HTA Policy 102

HTA Policy for the assessment of living organ donation cases

Board Members please note: The yellow highlight indicates areas that are either new or have undergone extensive revision. Where minor changes have been made throughout for clarity, these have not been highlighted.

Purpose

1. This policy sets out the Human Tissue Authority's (HTA's) interpretation of the legal requirements for the assessment of living organ donation cases and its policy requirements in discharging these responsibilities. This policy is informed by independent legal advice.

2. More detailed guidance on how this policy translates into practice is provided in HTA Standard Operating Procedures (SOPs) and associated guidance. For external stakeholders, the documents 'Guidance for Transplant Teams and Independent Assessors' and 'Guidance for Transplant Teams, Independent Assessors and Accredited Assessors in Scotland' provide clarity on how they should apply the policy in practice.

3. The purpose of this document is to set out the HTA policy on the assessment of living organ donation cases. The policy describes the approach that applies to all cases and the additional requirements for certain categories of panel cases.

The Human Tissue Act 2004

4. The Human Tissue Act 2004 (the Act) sets out the legal framework for the storage and use of human organs and tissue from the living and for the removal, storage and use of human organs and tissue from the deceased. The Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 and associated Regulations and Orders.

5. Under section 33 of the Act, a person commits an offence if they remove an organ 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 organ donation to be disapplied. The relevant extract from the Regulations is attached at **Annex A**.

6. Scottish law covering living organ donation is similar to the law in the rest of the UK, although there are some significant differences, particularly with respect to adults lacking capacity and children, who are only able to donate organs removed from their body out of clinical necessity, known as domino donation. The HTA assesses living organ donation cases on behalf of Scottish Ministers. The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 is the secondary legislation that sets out the requirements that must be met in order for the legal restriction on living organ donation to be disapplied.

7. The HTA's role is to disapply the legal restriction on transplants of organs involving a live donor where it is satisfied that the conditions set out in the Regulations have been met.

8. Specifically, Regulation 11 requires that:

a) A registered medical practitioner who has clinical responsibility for the donor must have caused the proposed donation to be referred to the HTA.

b) The HTA is satisfied that:
    i. No reward has been given or is to be given; and
    ii. that where transplantable material is removed.
        i. Consent for its removal for the purpose of transplantation has been given; or
        ii. its removal for that purpose is otherwise lawful.

c) When making its decision, the HTA must take into account a report from a qualified person. The HTA uses the term Independent Assessor (IA) to designate a qualified person in connection with assessing living organ donation cases. The IA must have interviewed the donor (or person giving consent, if different from the donor) and the recipient. The Regulations set out that the IA report must cover certain specified matters, including information about any evidence of duress or coercion, information affecting the decision to give consent and any evidence of an offer of a reward.

d) The HTA must give notice of its decision to both the donor and proposed recipient (or any person acting on their behalf) and to the registered medical practitioner who referred the proposed donation to the HTA.

9. Similar provision exists in Regulation 2 of the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.

10. The HTA must be satisfied that all living organ donors have given valid consent for the removal of their organ for transplantation. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. [Regulation 11(3)(b)(i) and Code of Practice A: Guiding Principles and the Fundamental Principle of Consent.]

11. While the report from the IA is a key component in the HTA's assessment of living donation cases, the HTA is free to seek appropriate additional information direct from the donor and/or the recipient before reaching a decision, although this is not usual. Further information is usually sought from the IA or the Living Donor Coordinator. This document (HTA-POL-102) describes the circumstances in which additional information may be sought. In all cases, the HTA will discharge its duties in line with the principles of best regulatory practice; which the Act defines as including the principles that regulatory activities be transparent, accountable, proportionate, consistent and targeted only at cases where action is needed. [Human Tissue Act s38(2)].

12. In reaching a decision about whether it is satisfied in relation to the tests described, the HTA interprets satisfied to mean satisfied on the balance of probabilities when considering the tests in their entirety. For each individual test, the HTA will consider whether it has sufficient evidence to be satisfied. In situations where it is not satisfied, the HTA will provide its reasoning as part of its notice of decision set out in Regulation 11(5).

13. Regarding duress and coercion, the HTA is required to make a judgement about whether the donor has exercised his or her own free will in making the decision to consent to organ donation, or whether external influences exist which are acting on the donor strongly enough to say that this is not the case. *There does not need to be evidence that there is no duress or coercion.* Instead, the HTA must consider whether there are any circumstances that cause the decision maker to have concerns, such that it cannot be satisfied there is no duress or coercion.

