative requirements are addressed in the

referral letter to the HTA. The HTA cannot make an assessment until it has received the referral letter.

42. For domino donations from adults with incapacity, the referral must state:

    a) that the clinician is satisfied that the donor's health and medical history are suitable for the purposes of donation;

    b) that the donor or one or more of the donor's relative, primary carer, named person, guardian or any person with an interest in the donor's welfare has been provided with the information required to understand the consequences of donation;

    c) that the clinician has endeavoured to obtain information from the donor that is relevant to the donation to determine whether the donor is unwilling to donate;

    d) that the organ to be removed or used during domino donation is intended to be used for transplantation purposes in another living person.

43. Arrangements for the statutory interview can be made at the point at which the IA receives the referral letter.

44. Transplant teams should ensure that they factor in sufficient time for both the IA interviews and HTA process to be completed when scheduling provisional surgery dates.

45. Where the donor is also the only suitable adult to accompany a child recipient to the IA interview, the transplant team is advised to contact the HTA's Living Donation Assessment Team (LDAT) for further advice.

The role of the Independent Assessor

46. In the case of a donation from an adult with capacity, the IA must carry out interviews with the donor and the recipient (where the donation is directed) and submit a report of their interviews to the HTA.

47. An IA must (see section one, paragraph 46) have conducted separate interviews with the donor and the recipient. The Regulations allow for donors and recipients to be interviewed separately and/or together. As part of HTA policy, both separate and joint interview should be carried out with the donor and recipient.

48. An IA is qualified to conduct such an interview if:

a) they appear to the HTA to be suitably qualified to conduct the interview and have completed the approved 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; and

c) in the case of an interview with the donor, the IA is not the same person who gave them information about the procedure and its risks.

49. The Regulations also specify the matters to be covered in the report submitted by the IA to the HTA. For every interview the IA must report:

a) any evidence of an offer of reward;

b) in any case of a directed donation,
   (i) the relationship (if any) between the donor and the recipient; and

   (ii) any evidence of duress or coercion affecting the decision of the recipient to be a recipient of the organ or part of an organ in question;

c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

50. In addition, for interviews with the donor, the following must be provided:

a) any evidence of duress or coercion affecting the decision of the donor to authorise removal and use of the organ for transplantation purposes;

b) the information given to the donor as to the nature of the medical procedure for, and the risk involved in, the removal of the organ or part organ in question;

c) the full name of the person who gave that information and that person's qualification to give it;

d) that the donor has capacity to understand:
   (i) the nature of the medical procedure and the risk involved; and

   (ii) that their authorisation for the removal and use of the organ or part organ for transplantation purposes may be withdrawn at any time before the removal of the organ or part organ in question.

e) any wider relevant implications arising from the intended donation including the effect on any children or dependent relatives of the donor.

51. For interviews with an adult with incapacity proceeding to domino donation the IA report must confirm:

a) that the donor is an adult with incapacity;

b) any difficulties in communication with the person being interviewed and an explanation of how these were overcome;

c) the information provided to the donor, along with the full name and qualification of the person who gave that information, in the event that the adult with incapacity is unwilling to proceed;

d) any evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor; and

e) that there is no offer of reward.

52. For interviews with the donor's nearest relative, primary carer, named person, guardian, continuing attorney or welfare attorney of the donor and any other person appearing to have an interest in the welfare of the donor, the IA report must confirm:

f) any difficulties in communication with the person being interviewed and explanation of how these were overcome;

g) whether the donor has previously indicated an unwillingness to be a donor;

h) there is no evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor; and

i) that there is no offer of reward.

53. 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 so is laid out within the Regulations and requires a fresh decision to be made by the HTA.

Prohibition of commercial dealings in parts of a human body for transplantation

54. The HTA requires that checks are made to ensure that no reward has been given, or is to be given, for the donation. However, the HT Scotland Act allows living donors to receive reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation.

