HTA
Human Tissue Authority

# Guidance to Independent Assessors

Published: March 2015

(updated April 2024)

## Contents

## Introduction

1. This document provides guidance to clinicians and transplant teams about the regulatory requirements for the assessment of living organ donations by the Human Tissue Authority (HTA).

2. Where the word organ is used, unless specified, this refers to kidney, liver lobe, small bowel and uterus.

3. This guidance, along with 'The Quality and Safety of Organs Intended for Transplantation: a Documentary Framework', supplements the HTA's code of practice F, part one: Living organ donation.

## Legislative Framework

4. The Human Tissue Act 2004 (the HT Act) sets out the licensing and legal framework for the storage and use of human organs and tissue from the living, and also for the removal, storage, and use of human organs and tissue from the deceased.

5. The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue, and the removal of material from the bodies of deceased people. The HT Act requires consent for the storage and use of organs or part-organs taken from a living or deceased person, for the purpose of transplantation.

6. 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 lifted. Please read Code of Practice F Part one: Living organ donation for information about the legal requirements under the Regulations that must be met in order for the HTA to give approval for living organ donations.

7. On 1 July 2022, an amendment was made to Section 32 of the Human Tissue Act 2004 and Section 20 of the Human Tissue (Scotland) Act 2006. This amendment extends the offences set out in Section 32 and Section 20 so that they have extraterritorial jurisdiction. These offences relate to financial or commercial dealings in human material for transplant, such as buying or selling human organs.

8. In practice, this means that any person will be committing an offence if they are involved in seeking, offering, or receiving payment or reward for donating

organs for transplantation or initiating, negotiating, advertising or being involved in buying or selling human organs for transplantation, anywhere in the world.

9. Section 33 of the HT Act sets out the restrictions on transplants involving a living donor.

## Overview of the regulatory framework for living organ donation

10. The purpose of regulating living donation in the UK is to make sure that donors are not made to act against their wishes, and to safeguard against people trafficking for the purpose of organ donation.

11. The HTA's role is to approve living organ donations, where it is satisfied that the conditions set out in the Regulations have been met. In short, the criminal offence that exists is only lifted when the requirements outlined below are met.

12. Specifically, the Regulations require that:

- A registered medical practitioner with clinical responsibility for the donor must arrange the referral of each case to the Authority [Regulations 11(2)]. Under the requirements of the Quality and Safety (Organs) Regulations, certain specified information from the donor's clinician, as part of this referral, is mandatory.

- The HTA is satisfied that no reward has been given or is to be given; and that where transplantable material is removed, consent for its removal for the purpose of transplantation has been given - or its removal for that purpose is otherwise lawful [Regulations 11(3)].

- The HTA must consider a report from a qualified person (the HTA uses the term Independent Assessor (IA) to designate a qualified person) [Regulations 11(4)]. The IA must interview the donor (or person giving consent on their behalf) and the recipient [Regulations 11(6)]. The report must contain information set out in the Regulations [Regulations 11(8) and 11(9)].

- The HTA must notify the donor, the recipient and the referring medical clinicians of its decision [Regulations 11(5)].

- The HTA must be satisfied that all living organ donors have given valid consent for the removal of their organ for transplantation [Regulations 11(3)(b)(i)]. For consent to be valid, it must be given voluntarily (free from duress or coercion), by an appropriately informed person who has the capacity to agree to the activity in question.

13. While the HTA must take the IA's report into account when making its decision the HTA is free to seek appropriate additional information from the donor and / or the recipient, as well as from the referring clinician before reaching a decision. In all cases, the HTA will discharge its duties in line with the principles of best regulatory practice (transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

14. In reaching a decision about whether the HTA is "satisfied" in relation to the tests described in paragraph 12, the HTA interprets the term "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 the Regulations 11(5).

15. The HTA interprets "duress or coercion" to mean that the will of the person required to act has been compromised, and they can no longer make an independent decision.

## Living donation concepts and definitions

16. The HT Act and the Regulations place an obligation on the HTA to assess all applications for living organ donation that are submitted. For either legislative or policy purposes, the HTA distinguishes several different concepts:

**Directed donation** - Where a person donates an organ to a specific identified recipient, with whom they have a genetic or pre-existing emotional relationship. These are usually assessed by the Living Donation Assessment Team (LDAT).

**Directed altruistic donation** - The HTA defines these as cases which fulfil two conditions:

(a) the donation is being directed to a specific individual and;

(b) there is no evidence of a 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 website - which brings the donor and recipient together for the purpose of transplantation. Examples of directed altruistic donations include donors coming forward following a social media campaign or donors donating to a friend of a friend.

**Non-directed altruistic donation (NDAD)** - Where a person donates an organ to an unknown recipient, that is, someone they have never met and is not known to them. These donors usually donate their organ into the UK Living Kidney Sharing Scheme. By matching two or more donors and recipients, a chain of transplants can be carried out. The remaining organ at the end of the chain is then donated to the best matched recipient on the UK waiting list.

The Regulations state that a panel of three Board Members must make the decision on these cases.

**Paired or pooled donation** - This applies to kidneys only. Where a donor is unable to (or chooses not to) donate to their intended recipient because they are either incompatible by blood group or HLA (tissue) type or would prefer a

closer age or HLA match. They may be matched with another donor and recipient in the same situation in the

UK Living Kidney Sharing Scheme. 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. The Regulations state that a panel of three Board Members must make the decision on all paired/pooled cases.

**Domino donation** - The HTA does not regulate domino donations. This is where an organ is removed for the primary purpose of a person's medical treatment. The removed organ may prove suitable to transplant into another person. NHSBT policies and further detail can be found at www.odt.nhs.uk

**Non-UK resident donor** – Where a donor is resident outside the UK. These cases are usually assessed by the LDAT. Please see the section on non-UK resident donors for more information.