14. The need for the HTA to be satisfied on these points necessitates an exploration of the donor's motivation to donate and any external pressures they may face. There is no directly relevant case law regarding duress and coercion in relation to consent to living organ donation. 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 is not satisfied the donor's consent has been freely given.

15. Section 32 of the Act creates offences relating to financial or commercial dealings in organs for transplantation, for example payment or reward for organs intended for transplantation. Reward is defined as 'any financial or other material advantage' [Section 32 (11) Human Tissue Act]. A payment of money will constitute reward even if it is a trivial sum because the word material only refers to the word advantage. Any non-monetary benefit has the potential to be properly described as a reward for the purposes of Section 32 if it could amount to a material advantage. A like offence is created at section 20 of the Human Tissue (Scotland) Act 2006.

16. This means a person will commit an offence if they:

    (a) give or receive a reward for supplying, or offering to supply, organs for transplantation;

    (b) seek to find a person willing to supply organs for transplantation for reward; ,

    (c) offer to supply organs for transplantation for reward;

    (d) initiate or negotiate an arrangement involving the giving of a reward for the supply or offer to supply any part of a human body for transplantation, or take part in the management or control of an organisation whose activities include the initiation or negotiation of such arrangements; or

    (e) publish or distribute an advert inviting people to supply or offer to supply part of a human body for transplantation or reward, or indicate that the advertiser is willing to initiate or negotiate such an arrangement.

17. On 1 July 2022, amendments to the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 came into force, inserting a new section 32A and 20A into each Act respectively. These amendments extended the offences set out in Section 32 and Section 20 to acts done outside of the United Kingdom in certain circumstances. This means a person habitually resident in England, Wales or Scotland who is a UK national and not habitually resident in Northern

Ireland, will be committing an offence if they do any of the matters outlined in paragraph 16 above, outside of the United Kingdom.

18. The Act does permit donors to receive reimbursement for expenses, such as travel costs and loss of earnings, which are incurred in connection with the donation. While the Act does not restrict who may reimburse expenses, NHS England, and relevant agencies in the other nations of the UK, have policies and procedures in place to reimburse living donor expenses. For NHS cases, this should make reimbursement by other means unnecessary. However, if expenses are reimbursed by other means, such as fundraising or from the recipient or their family, the HTA may request evidence to prove that the donor has not financially or materially benefitted from the donation.

19. In assessing whether removal for transplantation is 'otherwise lawful' the HTA will consider whether there appears to be any other basis, other than consent, which would make the donation lawful.

20. In England and Wales, in line with the Mental Capacity Act 2005 (MCA) and the Code of Practice [see paragraphs 6.18, 8.18, 8.20], an application should be made to the Court of Protection to establish whether the removal of an organ from an adult lacking capacity for the purposes of transplantation is lawful.

21. In Scotland, adults with incapacity cannot be considered as living organ donors unless the removal of the organ is for the patient's own medical treatment [Part 3, The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006].

22. The MCA does not apply in Northern Ireland. The Mental Capacity Act (Northern Ireland) was passed in 2016 and has partially been implemented at the time of publication of this policy. Once fully in force, it will provide a single legal framework for mental health and capacity issues. Until then, a dual system exists with the Mental Health (Northern Ireland) Order 1986 covering the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment in treatment. Decisions about capacity and treatment are considered by reference to the common law.

Broader legal framework

23. The HTA does not only consider the legislation that provides for its statutory function in living organ donation. The MCA, the Adults with Incapacity (Scotland) Act 2000 and the Human Rights Act 1998, in particular, have bearing on the way the HTA interprets its role.

24. The HTA has a statutory role to ensure that individuals only make donations if they have capacity to make that decision, that they have made an informed decision, free from duress and coercion, after receiving proper medical advice and that there is no reward offered or given for the organ(s).

25. The HTA recognises that its role must be balanced with other rights of the individual, including those set out in other legislation. In particular, there should be a presumption that a potential donor has capacity to consent 'unless it is established that he lacks capacity' (s1(2) MCA) and that every person with capacity has a right to make decisions concerning their own body.

26. The HTA must also 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.

27. Personal data processed by the HTA through the implementation of this policy will be done so in accordance with the HTA's Privacy Notice and data protection law, including the UK General Data Protection Regulation and the Data Protection Act 2018.