55. NHS Health Boards are permitted to make such payments. Further information on reimbursement arrangements is available in the Policy on Reimbursement of Living Solid Organ Donor Expenses by NHS Boards in Scotland.

56. 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 costs were paid.

57. The HT Scotland Act also prohibits commercial dealings in human material, including organs or tissue, for the purposes of transplantation. A person commits an offence if the person:

a) gives or receives a reward for the supply of or for an offer to supply, any part of a human body for transplantation;

b) seeks to find a person willing to supply any part of a human body for transplantation or reward;

c) offers to supply any part of a human body for transplantation for reward;

d) initiates or negotiates an arrangement involving the giving of a reward for the supply of, or for an offer to supply, any part of a human body for transplantation;

e) takes part in the management or control of any type of group whose activities consist of or includes the initiation or negotiation of such arrangements; or

f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any organ or part organ for reward, or indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media.

58. For further information, please see the guidance on matching websites and social media on the HTA website.

59. The offences, outlined in section one, paragraphs 19-22, carry the risk, on conviction, of a fine and / or up to three years' imprisonment.

60. No offence is committed, however, where payments relate to reimbursement of the donor's expenses, or where reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.

Guidance for Clinicians and Transplant Teams

61. 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 living organ donor is a matter for the practitioners concerned. The British Transplantation Society (BTS) has published guidance for clinicians in the United Kingdom guidelines for living donor kidney transplantation and the United Kingdom guidelines for living donor liver transplantation.

62. While the HTA provides advice on how our regulatory requirements will apply to individual cases, the decision on whether to work-up a case rests with the transplant unit.

63. All potential donors should be provided with a copy of the HTA leaflet Our role in living organ donation and the HTA Guidance for living organ donors on the Human Tissue Authority's independent assessment process at an early stage in the work-up process to ensure that they understand the way in which living donation is regulated and how this will affect them. They should also be provided with a copy of the donor declaration form relating to reward for organ donation, which is to be signed by the donor either before or at the IA interview. This form is available in multiple languages on the HTA website.

Securing valid authorisation

64. For authorisation to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The Clinician's responsibility is to provide appropriate information to each donor to enable them to make an informed decision. Clinicians also have the responsibility of ensuring that authorisation for the removal, storage and use of organs or part organs is in place prior to referral to the HTA. Part of the HTA's role is to act as an independent check that legally valid authorisation is in place.

65. The HT Scotland Act requires that authorisation be obtained to remove and use organs for transplantation.

66. While it is not a legal requirement, it is best practice to obtain written authorisation for significant procedures such as organ and tissue donation. When authorisation is obtained but is not in writing, this should be clearly documented in the patient's records. The record should detail when authorisation was obtained and the purposes for which it was given.

Ensuring the donor is properly informed

67. Potential donors must be provided with sufficient information to reach an informed decision about whether they wish to donate an organ or part organ. This information must be provided by the clinician responsible for the donor before the IA interview.

68. To ensure that the informed authorisation of the donor is secured, the transplant team must make sure the following areas are discussed with the donor:

a) the nature of the surgical/medical procedure and medical treatments involved for the donor, and any material short and long-term risks (this should be explained by a medical practitioner with appropriate qualifications to give this information). A material risk is where, in the circumstances, a reasonable person in the donor's position would be likely to attach significance to the risk, or the transplant team is, or should be reasonably aware that, the donor would be likely to attach significance to it. This information should include the risk of death to the donor;

b) the chances of the transplant being successful, and any significant side effects or complications for the recipient, and in particular the donor should be made aware of the possibility of graft failure in the recipient;

c) the right to withdraw authorisation at any time before the removal of the transplantable material;

d) that the decision to donate must be free of duress or coercion; and

e) that it is an offence to give or receive a reward for the supply of, or for an offer to supply, any organ. It is also an offence to seek to find a person willing to supply any organ for reward. If found guilty of this offence a person may face up to three years in prison, a fine, or both.