## Relationships

17. The following is a list of relationships the HTA considers when determining the category of donation:
    - 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
    - Stepbrother or stepsister
    - Mother-in law or father-in-law
    - Brother-in-law or sister-in-law
    - Friend of long standing
    - Work colleague

18. If a donor and recipient relationship (existing/or pre-existing) is defined on this list, then the donation will be considered by the LDAT. The HTA presumes that a case involving a donor and recipient with such a relationship will constitute a directed donation, subject to sufficient evidence of the claimed relationship being provided. This is because in most instances, the donor and recipient will have had an emotional relationship prior to the need for a transplant arising.

19. If the donor and recipient have a genetic relationship which is not included on

the list, the presumption that they know each other does not exist. However, if evidence is provided that they do have a pre-existing emotional relationship, then the case will be considered by the LDAT. If such evidence cannot be provided, the case will be designated as a directed altruistic donation. The case will be assessed either by the LDAT or by a panel of three HTA Board Members.

## Independent Assessors (IA)

20. The purpose of the role is to provide an independent check to help protect the interests of living organ donors. Each individual donor has an opportunity to speak freely to someone not connected with the transplant unit to confirm that their wish to donate is free from any pressure. IAs undertake interviews on behalf of the HTA to allow it to fulfil its role. IAs therefore play an essential role.

21. IAs must be totally independent of the living organ donation process, the clinical team and the donor and recipient. This applies to both NHS and private settings. IAs are usually, but not exclusively, based in hospitals with transplant units or referring units.

22. Once trained and accredited by the HTA, IAs interview potential living donors and recipients to explore whether the requirements of the HT Act and the Regulations have been met. The findings from the interviews are strictly confidential between the IA and the HTA and are not shared with the clinical team.

23. It is the responsibility of the clinical team to inform the HTA if there is a need for additional IAs.

24. It is not the role of the IA to determine medical suitability of the donor or recipient. This is the responsibility of treating clinicians and transplant teams.

25. IAs should not have access to the donor or recipient's medical notes. This is not necessary to fulfil the statutory requirements of the IA interview.

## Person specification

26. IAs must meet the following essential criteria:

- excellent oral and written communication skills;
- IT literate with an ability to grasp new systems;

- excellent interpersonal skills;
- confidence in interviewing patients and exploring and addressing distressing health issues and health risks;
- confidence to probe and challenge where necessary;
- familiar with requirements to maintain patient confidentiality;
- the ability to work confidently in a hospital environment;
- experience of report writing to a high standard;
- familiar with equality and diversity legislation.

27. IAs come from varied backgrounds and do not need to be medically qualified.

28. Once candidates have been identified, the HTA should be contacted for an application form.

29. The HTA will only accept applications where there is a clear need for additional IAs to be trained. The form must be completed and submitted to transplants@hta.gov.uk

30. Once the application and reference are approved, the HTA will contact the individual with details of the next training session.

31. Once IA training has been completed, an enhanced Disclosure and Barring Service (DBS) check will be conducted, paid for by the HTA. This certificate is considered valid for a period of three years. After this, it is the responsibility of the hospital to keep enhanced DBS checks up-to-date and send a confirmation to the HTA. IA training for delegates that have an existing enhanced DBS check dated within the last six months will be accepted by the HTA.

32. Once the enhanced DBS check has been received, a certificate confirming accreditation will be issued, with a letter of confirmation. A letter will also be sent to the Living Donor Coordinator (LDC), Clinical Director of the transplant unit, and Chief Executive of the hospital.

33. Once accredited, the HTA advises that newly accredited IAs observe an IA interview with an experienced IA. The HTA must be informed of changes to an IAs contact details and when an IA leaves their post.

## Resources required for the IA role

34. The resources required by IAs to carry out their roles are provided by the hospital.

35. These resources include:

- Hospital email address (it is not appropriate to use personal email addresses);
- Time built into job plan / timetable where the IA is an employee of the hospital;
- A room in which to see the donor and recipient;
- Translation and interpreting services, if required;
- Access to networked IT equipment;
- Access to document scanning equipment.

## IA remuneration and liability

36. The HTA is not remunerated to pay IAs. However the HTA recognises that many hospitals have chosen to provide remuneration to IAs in recognition of it being a statutory role. IAs must raise this with the hospital directly if they have any queries.

37. It is recommended that any travel expenses that an IA incurs as part of this role should be paid for by the hospital.

38. The nomination of IAs must be compliant with local hospital governance arrangements.

39. All liabilities in regard to IAs and independent assessment interviews fall to the HTA. The HTA has a duty of care to act in a reasonable manner towards IAs when they are acting on behalf of the HTA; the same duty of care also extends to donors and recipients. The HTA does not have responsibility for any liabilities which an IA may incur in the course of any other work they carry out, which falls outside the role of IA.

## The Independent Assessment process

## Accepting and receiving the statutory referral letter

40. Before accepting a referral for a case, IAs should make sure that they will be able to undertake the interviews within one month of referral and ensure they will:

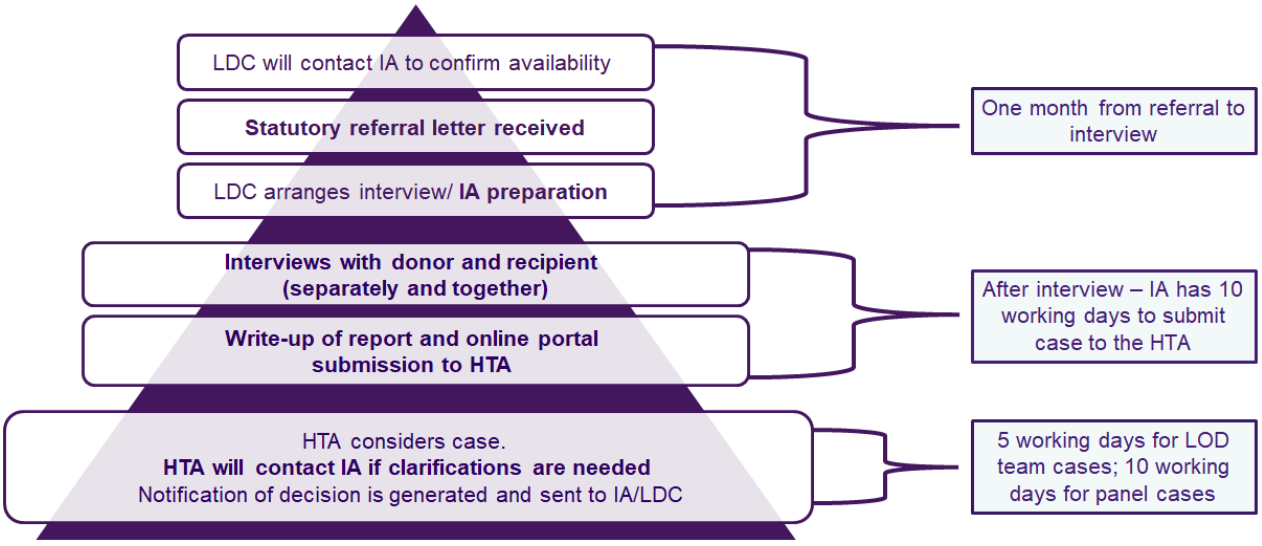
- submit their report to the HTA within 10 working days of the interview;
- be available following submission of their report (for five working days for LDAT cases and 10 working days for panel cases) in case the further information or clarification is needed;
- not accept referrals where they know they will be on holiday or unavailable.