Decision making in living donation case assessment

28. The HTA has a legal obligation to assess all cases that are referred to it. While decision making on some cases can be delegated to the HTA Executive (known as the Living Organ Donation (LOD) Team), others must be assessed by a panel of three Board Members ('panel cases').

29. The HTA currently distinguishes two types of panel cases:

    a) Those which by law (as prescribed in Regulation 12) must be dealt with by a panel of three Board members; and
    b) Those where the Board has made a policy decision to retain decision making and not delegate decision making to the LOD team (known as 'Retained panel cases').

30. Whether a case is categorised as retained is determined by characteristics of the case, including risk profile.

31. The HTA has identified some illustrative examples of circumstances the HTA would consider 'high risk'. These include:

    a. concern about potential reward (defined as material advantage);
    b. concern about potential duress and/or coercion;
    c. the donor is travelling from overseas and there is concern about the claimed relationship;

d. concern about the independence of a translator, or any other concern in relation to the translator;
e. apparent significant disparity between the donor and recipient (for example, age, wealth or education) that may be indicators of heightened risk of duress, coercion or reward.

32. For cases where the decision making is within the scope of the LOD team, the decision to reject a directed donation case can be made by the LOD team with the Director of Regulation in a formal Regulatory Decision making Meeting (RDM).

Panel cases by law

33. Panel cases by law comprise situations where:

a) The donor is a child,
b) The donor is an adult lacking capacity to consent,
c) Paired donations,
d) Pooled donations, and
e) Non-directed altruistic donations.

Retained panel cases

34. In all retained panel cases, the HTA considers that the nature of the relationship and / or the motivation for donation requires further exploration. The HTA considers these cases may present a higher risk of there being issues with the quality of the consent and / or of meeting the statutory criteria. Having such cases assessed by a Panel of three Board members enables the HTA to ensure there is robust assessment of these factors in cases considered to be potentially of higher risk.

35. The four categories of retained panel cases are set out below.

a) **Certain overseas donor cases:** These are directed altruistic donation cases where the donor is travelling from overseas, and which fulfil the following two conditions:
   i. the donation is being directed to a specific individual; and
   ii. there is no evidence of a genetic or pre-existing emotional relationship between the donor and recipient.

   (These cases can often involve a third party or mechanism bringing the donor and recipient together for the purpose of organ donation and transplantation.)

b) **Economic dependence cases:** These are cases where the donor has, or appears to have, some form of economic dependence on the recipient, for example, the donor is an employee of the recipient, or the donor is a tenant of the recipient and the donor has no genetic or pre-existing emotional relationship with the recipient. In cases where the donor and recipient have a genetic or pre-existing emotional relationship, the decision can be made by the LOD team.

c) **Some cases which enter the HTA's RDM process:** Any case that is otherwise delegated to the LOD team, but which the LOD team feels needs to be referred to panel. This is likely to include cases identified as 'high risk' and with significant elements of complexity or uncertainty for which panel consideration would be beneficial (these are likely to be the exception).

d) **Novel living organ donation cases:** These are organ donations that the HTA does not consider to be routine. The HTA defines routine living organ donation cases as follows:
   - Kidney
   - Liver Lobe.

Once the HTA has approved at least 8 novel donation cases (for any specific novel organ), the Board can consider redefining this organ as routine. More detailed information on novel organ donations is set out in Annex C.

36. For all cases referred to panel, the LOD team provide a summary document detailing relevant necessary information about the case to support the panel in its decision making. The CRM record for each case contains all relevant information and documentation pertaining to HTA decision-making for that case.

37. Where the LOD team identify that a case referred to panel is high risk, panel members are directed to review all the relevant primary documents relating to the case as well as the case summary. This is to enable the panel to make their decision based on an assessment of all pertinent factors, including the IA report, the hospital referral letter and donor declaration.

HTA requirements in all living donation cases

38. The remainder of this document should be read with reference to Code of Practice F part one: Living organ donation and Annex A.

39. In addition to the statutory requirements, HTA experience in the assessment of living donation cases has led to the introduction of a

number of other policy requirements (must) and recommendations (may) which need to be met as part of the referral process.