69. The donor must have a clear understanding of the benefits and disadvantages of living donor transplantation in their particular case, as well as the general risks and benefits. Further information can be found in the BTS documents United Kingdom Guidelines for living donor kidney transplantation and United Kingdom Guidelines for living donor liver transplantation.

70. For potential non-directed altruistic and paired/pooled donors, the donor must also be informed of how the non-directed altruistic and paired/pooled process works. This must include how a suitable recipient, or in the case of paired/pooled donation, suitable matches, are identified.

71. The donor must also be informed that anonymity of the donor and recipient is required before the operations, and that confidentiality must be respected.

Guidance for Independent Assessors (IAs)

Accepting referrals

72. Before accepting a referral for a case, IAs 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; and

    c) be available in the five working days following the submission of their report, in case the HTA LDAT needs to contact them for further information or clarification.

73. Where the IA 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.

74. It is important that annual leave arrangements are taken into account when scheduling interviews as delays may result in scheduled surgery not being able to proceed. If an IA 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 IA for that case.

Statutory interviews

75. This section should be read in conjunction with the HTA Guidance to Transplant Teams and Independent Assessors, which provides detailed information on all aspects of the IA role, including who can become an IA and good practice guidance on undertaking interviews.

76. The Regulations require that an IA must have conducted interviews with the donor in all cases and the recipient in any case of directed donation. Although not a legal requirement, the HTA requires that, for directed donations, an interview must be undertaken with donor and recipient together. The purpose of this is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor's decision to donate, and to explore the issue of reward jointly with the donor and recipient. In order to do this, the IA should consider asking the donor and recipient questions about duress, coercion and reward.

77. There may be rare circumstances where the donor and recipient do not wish to be interviewed together. In these cases, the HTA must be contacted to make an application for the requirement for the joint interview to be withdrawn.

78. The Regulations detail the matters to be covered in the reports on the interviews to be submitted by IAs, including any relevant wider implications of the intended donation. As a matter of policy the report should also contain an account of any relevant concerns the IA has, which should contribute to the HTA's assessment of whether or not it is satisfied in relation to the legal tests.

The donor interview

79. The interview with the donor must, by law, cover the matters described in section one, paragraphs 49-52.

80. The primary role of the HTA is to ensure that valid authorisation for the removal and use is in place. The IA report must address whether the donor has been placed under any duress or coercion to go ahead with the donation. For the purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor, either by the recipient or a third party, to go ahead with the donation. 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 donor has been overborne such that they can no longer make an independent decision.

81. The IA 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 either the donor or any third party, for example, to anyone acting as an intermediary to bring the donor and recipient together.

The recipient interview

82. The interview with the recipient must, by law, cover the matters described in section one, paragraph 49.

83. In directed cases the IA must 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 then attempting an interview would be disproportionate. In such cases the IA should, as a minimum, see the recipient and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible in the appropriate section of the report.

84. The IA report on the interview with the recipient must cover any evidence of duress and coercion affecting the decision to give authorisation. For the

purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor by the recipient to go ahead with the donation. The IA should also report evidence of any pressure placed on the recipient to accept the organ transplant.

85. 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 authorisation has been overborne such that they can no longer make an independent decision.

86. The recipient interview must also cover any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to the donor or a third party. 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 recipients

87. The IA interviews the potential donor and recipient to assess whether the HTA requirements have been met. Interviews should take place with the recipient at a level appropriate to their age and understanding.

88. 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 at a stage of development where language or comprehension are limited, IAs 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. It is good practice to involve the parent(s) in these discussions but there is no legal role for the parents to respond on behalf of the child.

Completing and submitting an application

89. The legal framework requires that the HTA, not the IA, make the decision on whether a case can proceed. In every case of living organ 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 IA report. This means that the IA must provide a comprehensive account of their interviews including the rationale for any conclusions they draw and not only the conclusions themselves.