41. Once a case is referred, the IA should:

- Familiarise themselves with the information provided in the referral letter
- Check that the correct donation category is included on the referral letter
- Check that any risks specific to the donor have been documented.

42. If there are any discrepancies, or anything is unclear, the IA should contact the transplant team to clarify before undertaking the interview.

43. The diagram below provides an overview of the referral and independent assessment process:




## The referral letter

44. The referral letter from the clinician should highlight any issues relating to the recipient's capacity to be interviewed. In general terms, the IA must undertake, or attempt to undertake, an interview with the recipient.

45. The referral letter will include whether an interpreter is required during the interview. In these cases IAs must seek assurance and be satisfied that the interpreter is completely independent of the donor, the recipient and of the clinical team. Family members must not be used. The interpreter must be a professional and must not be a staff member employed by the hospital, unless they are employed in their capacity as a professional interpreter. IAs should always speak with the interpreter before the interview to make clear their purpose and role. See section on interpreters for more information.

46. Upon receiving the referral letter, it is essential that IAs confirm whether the donor is a non-UK resident donor. If so, IAs must contact the HTA. Please see section on **non-UK resident donors** for more information.

## The requirements of the IA interview

47. The interview must enable the HTA to ascertain whether the legal requirements have been met. The HTA places the report of the IA interview 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 information will be sought.

48. The Regulations set out the requirement that the IA must conduct separate interviews with the donor (and person giving consent if different from the donor) and the recipient. In addition, it is HTA policy that a joint interview must be undertaken with donor and recipient together, with the exception of non-directed altruistic donation.

## Joint interviews

49. There may be exceptional cases of directed donation or directed altruistic donation where the donor and recipient do not wish to be interviewed together.

50. For example, the donor may have offered to donate as a result of a social media campaign and wish to remain anonymous to the recipient.

51. In these cases, the transplant team must contact the HTA to make an application for the requirement of the joint interview being withdrawn. These applications will be considered by the Director of Regulation. To manage

expectations, LDCs should explain to donors and recipients that they may still need to be prepared for a joint interview.

52. The purpose of the joint interview 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 re-visit questions about duress, coercion and reward and discuss this with the donor and recipient, as well as anything else that might be relevant to the decision making of the HTA. It would be expected that the joint interview would be shorter in length than the individual interviews with the donor and recipient.

53. While the donor and / or recipient may request that a third party sits in on the interview to provide support, third parties including other family members must not attend interviews unless there is a specific need to do so.

54. Please contact the LDAT in advance for advice and ensure donors and recipients are clear on expectations.

55. Equally, IAs must not invite those wanting to observe an interview unless permission has been sought from the HTA.

56. Each donor interview should contain a period of time where the donor is alone with the IA to provide the donor the opportunity to confirm that their consent is being freely given.

## Translation and communication issues

57. Where an interpreter has been required for discussions between the transplant team and the donor and / or recipient, this must be mentioned in the referral letter so that the IA is aware that an interpreter will be required for the interview.

58. In situations where an accredited local independent interpreter is not available, a facility such as 'Language Line' or equivalent can be used. In the case of someone with a speech or hearing disability, an accredited interpreter with experience in signing must be used.

59. The interpreter must not have any personal connection with either the donor, the recipient or the clinical team.

60. An interpreter who is personally known to either the donor, recipient or clinical team must not be used. For example, family members and members of the clinical team must never act as interpreters. IAs may also act as an interpreter, provided that they are fluent in the specified language.

61. The IA must document the interpreter's name, contact information and organisation.

## Interviewing a donor or recipient with a disability

62. If the donor and/or recipient has a disability, the IA should make appropriate adjustments during the interview. This may include allowing additional time during the interview for questions. Please contact the LDAT on transplants@hta.gov.uk for further information and support if required.

## Interviewing a child recipient

63. The IA must not be alone in a room with a child recipient, it is appropriate for an adult to accompany them. If this is not possible then the IA should contact the HTA prior to the interview to discuss the options.

64. The IA 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. While it may not be suitable to directly address financial reward with a child, a discussion on how the offer of donation arose involving both the child recipient and the adult accompanying them to the interview should be considered.

65. The IA must always endeavor to conduct an interview with the child themselves. 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 donating to them. It is good practice to involve the person(s) with parental responsibility in these discussions but there is no legal role for that individual to respond on the child's behalf. IAs must include full detail of their interaction with the child as well as their person(s) with parental responsibility in the IA report.

66. Where a child is too unwell to be interviewed this must be documented.

## Interviewing donors/recipients – face coverings

67. It is a requirement that IAs establish the identity of donors and recipients. IAs should sensitively ask any donor or recipient with a face covering to remove the covering in order that they may be identified as the right person to be interviewed.