Clinicians and transplant teams

40. As a matter of either legislation or policy, certain activities need to be completed prior to the case being referred to an IA.
41. Regulation 11(2) requires that a medical practitioner must have referred the proposed donation to the HTA. Specifically, the referral must state that the medical practitioner, or person acting on their behalf:

    a) is satisfied that the donor's health and medical history are suitable for the purposes of transplantation;
    b) has provided the donor with the information the donor requires to understand the consequences of donation; and
    c) has endeavoured to obtain information from the donor that is relevant to the transplantation.

42. As a matter of HTA policy, the referral must also state that the medical practitioner, or person acting on their behalf, is satisfied that the donor has capacity to consent to the donation.

43. The HTA must ensure that safeguards are in place to be satisfied that no reward has been, or is to be, given in contravention of Section 32 of the Act. As a matter of policy, all donors are asked to sign a declaration confirming that they have read the Guidance for living organ donors on the HTA's Independent Assessment process and no payment or reward is associated with the organ donation and transplantation.

44. All donors may be asked during work up what they wish to happen in the event that their organ or part organ cannot be transplanted into the intended recipient. This is a precaution to avoid the possible worst-case scenario of an organ being disposed of when the donor's wishes are not known. The HTA identified four potential options:

    - organ or part organ can be transplanted into an alternative recipient;
    - organ can be re-implanted into the donor (not appropriate for liver lobes);
    - organ or part organ can be used for research; or
    - organ or part organ can be disposed of.

45. The HTA must give separate approval where the donor has consented prior to surgery for the organ or part organ to be transplanted into an alternative recipient on the national deceased wating list. The HTA does not need to be informed of the donor's decision where they have chosen for the organ to be re-implanted, used for research or disposed of. However, the HTA must have assurance that where the donor has selected re-implantation, the donor understands the additional surgical risks attached to re-implantation.

46. The medical team must ensure that where there are risks specific to a donor, these have been addressed by the clinical team and have been understood by the donor. As a matter of HTA policy these risks and confirmation of the donor's understanding must be included in the referral letter and the IA report.

Cases in which a presumed genetic relationship is not substantiated by test results.

47. Donors may be asked to consider whether they wish to be informed if a presumed genetic relationship is revealed to be absent during the work up. The HTA will assess all cases regardless of whether this has been discussed with the donor, although evidence that the donor's wishes were sought may be requested.

Administrative requirements

48. Written referrals must include confirmation of the evidence of identity and relationship seen by the transplant team for both the donor and recipient. Proof of identity and relationship must be confirmed at the IA interview.

49. Where satisfactory documentary evidence of the relationship cannot be provided, or does not exist, the case will be treated as a directed altruistic case.

Independent assessment

Legislative and policy requirements

50. Regulation 11(6) sets out the requirement that the IA must have conducted separate interviews with the donor (or person giving consent if different from the donor) and the recipient. In addition, it is HTA policy that an interview must be undertaken with the donor and recipient together. The purpose of this is to allow the IA to observe the interaction between the donor and recipient to aid understanding of whether duress or

coercion are likely to be factors in the donor's decision to donate. It also allows the IA to explore the issue of reward jointly with the donor and recipient. The need for an IA interview with the donor is dispensed with in situations where the removal of an organ for transplantation is authorised by a court order. A recipient interview cannot be undertaken for non-directed altruistic donations as no recipient is identified until after HTA approval is given. Requests for the joint donor and recipient interview to be waived will be considered on a case-by-case basis by the Director of Regulation and the rationale for the decision will be documented with the case application.

51. Regulations 11(7) and (8) detail the content of the reports on the interviews to be submitted by IAs. As a matter of policy, the report may also contain an account of any relevant concerns the IA has that may contribute to the HTA's assessment of whether or not it is satisfied in relation to the three statutory tests.

52. ***Recipient interviews***. Regulation 11(8)(a) requires that the report on the interview with the recipient should cover any evidence of duress and/or coercion affecting the decision to give consent. As the recipient's consent to undergo surgery to receive transplantable material is a clinical matter, the HTA interprets this to mean any evidence of duress or coercion (which the recipient is aware of or has brought to bear) affecting the donor's decision to give consent to the removal of their organ for the purposes of transplantation.

53. ***Interviews with recipients lacking capacity to consent***. While the Regulations make provision for interviews where the donor lacks capacity to consent, they are silent on recipients lacking capacity to consent. HTA policy is that the referral letter from the clinician should highlight any issues relating to the recipient's capacity to undergo the interview. The IA must undertake, or attempt to undertake, an interview with the recipient except in circumstances where either the recipient lacks capacity or where an interview is not considered to be in the best interests of the recipient. In all circumstances, whether or not an interview was attempted, the IA should include this information in their report, commenting on any capacity issues under the provision of Regulation 11(8)(c) relating to communication difficulties and how (where possible) these were overcome. Where the recipient lacks capacity, there is no legal provision for someone to be interviewed on their behalf.