90. Following an interview, IAs 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 IA should inform both the transplant team and the HTA.

91. The IA report is a confidential document between an IA and the HTA. It is not appropriate to share any details of the report, or the report itself, with the clinical team.

92. A copy of the referral letter and donor declaration should also be submitted at the time of the report submission.

Panel cases

93. The HTA's responsibilities in respect of the role it has in decision making on all living organ donation cases is based on arrangements the HTA has entered into with Scottish Ministers. The HTA has a legal obligation to assess all cases that are referred to it.

94. Some cases are delegated to a member of the HTA LDAT for a decision; other cases are assessed by a panel of three Authority Members (panel cases).

95. Although there is no legal obligation to refer cases received from Scotland to panel, as a matter of policy and consistency the HTA refers those cases to panel which are required to be assessed in this way in all other parts of the UK.

96. Therefore the following types of donations are referred to a panel:

a) paired donations;

b) pooled donations; and

c) non-directed altruistic donations.

HTA decision making arrangements

97. The HTA aims to make decisions within deadlines published each year in the HTA Business Plan.

98. Once a decision has been made by the HTA, an automated notification will be issued to the IA, Living Donor Coordinator(s) and the clinicians detailed in the report. Living Donor Coordinators must inform the donor and recipient of the decision on the HTA's behalf.

99. There is no time limit on the HTA's approval, however, where a period of 12 months has lapsed since the approval was first given and the transplant has not taken place, the donor and recipient may need to be interviewed again if their circumstances have changed. In such circumstances, the HTA LDAT should be contacted for further advice on how to proceed.

100. In cases where the requirements have not been met and the HTA turns a case down, the donor (or someone acting on their behalf), 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.

101. 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.

102. Detailed information on the way in which the HTA makes decisions can be found in the HTA Decision-Making Framework, its policy for the assessment of living organ donation cases and HTA Standard Operating Procedures, which are available on request from the HTA.

Section two: Donation of allogeneic regenerative tissue

Donation of allogeneic regenerative tissue for transplantation

1. The purpose of this section is to provide guidance to Accredited Assessors (AAs), clinicians and clinical teams about the regulatory and legal requirements under the HT Scotland Act. This guidance is in relation to the assessment of prospective donations of regenerative tissue from children (those aged under 16). Beyond the general advice below, in the case of adults with incapacity, the HTA should be approached for more specific advice at an early stage.

Donation by adults with capacity

2. Adults aged 16 and over who are able to make their own decisions about their own medical treatment have the legal right to decide whether to donate regenerative tissue without seeking approval from the HTA.

Donation by adults with incapacity

3. The removal of regenerative tissue from adults with incapacity does not require court approval.

4. The HTA must consider other legislation when carrying out its duties. The Adults with Incapacity (Scotland) Act 2000, 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.

5. Adults with incapacity are able to act as donors of regenerative tissue, and the Regulations include additional protections for them, which are based on the provisions of the Adults with Incapacity (Scotland) Act. The donor must be certified as not having the capacity to understand what is involved in the donation of regenerative tissue. For further information please refer to The Adults with Incapacity (Removal of Regenerative Tissue for Transplantation) (Form of Certificate) (Scotland) (No.2) Regulations 2006.

6. Under the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (The Regulations) it is a requirement:

   a) that there is no other adult who could act as a donor;

   b) that removal of regenerative tissue involves at most a minimal foreseeable risk and no, or only a minimal, discomfort to the donor;

c) that the adult with incapacity has not indicated an unwillingness to be a donor; and

d) that the adult's nearest relative, primary carer, named person, guardian, continuing attorney or welfare attorney of the donor and any other person appearing to the AA to have an interest in the welfare of the donor is interviewed where reasonable and practical.

7. Where these requirements have been met, potential adult donors with incapacity then need to be referred to an AA who will submit their report to the HTA for decision.