68. The HTA recognises that individual sensitivities must be taken into consideration, therefore if a donor or recipient is uncomfortable removing their face covering in public, they should be escorted to a private room and asked to uncover their face. Female donors or recipients, who may be uncomfortable removing a face covering in public and/or in the presence of a male, should be identified in private by a female IA or LDC who can confirm their identity matches the photographic identity they have provided.

## Virtual Interviews

69. Where possible, interviews should be held face to face, however they may take place virtually. Where an interview is carried out virtually, this must be undertaken in line with the hospital's IT policy.

70. For virtual interviews, IAs should be provided with the ID and evidence of relationship documents ahead of the interview. This must be done in line with internal hospital data protection policies. Where this is not possible, IAs should request that identity and evidence of relationship documents are held up to the screen clearly for the IA to view.

71. Whether or not the donor and recipient live in the same accommodation, the IA must confirm that the person they are interviewing is alone and able to speak freely. This can be achieved by asking the donor and recipient to pan the device around the room before the start of their individual interviews.

72. It is not acceptable for the other party to be on the call, even if their camera is turned off and they are muted as this means the interview is not being carried out with the individuals on their own.

## Provision and review of ID and evidence of relationship documents

73. Donors and recipients must be able to provide evidence of the claimed relationship for the IA interviews.

## Photograph evidence of identity

74. The HTA considers the following documents as suitable photographic identification:
    - Passport
    - Driving licence (including provisional license)
    - Photographic identity cards
    - Blue Badge
    - Certain concessionary travel cards e.g. bus pass
    - Identity card with PASS mark (Proof of Age Standards Scheme)
    - Biometric Immigration Document
    - Defence identity card
    - Certain national identity cards

75. For donors and recipients who are unable to provide the identification listed above, the reasons should be stated in the IA report.

76. For child recipients who have no photographic ID, photographs of the child with person/s with parental responsibility where all concerned are identifiable will also be accepted.

77. In order to streamline processes and prevent delays, the HTA asks LDCs to ensure the ID and evidence of relationship documents are available and view these themselves in advance of the IA interviews. This mitigates the risk of delays in decision making due to incomplete or inadequate information being presented at a late stage. This applies to every living organ donation case.

78. For virtual interviews, where possible, IAs should be provided with the ID and evidence of relationship documents ahead of the interview. This must be done in line with internal hospital data protection policies. Please see section on Virtual Interviews for more details.

79. If the donor and recipient claim a relationship but are not able to provide any documentation or supporting evidence, the IA must contact the HTA for advice before submitting their IA report.

## Evidence of relationship

80. Evidence of relationship which clearly demonstrates the claimed relationship between donor and recipient must be provided.

    This must be brought to the IA interview for the donor and recipient to discuss with the IA.

## Directed cases – evidence

81. For genetically related individuals (such as siblings), birth certificates of donor and recipient are required. Where there is a more remote relationship, for example a nephew donating to a maternal aunt, the birth certificate of the donor's mother will also be required and must be brought to the IA interview to support the genetic connection.

82. Where birth certificates are not available, alternative supporting evidence could include the following:

- Family photographs clearly spanning the duration of the relationship (recent photographs in isolation will not be accepted)
- Text/WhatsApp/email/social media messages spanning the duration of the relationship (these are unlikely to be accepted alone as evidence of a claimed relationship, given the obvious issues in verifying the origin and source of any such material).

83. The following supporting evidence will only be considered in addition to the evidence listed above; these cannot be the sole piece of evidence supporting the claimed relationship:

- Certified family tree;
- A statement / testimonial, ideally from an individual in a position of authority (e.g., Lawyer, Teacher, GP, Pilot, Accountant, Police Officer) who is able to attest to the claimed relationship.

84. For emotionally related individuals (such as spouse, partner and friend of long standing) examples of documentary evidence could include the following:

- A marriage or civil partnership certificate
- Proof of joint residence, such as utility bills or mortgage/rent statements in joint names
- Photographs clearly spanning the duration of the relationship (recent photographs in isolation will not be accepted)
- Text/WhatsApp/email/social media messages spanning the duration of the relationship (these are unlikely to be accepted alone as evidence of a claimed relationship, given the obvious issues in verifying the origin and source of any such material).

85. The following evidence may on occasion be considered in addition to the evidence listed above, this cannot be the sole piece of evidence supporting

the claimed relationship:

- A statement / testimonial, ideally from an individual in a position of authority (e.g., Lawyer, Teacher, GP, Pilot, Accountant, Police Officer) who is able to attest to the claimed relationship.

  The HTA is unable to accept affidavits as evidence of a claimed relationship.

## Paired/Pooled cases – evidence

86. Donors and recipients are expected to present the evidence listed for directed cases outlined above.

## Directed altruistic cases – evidence

87. LDCs should include in the referral letter information which clearly states how the donor and recipient came to know about each other and provide an explanation about how the offer of donation arose. Please also see section on 'Joint interviews'

## Non-Directed Altruistic cases – evidence

88. Donors are expected to present their photographic identity listed in paragraph 74. As the recipient is not known to the donor, the evidence of relationship is not required.

## Organs or part organs that cannot be transplanted into intended recipient

89. The following guidance only applies to directed, directed altruistic and paired or pooled donors. It does not apply to non-directed altruistic donors.

90. During the work up process, donors will have been asked what their wishes are in the event that their organ cannot be transplanted into the intended recipient. This is a precaution to avoid the worst-case scenario of an organ being disposed of when the donor's wishes are not known.

91. Donors have the following four potential options:

- Organ can be transplanted into an alternative recipient on the national waiting list (if the donor's preference is for another family member or friend to receive the organ, and they are a suitable donor; then an additional directed donation IA report must be submitted – please see information below in *Request for re-direction to secondary recipient if organ cannot be transplanted into intended recipient section).*

- Organ can be re-implanted into the donor (not appropriate for liver lobes)

- Organ can be used for research; or

- Organ can be disposed of.

92. Once the donor has made their choice this must be included in the referral letter.

93. HTA provides separate approval in cases where the donor has consented for the organ to be transplanted into an alternative recipient.