54. In cases where the proposed donor indicates during an IA interview that they do not wish to proceed with the donation, the HTA should take this as evidence that the donor has withdrawn his or her consent. The IA must

inform the HTA and the relevant Living Donor Coordinator. The referring clinician may withdraw his or her referral to the HTA and the case should be submitted as a record of the interview, but the HTA is not obliged to make a decision. Transplant Units may benefit from developing local policies to halt the preparation for the transplantation in these circumstances in a way that ensures adequate protection for the donor.

Case assessment

55. Once the HTA receives a case it will assess this in line with the Standard Operating Procedure(s) and the service standards relevant at the time.

Regulatory decision making

56. For applications where, having considered the IA report, the HTA is not fully satisfied in line with Regulation 11(3), rejecting the application becomes a possibility. In these instances, the HTA will make its decision in line with the Standard Operating Procedure(s) and service standards relevant at the time.

57. Where there is insufficient evidence for the HTA to be satisfied that the donor has capacity to consent in line with the requirements of the MCA (or other relevant legislation), the HTA may refer the case back to the medical practitioner, who will be asked to provide the evidence underpinning their assessment of capacity to consent.

58. Where there is insufficient evidence for the HTA to be satisfied that the donor's consent is being given free from duress or coercion, or insufficient evidence for the HTA to be satisfied that reward is absent, the LOD team will undertake further investigation or request other information as appropriate in order to fulfil its statutory obligation.

59. In situations where a panel of three Board Members cannot reach a unanimous decision, the panel may reach a majority decision. The Chair of the panel records the decision on CRM but all panel members including the Chair, have equal status.

Reconsiderations

60. Once the HTA has given approval for a donation to proceed it will have done so on the basis of being satisfied that the statutory 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 surgery proceeding, that could affect the test of being satisfied, then it has power under Regulation 13 to reconsider the case as a fresh decision.

61. In deciding 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 there has been a material change of circumstances since the decision was made. Regulation 14 requires that reconsideration is made as a fresh decision and that any members involved in the original approval are disqualified from participating in the fresh decision. Depending on the facts of the case, further information may be required from the donor and/or recipient in order to reach a decision.

62. For reconsiderations initiated by specified persons [Regulations 13(2) and (3)] the reconsideration will be managed in line with the appropriate Standard Operating Procedure(s) and service standards.

Annexes:

Annex A: Relevant extract from The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006
Annex B: Sets out the cases where the Board delegates decision making to the LOD team.
Annex C: Novel organ donations
Annex D: Halted and paused cases
Annex E: Cases involving cross-border donations

Revision history

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- May 2023, Comprehensive revision, updated to clarify how higher risk cases should be handled. Legal review undertaken.

This policy will be reviewed every three years or as necessary.

Annex A - The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 - extract

Meaning of transplantable material for the purposes of section 34 of the Act
9. For the purposes of section 34 of the Act (information about transplant operations) “transplantable material” means—

(a) the whole or part of any of the following organs if it is to be used for the same purpose as the entire organ in the human body—
(i) kidney,
(ii) heart,
(iii) lung or a lung lobe,
(iv) pancreas,
(v) liver,
(vi) bowel,
(vii) larynx;
(b) face; or
(c) limb.

Meaning of transplantable material for the purposes of section 33 of the Act
10.—(1) Subject to paragraphs (2) and (3), for the purposes of section 33 of the Act (restriction on transplants involving a live donor), "transplantable material" means—
(a) an organ, or part of an organ if it is to be used for the same purpose as the entire organ in the human body,
(b) bone marrow, and
(c) peripheral blood stem cells, where that material is removed from the body of a living person with the intention that it be transplanted into another person.

(2) The material referred to in paragraph (1)(a) is not transplantable material for the purposes of section 33 of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1)(b) and (c) is transplantable material for the purposes of section 33 of the Act only in a case where the person from whose body the material is removed is—
(a) an adult who lacks the capacity, or
(b) a child who is not competent,
to consent to removal of the transplantable material.