Donation by children – regenerative tissue

Children under 16 years

8. For the purpose of the HT Scotland Act, children are defined as those aged under 16. In Scotland, all prospective allogeneic donations of regenerative tissue from a person who has not yet attained the age of 16 years must be referred to an AA.

9. HTA approval must be in place before the donation can proceed. This is the case whether or not the child is considered competent. For more information please refer to section two, paragraph 10-15.

The role of the HTA and requirements for HTA approval to be given

10. In the case of child donors, 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.

11. The HTA, on behalf of the Scottish Ministers, must be satisfied that:

a) no payment has been, or is to be, made;

b) the registered medical practitioner who has caused the matter to be referred to the HTA has clinical responsibility for the donor;

c) the donor is a child or adult with incapacity;

d) the tissue which is to be removed is regenerative tissue;

e) the tissue which is to be used is regenerative tissue;

f) both the donor and the person who has parental rights and parental responsibilities in relation to the donor (but who is not a local authority) have been provided with sufficient information about the removal and use of the tissue;

g) the donor does not indicate any unwillingness to be a donor;

h) there is no evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor;

i) there is no evidence of duress or coercion affecting the decision of the recipient to be a recipient of the tissue in question; and

j) the relationship (if any) between the donor and the recipient is as stated by each of the persons interviewed under paragraph 12.

12. The AA must have interviewed the donor, the person who has parental rights and responsibilities for the donor (not a Local Authority), and the recipient.

13. 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, the person who has parental rights and responsibilities, the recipient or the referring clinician before reaching a decision.

14. 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 are 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.

15. 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 4 (16) for child donors. 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.

HTA decision-making arrangements

16. The HTA aims to make decisions within deadlines published each year in the HTA Business Plan.

17. 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. Stem Cell Coordinators must inform the donor, the person authorising on their behalf, and the recipient, of the decision on the HTA's behalf.

18. Detailed information on the way in which the HTA makes decisions can be found in the HTA Decision-Making Framework, its policy for the assessment of bone marrow and PBSC donation cases and HTA Standard Operating Procedures, which are available on request from the HTA.

The assessment process and responsibilities of the Human Tissue Authority

19. The HTA has a legal obligation to assess all cases of allogeneic donation of regenerative tissue where the donor is either an adult with incapacity or a child.

20. 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.

The role of the Accredited Assessor

21. The HTA’s role in the donation of regenerative tissue 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. This ensures that each individual donor and person with parental rights and responsibilities 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.

22. 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 is a child aged under 16 and to ensure the person with parental rights and responsibilities has expressed their views about the donation. AAs therefore play a key role in the system as a whole.

23. AAs must be independent of the process, as well as 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.

24. 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 authorising on the donor’s behalf, and recipients, to explore whether the legal requirements have been met.

25. The donor and recipient will, in many cases, be very young children and 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.

26. The detail of the matters to be covered in the reports on the interviews to be submitted by AAs are provided in section two, paragraph 45-47. As a matter of policy, the report must also contain 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

27. 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.

28. 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.

29. 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 providing authorisation on their behalf and the recipient. Please see further information at section two, paragraphs 34-37.

30. 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.

Guidance for Clinicians and Transplant Units

Information for donors and people with parental rights and responsibilities

31. The clinical team should make sure the following areas are fully discussed:

    a) 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;

    b) the chances of the transplant being successful and any possible side effects or complications for both donor and recipient;

    c) the right to withdraw authorisation at any time before the removal of the transplantable material;

    d) the decision to donate must be free of duress or coercion; and

    e) 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.

32. 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 authorising on their behalf must be told about, in order to make an informed decision.

33. The donor, person with parental rights and responsibilities 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 with parental rights and responsibilities, and recipient on the areas, which will be covered in the interview and the type of questions, which will be asked.

Referral to the HTA

34. 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.