94. For donors who decide to have their organ re-implanted, the clinical team must explain the possible risks associated with additional surgery. They should also understand the expected function of the organ after re-implantation. The referral letter should confirm that a member of the clinical team has explained the risks, and the donor understands them.

## Request for re-direction to secondary recipient if organ cannot be transplanted into intended recipient

95. If a donor requests in advance to re-direct their organ to a secondary recipient, the HTA must be satisfied that there is no duress, coercion or reward involved in the re-direction.

96. For example, a father donating to his child at the same time that his wife also requires a transplant. In the unlikely event that the organ cannot be transplanted into the child, he may wish for the organ to go to his wife instead. Therefore, a separate IA interview and report must be submitted for the secondary recipient.

## Timeframes for decision making and points to note

97. Clinical teams should allow sufficient time for referral of all cases, particularly those requiring a decision by an HTA panel of three Board Members. See paragraph 16. IAs must submit their reports to the HTA as quickly as possible.

98. The HTA must receive cases by 9am on a Monday to refer to a panel that week.

99. Referrals to panel take place every Wednesday and the panel has 10 working days to make a decision. Board Members need appropriate time to make a considered decision for robust decision making, on average they each receive several cases a week for decision.

100. Requests for very short turnaround times are extremely difficult to accommodate. Clinical teams should review their referral timeframes and ensure 3 to 4 weeks are allowed for an HTA decision.

101. Clinical teams may refer donor and recipient pairs that have been registered, but not necessarily matched, in the National Kidney Sharing scheme, for IA and HTA decision. This does not apply to recipients registered with more than one potential donor.

102. LDC's will arrange a follow up phone call with an IA for all cases where a transplant has not taken place within 12 months of HTA approval. This is to ensure the donor still understands the nature and risks of procedure, there has been no change in circumstances affecting the donor's decision to consent, and that the donor still wishes to proceed with donation. Once this phone call has taken place, IAs should email a summary of the conversation to the HTA, the HTA will confirm whether the approval still stands.

## Interview overview

## Exploring duress and coercion

103. The decision about whether any duress or coercion is present is one the HTA must make, and the information in the IA report is used to do this. Therefore, it is important that the report covers the issue of whether any duress or coercion exists, and the impact of this on the donor's decision to go ahead with the donation.

104. Duress or coercion means that the will of the person required to act has been overborne such that they can no longer make an independent decision. In order for the donor's consent to be valid, they must be acting voluntarily and of their own free will. If a donor is being pressured by someone else to donate,

their consent may not be valid, and if they are only donating because of this pressure their consent would not be valid.

105. Many donors place pressure on themselves, both as the person selected to donate and for the donation to be a success. It is of value to explore this at the interview and make a note of these issues in the IA report. It is unlikely that such personal pressure would lead to the HTA making a decision not to approve a case, but this is often a key part of the discussion with the donor allowing exploration of any outside influences.

## Exploring evidence of an offer of a reward

106. The decision on whether a reward has been or is to be given is one the HTA must make, and the information in the IA report is used to do this. The interview must explore the extent to which there is any reward linked to the donation. It is also an offence under the HT Act for the donor to receive a reward after the donation has taken place, this is one of the reasons why reward should be explored in all cases, including non-directed altruistic donation cases.

107. Reward is defined as 'any financial or other material advantage'. A payment of money will constitute reward even if it is a trivial sum. Any non-monetary benefit has the potential to be properly described as a reward if it could amount to a material advantage.

108. Anything that contributes to the donor's decision to donate their organ or tries to persuade them to donate their organ could constitute a reward.

109. It is recognised that this is a complex area, and it is important that during the IA interview the donor and recipient are asked whether any reward is changing hands, and if it is, what this means to each party. It may be the case that a family holiday has been arranged after the transplant and the recipient is paying for this, and the donor is one of their guests. In one set of circumstances this may have no impact on the donor's decision to proceed, in another it may be the only reason they are going ahead.

110. A reward does not have to flow from a recipient to a donor, and may come instead from a third party, for example a subscription, charity organisation, faith group, recreation group or matching service. It is vital that this is addressed with both the donor and recipient, and information on any third-party involvement must be provided in the IA report.

111. The HT 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 HT 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. Reimbursement can only be made to the individual who has directly incurred costs.

112. If requested by the HTA, the donor and recipient must be able to provide evidence in order to prove that only direct travel costs and reasonable expenses were paid, and the donor has not materially benefitted in any way.

## Interview content

## Donor interview

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

- The information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the organ (this must cover both general risks and those specific to that donor). If the donor does not appear to understand the risks involved, IAs should pause the interview so that the donor can be re-counselled. If this is not possible, IAs must ask the LDC to rearrange the interview once the donor has had the opportunity to discuss the risks with a medical practitioner. It is acceptable to prompt the donor for more information; however, it is important not to assist donors when interviewing them by providing them with specific information.

- The full name of the person who gave that information and their qualification to give it;

- The capacity of the person interviewed to understand the nature of the medical procedure and the risk involved; and

- The capacity of the person interviewed to understand that consent may be withdrawn at any time before the removal of the organ.

114. IAs must explore any evidence of duress or coercion with the donor that may affect their decision to give consent.

115. IAs must explore any evidence of an offer of a reward with the donor.

116. The IA report must also cover any difficulties in communicating with the donor and how these were overcome.

117. The donor may inform the IA during interview that they wish to withdraw their

consent and not proceed with the donation. The IA should support the donor in communicating their decision to the transplant team. The referring clinician will withdraw their referral to the HTA. The IA report must be submitted in the usual way, but the HTA would not be required to make a formal decision if the referral has been withdrawn.

## Recipient interview

118. The Regulations require that the interview with the recipient covers any evidence of duress and coercion affecting the decision to give consent. In England, Wales and Northern Ireland, the recipient's consent to undergo surgery to receive an organ transplant is interpreted to be a clinical matter. Therefore, the HTA interprets this to mean any evidence of duress or coercion (which the recipient, or any other person, is aware of or has put on the donor) affecting the donor's decision to give consent to the removal of the organ.