Cases in which restriction on transplants involving a live donor is disapplied
11.—(1) Section 33(1) and (2) of the Act (offences relating to transplants involving a live donor) shall not apply in any case involving transplantable material from the body of a living person ("the donor") if the requirements of paragraphs (2) to (6) are met.

(2) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Authority.

(3) The Authority must be satisfied that—
(a) no reward has been or is to be given in contravention of section 32 of the Act (prohibition of commercial dealings in human material for transplantation), and

(b) when the transplantable material is removed—
(i) consent for its removal for the purpose of transplantation has been given, or
(ii) its removal for that purpose is otherwise lawful.

(4) The Authority must take the report referred to in paragraph (6) into account in making its decision under paragraph (3).

(5) The Authority shall give notice of its decision under paragraph (3) to—
(a) the donor of the transplantable material or any person acting on his behalf,
(b) the person to whom it is proposed to transplant the transplantable material ("the recipient") or any person acting on his behalf, and
(c) the registered medical practitioner who caused the matter to be referred to the Authority under paragraph (2).

(6) Subject to paragraph (7), one or more qualified persons must have conducted separate interviews with each of the following—
(a) the donor,
(b) if different from the donor, the person giving consent, and
(c) the recipient,
and reported to the Authority on the matters specified in paragraphs (8) and (9).

(7) Paragraph (6) does not apply in any case where the removal of the transplantable material for the purpose of transplantation is authorised by an order made in any legal proceedings before a court.

(8) The matters that must be covered in the report of each interview under paragraph (6) are—
(a) any evidence of duress or coercion affecting the decision to give consent,
(b) any evidence of an offer of a reward, and
(c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must be covered in the report of the interview with the donor and, where relevant, the other person giving consent—
(a) 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,
(b) the full name of the person who gave that information and his qualification to give it, and
(c) the capacity of the person interviewed to understand—
(i) the nature of the medical procedure and the risk involved, and
(ii) that the consent may be withdrawn at any time before the removal of the transplantable material.

(10) A person shall be taken to be qualified to conduct an interview under paragraph (6) if—

(a) he appears to the Authority to be suitably qualified to conduct the interview,
(b) he does not have any connection with any of the persons to be interviewed, or with a person who stands in a qualifying relationship to any of those persons, which the
Authority considers to be of a kind that might raise doubts about his ability to act impartially, and
(c) in the case of an interview with the donor or other person giving consent, he is not the person who gave the information referred to in paragraph (9)(a).

Decisions of the Authority: procedure for certain cases
12. (1) In any case to which paragraph (2), (3) or (4) applies, the Authority's decision as to the matters specified in regulation 11(3) shall be made by a panel of no fewer than 3 members of the Authority.

(2) A case falls within this paragraph if—
(a) the donor of the transplantable material is a child, and
(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(3) A case falls within this paragraph if—
(a) the donor of the transplantable material is an adult who lacks capacity to consent to removal of the material, and
(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(4) A case falls within this paragraph if—
(a) the donor of the transplantable material is an adult who has capacity to consent to removal of the material, and
(b) the case involves—
(i) paired donations,
(ii) pooled donations, or
(iii) a non-directed altruistic donation.

(5) In this regulation—
"non-directed altruistic donation" means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him;
"paired donations" means an arrangement under which—
(a) transplantable material is removed from a donor ("D") for transplant to a person who is not genetically related or known to D, and
(b) transplantable material is removed from another person for transplant to a person who is genetically related or known to D; and
"pooled donations" means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable

material from D is transplanted to the wife of another person (“E”), transplantable material from E is transplanted to the partner of a third person (“F”) and transplantable material from F is transplanted to D’s son).

Right to reconsideration of Authority’s decision

13. (1) The Authority may reconsider any decision made by it under regulation 11(3) if it is satisfied that—
(a) any information given for the purpose of the decision was in any material respect false or misleading, or
(b) there has been any material change of circumstances since the decision was made.

(2) A specified person may in any case require the Authority to reconsider any decision made by it under regulation 11(3).

(3) “Specified persons”, in relation to such a decision, are—
(a) the donor of the transplantable material or any person acting on his behalf,
(b) the recipient of the material or any person acting on his behalf, and
(c) the registered medical practitioner who caused the matter to be referred to the Authority
under regulation 11(2).

(4) The right under paragraph (2) is exercisable by giving to the Authority, in such manner as it may direct, notice of exercise of the right.