35. The letter must include confirmation that the medical practitioner is satisfied:

    a) that the donor's health and medical history are suitable for the purposes of transplantation;

    b) that the donor is aged under 16 or an adult with incapacity;

    c) that the material to be removed and used is regenerative material; and

    d) that they have disclosed any evidence of any dispute between those with parental responsibility as to whether authorisation should be provided.

36. 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.

37. 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.

Guidance for Accredited Assessors

Accepting referrals

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

    a) undertake the interviews within one month of referral;

    b) submit their report to the HTA within 10 working days of the interviews; and

    c) be available in the five working days following the submission of their report, in case the HTA LDAT needs to contact them for further information or clarification.

39. 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.

Statutory Interviews

40. There are statutory requirements that must be met in each case before the HTA is able to give approval for the donation (please see section two, paragraphs 10-15).

41. 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.

42. 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.

43. 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.

Requirements in every interview

44. Each of the three statutory interviews with the donor, the person with parental rights and responsibilities and the recipient must cover the following matter:

    a) any evidence of an offer or reward;

    b) any evidence of duress or coercion affecting the apparent lack of unwillingness on the part of the donor to be a donor;

    c) the relationship (if any) between the donor and the recipient; and

    d) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

Interview with the donor

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

    a) whether the donor is a child or an adult with incapacity;

    b) the information given to the donor as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question;

    c) the full name of the person who gave that information and his qualification to give it; and

    d) the capacity of the donor to understand the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question.

46. 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.

47. 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 or pre-verbal child

48. In all cases, the AA should undertake, or attempt to undertake, an interview with the donor. This will not be possible where the donor unarguably lacks capacity, for example if they are a baby or a pre-verbal child then attempting an interview would be disproportionate and result in unnecessary use of resources.

49. 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.

50. 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 with parental rights and responsibilities, or (c) any third party.

Interview with the person with parental rights and responsibilities

51. The interview with the person with parental rights and responsibilities must, by law, cover the following matters:

    a) the views of that person as regards the proposed removal and use of the tissue in question for transplantation;

    b) the information given to that person as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question; and

    c) the full name of the person who gave that information and his qualification to give it.

Interview with the recipient

52. 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.

53. The AA report on the interview with the recipient must cover any evidence of duress and coercion affecting the decision of the recipient to be a recipient of the tissue.

54. 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 with parental rights and responsibilities. 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.

55. 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.

56. 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:

a) where the recipient is a pre verbal child or very young baby;

b) where the recipient is extremely unwell and lacks capacity to be interviewed;

c) where the recipient is in isolation.

57. 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.

58. Where the recipient lacks capacity, there is no requirement for someone to be interviewed on his or her behalf.

Other requirements for the AA report

59. 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 section 2, paragraphs 11-12.

60. As above, Regulation 5 (8) (for children) and Regulation 3 (6) (for adults with incapacity) sets out the requirement that the AA must conduct separate interviews with the donor, the person with parental rights and responsibilities, 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.

61. It follows that a situation should not arise where the AA is alone in a room with a child, whether they are the donor or the recipient, unless the AA is a member of the Protecting Vulnerable Groups (PVG) scheme. 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.

62. It is not necessary for an AA to have a PVG check in order to interview a child where there is another adult in the room. NHS Health Boards may have different policy requirements and we would advise Stem Cell Coordinators to seek further information on these from their Health Board's legal team.

Annex A

Legislative background and context

1. The HT Scotland Act applies to the removal, storage and use of human organs and tissue for scheduled purposes[2] in Scotland with the exception of the provisions relating to the use of DNA, where the provisions in the Human Tissue Act 2004 also apply to Scotland.

2. The Human Tissue (Scotland) Act 2006 and The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (the Regulations) lay down the responsibilities for any donation of tissue from a person with incapacity and the donation of organs and tissues from all living people.

3. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.

4. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). 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.

5. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets quality and safety standards for organ donation and transplantation. The requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

[2] Defined by the HT Act