119. IAs must explore any evidence of an offer of a reward with the recipient.

120. The recipient interview should note any communication difficulties and how those were overcome. This section of the report may, under certain circumstances simply report that no interview was attempted and the reasons for this.

121. Where the recipient lacks capacity, the HTA has no requirement for someone to be interviewed on their behalf.

## Joint interview

122. It is HTA policy that a joint interview must be undertaken with donor and recipient, with the exception of non-directed altruistic donation cases. The purpose of the joint interview is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion could be factors in the donor's decision to donate and to explore the issue of reward with the donor and recipient jointly. The IA must also include their observation of the pair from the joint interview in the IA report. IAs may comment on how the offer of donation came about and the body language and interaction between the donor and recipient together.

123. There may be exceptional cases of directed donation or directed altruistic donation where the donor and recipient do not wish to be interviewed together. For example, the donor may have offered to donate as a result of a social media campaign and wish to remain anonymous to the recipient.

124. In these cases, the transplant team must contact the HTA to make an application for the requirement of the joint interview being withdrawn. These applications will be considered by the Director of Regulation. Joint interviews must be undertaken unless written authorisation not to undertake a joint interview has been received from the HTA.

## Cases involving non-UK resident donor cases

125. Sometimes cases involving non-UK resident donors can be complex and require additional scrutiny.

126. The HTA must be given sufficient time to review these cases and seek clarification where appropriate.

127. Where a visa is needed to enter the UK for the purposes of organ donation, the clinical team must have obtained their own assurance that the donor and recipient can sufficiently evidence the claimed relationship.

128. The clinical team, usually the LDC, should ask for, and review, all ID and evidence of relationship documents prior to considering a letter of support for a visa and before the IA interview.

129. IAs should contact the HTA at transplants@hta.gov.uk prior to the interview taking place to ensure the additional points to be addressed in the interview are clear.

## Prevention of trafficking - both of human beings and of organs

130. Organ and people trafficking and modern-day slavery are a concern for all healthcare professionals. IAs must remain aware of the risks and be vigilant at all times, using their professional curiosity to explore if something does not feel right.

131. There are some key signs and indicators to be aware of during contact with living donors and recipients:

- is the donor withdrawn and submissive, or afraid to speak to anyone in authority?
- does the donor provide vague and inconsistent explanations of where they live, or their employment?
- does the donor's appearance suggest general physical neglect?

- does the donor have official means of identification?
- Is the donor in possession of their own passport, identification or travel documents? Are these documents in the possession of someone else? Do the documents look suspicious?
- Does the donor act, or do you suspect, they have been instructed or coached by someone else?
- Does the donor allow others to speak for them when spoken to directly?
- Does the donor appear to be under the impression that they are bonded by debt, or in a situation of dependence?
- Is the donor accompanied by someone who appears controlling, who insists on giving information and speaking for them?
- Is there an apparent significant disparity between the donor and recipient (for example, age, wealth or education)?

132. All three of the following components must be present for an adult to be considered trafficked: *Action, Means and a Purpose* (however, in relation to children, the 'means' component is not required as they are not able to give consent*).*

- **Action** - Recruitment, transportation, transfer, harbouring or receipt, of persons.
- **Means** - Threat or use of force or other forms of: coercion, abduction, fraud, deception, the abuse of power, taking advantage of someone in a vulnerable position, giving or receiving payments or benefits to achieve the consent of a person having control over another person**.**
- **Purpose** - Removal of organ(s).

133. IAs are expected to:

- Trust and act on professional instinct if something is not or does not feel quite right
- Approach all IA interviews with a degree of professional curiosity
- Be vigilant and alert to this threat, do not presume that because a case has reached the stage of IA that all is OK
- Challenge and probe where appropriate, do not accept all information at face value
- Sensitively explore where there is an apparent significant disparity in wealth, education or age between donor and recipient
- Reassure donors that it is safe for them to speak
- Ask non-judgmental, relevant questions.

134. Please refer to the Royal College of Nursing Guidance on Modern Slavery and Trafficking: Modern Slavery and Trafficking | Royal College of Nursing (rcn.org.uk)

135. If IAs have concerns on any of these aspects, please speak to the LDC and HTA.
136. Remember: people can be trafficked within their own country, and trafficked people may not self-identify as victims of modern slavery.

### Duty to report

137. On 1 April 2024, the Supply of Information about Transplants Regulations 2024 ('Regulations') came into force under section 34 of the HT Act. It places a statutory duty on clinicians in England, Wales and Northern Ireland who work closely with patients that need or have received an organ transplant to report information to the HTA if:

    a. they have a reasonable suspicion that an organ transplant-related offence has been committed under sections 32, 32A or 33 of the HT Act, section 2 of the Modern Slavery Act 2015, or section 2 of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015, or

    b. they are made aware that a patient has received an organ transplant outside the UK.

138. Whilst IAs are not required to report under the Duty, it is important to remain aware of these requirements and notify the clinical team and the HTA of any concerns.

## Welfare or safeguarding issues

139. IAs should familiarise themselves with the hospital's safeguarding policies.

140. If during the interviews, the IA has welfare or safeguarding concerns in relation to the donor and/or the recipient, these should be documented in the report to the HTA. IAs should also contact the HTA to discuss in further detail.

141. The IA must also inform the LDC of their concerns so that the appropriate support can be provided through the hospital's safeguarding team.

## Other Scenarios

142. There may be occasions when either the donor, recipient, or both, come to the

interview and it is evident that they lack coherence, for example if they appear to be under the influence of drugs or alcohol. The IA interviews must not be attempted, and contact must be made with the LDC to discuss and reschedule where appropriate. The IA must also make contact with the LDAT to inform them.

143. There may be occasions during interviews where inconsistencies arise in the donor and recipients account of relevant facts. The IA should explore this using direct but sensitive language. IAs must document this in their report to the HTA.

144. If during the course of the interview there is an indication that either the donor, recipient, or both, may not have capacity, then this must be documented. The IA must contact the LDAT after the interview to discuss their concerns.