(5) A notice under paragraph (4) shall contain or be accompanied by such other information as the Authority may reasonably require.

(6) On receipt of the information required by paragraph (5), the Authority shall provide to the person requiring the reconsideration—
(a) a copy of each report made under regulation 11(6) of the interviews that were conducted in the case, and
(b) a statement of the Authority’s reasons for its decision.

(7) Paragraphs (1) to (6) do not apply to a decision made by the Authority on reconsideration in pursuance of a notice under this regulation.

Procedure on reconsideration

14. (1) Reconsideration shall be by way of fresh decision made at a meeting of the Authority.

(2) The meeting shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 13(6), having regard

to the need to allow time for the information contained in that material to be taken into account.

(3) Where a member of the Authority has taken part in the making of a decision subject to reconsideration (whether under regulation 12 or otherwise), he is disqualified from participating in the Authority's reconsideration of it.

(4) On reconsideration under regulation 13(2)—
(a) the person ("A") by whom the reconsideration is required under regulation 13(2) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard at the meeting of the Authority at which the decision is reconsidered, and
(b) the members of the Authority in attendance at the meeting at which the decision is reconsidered shall consider any such written representations and comments.

(5) The Authority shall give a notice of its decision to A.

(6) If on reconsideration the Authority upholds the previous decision, the notice under paragraph
(5) shall include a statement of the reasons for the Authority's decision.

(7) "Reconsideration" means reconsideration in pursuance of a notice under regulation 13.

Annex B - Retained panel cases and delegated cases

Retained panel cases

In addition to the cases which Board Members must consider as a matter of law, it has also decided to retain decision making in a number of other situations. These are referred to as retained panel cases.

Type of case	Description
Economic dependence cases: These are cases where the donor has, or appears to have, some form of economic dependence on the recipient.	Examples: • The recipient appears to have significant financial strength and independence, such as private income, business interests, or a secure and well-paid professional role, whereas the donor appears to be insecure financially with a low paid and insecure job • The donor has a low social status and the recipient has high social status and a significant and / or powerful public position. • The donor is an employee of the recipient • The donor is a tenant of the recipient (In cases where the donor and recipient have a genetic or pre-existing emotional relationship, the decision can be made by the LOD team).

Some cases which enter the HTA's Regulatory RDM process: Any case that is not a directed donation case, and the following two criteria apply: • the case has been identified as 'high risk' (see illustrative explanations of 'high risk') • the LOD team consider that rejecting the case is a possibility.	Examples: • The IA report for a directed altruistic case indicates that the translator may not have been independent • The IA report for a directed altruistic case suggests reward may be a factor.
Novel living organ donation cases: These are organ donations that the HTA does not consider to be routine. The HTA defines routine living organ donation cases as follows: • Kidney • Liver Lobe.	All novel living organ cases will be referred to a panel of Board Members for decision. Once the HTA has approved at least 8 novel donation cases (for any specific novel organ), the Board can consider redefining this organ as routine.

Cases delegated to the LOD team – subject to evidence of stated relationship

Type of case	Description
Directed donation (subject to evidence of claimed relationship being provided)	*Examples:* • *Spouse or partner* • *Parent or child* • *Brother or sister* • *Grandparent or grandchild* • *Niece or nephew* • *Uncle or aunt* • *Stepfather or stepmother* • *Cousin* • *Half-brother or half-sister* • *Step brother or step sister* • *Mother-in law or father-in-law* • *Brother-in-law or sister-in-law* • *Friend of long standing* • *Work colleague*
Directed altruistic cases where the donor is **not** travelling from overseas • Genetic relationship and no established emotional relationship. • No pre-existing relationship.	*Examples:* • *UK resident: Cousin who has come forward as a donor but has not had an active relationship with the recipient e.g. due to geographical location and they cannot evidence the genetic or emotional relationship.* • *UK resident: Relative with whom there has been no contact which may be due to a relationship breakdown or adoption (sibling, parent, child etc.).* • *UK resident: Friend of a friend (have an awareness of each other e.g. through a mutual person, but no relationship has been formed and there has been no contact / interaction).* • *An organisation has campaigned for a donor (have an awareness of each other e.g. through a mutual organisation, but no relationship has been formed and there has been no contact / interaction).* • *UK donor comes forward after a media campaign (but no relationship has been formed and there has been no contact / interaction).*

Domino donation in Scotland where the donor is an adult with incapacity or a child.	Adults with incapacity can only be considered as living organ donors in Scotland if the removal of the organ is for the patient's own medical treatment, known as domino donation. The same applies to children, who are defined in the HT Scotland Act as those aged under 16 years of age. *Example:* • *It is necessary for a person's treatment to have their kidney removed, which is then offered as a domino donation to be transplanted to someone else.*

Annex C - allocation and assessment of novel living organ donation cases

Background

The HTA has received a small number of novel living organ donation cases, such as small bowel and uterus. These cases are referred to a panel of Board Members to assess and provide a decision. The HTA adopted this approach to provide additional scrutiny to applications for donations which are not yet established or routine.