### Other requirements for the IA report

145. As a matter of policy, the report must also contain an account of any other issues that the IA would like to draw to the HTA's attention which may be relevant to the case decision and are not covered elsewhere in the report.

146. It is essential to cooperate fully with the HTA and share all pertinent information that may help in identifying issues or risks. It is useful to include the donor and recipients own words, along with information about your observations as to their attitudes and behaviours during the interview. The IA report should also include details about any suspicious concerning circumstances surrounding travel or activities, i.e. if a recipient mentions that they had previously travelled outside the UK to seek an organ. The aim is to ensure that all potential indicators of human trafficking and offences under the HT Act are thoroughly explored.

147. If the HTA deem an IA report to be lacking important detail, or too brief for the HTA to make an informed decision, we may require the IA to resubmit their report with more information to gather all the necessary facts. On occasion, the HTA may require a second interview to take place.

## Guidance for completing an IA report via the HTA online portal

### Section A – Category of transplant

148. In this section, IAs must confirm that they have read, understood and applied the guidance issued by the HTA. This section also determines how the case will be assigned for consideration once it is received by the LDAT based on the details provided by the IA. If there are any concerns about the category of donation mentioned in the referral letter, please contact the LDC.

## Section B – Details of donor, recipient / partner and location of transplant

149. Details of the donor, partner (recipient), referral unit and transplant centre must be entered here. If there are two LDCs, please include both names to make sure the HTA decision is sent to both. If an establishment or contact is not appearing in the list, please contact the LDAT.

## Section C – Evidence of identity and status of relationship

150. See section 74 on suitable photographic ID and evidence of claimed relationship.

151. If the donor and recipient are unable to provide any form of identification, or evidence to demonstrate the claimed relationship, please contact the LDAT for advice.

152. IAs must clearly state the documents which have been seen in terms of both ID and evidence of claimed relationship and clearly detail how this evidence confirmed the claimed relationship.

Example answer with sufficient detail:

*For photographic ID, I have seen UK passports for both the donor and recipient.*

*For evidence of relationship, I have seen a birth certificate which shows the donor is the recipient's father.*

*In addition I have seen 10 photos spanning a period of 15 years between 2008 and 2023. These photos were shown to me on the donor's mobile phone and include both the donor and recipient at various different social settings including at a party and on holiday in Greece. The donor and recipient are clearly identifiable and recognisable in these photos.*

Example answer with insufficient detail:

*I confirm I've seen ID documents.*

*For evidence of relationship, I have seen two birth certificates. In addition I have seen three photos.*

A drop-down list of relationships is provided in section C. If these options are not applicable, IAs can select 'other'. *This section is not relevant for non-directed altruistic cases.* For directed altruistic donation cases, IAs must provide information on how the donor and recipient came to know of each other and provide an explanation on how the

offer of donation arose.

## Section D – About the donor

153. In this section, IAs are asked to confirm whether:

*In the referral letter, has the registered medical practitioner responsible for the donor confirmed that the donor has capacity or competence to make the decision to donate their organ or part organ?* The IA must confirm that the donor is either: *An adult with capacity to understand the donation process in order to consent, or A child.* The IA must also state whether they have any concern about the donor's capacity to understand the nature of the medical procedure and the risks involved and their understanding that they can withdraw their consent.

## Section E – Communication

154. This section must be used to highlight any communication difficulties with those interviewed and how any communication difficulties were overcome.

## Section F – Understanding of the nature of the procedure and the risks involved

155. The IA must provide information on the donor's understanding and acceptance of the nature of the procedure and the risks involved in donating an organ. If there are any risks specific to the donor mentioned in the referral letter these must be explored with the donor in the interview. The IA must confirm that the donor understands any risks specific to them.

156. The IA must confirm that mandatory information was included in the referral letter.

157. The medical practitioner's details must also be provided.

158. The IA must confirm that the donor understands they are able to withdraw consent, however, does not wish to do so at present.

159. The IA must also confirm what the donor would like to happen to their organ in the event that it cannot be used for the intended recipient. If the donor has consented to their organ being re-implanted, the IA must confirm the donor's understanding of additional risks associated with re-implantation of an organ and the expected function of the organ following re-implantation.

160. The IA must also confirm that the donor and partner (recipient) were seen separately and together. This information is crucial as it goes towards the HTA's judgement of whether valid consent is in place.

Example answer with sufficient detail (kidney donation):

*The donor has a clear understanding of the proposed surgery to remove her kidney. She provided a comprehensive description of the incision sites for a laparoscopic nephrectomy and the need for a larger incision if, during the procedure, it became necessary. The donor understands that the risk of major complications such as bleeding, thrombosis or wound / chest infection and the risk of death approximately 1:3000. She accepts those risks and considers that the benefits outweigh the risks. The donor has no specific risks with regards to this donation.*

Example answer with insufficient detail (kidney donation)

*The donor has a clear understanding of the proposed surgery and detailed some of the risks. She accepts those risks and considers that the benefits outweigh the risks.*

## Section G – For directed cases, section G is on duress, coercion and reward

161. IAs must provide information on the details of the discussions had during the interviews with the donor and the recipient in order to determine (as far as possible) that:

    - There was no evidence of duress or coercion affecting the donor's decision to give consent;
    - There was no evidence of an offer of a reward that would affect the donor's ability to give consent.

162. There must be sufficient evidence and detail for the HTA to exercise an independent judgement. This evidence should, where possible, be in the form of direct answers provided by the donor and recipient and details of the discussions between the IA and the donor or the recipient.

163. IAs must also include their observation of the pair in the joint interview. IAs should also include detail on how the offer of donation came about and comment on body language and interaction. IAs must also provide details of the joint discussion with the donor and the recipient/partner to determine (as far as possible) there is no evidence of duress, coercion and reward that would affect the donor's ability to give consent.

164. This section must include the rationale as to why the IA reached a conclusion, not only that the IA reached a conclusion. The HTA must be able to exercise an independent judgment in considering whether it can be satisfied that no reward has been or is to be given and that there is no duress or coercion.