However, there is no statutory requirement in the Regulations or the Human Tissue Act for novel cases to be considered by a panel of Board Members. The only exceptions are set out in reg 12 which provide for cases of 'greater complexity' to be considered by a panel.

Decision Making

Independent legal advice supported our view that novel organ donation cases should be referred to a panel of Board Members. Legal advice confirmed this approach is in line with the statutory intention of regulation 12 and is a responsible way of exercising powers of delegation which would otherwise allow delegation to the LOD team for these decisions.

Routine donations

At the beginning of each financial year the HTA should review the list of routine living organ donation categories to take account of developments. Any organ donation categories not on this list should be considered as a novel organ donation and referred to a panel.

In order to decide whether to add a donation category to the list of routine living organ donations, the HTA must consider the following:

- How many cases have been submitted to the HTA, if more than **eight** this could be considered a routine donation;
- How often is, or has, the procedure been undertaken in the UK;
- The relative risk to life for both the donor and the recipient in this procedure;
- The relative risk of other serious complications to both the donor and the recipient; and
- Any unusual ethical considerations that might arise from donation.

Annex D - Halting and pausing living organ donation cases

Background

There have been a number of living organ donation cases referred to the HTA where it becomes apparent that a decision is either no longer required due to a change in circumstances, or the HTA is unable to make a decision until further clarifications have been sought. These cases should be halted or paused on the CRM system. The difference between halted and paused is outlined below.

Halting cases

Where a decision is no longer required on a living organ donation case, the HTA should resolve the case with the status of ‘halted’. An example of this may be if the donor and/or the recipient no longer wish to proceed, or the donation is unable to proceed for medical reasons. Therefore, the case is halted as the HTA is not required to make a decision.

Where a case is halted on the system, there is no need to provide a decision to external stakeholders, such as Independent Assessors, Living Donor Coordinators and Clinicians.

It is important for the LOD team to clearly document the reasons why the case has been halted in the case notes section.

Pausing cases

A case should be paused where there is further information or clarification required before the HTA is able to make a decision.

Pausing cases is more common than the need to halt cases. This is due to the number of clarifications that will often need to be sought on a case and how long it takes to provide the information requested. Paused cases remain open and active in the CRM case queue until further information or clarification is received and reviewed.

An example of when a case would be paused would be where the donation category is subject to change. This could be due to the case being submitted as a directed donation, and then being re-categorised because a decision has been made to enter the National Kidney Sharing Scheme matching run to see whether a better HLA tissue match can be identified and therefore proceed with paired/pooled donation instead. At present, the HTA can only provide a decision on one category of donation.

It is important to clearly document what information is outstanding in the case notes section, any updates and a record of all contact with the Independent Assessor or Transplant unit.

Annex E - Cases involving cross-border donation

Background

The HTA received two living organ donation cases for approval where the retrieval and subsequent transplant were to take place in two different UK nations, namely Scotland and England.

As the legislation is different for both countries, it is important that the approach to assessing cases involving cross-border donation is both reasonable and lawful. The decision as to which legislation these types of cases are to be assessed under also impacts whether the IA must cover two additional requirements under the HT (Scotland) Act 2006. These requirements concern the donor's consideration of the wider implications of donation and also confirmation that the recipient has not been subject to duress/coercion in their decision to accept the organ.

Decision making

Independent legal advice supported our approach and presented three options, one of which was to assess the case under the legislation of the location where the organ was removed. The independent legal advice confirmed this as being 'a reasonable and lawful approach, and the risks of legal challenge are low'.

After approval from the Director of Regulation, a decision was made that all cases involving cross-border donation are to be assessed under the legislation of the location where the organ is removed.

Cases involving cross-border donation are to be monitored by the Transplant Manager, in case of any changes needed to the current approach in decision making.