165. IAs must also confirm if they have received a signed donor declaration or document why this has not been provided. Confirmation that this has been requested and will be followed up with the LDC is required.

166. IAs are also given an opportunity to draw to the HTA's attention any other issues which may be relevant to the case decision and are not covered elsewhere in the report.

### For non-directed altruistic cases, section G

167. The IA must confirm that the donor is aware of the implications of being a non-directed altruistic donor and understands the process. This includes that the donor understands that they will be donating to the deceased donor waiting list or starting a non-directed altruistic chain.

### For paired / pooled cases, section G

168. The IA must confirm that the donor is aware of the implications of being a donor in the paired / pooled scheme and understands the process. This should include confirmation that the donor is aware of the anonymous nature of the scheme and the possibility of a break in the chain, such as if a recipient is too unwell or a donor withdraws consent. The IA must also confirm that the donor understands the small possibility that they may donate, and their partner (recipient) may not receive a kidney in return.

### Section H – For non-directed altruistic donations and paired / pooled donations, this section covers duress, coercion and reward

169. The IA must provide information on the details of the discussions had during the interview in order to determine (as far as possible) that:

- There was no evidence of duress or coercion affecting the donor's decision to give consent;
- There was no evidence of an offer of a reward that would affect the donor's ability to give consent.

170. IAs must also confirm if they have received a signed donor declaration or document why this has not been provided. Confirmation that this has been requested and will be followed up with the LDC is required.

Example answer with sufficient detail regarding duress and coercion (kidney donation)

*The donor approached the coordinator initially to find out if she could be tested to donate a kidney. She was found to be a suitable match and is delighted that she can help. The donor is anxious to help the recipient experience better health and to enable her to 'live her life again'. She finds it very upsetting watching her sister suffer on dialysis. I asked explicitly and the recipient said that she has not put the donor under any pressure and confirmed that the donor offered to donate of her own free will. She is not aware that anyone else has pressured or coerced her sister to donate. The donor confirmed this in her discussions with me and said she had not been placed under any pressure to donate. The donor and recipient understand that the donor can change her mind at any time.*

*I can confirm from my discussions with both donor and recipient today that there is no evidence of duress or coercion affecting the donor's ability to give consent.*

Example answer with insufficient detail regarding duress and coercion (kidney donation)

*I can confirm from my discussions with both donor and recipient today that there is no evidence of duress or coercion. The donor appears to be acting entirely voluntarily.*

Example answer with sufficient detail regarding reward (kidney donation)

*I explicitly asked both the donor and recipient together and separately if there was any reward involved in the donation and they both confirmed to me today that the offer was entirely voluntary and that there was no financial or other reward involved. The donor answered, 'Absolutely not, I hadn't even thought of anything like that' and the recipient replied 'No, not at all – he is donating purely to try and make me better. I have nothing to offer anyway, our income is shared'. I can confirm from my discussions with both donor and recipient that there is no evidence that the donor expects or has been promised any reward. The donor said the only reward for him is to see his wife as well as she can be and free from dialysis.*

Example answer with insufficient detail regarding reward (kidney donation)

*From my discussions today could find no evidence of any reward.*

## Additional information

171. The referral letter and donor declaration must be scanned and uploaded with the IA report electronically to the HTA. IA reports that are submitted without the relevant paperwork will not be assessed until all documents have been received.

172. Once the online report is submitted, the IA will receive an automated email notification that the report has been received by the HTA.

173. Once a decision has been made by the HTA, an automated notification will be issued to the IA, and the LDC(s) and Clinicians detailed in the report. The decision can be accessed by logging into the portal. The HTA recommends that more than one LDC is detailed in each report (where the unit has two or more).

174. An additional guidance document can be provided to IAs to support with interview techniques and how to approach and explore the subjects of duress, coercion and reward. This can be used when interviewing donors and recipients, and when completing reports. This is not meant to be prescriptive however it does contain good practice guidance on the areas of reports where the LDAT most often has to seek further information. Please contact the LDAT for more information.

## Contingency report system

175. Where the portal is unavailable:

- IAs should retry after a few hours and if still unavailable contact the HTA by calling 0207 269 1900 or by emailing transplants@hta.gov.uk

- if the HTA confirms that the portal is unavailable IAs should complete a contingency version of the report using the word template which can be downloaded from the HTA website.

- The report should be submitted by email to transplants@hta.gov.uk with IA report in the subject line.

## Emergency Out of Hours service

176. If an emergency decision is needed out of hours, please call the HTA emergency out of hours' number on 020 7269 1991.

177. There must be a clinical need for an emergency transplant. The HTA representative will ask for confirmation that there is a clinical need for an emergency decision to be made.

178. The HTA representative will request confirmation that an IA has interviewed the donor and recipient. If the donor and/or recipient have not been interviewed by an IA, then this must be arranged. The referral letter or the donor declaration form does not need to be emailed to the HTA representative at this stage.

179. The HTA representative will then request the IAs name and contact number from the clinical representative and will contact the IA to ascertain details of the IA interview.

180. The HTA representative will assess the case, once a decision has been made the LDC will receive:

    *a)* verbal decision via phone and
    *b)* written confirmation via email of the decision

181. The usual 'Txxxx' number will not be issued and is not required for emergency case approvals. The IA will submit a retrospective report to the HTA and upload the referral letter and donor declaration form. A 'Txxxx' number will be generated at that point.

182. Out of hours cases are rare and this process should only be used in urgent living liver lobe donation cases. The HTA recommends that all transplant units, and especially those which have a living liver programme, make arrangements for an IA to conduct interviews at short notice and out of hours.

## Cases from the private sector

183. Where a transplant takes place in the private sector, clinicians should endeavor to ensure that a LDC is involved (or equivalent role). This provides essential continuity and coordination of patient care.

184. If IAs are carrying out an IA interview for a private sector, they must seek assurance that the translator is independent (see section on translators) and maintain a suitable degree of professional curiosity as with all cases.

185. As cases taking place in a private setting often involve non-UK resident donors, please see the section on non-UK resident donor